Reviewed by Institutional Ethics Committee:

Sl.No.	Name and Position on the IEC	Signature with date
1.	Dr. (Prof.) S. K. Das, Chairperson, IEC	
2.	Prof. U.K Mishra, Member, IEC	
3.	Dr. (Prof.) A. K. Saksena, Member, IEC	
4.	Dr (Prof) V.S Narain, Member, IEC	
5.	Mr. Vijai Varma, Member, IEC	
6.	Dr. Kumud Srivastava, Member, IEC	
7.	Mr. Manish Hindvi, Member, IEC	
8.	Dr. (Prof.) Prabhakar Mishra, Member, IEC	
9.	Dr. S. Srivastava, Member, IEC	
10.	Dr. Rama Srivastava, Member, IEC	
11.	Dr. Sharad Singh, Member, IEC	
12.	Dr Anita Fotedar, Member, IEC	
13.	Dr. Manoj Kumar, Member Secretary, IEC	

Approved by:

Sl.No.	Name and Position on the IEC	Signature with date
1.	Dr. (Prof.) S. K. Das	

Accepted by:

Sl.No.	Name and Position on the IEC	Signature with date
1.	Prof. Ashok Kumar Srivastava	

Contents

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 1

Title: **Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing and Amending SOPs for the Institutional Ethics Committee**

DHMHSOP Code: **Date:** **Page: 01-14**

DHMHSOP 01/V1

- Responsibilities of IEC and IEC Secretariat for preparing/revising SOPs
- Instructions for amendment, approval and implementation of SOPs

These Standard Operating Procedures (SOPs) define the process for writing, reviewing, distributing, and amending SOPs of the Institutional Ethics Committee (IEC), DHMH.This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within DHMH.

1.1 Responsibilities

It is the responsibility of Chairperson of the IEC to appoint a **SOP team** to formulate the SOP. SOP team drafts SOP, gets it reviewed and approved by the IEC members and amends it as and when required. All members of IEC will review the SOP and approval will be given by **Chairperson of IEC**. The SOPs shall then be accepted by the **Chairman cum Managing Director, DHMH.**

IEC Secretariat will:

- Co-ordinate activities of writing, reviewing, distributing, and amending SOPs.
- Maintain on file all current and past SOPs and the list of SOPs.
- Maintain an up-to-date distribution list of each SOP circulated to IEC members.
- Maintain a record of the investigators to whom SOPs are distributed against requisition.
- Ensure all IEC members and involved administrative staffs have access to the SOPs.
- Ensure the IEC members and involved staffs are working according to current version of SOPs.
- Assist in the formulation of SOP procedures.
- Ensure availability of current SOPs on Organization website.

SOP team

A team of members including the Member Secretary, administrative staff, and any other member of IEC as identified by the chairperson which oversees the creation, preparation, review, or revision of the designated IEC, DHMH SOP.

The Chairperson will constitute an SOP team consisting of the Member Secretary and one or more members of the IEC and/or the IEC Secretariat. The SOP team will carry out the subsequent steps.

- Assesses the request(s) for SOP revision in consultation with the IEC Secretariat and

Chairperson.

- Proposes new/modified SOPs as and when required.
- Write down step by step all the procedures of the IEC.
- Organize, devise and, name each process.
- Make a list of SOPs with coding reference (AN1-V1/DHMHSOP01/V1).
- Selects the format and coding system for SOPs.
- Drafts the SOP in consultation with the IEC members and involvement of administrative staff.
- Review of draft SOP by IEC.
- Submit the draft for approval to Chairperson.

Chairperson of the ethics committee:

- Appoints one or more SOP Teams.
- Reviews and approves the SOPs.
- Signs and dates the approved SOPs.

IEC members and involved administrative staff:

- Review, sign and date SOPs.
- Maintain a file of all SOPs received.
- Return all out-of-date SOPs to IEC Secretariat.

1.2 Detailed instructions:

1.2.1 Identifying the need for new or amendment to SOP

Any member of the IEC, consultants or investigators, can make a request for revision or renewal of an inconsistency/discrepancy in the existing SOPs or requests to design new SOP through a request form (AN5-V1/DHMHSOP 01/V1). This form is submitted to the Member Secretary, IEC. If IEC members agree to the request, the Chairperson will appoint SOP team to revise/formulate the SOP. If IEC members do not agree to the request, no further action will be taken. The IEC member who made the request for modification of the SOP will be informed in writing by the Member Secretary about the decision.

1.2.2 List of relevant SOPs

The SOP team will:

- Write down step by step all the procedures of the IEC.
- Organize, devise and, name each process.
- Make a list of SOPs with coding reference (AN1-V1/DHMHSOP01/V1).

1.2.3 Designing a format and layout

- Each SOP should be given a number and a title that is self-explanatory and is easily understood. Each SOP will be prepared according to the template for Standard Operating Procedures in AN2–V1/DHMHSOP 01/V1. Each page of the SOP will bear a header with the effective date. The SOP number will be in the centre of the header while the left-hand corner of the footer will bear the title of the SOP and page number. A unique code number with the format DHMHSOP xx/V_y will be assigned to each SOP by the Ethics Secretariat. xx will be a two-digit number assigned specifically to a SOP. "V" refers to version of the SOP and "y" will be a number identifying the version e.g., DHMHSOP01/V1 is SOP number 01 with V-version no.1.
- Each Annexure (AN) will be given unique code number with the format ANn-Vp/DHMHSOP xx/Vy. e.g., AN1–V1/DHMH SOP01/V1 indicates AN is Annexure; n is Annexure no.1, V1 is version no. 2, belonging to the DHMH SOP01/V1.
- Each Appendix (AP) will be given unique code number with the format APn/Vy e.g., AP1/V1 indicates AP is Appendix, n is Appendix no 1, V1 is version no.1.
- The first page of SOP document will be signed and dated by the SOP team members, the IEC members who have reviewed the SOPs, IEC Chairperson who has approved and Chairman cum managing Director, DHMH who has accepted the SOPs. The SOP will be implemented from the date of the signature of the Chairman cum managing Director, DHMH.

1.2.4 Review by consultation

- The draft SOP will be discussed with members of IEC, administrative staff and relevant faculty members.
- The final draft version will be forwarded to the Chairperson for review and approval by IEC.

1.2.5 Preparation and submission of final draft

- All the members of IEC will review the draft/revised SOP.
- During the IEC meeting, members can put forth their suggestions/comments on the draft/revise the SOP accordingly.
- The suggestions agreed upon unanimously by all IEC members will be incorporated and the final draft SOP will be formulated.
- The SOP team would stand dissolved once the IEC takes final decision regarding the SOP.

1.2.6 Final Approval of new/revised SOP

- The final version of SOP duly approved by the IEC will be signed by the chairperson and accepted by the Chairman cum managing Director, DHMH.
- The implementation of SOP will be applicable from the of date and the signature of Chairman cum Managing Director, of the organization, who is the accepting authority.
- The SOP should be available in the Organization website www.divinehearthospital.com for information to all concern.
- IEC Secretariat may have its own Email Id for all the correspondence, notifications etc.

1.2.7 Implementation, distribution, and filing all SOPs

- Approved SOPs will be implemented from the effective date and will be distributed to IEC members and IEC staff according to the distribution list (AN4-V1/DHMHSOP01/V1).
- One complete original set of current SOPs will be archived in the SOP master file, by the Ethics Secretariat and maintained in the IEC Secretariat. Photocopies made from the official paper versions of the SOP can be considered current or official, if stamped and signed by Member Secretary or authorized individual for distribution, a log of which should be maintained (AN6-V1/DHMHSOP01/V1).

1.2.8 SOPs are made available to all Investigators on Organization website www.divinehearthospital.com

1.2.9 Management and archiving of superseded SOPs

Old SOPs should be retained and clearly marked “superseded” and archived in a file by the

IEC Secretariat. The process of evolution of previous SOPs of the IEC will be documented in defined format (AN3-V1/DHMHSOP01/V1).

AN1-V1/DHMHSOP 01/V1

List of SOPs of Institutional Ethics Committee

Sr. No.	SOP Title	SOP CODE
1.	Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing, & Amending SOPs for the Institutional Ethics Committee	01/V1
2.	Constitution of Institutional Ethics Committee	02/ V1
3.	Management of Protocol Submissions	03/ V1
4.	Initial Review of Submitted Protocol	04/ V1
5.	Exemption from the Ethical Review for Research Projects	05/ V1
6.	Agenda Preparation, Meeting Procedures and Recording of Minutes	06/ V1
7.	Review of Amendments/Notifications	07/ V1
8.	Continuing review of Study Protocols	08/ V1
9.	Reporting of Protocol Deviation/Non-Compliance/Violation/Waiver	09/ V1
10.	Review of Adverse Events (AE) Reports	10/ V1
11.	Review of Study Completion Reports	11/ V1
12.	Management of Premature Termination/Suspension/Discontinuation of the Study	12/ V1
13.	Request for Waiver of Written Informed Consent	13/ V1
14.	Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents	14/ V1
15.	Documentation of the IEC Activities	15/ V1
16.	Dealing with Research Participant's Requests and Complaints	16/ V1
17.	Site Monitoring and Post-monitoring activities	17/V1
18.	Reviewing Research Involving Vulnerable Population	18/V1

19.	Assessment and Audit of IEC	19/V1
20.	SOP for Review of Biomedical and Health Research during Covid-19 Pandemic	20/V1
	Appendices	AP1-AP22

AN2-V1/DHMHSOP01/V1

Template for SOP

Institutional Ethics Committee	
Title: *Title which is self-explanatory and is easily understood*	
SOP No: DHMHSOPxx/Vy	**Page:** a of b
Code: DHMHSOP xx/Vy	
Effective date: DD/MM/YYYY	

AN3-V1/DHMHSOP01/V1

Document History of the SOPs

Name of the SOP	Version	Effective date (dd-mm-yyyy)

AN4-V1/DHMHSOP 01/V1

Log of the IEC Members Receiving Printed Copy of SOPs

No.	Name of recipients	Designation	SOP code number	No. of copies	Signature	Date
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

AN5-V1/DHMHSOP01/V1

Request for Formulation of New SOP/Revision of SOP

This form is to be completed by any member of IEC, consultants of DHMH or investigators, whenever a problem or a deficiency in an SOP is identified or a new SOP is considered necessary.

Need to formulate new SOP (i.e., SOP not existing previously), justification should be provided:			
Details of problems or deficiency in the existing SOP:			
SOP No.			
Title:			
Identified by:			**Date (DD/MM/YYYY)**
Discussed in IEC meeting held on:			
New SOP to be formulated:		**Yes**	**No**
SOP revision required:		**Yes**	**No**
a. If yes, members of SOP team:			
b. If no, why?			
Date SOP revised/formulated:			
Date SOP approved:			
Date SOP becomes effective:			

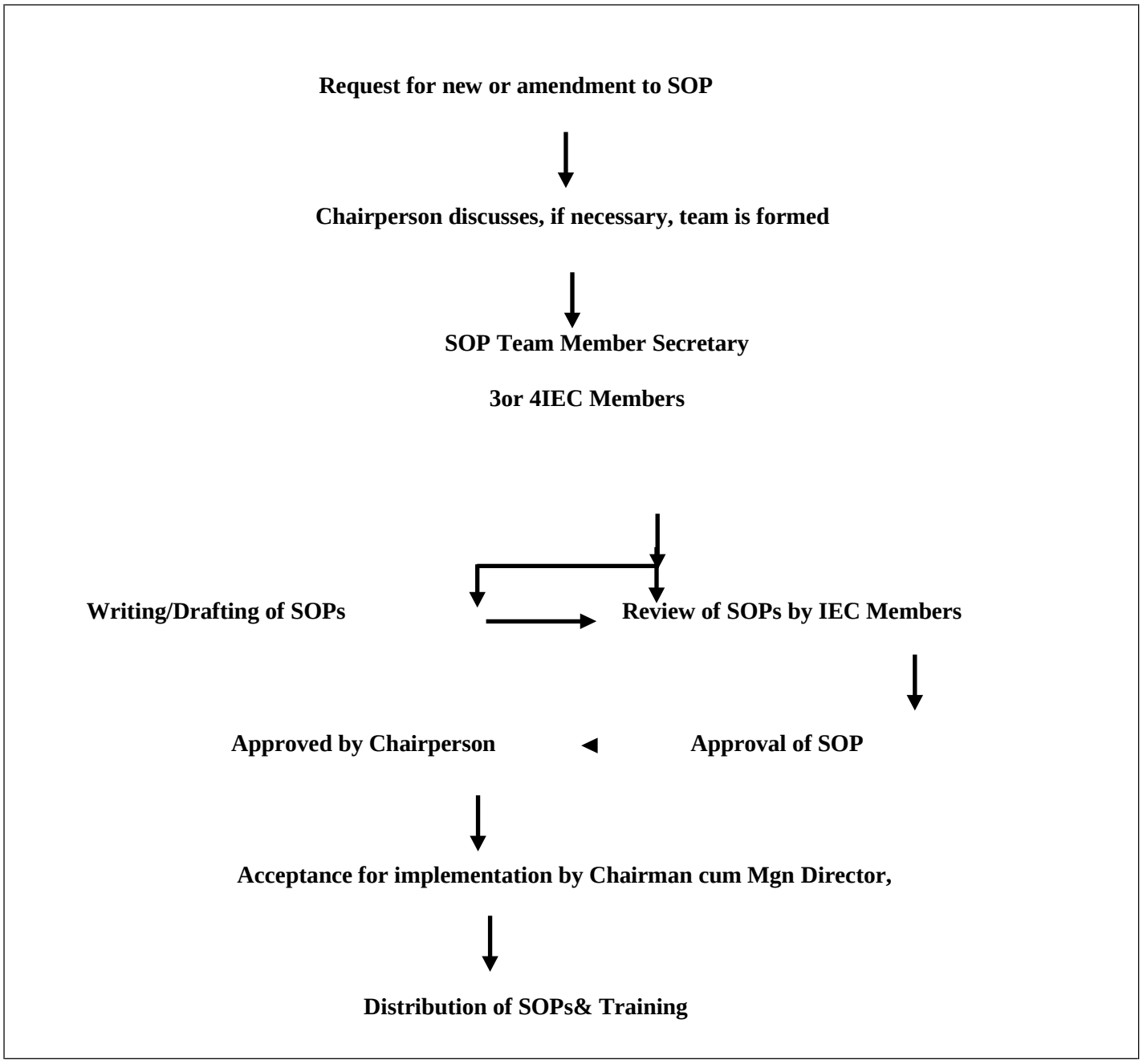
AN6-V1/DHMHSOP 01/V1

Log of Printed Copy of SOP Recipients

Log of the IEC Members Receiving Printed Copy of SOPs

No.	Name of recipients	Designation	SOP code number	No. of copies	Signature	Date
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

Flow Chart


Request for new or amendment to SOP
Chairperson discusses, if necessary, team is formed
SOP Team Member Secretary
3or 4IEC Members
Writing/Drafting of SOPs
Review of SOPs by IEC Members
Approval of SOP
Approved by Chairperson
Acceptance for implementation by Chairman cum Mgn Director,
Distribution of SOPs& Training

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow – 10

(SOPs, IEC, DHMH)

Chapter 2

Title: **Constitution of Institutional Ethics Committee**

DHMHSOP Code: **Date:** **Page: 15-48**

DHMHSOP 02/V1

- IEC constitution, composition and terms of appointment
- Independent Consultants: roles
- Office Bearers and IEC Members: roles and responsibilities
- IECsub-committees

The IEC has been established to formalize and specify the Institution's commitment to promotion of high ethical standards in clinical research related to the oncology & allied sciences and teaching. This SOP applies to the formation of the IEC.

The Institutional Ethics Committee (IEC) has been constituted by Chairman cum Managing Director, Divine Heart & Multispeciality Hospital Lucknow (DHMH) in accordance to the Gazette of India,19th March, 2019, the office memorandum IEC of DHMH, has been issued by the competent authority of organization in 2024.

2.1 Mandate and purpose of IEC

The IEC through its delegated sub-committee's functions independently for maintaining consistent ethical framework in research, and in the integration of ethical values into practice, policy relationships, and organizational activities.

- The purpose of IEC is to cultivate a pluralistic and democratic exchange of ethical values, concerns and to critically analyze them looking for opportunities to enhance the ethical integrity of the Institution within frame work of Biomedical Ethics Principle.
- The mandate of IEC, DHMH essentially targets ethical aspects of research andeducation as per the standard National/International norms of the Biomedical research.

The terms of reference for the IEC are as follows:

- To ensure that all proposed research projects/clinical trials conform to standard national and international ethical guidelines and ensure that the dignity, right and wellbeing of research participants are protected.
- Continuing education in Biomedical ethics research and ethical aspects of clinical practice byseminars, workshops and interactive discussions for IEC members, investigators, study coordinators, research staff, and officials of ethics secretariat.
- The committee does not address or interfere in matters of an administrative

nature, nordoes the committee function as a grievance cell for staff members working in the IEC secretariat.

Scope of IEC

All types of biomedical and health research (academic or investigator-initiated) which includes:

- Clinical
- Basic science
- Policy research
- Implementation research
- Epidemiological research
- Behavioural research
- Public health research etc.

Proposals from outside Institutions will not be accepted by the IEC.

2.2 Roles and Responsibilities

IEC has following roles and responsibilities within the institution:

- The IEC should be registered with the licensing authority as per the regulatory requirement.
- The IEC should ensure protection of dignity, right, safety & well-being of research participant's.
- The IEC should continue education and training programs to ensure that IEC members are qualified to perform their specific duties, by education of professional, administrative, and supporting staff of the secretariat about ethical issues and current ethical standards and guidelines.
- The IEC should create, develop, revise and implement ethical guidelines (SOPs).
- The SOP of the IEC should be given to the members at the time of their appointment, so that the members before accepting the offer may be well verse with the principles of the Biomedical Ethics.

- The IEC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
- The IEC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
- The IEC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- The IEC should assist in the d. velopment and education of the research community in the given organization (including researchers, clinicians, students and others), responsive to local healthcare requirements.
- Responsibilities of members should be clearly defined. The SOPs should be given to IEC members at the time of their appointment.
- The IEC Secretariat should support the Member Secretary in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
- The IEC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
- The IEC reviews progress reports, final reports and AE/SAE and gives needful suggestionsregarding care of the participant's and risk minimization procedures, if applicable.
- The IEC should recommend appropriate compensation for research related injury, wherever required.
- The IEC should carry out monitoring visits at study sites as and when needed.

2.3 Ethical basis

- The members representing medical/non medical scientist and clinicians shall possess at least post-graduate qualification in their respective area of specialization, adequate experience in representative fields and requisite knowledge and clarity about their role and responsibility as Committee members.

- Every member of the Ethics Committee shall be required to undergo training and development programmes as may be specified by the Central Licensing Authority from time to time.
- Any member, who has not successfully completed such training and developmental programs, shall be disqualified to hold the post of Member of the Ethics Committee and shall cease to be a member of such committee.
- The committee consists of members, who collectively have the qualifications and experience to review and evaluate the scientific, medical, ethical and legal aspects of a proposed research project/ClinicalTrials.
- In collaborative research, the IEC recognizes that the protocol has to be approved by National or institutional ethics committees prior to implementation/start of study.
- In evaluating protocols and ethical issues, the IEC should be aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world.
- The IEC also seeks to be informed, as appropriate, by national/other local ethics committees and researchers of the impact of the research, it has approved.

The IEC is guided in its reflection, advice and decision by;

- The ethical principles expressed in WMA Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and finally amended by the 64thWMA General Assembly, Fortaleza, Brazil, October 2013).
- It makes further reference to the International Ethical Guidelines like the Nuremburg Code (1945), the Belmont Report 1979, the CIOM International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 1993), European Convention on Human Rights and Biomedicine 1997, Standard and Operational Guidance for Ethics Review of Health-Related Research with Human Participant's (WHO 2011), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP2016).

The IEC establishes its own Standard Operating Procedures taking recognition of Indian Good Clinical Practice Guidelines (2001) by Central Drugs Standard Control Organization (CDSCO) for clinical trials, National Ethical Guideline for Biomedical and Health Research Involving Human Participant's by the Indian Council of Medical Research (ICMR 2017), National Ethical Guideline for Biomedical Research Involving Children (ICMR 2017),NABH Guidebook to Standards for Accreditation of Ethical Committees (1st ed., 2015) and Helsinki Declaration (Oct.,2015) and the New Drugs and Clinical Trials Rules, Drugs and Cosmetic act Govt. of India, Gazette of India, 19th March, 2019. National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic (ICMR April, 2020)

- The IEC seeks to fulfill the requirements for international assurances, is established, and functions in accordance with the national laws and regulations.

In view of the tremendous potential in clinical research in the field of multispecialty disciplines and such other sub-and super-specialties, as may emerge in future in the organization, the Chairman cum Manging Director, DHMH has constituted an IEC as per the policy of the organization as deemed fit and directed for preparation of a SOP to be prepared by the IEC team of the organization to facilitate the work of IEC and maintain high standard of ethical reviews as standard norms of Biomedical Ethics.

2.4 Composition

- The Ethics Committee will be multidisciplinary and shall consist of not less than seven members and a maximum of 15 members.
- One among its members, who is from outside the organization, shall be appointed as Chairperson (not affiliated to the DHMH), one member of the organization shall act as Member Secretary, to conduct the business of the meeting and rest of the members shall be from Medical, Scientific, Non-medical and Non-scientific fields including lay public representative and clinical pharmacologist, persons of the community, a legal expert, a social worker/layperson/ethicist/Participant's representative to represent different point of view.
- There shall be an appropriate balance of professional, ethical, legal, cultural, educational, and community interests with apossibily equitable representation of all specialties, age and gender.

- The external members shall be in majority (>50%) to ensure independence of the committee.
- Members shall be conversant with the provisions of Good Clinical Practice (GCP) Guidelines for clinical trials/projects in India and other regulatory requirements to safeguard the rights, benefits, safety and well-being of the study participant's.
- Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism.

The composition of IEC, DHMH would be as follows:

1. Chairperson (Not affiliated to DHMH)
2. Consultants of DHMH
3. Clinician(s) (Not affiliated to DHMH)
4. Basic Medical Scientist/Scentific Member
5. Clinical Pharmacologist(s).
6. One or two legal experts or retired judge or medico-legal expert
7. One or two social scientist/worker/ethicist/representative of non-governmental voluntary agency
8. Lay person(s) from the community or public representative

Table 2.1 Composition, affiliations, qualifications, member specific roles and responsibilities of IEC

S. No.	Members of IEC	Definition/description
1.	Chairperson Non-affiliated Qualifications - A well-respected person fromany background with prior experience of having served/ serving in an EC	• Conduct IEC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should bea non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of IEC data, etc.
2.	Member Secretary Affiliated Qualifications - • Should be a staff member of the institution • Should have knowledge andexperience in clinical researchand ethics, be motivated and have good communication skills • Should be able to devoteadequate time to this activitywhich should be protected by the institution	• Organize an effective and efficient procedure for receiving,preparing, circulating and maintaining each proposal for review • Schedule IEC meetings, prepare the agenda and minutes • Organize IEC documentation, communication and archiving • Ensure training of IEC secretariat and IEC members • Ensure SOPs are updated as and when required • Ensure adherence of IEC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions
3.	Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications inbasic medical sciences • In case of EC reviewing clinical trials with	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety

	drugs, the basic medical scientist should preferably be a pharmacologist	and pharmacodynamics.
4.	Clinician(s) Affiliated/ non-affiliated Qualifications - • Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design,methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness ofthe principal investigator, provision for medical care,management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5.	Legal expert/s Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stemcell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations, if any.
6.	Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated Qualifications - • Should be an individual with social/behavioural science/ philosophy/religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved inhealth-related activities	• Ethical reviews of the proposal, ICD alongwith the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal /community representative and bring in ethical and societal concerns.
7.	Lay person(s) Non-affiliated Qualifications - • Literate person from the public orcommunity • Has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community from which the participant's are to be drawn • Is aware of the local language, cultural and	• Ethical review of the proposal, ICD alongwith translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ communityrepresentative and bring in ethical and societal concerns. • Assess on societal aspects if any.

	moral values of the community • Desirable: involved in social and community welfare activities	

Criteria for selection of members:

- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge, expertise, and experience in domain field and profile.
- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.
- The members representing medical/non medical scientist/scientific member and clinicians should have postgraduate qualifications and adequate experience in their respective fields and be aware of their role and responsibilities as committee members.
- The Chairperson and Member Secretary should have a dual role in Ethics Committee. They could fulfill a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.
- The head of the Organization should not be the part of IEC, but should act as an appellate authority to appoint the committee or handle dispute.
- The IEC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a pediatrician for research in children, an oncologist for research on oncology or its related research, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/ voting rights.
- As far as possible, the organization may constitute a scientific committee for scientific review of the protocols. IEC can raise scientific queries beside ethical ones as both good science and ethics are important to ensure quality of research and participant protection.
- New members will be identified according to the requirement i.e., as per the composition specified in Section 2.5 of this SOP.

The following qualities are sought in IEC members:

- Interest and motivation
- Time and effort
- Commitment and availability
- Experience and education
- Respect for divergent opinions
- Integrity
- Conflict of Interest norms
- Confidentiality norms

2.5 Terms of reference of IEC members

2.5.1 Duration and renewal

- The IEC Members will be appointed by the Chairman cum Manging Director, DHMH for a duration of 5 years. The competent authority of the organization will issue letters of appointment to the Chairperson, Member Secretary and IEC members.
- The letter issued by the competent authority of the organization should include, at the minimum, the following:
    - Role and responsibility of the member in the committee
    - Duration of appointment
    - Conditions of appointment
- The appointment procedure for membership will be followed so that it allows for continuity, the development and maintenance of expertise within the IEC, and the regular input of fresh ideas and approaches.
- The members can be continued and there is no limit on the number of times the membership is extended. Extension of membership will be decided by the Chairman cum Manging Director, DHMH.

- Chairperson, Member Secretary and IEC members may be appointed before the completion of the tenure of the existing appointed committee at least prior to the 60 days.

2.5.2 Conditions of appointment

- Name, gender, profession, and affiliation of IEC members will be publicized.
- Members must accept the appointment in writing.
- Submit CV (AN7-V1/DHMHSOP 02/V1) and training certificates on human research protection and good clinical practice (GCP) guidelines, if available.
- Members must apprise themselves of the relevant documents, codes, GCP, ICH guidelines, Gazette of India 2019, ICMR guidelines 2017, National guidelines for Ethics Committees reviewing Biomedical & Health Research during Covid-19, ICMR 2020, the ICMR code, and IEC, DHMH SOP. Copies of these documents will be provided by the IEC Secretariat on written request.
- An investigator can be a member of the IEC; however, the investigator-as-member cannot participate in the review and approval process for any project in which the member is PI, Co-PI or has any other potential conflict of interest.
- The designated member of the IEC who accepts the membership should sign the Conflict of interest, if any, must be disclosed vide Confidentiality and conflict of Interest Document (AN1-V1/DHMHSOP02/V1).
- Members must be willing to undergo training or update their skills/knowledge during their tenure as an IEC member.
- Members must be committed and understanding to the need for research and for imparting protection to resaech participant’s in research.
- Member of the IEC should not have any known record of misconduct.

2.5.3 Resignation/replacement procedure

- If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of appointment stated above.

- IEC member who decides to resign should send a written notification of resignation to the Chairman cum Managing Director, DHMH.
- Chairman cum Manging Director, DHMH would appoint a new member, falling in the same category of membership (ex. NGO representative with NGO representative)
- Similarly, if internal consultant proceeds on leave for more than 6 months or leaves the organization, the Chairman cum Manging Director, may be replaced by another consultant of the organization.

2.5.4 Termination/disqualification procedure

A member may be relieved or terminated of membership in case of:

- Conduct unbecoming for a member of the Ethics Committee.
- If a member fails to attend more than 3 consecutive meetings of IEC, the matter shall be reviewed by the IEC. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairman cum Manging Director, DHMH, through the Chairperson IEC for necessary replacement.
- In all such situations/circumstances, Chairman cum Manging Director, DHMH, will send a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes and confirmed in the next IEC meeting and IEC membership notification will be revised. At any stage if, there is violation of conflict of interest by any member of the IEC, the Chairman cum Managing Director, DHMH, reserve the right to debar the membership of that particular member from the IEC.
- If the committee is not functioning properly, the Chairman cum Managing Director DHMH, reserve the right to reconstitute the entire committee without assigning any reason thereof.

2.6 Independent consultants

- The IEC may call upon, or establish a standing list of, independent consultants/ experts who may provide special expertise to the IEC on proposed research protocols, when the Chairperson or the IEC members determine that a study may involve procedures or information that is not within the area of expertise of the IEC members.
- These independent consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, (e.g., genetic disorders, stem cell research, project related to HIV etc.) or they may be representatives of communities, Participant's, or special interest groups. The independent consultants may be called as a special invitee for an

opinion on specific proposal only and they have to sign the confidentiality document as per (AN2-V1/DHMHSOP02/V1

- The independent consultants or subject experts cannot vote for decision and they will not be the part of full board meeting.

2.7 Office bearers

The IEC will have the following office bearers who have the expertise and professional qualifications to review the submitted documents:

2.7.1 Chairperson

The IEC Chairperson should be from outside the Institution, capable of managing the IEC and the matters brought before it with fairness and impartiality. He/she should not be a former consultant of DHMH. The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of this individual. The IEC must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources.

- The Chairperson will conduct IEC meetings and be accountable for independent and efficient functioning of the meeting. If the chairperson is not available for reasons beyond control, then his/her designee will act as alternate Chairperson (non-affiliated) In case, designee is not available, then an alternate Chairperson will be elected by the members present from among themselves during the particular IEC meeting.
- Ensure active participation of all the members (particularly non-affiliated, non-medical/non-technical) in all discussions and deliberations.
- Ratify minutes of previous meeting, seek conflict of interest declaration from members and ensure quorum and fair decision making.

2.7.2 Member Secretary

The Member Secretary will be a staff member of organization, responsible for coordinating and managing the activities of the committee including scheduling the meetings, describing the agenda, preparation of minutes and ensuring that the function of the committee is conducted as per the norms and policies described in this SOP.

- Organize IEC documentation, communication and archiving.
- Ensure training of IEC secretariat and IEC members.

- Ensure SOPs are updated as and when required and also ensure adherence of IEC functioning according to the SOPs.
- Prepare for and respond to audits and inspections.
- Assess the need of expedited review/exemption from the review or full board review.

2.7.3 IEC Secretariat

The IEC Secretariat is composed of IEC Member Secretary and the sufficient administrative supporting staff (Data Entry Operators, Attendents) with proper independent space, adequate furniture for the safeguard of the various documents to maintain the confidentiality. The supporting staff consist of staff members working at DHMH appointed by the Chairman cum Managing Director, DHMH or contractual staff approved by the Chairman cum Managing Director, DHMH.

The IEC Secretariat shall have the following functions:

- SOP operations.
- Organizing an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organizing IEC meetings.
- Preparation of agenda and minutes of the meetings.
- Maintaining IEC documentation and archive.
- To receive IEC processing fees as prescribed by the Organization time to time and issue official receipts for the same.
- Communicating with IEC members and Principal Investigators (PIs).
- Providing necessary administrative support for IEC related activities to the Member Secretary, IEC.
- Arrangement of training for personnel and IEC members.
- The IEC may conduct workshops from time to time for institutional faculty & IEC members.
- Prepare an annual activity report of the IEC for submission to the Chairman cum Managing Director, DHMH for its reporting to the statutory bodies as per requirement.
- A quantitative evaluation of the activities of the committee in a year.

- List of the research proposals reviewed in a year.

2.8 Roles and responsibilities of the IECmembers

The Committee's primary responsibilities will be protection of safety, rights, benefits, dignity and confidentiality of the research participant's.

- Review and discuss research proposals during the IEC meetings and submit the filled evaluation form as prescribed by the IEC for the particular protocols.
- Review progress reports and monitor on-going studies.
- Monitor SAEs and recommend appropriate action(s).
- Maintain confidentiality of the documents and deliberations of the IEC meetings.
- Declare conflict of interest, if any.
- To carry out work delegated by Chairperson and Member Secretary.
- To participate in continuing education activities in biomedical ethics and research.
- To provide information and documents related to training obtained in biomedical ethics and research to the IEC Secretariat.

2.9 Quorum requirements

No decision is valid without fulfillment of the quorum.

A. For Clinical Trials, Bioavailbilty and Bioequivalnce Studies, the quorum of Ethics Committee shall be at least **five members** with the following representation:

1. Medical scientist (preferably a pharmacologist);
2. Clinician;
3. Legal expert;
4. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person
5. Lay person.

B. For other Biomedical and Health Research Studies Involving Human Participant's, the quorum of Ethics Committee shall be as per the following.

1. A minimum of five members present in the meeting room.
2. The quorum should include both medical, non medical or technical or/and non-technical members.

3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. No decision is valid without fulfilment of the quorum.

2.10 Decision making

- Decisions are to be taken by consensus. In exceptional case, if consensus not possible, voting may be carried out.
- Opinions of absent members that are transmitted by E-mail or telephone or mobile may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.
- Any Committee member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.
- In case of a tie, the chairperson can have a casting vote.

2.11 Education and training for IEC members

- IEC members should be trained in human research protection, IEC function & SOP and should be conversant with the ethical guidelines, Good Clinical Practice (GCP) guidelines and relevant ethical regulations of the country.
- The Organization shall support the participation of IEC members in bio-medical ethics workshop/conference once a year, for capacity building. The request should be recommended by Chairperson, IEC.
- The trained members of IEC should submit their documentation for such training in workshop/conference to the IEC secretariat time to time for its documentation and record.

2.12 IEC sub-committees

Sub-committees of IEC may be formed as and when required for expedited review of new or revised proposals where major changes are not required. The same committee may also report for SAE. The decisions of all the subcommittees will be reported to the next meeting of IEC by the Member Secretary.

2.12.1 Sub-committee for expedited review

It will consist of the Member Secretary and two members designated by the chairperson. At least one member should be from outside the Organization. The sub-committee should report to the main IEC. The approval granted through expedited review must be ratified at the next full committee meeting.

2.12.2 Three-member sub-committee for revised proposal/clarifications

The sub-committee will consist of the Member Secretary (convener) and two outside members of the IEC designated by the chairperson. It will take decisions regarding revised proposals/clarifications in proposals where major changes are not required. The sub-committee should report to the IEC.

2.12.3 SAE sub-committee

The sub-committee will consist of the Member Secretary, one senior consultant of the Organization (Chairperson of SAE sub-committee) and 3-4 other members affiliated to the Organization. The SAE sub-committee will review SAE reports with assessment of causality, compensation and regulatory compliance. The decisions of the SAE sub-committee must be approved at the next full board committee meeting.

2.13 Frequency of IEC meeting

- The IEC will meet as and when the suitable numbers of protocols are available in the IEC Secretariat**.**
- At least minimum three meetings may be scheduled in a calender year.
- Emergency meeting may be held as decided by the Chairperson of IEC.
- During the active phase Covid-19/any panademic as per the declation by the Govt. of India the meeting may be conducted through virtual platform.

- During non-active Covid-19 period the IEC full board meeting may be conducted as per the Covid-19 protocols guidelines issued by the Govt. of India/Govt. of UP. time to time.

AN1-V1/DHMHSOP 02/V1

Confidentiality and Conflict of Interest Document for IEC Members

In recognition of the fact, that I, (name and designation ……....

…….....……..

....……

herein referred to as the "Undersigned", have been appointed as a member of the Institutional Ethics Committee (IEC), would be asked to assess research studies involving human Participant's in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines.

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/territory/community nor as the delegate of any organization or private interest;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human Participant's; the undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

That, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. All Confidential information (and any copies and notes thereof) shall not be copied and retained by member, and remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement.

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but I have faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human participant's.

In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC.

I will disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee,

and abstain from participation in discussions or recommendations in respect of such proposals.

Examples of conflict-of-interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

If an applicant submitting a protocol identifies a potential conflict of interest with the undersigned, then the investigator may request in writing to the Chairperson; and the undersigned may be excluded from the review of the project.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation ("Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any agenda items) to the IEC Secretariat upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, ……..... have read and I accept the aforementioned terms and conditions as explained in this Agreement.

_____

Signature

Name_____

Date:_____

AN2-V1/DHMHSOP 02/V1

Confidentiality Document Form for Independent Consultants

I,……

……...(name and designation) as a non-member of IEC understand that the copy (ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

_____

Signature

Name_____

Designation

_____

Date:_____

AN3-V1/DHMHSOP 02/V1

Invitation to Attend a Meeting as Independent Consultant

To,

_____

_____

_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairperson IEC has nominated you as an independent consultant/observer to evaluate a research protocol submitted to the Institutional Ethics Committee for approval.

You are requested to attend the meeting of IEC on …….at…….and to provide written opinion regarding the assigned research proposal (IEC code no

……. and title of project .....) You

will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Kindly note that all the documents submitted to you are confidential. These should not be disclosed to anyone and should be returned to the IEC Secretariat, DHMH after the meeting.

Yours faithfully,

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

Enclosures:

1. Research protocol

2. Confidentiality document

AN4-V1/DHMHSOP 02/V1

Invitation to Attend a Meeting as Observer

To,

_____
_____
_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairperson IEC has invited you as an independent observer to see functioning of the Institutional Ethics Committee meeting.

You are requested to attend the meeting of IEC on…….at.....You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Yours faithfully,

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

Enclosures:

1. Confidentiality document

AN5-V1/DHMHSOP 02/V1

Confidentiality Document Form for Observer Attendees to IEC, DHMH Meetings

I,……

…… (name and designation) understand that I am invited to attend the IEC meeting scheduled on…….at…….am/pm as an Observer. In the course of the meeting of the IEC some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

……

……. Signature

Name: ……

Date…….

AN6-V1/DHMHSOP 02/V1

Confidentiality Document Form for Non-members Requesting Copies of IEC/Documents

I,… .....,..,.,as and on-member of IEC,understand that the copy(ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IEC documents:

……

……

……

……

_____

Signature of the recipient

Name……

……

Designation and

address

Date……

…….

AN7-V1/DHMHSOP 02/V1

CV for Members of the Institutional Ethics Committee

BIO DATA: ETHICS COMMITTEE MEMBER

1. Name:

2. Address (full work address):

3. Telephone number: Whatsapp No.

4. E-mail-ID:

5. Present affiliation (job title, Speciality, and organization):

6. Affiliation with host organization: Yes/No

7. Qualification (starting from basic, add additional rows if needed):

COURSES/SUBJECT	INSTITUTION/ORGANIZATION	YEAR

8. Previous and other affiliation (add additional rows if needed):

AFFILIATION	DESIGNATION	DURATION

9. Role in proposed Ethics Committee (also add dual role if any):

10. Suitability of the member in the assigned role, Elaborate (less than 100 words):

11. Previous EC experience: yes/no, if yes add role /duration with name of EC :(previous EC experience is mandatory for the Chairperson):

NAME OF ETHICS COMMITTEE	DESGNATION /ROLE	DURATION	
		FROM TO	

12. Relevant research training /experience in the area * :(add additional rows if needed):

NAME OF ETHICS COURES /TRAINING	ORGANIZED BY	DATE	DURATION OF TIMING	ATTACH AGENDA/TOPICS COVERED

13. Relevant publication (any 5) and additional information (if any)

Signature: Date:

AN8-V1/DHMHSOP 02/V1

List of Members of Institutional Ethics Committee (2024-2029) (w.e.f. 27.07.2024 to 26.07.2029)

S. N.	Names of person	Designation	Capacity in IEC	Nature of Activity in IEC	Affiliation
1	Dr. (Prof) S.K. Das	President.Former Head, Dept of Rheumatology.KGMU Lucknow.	Chairperson	Chairperson	N
2	Dr. (Prof) U.K. Mishra.	Ex-Dean & Head of Neurology, SGPGIMS Lucknow	Ex-Officio Member	Member	Y
3	Dr. (Prof). A.K. Saxena	Former Prof & Head, Dept of Cardiology KGMU, Chief Consultant	Member	Member	N
4	Dr. (Prof). V.S. Narain	Former Prof & Head, Dept of Pharmacology KGMU.	Member	Member	Y
5	Shri Vijai Varma	Former District Judge & Former Chairman Upbhokta Forum Lucknow	Member	Legal Expert	N
6	Dr. Kumud Shrivastava	Clinical Psychologist	Member	Social Worker	N
7	Shri Maish Hindvi	Associate Professor, Vidyant P.G. college	Member	Social Scientist	N
8	Dr. (Professor) Prabhakar Mishra Srivastava	Head Dept of Biostatistics & Health informatics, SGPGIMS Lucknow.	Member	Scientific Member	N

9	Dr. S. Shrivastava	Ex- Senior Research Officer & Scientist-IV SGPGIMS, Lucknow, Expert (Research & Academics) Kalyan Singh Super Speciality Cancer Institute, Lucknow.	Member	Scientific Member	N
10	Dr. Rama Shrivastava	General & Laproscopic Surgeon, D-2226. Indira nagar, Lucknow	Member	Clinician	N
11	Dr. Sharad Singh	Addl Professor & Head Dept of Radiation Oncology. Kalyan Singh Super Speciality Cancer Institute, Lucknow.	Member	Clinician	N
12	Dr. Anita Fotedar	A1/407 Himalaya Enclave -3, Vrindavan Yojana, Sector 18 Raebareli Road, Lucknow	Member	Lay Person	N
13	Dr. Manoj Kumar	Consultant Cardiotharacic & Vascular Surgery, Divine Heart & Mutispeciality Hospital Lucknow	Member Secretary	Member Secretary	Y

AN9-V1/DHMHSOP 02/V1

Confidentiality Document Form for Faculty/Observer visiting IEC Secretariat

I,……

……. (Name and designation) understand that I visited IEC Secretariat on…….at... am/pm. In the course of the meeting intheIEC Secretariat some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

Signature: ……

Name: ……

Date: …….

AN10-V1/DHMHSOP 02/V1

Conflict of Interest Declaration for IEC Members (During IEC meeting)

To,

The Chairperson

Institutional Ethics Committee
DHMH, Lucknow.

IEC Meeting Number: _____ Date:

Conflict of Interest

I hereby declare that I have conflict of interest in the following agenda items:

1.

2.

3.

4.

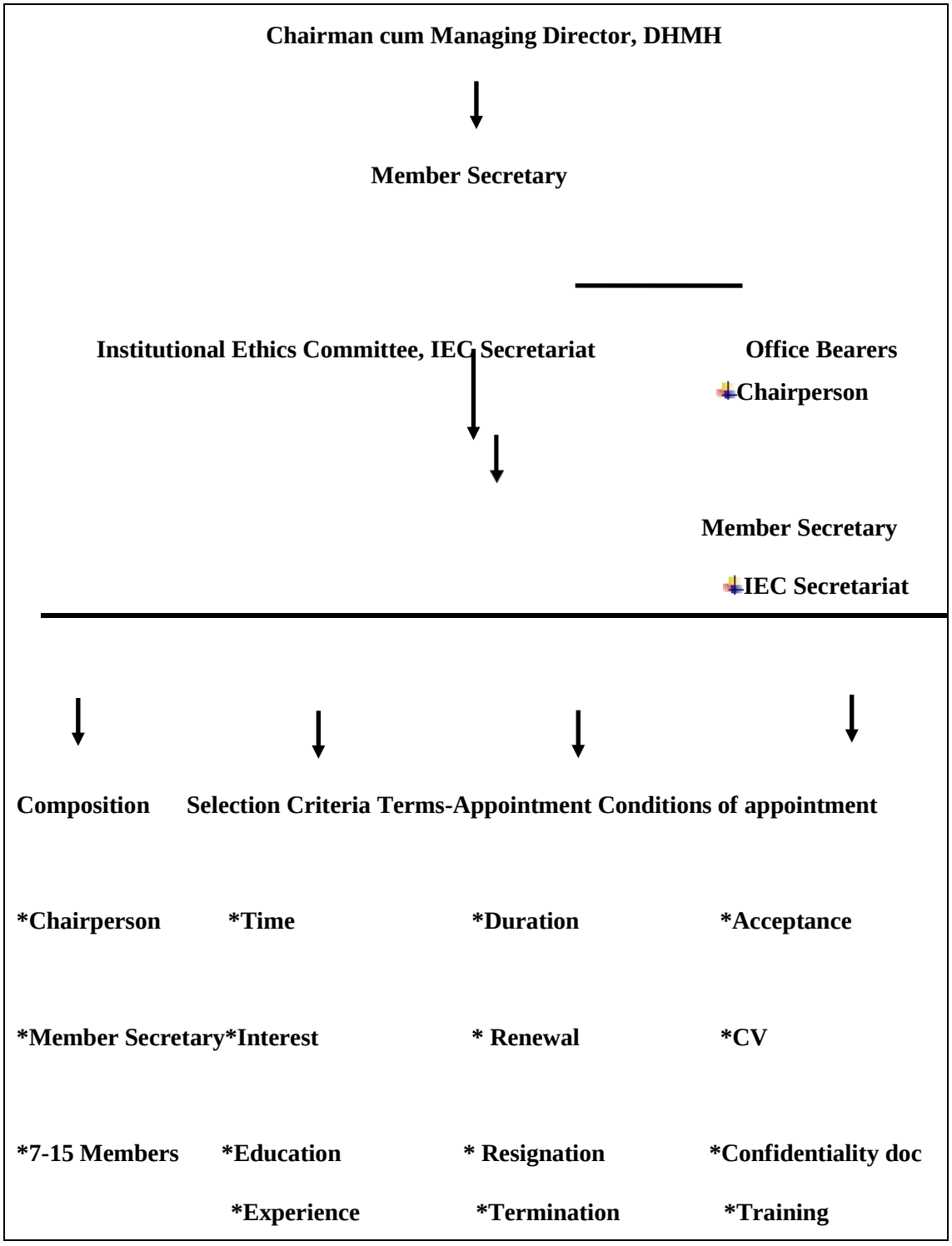
_____

Signature of member

Name_____

Date_____

Flow Chart


Chairman cum Managing Director, DHMH
Member Secretary
Institutional Ethics Committee, IEC Secretariat
Office Bearers
Chairperson
Member Secretary
IEC Secretariat
Composition
Selection Criteria
Terms-Appointment
Conditions of appointment
*Chairperson
*Time
*Duration
*Acceptance
*Member Secretary
*Interest
* Renewal
*CV
*7-15 Members
*Education
* Resignation
*Confidentiality doc
*Experience
*Termination
*Training

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow – 10

SOPs, IEC, DHMH)

Chapter 3

Title: **Management of Protocol Submissions**

DHMHSOP Code: **Date:** **Page: 49-94**

DHMHSOP 03/V1

- Type of protocols
- Process of submitting and receiving protocols
- Documents to be submitted for Initial review
- Reports/amendments/termination/revision of protocols
- CTA/MTA/Agreements and charges in sponsored studies

This SOP is designed to describe and act as a guideline for the IEC Secretariat of the IEC to manage research protocol lsubmissions.

3.1 Type of Protocols

The type of protocols includes:

I. Submission of protocols for initial review.

II. Resubmission of protocols with modifications.

III. Protocol amendments and any other amendments.

IV. Continuing review of approved protocols.

V. Protocol completion/termination.

VI. SAE reports (on-site/off-site)

VII. Final reports of the protocols.

3.2 Detailed Process

It is the responsibility of the IEC Secretariat to receive, record, and distribute the protocols for review by the IEC and communicate the decisions to PI in a prescribed format.

3.2.1Receiving protocols

The PI can submit research proposal to the IEC for review and approval under any of the 7 sections mentioned above (see section 3.1). Before submitting to the IEC Secretariat for initial review, all projects/proposals (intramural/extramural/student/investigator-initiated study/Collaborative projects) may be scientifically reviewed by a scientific committee and a copy of approval letter/document for the said protocol should be submitted to the IEC Secretariat, along with protocols.

3.2.2 IEC Secretariat

The IEC Secretariat will:

- Check the application documents to ensure that all required forms and documents are submitted as per checklist (AN14-V1/DHMHSOP 03/V1). Refer to **Table 3.1 (section 3.2.3).** Include**:**
    - Original Application form/Project submission form (AN1-V1/ DHMHSOP03/V1)
    - Study protocol
    - Case Record Form (CRF)
    - Other documents necessary for initial review (AN2 to13-V1/DHMHSOP03/V1)
- Check completeness of necessary information and signature at all appropriate places in the application form submitted for initial review.
- Notify the applicants, if incomplete.
- State clearly the missing documents in the document receipt Form (AN15-V1/DHMHSOP03/V1).
- Stamp, sign and put date of receipt on the cover letter confirming receipt of the documents.
- Return one copy of the document receipt form (AN15-V1/DHMHSOP 03/V1) to the applicant for their records
- Count number of copies [initially 5 (Five) hard copies and 1 (one) soft copy accepted by email/pendrive].
- Store the hard copies and soft copy of the research project. The hard copies will be archived in the office of the IEC Secretariat and soft copy will be saved on IEC Secretariat computer and external hard disc-drive/pendrive.
- The project file is uniquely numbered as "A-x-y-z" where "A" will indicate years, e.g., 2012 "x" is abbreviation for serial no. of project, "y" will be type of project such as EMP for extramural, IP for independent project, NBE for DNB/Dr. N.B direct six-year course (NBEMS), New Delhi/ DT for drug trial /device trail and so on, "z" will denote IEC meeting number.
- All correspondence for the project, should quote the complete project number assigned to it.

3.2.3

Table 3.1 Documents to be submitted for Initial review

	Document	**Annexure**	**Remarks**
1.	Original Application form/Project submission form	AN1-V1/ DHMHSOP 03/V1	Attach copy of protocol and case record form
2.	Consent of Head (regular) of the PI's Speciality	AN2-V1/DHMHSOP 03/V1	
3.	Organization Research Committee	AN3-V1/ DHMHSOP 03/V1	
4.	Undertaking by PI	AN4-V1/ DHMHSOP 03/V1	
5.	Conflict of Interest Declaration by PI	AN5-V1/ DHMHSOP 03/V1	
6	Recent signed and dated curriculum vitae (CV) of the student (DNB)/Dr. N.B.etc	AN6-V1/DHMHSOP 03/V1	
7.	Participant/volunteer/control/child information documents, consent forms (legally accepted guardian in case of Participant's incapable of giving consent e.g., unconscious, mentally deranged andparent consent forms if participant is a. child/ adolescent between 7–18 years of age) and assent form (child 7-18 yrs.)	AN7-V1/DHMHSOP 03/V1 to AN13-V1/DHMHSOP 03/V1	English and Hindi and any other language if necessary
8	Investigator Brochure andadvertisement/information brochure		For drug/device trials
9	CTRI (Clinical Trial Registry of India) registration		Prerequisite for sponsored clinical trials. In other trials, it can be done after IECapproval
10	DCGI approval letter with list of approved Institutions		For sponsored drug/device trials[§]
11	Details of funding agency/sponsors andfund allocation (Participant's care/staff/contingency/travel etc.)		In project tsubmission form andCTA

12	Clinical Trial Agreement (CTA) (as per DHMH format)	AP-20/V1	For drug/device trials
13	Insurance policy and certificate		For drug/device trials
14	For international export/import of biological materials: Material Transfer Agreement (MTA) and Health Ministry's screening committee (HMSC) clearance (DHR, New Delhi)		In collaborative projects. Copy of HMSC clearance should be submitted to IEC before start of study
15	For export of study samples: Director General Foreign and Trade (DGFAT) approval		In clinical trials
18	Study involving radioisotopes/ionizing radiations: Bhabha Atomic Research Centre (BARC) approval		
19	Decision of other concerned Ethics Committees		In collaborative studies
20	IEC Processing Fees		For pharma company sponsored project/ clinical/drug trials
21	Any other MOU/Agreement in International collaboration		
22	Any other document		

- Please see guidelines for device-based studies in Appendices (AP18/V1).

In investigator-initiated drug trials for academic purposes: the trial can be approved by the IEC and information to be sent to DCGI (as per recent guidelines)

* All clinical trials with any stem cells shall have prior approval of Institutional Committee for Stem Cell Research and Therapy (IC-SCRT), duly registered with (NAC-SCRT).

3.3 Informed consent process

For biomedical and health research involving human participant's, the investigator must obtain voluntary written informed consent of the prospective participant. It is based on the principle that competent individuals are entitled to choose freely whether to participate in research or not. Informed consent is a process that provides opportunity to

the individual to accept or refuse to participate in the study. It protects the individual's freedom of choice and respects the individual'sautonomy.

Table 3.2 Essential elements of an informed consent document

1	Statement mentioning that it is research.
2	Purpose and methods of the research in simple language.
3	Expected duration of the participation and frequency of contact with estimated numberof participant's to be enrolled, types of data collection and methods.
4	Benefits that might reasonably be expected as an outcome of research to the participantor community or to others.
5	Any foreseeable risk, discomfort or inconvenience to the participant resulting from participation in the study.
6	Extent to which confidentiality of records could be maintained i.e., the limits to which theinvestigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality.
7	Freedom of individual to participate and to withdraw from research any time without penalty or loss of benefits which the participant would otherwise be entitled to.
8	Free treatment and/ or compensation of participant's for research related injury and harms.
9	The identity of the research teams and contact persons with address and phone numbers (PI/ Co-PI) for queries related to the research and Chairperson/member secretary or helpline for appeal against violations of ethical principles and human rights.

In addition, the following elements may also be required depending on the type of study	
1	Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected to.
2	Payment/ reimbursement for participation and incidental expenses may be required depending on the type of study.

3.4 Information of change in funding agency/status of approved project:

If there is change in funding status/agency of approved project, the PI should inform

same to IEC through the IEC Secretariat stating the title of project, IEC code and date of approval and PI should also state that there are no changes in title, design, and methodology. The IEC Secretariat will notify to the IEC and PI will be given fresh approval letter for administrative purpose (if requested by PI).

3.5 Resubmission of protocols with corrections as per IEC suggestions

- For minor corrections as per the suggestions of the IEC, the PI will submit cover letter stating the changes along with one copy of the amended Protocol and related documents with clearly highlighted/demarcated sections which have undergone correction.
- For resubmitted/major changes in the protocol, the PI will submit 4 copies of the amended protocol and related documents along with justification for amendment, and clearly highlighted/demarcated sections which have undergone amendment.
- When the protocol has been revised and is being submitted for review as a new study, the PI will submit 5 copies with related documents as per the checklist for initial review.
- The IEC Secretariat will verify the completeness and confirm that the copy contains the modification highlighted with respect to the earlier protocol.
- The IEC Secretariat will perform the steps 3.2.2 as mentioned in initial review application.

3.6 Research protocol amendments and other study related documents

- The PI will submit 4 copies of the protocol amendments or any other study related documents to the IEC Secretariat.
- DCGI approval letter is required for amended protocol in drug/device trials.
- The PI must highlight the modification/s in the amendment, along with a summary of changes and whether these changes would entail changes in the ICF. If yes, details of changes should be summarized in tabular form.
- The Member Secretary in consultation with Chairperson will decide whether to:

  a. Carry out an expedited review

  b. Table for discussion at the full board meeting. This process is further elaborated in DHMHSOP06/V1.

3.7 Annual continuing reviews of approved protocols

The IEC Secretariat will:

- Send reminders for annual report to Individual PI, at least 20 days prior to the expiry date of approval, which usually is one year from the date of approval letter.
- The IEC Secretariat will receive 4 copies of Annual Study/Continuing Review Report/ progress report/request letter for extension of approval and related documents of the project in the prescribed format (as per DHMHSOP 08/V1) for each approved protocol.
- The IEC Secretariat will verify for completeness of the documents and signand date the documents. These will be tabled in the next full board meeting of IEC.

3.8 Project completion

- It is the responsibility of the PI to submit the final report within 6 months of completion of the project along with a copy of abstract/publication if any.
- The IEC Secretariat will receive 4 copies of Study Completion Report in the prescribed format (as per DHMHSOP 11/V1).
- The IEC Secretariat will send reminders for completion report to PI, atleast 20 days prior to the date ofcompletion.
- The IEC Secretariat will verify the completeness of the Study Completion Report Form (DHMHSOP 11/V1) filled by the PI and the study completion report will be tabled in the next full board meeting of IEC.

3.9 Clinical Trial Agreement (CTA) or Other Agreement for Sponsored Drug/ Device/ Collaborative Trials/ Study

After the approval from IEC, the sponsor/ principal investigator (PI) will submit the duly signed copies by the sponsor/CRO of CTA/other agreement on Rs. 100 quasi-judicial stamp papers (three copies) to the Organization with counter signature by PI, for signature of the Chairman cum Managing Director, DHMH. CTA/any other agreement and indemnity will safeguard the interest and right of the research participant, investigator and Organization. It should contain the main constituents of the CTA draft (Available at Organization website under IEC Secretariat (SOPs)-as Schedule ad links (www.divinehearthospital.com). As per existing policy of the organization, there would be 25% overhead charges in the financial part to the total cost of the trial/per Participant'scost (In case of pharma company sponsored study/trial only) for the Government funding agencies the amount of the overheads charges may be claimed as per their norms. The drug trial shall be started by the PI after the agreement is signed by

both the parties. Also, DCGI and other required regulatory approvals should be obtained for the concerned trial, and copy of the same should be submitted to IEC Secretariat before starting the trial. After approval of the CTA by the CTA screening committee (appointed by the Organization), a copy of the approved and duly signed CTA should be submitted to the IEC Secretariat before starting the trial.

Material transfer agreement (MTA): For any study, where there is exchange of biological samples, by import or export from abroad, there has to be an MTA as per ICMR format; and it should be submitted along with the study protocol to the IEC. After the approval from IEC, PI has to obtain approval from HSMC, DHR, ICMR New Delhi, before starting the study.

3.10 Charges

The Organization will charge a minimum Rs. 1,00,000/+GST (as per rules) as an administrative charge from the Sponsor/CRO of clinical drug/device/Intervention trial for IEC submission. The Organization will not charge any IEC fee for the protocols funded by Government funding agencies. The charges should be deposited by the sponsor/CRO of clinical drug/device/Intervention trial as DD in favour of **Divine Heart Hospital & Research Centre (P) LTD (A/c No, 50085000555, IFSC Code – IDIB000L561)**. This may be exempted in case of Academic institution or Academic Society by the Chairman cum Managing Director DHMH, case to case basis.

3.11 **Reporting of SAE/protocol violation/protocol amendment** is detailed in chapter 7,9and 10.

3.12 **Site Monitoring procedures** are detailed in Chapter 17 (DHMHSOP17/V1).

AN1-V1/DHMHSOP 03/V1

Project Submission Form for Review by IEC

(5 copies (Hard) & E-mail also)

To be filled by IEC Secretariat:
Project ID:_____Date of Submission of completed form:_____

A. Identification:

Project Title:				
Principal Investigator (PI)		**Speciality and Designation**	**Tel. no./E-mail**	**Signature**
Co-PI/ Collaborator*/Student*				
1.				
2.				
3.				
4.				
5.				
Project funded	☐No ☐Yes	Funding Agency: ☐Intramural ☐Extramural ☐ClinicalTrial	Sponsor/CRO/Funding agency: ……. Budget: …….	
Student project	☐No ☐Yes*	Dr.NB ☐PhD ☐JRF ☐ SRF ☐ DNB ☐ Any other☐		
Collaborative	☐No ☐Yes	☐National ☐International	Name of Organization/'s:	
Study duration				

*See instructions/notes

B. Project Details

I. Study Design	☐Interventional ☐Others …….. ☐Observational		☐Single Centre ☐Multicentre
II. Participant's			
1. From DHMH* Controls Participant's	Numbers ……..... …….....	Source …… …….	Total (if multicentre) …… …… …… ……
2. Gender	☐Both ☐Males only ☐Females only		
3. Clearly defined inclusion/ exclusion criteria: ☐Yes ☐No			
4. Vulnerable Participant's	☐No ☐Yes	☐Pregnancy☐Children☐Elderly☐Illiterate ☐Handicapped ☐Terminally/seriousl yill ☐Mentally challenged ☐Economically/socially backward☐Others	
5. Special group Participant's:	☐No ☐Yes	☐Captives ☐Employees ☐Students☐Nurses ☐Armed Forces ☐Healthcare workers ☐Any other	
6. Advertising for recruitment of Participant's	☐No ☐Yes	If yes, please attach copies of posters, flyers, brochures, websites etc.	
III. Specimen collection	☐No ☐Yes	If yes, complete section B.III	
IV. Interventional Study	☐No ☐Yes	If yes, complete section B. IV	

<table>
<tr><td>V. Risk and Benefits</td><td colspan="2">a. Does this study qualify for ☐ Minimal risk’*
☐More than minimum risk
☐High risk
b. Is their benefit a) to the Participant? ☐Yes ☐No; ☐Direct
☐Indirect
b) to the society? ☐Yes ☐No
c. Is the risk commensurate to the benefits to be accrued by the Participant’s/ community/country? ☐Yes ☐No</td></tr>
<tr><td>VI. Privacy and Confidentiality</td><td colspan="2">Study Involves: ☐Direct Identifier (Participant identified by name/ Cr. No) ☐ Indirect identifiers (Participant’s identified by study ID)
☐ Completely Anonymized (Participant cannot be identified)
Confidential handling of data by staff: ☐Yes ☐No</td></tr>
<tr><td rowspan="4">VII. Informed Consent Documents: a. Participant Information Document (PID)*
b. Informed Consent Forms (ICF’s)</td><td colspan="2">☐ None (Waiver of consentform)</td></tr>
<tr><td>☐Written
☐Verbal
☐Audiovisual</td><td>-Language: ☐Hindi ☐English ☐Others
-Study includes children: ☐Yes ☐No
If yes, Age group …….</td></tr>
<tr><td colspan="2">PID and ICF for: ☐Participant’s☐Controls/volunteers ☐Parents/LAR
LAR-Legally acceptable/authorized representative/guardian</td></tr>
<tr><td colspan="2">PID and Assent form (children 7-18yrs): ☐Child</td></tr>
<tr><td colspan="3">Consent will be taken by: ☐PI/Co-PI ☐Nurse ☐Counselor
☐Research Staff ☐Student ☐AnyOther</td></tr>
<tr><td colspan="3">VIII. Archival of records by IEC Secretariat for more than 3years (5years for clinical trials) after termination/completion of study: ☐Yes☐No
If yes, for how many years……
Reasons for Archival……</td></tr>
</table>

*See instructions/notes

C. Identify the ethical Issues (if any) related with thestudy:

……

……

……

D. Brief proposal summary

Aim(s) and objectives, methodology describing the potential risks and benefits, outcome measures (maximum 500 words).

_____

Signature of PI

Name_____ **Date**_____

Section B.III (Specimen collection)

1. Type	Nature	Amount	Frequency	Total amount	Comment
Blood					
Body fluid					
Tissue					
Others					

2. Collection of fetal tissue or abortus: ☐No ☐Yes

Specify……

3. Use of pre-existing/stored/left over samples: ☐No ☐Yes

Provide details……

……

4. Proper disposal of material: ☐Yes ☐No

5. **Storage for banking/future research:** ☐Yes ☐No

6. Will any sample collected from the Participant's be sent abroad? ☐Yes ☐No If yes, give details and address of collaborators:

_____

_____

Sample will be sent abroad because: ☐Facility not available in India

☐Facility in India is inaccessible

☐Facility available but not being accessed

If so, reasons_____

***Has necessary clearance been obtained*:** ☐Yes ☐No

Section B.IV (For Interventional studies only)

1. Study involves use of: ☐Drugs* ☐Devices* ☐Vaccines*☐Radio pharmaceutical

☐Recombinant DNA/Gene therapy ☐Stem cell ☐Indian/Alternate system of Medicine

☐Any other…….

*(Need approval from *DCGI; BARC for radioactive substances and from DBT for gene therapy. Research in alternate system of medicine in accordance to AYUSH-GCP guidelines)*

2. Is it approved and marketed in? ☐India ☐UK & Europe ☐USA ☐OtherCountries

Approved Indication, specify…….

3. Is it an Investigational New Drug? ☐Yes☐No.

If yes:

a. Investigator's Brochure enclosed ☐Yes☐No

b. Preclinical studies data available (If yes, provide summary ☐Yes☐No

c. Clinical studies data available (If yes, provide summary ☐Yes☐No

d. Clinical study in Phase: ☐I ☐II ☐III☐IV☐NA

If phase I-III will the drug/device provided free? ☐Yes ☐No

If phase IV will drug/device provided at cost less than Hospital pharmacy? ☐Yes ☐No

e. DCGI's permission obtained: ☐Yes ☐No, **if yes,** copy of letter enclosed ☐Yes☐No

5. Data monitoring

a. Is there plan for reporting of adverse events? ☐Yes☐No

If yes, reporting will be done to: ☐Sponsor ☐ IEC ☐DCGI

b. Is there a plan for interim analysis of data? ☐Yes☐No

Mention Date Monitoring Plan

……

…..

6. **Provision for travel/treatment due to injury from study funds:** ☐Yes ☐No

If yes, by: ☐Sponsor ☐Investigator ☐Insurance Company ☐Any Other

7. Registered with Clinical Trial Registry – India: ☐Yes ☐No

If yes, copy of certificate enclosed: ☐Yes ☐No

Instructions/ Notes:

1. Submit Five copies and one C.D/ pendrive of form and all documents as per checklist.
2. Submit detailed Study/Project Protocol (Short review of literature, justification for study, aim, methodology, inclusion, exclusion criteria, statistical analysis).
3. Submit case reportform (CRF)
4. Submit a page of recent, signed and dated curriculum vitae for **PI outside DHMH** or of the **student DNB/PhD)** who has submitted thesis/project.
5. Mention sample size calculation inprotocol
6. Mention source of controls/healthy volunteers.
7. PID should be in simple language avoiding technical terms
8. 'More than minimal risk': *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (US-FDA 2014).
9. Consider the following while framing Participant Information Sheet/Document (PIS/PID):

- Understandable language
- Alternatives to participation
- Statement that study involves research
- Confidentiality of records
- Sponsor of study
- Contact information
- Statement that consent is voluntary
- Purpose and procedures
- Risks & discomforts
- Consent for future use of biological sample
- Benefits if any infuture
- Right to withdraw
- Free supply of drug, asapplicable
- Compensation for study related injury

Note: - The content and the meaning in the english version of the PID and in hindi version should be the same.

AN2-V1/DHMHSOP 03/V1

Consent of Head (regular) of the PI's Speciality

Date: …….

I have reviewed the project "……." submitted by

…… Principal Investigator from my Speciality. I endorse the project and have 'no objection' for submission for consideration by ethics committee.

I concur with the participant's / investigators included in the study.

……	……..	……..
Signature & date	**Name**	**Speciality**

Note: To avoid conflict of interest, if the Head of the Specialityis himself/herself the PI, this form should not to be submitted.

AN3-V1/DHMHSOP 03/V1

Organization Scienctific Committee/Specialityal Research Committee/ Doctoral Committee

The project titled "……" with all the accompanying documents listed above was reviewed by the Organization Research committee/Specialityal Research Committee/Doctoral committee presenton..... at DHMH. The committee has granted approval on the scientific content of the project.

The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

……Signature of Head of the Speciality or Chairperson Scientific Committee

Name: ……..……..……

Date: ……..…...…

Not applicable to sponsor/CRO initiated drug/device trials

AN4-V1/DHMHSOP 03/V1

Undertaking by the Principal Investigator

1. **Name of the project:**

2. **Name, designation and Speciality of the principal investigator:**

3. **Other members of the research team:**

4. **Name and address of any other medical college, hospital or institution where parts of the study will be done:**

5. **Number of ongoing projects/clinical trials in which you are PI:**

a. Number of sponsored clinical trials with active enrolments: _____

b. Number of sponsored clinical trials with follow up only: _____

c. Total number of ongoing projects (any)(Projects+a+b): _____

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
3. I confirm that the Co-PI and other members of the study team have been informed about their obligations and are qualified to meetthem.
4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under national regulatory and ICMR guidelines are adhered to.
5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, regulatory authorities, sponsors or their authorized representatives.
6. I will inform the IEC and the sponsors of any unexpected or serious adverse event at

the earliest and definitely as per the national regulatory guidelines.

7. I will maintain confidentiality of the identity of all participating Participant's and assure security and confidentiality of study data.
8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
9. I will inform IEC if there is change in funding agency/status.
10. I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

_____

Signature of PI

Name_____ **Date**_____

Speciality_____

AN5-V1/DHMHSOP 03/V1

Conflict of Interest Declaration by PI

To,

The Member Secretary
Institutional Ethics
Committee DHMH,
Lucknow.

Project entitled: …….

Name of PI:

Conflict of Interest

[ ] I hereby declare that I have no conflict of interest in my project.

[ ] I have following conflict of interest:

_____

Signature of PI

Name_____ **Date**_____

Speciality _____

AN6-V1/DHMHSOP 03/V1

CV* of New PI or Investigator outside DHMH or of the student

Name:		
Date of Birth (dd/mm/yyyy):		**Sex: Male [] Female []**
Study Site Affiliation (e.g., Principal Investigator, Co-Investigator, Coordinator):		
Professional Mailing Address: **(Include institution name)**	**Study Sited Address:** **(Include institution name)**	
Telephone (Office):	**Mobile Number:**	
Telephone (Residence):	**E-Mail:**	
Academic Qualifications (Most current qualification first):		
Degree/Certificate	**Year**	**Institution, Country**
Current and Previous 3 Relevant Positions Including Academic Appointments **(Most current position first):**		
Month and Year	**Title**	**Institution/Company,** **Country**
Brief Summary of Relevant Clinical Research Experience:		
Signature:		**Date:**

*Signed and dated curriculum vitae of the investigators indicating qualifications and relevant experience for **new or investigator outside DHMH** or of the **student (Dr.NB/PhD)** who has submitted thesis/project.

AN7-V1/DHMHSOP 03/V1

Guidelines for Devising a Participant / Legally Acceptable Guardian Information Document (PID) in English

Kindly refer to Table 3.2 for the essential elements of an informed consent document. For example, of PID in non-interventional studies, see appendix (AP7/V1). For 'Recommended Terms for use in Informed Consent Document', see appendix (AP12/V1)

1. Study Title

Is the title self-explanatory to a lay person? If not, an additional simplified title may also be included.

2. Invitation Paragraph

You should explain that the Participant's is being asked to take part in a research/trial study. "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part."

3. What is the purpose of the study?

The background and aim of the study should be given here.

4. Why have I been chosen?

You should explain how and why the Participant's/volunteer was chosen and how many other participant's will be studied.

5. Do I have to take part?

You should explain that taking part in the research/trial is entirely voluntary. States:

"It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. What will happen to me if I take part?

You should say how long the participant's will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the Participant's will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g., blood tests, x-rays, interviews etc.? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the Participant's's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use States:

Randomized Trial: Sometimes, because we do not know which way of treating Participant's is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual i.e., by chance. Participant'ss in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the Participant's what chance they have of getting the study drug/treatment: e.g., a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double-blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the participant's if there are any dietary restrictions. Can the Participant's drive? Drink? Take part in sport? Can the Participant's continue to take his/her regular medication? Should the Participant's refrain from giving blood? What happens if the Participant's becomes pregnant? Explain (if necessary) that the Participant's should take the medication regularly and dangers of non-compliance.

8. What is the drug or procedure that is be ingtested?

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Participants' entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research/trial the participant's should be told what other treatment options are available.

10. What are the side effects of taking part?

For any new drug or procedure, you should explain to the participant's the possible side effects. If they suffer these or any other symptoms, they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the participant's will clearly understand (e.g., 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For any relatively new drug it should be explained that there may be unknown side-effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the participant's were pregnant or became pregnant during the study, States:

"It is possible that if the treatment is given to a pregnant woman, it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g., terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of fetal damage.

If future insurance status, e.g., for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g., high blood pressure is detected). If the Participant'ss have private medical insurance, you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the Participant's was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g., high blood pressure, HIVstatus)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the participant'sfrom taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the participant'sduring the course of the study, e.g., saying they will be given extra attention. States:

"We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future Participant's with (name of condition) better".

13. What if new information becomes available?

If additional information becomes available during the course of the research/trial, you will need to tell the participant's about this. States:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be explained to the participant's. You would also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the participant's.

15. What if something goes wrong?

You should inform participant's how complaints will be handled and what addresses may be available. Is there a procedure in place? You will need to distinguish between complaints from participant'sas to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial, i.e., a reportable serious adverse event. You should incorporate following line in PID "In case of study related injury or death, (name of CRO/ company), will provide the complete medical care as well as compensation for the injuries or deaths".

16. Will my taking part in this study be kept confidential?

You will need to obtain the participant's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. "If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

You should be able to tell the participant's what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

The information should include the organization or company sponsoring or funding

the research/trial (e.g., Govt. agency, pharmaceutical company, NGO, academic institution).

The participant's should be told whether he has to pay for drugs/tests, the doctor conducting the research/trial is being paid for including and looking after the participant'sin the study. The information regarding payment and compensation should be included in PID.

19. Will the drug be made available after trial is over? (New drug requires continued use, till it is marketed in India)

Please explain to participant regarding the query of availability of study drug.

20. Who has reviewed the study?

You may should mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

21. Contact for further information

You should give the participant's contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers.**

Remember to thank your Participant's for taking part in the study!

The PID should be dated and given a version number. It should state that the participant will be given a copy of the information sheet and the signed consent form.

_____

Signature of PI

Name_____ **Date**_____

Speciality_____

AN8-V1/DHMHSOP 03/V1

Consent Form (English)

StudyTitle_____

ofParticipant_____

_____

Qualification_____

Occupation: Student/self-employed/service/housewife/other (please tick as appropriate) Annual income of participant's_____

Name and address of nominee(s) and his relation to participant's_____

_____

1. I confirm that I have read and understood the information document dated _____for the above study and have had the opportunity to ask questions.

   OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the clinical trial/study, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study/ trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I permit the use of stored sample (tissue/blood) for future research. **Yes☐** **No☐**

6. I agree to take part in the above study.

Signature (or Thumb impression) of the Participant's/Legally Acceptable Representative:

_____

Signatory'sName_____Date_____

Signature of the Investigator_____Date_____

Signature of the Witness_____Date_____

Name of the Witness _____

Received a signed copy of Participant Information Document and Consent Form.

Signature (or Thumb impression) of the Participant/Legally Acceptable Representative:

_____ Date_____

AN09-V1/DHMHSOP 03/V1
प्रतिभागी के लिए सूचना–पत्र
हिन्दी में प्रतिभागी के लिए सूचना पत्र के नमूने के लिए, अपेंडिक्स (परिि"ाश्ट) AP7/V1(देखें)

1. अध्ययन भीर्शक

क्या आपका अध्ययन शीर्षक एक आम आदमी के समझने योग्य है? यदि नहीं, तो आप एक अतिरिक्त सरल शीर्षक शामिल कर सकते हैं।

2. निमंत्रण अनुच्छेद

आपको समझना चाहिए कि मरीज को एक अध्ययन/"ाोध परीक्षण में भाग लेने के लिए कहा जा रहा है, निम्नलिखित एक उदाहरण है:

आपको एक अध्ययन/"ाोध परीक्षण में भाग लेने के लिए आमंत्रित किया जा रहा है। इससे पहले आपके लिए यह समझना जरूरी है कि यह अध्ययन क्यों किया जा रहा है और उसमें क्या चीजें शामिल है। कृपया आप अपना समय निकाल कर इस सूचना को पढ़े तथा अपनी इच्छानुसार अपने मित्रों, परिजनों तथा अपने चिकित्सक के साथ चर्चा करें। अगर आपको कोई जानकरी समझ में नहीं आती है या और चाहिए तो हमें बताएं। आप अपना समय निकाल कर इस सूचना को पढ़ें और बताए कि आप अध्ययन में भाग लेना चाहते हैं कि नहीं।

3. अध्ययन का उद्दे"य क्या है?

पृष्ठभूमि और अध्ययन के उद्दे"य कि जानकारी सरल शब्दों में यहाँ देनी चाहिए।

4. मुझे इस अध्ययन के लिए क्यों चुना गया है?

कृपया आप प्रतिभागी को यह बताए कि उसे क्यों चुना गया है और इस अध्ययन और कितने लोगों का चुनाव किया जाना है।

5. क्या इसमें मुझे भाग लेना चाहिए?

कृपया आप भागी को समझाए कि अनुसंधान/परीक्षण में भाग लेने के पूरी तरह स्वैच्छिकता है। आप निम्नलिखित पैराग्राफ का इस्तेमाल कर सकते है:–

"यह आप पर निर्भर है कि आप को भाग लेना चाहिए कि नहीं। यदि आप भाग लेने का फैसला करते हैं तो आप को अपने पास रखने के लिए एक सूचना पत्र दिया जाएगा और एक सहमति फार्म पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आपने भाग लेने का फैसना किया फिर भी किसी भी समय बिना कारण वापस भाग न लेने के लिए स्वतंत्र हैं। इस कारण आपके इलाज में कोई फरक नही पड़ेगा।"

6. मुझे क्या होगा यदि मैं इस अध्ययन में भाग लेता हूँ?

आपको यह बताना चाहिए कि प्रतिभगी को कितने समय के लिए अध्ययन में भाग लेना है और यह अध्य यन कितने समय चलेगा। आपको यह भी बताना होगा कि भागी को कितनी बार और कितने दिनों के लिए परीक्षण के लिए अस्पताल में आना होगा। आप प्रतिभागी को यह भी बताए कि उसे अस्पताल में नियमित विजिट के अलावा आना होगा और आप बताए कि आने जाने का खर्च किसे देगा होगा? आप भागी को यह भी बताए कि उसे आने पर हर बार कौन–कौन सी जाँचें करना होगा। आप प्रतिभागी को यह भी बताए कि उसकी क्या जिम्मेदारी होगी। प्रतिभागी को लिखकर यह दीजिए कि उसे क्या सावधानी बरत कर आना चाहिए। आप प्रतिभागी को अध्ययन के विभिन पहलुओं के बारे में जानकारी दीजिए।

7. मुझे क्या करना है?

क्या अध्ययन में भाग लेने से जीवन शैली पर किसी तरह का फर्क पड़ेगा? आप भागी को यह भी बताए कि उसे आहार में कोई सावधानी बरतनी होगी। आप प्रतिभागी को यह बताए कि क्या वह रोज की तरह गाड़ी चला सकता है? क्या वह खेलकूद में भाग ले सकता है? क्या वह अपनी रोज कि दवायें ले सकता है? क्या उसे रक्त देने से बचना चाहिए? आप यह भी बताए कि उसे गर्भवती हो जाने पर क्या करना चाहिए। भागी को नियमित रूप से दवा लेने के बारे में बताए और उसे न लेने के नुकसान के बारे में बताए।

8. दवा या प्रक्रिया का परीक्षण किया जा रहा है?

आप को दवा या प्रक्रिया या डिवाइस का एक संक्षिप्त विवरण देना चाहिए। आपको उनके विकास के बारे में जानकारी देना चाहिए। आपको दवा की खुराक और उसे देने की विधि के बारे में जानकारी देना चाहिए। यदि मरीज को दवा के परीक्षणों में शामिल किया जाता है तो उसे अध्ययन की जानकारी का एक पहचान पत्र जैसा कार्ड देना चाहिए।

9. निदान या उपचार के लिए और विकल्प क्या हैं?

चिकित्सकीय शोध/परीक्षण के लिए रोगी को आप यह बताए कि उसके उपचार के अन्य कौन से विकल्प उपलब्ध हैं।

10. इस अध्ययन भाग लेने के क्या दुश्प्रभाव हैं?

किसी भी नई इवा या प्रक्रिया के लिए आप प्रतिभागी को उसके संभव दुष्प्रभाव को समझा जाना चाहिए। यदि वे इन या किसी भी अन्य लक्षण से पीड़ित हैं तो उन्हें अगली बार जब आप से मिलने आए तो बताना चाहिए। आपको भी उन्हें अपना नाम और फोन नंबर देना चाहिए ताकि यदि वे

किसी भी आपातकालीन स्थिति में आप से संपर्क कर सकें। ज्ञात दुष्प्रभाव को भागी को सरल भाषा में समझकर लिख कर देना चाहिए। किसी भी नई दवा के लिए अज्ञात दुष्प्रभाव के बारे में रोगी को पता होना चाहिए।

11. इस अध्ययन भाग लेने के सम्भावित जोखिम और नुकसान क्या हैं?

अध्ययन के पहले या उसके दौरान महिला यदि गर्भवती हो जाती है तो बच्चे पर नुकसान हो सकता है, उसे आप को

इन शब्दो में बताना होगाः

"यह संभव है कि अगर एक गर्भवती महिला को उपचार के लिए दिया जाता है तो अजन्मे बच्चे को नुकसान होगा। इसलिए गर्भवती महिलाओं को इस अध्ययन में भाग नहीं लेना चाहिए, जो औरत अध्ययन के दौरान गर्भवती होने कि संभावना है उन्हे भी इस अध्ययन में भाग नहीं लेना चाहिए। जिन महिलाओ को गर्भवस्था कि संभवना है ऐसे भागी का पहले एक गर्भवस्था परिक्षण के लिए कहा जा सकता है। यदि संभव है तो उन्हे इस अध्ययन के दौरान एक प्रभावी गर्भ निरोधक का उपयोग करना चाहिए। किसी भी औरत को यदि पता चलता है कि वह गर्भवती बन गई है, तो उसे तुरन्त अन्वेषक को सुचित करना चाहिए। गर्भवस्था के बयान को सावधानी से करें।

आप को प्रतिभागी को एक उपयुक्त चेतावनी देती होगी जिसमें पुरूषों के शुक्राणु खराब होने का डर है। परीक्षण में भाग लेने के लिए सहमत होने से पहले बिमा कम्पनी के साथ जाँच करनी चाहिए कि उनकी भागीदारी उनकी चिकित्सा बिमा को प्रभावित नही करेगा।

आप को यह स्पष्ट बताना होगा कि अध्ययन के दौरान आपको ऐसी जानकारी मिलती है जिसे भागी को पहले से नही मालूम है। आप उसे क्या करेगें, आप उसकी जानकारी को क्या करेगें, अगर वह ठीक होने लायक नही है तो?

12. अध्ययन में भाग लेने के संभावित लाभ क्या है?

क्या प्रतिभागी को अध्ययन में भाग लेने से उसकी बिमारी में सहायक होगा? यह स्पष्ट रूप से कहा जाना चाहिए। यह महत्वपूर्ण है अध्ययन के बारे में प्रतिभागी को बढ़ा–चढ़ा कर नही बताना चाहिए। बाल्कि उसे एक भाषा में समझना चाहिएः

"हमें आ"ाा है कि दोनों (सभी) उपचार से आपको मदद मिलेगी। हालांकि, यह गरंटी नही हो सकती, इस अध्ययन से प्राप्त जानकारी में भविष्य में लोगों का इलाज करने के लिए मदद मिल सकती है।"

13. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

यदि अनुसंधान/परीक्षण के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है आप इस बारे में प्रतिभागी को बताएँ। आप निम्न शब्द इस्तेमाल कर सकते हैः

"कभी कभी एक अनुसंधान परियोजना/परीक्षण के दौरान इलाज/दवा के बारे में नई जानकारी उपलब्ध हो सकती है। आगे यदि ऐसा होता है तो आप के चिकित्सक आप को इस के बारे में बताएँगे और आप के साथ चर्चा करेंगे कि क्या आप इस अध्ययन में भाग लेना जारी रखना चाहते हैं या नही। यदि आप वापस लेने का फैसला करते हैं तो आपका चिकित्सक आप के इलाज को जारी रखने की व्यवस्था करेगें यदि आप अध्ययन में जारी रखने का निर्णय लेते हैं? तो आप को एक अपडेटेड सहमति फार्म पर हस्ताक्षर करने के लिए कहा जा सकता है। इसके अलावा, नई जानकारी प्राप्त होने पर आपका चिकित्सक आपके हित के लिए अध्ययन से वापस लेने के लिए कह सकता है। वह इन कारणों को आपको बताएगें और इलाज जारी रखने की व्यवस्था करेंगे।"

14. क्या होता है जब अध्ययन/"ोध परीक्षण बंद हो जाता है?

आप प्रतिभागी को यह समझाए कि अध्ययन समाप्त होने के बाद उस दवा से इलाज हो पाएगा कि नहीं? आप यह भी बताए कि उसकी जगह पर कौन सी दवा दी जाएगी। अगर कभी अध्ययन बीच में बंद हो जाता है तो आप उसका कारण प्रतिभागी को बताएँगें।

15. क्या होगा अगर कुछ गलत हो जाता है?

आप को प्रतिभागी को सूचित करना चाहिए कि उसकी f"ाकायतों का निवारण कैसे होगा और जिनके पास f"ाकायत करनी है, उनके पते क्या है? आप को f"ाकयत करने की प्रक्रिया की जानकारी देती होगी। आप को प्रतिभागी को यह भी बताना होगा कि दवा के अध्ययन के दौरान यदि कोई शारीरिक हानि या मृत्यु होती है (दवा की कंपनी का नाम) तो आप दवा का खर्च और समुचित मुवावजा दिया जायेगा।

16. क्या मेरे इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा?

आप को अध्ययन के दौरान मेडिकल रिकॉर्ड प्राप्त करने के लिए रोगी कि अनुमति लेना जरूरी होगा। आप को स्पष्ट करना चाहिए कि उनके बारे में एकत्र सभी जानकारी को कड़ई से गोपनीय रखा जाएगा। दवाा शोध/परीक्षण प्रायोजित कंपनी के लिए एक फार्म का सुझाव दिया हैः

"यदि आप शोध में भाग लेने कि सहमति देते है तो परीक्षण के लिए आप के मेडिकल रिकॉर्ड/परिणामें का वि"लेषण जाँच प्रायोजित कंपनी द्वारा किया जा सकता है। यह कंपनी और नियामक अधिकारियों द्वारा अध्ययन सही ढंग से किया जा रहा है कि नही इसे देखने के लिए किया जाता है। आपका नाम का, अस्पताल/क्लिनिक और प्रयोग"ाला के बाहर खुलासा नहीं किया जाएगा।"

"सभी अनुसंधान/परीक्षण के दौरान आप के बारे में एकत्र जानकारी कड़ाई से गोपनीय रखी जाएगी। कोई भी जानकारी है जो अस्पताल/क्लीनिक और प्रयोग"ाला से बाहर जाएगी, तो उसके ऊपर से आप का नाम और पता हटा दिया जायगा।"

17. अध्ययन/"ोध परीक्षण के परिणाम का क्या होगा?

आप को रोगी के अनुसंधान/परीक्षण के परिणाम को यह बताना होगा कि आगे उसका क्या होगा। आपको यह भी समझाना होगा कि उसकी पहचान किसी भी रिपोर्ट/प्रका"ान में नहीं की जायेगी।

18. इस अध्ययन को कौन आयेजित कर रहा है और इस परीक्षण के लिए धन कहाँ से आयेगा?

आपको प्रतिभागी को यह जानकारी देनी होगी कि कौन इसे करा रहा है और इस अध्ययन के लिए कहाँ से धन आ रहा है। आपको यही बताना चाहिए कि चिकित्सक जो प्रतिभागी कि देखभाल कर रहा है तथा और जो उसमें शामिल है उन्हें इसके लिए धन दिया जा रहा है कि नहीं। **आप प्रतिभागी को यह बताये कि उसे अध्ययन में भाामिल होने**

<u>पर उसमें भामिल जाँच और दवा के लिए पैसे अलग से नहीं देना होगा। अगर इस अध्ययन में क्षतिपूर्ति देने का प्रावधान नहीं तो उसकी जानकारी प्रतिभागी को दी जानी चाहिए।</u>

19. क्या अध्ययन या भाोध की दवा परीक्षण खत्म होने के बाद भी उपलब्ध रहेगी?

इस जानकारी को कृपया आप सूचना पत्र में शामिल करे।

20. इस अध्ययन का पुर्न–निरीक्षण किसने किया है?

आप यह बताये कि इसका पुर्न–निरीक्षण या पुर्न–अवलोकन हमारे संस्थान कि नैतिकता/आचार समिति ने किया है तथा अध्ययन करने की सहमति दी है।

21. अधिक जानकारी के लिए निम्न लोगों से संपर्क करे

अपने रोगी को अधिक जानकारी के लिए संपर्क का नाम तथा पता देना चाहिए। यह आपका या अध्ययन में शामिल एक और चिकित्सक/नर्स का नाम पता हो सकता है।

(प्रमुख अन्वेशक का नाम, पता तथा टेलीफोन नंबर और आचार समिति के सदस्य सचिव का नाम, पता और टेलीफोन नंबर)

अध्ययन में भाग लेने के लिए अपने मरीज को धन्यवाद करने के लिए याद रखना चाहिए!

प्रतिभागी के सूचना पत्र को दिनांकित और संस्करण संख्या दी जानी चाहिए।

सूचना पत्र में आप यह लिखिए आपने जानकारी पत्रक और सहमति फार्म पर हस्ताक्षर किए तथा एक प्रतिलिपि आपने प्रतिभागी को दिया है।

_____

प्रमुख अन्वेशक के हस्ताक्षर_____

दिनांक_____

प्रमुख अन्वेशक का नाम_____

AN10-V1/DHMHSOP 03/V1
Consent Letter
सहमति पत्र

अध्ययन शीर्षक:_____

अध्ययन संख्या_____

प्रतिभागी का पूर्ण नाम (पिता का नाम के साथ)_____

जन्मतिथि / आयु_____

पता_____

—

अर्हता_____

व्यवसायः विद्यार्थी/स्वतः नियोजित/सेवा/गृहणी/अन्य (कृपया समुचित पर नि"ाान लगायें)

व्यक्ति की वार्षिक आय_____

नाम निर्दि"ाती का नाम एवं पता उनका व्यक्ति से सम्बन्ध_____

1. मेरी पुष्टि है कि मैंने अध्ययन हेतु सूचना पत्र दिनांक_____को पढ़ व समझ लिया तथा मुझे प्र"न पूछने या मुझे अध्ययन अन्वेषक ने सभी तत्थों को समझा दिया है तथा मुझे प्र"न पूछने के समान अवसर प्रदान किये गए।
2. मैंने यहाँ समझ लिया कि अध्ययन मे मेरी भागीदारी पूर्णतः स्वैच्छिक है और मैं किसी भी समय किसी भी कारण के बिना, मेरे इलाज या कानूनी अधिकारों को प्रभावित किये बिना, अध्ययन में भाग न लेने के लिए स्वतंत्र हूँ।
3. मैंने यह समझ लिया है कि अध्ययन के प्रायोजक, प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को अपना नाम वापस ले लिया हो। हालांकि, मैं यह समझता हूँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाि"ात माध्यम में नहीं दी जायेगी।
4. मैं इस से सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्दे"य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबन्ध नहीं है।
5. मैं भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हूँ।

हां ☐ नहीं ☐

6. मै उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ।

प्रतिभागी/कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर (या अंगूठे का नि"ाान)_____

हस्ताक्षर कर्ता का नाम _____ दिनांक _____

अन्वेषक के हस्ताक्षर_____ दिनांक _____

अध्ययन अन्वेषक क नाम_____

गवाह के हस्ताक्षर_____दिनांक_____

गवाह का नाम_____

मैंने हस्ताक्षर युक्त सूचना तथा सहमति पत्र प्राप्त किया।

प्रतिभागी/कानूनी तौर पर प्रतिनिधि का हस्ताक्षर/अंगूठे का नि"ाान_____दिनांक_____

AN11-V1/DHMHSOP 03/V1

*Child Information Document

Study title: " ..... "

Introduction

You have come to meet the doctor as you are suffering from ……...

You may be having symptoms…….

Describe briefly the purpose of this study

If this is a randomized trial, details of both arms of the trial/study must be explained in writing to the Participant being enrolled.

Disclose appropriate alternative treatments available, if any.
We invite you to participate in this study.

What will you have to do?

To participate in this research study, you will be examined by your doctor and if found to fulfill pre-specified criteria, you will be eligible to be enrolled in this research study.

Since you are in the age group of 7-18 years, we ask your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, nontechnical & direct language.

In addition, to record the same parameters daily your parent/guardian will also be provided with a diary where they will enter the same findings accordingly. You will have to tell them about your symptom and they will mark accordingly in the diary

Risks and discomforts

There is no foreseen significant risk/hazard to your health, if you wish to participate in the study. If you follow the directions of the doctors in charge of this study and you are injured due to any substance or procedure given under the study plan, the Sponsor will pay for the medical expenses for the treatment of that injury.

Benefits

If you participate in the study, you will receive .....If you appear to have any acute

illness..... you will be offered free treatment for those visits in accordance with local standard medical care. You will not be offered free treatment for chronic diseases or conditions not related to study procedures.

Your participation in the study may help others, because this participation will help us determine if the study drug/procedure is safe.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study.

Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority.

Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent / guardian can take away your authorization to collect process and disclose data about you at anytime.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment. You will still have all the benefits that you would otherwise have got at this clinic/hospital. You may stop participating in the research at any time you wish without losing any of your rights. Your treatment will not be affected in any form. The study doctor may decide to withdraw you from the study if he/she considers it is in your best interest

You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information **Parents responsibilities**

It is the responsibility of your parent / guardian to come along with you to the hospital during the study period for all the visits unless you withdraw or are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report to PI for any expected or unexpected reactions (side effects) that you notice during the study period.

It is also the responsibility of your parent / guardian to inform the doctor if you consume any other medication apart from the study treatment.

We expect your co-operation throughout the study.

Contact for further information

You should give the participant's a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **Name of the PI, Address, Telephone/Mobile Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers**

***(please translate in Hindi also)**

AN12-V1/DHMHSOP 03/V1

Child Assent Form

StudyTitle_____

_____

_____

I_____, exercising my free power of choice, hereby give my consent for participation in the study entitled: "……"

I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any study/trial related injury, which has causal relationship with the said study/trial drug. I am also aware of right to opt out of the study/trial, at any time during the course of the study/trial, without having to give reasons for doing so.

Signature of the study participant Date:

_____

Name of the Study Participant

_____ Date_____

Signature of Witness

Name of theWitness: _____

_____

Signature of the attending Physician Date:_____

Name of the attending Physician: _____

AN13-V1/DHMHSOP 03/V1

Child Consent Letter

अध्ययन शीर्षक_____

अध्ययन संख्या_____

प्रतिभागी का पूर्ण नाम (पिता के नाम के साथ)_____

जन्मतिथि/आयु_____

पता_____

मैं_____में भाग लेने के लिए अपनी सहमति प्रदान करता हूँ। मुझे इस अध्ययन के उद्दे"य एवं किये जाने वाली प्रक्रिया के बारे में चिकित्सक द्वारा बता दिया गया है। मुझे पता है कि परीक्षण सम्बन्धी किसी क्षति जिसका परीक्षण की दवाई से हेतुक सम्बन्ध है उसका खर्च मेरे माता–पिता अभिभावकों को वहन नहीं करना है। मुझे यह भी पता है कि मैं इस परीक्षण से किसी समय बिना कोई कारण बताये बहार हो सकता हूँ।

प्रतिभागी का हस्ताक्षर_____

प्रतिभागी का नाम_____ दिनांक_____

गवाह के हस्ताक्षर_____ दिनांक_____

गवाह का नाम दिनांक_____ दिनांक_____

अन्वेषक के हस्ताक्षर_____ दिनांक_____

अध्ययन अन्वेषक का नाम दिनांक_____ दिनांक_____

AN14-V1/DHMHSOP 03/V1

Checklist of Documents (5copies (on email and a CD or pendrive) of all documents listed below) (non-Interventional trial require documents listed in Item no. 1 to 11 and27)

Please give page no. to all documents (start from 1,2,3..... 40 and soon.)

Please provide version no. and date of each document* (for drug/device trial*)

Protocol Title:
Principal Investigator:
Type of document: Extramural/student project/investigator initiated/collaborative study/drug or device trial

As per **Table 3.1, Section 3.2.3** in SOP

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	Page No.
1.	Project Submission Form (AN1-V1/DHMHSOP 03/V1)	☐	☐	☐	
2.	Study Protocol	☐	☐	☐	
3.	Case Report Form (form to enter data)	☐	☐	☐	
4.	Consent of Head of the PI's Speciality (AN2-V_1/DHMHSOP 03/V1)	☐	☐	☐	
5.	Research/Speciality research/Doctoral/Dr.NB Protocol committee's approval (AN3-V1/DHMHSOP 03/V1)	☐	☐	☐	
6.	Undertaking by the PI (AN4-V1/DHMHSOP 03/V1)	☐	☐	☐	
7.	Conflict of Interest Statement by PI (AN5-V1/DHMHSOP 03/V1)	☐	☐	☐	

8.	CV of new investigator or investigator outside DHMH or of the student (AN6-V1/DHMHSOP 03/V1)	☐	☐	☐	
9.	Participant Information document (PID) and consent forms CF) in English and Hindi (and if required in any other language) (For participant's/controls/volunteers/guardian/parents) (AN7 to 10 -V1/DHMHSOP 03/V1)	☐	☐	☐	
10.	Child Information Document and assent form in English and Hindi (and if required in any other language) (AN11-13V1/DHMHSOP 03/V1)	☐	☐	☐	
11.	Ethics Committee clearance of other centers	☐	☐	☐	
12.	Clinical Trials Registry- India (CTRI)	☐	☐	☐	
13.	Investigator Brochure	☐	☐	☐	
14.	Advertisement/Information brochure	☐	☐	☐	
15.	Insurance policy and certificate	☐	☐	☐	
16.	DCGI approval letter	☐	☐	☐	
17.	Director General of Foreign Trade (DGFAT) approval	☐	☐	☐	
18.	Genetic Engineering Advisory Committee (GEAC) approval	☐	☐	☐	
20.	Bhabha Atomic Research Centre (BARC) approval	☐	☐	☐	
21.	Stem cell (NAC-SCRT) registration and approval	☐	☐	☐	
22.	DCGI marketing/manufacturing license for herbal formulations/nutraceutics	☐	☐	☐	
23.	Clinical Trial Agreement (CTA)	☐	☐	☐	
24.	Material Transfer Agreement (MTA)/MOU/Health Ministry Screening Committee (HMSC) approval	☐	☐	☐	
25.	IEC processing fee (applicable for sponsored trials)	☐	☐	☐	
26.	Any other Agreements/documents	☐	☐	☐	
27.	Document Receipt Form (AN15-V1/DHMHSOP 03/V1, induplicate)	☐	☐	☐	

AN15-V1/DHMHSOP 03/V1

IEC Document Receipt Form (to be submitted in duplicate)

Type of Submission:	o **New** o **Revised**
Protocol Title:	
Principal Investigator:	
Type of document: Extramural Project/student project/investigator initiated/collaborative study/drug or device trial	

Checklist to assess the projects before they are submitted to IEC for review

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	Page No.
1.	Project Submission Form (AN1-V1/DHMHSOP 03/V1)	☐	☐	☐	
2.	Study Protocol	☐	☐	☐	
3.	Case Report Form (form to enter data)	☐	☐	☐	
4.	Consent of Head of the PI's Speciality (AN2-V1/DHMHSOP 03/V1)	☐	☐	☐	
5.	Scientific research/Dr.NB Protocol committee's approval (AN3-V1/DHMHSOP 03/V1)	☐	☐	☐	
6.	Undertaking by the PI (AN4-V1/DHMHSOP 03/V1)	☐	☐	☐	
7.	Conflict of Interest Statement by PI (AN5-V1/DHMHSOP 03/V1)	☐	☐	☐	
8.	CV of investigator outside DHMH or of the student (AN6-V1/DHMHSOP 03/V1)	☐	☐	☐	

9.	Participant Information document (PID) and consent forms CF) in English and Hindi (and if required in any other language) (For participant's/ controls/ volunteers/ guardian/ parents) (AN7to 10 -V1/DHMHSOP 03/V1)	☐	☐	☐	
10.	Child Information Document and assent form in English and Hindi (and if required in any other language) (AN11-13V1/DHMHSOP 03/V1)	☐	☐	☐	
11.	Ethics Committee clearance of other centers	☐	☐	☐	
12.	Clinical Trials Registry- India (CTRI)	☐	☐	☐	
13.	Investigator Brochure	☐	☐	☐	
14.	Advertisement/Information brochure	☐	☐	☐	
15.	Insurance policy and certificate	☐	☐	☐	
16.	DCGI approval letter	☐	☐	☐	
17.	Director General of Foreign Trade (DGFAT) approval	☐	☐	☐	
18.	Genetic Engineering Advisory Committee (GEAC) approval	☐	☐	☐	
20.	Bhabha Atomic Research Centre (BARC) approval	☐	☐	☐	
21.	Stem cell (NAC-SCRT) registration and approval	☐	☐	☐	
22.	DCGI marketing/manufacturing license for herbal formulations/nutraceutics	☐	☐	☐	
23.	Clinical Trial Agreement (CTA)	☐	☐	☐	
24.	Material Transfer Agreement (MTA)/MOU/Health Ministry Screening Committee (HMSC) approval	☐	☐	☐	
25.	IEC processing fee (applicable for sponsored trials)	☐	☐	☐	

26.	Any other Agreements/documents	☐	☐	☐	
27.	Document Receipt Form (AN15-V1/DHMHSOP 03/V1, in duplicate)	☐	☐	☐	

Note: Please provide version no. and date of each document (for drug/device trial)

Documents submitted:

( ) Complete

( ) Incomplete; will submit on……...

Comments:

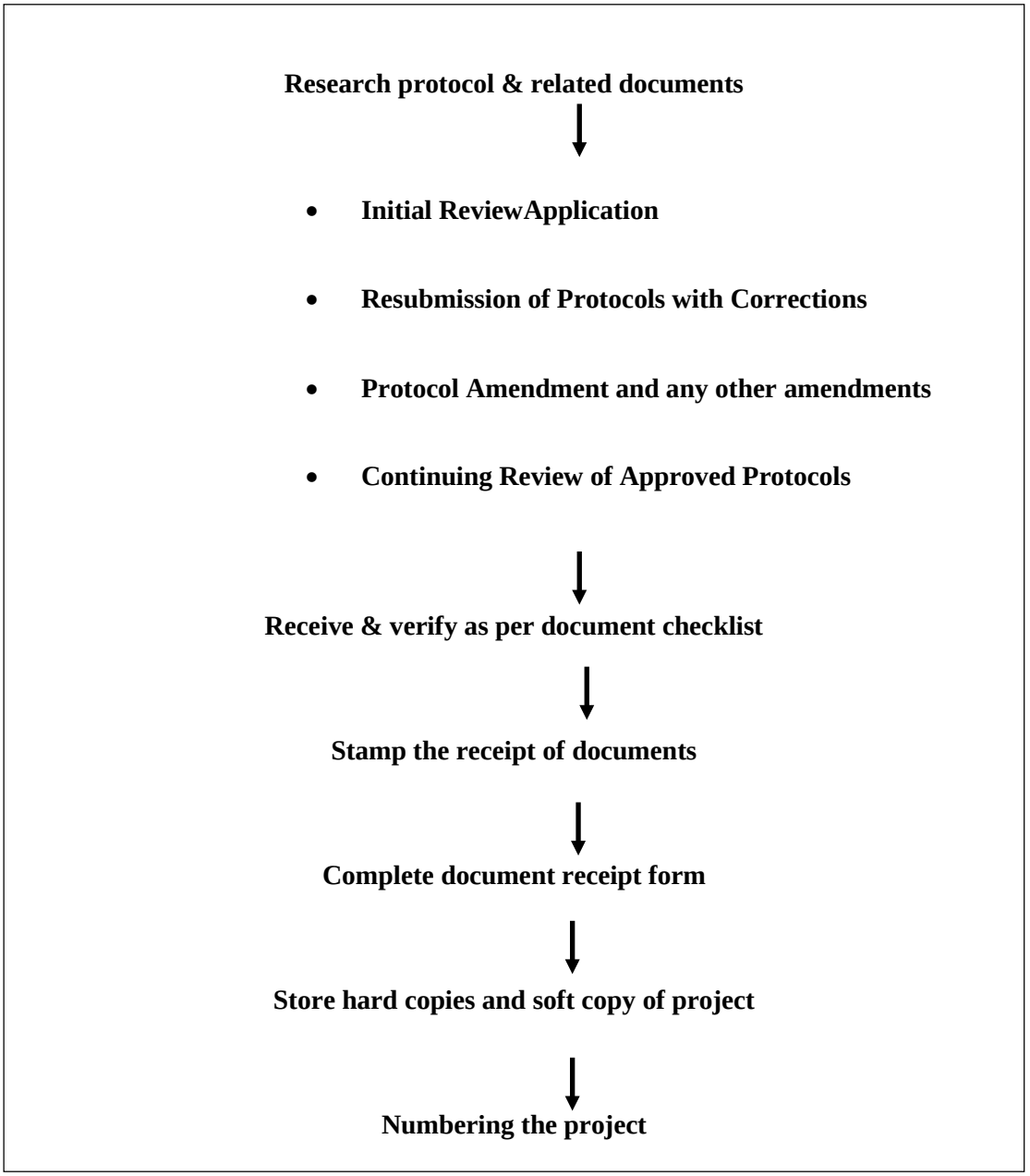
Receiver Name, Sign &Date: _____

(IEC Secretariat)

Project submitted by Name &sign: _____

(Project or study team member)

Flow Chart


Research protocol & related documents
Initial ReviewApplication
Resubmission of Protocols with Corrections
Protocol Amendment and any other amendments
Continuing Review of Approved Protocols
Receive & verify as per document checklist
Stamp the receipt of documents
Complete document receipt form
Store hard copies and soft copy of project
Numbering the project

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 4

Title: **Initial Review of Submitted Protocol**

DHMHSOP Code: **Date:** **Pages: 95-110**

DHMHSOP 04/V1

- Purpose and scope
- Categorization of protocols
- Elements of review
- Responsibility and detailed instructions for review of protocols

4.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC members will review an initially submitted protocol for approval.

The IEC must review every research proposal on human participant's and approve it before the research is initiated. IEC should ensure that scientific evaluation has been completed and approved by Organization Research Committee/Specialityal Research Committee/Doctoral Committee before ethical review is taken up. The committee should evaluate the possible risks to the participant's with proper justification, the expected benefits to participant's/community and adequacy of documentation for ensuring privacy & confidentiality.

4.2 Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. The specific points in the guidelines attached to the assessment form (AN2-V1/DHMHSOP01/V1) for initial review must be adequately addressed in the protocol itself and/or protocol- related documents under review. Relevant comments made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting. The decision taken by the IEC will be communicated to the PI in writing.

4.3 Categorization of protocols

The Member Secretary, IEC or IEC Secretariat shall screen the proposals for their completeness before putting at the IEC meeting for review. It is categorized as exempt, full review or expedited. In case of an emergency proposal needing immediate approval; an ad-hoc meeting will be called by the Chairperson.

Types of Review

4.3.1 Exemption from review

Proposals that can be exempt from review include those with less than minimal risk where there are no linked identifiers, e.g.

• Research conducted on data that is in the public domain for systematic reviews or meta- analyses.

• Observation of public behavior when information is recorded without linked identifiers and disclosure would not harm the interests of the observed person.

• Quality control and quality assurance audits in the institution.

• Comparison among instructional techniques, curricula, or classroom management methods.

• Consumer acceptance studies related to taste and food quality.

• Public health programmes including programme evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring.

4.3.2. Expedited review

Proposals that pose no more than minimal risk may undergo expedited review, e.g.

• Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, left over clinical samples.

• Research involving clinical documentation materials which are non-identifiable (data, documents, records)

• Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change ininvestigator(s).

• Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.

• Minor deviations from originally approved research causing no risk or minimal risk.

• Progress/ Annual reports where there is no additional risk e.g., activity limited to data analysis.

• Expedited Review will be conducted byMember Secretary and 1-2 designated members.

• Expedited review of SAEs/ unexpected AEs will be conducted by SAE subcommittee.

• The approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next Full board meeting.

• Research during emergencies and disasters.

• Research study during Covid-19 Pandemic active phase.

4.3.3. Full Committee Review

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, e.g.

• Studies involving vulnerable population even if the risk isminimal.

• Studies involving deception of participant's (Refer Informed Consent Process for further detail).

• Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee. Full committee has a right to reverse/or modify any decision taken by the subcommittee or expeditedcommittee.

• Amendments of proposals/related documents (including but not limited to informed consent documents, Investigators Brochure, advertisements, recruitment methods etc.) involving an increase in risk.

• Major deviations and violations.

• Any new information that has emerged during the course of the research must also be reviewed and decisions taken, if necessary, to terminate the study or not in view of altered benefit–risk assessment.

• Research during emergencies and disasters through unscheduled meetings.

• Program evaluation research activities other than those mentioned in the exempt category.

• Online Board meeting through approved institutional mechanism during Covid-19 pandemic.

4.4 Elements of review

The primary task of the IEC is review of research proposals and their supporting documents with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. IEC will consider the prior scientific review by the Organization Scientific Committee and the requirements of applicable laws and regulations. Primary reviewer assigned by the Member Secretary will review and present the project in the meeting.

The IEC Member receives the letter for review (AN1-V1/DHMHSOP 04/V1) and assessment Form (AN2-V1/DHMHSOP 04/V1). The assessment form is designed to standardize the review process and to facilitate reporting, recommendations, and comments offered on each individual protocol.

The following will be considered (as applicable):

4.4.1Scientific design and conduct of the study

- The appropriateness of the study design in relation to the objectives of the study.
- The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participant's.
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participant's and the concerned communities.
- The justification for the use of control arms and source of control, criteria for prematurely withdrawing research participant's.
- Criteria for suspending or terminating the research as a whole.
- The adequacy of provisions made for monitoring and auditing the conduct of the research, the adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
- The way the results of the research will be reported and published.

4.4.2 Care and protection of research participant's

- Suitability of the investigators' qualifications and experience for the proposed study.
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.

- Medical care to be provided to research participant's during and after the course of the research.
- Adequacy of medical supervision and psycho-social support for the research participant's.
- Steps to be taken if research participant's voluntarily withdraw during the course of the research.
- Criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
- Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to doso.
- Description of any plans to make the study product available to the research participant's following the research; a description of any financial costs to research participant's (Refer AP6/V1).
- Rewards and compensations for research participant's (including money, services, and/or gifts).
- Provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research as per Gazette of India (2019) dated 19th March, 2019 & ICMR guidelines for Biomedical Research (2017).
- Valid Insurance policy for the participant and indemnity agreements with proper validity document.

4.4.3 Protection of research participant confidentiality

- A description of the persons who will have access to personal data of the research participant's, including medical records and biological samples.
- The measures taken to ensure the confidentiality and security of personal information concerning research participant's.

4.4.4 Participant information document and consent process

- A full description of the process for obtaining consent, including the identification of those responsible for obtaining consent (ReferAP6/V1).
- Adequacy, completeness, and comprehension of written and oral information to be given to the research participant's, and, when appropriate, their Legally Acceptable

Representative(s).

- Clear justification for the intention to include research participant's who cannot consent, and a full account of arrangements made to obtain their consent /authorization.
- Assurances that research participant's will receive information that becomes available during the research relevant to their participation including their rights, safety, and well- being.
- Provisions made for receiving and responding to queries and complaints from research participant's or their representatives during the currency of the research project.
- In clinical trials of new chemical entity or new molecular entity, **audio-visual recording of informed consent process is required when vulnerable participant's are enrolled.**

4.4.5 Community considerations

- Impact and relevance of the research on the local community and on the concerned communities from which the research participant's are drawn.
- Steps taken to consult with the concerned communities during designing the research.
- Influence of the community on the consent of individuals.
- Proposed community consultation during the research.
- Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs.
- A description of the availability and affordability of any successful study product to the concerned communities following the research.
- The way the results of the research will be made available to the research participant's and the concerned communities.

4.4.6 Recruitment of research participant's

- The characteristics of the population from which the research participant's will be drawn (including gender, age, literacy, culture, economic status, and ethnicity) (ReferAP1/V1).
- The means by which initial contact and recruitment is to be conducted.
- The means by which full information is to be conveyed to potential research participant's or their representatives.
- Inclusion criteria for research participant's.
- Exclusion criteria for research participant's.
- Students or staff recruitment in research (Ref.AP1/V1).

4.4.7 Risk-Benefit Analysis

While reviewing the research protocols, the following points should be carefully assessed for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture (Refer AP5/V1).

b. Prospective collection of biological specimens for research purposes by noninvasive means. E.g., skin, saliva, sputum, other body fluids etc.

c. Collection of data through noninvasive procedures routinely employed in clinical practice. E.g., Magnetic Resonance Imaging, Radiation Oncology Procedures, sensory acuity, Electrocardiography, Echocardiography, Electroencephalography, Ultrasound, Doppler Blood Flow and other similar procedures.

d. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical)purposes.

e. Collection of data from voice, video, digital, or image recordings made for research purposes.

f. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, focus group, or quality assurance methodologies.

g. Research involving collection and storage of genetic materials (ReferAP9/V1).

h. Research involving gene therapy and gene transfer protocols (ReferAP10/V1).

Where medical devices are employed, they must be cleared/ approved for marketing (Refer for detailed guidelines, Medical Device Rules 2016 & 2017: www.cdsco.nic.in/)

4.5 Responsibility

The IEC Secretariat will be responsible for receiving, verifying, and managing the hard/soft copies of the received protocols and documents. In addition, the IEC Secretariat should create a protocol specific file, distribute the protocols to the IEC members for review by IEC and communicate the review results to the investigators. IEC members are responsible for receiving and reviewing the research protocols.

4.6 Detailed instructions

Distribution of the project documents

- The distribution of the project documents for IEC review will be as follows: Chairperson, Member Secretary, and all members will get complete project proposal as hard/soft copy/by email.

Assigning Primary reviewer

- Member Secretary, IEC may assign 1 or 2 Primary reviewers for each research protocol. A Primary reviewer is the member of IEC responsible for an initial detailed review of the assigned protocol.
- The Primary reviewer is informed preferably 10 days prior to the meeting through the agenda. A project evaluation form will also be sent along with the necessary document for each project assigned to the IEC Member. In case, the lead discussant is not in a position to review due to some reason including conflict of interest; he/she should inform the Member Secretary, IEC at the earliest, so that the research protocols can be assigned to other member.
- In the event of his/her absence, a Primary reviewer can send written comments on the research protocols to the Member Secretary, which will be tabled and discussed during meeting. However, a final decision on the research protocol will be arrived at, by a consensus at the end of discussion among attending members and not solely based on written comments.
- The assigned lead discussant/s shall review the assigned research protocols offer their observations, comments, and decisions to the IEC during the meeting and return all the documents including a completed evaluation form to the IEC Secretariat on the day of the meeting.

Responsibilities of IEC members

- Check the contents of the documents received and acknowledge receipt.
- Return the acknowledgement form/receipt back to the delivery person / IEC Secretariat.
- Check the meeting date and inform the Member Secretariat immediately, if unable to attend the meeting.
- Identify the project assigned for review.
- Notify the IEC Secretariat immediately regarding the missing documents, if any.
- The members must return the documents to the IEC Secretariat on the day of the scheduled meeting. In case, IEC member is not able to attend the scheduled meeting, the proposals should be returned at the next meeting.

4.7 Review of protocol

Review all elements as per section 4.4. The Chairperson will invite comments from IEC members following the presentation of Primary reviewer covering the element mentioned in AN2-V1/DHMHSOP 04/V1.

4.8 Study assessment forms

The primary reviewer for a particular project should use assessment form as a checklist while reviewing each research protocol. The duly filled, signed and dated assessment forms should be returned back along with the research protocols to the IEC Secretariat at the end of the meeting. The assessment form is designed to standardize the review process. The study assessment form helps to ensure that all elements of research protocol are reviewed and are accordingly documented during the discussion/meeting (Study Assessment Form template [AN2- V1/DHMHSOP04/V1]).

Note: **The completed assessment form is part of the official record of the decision reached by the IEC for the specific protocol**

4.9 Collection of assessment reports

The IEC Secretariat will collect the filled Study Assessment Forms AN2-V1/DHMHSOP 04/V1, from the primary reviewersat the end of meeting and file it in the original set of the study file.

4.10 At IEC meeting

The details of review procedures and communication of decision is described in detail in DHMHSOP 06/V1.

AN1-V1/DHMHSOP 04/V1

Letter to IEC Members Requesting Initial Review with Study Assessment Form

Dear member,

The next meeting of the IEC will be held

on_____at_____in_____.

You are requested to review the below mentioned proposals before the IEC meeting. Please review the protocol and related documents as per the guidelines and provide your comments on the form provided with the package (AN2-V1/SOP 04/V1). Please also confirm your availability for the meeting.

IEC code no.:

Project Title:

Name of the Principal Investigator:

Name of the Reviewer:

Name of Member	**Date of Receipt**	**Signature**	**Attending meeting Y/N**

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

AN2-V1/DHMHSOP 04/V1

Study Assessment Form

IEC Code:	**Date of IEC meeting:**	**Date (DD/MM/YY):**
Protocol Title:		
Principal Investigators:		
Primary reviewer's name:		

Mark and comment on whatever items applicable to the study

Items	Comments
1. Objectives of the Study () Clear () Unclear	
2. Need for Human Participant's () Yes () No	
3. Methodology: () Clear () Need changes	
4. Background Information and Data () Sufficient () Insufficient	
5. Risks and BenefitsAssessment () Acceptable () Unacceptable	
6. Inclusion Criteria: () Appropriate () Inappropriate	
7. Exclusion Criteria () Appropriate () Inappropriate	
8. Discontinuation and Withdrawal Criteria () Appropriate () Inappropriate	
9. Involvement of Vulnerable Participant's () Yes () No	
10. Voluntary, Non-Coercive Recruitment of Participant's	

() Yes () No	
11. Sufficient number of participant's? () Yes () No	
12. Control Arms (placebo, if any) () Yes () No	
13. Are qualification and experience of the Investigators appropriate? () Yes () No	
14. Disclosure or Declaration of Potential conflicts of Interest () Yes () No	
15. Facilities and infrastructure of Participating Sites () Appropriate () Inappropriate	
16. Community Consultation () Yes () No	
17. Involvement of Researchers and Institution in the Protocol Design, Analysis and Publication of Results () Yes () No	
18. Contribution to Development of Local Capacity for Research and Treatment () Yes () No	
19. Benefit to Local Communities () Yes () No	
20. Are blood/tissue samples being sent abroad? () Yes () No	
21. Are procedures for obtaining Informed Consent appropriate? () Yes () No	
22. Contents of the Informed Consent Document () Clear () Unclear	

23. Language of the Informed Consent Document () Clear () Unclear	
24. Contact Persons for Participant's () Yes () No	
25. Privacy & Confidentiality	
() Yes () No	
26. Provision for Medical / Psychosocial Support () Appropriate () Inappropriate	
27. Provision for Treatment of Study-Related Injuries () Appropriate () Inappropriate	
28. Provision for Compensation () Appropriate () Inappropriate	

Comments:_____

_____

_____

_____

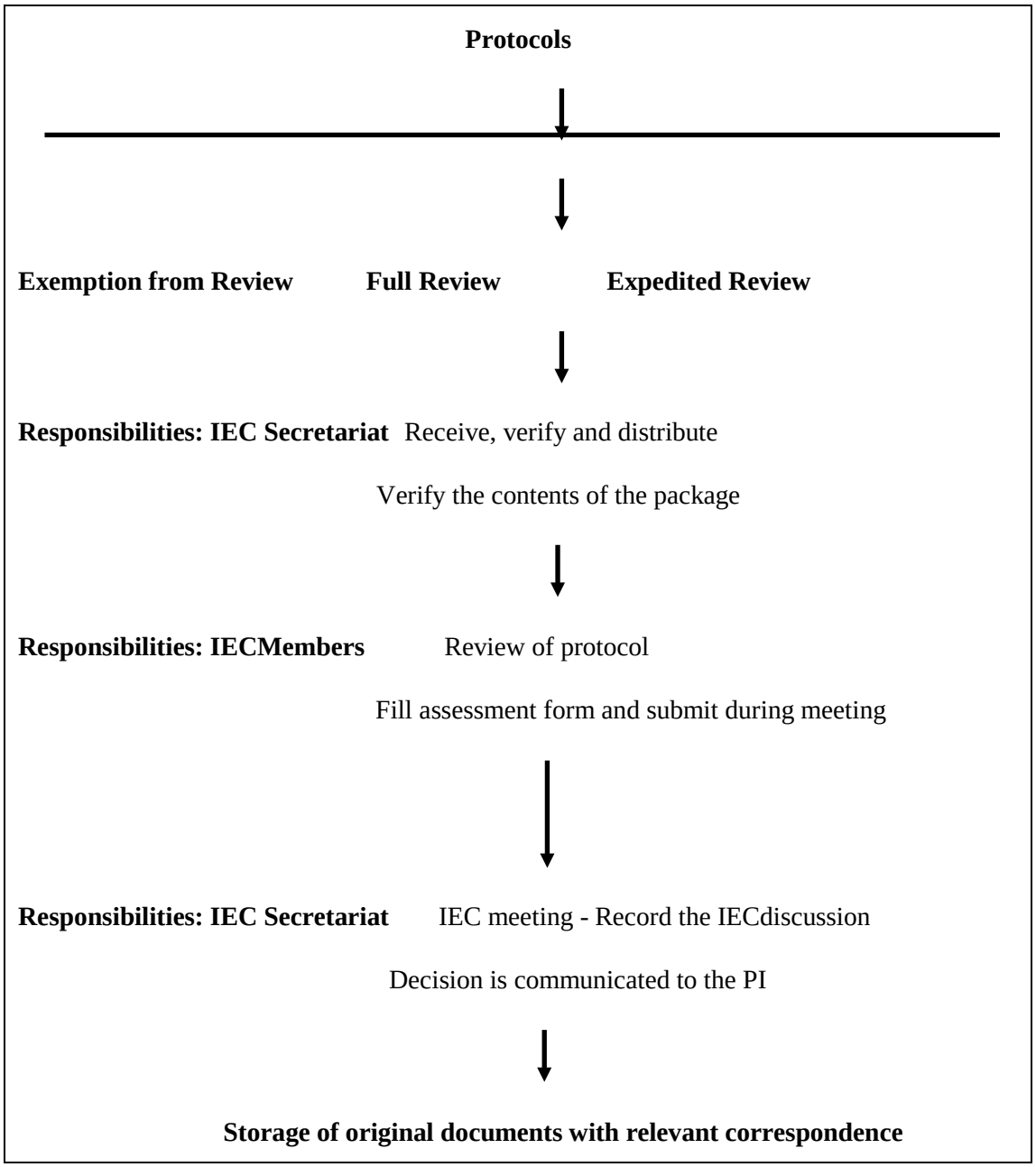
If minor / major revision or rejection of project is recommended Yes [] No []

Signature of Primary reviewer

Name_____

Date:_____

Flow Chart


Protocols
Exemption from Review
Full Review
Expedited Review
Responsibilities: IEC Secretariat Receive, verify and distribute
Verify the contents of the package
Responsibilities: IECMembers Review of protocol
Fill assessment form and submit during meeting
Responsibilities: IEC Secretariat IEC meeting - Record the IECdiscussion
Decision is communicated to the PI
Storage of original documents with relevant correspondence

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 5

Title: **Exemption from Ethical Review for Research Projects/Trials**

DHMHSOP Code:	Date:	Pages: 111-118
DHMHSOP 05/V1		

- Purpose and scope
- Categorization of protocols as exemption from review
- Responsibility and detailed instructions

5.1 Purpose and scope

This SOP applies to the all protocols submitted for exemption from review by the IEC.The purpose of this SOP is to describe which research project/study can be exempted from ethics review and do not require the approval of the IEC. The Exemption Form AN1-V1/DHMHSOP 05/V1 is designed to standardize the process of exemption.

5.2 Type of Protocol for Exemption from review

The exemption from review may be seen in following situations:

Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods or clinical data from records etc.

Exceptions:

1. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
2. When interviews involve direct approach or access to private papers.

Proposals which do not involve the live human participant's or data derived from the mare exempt from ethics review.

For example:

- Audits of educational practices
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Research on cadavers or death certificates provided, such research reveals no identifying personal data
- Analysis of data freely available in public domain

In some circumstances research which meets above criteria may need to be reviewed by the IEC. ***This might be because of the requirements of.***

- The publisher of the research.
- An organization which is providing funding resources, existing data, access to participant's etc.

5.3 Responsibility

The Member Secretary will record the decision in the Exemption Form with reasons. The IEC Secretariat will be responsible for recording and filing the decision including the reasons for exemptions and the decision (AN2-V1/ DHMHSOP05/V1).

5.4 Detailed instructions for IEC Secretariat

5.4.1 Receive the submitted documents

- The IEC Secretariat will receive the Exemption application form filled by the PI, AN1-V1/DHMHSOP 05/V1, Project Submission Form for Review by IEC (AN1-V1/DHMHSOP 03/V1) for Protocol and other documents submitted by the investigators.
- Acknowledge the submitted documents.
- Place the documents for full board meeting of the IEC.

5.4.2 Exemption process

IEC may exempt a proposal from ethical review.

- The Member Secretary records the decision on the Exemption Form.

AN1-V1/DHMHSOP 05/V1

Review Exemption Application Form

IEC Code no.: _____(To be filled by the IEC Secretariat)

1 **Principal Investigator's Name:** _____

2 **Speciality:** _____

3. **Title of Project/Study:** _____

_____

4 **Names of other participating staff and students:**

5 **Brief description of the project:**

- Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participant's' description, and procedures/ methods to be used in the project [Please fill Project Submission Form for Review (AN1-V1/DHMHSOP03/V1)].

6 **State reasons why exemption from ethics review is requested?**

- Audits of educational practices.
- Research on microbes cultured in the laboratory.
- Research on immortalized cell lines.
- Research on cadavers or death certificates provided such research reveals no identifying personal data.
- Analysis of data freely available in public domain.
- Any other.

(This should include justification for exemption e.g., study does not involve human participant's. If exemption is being requested on the basis of low risk involved in the study, please refer to AP15/V1).

Principal Investigator's signature:_____ Date _____

Countersigned by the Head of the organization:

Name:_____

Signature:_____

Date _____

AN2-V1/DHMHSOP 05/V1

Decision of IEC Regarding Exemption from the Ethical Review

To,

Dr._____

Principal Investigator,

DHMH.

Ref: IEC code.

Title of project:

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application (dated) for waiver to exemption from the ethical review during the IEC (number of meeting) meeting held on (date).

Exemption granted: Yes [] No [ ]

Cannot be exempted,reasons

_____

_____

_____

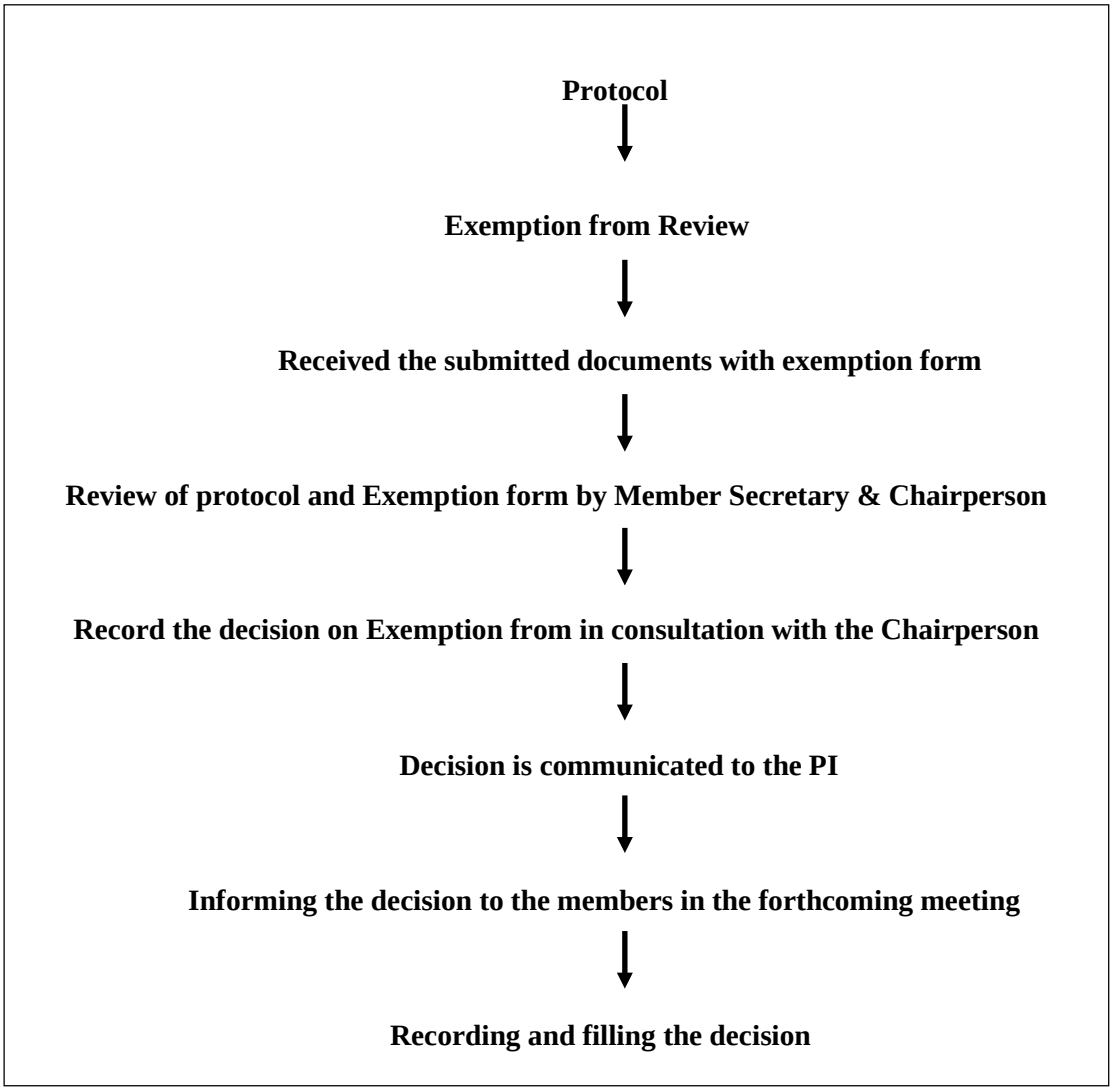
Thanking You,

Yours Sincerely,

Signature of the Member Secretary_____ **Date** _____

Name of the Member Secretary _____

Flow Chart


Protocol
Exemption from Review
Received the submitted documents with exemption form
Review of protocol and Exemption form by Member Secretary & Chairperson
Record the decision on Exemption from in consultation with the Chairperson
Decision is communicated to the PI
Informing the decision to the members in the forthcoming meeting
Recording and filling the decision

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 6

Title: **Agenda Preparation, IEC Meeting Procedures and Recording of Minutes**

DHMHSOP Code:	**Date:**	**Pages: 119-134**
DHMHSOP 06/V3		

- Responsibility and instructions for conduct of IEC meetings
- Process of decision making
- Preparation of minutes and communicating decisions

This SOP applies to administrative processes concerning the conduct of the meeting. The purpose of this procedure is to elaborate administrative process and provide instructions for preparation, review, approval, and distribution of meeting agenda, minutes, and notification letters of IEC, DHMH meetings.

The day, time, and venue of IEC meetings will be communicated at least **two weeks** in advance.

6.1 Responsibility

It is the responsibility of the IEC Secretariat to prepare agenda for the respective IEC meeting.

6.2 Detailed instructions

6.2.1 Agenda for full board IECmeeting

- Prepare the agenda of the IEC meeting (AN1-V1/DHMHSOP06/V1)
- Schedule protocols on the agenda on a first come first servebasis.
- The protocol received in the IEC Secretariat after the due date will be taken up in the next IEC meeting.

6.2.2 Distribution of Protocol/Documents to the IEC Members

- Circulate meeting agenda with date, time, venue, and submitted documents to the IEC members preferably **two weeks** in advance of the scheduled meeting.
- Verify (verbally, by e-mail, or by phone) with the members whether all relevant documents are received.
- It is the responsibility of the IEC member to verify items on receipt and in the event of any missing items, intimate the IEC Secretariat/Member Secretary immediately so that the relevant documents could be made available to the members before the meeting.
- The Meeting notice & Agenda items may also be sent to the members on their E-mail-id.

6.2.3 Preparation for the meeting

- Circulate meeting notice with agenda to investigators by email, with request to be available on meeting date.
- All relevant guidelines related to the Bio-Ethics and SOPs should be available at venue on the day of meeting along with the Minute's books.

6.2.4 Conduct of meeting

- The members should reach IEC meeting room on scheduled time.
- The Chairperson should determine that the quorum (DHMHSOP 02/V1 section no. 2.9) requirements are met properly in each agenda items during the meetings.
- The Chairperson should ask for declaration of conflict of interest either verbal or written on any protocol for discussion, before the meeting is conducted.
- If an IEC member has conflict of interest involving on a project in any capacity, then he/she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This should be recorded in the minutes.
- The Member Secretary should table the minutes of the previous meeting and minutes should be confirmed during the meeting.
- It is responsibility of Member Secretary to describe the action taken arising from the previous minutes to the full board meeting.
- The IEC may invite investigators to attend the full board meeting related to their studies, and clarify doubts, if any. This should be informed to the Investigator at the time of circulating the agenda item that they should be available in the Speciality on that particular day.
- The meeting proceeds in the sequential order of the agenda; however, the Chairperson may change the order, if the situation so demands.
- The Member Secretary will request the lead discussant (primary reviewer) to discuss the research protocol. The primary reviewer will submit the duly filled study assessment form at the end of the discussion or at the conclusion of IECmeeting.
- In case the primary reviewer cannot attend the meeting, Member Secretary, IEC or any other IEC member may brief the IEC about the research protocol and also discuss the written comments/duly filled study assessment form, if provided by the primary reviewer
- The Member Secretary, IEC will record the Minutes of the Meeting.

6.2.5 Decision Making Process

IEC shall provide complete and adequate review of the research proposals submitted to them. The committee will review new project proposals, amendments, annual progress of ongoing projects, SAE reports, protocol violations/deviations and assess final reports of all research activities through a scheduled agenda.

- If IEC member has her/his own proposal for IEC review, he/she will not participate in the IEC discussion on that particular project.
- The documents required for a full review of the application should be complete and the relevant elements considered before a decision is made.
- Decisions will only be made at meetings where members are present as per the quorum (DHMHSOP 02/V1 section no. 2.9) requirement.
- Decisions will be arrived through consensus. When a consensus is not possible, the IEC will vote. In case of tie, the Chairperson can have a casting vote.
- If the full board approves a research proposal in principle subject to minor modifications, the revised project proposal submitted by the PI will be reviewed and approved by the Member Secretary, IEC or subcommittee of IEC on behalf of the full board. The Member Secretary will report the decisions for the same to the next IEC meeting. Such revised proposals will not be taken up for the full board review again. However, in case of major changes, the revised documents will be discussed by 3-member subcommittee or in full board meeting.
- An IEC may decide to reverse its positive decision on a study, if it receives information that may adversely affect the risk/benefit ratio for a particular project/study.
- Any advice that is non-binding will be appended to the decision.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified in the minutes.
- A negative decision on an application will be supported by clearly stated reasons for that particular decision. If the investigator wishes to appeal against the decision, he/she may do so in writing to Member Secretary.
- The discontinuation of a study/trial will be recommended if the IEC finds that the goals of the study/trial have already been achieved midway, unequivocal results are obtained or SAE have been observed due to that particular study/trial.

- If necessary, the investigator may be invited to present the protocol ro offer clarifications in the meeting. This will be decided by the Chairperson IEC during the meeting. Representative of the Participant's groups or community can be invited during deliberations to offer their viewpoint, but should not participate in the decision-making process.
- Subject experts may be invited as consultant to offer their views but shall not participate in the decision-making process. However, his/her opinion must be recorded.
- The proceedings of the IEC meetings will be documented and signed by the Member Secretary and the Chairperson only.

6.2.6 After the IEC meeting

A Preparing the minutes and decision letters

- The Member Secretary will compile the proceedings of IEC meeting in a concise manner in simple language and will check spellings, grammar and context of the written minutes.

B Approval of the minutes and the decision

- The minutes of the IEC meeting will be signed by Member Secretary, IEC and the Chairperson only.
- The minutes of the IEC meeting will be ratified in the subsequent IEC meeting.
- The IEC decisions will be communicated to the PIs by the Member Secretary within two weeks of the scheduled meeting.

C Filing of the minutes of the meeting

- Original version of the minutes should be placed in the minute's file/folder/book and copy of the minutes are filed in the corresponding research protocol file.

6.2.7 Communicating decisions

The decision will be communicated in writing by the Member Secretary to the PI, preferably within a period of 2 weeks of the IEC meeting at which the decision was made.

The communication of the decision will include, but is not limited to, the following,

- IEC code of project and title of the research proposal reviewed.
- Name of Members and their designation who were present during the meeting.
- The clear identification of the protocol of the proposed research or amendment, date and version number (if applicable).

- The names and specific identification number version numbers/dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form.
- The name of the Principal Investigator and title of the Project.
- The date and place of the decision.
- A clear statement of the decision reached.
- Validity of approval usually will be **yearly;** for the projects which are for more than one-year duration, however changing on case-to-case basis.
- Any suggestions by the IEC.
- A dead line of **4 weeks** will be given to PI. If clarification is received after dead line, the project may not be put up in next meeting for approval. Conditional approval pending clarification will not be given. If PI fails to provide clarification, reminder will be sent by IEC Secretariat stating that failure to respond will lead to closure of the file. (AN3-V1/DHMHSOP06/V1).
- In the case of a positive decision, the PI is notified of the following requirements through an approval letter (AN2-V1/DHMHSOP 06/V1):
    - A statement of the responsibilities of the PI; for example, Confirmation of the acceptance of any requirements recommended by the IEC.
    - Registration with CTRI if applicable.
    - Communicate date of start of study to IEC (AN5-V1/DHMHSOP06/V1).
    - Submission of annual progress report.
    - The need to notify the IEC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study).
    - The need to notify the IEC in the case of amendments to the recruitments like the potential research participant information, the informed consent form or participant numbers.
    - The need to report serious and unexpected adverse events related/unrelated to the conduct of the study.
    - The need to report unforeseen circumstances, the withdrawn/ termination of the study, or significant decisions by another IEC.

  - The information of the IEC expects to receive in order to perform ongoing review.
  - The final summary or final report.
  - The schedule/plan of ongoing review of sponsored trials/projects.

- In the case of a negative decision, the reasons should be clearly stated in the communication to the PI.
- The PI will also be notified of the duration of the approval, which normally will not exceed one year or duration of project whichever is later.
- All decision and approval letters will be signed by the Member Secretary, IEC.
- The Member Secretary, IEC will sign and date the approval letter and approval certificate in the original research protocol.

AN1-V1/DHMHSOP 06/V1

Agenda Format

I.	Meeting Notice & Copy of the previous Minutes
II.	Acton taken arising from the previous minutes
III.	New Projects for Review
IV.	Report of approved clarification/revision by of 3 Member Committee/Member Secretary
V.	Amendments/Addendum
VI.	Letters/General notification
VII.	SAEs related or not related
VIII.	Protocol violation/deviation
IX.	Progress report
X.	Final report
XI.	Closed out notification
XII.	Publications / Abstracts
XII.	Any other item with the permission of Chair

AN2-V1/DHMHSOP 06/V1

Format for Approval Letter of Ethics Committee

To,

Dr._____

Principal Investigator,

DHMH.

Ref: IEC code & Project title:

Study/Protocol No.

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application (dated) to conduct the research study entitled "_____" during the IEC meeting held on(date).

The following documents were reviewed and approved:

1. Project Submission form (IEC Proforma).
2. Study protocol (including protocol amendments), dated_____, version no(s)_____.
3. Organization Research Committee/Specialityal Research Committee/ Doctoral Committee /funding agency.
4. Investigator's brochure, dated_____, version no._____
5. Participant's information document and consent form (including updates if any) in English and/Vernacular language.
6. Proposed methods for Participant's accrual including advertisement(s) etc. proposed to be used for the purpose.
7. One page, recent, signed and dated curriculum vitae of a new investigator or investigator outside DHMH or of the student (Dr.NB//Ph.D/DNB) who has submitted thesis/project.
8. Insurance policy/compensation for participation and for serious adverse events onsite /offsite occurring during the study participation.

9. Investigator's Agreement with the sponsor.
10. Investigator's undertaking.
11. DCGI/DGFT approval
12. Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU)/Material Transfer Agreement (MTA), if applicable
13. Clinical Trials Registry-India (CTRI), in case of drug trial require at time of submission but in other case this must be done after approval of the study but before initiation

The following members of the Institutional Ethics committee (IEC) were present at the meeting held on Date_____Place _____

Name of member/Position on IEC/Affiliation/Gender

_____Chairperson of the Ethics committee

_____Member Secretary of the Ethics committee

_____Name of each member with their designation

The trial/study is approved in its presented form. The approval is valid until one year or duration of project whichever is later from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of annual status report.

Following points must be noted:

1. IEC should be informed of the date of commencement of the study (AN5-V1/DHMHSOP 06/V1) and annual progress.

2. IEC has approved recruitment of____Participant's on this study.

3. PI and other investigators should co-operate with IEC, which may monitor the trial / study from time to time.

4. The decision was arrived at through consensus. Neither PI nor any of proposed study team members was present during the decision making of the IEC.

5. At the time of PI's superannuation/intention to leave the Organization, responsibility for the study should be transferred by the PI to the next Co-Investigator of the same Speciality after obtaining necessary clearances from Head of the concerned Speciality with due approval from the Extramural/Sponsor funding agency, and getting IEC concurrence and the status report, including accounts details should be submitted to Head of the Speciality, IEC and Extramural funding agency /sponsors.

6. The IEC functions in accordance with the GCP, Gazette of India, 19.03.2019, and ICMR guidelines 2017.

7. New information or any SAE, which could affect any study, must be communicated to IEC and sponsors. The PI should report SAEs occurred for IEC approved studies within 7 days of the occurrence of the SAE. If the SAE is reported as 'Death', the IEC Secretariat should receive the SAE reporting form from PI within 24 hours of the occurrence.

8. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms asfollows:

a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no.etc.)

b. The PI must comment how proposed amendment will affect the ongoing study/trial.

c. Alteration in the budgetary status, staff requirement should be clearly indicated and the revised budget form should be submitted.

d. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval.

e. If the amendment demands a re-look at the toxicity or side effects to participant's, the same should be documented.

f. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IEC, only then they can be implemented.

g. Approval for amendment changes must be obtained prior to implementation of changes. The amendment is unlikely to be approved by the IEC unless all the above information isprovided.

9. Any deviation/violation/waiver in the protocol must be informed to the IEC as detailed in DHMHSOP09/V1.

10. If project/drug/device trial initiation not done in next 6 months from date of approval from IEC, further extension will not be granted and it will require resubmission to IEC.

Thanking You,

Yours Sincerely,

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

AN3-V1/DHMHSOP 06/V1

Format for Communication of IEC decisions project/trials

To,

Dr._____

Principal Investigator,

DHMH.

IEC code and Project title:

Study/Protocol No.:

Dear Dr.

The above referenced project was tabled, reviewed and discussed during the Institutional Ethics Committee meeting held on(date)_____

List of documents reviewed.

The following members attended the meeting.

The committee suggested the following changes or additional information in project proposal:

a.

b.

c.

The approval will be granted subject to the compliance with all the above suggestions of the IEC.

PI advised to submit above clarifications within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Kindly resubmit the **one copy** of revised proposal or documents within 4 weeks for re-review by the Member Secretary/three Member Sub-committee.

Thanking you,

Yours Sincerely,

Signature of the Member Secretary_____Date_____

Name of the Member Secretary_____

AN4-V1DHMHSOP 06/V1

Format for Three-Member Subcommittee of IEC Approval for Project

Deliberation by the 3 member's committee for the review of the clarification made by the PI regarding the objections raised about the research protocol presented during IEC meeting held in the Committee Room, DHMH, on_____

IEC code:

Title of projects:

The clarification made by the Principal Investigator was reviewed by the 3 Members Committee comprising of:

1

2.

3.

After due deliberation the committee made the following decisions regarding the clarifications presented by the PI.

Name_____ Signature and date _____ (Member)	Name_____ Signature and date _____ (Member)
_____ _____ Signature and date (Member& Convener) _____	

AN5-V1/DHMHSOP 06/V1

Intimation of Start of Study

1. **IEC code Number:**
2. **Study/Protocol No. (For drug/device trials/any other):**
3. **Title of the study/drug/device/multicentric trial:**
4. **Principal Investigator (Name & Department):**
5. **Sponsor:**
6. **Contract Research Organization (CRO) if any:**
7. **Date of sanction byIEC:**
8. **Date of start**:

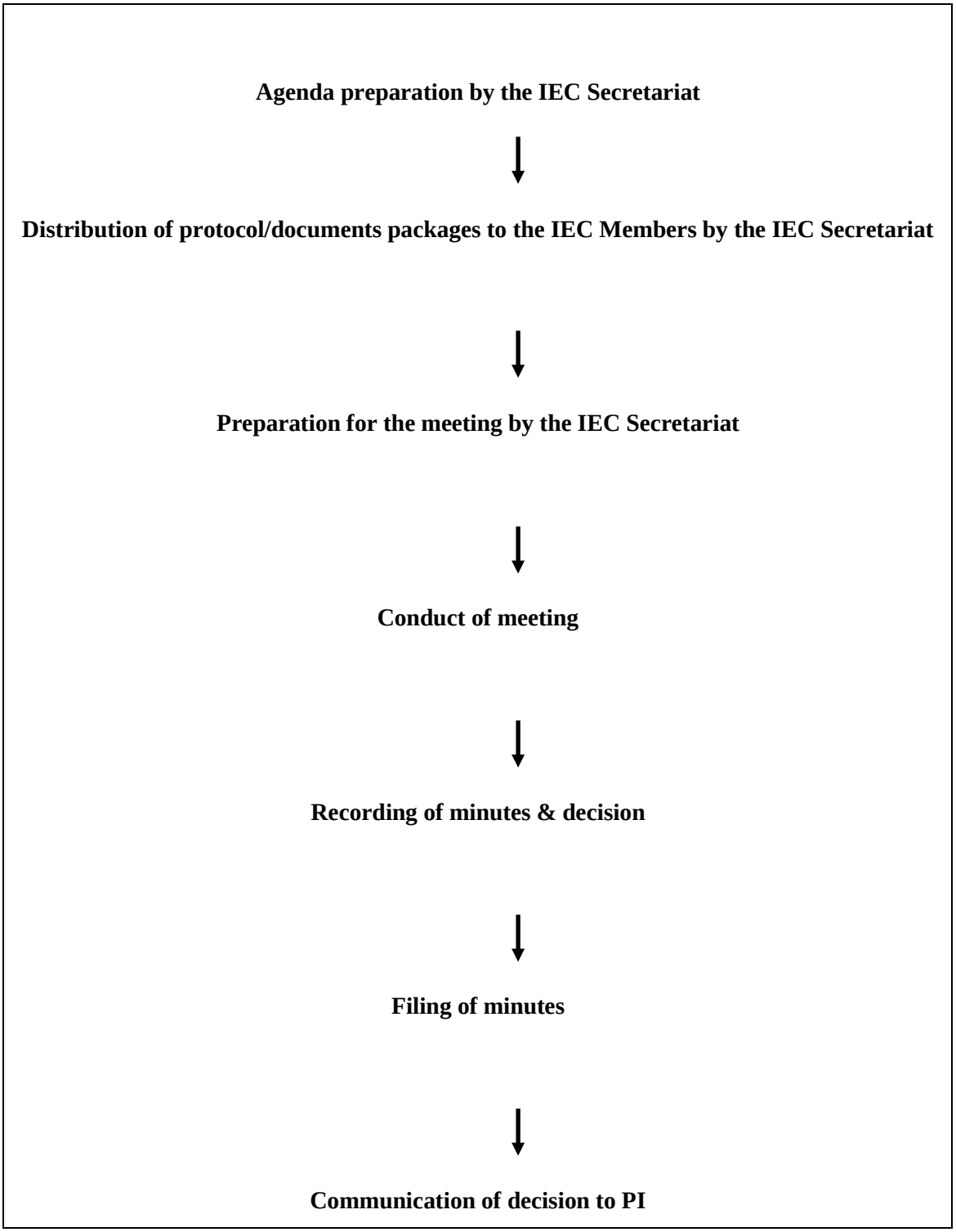
_____

Signature of PI

Name_____

Date_____

Flow Chart


Agenda preparation by the IEC Secretariat
Distribution of protocol/documents packages to the IEC Members by the IEC Secretariat
Preparation for the meeting by the IEC Secretariat
Conduct of meeting
Recording of minutes & decision
Filing of minutes
Communication of decision to PI

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 7

Title: **Review of Amendments/Notifications**

DHMHSOP Code: **Date:** **Pages: 135-142**

DHMHSOP 07/V1

- Procedure for amendments/notifications
- Decision making
- Storage of documents

The purpose of this procedure is to describe how protocol amendments or any other amendments/letters are reviewed by the IEC. This SOP applies to amended study protocols/documents and letters that are submitted for IEC approval. Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the IEC.

7.1 Procedures

7.1.1. Receipt of the amended protocol

- The amendment forwarded by the PI is received by the IEC Secretariat. The amendment along with the covering letter should be accompanied by Amendment Reporting Form (AN1-V1/DHMHSOP07/V1).
- It is the responsibility of the IEC Secretariat to manage protocol amendments, documents and letters.
- The IEC Secretariat should follow the procedures as in DHMHSOP 03/V1 (Procedures for Management of protocol submission).

7.1.2. Review of amended protocols/documents/letters: Review as per DHMHSOP04/V1.

7.1.3. Minor amendments and notifications

Minor amendments (those that do not increase the risk or decrease the potential benefit to Participant's) may be approved in the 3-member subcommittee meeting.

Minor notifications may be noted by the Member Secretary, IEC and reported in IEC meeting. This may include but may not restrict to: Renewed insurance policy, Clinical Trail Agreement Amendment, DCGI and DGFT approvals, administrative notes, etc.

7.2 Decision

- If the IEC approves the amendments, the IEC Secretariat staff communicates this decision to the PI (AN2-V1/DHMHSOP 07/V1 or AN3-V1/DHMHSOP07/V1).
- If the IEC does not approve the amendments, the Member Secretary should notify the investigator in writing of the decision and the reason for not approving the amendment.

- If the IEC recommends or suggests modifications to any of the documents, or the amendments, the IEC Secretariat sends a written communication to the investigator about the specific changes asking him or her to make the necessary changes and resubmit the documents to IEC.

7.3 Storage of documents

File the amendments in the corresponding research protocol file, as per the DHMHSOP 14/V1 on documentation and archival.

AN1-V1/DHMHSOP 07/V1

Amendment Reporting Form (4 copies required)

1. IEC code No.:	
2. Study/Protocol No. (For drug/device trials/any other):	
3. Title:	
4. Principal Investigator: Speciality:	
5. Please mention version no. and date of amended Protocol/Investigators brochure/Addendum	
6. Have you highlighted the amended portion in the document or tabulated details of changes?	
7. Do you wish to extend the approval for your study? If so, please provide details of date of completion, how long you require and the justification for the extra time:	**Yes/No**
8. Does this amendment lead to any change in trial protocol? **If yes: please specify the changes**	**Yes/No**
9. Does this amendment entail any changes in Participant information documents (PID)?	**Yes / No**
10. If yes, is the amended PIDs is enclosed	**Yes / No** **If No, reasons for not submitting**
11. Does it require signing of new consent form by participant already on trial	**Yes/No**
12. No. of active trial participant	
13. Any other additional comment including changes to budgetary or staff requirement: Yes/No	

_____

Signature of PI

Name_____ **Date**_____

AN2-V1/DHMHSOP 07/V1

Format for Project Amendment/Document Amendment Approval letter

To,

Dr. _____ Speciality _____

Principal
Investigator, DHMH

IEC code no. and project title:

Study/Protocol No. (For drug/device trials/any other):

Dear Dr.

We have received the following document/s on(date)_____

1.

2.

At the IEC meeting held on (date) ——, the above-mentioned documents were reviewed. After deliberation, the committee has decided to approve the aforementioned study-related documents.

The members who attended this meeting held on —— date and place of meeting—— at which the above-mentioned document was discussed, are listed below.

1.

2.

3.

Yours Sincerely,

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

AN3-V1/DHMHSOP 07/V1

Format for Project Amendment/Approval letter

To,

Dr. _____Speciality_____

Principal Investigator, DHMH.

IEC code and Project title:

Study/Protocol No. (For drug/device trials/any other):

Dear Dr.

We have received the following document/s on(date)_____

1.

2.

At the IEC meeting held on (date) ——, the above-mentioned documents were reviewed. After deliberation, the committee has decided to approve the aforementioned study-related documents.

The members who attended this meeting held on —— date and place of meeting—— at which the above-mentioned document was discussed, are listed below. The following members attended the meeting.

The committee suggested the following:

A.

B.

C.

The approval will be granted subject to the compliance with all the above suggestions of the IEC. Kindly resubmit one of revised proposal or documents within 4 weeks for re-review by the Member Secretary/three Member Sub-committee/IEC.

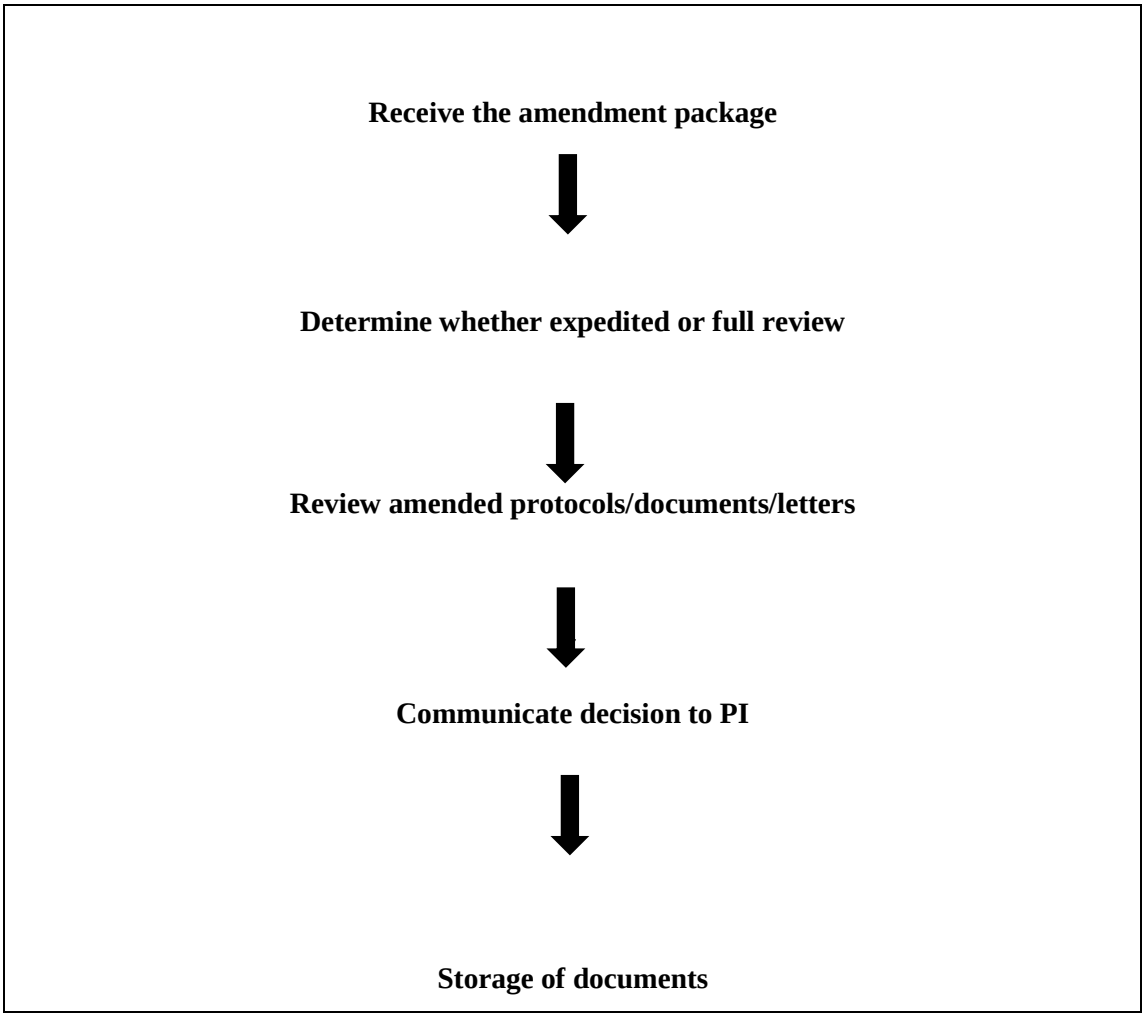
Thanking you

Yours Sincerely,

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

Flow Chart


Receive the amendment package
Determine whether expedited or full review
Review amended protocols/documents/letters
Communicate decision to PI
Storage of documents

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 8

Title: **Continuing Review of study Protocols**

DHMHSOP Code: **Date:** **Pages: 143-156**

DHMHSOP 08/V1

- Responsibility and procedures for Continuing review
- Decision making
- Communication to PI

The purpose of continuing review is to monitor the progress of the study which was previously approved; not just the changes in it to ensure continued protection of the safety benefits, right and welfare of research participant's.

This SOP applies to continuing review of study protocols involving human participant's, at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participant's, the nature of the studies and the vulnerability of the study participant's and duration of the study, the IEC may choose to review a study more frequently.

8.1 Responsibility

- It is the responsibility of Principal Investigator (PI) to submit the periodic/annual progress report of the approved ongoing studies.
- The Chairperson is responsible for determining the date of continuing review, if the project requires more frequent review. This decision is taken during the IEC meeting wherein the project is finally approved.
- The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participant's. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate for the study participant's.
- PI will also apply for extension of approval of the project, if necessary, along with the submission of the annual progress report of the project/study.
- Any PI who fails to submit the report for review within the stipulated time, will have to clarify the delay in writing, this will be forwarded to the Chairperson IEC.
- The IEC may not consider the review of the project reports which are submitted very late. A penalty may be imposed to the PI for the same as decided by the IEC

8.2 Procedures

The responsibility of the IEC Secretariat:

- Check the master file of projects approved by the IEC for the due date of continuing reviews.
- The IEC Secretariat will inform the PI well in advance at least one month before the due date for the continuing review in writing, (AN3-V1/DHMHSOP 08/V1) requesting for 4 copies of the annual/periodic progress report to allow the study team sufficient time to collate the information and to prepare a report required for the continuing review.
- It will verify that the following documents are submitted:

1. Continuing Review Application Form (AN1-V1/DHMHSOP08/V1 orAN2-V1/DHMHSOP 08/V1) with signature of PI.
2. The Progress Report with information about the number of participant's enrolled to date and since the time of the last review, an explanation for any "yes" (ticked on the Continuing Review Application Form AN1-V1/DHMHSOP 08/V1 orAN2-V1/DHMHSOP08/V1) answers on the application form and a discussion of scientific development, either through the result of this study or similar research elsewhere that may alter risks to research participant's.
3. Summary of the progress since the time of the last review.
4. Request letter for extension of approval of the project, if requested beeps.

- The IEC follows the procedure for review and decision making same as for an initial review.
- The Member Secretary will consult the Chairperson whether to include the annual project report/s in the forthcoming IEC meeting for discussion. After consultation with Chairperson, it can be reviewed by Member Secretary/Chairperson and informed in the full board meeting or sent to two more IEC members nominated by Chairperson for review.

8.3 Decision-making

The IEC members could arrive at any one of the following decisions at the IEC meeting:

1. Noted and the project can be continued without any modifications.
2. Modifications recommended - Protocols for which modifications have been suggested by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within four weeks for re- review.

3. Disapproved and no further continuation.

- This decision is recorded by the Member Secretary on AN4-V1/DHMHSOP08/V1.
- The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
- The IEC Secretariat will maintain and keep the IEC decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

8.4 Communicate the IEC decision to thesis

The Member Secretary IEC will notify the PI of the decision (AN5-V1/DHMH SOP 08/V1) within 14 days.

AN1-V1/DHMHSOP 08/V1

Continuing Review Application Form/Annual status Report form (For Interventional Study, 4 copies required)

IEC code No.:

Study/Protocol No. (For drug/device trials/any other):

Protocol Title:

PI:

Speciality/Organization:

Date of IEC approval:

Start Date of study:

Duration of study:

1. Project Status

[ ] Ongoing

[ ] Completed

[ ] Accrual completed
[ ] Follow-up

[ ] Suspended

[ ] Terminated
[ ] Closed

[ ] Not started/Not initiated

If 'Not started' state reasons:

2. Provide the date of last status review report submitted to IEC for this project

3. Have there been any amendments since the last status report?

[ ] YES

[ ] NO

If 'Yes', were these Protocol amendments approved by IEC

- YES, if 'YES', please provide date of approval_____

- No

Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

4. Have there been any Participant Information Document (PID) amendments since the last status reports?

[ ] YES

[ ] NO

If 'Yes', were these PID amendment approved by IEC

- YES, if 'YES', please provide date of approval_____
- No

Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

5. Summary of protocol Participant's:

- Accrual ceiling set byIEC_____
- New participant's accrued since last review_____
- Total participant's accrued since protocol began_____
- Number of active Participant's_____
- Number of Participant's who have completed the study_____
- Impaired participant's:
  - None_____
  - Physically_____
  - Cognitively_____
  - Both_____

6. Is the recruitment on schedule?

[] YES

[] NO

(If 'NO', please attaché a sheet giving reason and your plans to improve accrual)

7. Have there been any changes in the participant population, recruitment or selection criteria since the last status report was submitted to IEC review?

[ ] YES (If 'YES', kindly attach a sheet explaining the changes)
[ ] NO

8. Have any participating Investigators been added or deleted since last status report was submitted to IEC? [ ] YES (If 'YES', kindly attach a sheet with details regarding the changes) [ ] NO
9. Have any new collaborating sites (institutions) been added or deleted since the last status report was submitted to IEC? [ ] YES (If 'YES', kindly attach a sheet with details) [ ] NO
10. Does the Protocol have an inbuilt monitoring plan? [ ] YES [ ] NO
11. Is interim data analysis report available? [ ] YES (If 'YES', kindly submit as an attachment) [ ] NO
12. Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC evaluation of the Risk/Benefit analysis of human Participant's involved in this protocol? [ ] YES (If 'YES', kindly attach a sheet with details) [ ] NO
13. Have any unexpected complications, AEs or SAE been noted since last status report? [ ] YES (If 'YES', kindly attach a sheet explaining the changes) [ ] NO **(If 'YES', please attach a sheet giving complete details regarding number of SAEs occurred, whether reports of SAEs have been submitted to IEC, type of adverse events in a tabular format.)**
14. Have any unexpected complications, AEs or SAE been noted since last status report? [ ] YES (If 'YES', kindly attach a sheet explaining the changes) [ ] NO **(If 'YES', please attach a sheet giving complete details regarding number of SAEs occurred, whether reports of SAEs have been submitted to IEC, type of adverse events in a tabular format.)**

15. Have any participant's withdrawn from this study during the last one year/since the last status review?

[ ] YES (If 'YES', kindly attach a sheet stating reasons for drop-outs)

[ ] NO

16. When was study last monitored?

Date of monitoring_____

Monitored by_____

Number of Participant's monitored_____

17. Is report of the data safety and monitoring board report available?

[ ] YES (If 'YES', submit as an attachment)

[ ] NO

18. Did the monitoring team have any adverse comments regarding the study?

[ ] YES (If 'YES', please attach a copy of their comments)

[ ] NO

19. Has there been any presentation/publication related to the data generated in this trial?

[ ] YES (If 'YES', kindly attach a sheet with details)
[ ] NO

20. Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered as conflict of interest?

[ ] YES (If 'YES', kindly append a statement of disclosure for the same)

[ ] NO

_____

Signature of PI

Name_____ **Date**_____

AN2-V1/DHMHSOP 08/V1

Continuing Review Application Form/Annual status Report form (For Non-Interventional Study, 4 copies required)

1. **IEC code no.**
2. **Title of the project:**
3. **Principal Investigator (Name & Speciality/Organization):**
4. **Sponsor:**
5. **Date of sanction by IEC**
6. **Date of start:**
7. **Duration of project:**
8. **Objectives of the study:**
9. **Total number of Participant's to be recruited for the study:**
10. **Progress report as per objectives (summary in 250word):**

_____

_____

_____

_____

_____

11. **Protocol deviation if any with reasons/justifications:**

_____

Signature of PI

Name_____ **Date**_____

AN3-V1/DHMHSOP 08/V1

Reminder Letter by the IEC to PI

Name of P I:

Speciality:

IEC code no. & Project Title:

Study/Protocol No. (For drug/device trials/any other):

The above referenced project was approved by the IEC on… .....and is due for continuing annual/_____monthly review by the IEC. You are requested to submit an annual status report in the prescribed format AN1-V1/DHMHSOP 08/V1 or AN2-V1/DHMHSOP 08/V1 on or before……

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

AN4-V1/DHMHSOP 08/V1

IEC Decision on Continuing Review Report

IEC code no:

ProjectTitle:

PI:

Review: Annual Progress Report

Date of IEC meeting:

Further the review and approval of resubmitted protocol is subjected to:

- Reviewed in Full Board

Decision:

- Noted and the project can be continued without any modifications
- Modifications recommended, requiring protocol resubmission
- Protocol discontinued
- Extension of project (if extension necessary, Yes/No, if Yes, period of extension)

State the recommendations:

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

AN5-V1/DHMHSOP 08/V1

Project Annual Report Approval Letter

PI Name:

PI Speciality:

Project Title:

IEC code no.

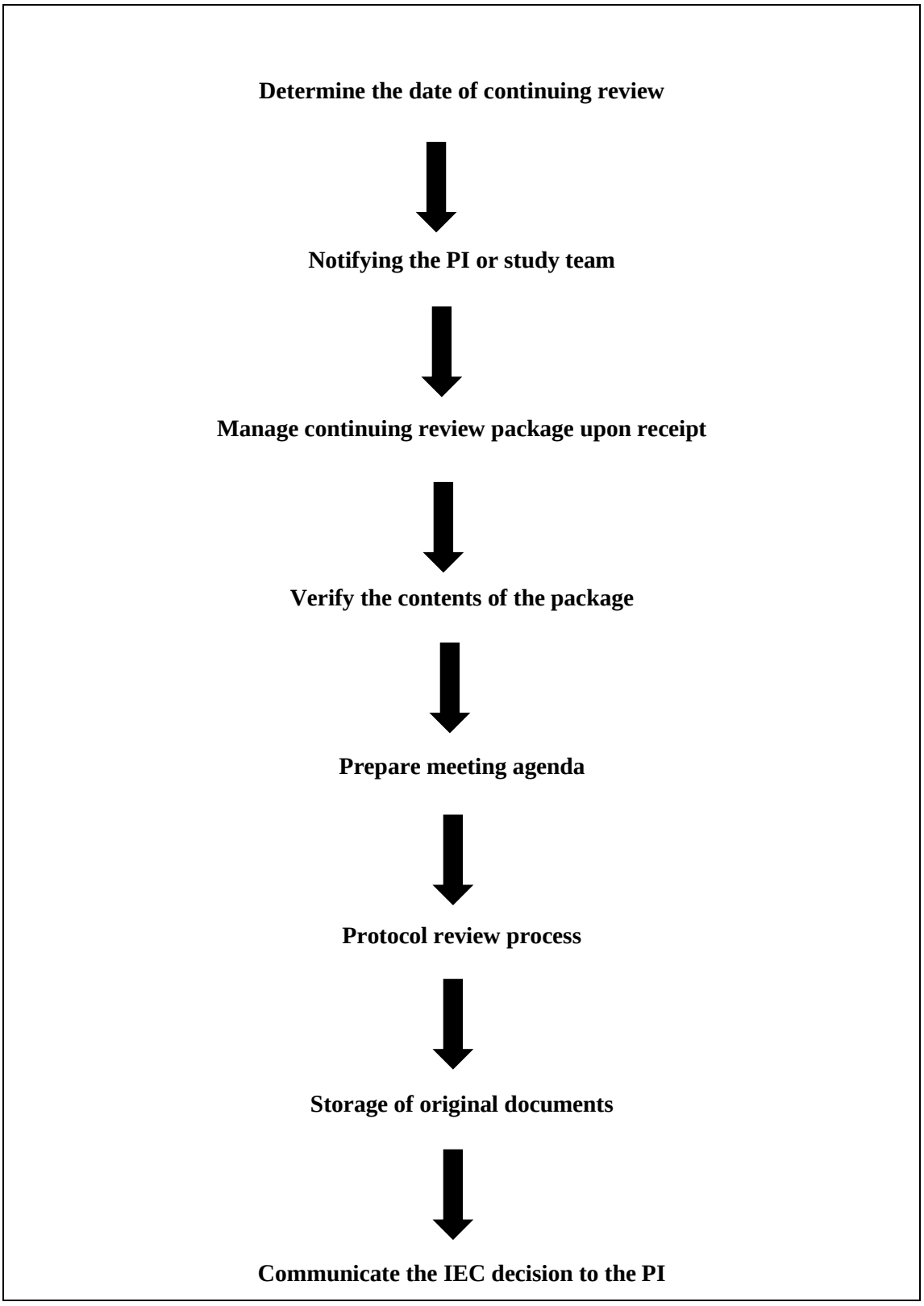
Study/Protocol No. (For drug/device trials/any other):

This is with reference to your letter regarding the status report of the above-mentioned project. The Study Status Report was discussed and noted in the IEC meeting held on _____The IEC has noted the progress report. The following recommendations are suggested (wherever applicable);

Signature of the Member Secretary_____Date _____

Name of the Member Secretary_____

Flow Chart


Determine the date of continuing review
Notifying the PI or study team
Manage continuing review package upon receipt
Verify the contents of the package
Prepare meeting agenda
Protocol review process
Storage of original documents
Communicate the IEC decision to the PI

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Title: **Reporting of Protocol Deviation/Non-Compliance/Violation/Waiver**

Chapter 9

DHMHSOP Code:	**Date:**	**Pages: 157-164**
DHMHSOP 09/V1		

- Responsibility
- Detailed Instructions, decisions and actions
- Notifying the investigator
- Records and follow-up

These SOPs provide instructions for taking action and maintaining records, when investigators/ trial sites, fails to:

- Follow the procedures written in the approved protocol.
- Comply with national/international guidelines for the conduct of human research.
- Respond to the IECrequests.

This SOP applies to all IEC approved research protocols involving human Participant's.

9.1 Responsibility

- The PI should forward protocol deviation/non-compliance/violation/waiver reports to the IEC. Protocol Waiver is analogous to a Protocol Deviation, except that prior IEC approval must be obtained before implementing the necessary departures from the protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not. e.g., Protocol Waiver means a prospective decision by a sponsor or investigator to permit accrual of a Participant who does not satisfy the approved inclusion/exclusion criteria for enrollment.
- The IEC Secretariat will receive deviations /violations/waiver reports as per (AN1-V1/DHMHSOP 09/V1) submitted by the PI. Reporting of deviation/non-compliance/violation/waiver in any other reporting format will not be accepted. It will be placed in the meeting agenda.
- IEC members should review and take action on such reports.

9.2 Detailed instructions

9.2.1Detection of protocol deviation/non-compliance/violation/waiver

A. The IEC members performing monitoring of the project at trial site can detect protocol deviation/non-compliance/violation, if the project is:

- Not conducted as per protocol/national/international regulations
- When scrutinizing annual/periodic reports/SAE reports
- Any other communication received from the Investigator as per IEC

decision, trial site/sponsor/study monitor/CRO etc.

B. IEC Secretariat can detect protocol deviation/non-compliance/violation from failure to

- Comply with statutory requirements
- Respond to requests from IEC within reasonable time limit
- Respond to communication made by IEC

D. Communication/complaint/information received from research participant, who has been enrolled or any individual who has been approached for enrollment

E. Any report/communication brought to the notice of the Member Secretary/Chairperson of IEC

F. Communication received from the Director, DHMH informing IEC about an alleged protocol violation/non-compliance/protocol deviation

9.2.2. Noting protocol deviation/non-compliance/violation/waiver by the IEC Secretariat

- The members of site monitoring committee who have performed monitoring of a particular trial site and detect protocol deviation/non-compliance/violation will inform the IEC Secretariat in writing within 48 hours [two working days].
- Whenever protocol deviation/non-compliance/violation have been observed, the IEC Secretariat will ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the IEC meeting.

9.2.3. Board discussion, decision and action

- If the protocol deviation/non-compliance/violation is detected by IEC member during monitoring visit he/she will present, the protocol deviation/noncompliance/violation information.
- If detected by the IEC Secretariat forwarded by PI, the Member Secretary will present the protocol deviation/non-compliance/violation/waiver information.
- The deviations/violations will be scrutinized for gravity and implications in the formal full board IEC meeting. The IEC members will review the information available and take a decision depending on the seriousness of the violation.
- The decision will be taken to ensure that the safety benefits and rights of the

research participant's are safeguarded & protected. The decision will be taken by consensus and if no consensus is arrived at, voting will be done during the full board meeting.

- The IEC decision will be communicated to PI.

The actions taken by IEC could include one or more of the following:

- Inform the PI that IEC has noted the violation/noncompliance/deviation and inform the PI to ensure that deviations/noncompliance/violations do not occur in future and follow IEC recommendations.
- Enlist silent measures also that the PI would undertake to ensure that deviations/noncompliance/violations do not occur in future.
- Reprimand the PI.
- Call for additional information.
- Suspend the study till additional information is made available and is scrutinized.
- Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
- Suspend the study for a fixed duration of time.
- Inform the Chairman cum Managing Director, DHMH for suitable action.
- Revoke approval of the current study.
- Keep other research proposals from the PI/ Co-PI under abeyance.
- Review and / or inspect other studies undertaken byPI/Co-PI.

9.3 Notifying the investigator

- The IEC Secretariat records the IEC decision and prepares a notification letter (AN2- V1/DHMHSOP09/V1).
- The Member Secretary will sign and dates the letter.
- The IEC Secretariat sends a copy of the notification to the investigator.
- The IEC Secretariat sends a copy of the notification to the relevant national authorities, the sponsor or the CRO of the study and other trial sites, in case of multi-centric trial, if so, recommended by IEC.

9.4 Records and follow up by IEC Secretariat

- Keeps the original copy of the notification letter in the "non-compliance'file.
- Stores the file on the shelf with an appropriate label.
- Follows up the action after a reasonable time.
- Maintains a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IEC request for information/action.

AN1-V1/DHMHSOP 09/V1

Deviation (D)/Waiver (W)/Violation (V) Reporting Form (4 copies required)

IEC Code No: **Study/Protocol No. (For drug/device trials/any other):** **Project Title:** **PI&Speciality:**
Specify if D/W/V-
Date of occurrence: did/mm/yyyy (Not applicable in case of Waiver)
No of similar D/W/V occurred the same trial:
Participant's No. and name:
Complete Details of D/W/V (attach separate sheet if necessary):
Action taken by PI/Co-PI/guide: (Not applicable in case of Waiver)
Impact on trial Participant (if any): (Not applicable in case of Waiver)
Whether D/W/V informed to sponsor/CRO:
Signature of PI **Name_____** **Date_____**

AN2-V1/DHMHSOP 09/V1

Form for communicating decision of Deviation (D)/Waiver (W)/Violation (V) to PI

IEC Code No:

Study/Protocol No. (For drug/device trials/any other):

Project Title:

PI & Speciality:

Sub:

Reviewed by the IEC

Final decision at the full board meeting held on_____

Action taken:

[ ] Noted

[ ] Request the Principal Investigator to take immediate action to prevent such deviations/non compliances/violations in future

[ ] Specific recommendations stated below to be followed

_____

_____

[ ] Suspend the study till the IEC recommendations are implemented

[ ] Suspend the study till information available

[ ] Terminate approval of the current study

Reasons for termination:

_____

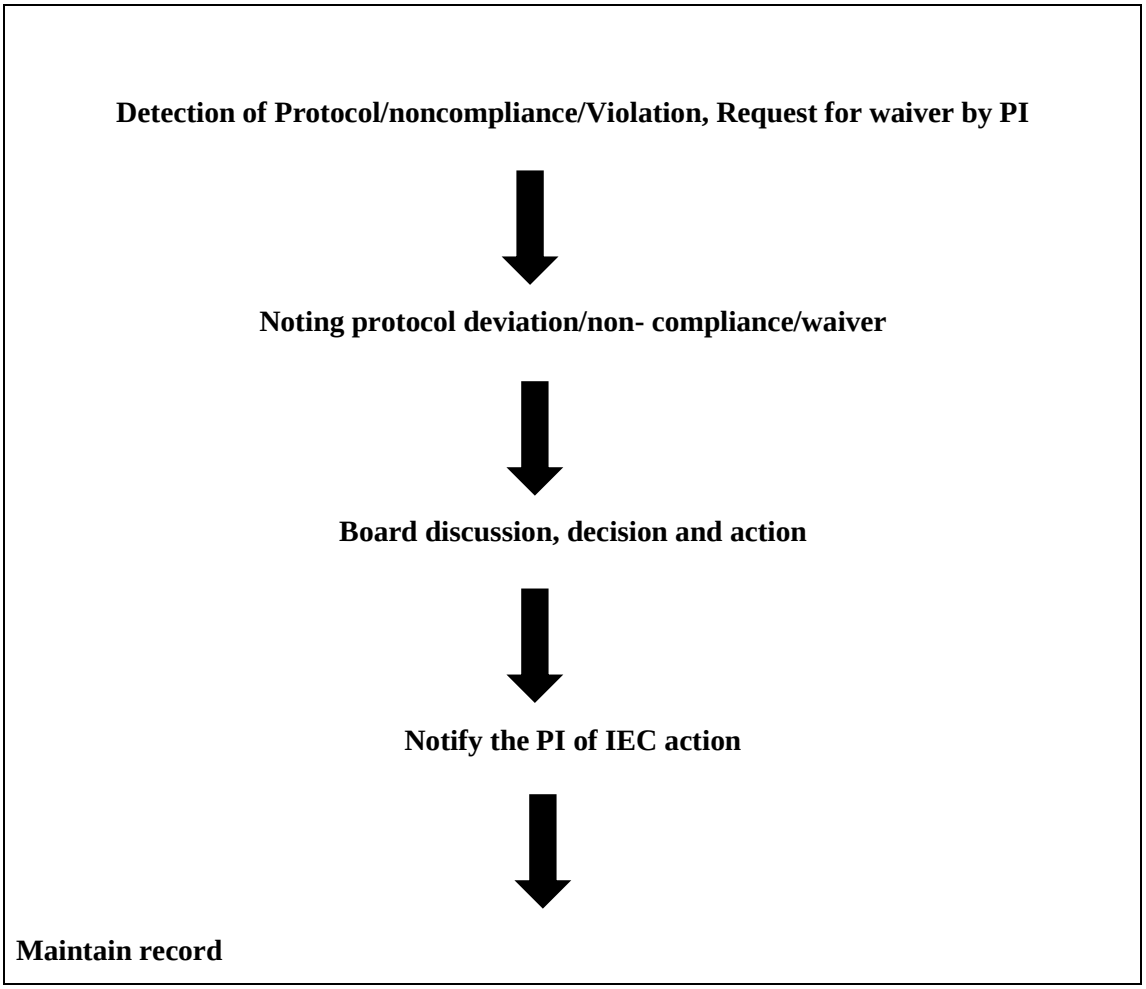
_____

Any other comment_____

Signature of the Member Secretary_____Date_____

Name of the Member Secretary _____

Flow Chart


Detection of Protocol/noncompliance/Violation, Request for waiver by PI
Noting protocol deviation/non- compliance/waiver
Board discussion, decision and action
Notify the PI of IEC action
Maintain record

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 10

Title: **Review of Adverse Events (AE) Reports**

DHMHSOP Code: **Date:** **Pages: 165-184**

DHMHSOP 10/V1

- Purpose and scope
- Categorization of protocols as exemption from review
- Responsibility and detailed instructions
  - On site SAE
  - Off site SAE

10.1 Purpose

The purpose of this SOP is to provide instructions on the review and follow-up reports of serious adverse events (SAEs) and unexpected events for study approved by the IEC. The reporting is in accordance to the Gazette of India, Dated 19 March 2019, and ICMR National Ethical guidelines 2017.

Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio, should be promptly reported and reviewed by the IEC or SAE monitoring sub-committee (formed by IEC) to ensure adequate protection, safety and welfare of the study participant's. The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of participant's in the study.

10.2 Scope

This SOP applies to the IEC and SAE monitoring sub-committee review of SAE and unexpected events reports, both on site and off site, including follow up reports submitted by investigators.

10.3 Responsibility

It is the responsibility of the PI to report any AE/SAE (onsite or offsite) in the enrolled participant's as per rules as described in Gazette of India, 19thMarch, 2019, and ICMR National Ethical guidelines 2017.

The primary responsibility of the IEC or SAE monitoring sub-committee is to review and address SAE and unexpected events involving risks to research participant's. IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements for SAE.

In case, the investigator fails to report any SAE within the stipulated period, s/he shall have to furnish the reason for the delay to the satisfaction of DCGI along with the report of the SAE.

10.4. Detailed instructions

A. On site SAEs

10.4.1 SAE related activities before IEC meeting

- The IEC Secretariat will verify that the reports are complete, signed and dated by the PI. In case the IEC Secretariat notes that the report is incomplete, it will be forwarded to Member Secretary, IEC for decision and also revert back to PI.
- The IEC Secretariat should receive the reports of SAEs occurred for IEC approved studies within the stipulated time of the occurrence of theSAE.
- If the SAE is reported 'Death', the IEC Secretariat should receive the SAE reporting form (AN1- V1/DHMHSOP 10/V1) within the stipulated time prescribed by the regulatory authority of its occurrence.
- If the PI has not adhered to the above stipulated time period, the IEC Secretariat will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

10.4.2 Actions to be taken by Member Secretary, IEC

- If the SAE reported as 'death', the Member Secretary will send to SAE monitoring sub-committee, and it will report to the Chairperson, IEC for further action.
- The Member Secretary will table SAE report (as submitted by SAE monitoring sub-committee) at the next scheduled IEC full boardmeeting or a special meeting may be called by the Chairperson IEC to review the SAE.

10.4.3 Actions to be taken by SAE subcommittee

The SAE subcommittee will look at the report of SAEs submitted by PI (on site) and will report to the Chairperson, IEC. Decision of subcommittee will be reported in the next IEC meeting (AN5-V1/DHMHSOP 10/V1).

10.4.4 Actions to be taken by Chairperson

The Chairperson, IEC on basis of the information and comments received from the Member Secretary, IEC, and SAE monitoring sub-committee and applying his/ her judgment will direct the IEC Secretariat to any one or more actions listed below, but are not limited to;

- Suspending enrolment of new research participant's till further review by the IEC.
- Suspending all trial related procedures (except those intended for safety, risk and wellbeing of the trail participant) till further review by the IEC.
- Suspend some trial-related procedures (to be listed).

- Calling for an emergency review by full board.

❖ This review should be initiated within 48 working hours (2 working days) of receipt of information from the SAE subcommittee

❖ This review could be done through a meeting, tele conference, email or telephonic conversation.

❖ The IEC Secretariat will take appropriate steps to ensure that IEC members are informed about this full board emergency review.

❖ The chairperson could direct the Member Secretary, IEC, to invite one or more experts if necessary. These experts could participate after they agree to the confidentiality clause and abide by the rules and regulations of IEC.

❖ Soliciting opinion of one or more expert in writing. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality clause and abide by the mandate of IEC. The expert would be requested to provide an opinion in writing within 14 working days, depending upon the gravity and seriousness of the matter.

❖ Report at the next IEC meeting for discussion.

B. Off Site SAEs

- Off Site SAEs where adverse event reports that are serious, unexpected and related (definitely, probably and possibly) to the drug/device need prompt reporting to the IEC with reporting of center-wise SAE's.

- The SAEs that are expected (if listed in the informed consent) or unexpected but unrelated to the drug (classified as per the Offsite Safety Report Classification form (AN3-V1/DHMHSOP 10/V1) have to be logged (AN4-V1/DHMHSOP 10/V1) by the PI and to be submitted every 3 months and/or submitted along with continuing review report. The log has to be maintained continuously until the end of the study.

- Those off-site SAEs which qualify for prompt reporting, (classified as per the Offsite Safety Report Classification form AN3-V1/DHMHSOP 10/V1) will be reported to the IEC Secretariat and forwarded to Member Secretary, IEC for further action.

- If a trend is observed in SAEs by PI, such a trend will be reported to the IEC Secretariat, action on such reports will be taken by the Member Secretary, IEC as per 10.3-10.4.

- The IEC Secretariat will require complete set of "Off-site Safety Reports" and/or the log. The IEC will review the log of (AN4-V1/DHMHSOP 10/V1) the SAEs every 3 months and at the time of continuing review/submission of annual status report.

- **The PI must comment possible effect of previously reported and current SAE reports on ongoing study while submitting the documents.**

10.5 During the IEC meeting (On site or off-site SAEs)

- If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the IEC discussion. Some of these are listed below:

o Terminate the study.

o Suspend the study till review is completed.

o Suspend the study till additional information is obtained.

o Suspend the study for a fixed duration of time.

o Suspend the study till amendments requested for by the IEC are accepted.

o Suspend enrolment of new research participant's.

o Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participant's who have already been enrolled).

o Recommend an amendment to the protocol, the ICD, Participant information document, Iinvestigator brochure and/ or any other document.

o Request additional details.

o Request further follow up information.

o Direct the PI to inform participant's already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial/study, if necessary.

o Direct the PI to inform participant's already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.

o Note the SAE report in the IEC.

o Recommend for compensation and send to DCGI.

Any other action (as per Gazette of India 19th March, 2019 or ICMR National Ethical Guidelines 2017

10.6 After the review of SAE

- The IEC Secretariat will send a formal letter signed by the Member Secretary to the

investigator/s with instructions for specific actions as per the IEC decision and compliance to actions recommended by the IEC within 14 days of receipt of the IEC letter.

- The IEC will instruct the PI to forward follow-up reports of the SAE to the IEC.
- The IEC Secretariat keep a copy of the letter in the master file of the research protocol.
- In case a PI fails to respond to the IEC letter, the matter will be discussed at the next full board meeting and a decision will be taken for specification.
- Inform the DCGI (within 30 days) of IEC decision in case of drug/device trials.
- IEC will decide if it is necessary to suspend recruitment/modify the protocol/PID.

10.7 Time line for reporting of SAE(‘s)/SAE for ‘death’ (as per Gazette of India, 2013, 2014 and finally 19 March 2019.

Responsibility of PI

The researcher is responsible for reporting all SAEs to the IEC within 24 hours of knowledge. Reporting of SAE may be done through email communication (including on non- working days).

A report (after due analysis) has to be submitted by the PI to DCGI, Chairperson of IEC and the Head of Institution where the trial is being conducted, within 14 days of the occurrence of SAE**.**

Responsibility of IEC

The IEC shall forward its report on the SAE, after due analysis, along with opinion on the financial compensation, if any to be paid by the sponsor, to DCGI **within 30 days of the occurrence of the SAE**

Responsibility of DCGI

DCGI shall forward the report of the Investigator, sponsor and the IEC to the Chairperson of the independent Expert Committee of DCGI.

The Expert Committee of DCGI shall examine the report of SAE and give its recommendations to DCGI for the purpose of arriving at the cause of SAE **within 105 days of occurrence of the SAE.** In case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the sponsor/representative.

DCGI, after considering the recommendations of Expert committee, shall decide the quantum of compensation to be paid by the sponsor/representative and pass orders **within 150 days of occurrence of the SAE.**

Responsibility of sponsor/PI

The sponsor/representative, shall pay the compensation in case of clinical trial related injury or death as per the order of the DCGI **within 30 days of the receipt of such order**.

AN1-V1/DHMHSOP 10/V1

Onsite Adverse Drug Event Reporting Form (3 copies required)

1. IEC code no.:

2. Study/Protocol No. (For drug/device trials/any other):

3. Title of project:

4. Principal Investigator&Speciality:

5. Suspected Adverse Reaction(diagnosis):

6. Report date:

7. Date of onset of SAE:

8. Report type:

a. Initial:

b. Follow up---------- If Follow-up report, state date of Initial report----------

c. Final:

9. Participant's information:

a. Participant'sInitial and Case No./Participant ID.

b. Age: c. Gender:

d. Height: e. Weight:

10. Information related to no. of recruitment/prior SAE and death

	Total number of recruitments at	Total number of SAE (prior) occurred at	Number of similar SAEs (prior) occurred for same study at	Total number of deaths at
This site				
Other site (s)				

11. Tick which event is applicable for serious adverse event

A] Expected event [] Unexpected event []

B] Hospitalization [] Increased hospital stay [] Death [] Others []

In case of Death, state probable cause of death…….

(If other, please specify: …….

C] No permanent significant functional/cosmetic impairment [ ]
Permanent significant functional/cosmetic impairment [ ]

Not applicable [ ]

12. If there was a research related injury/hospitalization, the cost of treatment/

hospitalization was borne by:

Participant's [] Organization [ ] Sponsor/CRO []

13. Suspect drug information

a. Suspect drug (include generic name) device/intervention:

b. Indication(s) for which suspect drug was prescribed or tested:

c. Daily dose and regimen:

d. Route(s) of administration:

e. Dosage Form and Strength:

f. Therapy dates (start and stopped date):

14. Did the reaction decline after stopping the drug/procedure (Dechallenge & Rechallenge information):

YES[ ] NO[] NA []

Concomitant drugs history and lab investigations

15. Concomitant drug (s) and date of administration:

16. Relevant test/laboratory data with dates:

17. Participant's relevant history (e.g., diagnosis, allergies):

Reaction information
18. Description of adverse event a. Start date (and time) of onset of reaction: b. Stop date (and time) or duration of reaction: c. Setting (e.g. hospital, Out-Participant's clinic, home, nursing home): d. [Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction, indicate if this is follow-up report and if so, include follow-up information only]:
19. Describe the medical treatment provided for adverse reaction (if any) to the research Participant's. This is an update on treatment given during hospitalization:
20. Outcome: Resolved [] Ongoing [ ] Death []
21. Was the research Participant continued on the research protocol? Yes[] No[] NA (Mark 'NA' in case of death) []
22. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes [] No [] Provide details if communicated (including date):
23. In your opinion, does this reaction require any alteration in trial protocol? Yes [] No [] **If yes then please specify:**
24. Causality Assessment:

25. Details about the Investigator

Name:

Address:

Telephone/Mobile number/email:

Profession (Speciality):

_____

Signature of PI

Date _____

Upon receipt of this report, the IEC will decide whether additional information is needed or whether further investigation of the reaction is required.

AN2-V1/DHMHSOP 10/V1

Form to Record Recommendations by IEC

• Noted and follow up report requested (if applicable) No[] Yes []

• Changes to the protocol recommended? No [ ] Yes [ ]

If yes then recommendations:

_____

_____

• Changes to the informed consent form recommended? No[] Yes [ ]

If yes then recommendations:

_____

_____

• Request for additional information [ ]

Additional Information needed:

_____

_____

(Till additional information is received, new recruitment should be withheld)

• Terminate the project []

Reasons for termination:

_____

_____

_____

• Any other including communication of information to sponsor/CRO/regulatory agencies

_____

_____

Signature of theMember Secretary_____Date_____

Name of the Member Secretary_____

AN3-V1/DHMHSOP 10/V1

Off-site Safety Reports Classification Form

Note to PI:

The following questions will act as a guide for submission of the "Safety Reports". This form is merely providing guidance for reporting / logging of Offsite Safety Reports.

If the answer to initial three questions (1-3) is **"Yes", prompt reporting is required and such off-site Safety Reports need to be reported to IEC along with the log.**

If any one answer is "No", it needs to be logged as prescribed format (AN4-V1/DHMHSOP 10/V1). This log should be submitted to the IEC Secretariat every 3 months and/or along with Continuing Review report.

IEC Code No.:

Project No.

Project Title:

Participant ID.:

Type of SAE (initial/follow up/any other):

Sr. No.	**Questions**	
1.	**Is adverse event serious? Yes/No**	
2.	**Is adverse event related to the trial medication/procedure? Yes/No**	
3.	**Is adverse event unexpected? Yes/No**	
4.	**Does warrant any change in protocol, PID? Yes/No**	**If yes, please provide details**

Date of reporting:

_____

Signature of PI

Name_____ **Date**_____

AN4-V1/DHMHSOP 10/V1

Off Site Safety Reports Log (4 copies required)

Note to PI:

1. Please log in details of Off-Site Safety Report.
2. The following log has to be maintained continuously until the end of the study.
3. This log should be submitted to the IEC Secretariat every 3 months and/or along with Continuing Review report.
4. The log must be submitted to the IEC Secretariat immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
5. Please note the complete sets of Offsite Safety Reports need to be sent to IEC Secretariat as and when received.

IEC Code No.:

Study/Protocol No. (For drug/device trials/any other):

Project Title:

PI:

No. of Participant's enrolled in DHMH:_____ No. of Participant's enrolled globally:

No. of Participant's on trials at DHMH:____ No. of SAE at DHMH:_____

No. of death at DHMH:_____ No. of death globally:___

S. No.	Participant ID/SAE No.	Country	Date of Onset	Adverse event	Out Come	Remarks

Is any change in protocol, PID required on the basis of these and of previously reported SAE? Yes/No, if yes, please provide details.

_____

Signature of PI

Name_____ **Date**_____

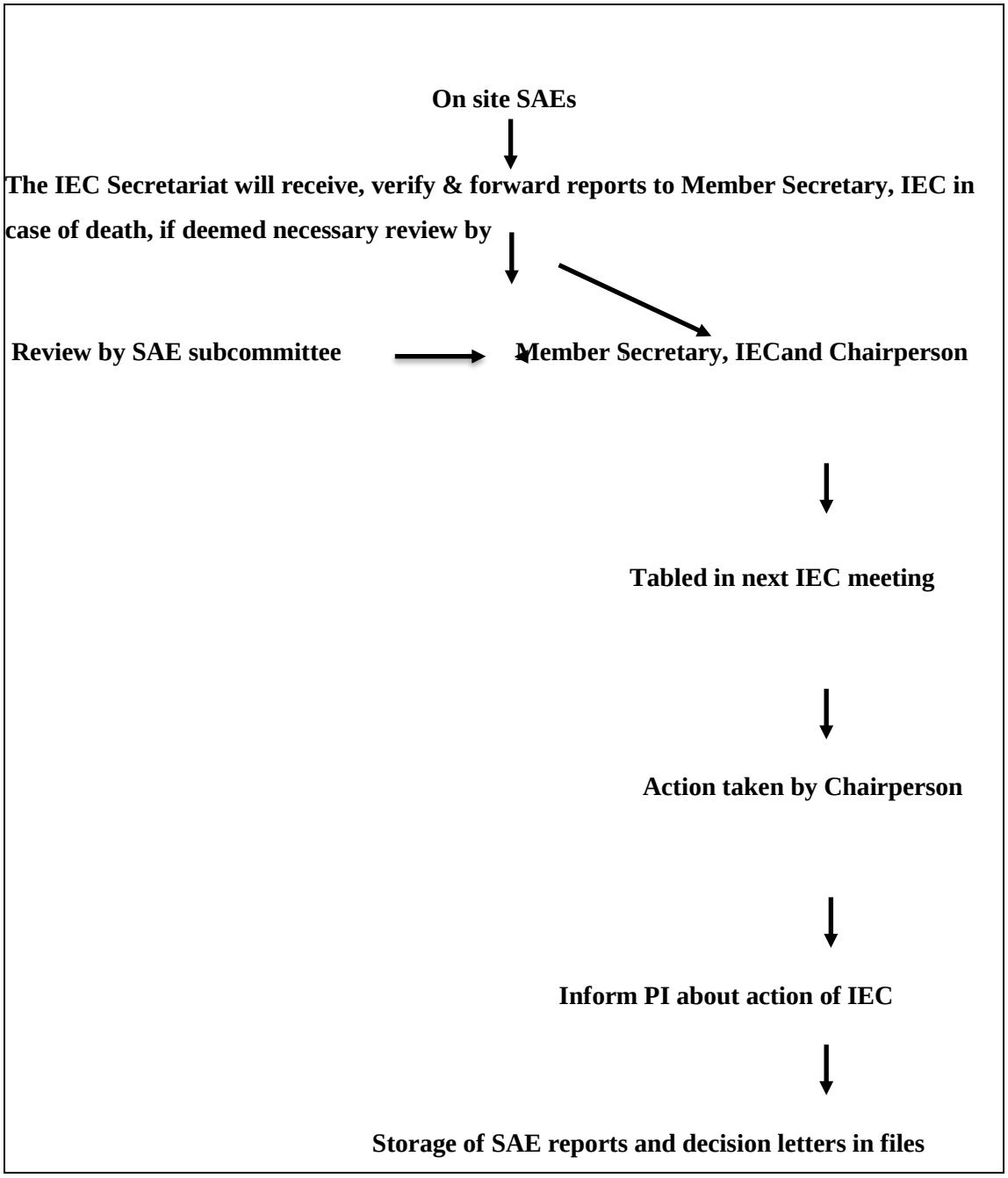
AN5-V1/DHMHSOP 10/V1

Form to Record SAE assessment by SAE monitoring subcommittee

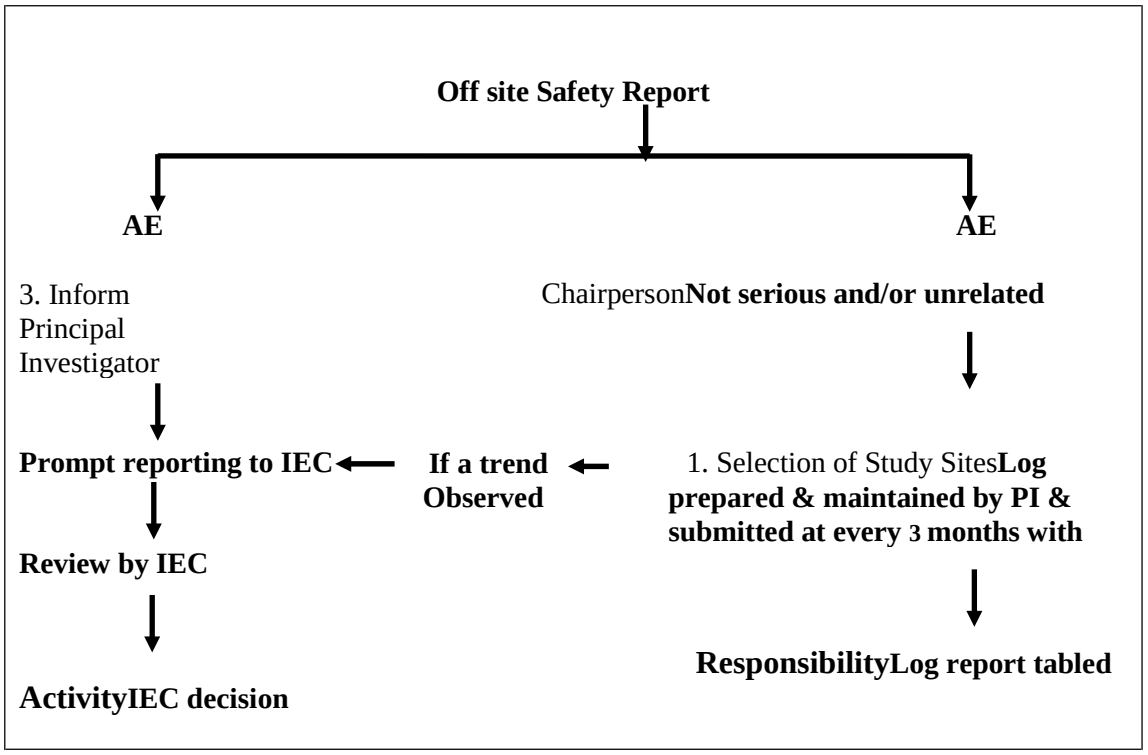
1. Details of the communication between you & Investigator along with other details etc. with regard to the event.
2. Details of examination of event by the SAE monitoring subcommittee, minutes of meeting including cause of death & recommendation on compensation, if any.
3. Details of the documents considered during the assessment of the SAE.
4. Indicate with justification and documentary evidence to as whether the SAE (death) is related/no related to each of the following criteria mentioned under Gazzette of India, 19 March 2019.
   (a) Adverse effects of investigational product(S);
   (b) Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
   (c) Failure of investigational product to provide intended therapeutic effect;
   (d) Use of placebo in a placebo-controlled trial;
   (e) Adverse effect due to concomitant medication excluding standard care necessitated as part of approved protocol;
   (f) For injury to a child in-utero because of the participation of parent in clinical trial;
   (g) Any clinical trial procedures involved in the study.
5. Inform the risk Factor depending on the Seriousness and severity of disease, presence of co-morbidity and duration of disease the Participant at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as per the compensation formula decided by IEC (available on website: https//: cdsco.nic.in)/Gazette of India, 19 March 2019.

   (a) 0.50 terminally ill Participant'ss (expected survival not more than (NMT) 06month).
   (b) 1.0 Participant's with high risk (expected survival between 06 to 27months)
   (c) 2.0 Participant's with moderate risk.
   (d) 3.0 Participant's with mild risk.
   (e) 4.0 Healthy Volunteers or Participant of no risk.

Flow Chart


On site SAEs
The IEC Secretariat will receive, verify & forward reports to Member Secretary, IEC in case of death, if deemed necessary review by
Review by SAE subcommittee
Member Secretary, IECand Chairperson
Tabled in next IEC meeting
Action taken by Chairperson
Inform PI about action of IEC
Storage of SAE reports and decision letters in files

Flow Chart


Off site Safety Report
AE
AE
3. Inform Principal Investigator
ChairpersonNot serious and/or unrelated
Prompt reporting to IEC
If a trend Observed
1. Selection of Study SitesLog prepared & maintained by PI & submitted at every 3 months with
Review by IEC
ResponsibilityLog report tabled
ActivityIEC decision

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 11

Title: **Review of Study Completion Reports**

DHMHSOP Code: **Date:** **Pages: 185-194**

DHMHSOP 11/V1

- Responsibility
- Detailed Instructions/procedures

The purpose of this SOP is to provide instructions on the review of Study Completion Report for every study previously approved by the IEC. Review of the Study Completion Report which is an obligatory review of each investigator's activities presented to the IEC as a written report of study completed.

11.1 Responsibility

- It is the responsibility of the PI to submit Study Completion Report for the concerning project to the IEC Secretariat within 8 weeks of completion of the study as per the Study Completion Report form (AN1-V1/DHMHSOP 11/V1 or AN2-V1/DHMHSOP 11/V1). Any alternate from Pharma company driven trials (provided by the Sponsor/CRO etc.) may also be used, provided that the information submitted covers all the points mentioned in Study Completion Report forms. Site closure information for Pharma company driven trials should also be submitted.
- It is the responsibility of the IEC members to review the study completion report and notify its approval or request for further information, if necessary.

11.2 Detailed instructions

11.2.1 Before board meeting

- The IEC Secretariat will receive 4copies of Study Completion Reports from the PI and check for completeness before submission for the Board meeting.

11.2.2 During board meeting

- IEC member(s) should review and discuss the Final Report in the IEC meeting.
- If appropriate to the discussions, the Chairperson may call for consensus to accept it or request further information or take any other action as suggested by IEC.

11.2.3 After board meeting

- The IEC Secretariat will note the decision in the meeting and minute it properly. The study will be considered as closed if the document is accepted.

- The IEC decision is communicated to the investigator. In case further information/action are requested, the same should be followed by the PI and communicated to the IEC office within 4 weeks. This update will be tabled in the full board meeting of IEC (AN3-V1/DHMHSOP11/V1).

The IEC Secretariat will archive the entire study protocol and the report for a period of 05 (Five), years or longer as per the requirement of the study and as specified by the sponsor.

AN1-V1/DHMHSOP 11/V1

Study Completion Report form

(For Interventional Study)

(To be Filled by PI and submit 4 copies)	
IEC code No. **Study/Protocol No. (For drug/device trials/any other):** **Protocol Title:** **Principal Investigator:** **Phone/Mobile number, email ID:**	
Sponsor: Address: **Phone/ Mobile, E mail:**	
Study Initiation Date:	
Study Completion Date:	
Number Screened: **Number Enrolled:** **Target Number:**	
Date of first Participant enrolled: Date of last Participant enrolled: **Date of first Participant completed study:** **Date of last Participant completed study:**	
No. of study arms:	
Duration of the study:	
Objectives:	
SAEs at the center: **(Total number and type)**	
Whether all SAEs intimated to the IEC (Yes/No):	

No. of Participant's withdrawn/lost to follow up **(Drop out):**	
Reasons for withdrawal: **Protocol deviations/violations:** **(Number and nature)**	
Storage of document for more than 5 years, Yes [ ] No [ ] **If yes, for how many years? _____**	
Results please attach a separate sheet if necessary):	
Conclusion:	
_____ **Signature of PI** **Name_____ Date_____**	

**Please submit thesis/ summary/manuscript / abstract / any publication resulted from the study (if applicable)*

AN2-V1/DHMHSOP 11/V1

Study Completion Report form

(For Non-Interventional Study, 4 copies required)

IEC code no.

Title of the project:

Principal Investigator (Name &Speciality):

Sponsor:

Date of sanction by IEC:_____Date of start:_____

Date of termination:_____

Duration of project:

Objectives of the study:

Total number of Participant'ss to be recruited for the study:____

Number actually recruited:_____

Protocol deviation/violation(number):_____

Result:_____

_____

_____

Conclusion:

Storage of document for more than 5 years, Yes [ ] No [ ]

If yes, for how many years? _____

_____

Signature of PI

Name_____Date_____

**Please submit thesis/ summary/manuscript / abstract / any publication resulted from the study (if applicable)*

AN3-V1/DHMHSOP 11/V1

Notification for Acceptance of Study Completion Reports

Reviewed by the IEC

• Full Board meeting held on(date)_____

Comments (if any):

_____

_____

Action taken:

Noted [ ]

Requires more information/ action as follows [ ]:

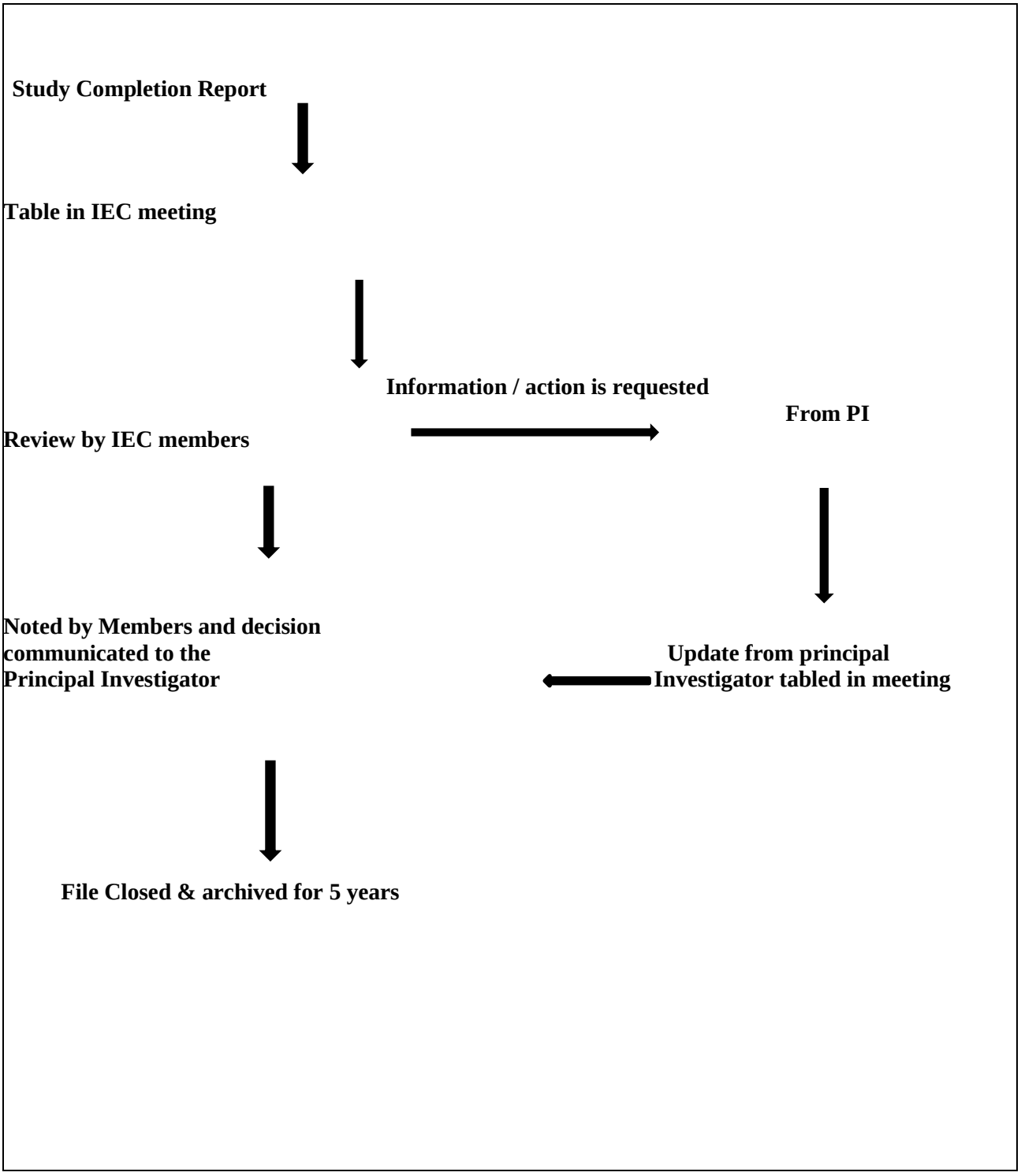
_____

_____

Signature of theMember Secretary_____Date_____

Name of the Member Secretary _____

Flow Chart


Study Completion Report
Table in IEC meeting
Information / action is requested
From PI
Review by IEC members
Noted by Members and decision communicated to the Principal Investigator
Update from principal Investigator tabled in meeting
File Closed & archived for 5 years

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 12

Title: **Management of Premature Termination/Suspension/ Discontinuation of the Study**

DHMHSOP Code:	**Date:**	**Pages: 195-200**
DHMHSOP 12/V1		

- Responsibility
- Detailed Instructions
  - ❖ Receipt and decision making
  - ❖ Communication to PI

The purpose of this SOP is to describe how the IEC proceeds and manages the premature termination/suspension/discontinuation of a research study. Protocols are usually terminated at the recommendation of the IEC, PI, sponsor or other authorized bodies, wherein Participant enrollment and Participant follow-up are discontinued before the scheduled end of the study.

This SOP applies to any study approved by IEC that is being recommended for termination/ suspension/discontinuation before its scheduled completion.

12.1 Responsibility

It is the responsibility of the IEC to terminate any study that it has previously approved, when the safety or benefits of the study participant's is doubtful or at risk. The IEC Secretariat is responsible for management of the premature termination/suspension/discontinuation process.

12.2 Detailed instructions

12.2.1 Receiving recommendation for study termination/suspension/discontinuation

- The IEC Secretariat will receive recommendation and comments from PI, sponsor or other authorized bodies for premature termination of study protocol and place them before the board.
- The IEC Chairperson can recommend the premature termination of a study, if protocol lnon-compliance /violation are detected and IEC decision is to terminate the study.
- SAE occurring at trial site may require the study to be prematurely terminated for the safety of the Participant's.
- The IEC Secretariat will inform the PI to prepare and submit a protocol termination report.
- The IEC Secretariat will receive the Premature Termination Report (AN1-V2/DHMHSOP 12/V1) submitted by the PI and check for completeness. It should contain a brief written summary of the protocol, its results, and accrual data. The IEC Secretariat will initial with the date upon its receipt.

12.2.2 Review and decision on termination/suspension/discontinuation report

- IEC will review the Premature Termination Report (AN1- V1/DHMHSOP 12/V1) at

regular full board meeting and make appropriate recommendation(s).

- If the report is unclear, a query can be sent to the PI for more information.

12.2.3 Notifying the PI

- The IEC Secretariat will make notification letter acknowledging the approval of termination or query letter to request additional information regarding the premature termination within 14 days after the meeting (AN2- V1/DHMHSOP12/V1).
- If a query is sent to PI, the reply letter will be reviewed in the next full board meeting.

AN1-V1/DHMHSOP 12/V1

Premature Termination/Suspension/Discontinuation Report (4 copies required)

IEC code No.:	
Study/Protocol No. (For drug/device trials/any other):	
Protocol Title:	
PI:	
Sponsor:	
IEC Approval Date:	**Date of Last Progress Report Submitted to IEC:**
Starting Date:	**Termination Date:**
No. of Participant's Enrolled:	**No. of Participant's Completed:**
No. of Ongoing Participant's:	**No. of Drop Outs:**
SAE (Total No.):	**SAE Event:**
Summary of Results (attach a separate sheet if necessary):	
Reason for Termination/Suspension/Discontinuation: • **Safety concern** • **Lack of efficacy** • **Others**	
Storage of document for more than 5 years, Yes [ ] No [ ] **If yes, for how many years? _____**	
_____ **Signature of PI** **Name_____** **Date_____**	

AN2-V1/DHMHSOP 12/V1

Notification from IEC for Premature Termination/Suspension/Discontinuation of the Study

IEC code no.

Study/Protocol No. (For drug/device trials/any other):

Title of the project:

PI:

Reviewed by the IEC

• Full Board meeting held on(date)

_Action taken:

Approval of the Premature Termination of the project [ ]

Requires more information/ action as follows [ ]:

_____

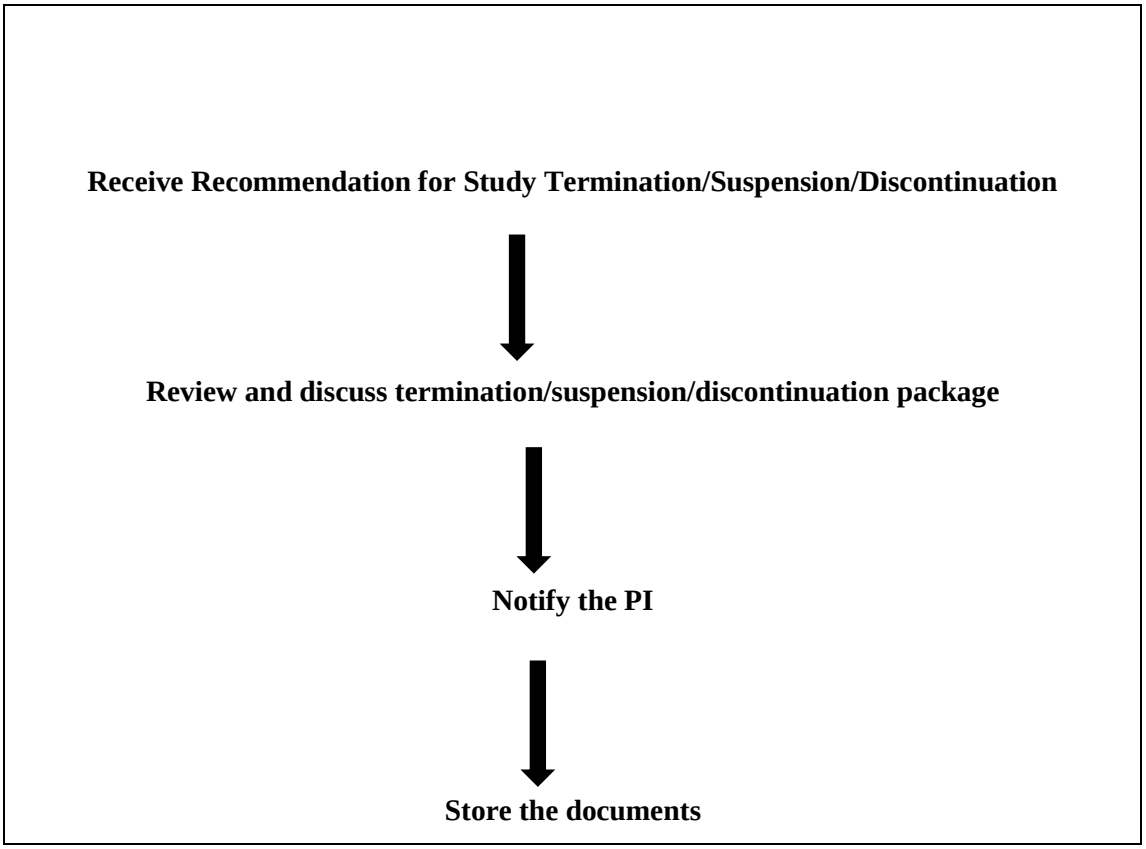
_____

_____

Signature of theMember Secretary_____Date_____

Name of the Member Secretary _____

Flow Chart


Receive Recommendation for Study Termination/Suspension/Discontinuation
Review and discuss termination/suspension/discontinuation package
Notify the PI
Store the documents

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 13

Title: **Request for Waiver of Written Informed Consent**

DHMHSOP Code: **Date:** **Pages: 201-206**

DHMHSOP 13/V1

- Projects which may qualify for consent waiver
- Detailed instruction/procedures

Purpose:

The purpose of this SOP is to describe the type of research projects for which the IEC may grant waiver for requirement of obtaining written informed consent and the format of the application form to be used by the investigators for requesting waiver of consent.

This SOP applies to all the protocols with a request of granting consent waiver submitted for review by the IEC. The decision should be taken by the IEC members at the expedited subcommittee/full board meeting.

13.1 Type of research projects which may qualify for waiver consent.

The investigator can apply to the IEC for waiver of consent if the ***proposed research should present no more than minimal risk to the participant's and the waiver will not adversely affect the rights and welfare of the participant's***. A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participant's and maintenance of confidentiality about the data of the research participant's. As per the ICMR 2017 guidelines(http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf)in the following conditions consent waiver may be granted by IEC:

1	Research cannot practically be carried out without the waiver and the waiver is scientifically justified (e.g., disease burden estimation in HIV, genetic studies etc.).
2	Retrospective studies, where the participant's are de-identified or cannot be contacted.e.g., a retrospective review of Participant's case records
3	Research on anonymized biological samples/ data.
4	Surveillance programmes/ programme evaluation studies
5	Research on data available in public domain.
6	Research on humanitarian emergencies and disasters, when the participant may not be in a position to give consent. However, information about the study should be given to the Participant'ss whenever he/she gains consciousness, or to relative/ legal guardian when available later.

The requirement for obtaining consent can be waived off by the IEC, if there is a possible legal, social, economic& personal risk to the study participant entailed in signing the consent form as they might be identified as such by signing the consent form,

In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized.

For verbal consent/telephonic interviews, the following documents need to be submitted by the PI:

- A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each study participant should be provided with an information sheet that describes the study and gives contact names and numbers.
- The interview schedule will confirm that the interview is a simple 5-minute call and that no questions are asked that compromise a person's confidentiality or position.
- Normally, investigators will be asked to keep a log for those, who were approached about the study, and offered verbal consent. A simple chart can indicate the Participant's as participant 1,2,3. A column can indicate that verbal consent was given with a date. Since a specific number of study participant's are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more participant's than they originally requested.

13.2 Detailed instructions

- The PI will submit request for waiver of consent along with the study documents to the IEC Secretariat, in the given format AN1-V1/DHMHSOP 13/V1 stating the reasons for the consent waiver.
- The IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participant's and maintaining confidentiality of the study data.
- The decision regarding approval/disapproval of waiver is informed to the PI in writing. If the waiver is not granted, the IEC will provide reasons for the same in the given format AN2-V1/DHMHSOP13/V1.

AN1-V/DHMHSOP 13/V1

Application Form for requesting Waiver of Consent

1. **Principal Investigator's name**:_____

2. **Speciality**:_____

3. **Title of project**:_____

_____

4. **Names of other participating co-investigators, staff, and students:**

5. **Request for waiver of informed consent:**

o Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

1. Research involves 'not more than minimal risk'
2. There is no direct contact between the researcher and participant
3. Emergency situations as described in ICMR Guidelines (ICMR 2017 Guidelines- http://www.icmr.nic.in/ethical_guidelines.pdf)
4. Any other (please specify)

_____

Statement assuring that the rights of the participant's is not violated

_____

State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

_____

_____

Signature of PI

Name_____ **Date**_____

AN2-V1/DHMHSOP 13/V1

Decision of IEC Regarding Waiver of Consent

To,

Dr._____Speciality _____

Principal Investigator, DHMH.

Ref: IEC code.

Title of project:

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application (dated) for waiver to written informed consent during the IEC (number of meeting) meeting held on (date).

Waiver granted: Yes [] No [ ]

If not granted, reasons

_____

_____

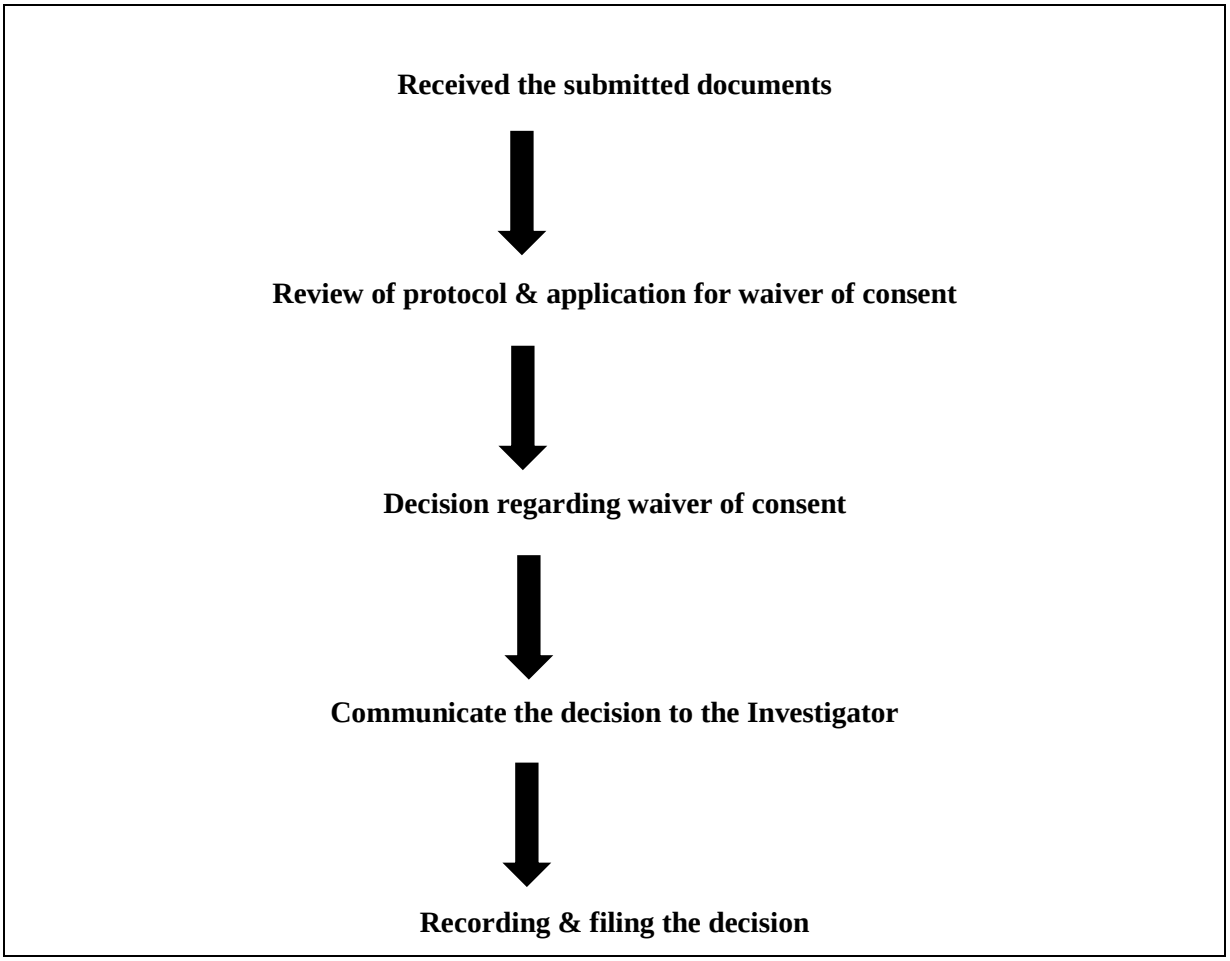
Thanking You,

Yours Sincerely,

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

Flow Chart


Received the submitted documents
Review of protocol & application for waiver of consent
Decision regarding waiver of consent
Communicate the decision to the Investigator
Recording & filing the decision

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 14

Title: **Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents**

DHMHSOP Code:	**Date:**	**Pages: 207-212**
DHMHSOP 14/V1		

- Responsibility
- Maintenance of active study file
- Accessibility/retrieval
- Disposal of closed files and related documents

Purpose:

This SOP provides instructions for maintenance of active study files and other related documents approved by the IEC, DHMH, and storing of closed files and retrieval of documents.

14.1 Responsibility

It is the responsibility of IEC Secretariat to ensure that all study files are prepared, maintained, and kept securely for a period of five (05) years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time) or till the time stipulated in the project whichever is later.

14.2 Maintenance of the active study files

- Master file is the file comprising of all essential documents and correspondence related to the study/protocol. Trial master files shall be established at the beginning of the trial, in the IEC Secretariat.
- The approved study files will assign unique identifiers (serial IEC code no.).
- All related documents of the approved study files appropriately should be collected together.
- All active files will be kept in a secured file cabinet with controlled access. A log book of authorized individuals accessing the files will be maintained.
- All closed study files will be separately archived.
- Final disposal of study/master files, on completion of archival period, will be done by a committee constituted by Chairperson, IEC.

14.3 Accessibility/retrieval

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing. In case, any investigator needs a copy of any document from the master file, he/she should make a written request (AN1-V1/DHMHSOP 14/V1). The staff of the IEC Secretariat will furnish a copy of the required

document within a week with IEC Member Secretary's approval.

14.4 Disposal of closed files and copies of protocols and documents

The records for any study in master file will be maintained in the IEC Secretariat for a period of 5 years or longer if required in the protocol following closure of the study. After completion of archival period, the records for closed files will be shredded by the IEC Secretariat and disposed of, without any notification to PI. This will be done preferably within 1 year of completion of archival period. A log book of disposed documents will be maintained (AN2-V1/DHMHSOP14/V1).

AN1-V1/DHMHSOP 14/V1

Document Request Form

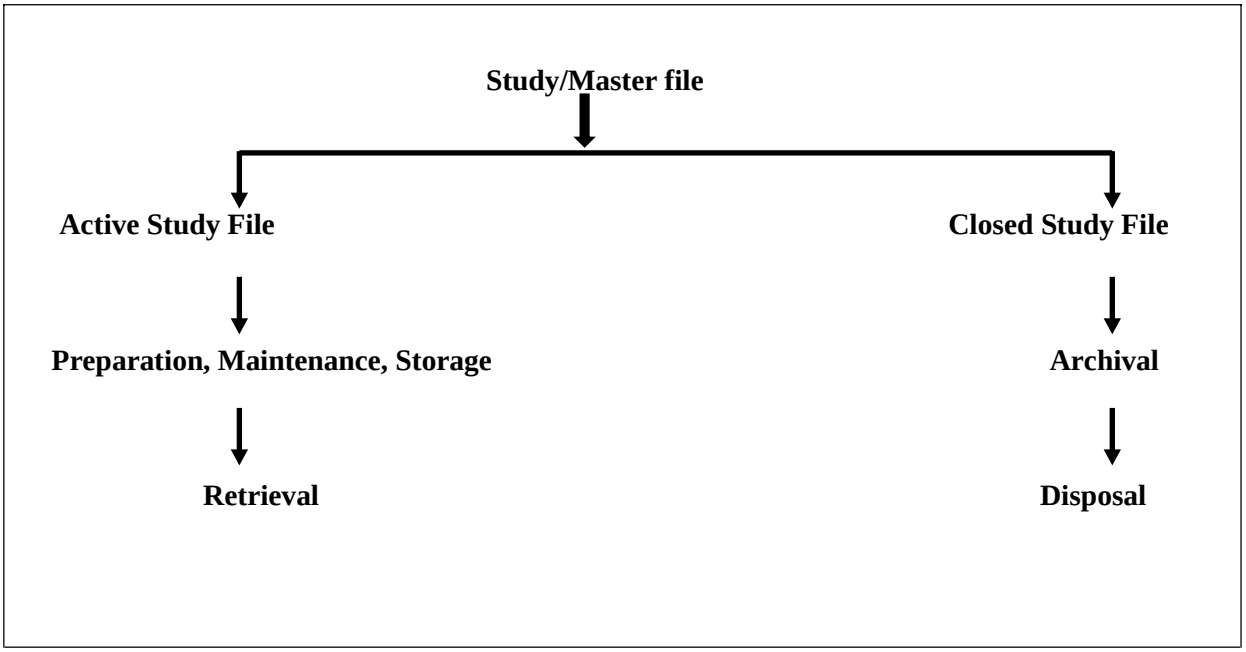
IEC code no.:	**Project Title:**
Name of PI&Speciality:	**Requested by:**
Documents requested:	
Purpose of the request:	
Principal Investigator's Signature:	
Signature of the requesting person:	
Permission of Member Secretary, IEC YES/NO **Signature of the Member Secretary_____Date_____** **Name of the Member Secretary _____**	

AN2-V1/DHMHSOP 14/V1

Format of Written Off Register

Project No.	Title	PI	No of files	EC approval	Study Initiation Date	Study Closure Date	Name & Sign of Authorized Individual

Flow Chart


Study/Master file
Active Study File
Closed Study File
Preparation, Maintenance, Storage
Archival
Retrieval
Disposal

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 15

Title: **Documentation of the IEC Activities**

DHMHSOP Code: **Date:** **Pages: 213-218**

DHMHSOP 15/V1

- Responsibility
- Detailed Instructions
  - List of IEC records
  - Access to IEC records

This SOP describes the procedures for documenting all the IEC activities.

15.1 Responsibility

It is the responsibility of the IEC Secretariat to maintain all records.

15.2 Detailed instructions

15.2.1 IEC records. It will include the following:

1. IEC members' records.
   a) Acceptance letters of each member.
   b) Signed and dated recent Curriculum vitae and confidentiality and conflict of interest document of each member.
   c) Records for each IEC member's participation in National/International Bioethics related activities
   d) Documentation of resignation/termination.
2. IEC members list
3. IEC attendance roster.
4. IEC meeting agenda and minutes.
5. Standard Operating Procedures.
6. Archival of current and completed/terminate study files.
7. Annual/ continuing/ completion reports.
8. National / International guidelines on medical Bio-Ethics.

15.2.2 Access to IEC records

IEC records will be made available for inspection by authorized representatives of regulatory authorities'/funding agency after receiving the request (AN1-V/DHMHSOP 15/V1) in writing and log will be maintained (AN2-V1/DHMHSOP 15/V1).

AN1-V1/DHMHSOP 15/V1

Request/Compliance Form

To,

The Member
Secretary, IEC,
DHMH,

Dear Sir/Madam,

I would like to inform you that I want to take documents for following purpose. I will ensure you I will not divulge any information from the documents to anyone without your written authorization.

Purpose_____ List of documents,

_____

_____

_____

_____

Your's faithfully,

Signature:_____

Date:_____

Name and designation_____

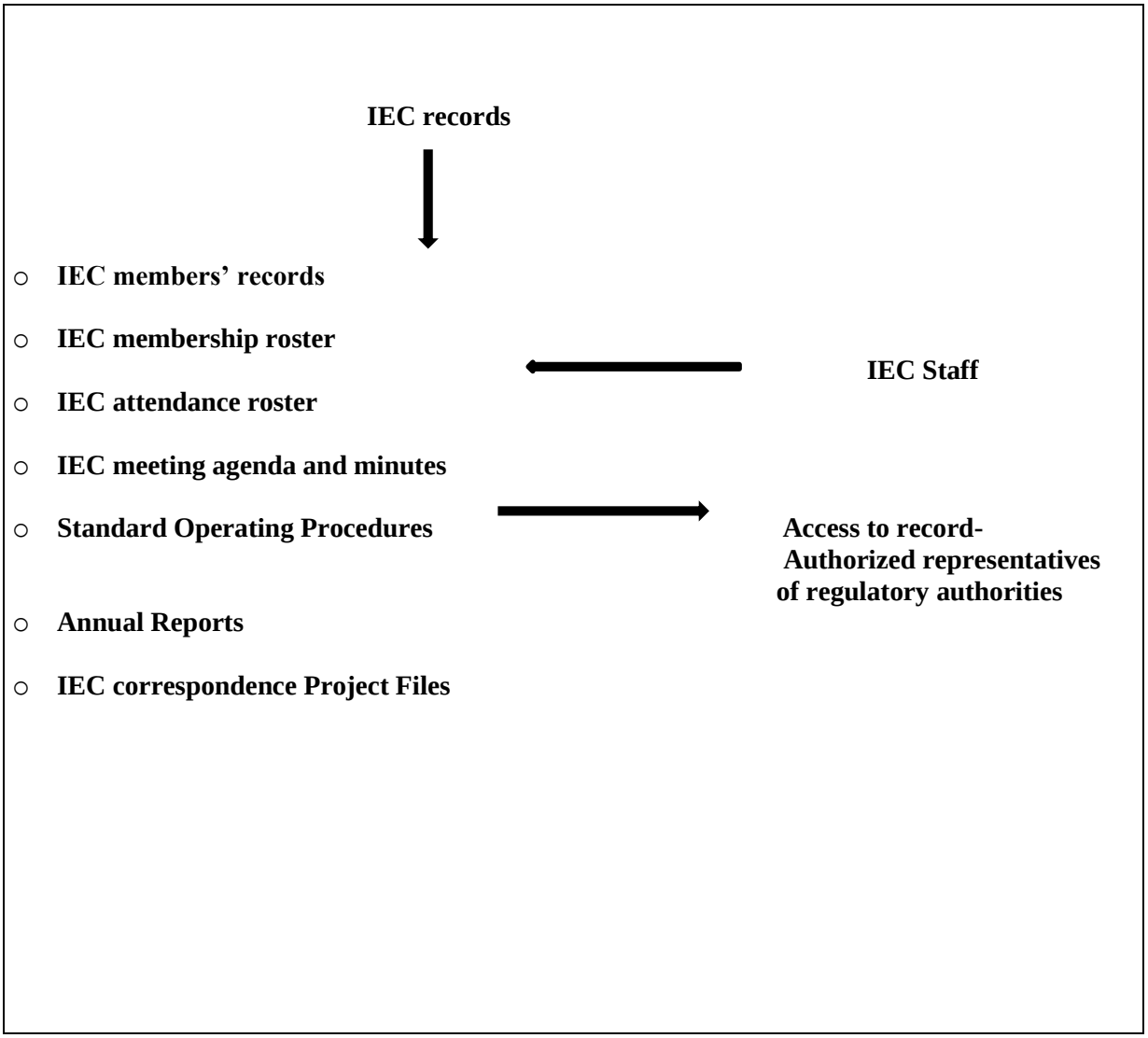
Address_____

AN2-V1/DHMHSOP 15/**V1**

Log of Requests for Copies of IEC Documents

No./ date of request	**Documents requested (including file number if relevant)**	**No. of Copies**	**Name address of the individual requesting copies**	**Reason for request**	**Signature of the individual receiving the copy and date**	**Name and Signature of the IEC staff providing the copy and date**

Flow Chart


IEC records
IEC members' records
IEC membership roster
IEC attendance roster
IEC meeting agenda and minutes
Standard Operating Procedures
Annual Reports
IEC correspondence Project Files
IEC Staff
Access to record-
Authorized representatives
of regulatory authorities

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 16

Title: **Dealing with Research Participant's Requests and Complaints**

DHMHSOP Code:	**Date:**	**Pages: 219-224**
DHMHSOP 16/V1		

- Responsibility
- Detailed Instructions
  - List of IEC records
  - Access to IEC records

Purpose:

This SOP applies to all requests concerning the rights and well-being of participant's enrolled in the studies approved by the IEC. This procedure provides guidelines for dealing with and accommodating requests by participant's/Participant's regarding their rights as a participant or to resolve their complaints in any approved research study.

The IEC considers protection of the rights and welfare of the human Participant's participating in clinical research approved by the IEC as its primary responsibility. Informed Consent documents reviewed by the IEC contain the statement, "The queries related to the study and rights of participant's may be addressed to the IEC, Member secretary (with the IEC address and phone number)".

16.1 Responsibility

It is the responsibility of the IEC Secretariat for providing required information to the research participant's in case of queries received from research participant's as per the guidelines/ regulation of Right to Information (RTI) Act-2005 and its subsequent amendments thereof.

It is the responsibility of the IEC to initiate a process to give information to the participant's or to identify and address any injustice that has occurred, if complaints are received from research participant's.

16.2 Detailed instructions

- The Chairperson / Member Secretary/ IEC Secretariat receives an inquiry or request from research participant/Participant's.
- The request and information are recorded in the request record form (AN1-V1/DHMHSOP 16/V1)
- The IEC Secretariat will inform the Chairperson about the query /complaint received from the research participant.
- The Chairperson/Members designated by the Chairperson will provide information required by the research participant as per (RTI) Act-2005.
- In case of complaints received from a research participant, the Chairperson initiates a

process to identify and address any injustice that may have occurred.

- The Chairperson will direct the Member Secretary to consider the matter for discussion at a full board meeting or to call an emergency meeting of 2 or more IEC members for discussion or enquiry in order to resolve the matter preferably outside members including a legal expert who is a member of the IEC.
- The Chairperson/Member Secretary/designated IEC members will assess the situation and mediate a dialogue between the research participant and the investigator to resolve the matter.
- The IEC will insist on factual details to determine reality between truth and individual perception.
- The final decision will be informed to the research participant by the IEC Secretariat. The information including any action taken or follow-up will be recorded in the form AN1-V1/DHMHSOP 16/V1 and the form is signed and dated.
- The IEC members shall be informed about the action taken and the outcomes in the forthcoming IEC meeting.

16.3 Filing the request document

The request details and copy of response by IEC Secretariat will be kept in the study file.

AN1-V1/DHMHSOP16/V1

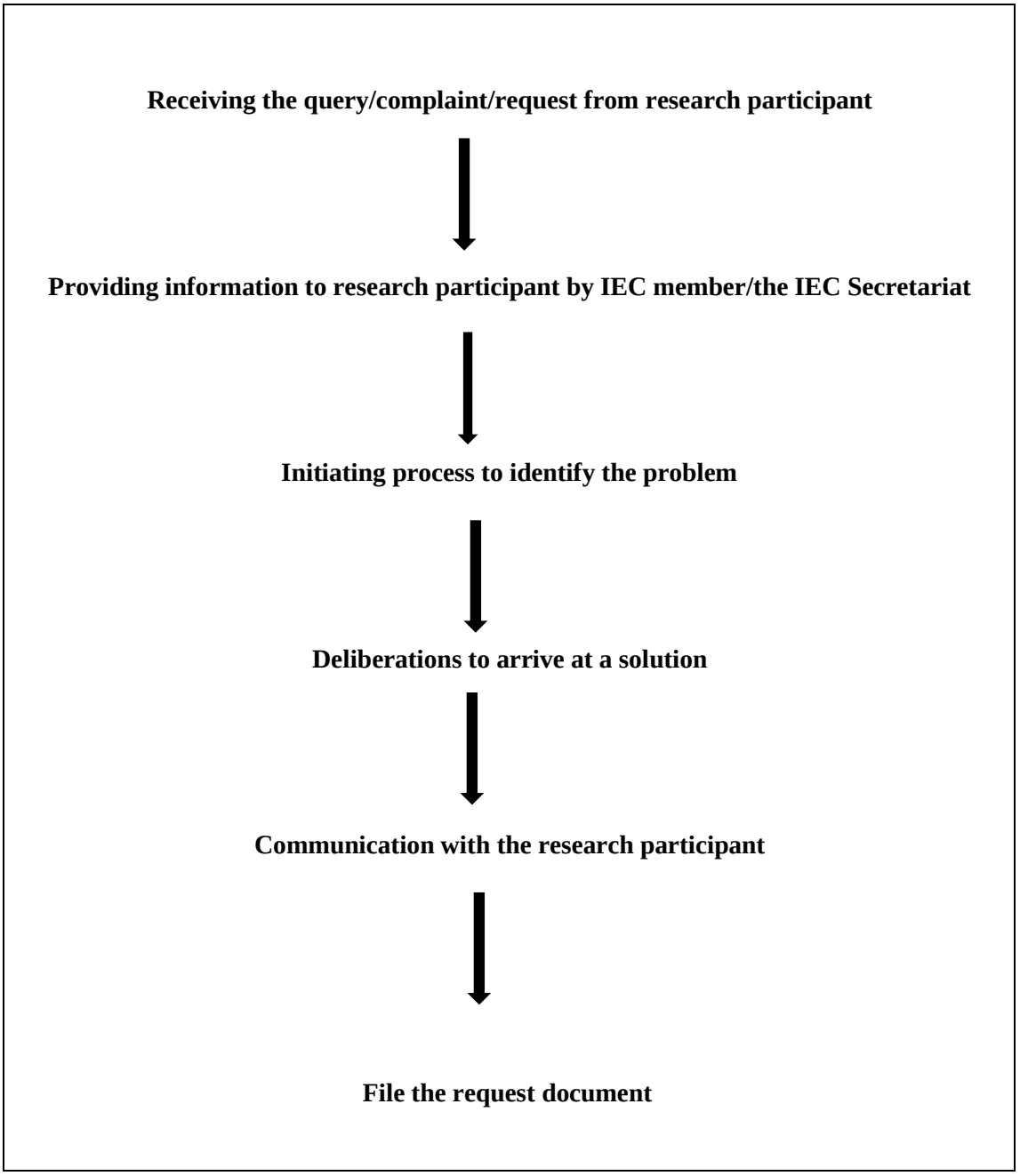
Request Record Form

Date Received:	
Received by:	
Request from:	o **Telephone / Mobile No** o **letter /Date** o **E-mail /Date** o **Walk-in: Date /Time** o **Other, specify**
Participant's Name:	
Contact Address: **Phone / Mobile no:**	
Title of the Participating Study:	
Starting date of participation:	
What is requested?	
Action taken:	
Outcome:	

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

Flow Chart


Receiving the query/complaint/request from research participant
Providing information to research participant by IEC member/the IEC Secretariat
Initiating process to identify the problem
Deliberations to arrive at a solution
Communication with the research participant
File the request document

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Chapter 17

Title: **Site Monitoring and Post-Monitoring Activities**

DHMHSOP Code: **Date:** **Pages: 225-238**

DHMHSOP 17/V1

- Purpose and scope
- Responsibility
- Detailed Instructions
    - Selection of study sites
    - Before the visit
    - During the visit
    - After the visit

17.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of an Institutional Ethics Committees (IEC) approved protocol to ensure participant rights, safety, and well-being.

17.2 Scope

This SOP applies to all IEC approved studies for which a **routine or 'for-cause' on-site** monitoring may be undertaken by the IEC.

17.3 Responsibility

It is the responsibility of the IEC to decide for conduct on-site monitoring. It is further the responsibility of the designated IEC member(s) to perform on-site monitoring of selected study site(s).

17.4 Detailed instructions

17.4.1 Selection of study sites

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Board.
- This is recorded in the IEC minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson.
- The reasons for identifying a particular site for "*for-cause monitoring*" could include any one or more of the following:
    - High number of protocol violations,
    - Large number of studies carried out at the study site or by the investigator,
    - Large number of Serious Adverse Events (SAE) reports,

- High recruitment rate,
- Large number of Protocol deviations,
- Complaints received from participant's or any other person,
- Frequent failure to submit the required documents
- Any other cause as decided by IEC.

17.4.2 Before the visit

Irrespective of the cause for conducting monitoring the following procedure will be followed:

- The IEC will identify and select one or more IEC members (preferably not affiliated to the Institution) (henceforth referred to as monitors) to conduct monitoring of a site.
- The selected member/members will be given a letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson.
- The IEC Secretariat will decide the date of the monitoring in consultation with the monitors and thePI.
- The final date will be communicated to the PI (with a request to be available) and monitors.
- The monitor/monitors will receive documents from IEC Secretariat and review the relevant project documents and make appropriate notes.
- Monitors will carry with them Site Monitoring Visit Report Forms-AN-1/DHMHSOP17/V1 and AN-2/DHMHSOP 17/V1 (if applicable) collected from the IEC Secretariat.

17.4.3 During the visit

- The Monitor will follow the check list and will:
  - Check the log of delegation of responsibilities of study team.
  - Check if the site is using latest IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
  - Observe the informed consent process, if possible.
  - Review randomly selected participant files to ensure that participant's are

signing the correct informed consent.

- Check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the participant and return destruction after the study).
- Check for storage times, conditions, and expiry dates to be acceptable and sufficient supplies available, wherever applicable.
- Verify that the investigator follows the approved protocol and all approved amendment(s), if any.
- Ensure that the investigator and the investigator's trial staff are adequately informed about the trial.
- Verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.
- Verify that the investigator is enrolling only eligible participant's.
- Determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e., Adverse Events (AEs) and SAEs for the volume or severity of adverse events.
- Review the project files of the study to ensure that documentation is filed appropriately.
- Review the source documents for their completeness.
- Collect views of the study participant's, if possible.
- Consent forms are properly kept in the records with the signatures of the participant's.

- The Monitor will fill the Site Monitoring Visit Report Form- AN-1/DHMHSOP 17/V1 and AN-2/DHMHSOP 17/V1 (if applicable), sign and date it.

17.4.4 After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Form- AN-01/SOP 17/V1and AN-02/SOP 17/V1(if applicable) to the IEC Secretariat within 7 working days of conducting a site monitoring visit or at the time of full board meeting

(whichever is earlier).

- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next full board IEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
    - Continuation of the project with or without changes,
    - Restrictions on enrollment,
    - Recommendations for additional training,
    - Recruiting additional members in the study team,
    - Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
    - Suspension of the study, etc.
- If the Monitor has found the less impact on safety/benefits of the participant's, the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.
- The final decision will be taken at the full board IEC meeting by the Chairperson, and decision will be recorded in the Site Monitoring Visit Report Form- AN-01/SOP17/V1.
- The IEC Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The IEC Secretariat will place the copy of the report in the protocol file.

AN-1/DHMHSOP 17/V1

Site Monitoring Visit Report

(Please tick the box corresponding to the answer)

IEC project no.	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Type of study: ☐Investigator initiated ☐Pharma ☐Thesis	
☐ Government agency ☐ Others _____	

Date of IEC approval: Date of Initiation of the study: Duration of study:
Reason for monitoring: □ Routine □For-cause (State reason/s) □ Protocol Violations/Deviations □ SAE reporting □ Recruitment rate □ Other _____
Last monitoring done, if any, □Yes Date of last monitoring _____ □ No
Project Status: 1. Ongoing □ 2. Completed □ 3. Recruitment Completed □ 4. Follow-up, extension study □ 5. Suspended □ 6. Terminated □ In case of the response to the above question is option 5 or 6, kindly provide reason/s: _____ _____
Recruitment Status: □ Total patients to be recruited: _____ □ Screened: _____ □ Screen failures: _____ □ Enrolled: _____ □ Withdrawn: _____ Reason: _____ _____ □ Discontinued: _____ Reason: _____ _____ □ Completed: _____ □ Active: _____

Are the present study team members as per the list approved by the IEC ☐ Yes ☐ No	Comment:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Is the recent version of Informed Consent Document (ICD), after IEC approval, used? ☐ Yes ☐ No	Comment:
Whether appropriate vernacular consent has been taken from all patients? ☐ Yes ☐ No	Comment:
Any other findings noted about the ICDs? ☐ Yes ☐ No	Comment:
Is recent IEC approved version of protocol used? ☐ Yes ☐ No	Comment:
Have the eligibility, inclusion exclusion criteria been adhered to? ☐ Yes ☐ No	Comment:
Any adverse events found? ☐ Yes ☐ No	Comment:

Any SAEs found? ☐ Yes ☐ No	Comment:
Were the SAEs informed to IEC within timelines specified by CDSCO? ☐ Yes ☐ No	Comment:
No. of deaths reported: ☐ Deaths unrelated to participation in the trial: ☐ Deaths related to participation in the trial Any other non-death study related injury	_____ _____ _____ ☐ Yes ☐ No ☐ NA Comments (If Any) _____ _____
Compensation paid for study related injury or death	☐ Yes ☐ No ☐ NA Comments (If Any)
Are there any protocol non-compliance deviations/violations? ☐ Yes ☐ No	Comment:
Have the protocol non-compliance deviations/violations been informed to IEC? ☐ Yes ☐ No	Comment:
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:

Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:
How well are the participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any other remarks ☐ Yes ☐ No	Give details:
Duration of visit:_____ hours	Starting from: Finish:
Name of the study team member/s present: Signature _____	Date:
Name of IEC members and representatives who attended monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the IEC meeting held on_____

_____

_____

_____

Signature of Chairperson, IEC

with date

AN2-V1/DHMHSOP 17/V1

Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured):

- Yes,_____No_____
- Remarks:_____

2. The consent is taken in language the participant/LAR understands best and is literate in.

- Yes,_____No_____
- Remarks:_____

3. Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process and information about necessity for audiovisual recording

- Yes,_____No_____
- Remarks:_____

4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.

- Yes,_____No_____
- Remarks:_____

5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participant's is assured.

- Yes,_____No_____
- Remarks:_____

6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC.

- Yes_____No_____
- Remarks:_____

7. Explanation or narration by the person conducting the informed consent discussion.

- Yes,_____No_____
- Remarks:_____

8. Questions asked by the potential participant/LAR are answered satisfactorily.

- Yes,_____No_____
- Remarks:_____

9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.

- Yes,_____No_____
- Remarks:_____

10. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.

- Yes,_____No_____
- Remarks:_____

11. Documentation of signatures of all those involved in the Informed Consent Process.

- Yes,_____No_____
- Remarks:_____

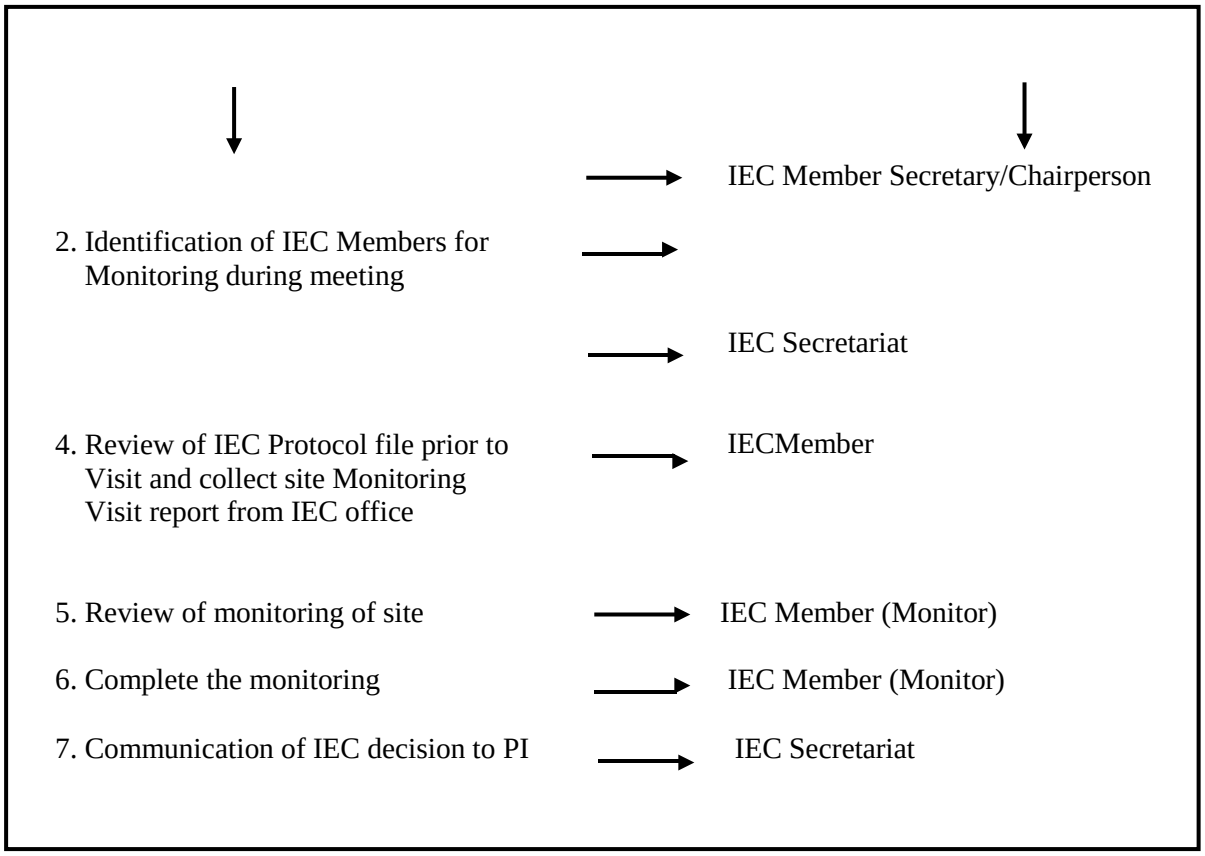
12. Clarity and completeness of AV recording

- Yes_____No_____
- Remarks:_____

13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive with access allowed only to the principal investigator and designated members of the study team.

- Yes,_____No_____
- Remarks:_____

Flow chart


IEC Member Secretary/Chairperson
2. Identification of IEC Members for Monitoring during meeting
IEC Secretariat
4. Review of IEC Protocol file prior to Visit and collect site Monitoring Visit report from IEC office
IECMember
5. Review of monitoring of site
IEC Member (Monitor)
6. Complete the monitoring
IEC Member (Monitor)
7. Communication of IEC decision to PI
IEC Secretariat

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

(SOPs, IEC, DHMH)

Title: **Chapter 18**
Reviewing Research Protocols Involving Vulnerable Populations

Date:

DHMHSOP Code: DHMHSOP 18/V1

Pages: 239-262

Reviewing Research Protocols Involving Vulnerable Populations

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review research protocol involving vulnerable populations. The SOPs provide clear, unambiguous instructions so that the related activities of the Board are conducted in accordance with Indian laws and relevant, National and International Guidelines. It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

Scope

- This SOP applies to all policies and procedures of review and assessment applied to all research dealing with vulnerable population that require additional consideration or protection, submitted and approved by the IEC.

Criteria

- **Vulnerable persons** are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.
- **Vulnerable groups**:

    a) Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed research on genetics should not lead to racial inequalities;

    b) Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;

    c) Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;

    d) Adequate justification is required for the involvement of participant's such as prisoners, students, subordinates, permanent/contractual employees, service personnel etc. who have reduced autonomy as research participant's, since the consent provided may be under duress or various other compelling reasons.

- Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response

from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention.

A. "Vulnerable" or "special" classes of Participant's include as listed below This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchal society, or terminally ill cancer Participant's.

- pregnant women, human fetuses and neonates,
- prisoners,
- children,
- cognitively impaired persons
- students and employees, sub-ordinates
- Minorities (as defined by national constitution and / or socio-economically backward, refugees and such others.
- Economically and/or educationally disadvantaged
- AIDS/HIV+ Participant's
    - Terminally ill participant's
    - Geriatric population
    - Cancer Patient

B. Vulnerable populations: Children, adolescent, pregnant or nursing women

The following is required when children are enrolled in research:

Children will not be involved in research that can be carried out equally well with adults. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. For studies prior to phase III the drug has a therapeutic value in a primary disease of the children. The settings of the research provide the child and parent adequate medical and psychological support. Interventions intended to provide direct diagnostic, therapeutic, or preventive benefit for the individual child participant's must be justified in relation to potential risks involved in the study and potential benefits to

society. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions. A parent or legal guardian of each child has given proxy consent. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors or adolescents, unless there is no medically acceptable alternative to the therapy provided or tested, and consent has been obtained from at least one of the parents.

If research involves adults unable to consent, the Ethics Committee must consider additional safeguards to protect their rights and welfare:

When conducting nontherapeutic research, consent must be obtained directly from the participant, unless:

o The objectives of the clinical trial cannot be met by means of a trial in participant's who can give consent personally.

o The foreseeable risks to the participant's are low.

o The negative impact on the participant's wellbeing is minimized and low.

o The clinical trial is not prohibited by law.

o The opinion of the ethics committee is expressly sought on the inclusion of such participant's, and the written opinion covers this aspect.

Such trials, unless an exception is justified, should be conducted in Participant's having a disease or condition for which the investigational product is intended. Participant's in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed. When adults are unable to consent, the IEC determines: A non-therapeutic clinical trial (i.e., a trial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participant's who personally give consent and who sign and date the written consent document. Non-therapeutic clinical trials may be conducted in participant's with consent of a legally acceptable representative provided the following conditions are fulfilled:

- The objectives of the clinical trial cannot be met by means of a trial in participant's who can give consent personally.
- The foreseeable risks to the participant's are low.
- The negative impact on the participant's wellbeing is minimized and low.
- The clinical trial is not prohibited by law.
- The opinion of the IEC is expressly sought on the inclusion of such participant's, and the written

opinion covers this aspect.

- Such trials, unless an exception is justified, should be conducted in Participant's having a disease or condition for which the investigational product is intended. Participant's in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

Pregnant or nursing women enrolled in research:

Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the fetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participant's of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participant's.

a. The justification for participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

b. **Research related to termination of pregnancy:** Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participant's for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

c. Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the fetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the fetus.

- Categorization of protocols Vulnerable population will be subjected to full board Initial review.
- Research involving vulnerable populations is not eligible for expedited review or exemption from review.
- The IEC evaluates whether additional safeguards have been included in the study to protect the rights and welfare of vulnerable participant's.

- The IEC requires at least one or more individuals who are knowledgeable about or have experience in working with these participant's are part of the review process.

- New study submissions, amendment and continuing review applications involving vulnerable populations (except prisoners, which should be reviewed by the full board) may be reviewed by the convened board or by expedited review, as decided during initial review and as per SOP. The research protocol involving Vulnerable population will be reviewed according to current requirement and guidelines. The decisions are arrived at using the approved checklist for reviewers (Refer Annexure AN1-6). If the research includes a vulnerable population that is not covered in the above list or there are no national or international guidelines for ensuring protections. IEC will evaluate the research proposal to ensure that precautions are taken to protect the participant's.

Review Procedures:

The protocol should be reviewed keeping in mind the following points:

- measures to protect autonomy,
- risk/benefit determinations with respect to the vulnerability
- whether vulnerable subjects are bearing unequal burden in research.
- Safety of the participant's.

Member of the IEC who would be reviewing such protocols should be well versed with the potential harm or risk of such population participating in the study.

checklist for different vulnerable population provided in Annexure (AN1-AN6) may be used.

Special justification is required for inviting vulnerable individuals to serve as research Participant's and, if they are selected, the means of protecting their rights and welfare must be strictly adhered to. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgement that any individual lacks autonomy should be periodically reevaluated and will vary in different situations. The central issue for the IEC to consider is whether the potential Participant's ability to exercise free choice is limited in some way. Reviewing research protocol involving vulnerable population: When researchers are likely to approach participant's, who lack the ability to consent, the IEC evaluates whether: The proposed plan for the assessment of the capacity to consent is adequate. Assent/surrogate consent of the participant's is a requirement wherever possible, and, if so, whether the plan for assent/ surrogate consent is adequate. There may be adequate room for ensuring the involvement of the LAR in the consenting process When a research participant regains consciousness from unconscious state or is mentally competent to understand the study. If such an event is expected, then procedures to address it should be spelt out in the informed consent form.

Audio-visual recording is necessary while taking consent to any of the vulnerable participant's.

Studies on Oncology Participant's

- Phase I studies with oncology drugs are conducted in Participant's. However, there may or may not be any benefit and there may be a high degree of therapeutic misconception. Further, there will be foreseeable and unforeseeable risks that need to be considered before a protocol is approved.
- The Participant's population may be vulnerable as they are often terminally ill or cancer patient. Economically disadvantaged populations may participate in the research to gain free access to an intervention. It is important to ensure that the participant has understood that this is research and the benefits expected may be small or they may not occur at all.
- Participant's must be made to understand that they may be randomized to a placebo group and therefore receive an inert drug, in case of a placebo-controlled study. Where, there is no alternative treatment/drug is available to the participant's.
- If the trial is a placebo- or active-controlled trial, all the groups must be given the current standard of care.
- Perceptions of benefits and risks may be different for Participant's, healthcare workers and EC members. All these perspectives must be taken into consideration while reviewing the protocol.
- Undue inducement must be avoided.
- Participant's should not be charged for any intervention including standard of care in the control arm. If the trial is an add-on design, the background standard of care may not be given free. The EC should review this carefully.
- A post-trial access plan must be in place for Participant's, who show benefit from an IP. In case it is a placebo-controlled trial, those participant's who have been in the placebo group may be offered post-trial access to the IP if found effective in other Participant's.

Responsibility of IEC Secretariat

- The IEC Secretariat is responsible for receiving, verifying, and managing the hard copies of the received research protocols pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines as per the checklist. The Secretariat should create a study specific file, distribute the packages and study assessment forms to the IEC members for review with the updated checklist (1-6), and communicate the review results to the investigators.
- It is the responsibility of the IEC Secretariat to maintain up-to-date tools (e.g., checklist) for review of

research pertaining to vulnerable groups based on new and evolving applicable national and international regulations and guidelines.

- Maintain file for update-checklist (1-6) which conforms to recent / current applicable regulations and guidelines.
- The Member Secretary will place the protocols before three-member committee members of the IEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. The reviewers should be familiar and trained in the concept of vulnerability and protections for participant's with diminished autonomy.
- IEC Chairperson/ Member Secretary is responsible for ensuring that EC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable population through regular training programmes, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.
- EC members are responsible for receiving, verifying, and reviewing the research protocols pertaining to vulnerable populations using study assessment form and checklist (Refer SOP18, Annexure 1-6) EC members may be responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources. As described in this SOP EC Members will review the protocol and the informed consent document or assent form. The suggestions that are agreed upon by the EC members present at the meeting will be discussed.

AN1-V1/DHMHSOP18/V1

Requirements for Research Involving Children

Name of Investigator

Speciality **IEC Code No:**

Study Protocol No:

Study Title:

RISK DETERMINATION	**BENEFIT ASSEMENT**	**IEC ACTION**
Minimal (i)	With or without direct benefit	Approvable
Greater than minimal risk	Potential to child	Approvable
Greater than minimal risk	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit. .	Approvable case –by- case (ii) with special safeguards

(i) **Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

(ii) **Risk may not be more than a minor increase over minimal risk, consent of both parents required under normal circumstances.**

(iii) **Approval to proceed with this category of research must be made by the IEC with input from selected experts**

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justification given?			
If yes: Are adequate safeguard in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			
Have appropriate studies been conducted on animals and adults justified?			
If No: Is the lack of appropriate studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
If Yes: Are conditions under which one of the parents may be considered: not reasonably available" describe?			
If Yes: Are the conditions acceptable?			
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 8 and, where appropriate, honoring their dissent?			

Are provisions made to protect Participant's' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve a which has implications for other family member? (for example, genetic risk, HIV infection, Hepatitis- B/C), etc.			
If Yes: Are adequate mechanisms in place to deal with other members of the family?			
Should parents be required to be present during the conduct of the research? (Are proposed Participant's to be very young? Are the procedures involved painful? Must Participant stay overnight in the hospital when they otherwise would not have to?)			

Comments:

_____

_____ _____

Primary Reviewer
Date

AN2-V1/DHMHSOP18/V1

Requirements for Research Involving Pregnant or nursing women, Fetuses & nursing infant

Investigator Name: **IEC Code No.:**

Study Title:

Research Involving Pregnant or nursing women, Fetuses & nursing infant

RISK DETERMINATION	**BENEFIT ASSEMENT**	**IEC ACTION**
Minimal	With or without direct benefit	Approvable
Greater than minimal risk	Potential benefit	Approvable
Greater than minimal risk	No direct benefit to individual but offer general knowledge about disorder and may benefit to the society or future generations are likely to benefit. .	Approvable case –by- case (ii) with special safeguards

A. Pregnant Women	**Yes**	**No**	**NA**
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant or nursing women, nursing infant; and fetuses;	☐	☐	☐
The risk to the fetus or nursing infant is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus or nursing infant;	☐	☐	☐
Any risk is the least possible for achieving the objectives of the research;	☐	☐	☐
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions, unless altered or waived in accord with SOPs	☐	☐	☐
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably,foreseeable impact of the research on the fetus or resultant child;	☐	☐	☐
If the research involves minors who are pregnant, and permission will be obtained in accordance with the Schedule Y and ICMR guidelines	☐	☐	☐
No inducements, money or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
Individuals engaged in the research will have no part in any decision as to the timing, method, or procedures used to terminate a pregnancy;	☐	☐	☐
Individuals engaged in the research will have no part in determine the viability of fetus.	☐	☐	☐
Does this research premises therapeutic or preventive benefits	☐	☐	☐
Does the study involve discontinuation of nursing for the sake of participation in research?	☐	☐	☐
Is the cessation of breast-feeding to the nursing child justified? Is breast feeding harmful to the infant?	☐	☐	☐
Does the research have provisions for compensation in terms of supplying supplementary food such as milk formula?	☐	☐	☐

Can this research be conducted in women who are not pregnant or nursing	☐	☐	☐
Does this research protect or advance the health of pregnant or nursing women or fetuses or nursing infants?	☐	☐	☐
Is this research related to termination of pregnancy and is as per the Medical Termination of Pregnancy Act, GOI, 1971? Does this research violate any provisions of the Medical? Termination of Pregnancy Act, GOI, 1971	☐ ☐	☐ ☐	☐ ☐
Is this research related to pre-natal diagnostic techniques in pregnant women? Is this research limited to detect the fetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the fetus Does this research violate any provisions of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994	☐ ☐	☐ ☐	☐ ☐
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetus;	☐	☐	☐
The individual(s) providing consent in fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;	☐	☐	☐
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
Individuals engaged in the research will have no part in any decision as to the timing, method or procedures used to terminate pregnancy;	☐	☐	☐
Individuals engaged in the research will have no part in determining the viability of a fetus.	☐	☐	☐

Fetuses of uncertain viability	**Yes**	**No**	**NA**
Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research	☐	☐	☐
The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research.	☐	☐	☐
The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained	☐	☐	☐
D. Nonviable fetuses	**Yes**	**No**	**NA**
1. Vital functions of the fetus will not be artificially maintained.	☐	☐	☐
2. There will be no risk to the fetus resulting from the research.	☐	☐	☐
3. The purpose of their research is the development of important biomedical knowledge that cannot be obtained by other means; and	☐	☐	☐
4. The legally effective informed consent of both parents of the fetus will be obtained in accord with the ICMR guidelines except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirement of this paragraph.	☐	☐	☐

AN3- V1/SOP 18/V1

Checklist- Research Involving Cognitively Impaired Adults

The purpose of this checklist is to provide support for IEC members or the Designated Reviewer when reviewing research involving cognitively impaired adults as Participant's.

1. **For review using this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.**

2. **For review using the convened IEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.**

Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the Participant's

☐ Yes ☐ No	One of the following is true (Check the box that is true) The risk to the Participant's is presented by an intervention or procedure that holds out prospect of direct benefit for the individual Participant. More than minimal risk to Participant's is presented by monitoring procedure that is likely to contribute to the Participant's well – being.
☐ Yes ☐ No	The risk is justified by the anticipated benefit to the Participant's.
☐ Yes ☐ No	The relation of anticipated benefit to the risk is at least as favorable to the Participant's as that presented by available alternative approaches.
☐ Yes ☐ No	The proposed plan for the assessment of the capacity to consent is adequate.

☐ **Yes No** ☐	Assent is required of: (One of the following must be Yes") One of the following is true (Check box that is true) ☐ All Participant's ☐ All Participant's capable of being consented. ☐ None of the Participant's
☐ **Yes No** ☐	The consent document includes a signature line for a legally authorized representative.

2.Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the Participant's

Yes ☐	☐ **No**	The proposed plan for the assessment of the capacity to consent is adequate.
☐ **Yes**	☐ **No**	The objectives of the trial cannot be met by means of study of Participant's who can give consent personally.
☐ **Yes**	☐ **No**	The foreseeable risks to the Participant's are low.
☐ **Yes**	☐ **No**	The negative impact on the Participant 's wellbeing is minimized and low.
☐ **Yes**	☐ **No**	The trial is not prohibited by law/regulators.
☐ **Yes**	☐ **No**	Participant's have a disease or condition for which the procedures in the research are intended.
☐ **Yes**	☐ **No**	Participant's will be particularly closely monitored.

☐ **Yes**	☐ **No**	Participant's will be withdrawn if they appear to be unduly distressed.
☐ **Yes**	☐ **No**	The proposed plan for the assessment of the capacity to consent is adequate.
☐ **Yes**	☐ **No** ☐ ☐ ☐	Assent is required of: (One of the following must be Yes") One of the following is true (Check box that is true) All Participant's All Participant's capable of being consented. None of the Participant's
☐ **Yes**	☐ **No**	The consent document includes a signature line for a legally authorized representative.

Comments-

Name & Sign of Primary Reviewer:

Date:

AN4- V1/DHMHSOP 18/V1		
Research Involving Students, Employees, Residents or Research Staff		
Does the employer or supervisor of the research subject need to be aware of the research project?	☐ **Yes**	☐ **No**
Have the Participant's been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	☐ **Yes**	☐ **No**
Have the risks to Participant's been minimized?	☐ **Yes**	☐ **No**
Have Participant's been assured that participation is voluntary (no signs of coercion)?	☐ **Yes**	☐ **No**
Have Participant's been assured that confidentiality will be protected or maintained?	☐ **Yes**	☐ **No**
Comments		
Name & Sign of Primary Reviewer **Date:-**		

AN5- V1/DHMHSOP 18/V1

Checklist - Considerations for Genetic Research

Principal Investigator:

IEC Code No

Study Title:

1. Will the samples be made anonymous to maintain confidentiality? If yes, stop here	☐ **Yes**	☐ **No**
2. Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?	☐ **Yes**	☐ **No**
3. Has the appropriateness of the various strategies for recruiting participant's and their family members been considered?	☐ **Yes**	☐ **No**
4. Does the proposed study population comprise family members?	☐ **Yes**	☐ **No**
5. Will family members be implicated in the studies without consent?	☐ **Yes**	☐ **No**
6. Will the samples be destroyed in the future?	☐ **Yes**	☐ **No**
Comments		
Name & Sign of Primary Reviewer **Date:-**		

AN6- V1/DHMHSOP 18/V1

Requirement for Research involving terminally ill Participant's

Principal Investigator:

IEC Code No

Study Title:

RISK DETERMINATION	BENEFIT ASSEMENT	IEC ACTION
Minimal	☐ With direct benefit ☐ Without direct benefit	Approved ☐ Not Approved ☐
	☐ Potential benefit	Approved ☐ Not Approved ☐
	☐ No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	Approved ☐ Case by case (with special safeguards ☐ Not Approved ☐
Less than minimal risk	☐ With direct benefit ☐ Without direct benefit	☐ Approved ☐ Not Approved
	☐ Potential benefit	☐ Approved ☐ Not Approved
	☐ No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	☐ Approved Case by case (with special safeguards ☐ Not Approved
Minor increase over minimal risk	☐ With direct benefit ☐ Without direct benefit	☐ Approved ☐ Not Approved
	☐ Potential benefit	☐ Approved ☐ Not Approved
	☐ No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	☐ Approved Case by case (with special safeguards ☐ Not Approved

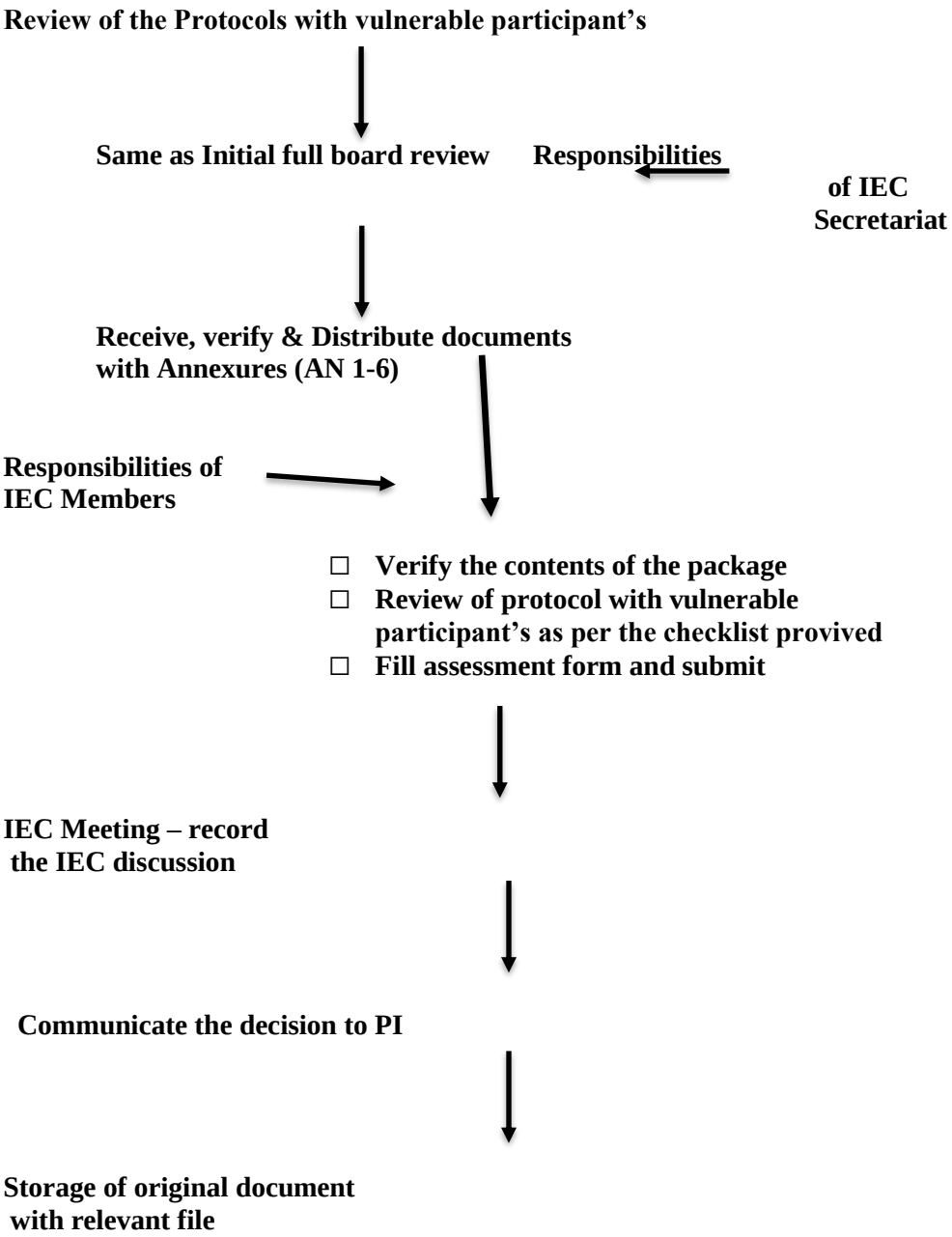
More than minimal risk or High risk	☐ With direct benefit ☐ Without direct benefit	Approved ☐ Not Approved ☐
	Potential benefit ☐	Approved ☐ Not Approved ☐
	☐ No Direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit	Approved ☐ Case by case (with special safeguards Not Approved ☐

Minimal risk- Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely.

	Yes	**No**	**NA**
Does the research pose than minimal risk to Participant's?			
If yes: Are convincing scientific and ethical justification given?			
If yes: Are adequate safeguard in place to minimize these risks?			
Are appropriate studies that have been conducted on animals and adults justified			
If No: Is the lack of appropriate studies conducted on animals and adults justified			
Do the anticipated benefits justify requiring the Participant's to undertake the risk			
Is inclusion of vulnerable population			

warranted?			
Can the research question be answered by using a non-vulnerable population?			
	Yes	**No**	**NA**
Will efforts be made ensure that participant's are free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the consent?			
Are provisions made to protect participant's privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of counseling and confidentially accounted for in the research design?			
Are there any special problem such as confidentially and reporting that might arise in this research			
Comments			
Name & Sign of Primary Reviewer **Date: -**			

FLOW CHART


Review of the Protocols with vulnerable participant's
Same as Initial full board review
Responsibilities of IEC Secretariat
Receive, verify & Distribute documents with Annexures (AN 1-6)
Responsibilities of IEC Members
☐ Verify the contents of the package
☐ Review of protocol with vulnerable participant's as per the checklist provived
☐ Fill assessment form and submit
IEC Meeting – record the IEC discussion
Communicate the decision to PI
Storage of original document with relevant file

Standard Operating Procedures of Institutional Ethics Committee

(SOPs, IEC, DHMH)

Title: **Divine Heart & Multispeciality Hospital**

Viraj Khand Institutional Area-5. Gomti Nagar

Lucknow - 10

Chapter 19

Assessment and Audit of IEC

DHMHSOP Code: **Date:** **Pages: 263-290**

DHMHSOP 19/V1

1. Purpose

This SOP outlines the procedure for the self-assessment of the IEC members/staff and internal audit of the IEC to maintain high standards of research conducted at DHMH

2. Scope

This SOP is applicable to the IEC members and staff, the IEC can self audit time to time by using the various assessment tools, which are already in practice by the National Accreditation Board for Hospitals & healthcare Providers (NABH).

3. Responsibility

Chairpersons, Member Secretaries and IEC staff will be responsible for the assessment and audit of IEC**.**

4. Procedure

Assessment of IEC members and IEC Secretariat

The Chairperson will perform assessment of the IEC members annually. This assessment will cover regularity in attendance to IEC meetings, quality of review, time taken to review documents, completion of study assessment forms, etc.

The Chairperson will also perform self-assessment annually.

The Member Secretary will perform assessment of the Administrative Staff of the IEC annually. Evaluation forms will be circulated to individual members and the respective IEC staff via email and a copy of the same will be maintained in the IEC records.

Internal Audits

- Periodicity of Self-Assessment / Internal Audit

03 to 04 internal audits will be conducted in a year

IEC staff will conduct quarterly internal audits as per the checklist AX5-V1/SOP20/V1

IEC staff will conduct annual internal audit as per checklist AX4-V1/SOP20/V1 which involves standard and objective elements as per NABH Accreditation Standards for Ethics Committee**.**

-

AN1-V1/DHMHSOP19/V1

IEC Evaluation Form of Chairs & Member Secretary

Section 1

---

1. **Mention (□) the individual who is performing the evaluation:**
2. **Self – evaluation: ☐**
3. **Name of the person who is evaluated: _____**
4. **Number of Meetings attended out of total meetings: /** ☐ ☐
5. **Number of exempt determinations made:** ☐
6. **Number of new protocols reviewed by the expedited review procedure:** ☐
7. **Number of new protocols reviewed by subcommittee that went to the convened full board meeting of IEC:** ☐
8. **Number of continuing reviews completed as the primary reviewer:** ☐
9. **Completion of educational requirements: ☐ Yes ☐ No**
10. **Attendance at IEC Meeting (Make tick (□) in the column)**

    □ **Regular**

    □ **Irregular**

11. **Number of IEC meetings conducted:** ☐
12. **Quorum in each project evaluation maintained in EC meetings:**

    ☐ Yes ☐ No

Evaluation of Chairs &Member Secretary for Internal Audit

Section 2

i) Preparedness for meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

ii) Contribution to IEC meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

iii) Quality of reviews Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

iv) Communication with IEC staff Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

Name:

Signature:

Date:

AN2-V1/DHMHSOP19/V1

IEC Evaluation Form of IEC Member Secretary/Members for Internal Audit

Section 1

Mention (□) the individual who is performing the evaluation:

Self – evaluation: □

Member secretary IEC: □

Name of the person who is evaluated: _____

Number of Meeting attended out of total meetings: □/ □

□ Poor (1-4) □ Average (5-8) □ Good (9-10) □ Excellent (11-12)

Preparedness for meetings: (tick (□) in the box)

□Good □ Average □Poor

Contribution to IEC meetings: (tick (□) in the box)

□Good □ Average □Poor

Quality of Reviews: (tick (□) in the box) (tick (□) in the box)

□Good □ Average □Poor

Time taken to respond to modification sent (tick (□) in the box)

□Good (1 week) □ Average (2 weeks) □Poor (above 2 weeks)

Number of exempt determinations made: □ □ NA

Number of new protocols reviewed by the expedited procedure: □ □ NA

Number of new protocols reviewed that went to the convened for full board IEC: □

Number of continuing reviews completed as the primary reviewer: □

Number of reviews completed as the primary reviewer for study amendments: □

Completion of study assessment forms: (tick (□) in the box)

□ Yes (out of) □ No (out of)

Completion of educational requirement: (tick (□) in the box)

□ Yes □ No

Attendance at educational sessions: (tick (□) in the box)

□ Regular (out of) □ Irregular (out of)

Number of educational sessions conducted: □ □ NA

Communication with IEC staff: (tick (□) in the box)

□Good □ Average □Poor

IEC Evaluation Form of IEC Member Secretary/Members

Section 2

Name of the person who is evaluated- __Period_____

i) Preparedness for meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

ii) Contribution to IEC meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

iii) Quality of reviews Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

iv) Communication with IEC staff Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

Name:

Signature:

Date:

AN3-V1/DHMHSOP19/V1

IEC Evaluation Form of Staff

1. Mention (□) the individual who is performing the evaluation: Member secretary IEC:

   Name of the person who is evaluated:

2. Handles workload efficiently: (tick (□) in the box)

   Yes: ☐ No: ☐

3. Number of new protocols processed that were reviewed by the expedited procedure: ☐

4. Number of new protocols processed that went to the convened IEC: ☐

5. Completion of required checklists and documentation: (tick (□) in the box)
   Yes: ☐ No: ☐

6. Maintains paper files efficiently and correctly: (tick (□) in the box)

   Yes: ☐ No: ☐

7. Drafting Agenda and Minutes in timely manner: (tick (□) in the box)

   Yes: ☐ No: ☐

8. Maintain IEC rosters efficiently and correctly: (tick (□) in the box)

   Yes: ☐ No: ☐

9. Prepare IEC records efficiently and correctly: (tick (□) in the box)

   Yes: ☐ No: ☐

10. Completion of educational requirement: (tick (□) in the box)

    Yes: ☐ No: ☐

11. Attendance at educational sessions: (tick (□) in the box)

    Yes: ☐ No: ☐

12. Number of educational sessions conducted: ☐

13. Preparedness for meetings: (tick (□) in the box)

    Good: ☐ Average: ☐ Poor: ☐

14. Quality of pre-reviews: (tick (□) in the box)

    Good: ☐ Average: ☐ Poor: ☐

15. Communication with IEC chair and vice-chair: (tick (□) in the box)

Good: ☐ Average: ☐ Poor: ☐

16. Communication with supervisor: (tick (□) in the box)

Good: ☐ Average: ☐ Poor: ☐

17. Communication with investigators: (tick (□) in the box)

    Good: ☐ Average: ☐ Poor: ☐

18. Ability to help investigator:(tick (□) in the box)

    Good: ☐ Average: ☐ Poor: ☐

Name of Member Secretary:

Signature:

Date:

AN4-V1/DHMHSOP19/V1

IEC Audit						
Internal Auditors:						
Date of Audit Conducted:						
Standard 1	**Authority for formation of Ethics Committee: There shall be documented procedures to establish the authority for formation of Ethics Committee as per applicable rules and regulations.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate the requirement is met:					
1.1	Does IEC follow procedures to specify the authority under which the Ethics Committee is established and administratively governed?	SOP				
1.2	Is there any documented policy to ensure the independence of the Ethics Committee in its functioning? and decision making?	SOP				
1.3	Does Ethics Committee function as per applicable rules and regulations	SOP				
Compliance						
Standard 2	**Standard Operating Procedures (SOPs): The Ethics Committee has and follows written SOPs for its different functions as per applicable rules and regulations.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
2.1	Do the IECs have procedures in place and well defined for the development, review and revision of SOPs?	SOP				
2.2	**List of mandatory procedures for EC**					

A	**Terms of reference for EC**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Is the composition (names and qualification of the members) as per DCGI: for new induction, resignation, replacement or removal of members.	SOP, roster, circular, membership files				
ii)	Is there a clause for Declaration of Conflict of Interest and Confidentiality Agreement?	SOP/member file				
iii)	Frequency of ethics committee meetings.	SOP				
iv)	Is there any policy regarding training for new and existing committee members?	SOP, training records				
v)	Is there any policy of communication with different stake holders?	SOP				
Compliance						
B	**Protocol Submission**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**

i)	Is there any procedure for receipt of applications – original, revised, amended with supporting annexes?	**SOP/Manual**				
Compliance						
C	**Ethical review**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	
i)	Is appropriate review and decision making of proposals done by IEC?	• Minutes • IEC decision letters				
ii)	Is there any procedure to be followed for vulnerable population?	• SOP • Study assessment form • Minutes				
iii)	Is there any procedure for risk-benefit analysis?	• SOP • Study assessment form • Minutes				
iv)	Is there any procedure for review of Informed Consent Document (Participant Information Sheet and Informed? Consent Form) and informed consent process?	• SOP • ICF assessment • Minutes				
Compliance						
D	**Decision making, Minutes recording, post meeting activities including monitoring**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**

i)	Is there any procedure for deliberations and maintaining minutes?	SOP Minutes				
ii)	Is there any procedure for reporting, analysis of SAEs and making opinion on compensation?	• SOP • Procedure for report of any onsite/offsite SAEs • Minutes				
iii)	Is the CRA reviewed by IEC? • Conduct of on-site monitoring in the past	• SOP • Minutes				
iv)	Procedure for handling issues related to non-compliance, protocol violation, negligence, complaints by the participant's and other stake holders.	• SOP Review of deviation/violation/non compliance reports • Minutes				
v)	Procedure for review of protocol amendments.	• Procedure for filing an amendment review appropriate - How is the amendment reviewed by IEC?				
Compliance						
E	**Documentation and archiving**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Procedure for control and archiving of records with confidentiality.	• Procedure for control and archiving of records with confidentiality •Does EC maintain an Archival record?				
Compliance						

Standard 3	**Ethics Committee Composition: The Ethics Committee meets the requirement for membership as per applicable rules and regulations. Procedures are documented and followed.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Is the Composition of IEC multidisciplinary, multisectorial and appropriate for its functioning?	• IEC Roster • Circulars • SOP/manual				
ii)	Are any Participant Experts and representatives of vulnerable Participant's invited as required with prior intimation?	• IEC Roster • Minutes of IEC meeting • SOP/manual				
iii)	Are Membership, appointment, reconstitution and resignation defined as per terms of reference.?	• Does the Membership File have proper documentation of reconstitution, appointment and resignation of EC members? • SOP				
iv)	Are the roles and responsibilities of members well defined?	• SOP • TOR (Do appointment letters mention roles and responsibility of member)				
v)	Are the Ethics Committee members trained (initial and ongoing) in applicable rules and regulations and? Ethics Committee SOPs?	• SOP • Training Calendar				
vi)	Are Conflict of Interest and Confidentiality addressed at the time of composition?	• Membership file				

Compliance						
Standard 4	**Protection of Participant rights, safety and wellbeing: The Ethics Committee follows documented procedures for Participant protection.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Are the rights and responsibilities of Participant's documented and specified in the SOP/ ICF template?	• SOP/ ICF template • ICF review/assessment form				
ii)	Participant's participation and withdrawal from the trial shall be voluntary and with prior intimation?	• SOP/ ICF template • ICF review/assessment form				
iii)	Participant's shall be informed and should comprehend (initial and ongoing) the associated risks and benefits of the trial.	• SOP/ ICF template • ICF review/assessment form				
iv)	Are Confidentiality and Privacy of Participant's protected?	• SOP/ ICF template • ICF review/assessment form				
v)	Monitoring of trials shall be done to ensure equitable selection of Participant's, with special attention to vulnerable and high risk	SOP				
vi)	Is compensation provided to Participant's for participation in the trial appropriate and as per the rules and regulation and is reflected in the contract?	• SOP/ ICF template • ICF review/assessment form Insurance				
vii)	Is the review of Serious Adverse Events adequate with provision for medical care and an appropriate reporting mechanism is followed as per applicable rules and regulations?	DSMB/IEC minutes				
viii)	Is the Compensation for injury to the Participant as per the rules and regulations and are they monitored for compliance?					
ix)	How are Complaints and concerns of Participant's addressed and managed appropriately, if the need arises?	SOP				

Compliance						
Standard 5	**Administrative support: The Ethics Committee follows documented procedures / terms of reference (TOR) to ensure that administrative support for its activities is adequate.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Are adequate finance, human resource allocation and Secretariat for administrative work and record keeping with due care and confidentiality provided?	• HRPP manual • SOP				
ii)	Is there adequate financial transparency of Ethics Committee activities and functioning?	• HRPP manual • SOP				
iii)	Is there any procedure for communication between ethics committee, investigator/ relevant site staff, institution and regulatory? authority?	• HRPP Manual • SOP				
Compliance						
Standard 6	**Review Process: The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and periodic review.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Is the review done in a formal meeting within a reasonable time by the Ethics Committee following appropriate submission of documents by investigator as per rules and regulations and Ethics committee requirement?	• SOP				
ii)	Does the initial review of proposed clinical trial evaluate the scientific validity of the protocol, risk to Participant's, expected benefit and ethical standards as per applicable rules and regulations?	• SOP • Study assessment Forms • Minutes of meeting				

iii)	Are Informed consent document, assent form (as applicable) and translations reviewed for appropriateness of language, accuracy and completeness of information?	• SOP •ICF assessment Form, • Minutes of meeting				
iv)	Does Ethics Committee review the informed consent processes proposed to be followed at the site for a particular trial to ensure that Participant/LAR/ impartial witness are provided appropriate information, adequate time is given and impartial witness used as applicable?	• SOP				
v)	Recruitment strategies	• SOP				
vi)	Proposals involving special group and vulnerable population shall be evaluated as per rules and regulations.	• SOP • Study assessment Form • Minutes of meeting				
vii)	Is Contract and budget evaluated, for indemnity, compensation, roles and responsibilities as per applicable rulesand regulations.	• SOP				
viii)	Are the amendments to the originally approved protocol, consent forms and investigators brochure reviewed in formal meetings to evaluate the risk to trial Participant's.	• SOP • Minutes of meeting				
ix)	Periodic review of trial shall be done for continuation, risk evaluation and adverse event monitoring.	• SOP • DSMB/IEC minutes				
Compliance						
Standard 7	**Decision making and post meeting activities: The Ethics Committee follows documented procedures for decision making process and post meeting activities.**					

Sr. No.	Check Parameters	Documents /evidence to be checked against the parameter	Yes	No	NA	Comments
i)	Are decision making process (approval/disapproval/pending/revoking g) as per applicable rules and regulations, ensuring quorum and consensus/voting requirements fulfilled.	• SOP • Decision letters				
ii)	Does SOP mention statement that the Participant shall be recruited into the trial only after written approval from Ethics Committee and approval by regulatory authority.	• SOP				
iii)	Do minutes' capture about declaration of Conflict of Interest prior to the review and voluntary withdrawal during decision making process.	• SOP • Minutes of meeting				
iv)	Whether decisions are based on risk assessment, scientific validity and adherence to ethical principles for the initial and periodic approvals.	• SOP • Minutes of meeting				
v)	Are deliberations and decisions made during the meetings documented, approved, signed and maintained asminutes of meeting.	• SOP • Minutes of meeting				
vi)	Are Protocol deviations and non-compliances reviewed and appropriate actions taken as per rules & Regulations.	• SOP • Minutes of meeting				
vii)	Are serious adverse events analyzed and compensation amount assessed and reported to Regulatory Authority as per rules and regulations.	•SOP • DSMB/IEC minutes				
viii)	Does PI notify all decisions/opinions in writing?	• SOP • IEC decision letters				
Compliance						

Standard 8	**Monitoring: The Ethics Committee follows documented procedures for monitoring and for- cause assessment.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Are Participant's rights, safety and wellbeing monitored appropriately.	• SOP • Study assessment Form				
ii)	Is adequacy and continuity of consent process ensured.	• SOP • Study assessment Form				
iii)	For-cause assessments shall be conducted following non-compliance and/or complaints for the trials approved by the ethics committee.	• SOP • DSMB/IEC minutes				
iv)	Have any opportunities for improvement identified and? appropriate actions initiated.	• SOP • DSMB/IEC minutes				
Compliance						
Standard 9	**Self-assessment: The Ethics Committee has and follows documented procedures for self- assessment.**					

Sr. No.	Check Parameters	Documents /evidence to be checked against the parameter	Yes	No	NA	Comments
i)	**Does periodic self-assessments conducted.**	• SOP • Member Evaluation File				
Compliance						
Standard 10	**Record keeping and archival: The Ethics Committee follows documented procedures for record keeping and archiving.**					
Sr. No.	**Check Parameters**	**Documents /evidence to be checked against the parameter**	**Yes**	**No**	**NA**	**Comments**
i)	Are security, confidentiality and integrity of all proposals and associated documents reviewed from time to time and administrative communication and maintained as per regulatory requirement and with confidentiality.	• SOP				
ii)	Are documents and records archived after completion /termination of trial as per applicable rules and regulations.	• SOP • Archival Log				
iii)	Are record retrieval policies and procedures in place to ensure access to information for inspection and audit and continual protection of	• SOP • Document request form				

	trial Participant's, post-trial closure with prior permission in writing.					

AN5-V1/DHMHSOP19/V1

Institutional Ethics Committee Internal Audit					
Date of Audit Conducted:					
IEC:					
Date of Meeting Minutes:					
A.	**Documentation of Attendance**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate the requirement is met:				
1	Name of members present				
2	Name of members absent				
3	Name of alternate members and the members they are replacing				
4	Inclusion of consultants or permanent members, with competence to review issues that require additional expertise				
5	Researchers or other guests present				
Compliance					
B.	**Documentation of Quorum:**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate whether the requirement is met:				
1	Statement that a quorum is met				
2	A lay (non-scientist) person from the community.				
3	A basic medical scientist/clinical pharmacologist.				
4	A non-affiliated member				
5	A clinician (if research falls under FDA regulations, the physician must be licensed)				
6	A legal expert				

7	A philosopher, ethicist, theologian (or similar person), social scientist, representative of a non-government agency				
Compliance					
C.	**Quality of protocol review**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate the requirement is met:				
1	Incomplete assessment form				
2	Unsuitable reviewer				
3	Appropriate independent expert (if required)				
4	Independent expert comments documented				
5	Appropriate review of recruitment strategies				
7	Failure to assess PI competence/Conflict of interest				
8	Failure to recognize vulnerability				
9	Failure to address vulnerability				
10	Inappropriate risk/benefit assessment				
11	Inappropriate study design				
12	Appropriate review of PID				
13	Appropriate review of parent PID				
14	Appropriate review of assent form				
15	Whether criteria for expedited have been met				
16	Whether criteria for waiver of consent have been met				
17	Documentation of IEC deliberations as per SOP				
	Compliance				
D.	**Documentation of Conflict of Interest**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate the requirement is met:				
1	Minutes specify Conflict of Interest declaration by members				
2	When members report conflicts, they do not participate in discussion or vote, except to provide information to the IEC				

3	Minutes list criteria for Conflicts of Interest that organization should declare				
	Compliance				
E.	**Membership / Experts file review**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate that all IEC membership files have following elements:				
1	Latest CV signed and dated				
2	GCP training certificate				
3	GCP certificate valid				
4	Confidentiality agreement				
5	SOP training and other training documentation				
6	COI declaration				
7	Letter of resignation if applicable				
8	Resignation intimation within specified period as per SOP				
9	Letter of replacement /removal with reasons (if applicable)				
10	Confidentiality agreement (Independent expert)				
	Compliance				
F.	**Documentation of whether files contain additional information for continuing review of ongoing studies**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate whether IEC records also include the following additional information at the time of continuing review:				
1	Mandatory documents submitted				
2	Records of continuing review activities				
3	Modifications to previously approved research				
4	Unanticipated problems involving risks to participant’s or others				
5	Documentation of non-compliance (whether there is non-compliance in fact, whether non-compliance is serious, whether non-compliance is continuing)				

6	Significant new findings				
7	Documentation of Participant's complaints/concerns if any addressed adequately				
8	All correspondence between the IEC, researchers/ site staff, institution, regulatory authorities (e.g., approval letters and other correspondence)				
	Compliance				
G.	**IEC Records**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate the requirement is met:				
1	All minutes				
2	All attendance records, if kept separately from minutes				
3	The Constitution and composition of the IEC				
4	Standard operating procedures of the IEC				
5	Agenda of all IEC meetings				
6	Record of all notification issued for premature termination of a study with a summary of the reasons				
7	Members Evaluation form				
8	CV and GCP of IEC staff				
9	Archival log & shredding log				
10	Procedures followed for record retrieval				
	Compliance				
H	**Review of Records (Random records reviewed)**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
1	IEC approval letter				
2	Has the study undergone continuing review?				
3	Does an amendment/s have IEC approval?				
4	Has there been a premature termination / suspension of the study and whether reason for the same is documented				
5	Schedule Y regulated study				
6	DCGI approval				

7	Import/export license				
8	Recruitment methods and materials are approved by IEC				
9	Protocols or research plans				
10	Investigator brochure				
11	Insurance validity				
12	CTA available				
13	HMSC approval				
	Compliance				
I.	**Authority for IEC Formation**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate that all IEC records for each study include:				
1	Letter of Authority (sign and dated)				
2	Valid period of Authority				
3	Terms of reference (sign and dated)				
4	Valid period of SOP				
	Compliance				
J.	**Quality of Initial/Ongoing Review of Submission**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate the requirement is met:				
1	Mandatory documents submitted				
2	IEC fees collected				
3	Document Receipt form present				
	Compliance				
K.	**Review of protocol deviation/violation**				
Sr. No.	**Check Parameters**	**Yes**	**No**	**NA**	**Comments**
	Tick the box to indicate the requirement is met:				
1	Protocol deviation/violation Review in IEC meeting				
2	Action taken on deviation /Violation (Noted, Warning to the PI, etc)				
	Compliance				
L.	**SAE Review**				

	Check Parameters				
Sr. No.	**Tick the box to indicate the requirement is met:**	**Yes**	**No**	**NA**	**Comments**
	Review in DSMB				
1	DSMB minutes ratified in the IEC meeting				
2	Causality assessment appropriate				
2	IEC reporting to DCGI				
3	Reporting timelines met for forwarding IEC assessment to CDSCO/DCGI				
4	DCGI orders for SAE compensation				
5	IEC intimation to PI for payment of compensation				
6	Documentary evidence submitted for compensation/reimbursement paid by the sponsor to IEC				
	Compliance				
M	**CRA Review**				
	Check Parameters				
Sr. No.	**Tick the box to indicate the requirement is met:**	**Yes**	**No**	**NA**	**Comments**
1	CRA reminder timelines met				
2	Is the CRA delayed (Has submission timelines as per SOP met by PI)				
3	Action taken by IEC for delayed submission of CRA				
4	Review by DSMB Member Secretary				
5	Appropriate CRA review				
6	Action taken by IEC in case of lapse in IEC approval				
7	Whether CTRI registration done for the studies which are applicable for CTRI				
	Compliance				
N	**Completion Report Review**				
	Check Parameters				
Sr. No.	**Tick the box to indicate the requirement is met:**	**Yes**	**No**	**NA**	**Comments**
1	IEC review of Completion Report				
2	Action taken by IEC in case of any adverse findings				

3	Study file archived as per SOP				
	Compliance				
O	**Monitoring Review**				
	Check Parameters				
Sr. No.	**Tick the box to indicate the requirement is met:**	**Yes**	**No**	**NA**	**Comments**
1	Is the monitoring sample size as per the SOP i.e.,≥ 10%				
2	ICF monitoring				
3	Risk evaluation and SAE				
	monitoring				
4	Protocol deviation/violation reported by the PI to IEC				
5	For cause monitoring done				
6	Study Monitoring Visit Report completed				
7	Report reviewed by DSMB secretary				
8	Report reviewed by IEC				
9	Findings communicated to PI				
10	PI response review by IEC				
	Compliance				

Standard Operating Procedures of Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

,

C.G. City, Sultanpur Road, Lucknow

(SOPs, IEC, DHMH)

Title:

Chapter 20

SOP for Review of Biomedical and Health Research during Covid-19 Pandemic

DHMHSOP Code: DHMHSOP 20/V1 **Date:** **Pages: 291-294**

SOP for Review of Biomedical and Health Research during Covid-19 Pandemic

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the EC will function and conduct ethics review is an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak.

Procedures & Responsibilities:

a. **Research Protocol:**

It will be the responsibility of the PI to submit Research protocol electronically to the IEC Secretariat by mail.

b. **Receiving, record, verification of completeness and generate IEC code no.:**

After receiving the protocol electronically, it will be the responsibility of the IEC Secrearatiat and Member Secretary to verify the documents and annexures as per the checklist as per AN14-V1/DHMHSOP 03/V1, and accordingly allot the IEC code no. for the protocol.

c. **Categorization of Primary & Secondary reviewer, Independent Consultatnt requirement/Participant's/others:**

- The Member Secretary in consultation with the Chairperson will decide depending upon the risk Vs benefit for the categorization of the protocol for Exemption, Expedited or full board review.
- The Member Secretary in consultation of the Chairperson will also identify the Primary/Secondary reviewer for the protocol amongs the IEC members, identify if anyIndependent consultant/Expert opinion required for the protocol or any participant's input requirement.

d. **Perform initial review documents by primary & secondary reviewer:**

The Member Secretary IEC Secretariat may send the protocols and all the filled forms to primary & secondary reviewers electronically for their review.

e. **Meeting notice, Agenda items and schedule for virtual meeting:**

- The Member Secretary will prepare the agenda items.
- The Member Secretary in consultation with fixed the meeting date & duration of time for virtual meeting and accordingly send the meeting notice, invitation to the members along with the agenda items.
- The Member Secretary will use the virtual meeting platform as per the organization mechanism for other virtual meetings.

f. **Virtual EC Meetings:**

- As the virtual meeting sites opens as per the scheduled time, the Chairperson, starts

the business meeting, ensureing the quorum requirement as per the norms described in the SOP/National Guidelines.

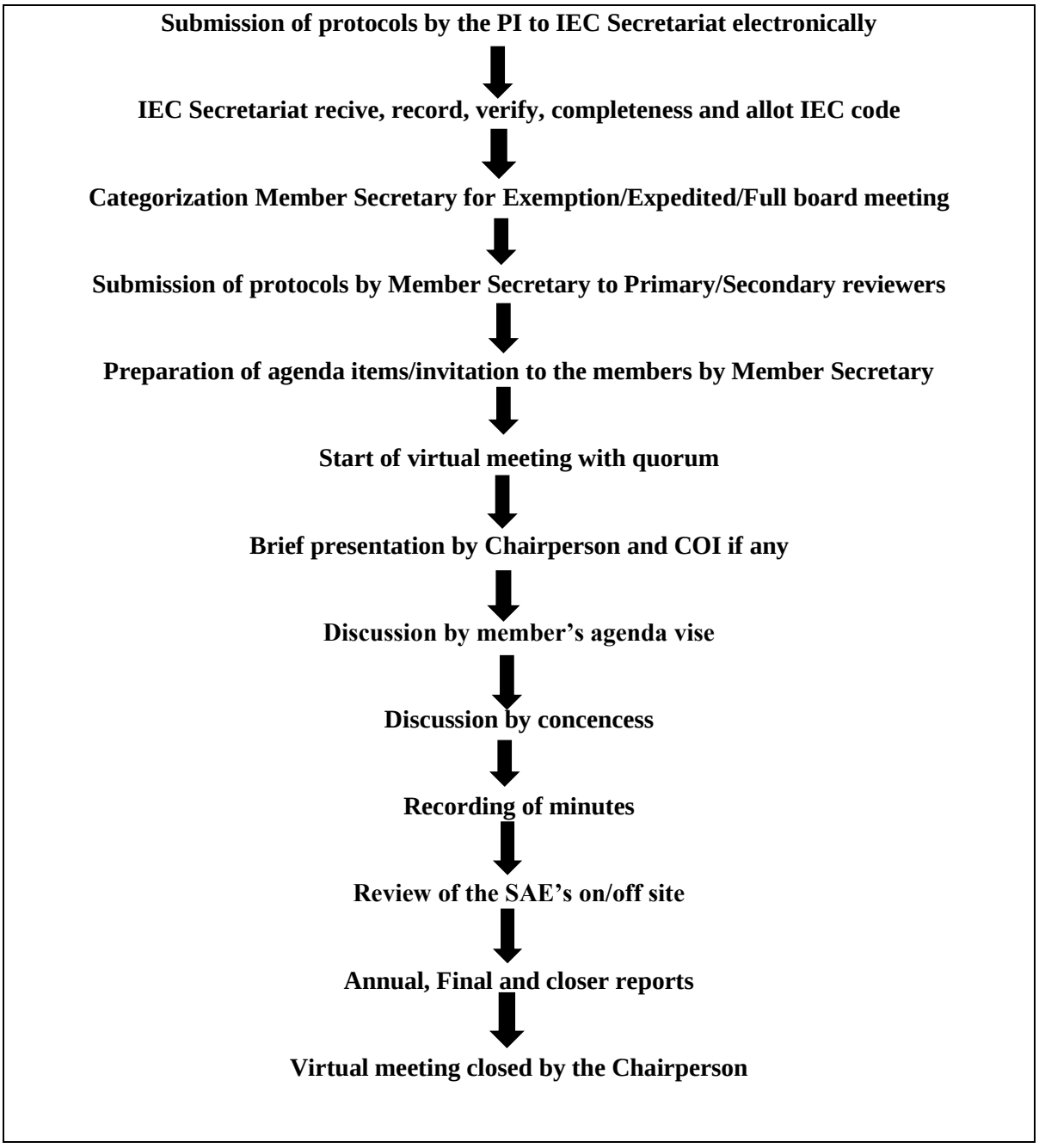
- The Conflict-of-interest declaration by any members will be noticed by the chairperson and further he/she will summaries the agenda items or/any other remarks to be addressed to the board.
- The Primary & Secondary reviewers will present their observations on the protocols as per their allotted agenda items to the full board meeting virtually. Any queries if the board feels that the presence of PI/participant's are required, the Member Secretary will arrange the communication with them through virtual platform.
- The IEC members will discuss on the agenda items and reach to concensus for the decisions taken by the chairperson.
- The Member Secretary will record the decision taken by concensus and the member is to be aksed to rejoin the meeting, who had declared the conflict of interest to the chairperson for the said agenda items, and the meeting will go further for subsequent agenda items.
- The Member Secretary will record the minutes of the meeting agenda vise and also ratify the agenda items, which are under the provisions of Exemption/Expedited approved decisions as well as 03 members of sub-committee review reports. The Member Secretary will also record the notifications under the agenda items of SAE's on/off site, annual, finaland closer reports of the protocols.

g. **Post Meeting Activities:**

- The Member Secretary with the help of EC Secretariat may communicate the decisions as well as maintaining the activities for record.
- The Member Secretary in consultaion with Chairperson will discuss the issues of the follow up/monitoring/analysis of SAE's as well as handling the issues related to compliance/violation and complaints etc.
- The meeting After permission fron the Chairperson the Member Secretary may close the virtual IEC meeting.
- The Member Secretary may record the entire virtual meeting on suitbale mode of electronic documentation for record purpose and should be available in the IEC Secretariat.

Note: - The Members may be briefed about the technological requirments and virtual platform used for conduct of the IEC meeting much advance through electronic communication.

Flow Chart


Submission of protocols by the PI to IEC Secretariat electronically
IEC Secretariat recive, record, verify, completeness and allot IEC code
Categorization Member Secretary for Exemption/Expedited/Full board meeting
Submission of protocols by Member Secretary to Primary/Secondary reviewers
Preparation of agenda items/invitation to the members by Member Secretary
Start of virtual meeting with quorum
Brief presentation by Chairperson and COI if any
Discussion by member's agenda vise
Discussion by concencess
Recording of minutes
Review of the SAE's on/off site
Annual, Final and closer reports
Virtual meeting closed by the Chairperson

Institutional Ethics Committee

Divine Heart & Multispeciality Hospital

Viraj Khand Institutional Area-5. Gomti Nagar Lucknow - 10

Appendices

AP1/V1Policy on the Recruitment of Research Participant's

AP2/V1Policy on Research Costs to Participant's

AP3/V1Guidelines on Compensation for Research Participant's

AP4/V1Policy on the Use of Third Party/Surrogate Consent in Research at DHMH

AP5/V1Guidelines on Blood Withdrawal for Research Purposes

AP6/V1Guidelines for obtaining Informed consent

AP7/V1 Examples of PID (Hindi and English in Non-interventional studies)

AP8/V1Health Record Research

AP9/V1Guidelines for Research Protocols That Require Collection and/or Storage of Genetic Material

AP10/V1 Guidelines: Submission and EC Review of Gene Therapy/Gene Transfer Protocols

AP11/V1 Ethical Policies on the Human Genome, Genetic Research and services, DBT, 2002

AP12/V1 Recommended Terms for Use in Informed Consent Documents

AP13/V1 Good Clinical Practices for Clinical Research in India (Essential documents for the conduct of a clinical trial) by CDSCO, DGHS, New Delhi, 2001

AP14/V1 Declaration of Helsinki Fortaleza, Brazil, October2013

AP15/V1 IND Application Exemption Checklist

AP16/V1 Clinical Trial Registry – India

AP17/VI Guidelines for Stem Cell Research and Therapy

AP18/V1 Guideline for Medical Device Related Studies

AP19/V1 Gazette of India, 19th March, 2019.

AP20/V1 Clinical Trial Agreement

AP21/V1 National Ethical Guidelines for BioMedical Health Research Involving Human Participant's (ICMR 2017)

AP22/V1 National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic (ICMR April, 2020)

AP1/V1
Policy on the Recruitment of Research Participant's

Specific recruitment guidelines

1. In addition to its review for scientific merit and protection of Participant's from unnecessary research risks, the IEC will evaluate all protocols for Participant recruitment especially with respect to women with childbearing potential, children and normal volunteers as controls. Exclusion of women of child bearing age or children will be recommended or approved when inclusion is inappropriate with respect to the health of the Participant's or the purpose of the research.

2. DHMH Participant's - Participant's may be identified as potential research Participant's through direct contact of the PI with the Participant'ss, collaboration with physicians of other medical specialties, contact with individual attending physicians, posted written notices, radio announcements, or other IEC approved methods.

a. **In Participant's** - May be recruited by the investigator or other member of the research team only after consultation with the Participant's's attending physician.

b. Out Participant's - For minimal risk research which does not bear directly upon a specific continuing therapeutic relationship between the individual and a DHMH consultant, out Participant'ss may be recruited without prior notification of their personal physicians. However, when possible, Participant's personal physician should be notified of the study and informed that the Participant's has been entered into a clinical study**.**

c. Community studies

Epidemiology is defined as the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to control health problems. Epidemiological studies are of primary importance in a large developing country like ours where the natural history, incidence, prevalence and impact on morbidity and mortality of a variety of diseases are not known. Such studies are on large scale and assist in improving the public health, which includes both Participant's and healthy people and communities.

In most epidemiological research it would be necessary to have the consent of the community, which can be done through the Village Leaders, the Panchayat head, the tribal leaders etc. who are considered to be gate keepers of the society/ community. Particularly in a country like India, with the level of poverty that is prevalent it is easy to use inducements, especially financial inducements, to get individuals and communities to consent. Such inducements are not permissible. However, it is necessary to provide for adequate compensation for loss of wages and travel / other expenses incurred for participating in the study.

Benefits: When epidemiological studies (like those on mortality and morbidity as a

result of exposure to an agent) lead to long associations with the community, the results if released in timely manner could give improved health care facilities or educate the community to reduce the impact of adverse environment on health and tackle the problem at their end in time.

A community can be defined as a group of people sharing the same location, beliefs, culture, ideals, goals, age, gender, profession, lifestyle, common interests, geographical locations or settings or disease. When research participant's are drawn from a specific community, members of that community can be involved to discuss any concerns it may have regarding the research. In different ways such a dialogue can be facilitated.

If an ethics committee does not have a member from the community, it may ask a local community representative to be the voice for all participant's. On the other hand, community representatives can formally join together to form a group termed as Community Advisory Board, Community Working Group, or Community

Advisory Group, which takes part in the research at all stages of the study. In international studies, particularly on issues involving communities, representation from this body ensures that the community's health needs and expectations are addressed, informed consent is appropriate, and access to research benefits is provided through research that is designed and implemented in the best interests of science and community. Community representation should be involved before, during and after the study.

Before the study is initiated the community is informed to see if it agrees that the research addresses a need or problem relevant to that community and to confirm that the design is culture specific and brings some benefits to research participant's or the community. Since some risk may be associated the community representation is needed to assist in developing appropriate ways to protect the participant's. During the study, the association with community representatives continues to educate others about the research and to alert the researcher to ethical issues related to the research. After the study is completed, community representatives can help in making the results known to the entire community. However, application of research findings may take a long time, which the community representatives should be made to understand. The benefits may be participant's' and community's access to intervention. Whose responsibility and conditions under which this would be done, duration of availability of intervention, methods of improving the quality of health care in the community and any expected desirable behavioral change in the community should be clearly explained to community by the Ethics Committee or community representatives.

AP2/V1
Policy on Research Costs to Participant's

If a research participant has to bear any costs, all potential participant's must be fully informed of the nature and estimated extent of these costs when obtaining consent. Examples of additional research costs include:

1. Prolongation of treatment or hospitalization.
2. Extra diagnostic tests necessary for the research.
3. Extra clinical or laboratory assessments to evaluate research treatment outcome.
4. A research treatment (whether randomly assigned or not) which may be costlier than a standard treatment.
5. Other substantial costs associated with extra visits to DHMH.

AP3/V1
Guidelines on Compensation for Research Participant's

1. http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf(pg.8-9)
2. www.cdsco.nic.in**Formula to Determine the quantum of compensation in the cases of Clinical Trial related serious Adverse Events(SAEs) of Injury other than Deaths Occurring During ClinicalTrials_Chapter 6**

We will also follow guideline issued by DCGI / Gazette notifications by Govt. of India, time to time.

AP4/V1
Policy on the Use of Third Party/Surrogate Consent in Research at DHMH
Applicability

When a DHMH investigator proposes to conduct a research, project utilizing adult Participant's who by virtue of age, physical impairment, mental impairment, language barrier or any other reason may not be able to personally execute legally effective informed consent, the IEC shall review the project on the basis of "risk" and "benefit" and shall determine that each project be assigned to one of the categories below. This policy does not mean to imply that the requirement for written documentation of consent is waived. Rather, it applies to those studies in which third party/surrogate consent is obtained from a legally authorized representative.

Investigators must complete and submit an IEC Form for review and approval of inclusion of Participant's who are decisional impaired.

Category I - Risks to Participant's are minimal, direct benefits may or will accrue to Participant's. **Category II** - Risks to Participant's are minimal, direct benefits will not, or are unlikely, to accrue to Participant's but potential societal benefits are inherent in research.

Category III - Risks to Participant's are greater than minimal, direct benefits may or may not accrue to Participant's.

Category IV - Risks to Participant's are greater than minimal, direct benefits will not, or are unlikely, to accrue to Participant's but potential societal benefits are inherent in the research.

IEC recommendations to the administration

When categorization has been accomplished, the IEC will recommend to the DHMH Administration to consider implementation or non-implementation of the project based upon the level of benefit to be gained by the individual or society from this project as compared to the level of risk involved.

IEC will recommend normally Category I projects to be initiated.

IEC will not recommend normally initiation of any Category IV projects.

IEC recommendation on Category II and III projects will depend on case-to-case assessment of risk/benefit ratio to Participants and community.

AP5/V1
Guidelines on Blood Withdrawal for Research Purposes

Applicability

For many studies where the only research intervention is the collection of blood for analysis, the IEC categorizes the following procedures for obtaining blood from children and adults as having minimal risk:

A. General Requirements

1. There are no special health reasons (e.g., anemia) to contraindicate blood withdrawal.

2. Participant's in whom blood is already being drawn for clinical purposes, there are no other health reasons to preclude additional blood collection provided the amount is limited to as mentioned in B and C.

3. In Participant's from whom blood is not already being drawn for clinical purposes, the withdrawal method is by cutaneous pricks (e.g., heel or finger) or by standard venipuncture in a reasonably accessible peripheral vein, and the frequency of punctures should not exceed two per week except in pharmacokinetic study.

4. The volume of blood drawn from lactating or known pregnant Participant's does not exceed 20 ml per week.

5. All blood withdrawals and collections should be carried out by experienced professional or technical personnel.

B. Additional Requirements for Adults (Participant's over 18 years of age)

1. If less than 50 ml is being collected, there are no additional restrictions with regard to hemoglobin or hematocrit.

2. If a volume greater than 50 but less than 200 ml is being collected for "no-benefit" studies, hemoglobin levels should be>11.0g/dl for males and>9.5g/dl for females with MCVs >85 (These restrictions would not apply if iron deficiency anemia or other forms of anemia were critical for inclusion in the study).

3. The cumulative volume withdrawn or collected may not exceed 450 ml per twelve-week period (this maximum includes blood being drawn for clinical purposes) from Participant's 18 years of age or older in good health and not pregnant.

C. Additional Requirements for Children (Participant's under 18 years of age)

1. No more than three (3) skin punctures are to be made in any single attempt to draw blood,

and the frequency of punctures does not exceed twice per week.

2. The volume of blood withdrawn, including blood for clinical purposes, does not exceed the limit of 50 ml or 3 ml/kg in an eight-week period and collection may not occur more frequently than 2 times per week.
3. The cumulative volume of clinical and research blood withdrawn per eight-week period does not exceed six per cent (6.0%) of the child's total blood volume.
4. In Participant's from whom blood is already being drawn for clinical purposes and when the research is directly related to the child's condition, there is no maximum number of extra volume specimens which can be collected as long as the preceding requirements are met.
5. In Participant's from whom blood is not already being drawn for clinical purposes, the maximum number of allowable separate specimens (again, within the limits of the preceding restrictions) depends upon the child's age and whether the research is directly related to the child's condition.

D. Cord Blood

Cord blood from newborns can be used without restrictions when blood is extracted from the placental side of the cord, after it has been clamped and severed.

AP6/V1
Guidelines for obtaining Informed consent [Participant Information Document and (PID) and Consent Form (CF)]

Available at

http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf(Page49-55)

AP7/V1
Examples of PID (Hindi and English in Non-interventional studies)

Available at www.divinehospita.com

AP8/V1
Health Record Research

The following is the IEC policy concerning research involving the study of medical records or other forms of health information.

Research projects may involve the study of Participant's case files with the stipulations described below. Such studies raise issues of confidentiality that must be carefully addressed by the investigator and the official custodian of the records. If it is anticipated that if an individual's records or specimens are likely be used for research purposes, the potential Participant should be informed of the potential use of such materials upon entry into the institution or program in which the materials will be developed or collected and be given an opportunity to either provide or refuse consent to such research. Participant's case files may be used or disclosed for research purposes if it has been de-identified and linkage back to a specific Participant's would not be possible.

To use or disclose identifiable Participant's case files without authorization of the research participant, the investigator must accomplish one of the following:

1. Complete and submit an IEC Form to request waiver of the requirements for obtaining informed consent;
2. Provide written documentation that the use of disclosure of Participant's case files is solely used to design a research protocol or to assess feasibility of conducting a study, or;
3. Document that the use or disclosure is solely for research on the Participant's case files of decedents.

Investigators must maintain in their files a letter from the IEC identifying the date on which the waiver or alteration of the requirements to obtain informed consent was approved by the IEC, and a statement that the IEC has determined that the waiver or alteration satisfies the following criteria:

1. The use or disclosure of Participant's case files involves no more than minimal risk to the research participant's;
2. The alteration or waiver will not adversely affect the privacy rights and welfare of the Participant's;
3. The research cannot practicably be conducted without the alteration or waiver;
4. The research could not practicably be conducted without access to or the use of the Participant's case files;

5. The privacy risks to individuals whose case files is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonable be expected to result from the research;
6. There is an adequate plan to protect the identifiers from improper use and disclosure;
7. There is an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, and;
8. There are adequate written assurances that the Participant's case files will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of Participant's case files would be permitted by this policy.

The IEC letter should also contain a brief description of the Participant's case files for which use or access has been determined by the IEC to be necessary, a statement that the waiver or alteration was approved by Expedited Review or at a convened meeting, and the letter should be signed by the IEC Chair or the Member Secretary.

Research use or disclosure of identifiable Participant's case files with authorization of the research participant is permitted providing that use or disclosure is for only the Participant's case files that were originally authorized. In order to use or disclose additional information, the investigator would either have to obtain consent or request a waiver of the requirements to obtain consent.

AP9/V1

Guidelines for Research Protocols which require Collection and Storage of Genetic Materials

For the purpose of these guidelines, "Genetic Materials" are defined as human tissue samples (blood, serum, tumor, etc.) on which genetic related research, such as biochemical studies of inherited human traits or identification of DNA mutations may be performed.

A. Previously acquired samples

i. Previously acquired genetic material may be used if identifiers are stripped irrevocably from samples.

ii. If identifiers are present, experiments not described in present protocols must be submitted for fresh IEC review.

B. Prospectively acquired samples

1. Anonymous samples (further identification made impossible)

i. Ownership of genetic material will generally remain with the institution. This must be stated in the consent form.

ii. The general scope of the investigations must be explained in the consent form, but new avenues of investigation in the future are permissible if this possibility is explained in the consent form and agreed upon by the participant.

iii. Whether the genetic material will be shared by other investigators should be explicit in the consent form.

iv. The consent form should make clear that no specific information relative to the individual donor will be forthcoming; however, information that accrues from the study that is valuable to society may be shared with the individual.

2. Identified samples

i. If genetic material is linked to the donor by specific identifiers, ownership of the material will generally remain with the institution. If a commercial use is anticipated for the genetic material, the individual must be notified. The general policy of ownership should be stated in the consent form using the following wording:

"I understand that additional or "leftover" (blood, serum, tumor, etc.) tissue may be used for future research which may result in financial gain for DHMH and the researchers. I also understand that my donated tissue will be one of many that are used in the research and it will be virtually impossible to attribute findings to any one sample. I understand,

however, that I am not otherwise waiving any of my legal rights by participating in this study."

ii. If identifiers are present, new experiments must be reviewed by the IEC and new consent obtained from the research participant regardless of the details of ownership.

iii. The investigator may include a provision in the consent form for new experiments not requiring new consent if identifiers are irrevocably removed from the samples. If the investigator anticipates future experiments without identifiers, this possibility should be present in the original consent form. The methods for removal of identifiers must be approved by the EC. Removal of identifiers must not be employed as a method of avoiding ownership issues.

iv. A satisfactory method for sharing or withholding information gained by the research must be in the research protocol and clearly indicated in the consent form.

v. Details for sharing or not sharing the genetic material with other investigators must be present in the protocol and clearly indicated in the consent form.

vi. The length of time the genetic material will be maintained must be indicated in the consent form.

C. Donation of genetic material as a requirement for participation in a research protocol.

i. Donation of genetic material may be required for participation in a protocol only if the presence of the genetic material is necessary to satisfy the central question of the research.

ii. The investigator will be required to make a clear case in the research protocol for the necessity of the genetic material, if donation of genetic material is mandatory.

iii. This policy applies to genetic material with or without identifiers.

AP10/V1

Guidelines for Submission and IEC review of Gene Therapy/Gene Transfer Protocols

Available at:

http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf (pg. 122)

AP11/V1

Ethical Policies on the Human Genome, Genetic Research and services, Speciality of Biotechnology, Ministry of Science and Technology, Govt. of India, 2002

Available at: https://www.india.gov.in/ethical-policies-human-genome-genetic-research-and-services-Speciality-biotechnology

AP12/V1

Recommended Terms for Use in Informed Consent Document

To facilitate understanding of informed consent document by the participant, it is recommended that the language used is at a reading level of a12-year-old. The following lay terms, definitions and suggestions are recommended to help investigators in this process.

For	Use
Adjuvant	Helpful; assisting; aiding
Ambulates(-action–ory)	Walk; able to walk ability to walk
Ameliorate	Make smaller or less, reduce
Analgesia	Pain relief
Anaphylactic reaction	A severe and sometimes dangerous reaction which may cause problems breathing, fainting, itching and skin rash
Anorexia	Lack of appetite
Arrhythmia	Abnormal heartbeat
Aspiration	Removal by using a sucking machine; fluid entering the lungs
Asymptomatic	Without symptoms; having no symptoms
Barrier method	Diaphragm and condom (with spermicide), cervical cap, or sponge
Benign	Not malignant; usually without serious consequences
Bolus	An amount given all at once
Bradycardia	Slow heartbeat
Carcinogenic	Capable of causing cancer
Cardiac	Heart
Cerebral	The brain; of the brain
CHD	Coronary heart disease; heart disease
Chemotherapy	Treatment with Cancer related drugs

Controlled trial	Study in which the experimental treatment is compared to a standard treatment
Conventional therapy	Standard treatment
Coronary	Pertaining to the blood vessels that supply the heart
CT	Scan computerized series of x-rays
Cutaneous	Relating to the skin
DCGI	Drug Controller General of India
Diastolic	The lower number in a blood pressure reading
Disseminated	Widely-spread, all through the body
Distal	Toward the end; away from the center of the body
Diuretic	Drug that causes an increase in urine secretion
Double-blind	Neither the Participant nor physician knows what is being given
Dysfunction	Improper function
Dysplasia	Abnormal cells
Echocardiogram	Sound waves test of the heart
Edema	Fluid in the tissues; puffiness; swelling
Emesis	Vomiting
Endoscopic	Examination of the inside of the body with a lighted tube
Epidural	Outside the spinal cord
Erythrocyte	Red blood cell
Fibrillation	Irregular heart beat
Fibrous	Like scar tissue
Granulocyte	White blood cell
Hematocrit	Concentration of red blood cells

Halter monitor	Portable machine for recording heart beats
Hypoxia	Low oxygen level in the blood
Immunosuppressive	A drug or therapy that reduces the body's ability to fight infection; helps prevent rejection of a transplanted organ
Infarct	Death of tissue due to loss of blood flow
Intubate	The placement of a tube into the airway
Ischemia	Decreases in oxygen in a tissue, usually because of decreased blood flow
Laparotomy	A procedure where an incision is made in the abdominal wall to enable a physician to look at the organs
Lumen	Cavity of an organ; inside a blood vessel
Lymphocyte	A type of white blood cell important for defense against infections
Marrow suppression	Decreased growth of the bone marrow
Metastasis	Spread of cancer cells from one part of the body to another monoclonal antibody very specific, purified antibody
Morbidity	Sickness/illness
MRI	Pictures of the body created using magnetic rather than x-ray energy
Murine	Obtained from mice
Myalgia	Muscle aches
Myocardial	Infarction heart attack
Nasogastric	Tube a tube from the nose to the stomach
Necrosis	Death of tissue
Neoplasia	A tumor that may be cancerous onion-cancerous
Neural	Brain or nerves
Neutropenia	Decrease in white blood cells
Occult blood test	Testing a stool sample for invisible amounts of blood oncology the study of tumors or cancer

Pancytopenia	Low number of blood cells
Percutaneous	Through the skin
Phlebitis	Irritation or inflammation of vein
Placebo	Inactive medication; dummy pill; sugar tablet; containing no medication
Platelets	Blood cells that help the blood clot normally
Prenatal	Before birth
Prognosis	Outlook, probably outcomes
Prophylaxis	A drug given to prevent disease or infection
Prosthesis	Artificial body parts, such as arms, legs, hips
Proximal	Closer to the center of the body, away from the end
Psychosis	Major psychiatric problem
Pulmonary	Pertaining to the lungs
Radiotherapy	Treatment with radiation
Randomly assigned	Similar to the toss of a coin; assignment to a treatment group by chance
Refractory	Not responding to treatment
Regimen	Pattern of giving treatment
Renal	Kidney
Resect	Remove or cut out surgically
Somnolence	Sleepiness
Staging	A determination of the extent of the disease
Stenosis	Narrowing of a duct, tube, or blood vessel
Stratify	Arrange in groups by age, sex, etc., for analysis
Subcutaneous	Under the skin

Supine	Lying on the back
Syndrome	A condition with a certain set of symptoms
Systolic	The top number in blood pressure
Tachycardia	Fast heartbeat
Taper	Decrease; reduce
Thrombosis	To get or have a blood clot in a blood vessel
Titration	Gradual alteration of a drug dose to get the desired effect
Topical	Applied to the skin
Transdermal	Through the skin
Uremia	Kidney failure
Varices	Enlarged veins
Vasodilation	Widening of the blood vessels
Vasospasm	Narrowing of blood vessels due to a spasm of the vessel walls
Venipuncture	Taking blood from the vein

AP13/V1

From Essential documents for the Conduct of a Clinical Trial Good Clinical Practices for Clinical Research in India by Central Drugs Standard Control Organization, Directorate General of Health Services, New Delhi, 2001

Available at: http://www.cdsco.nic.in/html/GCP1.html; **Good ClinicalPractice Guidelines**

AP14/V1

WMA Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Participant's

Adopted by the18th WMA General Assembly, Helsinki, F inland, June1964 and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975

8th WMA General Assembly, Somerset West, Republic of South Africa, October1996,

35th WMA General Assembly, Venice, Italy, October1983

41s t WMA General Assembly, Hong Kong, September 1989

52NdWMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington DC, USA, October 2002(Note of Clarification added)

5th WMA General Assembly, Tokyo, Japan, October 2004(Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008 64th WMA General Assembly, Fortaleza, Brazil, October 2013

WMA General Assembly (Online), London, UK October 2021

Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

AP15/V1

IND Application Exemption Checklist

This checklist is intended to be used by the investigator as a preliminary test of whether an IND application needs to be submitted to the DCGI for studies involving DCGI/RA-approved drugs.

If any question is answered "yes", an IND application must be submitted to the DCGI. If the answers to all questions are "no", then the study may meet the criteria for an exemption from an IND.

1. Name of drug
   Dosage Route

2. Does the study involve a different route of administration of the marketed drug than already approved?

   () YES () NO

3. Does the study involve the administration of different drug dosage levels that significantly increase risk or decrease the acceptability of risk to study Participant's? () YES () NO

4. Does the study involve the administration of the drug to a different Participant's population for whom there may be increased risk or decreased acceptability of risk?

   () YES () NO

5. Does the study entail any other factor that significantly increases the risk or decreases the acceptability of risk to study Participant's?

   () YES () NO

6. Are the results of the study intended to be reported to the DCGI/RA in support of any significant change in labeling or advertising for the drug (only for corporate sponsored studies)?

   () YES () NO

Principal Investigator's Signature:_____Date _____

AP16/V1

Clinical Trial Registry – India

The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Organization of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI) (www.cdsco.nic.in). Moreover, Editors of Biomedical Journals of India declared that only registered trials would be considered for publication.

Today, any researcher who plans to conduct a trial involving human participant's, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Speciality of AYUSH (http://indianmedicine.nic.in/) is expected to register the trial in the CTRI before enrollment of the first participant. Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, Participant's population etc. before the enrollment of the first Participant's. Submission of Ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured. After a trial is registered, trial lists are expected to regularly update the trial status or other aspects as the case may be. After a trial is registered, all updates and changes will be recorded and available for public display.

Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP)

(http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHO's search portal, the ICTRP as well as from the CTRI (www.ctri.nic.in).

AP17/V1

National Guidelines for Stem Cell Research (ICMR, 2017).

Available at: www.dbtindia.nic.in/wp-content/uploads/National_Guidelines_StemCellResearch-2017.pdf; http://www.dbtindia.nic.in/guidelines/

AP18/V1

Guideline for Medical Device Related Studies

As per Medical Device Rules 2016 and 2017 (Available at: www.cdsco.nic.in/)

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to commence from 01.01.2018.

AP19/V1

Guidelines for conducting the Bio-Medical Research on Human Participant's.

Gazette of India, EXTRAORDINARY, Ministry of Health and Family Welfare, New Delhi, PART II, Section 3, Sub-section (i) March, 19 2019.

AP20/V1

CLINICAL TRIAL AGREEMENT

Preamble:

Divine Heart Mutispeciality Hospital Lucknow is a Multispecialty Hospital to provide superspecialty care in the field of Cardic Sciences and allied specialities, located at Viraj Khand Institutional Area-5. Gomti Nagar Lucknow.

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day ……2024 **AMONG**

……., a company originally incorporated in …… and registered under section 592 of Companies act, 1956 as having "……. and one of its offices is located at ……. through it……. "…….."…… "Sponsor"] of the First part

AND

Divine Heart & Multispeciality Hospital has been established as an multispecialty hospital by Company Act 1956 vide no. U85110UP2003PTC028015 dated 23.10.2003 situated at Viraj Khand Institutional Area-5. Gomti Nagar Lucknow, through its "Chairman cum Managing Director/Director's Nominee…….[herein referred to as "Organization"] of the Second part.

AND

Dr. ……a ……, Speciality of …….

Divine Heart & Multispeciality Hospital [hereinafter referred to as "Principal Investigator"] of the Third Part.

WHEREAS The Sponsor, Organization and, Principal Investigator are willing to jointly carry out the Study Number: _____
Entitled……..".……
…… ……..." [**Hereafter referred to as "Study**"] described in Study Protocol;

AND WHEREAS Sponsor is desirous of engaging the said Principal Investigator and Organization for carrying out the Study through **Contract Research Organization (CRO)** [if needed] NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

1.0 Statement of work

1.1 “Study” shall be deemed to be “Clinical Trial” as defined in Gazette of India notification 19 March 2019.

1.2 Sponsor shall provide Principal Investigator with a sufficient quantity of Study Supplies to conduct the Study at investigational Site in timely manner. Organization and Principal Investigator shall use Study Supplies only to conduct the Study in accordance with the Protocol; All Study Supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of Sponsor, unless otherwise designated. The Organization and Principal Investigator will be responsible for the return of excess, unused Study Supplies to the Sponsor.

1.3 Study Time lines: Study Timelines for the purpose of this Agreement will be as per need of Protocol.

2.0 Obligations and Responsibilities of the Principal Investigator

2.1 The Principal Investigator will recruit only qualified participant’s as per Inclusion and Exclusion criteria.

2.2 The Principal Investigator will conduct the study in accordance with protocol, Gazette of India notification 19 March 2019, and Indian Council of Medical Research (ICMR) 2017, Guidelines along with Helsinki and The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for international studies and Gazette of India, 19th March, 2019 and subsequent amendment thereof.

2.3 The Principal Investigator will make necessary arrangement for inspection of documents etc. by sponsor’s monitor, official of regulatory agency or Institutional Ethics Committee (IEC) nominee.

2.4 The Principal Investigator shall report all serious and unexpected adverse events and/ or

death to the Licensing Authority, Sponsor, and IEC as per Gazette of India notification 19 March 2019.

2.5 The Principal Investigator shall forward its report on Serious Adverse Event of Death after due analysis of all factors with his opinion to Chairperson of IEC, Chairperson of Expert Committee and Head of the Organization and the Licensing authority as per Gazette of India, notification 19 March, 2019.

2.6 The Principal Investigator shall forward its report on Serious Adverse Event (SAE) other than Death after due analysis of all factors with his opinion to Licensing Authority, Chairperson of IEC and Head of the Organization as per Gazette of India notification 19 March 2019.

2.7 The Principal Investigator will be responsible for proper and prompt filling of Case Report Form (CRF), preservation of investigation reports and recordings.

2.8 During and following a Clinical Trial Participant's participation in Study, the Principal Investigator shall ensure that adequate medical care is provided to the participant (Clinical Trial Participant) for any adverse events.

2.9 The Principal Investigator will ensure enrolment of trial participant's after obtaining informed consent including audiovisual recording and also informing the provisions of adequate treatment and compensation for Serious Adverse Event (SAE) as per Gazette of India notification 19 March 2019, and Indian Council of Medical Research (ICMR) 2017.

2.10 Principal Investigator (PI) shall complete the Clinical Trial under his supervision as per the agreement and the Statutory provisions, but if for any reason he/she is unable to carry over the study it shall be his/her responsibility to hand over the study to his/her Co-Principal Investigator (Co-PI) or to any of the consultants of the Organization, to be decided by the Head of Speciality of the PI or Chairman cum Managing Director and obtain the approval of the Ethics Committee and the Sponsor.

2.11 The Principal Investigator will be responsible for proper account of receipt, utilization and

return of unused sample of trial drug to sponsor and prevent its use for any other study.

2.12 The Principal Investigator will be responsible for providing non-compliance and progress report to Institutional Ethics Committee (IEC)as per the criteria given in the SOP.

2.13 The Principal Investigator will be responsible for forwarding to IEC communications from sponsors within a week of receipt with comments for the need of any change in protocol or Participant's Information Document (PID).

2.14 The Principal Investigator will be responsible for obtaining IEC and sponsors permission for storage of blood or tissue samples for future use.

2.15 The Principal Investigator shall be responsible for obtaining sponsor's permission before publication or conference presentation of any data.

3.0 Obligation and Responsibilities of the Organization:

3.1 Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirement.

3.2 Ensuring that the rights, safety and well-being of Clinical Trials Participant are protected.

3.3 Fulfillment of necessary obligations by Institutional Ethics Committee (IEC), The Principal Investigator (PI) and supporting staff.

3.4 Protection of confidentiality, rights, safety and wellbeing of clinical trial participant's.

3.5 Adequate treatment and compensation for Serious Adverse Event (SAE) to trial participant's. 3.6 Necessary infrastructure support to PI.

3.7 Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related Study documents.

3.8 Ensuring accuracy, completeness, legibility and timelines of the Data reported to the Sponsor in the Case Report Forms (CRFs) and in all required reports.

3.9 Study shall be terminated on the recommendation of IEC, when safety and benefit of Clinical Trial Participant's is doubtful.

3.10 Safety reporting as per Gazette of India, notification 19th March, 2019.

3.11 Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Organization should make available for direct access all requested trial related records.

3.12 The confidentiality of record that could identify Clinical Trial Participant should be protected and maintained.

3.13 If Sponsor or Contract research organization (CRO) violates the terms of this Agreement or does not provide the claimed compensation to the Participant then the Organization or Principal Investigator may not conduct any other further clinical trials of this sponsor.

3.14 Approval of study within 8 weeks of receipt of Investigator's brochure, protocol including Participant's Information Sheet (PIS) & Case Report Form (CRF), regulatory approvals, draft Clinical Trial Agreement (CTA), Insurance policy and IEC fee as prescribe in the SOP from the sponsor.

3.15 Approval of midterm changes within 8 weeks of receipt of documents.

3.16 Review of progress report Data and Safety Monitoring Board (DSMB) report & Serious Adverse Event (SAE) from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

3.17 Review of SAE at Divine Heart & Multispeciality Hospital and necessary action within the time frame decided by regulatory agencies.

3.18 Review of final report.

3.19 Approval of storage of blood or tissues for use in future studies.

3.20 Facilitate visit of sponsor's monitor or representative of regulatory agencies.

3.21 Institutional clearance for sample to be sent abroad for non-pharmacokinetic studies.

3.22 Archiving of data for 5 years (or longer if required by sponsor/regulatory agency).

3.23 Safeguarding Intellectual property rights (IPR) of sponsor and DHMH.

3.24 Providing alternate Principal Investigator (PI) if PI unable to continue.

3.25 Audited statement of utilization of Funds

4.0 Obligation and Responsibilities of the Sponsor

4.1 To provide Protocol, investigator'sbrochure, Participant's Information Document (PID), Consent form, Case Report Form (CRF), draft Clinical Trial Agreement (CTA), Insurance policy from an Indian Insurance company and regulatory approvals.

4.2 To provide adequate supplies of trial drug, comparator and /or placebo prepared under proper quality control.

4.3 To provide Insurance cover for treatment and compensation of Serious Adverse Event (SAE) and an undertaking to supplement any amount not covered by the Indian Insurance Company. Sponsor will also provide copy of Policy document to the Organization.

4.4 Undertaking to provide test drug free of cost to participant's after termination of the trial if necessary, till it become available in the country.

4.5 **Not to send samples for Pharmacogenetic study abroad.**

4.6 To permit the storage of samples for future study if requested by Principal Investigator.

4.7 Provide a copy of final report at termination of the study.

4.8 Appropriate acknowledgement of contribution of DHMH investigators in any resulting publication.

4.9 To define and follow procedure for premature termination.

4.10 To provide budget which should include cost of treatment, investigations and investigators charges, reimbursement of travel expenses to participant's, if necessary, Organization's overhead at the rate of 25% of the total budget and INR 1,00,000/- fee of IEC, through DD. Details of release of budget to be mutually settled

5.0 **Consideration of injury or death or permanent disability to be related to clinical trial or bioavailability and bioequivalence study**

5.1 Sponsor agrees that any injury or death of the Clinical Trial Participant occurring in Clinical Trial due to following reasons shall be considered as Clinical Trial related injury or death and the Participant or his nominee, as the case may be, will be entitled to receive from the sponsor financial compensation for such injury or death as per the notification of the Drug Controller General of India (DCGI) & Government of India issued from time to time.

(a) Adverse effect of Investigational Product(s);

(b) Violation of the approved Protocol;

(c) Scientific misconduct or negligence by the Sponsor or his representative or Contract research organization (CRO) or Principal Investigator, Co-investigator or any member of his/her team

(d) Failure of Investigational Product to provide intended therapeutic effect;

(e) Use of placebo in a placebo-controlled Clinical Trial;

(f) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved Protocol;

(g) For injury to a child in utero because of the participation of parent in Clinical Trial;

(h) Any Clinical Trial procedures involved in the Study.

5.2 Sponsor should submit a status report on the Clinical Trial to the Licensing Authority at the prescribed Periodicity;

5.3 In case of studies permanently discontinued for any reason Sponsor shall submit a summary report to the Licensing Authority as per provisions of Gazette of India, notification 19 March, 2019.

6.0 Undertaking and Representation of Principal Investigator

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format as prescribed in the Gazette of India, notification 19 March, 2019.

7.0 Undertaking and Representation of Organization

Organization hereby represents that: - It has constituted the Institutional Ethics Committee as per the guidelines given in the Gazette of India & it has been registered with the Drug Controller General of India (DCGI) vide letter No: dated…. (i) SOP is in compliance with Good Clinical Practice (GCP) guidelines and applicable regulations; (ii) It will ensure that IEC will discharge its responsibilities as per provisions of Gazette of India, notification 19 March, 2019, and ICMR guidelines 2017.

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that: - It has furnished an undertaking along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of clinical trial related injury or death for which Participant's will be entitled to compensation; as per provisions of rule 122 DAB (b) of Rules (Drug and Cosmetics Rules, 1945).

9.0 Administration

9.1 Overall responsibilities of the Study will rest with Principal Investigator, Organization and Sponsor to conduct the Study at Organization's premises.

9.2 The following Study plan will apply to the Study:

(a). Participant enrollment up to Organization's Enrollment Maximum (i.e.: Clinical Trial Participant's) shall be completed as stated in protocol. However, if the Organization and Principal Investigator are unable to enroll Participant'ss for the Study within 6 months of Investigation Site Initiation Sponsor will be having the authority to change the Organization's Enrollment Maximum in a unilateral manner.

(b). Organization or Principal Investigator will not enroll more Study Participant's than Organization's Enrollment Maximum Sponsor will not be obligated to make any payment with respect to any Participant enrolled in excess of Organization's Enrollment Maximum.

(c). Participant to applicable law: Sponsor and Organization without any further obligation mutually may agree in writing to modify Organization's Enrollment Maximum.

(d). All Participant visits will be conducted as proposed in the protocol. The sponsor will be informed is a visit is delayed by more than 2 weeks along with reason of delay.

(e). Case Report Forms ("CRFs") information associated with a Participant's visit must be satisfactorily completed within 7 days after the Participant's visit or, if applicable, receipt of the Participant's test results.

(f). All Data Queries from Sponsor must be completed and returned to Sponsor within a time frame mutually negotiated.

(g). Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or Study team will not be the liability of Sponsor.

10.0 Trial Drug; Materials Transfer; Records Retention; Inspection

10.1 Trial drug:

(i) Organization and Principal Investigator acknowledge that the trial drug/device is owned or controlled by Sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Organization or Investigator for the Trial, shall be construed to grant to either Organization or Principal Investigator any rights in or to the Compound.

(ii) Except as otherwise agreed by the Parties, Sponsor will provide the Compound and any control/placebo material to be administered to Trial Participant's as part of the Trial (collectively, the "Trial Drug") free of charge to Organization for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Trial Participant's at the Trial Site in Strict compliance with the Protocol.

(iii) Organization and Principal Investigator shall use the Trial Drug solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial drug to any third parties. Organization and Principal Investigator shall handle, store, ship and dispose of the Trial drug as directed by Sponsor or its designee and in compliance with all applicable laws, rules and regulations.

(iv) Organization and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

(v) Neither support of the Trial, nor Organization participation in the Trial, impose any obligation, express or implied, on Organization or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's products.

(vi) Unless required by the Protocol, Organization will not modify the Trial Drug or its container. If the Organization policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Organization for use in a future study to be approved by Institutional Ethics Committee (IEC).

10.2 Records Maintenance and Retention Investigator and Organization will maintain adequate and accurate records relating to the disposition of the Trial Drug and the performance of all required Protocol procedures on Trial Participant's including but not limited to, written and audiovisual documents, medical records, charts pertaining to individual Trial Participant's, "Case Report Forms ("CRF") accounting records, notes, reports, and data. Institution will retain these documents for the longer period of at least 5 yrs. after completion or earlier termination of

the Trial.

11.0 Representation and Warranties

11.1 Organization represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Organization shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the Trial in accordance with this Agreement and the Protocol.

11.2 Organization represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

12.0 Confidentiality

12.1 Organization will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of Participant or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than Participant's medical records), including the Trial Results, Trial Inventions and information related thereto (Confidential Information). Organization and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential Information will not include information that:

(i) Is or becomes publically available through no fault of Investigator or Institution.

(ii) Was known to Principal Investigator or Organization without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Organization form other source.

(iii) Is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

(iv) Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

12.2 Not withstanding any other provision of this Agreement, Organization and Principal Investigator may disclose Confidential Information to the extent required.

(i) To comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Organization cooperate with Sponsor efforts to limit

such disclosure by appropriate legal means:

(ii) To protect any Trial Participant's safety or provide appropriate medical care for any Trial Participant, or to prevent a public health emergency with prompt notice to Sponsor

(iii) For purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial Participant related to the procedures included in the Protocol.

13.0 Return of Confidential Information

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Organization will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to Sponsor the completion of such return and/or destruction, provided, however, that Organization may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

14.0 Trial Results and Inventions

14.1 Sponsor owns all data, Trial Results, Confidential Information, Case Report Forms (CRFs) and all other information generated as a result of or in connection with the conduct of the Trial, excluding Institution's Participant's medical records and Principal Investigator's personal notes and hereby grants to the Organization a nonexclusive, non–transferable, non-sub licensable right to use the Trial Results solely for its own internal, non-commercial research, Participant's care, and educational purposes.

14.2 All inventions, ideas, methods work of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Organization, Principal Investigator or Trial Personnel:

(i) as a result of or in connection with the conduct of the Trial

(ii) that incorporate or use Confidential Information: or

(iii) that are directly related to the Compound and in each case together will all intellectual property rights relating thereto (collectively, Trial Inventions"), will be the sole and exclusive property of Sponsor or its designee. Organization and Principal Investigator will promptly disclose all Trial Investigations to sponsor in writing and interest in all Trial Investigations to sponsor or its designee. At sponsor's request and expense, Organization shall take and shall cause Principal Investigator and Trial Personnel to take, all additional actions as it deems necessary to protect the interest of sponsor or its designee in Trial Investigations or to obtain

patents or otherwise protect the interest of sponsor or its designee in Trial Investigations.

15.0 Payment

15.1 In consideration for conducting the Study Sponsor shall pay Organization and Principal Investigator as described in Annexure-A. Sponsor will not make further payments, towards Study visits, procedures, or other work associated with a Study Participant if Sponsor determines that the Clinical Trial Participant's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

15.2 Sponsor shall pay on a Per Participant Cost for each Satisfactorily Completed Participant (as defined below) in accordance with Annexure-A as attached to this Agreement. If a Participant is discontinued for reason stipulated in the Protocol, the Organization and Principal Investigator shall be paid a prorated rate for work completed.

(a). Per Participant Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Annexure-A. The estimated total amount per Clinical Trial Participant listed in Annexure-A is calculated for a Clinical Trial Participant that completes all the Study visits. Screening Visits are paid for consented Clinical Trial Participant's for whom all screening procedures are performed. All visit costs include Institutional overhead, staff fees and applicable taxes.

(b). The per Participant costs are a fixed fee per Participant's which includes all costs and honoraria, including but not limited to; - All Study related activities such as conduct of visit assessment and CRF completion - Time and efforts of Principal Investigator/s and other Organization's Study personnel - All manpower cost involved in the Study conduct - All diagnostic test and other investigations (ECG, Chest X-ray, Spinal X-ray, Linear accelerator, MRI, CT scan etc.) - Housing or hospital stay for Participant'ss including meals - Participant's reimbursement/ Compensation - All overhead costs - Usage of Instruments/ equipment's which during the Study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract - Miscellaneous (telephone/Mobile, courier, storage cupboards and maintenance of Organization infrastructure).

(c). A completed and evaluable Patient means Patient:

(i). Participants to Study on whom all procedures have been performed and completed according to Protocol;

(ii). Who is enrolled for the Study according to inclusion and exclusion criteria;

(iii). For whom all Data documented accurately and completely;

(iv). All Data queries resolved completely in mutually agreed timely manner; and

(v). For whom all source, CRF and other Study related documents completed as per protocol standard requirements as mentioned in Annexure-A

15.3 Screen Failures/ Drop-outs: For drop-outs payment will be made by Sponsor on a pro-rated basis for the number of completed visits and per screen failures (if applicable).

15.4 Set-Up Fees: Sponsor will pay the Organization an initial advance amount of INR ……within 15 days after obtaining the Ethics Committee and necessary regulatory approval. This up-front advance payment would be exclusive of Institutional overhead and service charges and shall be deducted/ adjusted on pro-rata basis from further subsequent payments.

15.5 Hospitalization costs: Apart from Study specific the in-house, treatment of the Participant in the event of any Serious Adverse Event (SAE) shall be paid by Sponsor to the Clinical Trial Participant.

15.6 Institutional Ethics Committee Fees: Institutional Ethics Committee review fees will be paid by sponsor at the time of submission of clinical trial documents.

15.7 Payments by Sponsor to Organization shall be directed as follows: Principal Investigator Fee/ Clinical Trial Participant Reimbursement and Hospitalization:

Payee Name (Account name)	Divine Heart Hospital & Research Centre(P) LTD
Account Number	50085000555
Bank Name	Indian Bank Branch, Vibhav Khand Gomtinagar Lucknow
PAN Number	AABCD9643C
TAN Number	LKND05860B
Swift/IFSC Code	IDIB000L561
GST number	09AABCD9643C1ZP
Send to < Cheque Delivery Address >	Dr. …….. Speciality of ……

Divine Heart Mutispeciality Hospital, Viraj Khand
Institutional Area-5. Gomti Nagar Lucknow - 10
India.

15.8 Payments will be made on monthly basis according to actual work performed (CRF completion, source Data verification and CRF retrieval for completed visits). Advance payment will be adjusted against the 1st payment. Final payment will be made at the time of Investigation Site close-out visit or immediately after Investigation site close-out visit and payment will not be made until all queries are resolved. After closure of the trial any leftover money will not be return to the sponsor/CRO. The Institte will utilize the leftover money as per the prescribe norms.

15.9 Participant travel reimbursement is exclusive of Institutional overhead and will be done as mentioned in Annexure-A. However, Sponsor will release the funds to Organization and Principal Investigator for each Clinical Trial Participant, i.e., Rs. ……as per the Study schedule. However, it will be the obligation of Principal Investigator to pay the Clinical Trial Participant reimbursement on a pro rata basis (Rs……. - per visit). Sponsor will provide an amount of ……. only for the future treatment Reimbursement to the Clinical Trial Participant who have completed the study

15.10 Payment will be made by Sponsor for Clinical Research Coordinator salary per month Rs. …….. (…….. rupees) only for his/her efforts contribution to the Study. This payment would be exclusive of Institutional overhead and will be from the Investigation Site initiation visit to Investigation Site close out visit (until all the Data queries are resolved at the Organization's premises). The CRC will be appointed by the PI as per the norms of the Organization for appointment of Resaerch staff. The sponsor/CRO should not appoint any CRC in concerning Drug trial.

15.11 At the time of premature termination of this Agreement by any party, the Organization agrees to retain the funds submitted by sponsor and will utilize the money as per Organization norms.

15.12 Tax deduction: All fees and amounts listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the Organization for the Study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year

16.0 Use of other parties' names

16.1 The Principal Investigator and Organization shall not use Sponsor's name or the name of

any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ CRO/Organization.

4.0 No joint venture etc.

4.1 This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18.0 Insurance and Indemnification Insurance:

Organization shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Indemnification: Sponsor shall, at all times to come, indemnify the Principal Investigator and Organization without demure for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Organization arising directly or indirectly out of the performance of the Study pursuant to the Protocol and SOP. The Sponsor will indemnify the Participant suffering in any manner as a result of trial for any reason whatsoever including negligence or violation of the protocol by the Principal Investigator or any member of his team as per order of the Licensing authority or the Institutional Ethics Committee

19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

19.1 The Principal Investigator and Organization shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

19.2 The Principal Investigator and Organization shall notify to the Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Organization's facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the Principal Investigator and Organization receives, obtains, or generates pursuant to any such study.

19.3 The Principal Investigator and Organization will permit the Sponsor to;

(a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.

(b) Inspect and copy all Data, documents and records related to such work and the Study

19.4 The obligations of this Section shall survive termination of this Agreement.

20.0 Term; Waiver; Severability (The trial on its time extended)

20.1 This Agreement will be in force for a period of the trial or its time extended from the date of its signing. The term of this Agreement may be extended by consent of all parties to this Agreement.

20.2 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 12 months after the Effective Date. The Date of execution of this Agreement shall be the effective Date.

20.3 This Agreement will become effective after by the last signatory it is fully executed by all the parties hereto and shall continue in effect for the full duration of the Study according to the Protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

20.4 This Agreement may be terminated by any party upon giving at least thirty (30) days written notice to that effect to the other parties. The day following the 30th day of such notice shall be "Effective Date of Termination". A reasonable adjustment will be made between the parties to ensure the Principal Investigator and Organization is reimbursed for project costs incurred to the date of termination of this Agreement for completing the study as per protocol or already enrolled Participant's.

20.5 Sponsor may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Organization Participant to the discharge of their respective obligations under the terms of the agreement.

21.0 Effect of termination

(i). Upon notice of termination of this Agreement by either Organization or Sponsor or Principal Investigator, Organization shall cease enrolling Clinical Trial Participant's into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(ii). Upon notice of termination of this Agreement by Organization or Sponsor or Principal Investigator, Organization shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Organization shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Organization shall repay such funds.

(iii). Upon termination of this Agreement, all unused Materials and all Sponsor Confidential Information (except for such records that Organization is required by law or regulation to retain) in Organization's possession shall be promptly delivered to Sponsor at Sponsor's expense, or, at Sponsor's option, destroyed with the destruction certified in writing.

22.0 Record keeping

The Organization and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, Institutional Ethics Committee (IEC) requirements, and in accordance with all applicable local, state and Central laws and regulations. Organization or Principal Investigator shall cooperate with the Sponsor in making records, reports and Data developed under this Agreement. Organization or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity, whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

23.0 Publication

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the Clinical Trial Study is the sole property of the Sponsor. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but his name should to be included in any publication either author or as participant in the study

24.0 Miscellaneous

24.1 Parties to this Agreement shall comply with the current provision of Gazette of India, 19th March 2019, and its amendments time to time. For providing insurance to Clinical Trial Participant's in case of injuries or death, 000.the parties to this Agreement have tied up with insurance company (The…….) which covers per Participant's amount (……. per Participant's limit). This insurance is valid from the period from ……) to (…….). This insurance shall be extended well in advance from time to time till the expiry of Agreement.

24.2 The Study shall be started by Principal Investigator after this Agreement is executed by all

the parties and required regulatory approvals/consent is available for the study.

24.3 The parties to this Agreement shall ensure that safety, welfare and right of the research participant's (Clinical Trial Participant) are safeguard.

24.4 The Principal Investigator shall forward all Protocol deviation/non-compliance/violation/waiver reports to the IEC as per SOP.

24.5 The safety completion Report shall be sent to IEC by Principal Investigator.

25.0 Governing Law

The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA as applicable in the State of Uttar Pradesh.

26.0 Jurisdiction

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be Lucknow, not withstanding any other provision to the contrary in any law in this regard.

27.0 Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial Participant or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed by the Chairperson of the Institutional Ethics Committee of the Organization within 30 days of the receipt of a written request by the aggrieved. The Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings Participant to the exception that the trial Participant or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

28.0 Amendment

This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the Study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, in triplicate, by their officers, thereunto duly authorized to sign on behalf of their party. 1. Principal Investigator, Divine Heart & Multispeciality Hospital Lucknow

Signature and date: _____

1. Principal Investigator, Divine Heart & Multispeciality Hospital Lucknow

   Signature and date: _____

   Dr. ……

   (Name)

   Title/Designation: ……. Speciality of……..

   Seal

2. Chairman cum Managing Director his nominee, Divine Heart & Multispeciality Hospital Lucknow Signature and date: _____

   Dr. …… (Name) Title/Designation: …… (Chairman cum Managing Director/his nominee)

3. Sponsor

   Signature and date: _____

   Mr. /Dr. ……

   (Name)

   Title/Designation: …….……..

OR

……. Clinical Research Orgnization/CRO

Signature and date: _____

Mr./Dr. ……

(Name)

Title/Designation: …….……..

Seal

Witness

1. Name_____

Signature_____

2. Name_____

Signature_____

ANNEXURE- A

The site will recive IEC fee…… as DD at the time of site initiation by the sponsor and submission of documents to PI for IEC review.

It was agreed that the Site will receive INR ……../- (……..) per Satisfactory Completed Participant for the Study according to the schedule indicated below. This Satisfactory Completed Participant amount is intended to cover the following Study-related costs incurred by the Investigation Site which includes (costs related to the Clinical Trial Participant visits, tests X-ray etc. Study related Communications, Organization service charges and Overheads). As this Study required in Participant's hospitalization, hospitalization fees of INR ……. (…… only) per completed Clinical Trial Participant will be reimbursed by …… to Institution. Clinical Trial Participant will be paid INR ……. (……rupees only) as a reimbursement for loss of daily wages due to participation in Study. In case of early withdrawal of Clinical Trial Participant's, the reimbursement can be provided on Prorata basis. Apart from the Principal Investigator grant as listed below, on successful completion of all the visits, sponsor will provide the Participant's Future treatment Reimbursement of ……..- (Rupees …… only) to the Participant's (who have completed the Study).

Investigator/ Hospitalization/ Participant's reimbursement Grant (Inclusive of Institutional overhead)

Grant Distribution Per completed Clinical Trial	
Principal Investigator Grant	INR ……..Per completed Clinical Trial Participant
Coordinator Payment	INR ……. per month (From Investigation Site Initiation to Investigation Site Close out)
Investigational Cost	This amount is included in per Clinical Trial Participant amount
Hospitalization Cost	INR …….. per Clinical Trial Participant
Stationary and Miscellaneous	This amount is included in per Clinical Trial Participant amount
Participant's Travel convenience	INR ……. per Clinical Trial Participant's
Participant's Future treatment Reimbursement	INR …….. per Clinical Trial Participant completed the Study

All the above-mentioned amount is exclusive of 25% Institutional overhead

AP21/V1

National Ethical Guidelines for Bio Medical and Health Research Involving Human Participation (Indian Council for Medical Research 2017)

Available at: https://www.icmr.gov.in

AP22/V1

National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, ICMR April 2020.

Available at:
https://www.icmr.gov.in/pdf/covid/techdoc/EC_Guidance_COVID19_06052020.pdf