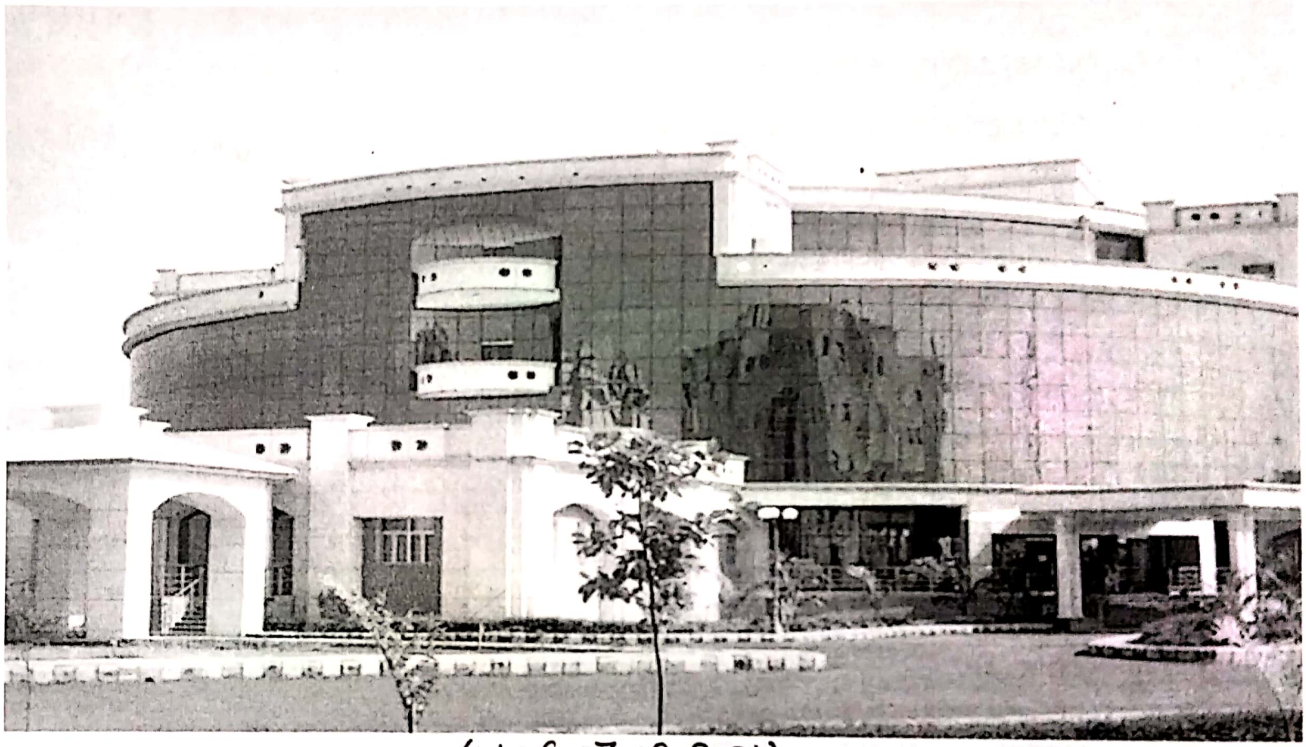
# Standard Operating Procedures (SOPs) version 2.0
# "Institutional Ethics Committee - Uttar Pradesh University of Medical Sciences, Saifai, UP"



(W.e.f. 07-09-2024)

Prepared By: Dr. Kamal Pant (Member Secretary, IEC)

Reviewed By: Dr. Sushil Kumar Shukla (Member, IEC)

Approved By: Dr.Balvir Singh (IEC Chairman)

Accepted By: Dr. Chandra Veer Singh (Registrar, UPUMS)

**INDEX OF STANDARD OPERATING PROCEDURES VERSION-2.0**

## i. Introduction

**Introduction**

The Uttar Pradesh University of Medical Sciences, Saifai, Etawah is established by Govt. of U.P. under Act, 15 of the year 2016. The University has established faculties of Medical Sciences, Dental Sciences, Paramedical Sciences, Nursing, and Pharmacy for imparting training and education to all deserving students. Also, it has a running full-fledged Tertiary Care 900 bedded hospital along with 150 bedded Trauma and Burn Centre. The University has excellent road and railway connectivity; it is located about 7 km from Agra-Lucknow expressway, 20 km from NH-2, and about 20 km from the nearest railway station Etawah Jn.

The University is presently running M.Ch. programme in the Department of Neurosurgery as well as Post Graduate programmes in medical (86 seats) such as M.D./ M.S. and M.D.S. as well as Paramedical (30 seats) in various specialties of Physiotherapy, Medical Laboratory Technology, Optometry, Radiological and Imaging Technology. In addition to Undergraduate programmes such as M.B.B.S. (200 seats) along with Physiotherapy, Medical Laboratory Technology, Optometry, Radiological and Imaging Technology, Nursing and Pharmacy with an intake of 60 seats in each; various diploma programmes in the faculties of Paramedical and Nursing are also running.

The University presently has 250 faculty members in various academic departments. The academic departments are engaged in teaching, training, patient care and research with state of art infrastructure facilities. In order to have optimal healthcare, non-academic support wings of various services such as paramedical, hospital services, engineering, ministerial secretarial services etc. provides their best inputs thus ensuring the management of the patient care services. In addition to imparting education, its important role is to promote medical & scientific research through various programs along with intra-mural and extra-mural projects.

**Hospital Introduction**

The hospital is a tertiary care facility with a total of 1050 beds. It includes specialized units such as a 150-bed Emergency Trauma and Burn Centre and additional upcoming 500-bed Super Specialty Hospital.

Clinical Departments: There are 27 clinical departments covering a wide range of medical specialties including General Surgery, General Medicine, Dentistry, ENT, Ophthalmology, Psychiatry, Paediatrics, Obstetrics & Gynaecology, and various super-specialty departments like Cardiology, Neurology, Oncology, etc.

Infrastructure and Equipment: The hospital is well-equipped with modern medical facilities including CT/MRI scanners, dialysis units, ventilators, ICUs, OTs, emergency services, neuro rehab centre, physiotherapy units, paediatric ICUs, dental and cardiac OPDs, cath labs, and more.

Laboratory Services: The hospital has centralized laboratory services operating 24/7, covering biochemistry, pathology, and microbiology. It includes specialized labs for different diagnostic tests and research purposes.

Biochemistry Department: The department offers both undergraduate and postgraduate teaching and training. It has practical labs equipped with necessary instruments and also runs specialized investigation labs.

Microbiology Department: This department focuses on the identification and characterization of bacterial pathogens using advanced automated technology such as Bactec and Vitek systems. It also offers services for the detection of tuberculosis and other infectious diseases.

Pathology Department: It includes labs for hematology, histopathology, immunohistochemistry, cytopathology, and liquid-based cytology. The department also has research facilities and practical laboratories for teaching purposes.

IEC SOP-01: WRITING, REVIEWING, DISTRIBUTING AND AMENDING SOPs

# IEC SOP-01: WRITING, REVIEWING, DISTRIBUTING AND AMENDING SOPs

## 1. PURPOSE:

The purpose of Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committees (IEC). The SOPs provide clear, explicit instructions so, that the related activities of the institutional ethics committee are conductedin accordance with applicable utmost national and international ethical rules, regulations and guidelines.

## 2. SCOPE:

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within theinstitutional ethics committee. The IEC SOP will be reviewed periodically at least once every 36 months and revised when necessary.

**The below mentioned reasons for the amendment of SOP:**

- Any changes in IEC membership requirements
- As per utmost Clinical Trial rules and regulations
- Problems or deficiency in the SOP
- Regulatory authority requirements
- Stake holders' requirements

## 3. RESPONSIBILITY:

It is the responsibility of the Chairperson of ethics committee to appoint the Team members for preparing, drafting or editing any SOP of the Ethics Committee.

### 3.1. Secretariat of Ethics Committee:

**3.1.1.** Assist Chairperson to formulate an SOP Team

**3.1.2.** Co-ordinate activities of writing, reviewing, distributing and amending SOPs

**3.1.3.** Ensure that all the IEC members and involved administrative staff have access to the SOPs

**3.1.4.** Ensure that all the IEC members and involved staff are working according to current Version of SOPs and maintain an up-to-date distribution list for each SOP.

**3.1.5.** Maintain a file of all current versions of SOPs

**3.1.6.** Maintain a file of all past SOPs of the IEC

**3.2. SOP Team:**

- Assess the request(s) for SOP/s revision in consultation with the Member Secretary and Chairperson.
- Propose new / modified SOP/ s as needed
- Draft the SOP/s in consultation with the IEC members and appropriate administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson
- Final SOP will be accepted by the Registrar-UPUMS, Saifai
- Chairperson of the ethics committee
  - Approves the SOPs
  - Signs and dates the approved SOP versions.

**4. FLOW CHART:**

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1. | Appoint the SOP Team | Chairperson |
| 2. | List all relevant SOPs | SOP Team |
| 3. | Design a format and layout | SOP Team |
| 4. | Write a new/revised SOP | SOP Team |
| 5. | Approve a new/revised SOP | Chair person |
| 6. | Implement, distribute and file all SOPs | Member Secretary |
| 7. | Review and request for a revision of existing SOPs | SOP Team / EC members / Administrative staff/ Chairperson |
| 8. | Manage and archive superseded SOPs | Administrative staff |

## 5. DETAILED INSTRUCTIONS:

### 5.1. Chairperson of IEC:

5.1.1. Appoint one or more SOP Teams

5.1.2. Approve the SOPs

5.1.3. Sign and date the approved SOPs

### 5.2. List all relevant procedures:

5.2.1. Write down step by step all the procedures of the IEC that are to be standardized in the form of an SOP

5.2.2. Organize, divide and name each process

### 5.3. Format and layout:

5.3.1. Each SOP should be given a number and a title that is self-explanatory. A unique code number with the format SOP/XX/VV.W

5.3.2. XX - Two-digit numbers assigned specifically to the SOP.

5.3.3. VV - version with two-digit number identifying the version of the SOP

5.3.4. W is a one-digit number identifying the version of SOP with minor changes in the SOP.

5.3.5. The number of version should be started from 01 and the W should be started with 0, for example, SOP 01/V-1.1 is the SOP number 01 version 01 with one minor revision i.e. V-1.1

5.3.6. Each SOP will be prepared according to the standard template.

### 5.4. Write and approve new SOP:

5.4.1. The approved SOPs will be implemented from the effective date.

5.4.2. The approved SOPs will be distributed to the EC members and the relevant staff By the Secretariat. When revised version is distributed, the old version will be retrieved from the members and destroyed. However, one copy of the old version will be retained at the Secretariat.

### 5.5. Implement, distribute and file ALL SOPs

5.5.1. A draft will be prepared by the member of the SOP team

5.5.2. The draft SOP will be discussed with the other members of the SOP team

5.5.3. The final version will be passed to the Chair person for review and approval.

**5.6.** **Review and request for a revision of an existing SOP:**

5.6.1. Any member of the ethics committee, secretariat or administrative staff who notices an inconsistency between two SOPs or has any suggestion on how to improve a procedure should use the form (Annexure-2) to make a request.

5.6.2. If the SOP Team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the person who made the request of the decision.

5.6.3. Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section 5.4).

**5.7. Manage and archive superseded SOPs:** Superseded SOPs should be retained and clearly marked "SUPERSEDED" and archived in the historical file by the secretariat.

## 6. GLOSSARY:

- **SOP:** Detailed, written instructions, in a certain format, describe all procedures (Standard Operating activities and action undertaken by an organization to achieve Procedure), with uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.
- **IEC members:** Individuals serving as regular and alternate members on the Institutional Ethics Committee. These committees are constituted in Accordance with the IEC membership requirements set forth in ICH GCP and NDCT Rules, 2019.
- **SOP Team**: A selected committee of the members of UPUMS Ethics Committee and administrative staff who oversee the creation, preparation, review and periodic revision of the institute SOPs.
- **Master SOP files**: An official collection of the institute standard operating procedures (SOP) accessible to all staff, IEC members, auditors and government inspectors as a paper copy with an official stamp on first and last pages, and the approval signatures with effective date.

| ANNEXURE: 01 | |
|---|---|

**INDEX OF STANDARD OPERATING PROCEDURES VERSION-2.0**

**ANNEXURE: 02** **AF/IEC/01/02/V-2.0**

**Standard Operating Procedures Template**

Institutional Ethics Committee, Uttar Pradesh University of Medical Sciences, Saifai

Title: Title which is self-explanatory and is easily understood SOP/xx/vv.w

Effective Date:

Page: of TITLE

Title which is self-explanatory and is easily understoodSOP/xx/vv.w

Supersedes:

---

Written By:

Date…

Reviewed By:

Date

Approved by: Chairperson

(Name)

Signature with Date

Acceptance by: Registrar-UPUMS,Saifai

Date:

# IEC SOP-01: WRITING, REVIEWING, DISTRIBUTING AND AMENDING SOPs

**Table of CONTENTS**



**Main Text:**

**Purpose:** summarizes and explains the objectives of the procedure.

**Scope:** **s**tates the range of activities that the SOP applies to.

**Responsibility:** refers to person(s) assigned to perform the activities involved

**Flow chart:** simplifies the procedures in step-by-step sequence and states clearly theresponsible person(s) or position for each activity

**Detailed instructions:** describe procedures step by step in short and clear phrases or sentences. Split along sentence into shorter ones.

**Glossary:** clarifies uncommon or ambiguous words or phrases by explanation.

**Reference**: lists sources of the information given in the SOP.

**Annexure:** documents that explain further or clarify complex descriptions. "Description-by- example" is always recommended to avoid difficult texts which may be hard to understand.

**ANNEXURE: 03** **AF/IEC/01/03/ V-2.0**

Document History

(The final version is the version after the approval by the Chairperson which is V-2.0)

| **Author –** | **Version** | **Date** | **Describe the main change** |
|---|---|---|---|
| Name | | dd-mm-yy | final version |
| Name | | dd-mm-yy | Minor changes |
| Name | | dd-mm-yy | Major changes |
| Name | | No change | (Routine review) |

**ANNEXURE: 04** **AF/IEC/01/04/ V-2.0**

**Log of SOP Recipients**

| Sl.No. | Name of Recipients | SOP Code | No. of Copies | Signature | Date |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**ANNEX URE: 05** **AF/IEC/01/05/V-2.0**

## Request for Revision of an SOP

IEC of Uttar Pradesh University of Medical Sciences SOP Version: 2.0-Aug-2024

| **Requirements for the revision of SOP** | |
|---|---|
| Any changes in IEC membership requirements | NA |
| As per utmost CT rules and regulations | NA |
| Problems or deficiency in the SOP | Yes |
| Any Regulatory authority requirements, If applicable | NA |
| Any stake holders' requirements, If applicable | NA |

Identified by: Date (D/M/Y): During FERCAP Accreditation from 11-15-Aug-2024Discussed with: IEC

Members

SOP revision required: **Yes**

If yes, to be carried out by whom? Chairman and Members[Changes in the

Membership requirements]

If no, why not?

Date SOP re-finalized:17-Aug-2024 Date

SOP approved: 24-Aug-2024

Date SOP becomes effective: 24-Aug-2024

The Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai is constituted by The Hon'ble Vice-Chancellor of Uttar Pradesh University of Medical Sciences, Saifai. It provides the necessary support and facilities and independence in functioning and decision making in the protocol review process by the IEC members.

1. **Purpose:**

The Ethics Committee of UPUMS was established in 2023 in order to formalize and specify the Institution's commitment to promotion of high ethical standards in Participants care, professional education, clinical research and community interests.

Applicable to all clinical trials including Bioavailability/ Bioequivalence (BA/BE) studies [other than Phase-I], Phase II, III, IV studies, Non-Therapeutic and Non interventional studies and any research projects conducted at Uttar Pradesh University of Medical Sciences, Saifai

All Research involving human subjects should be conducted in accordance with three basic ethical principles, which include,

- **Respect for persons**
- **Beneficence**
- **Justice**

IEC members shall be appointed by the Hon.Vice-Chancellor of Uttar Pradesh University of Medical Sciences, Saifai in accordance with current local rules and regulations.

The registration is valid through 15-June-2028 unless suspended or canceled by the Central Licensing Authority.

2. **Scope:**

The SOP applies to the functioning of all activities of Institutional Ethics Committee under the Uttar Pradesh University of Medical Sciences, Saifai. This includes the basic responsibilities of the IEC, composition, appointment, Dissolving of the IEC, and conduct of the meeting.

3. **Responsibility:**

3.1. The IEC will allow inspectors or officials authorized by the CDSCO to enter its premises to inspect records, data or any documents related to clinical trials and provide adequate replies to any query raised by such inspectors or officials.

3.2. The IEC will apply to the CDSCO/ Drug Controller General (India) office to renew the registration, 3 months prior to the expiry of the awarded registration.

3.3. The IEC will regularly inform the CDSCO/ Drug Controller General (India) office of change in the membership/ constitution of the ethics committee.

3.4. The IEC will competently review and evaluate all ethical aspects of research projects received to ensure compliance with the appropriate laws and safeguarding the welfare of subjects.

3.5. The IEC will ensure education of professional, administrative, and support staff about ethical issues in creating,developing, revising and implementing ethical guidelines.

**4. Flow chart:**

| **Sl.No.** | **Activity** | **Responsibility** |
|---|---|---|
| 1. | Ethical basis and mandate | IEC Members, Secretariat |
| 2. | Composition of the IEC | Vice Chancellor of Uttar Pradesh, University of Medical Sciences, Saifai |
| 3. | Appointment of IEC members | Vice Chancellor of Uttar Pradesh University of Medical Sciences, Saifai |
| 4. | Membership Requirements | IEC Members and Secretariat |
| 5. | Resignation, Disqualification, Replacement of Members | Vice Chancellor of UPUMS, IEC Members and Secretariat |
| 6. | Independent Consultants | Chairperson of the IEC |
| 7. | Conditions of Appointment | IEC chairman and Secretariat |
| 8. | Secretariat including supportive staff | Vice Chancellor of UPUMS and Research in-Charge in consultation with the IEC member-Secretary. |
| | Quorum Requirements | IEC Members and Secretariat |

## 5. Detailed Instructions:

**5.1 Ethical basis and Mandate:** The IEC seek to fulfill the requirements for international assurances and in accordance with the national law and regulations. the Institutional ethics committee ofUttar Pradesh University of Medical Sciences, Saifai is registeredwith the DCGI with accession number ECR/1830/Inst/UP/2023 dated 16-June-2023 under New Drug and Clinical Trials, 2019

**5.2** The Ethics committee will have a minimum of seven and a maximum of fifteen members from medical or non-medical, scientific and non-scientific areas with at least

- **a.** One lay person;
- **b.** One woman member;
- **c.** One legal expert;
- **d.** One independent member from any other related field such as a social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian

**5.3** The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

**5.4** The committee shall include at least one member whose primary area of interest or specialization is nonscientific and at least one member who is independent of the institution.

**5.5** Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India, and other regulatory requirements to safeguard the rights, safety, and well-being of the trial subjects.

**5.6** While considering an application that involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

**5.7** Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licensing Authority within thirty working days.

**5.8** Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

**5.9** SOPs for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of the Ethics Committee shall be maintained for review and

inspection.

**5.10** The Chairman of Ethics Committee shall enter into Independence with head of institution, that necessary support and facilities and independence shall be provided to Ethics Committee and their records will be maintained.

**5.11** The Ethics Committee shall allow any officer authorized by the Central Licensing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

**5.12** Ethics Committee (IEC) shall review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. To ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner, the IEC may refer to the SOPs and Guidelines of the Institutional Ethics Committee of UPUMS.

**5.13** It will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

**5.14** It is a dictum that the goals of research, however important, should never be permitted to override the health and well-being of the research participants.

**5.15** IEC shall only review the research proposals (clinical trials, basic research, socio-behavioral or operational studies), which are conducted at the Institute.

**5.16** Genetics studies in any form cannot be approved by IEC of UPUMS, Saifai-206130 and the genetic studies to state that appropriate expert will review such studies as per ICMR Guidelines.

**5.17** IEC meeting Schedules: Meeting will be convened on Quarterly basis. If needed as per the requirement.

**5.18** **<u>Quorum Requirements:</u> For review of each protocol at least 5 members under quorumrequirements or require majority or 50% + 1 of Regular Members for quorum**

i. Clinician
ii. Layperson
iii. Medical Scientist
iv. Member from NGO
v. Legal Expert

## 6. Alternate Members<u>:</u>

**6.1** The IEC should nominate alternate Chairperson who can be selected from the non- institutional IEC members. The alternate Chairperson can oversee / conduct the meeting in the absence of the Chairperson.

**6.2** Considering the fact that there may be conflict of interests when the Member Secretary is the Principal Investigator/ co-investigator or is absent from the meeting, the IEC may consider appointing alternate Member Secretary who should be the institutional IEC member.

**6.3** The alternate member of required specialty (Legal Expert, Clinical Pharmacologist, Community Member) can be selected for fulfilling the quorum, in case the present member is not able to attend the meeting due to unprecedented prior commitments and the meeting is to be held as per schedule

**6.4** Alternate members are suggested by the IEC member and nominated by chairperson of IEC.

## 7. COMPOSITION OF THE IEC-UTTAR PRADESH UNIVERSITY OF MEDICAL SCIENCES, SAIFAI:

**7.1** He/She is Non- Voting Member in the committee and look after the member secretary duties and IEC administrative activities

**7.2 Membership requirements:** In the interest of the Institute's research program, the IEC members including the Chairperson, Member Secretary will be selected by the Vice-Chancellor of Uttar Pradesh University of Medical Sciences, Saifai/Officer-in-Charge taking into consideration their expertise, research interests and experience in ethics.

**7.2.1.** Selected members should possess the necessary research experience- scientific knowledge and expertise; knowledge of ethics, and their commitment and willingness to volunteer the necessary time and effort for the IEC work.

**7.2.2.** Community members will be selected based on the basis that they are willing to publicize the full name, profession, and affiliation. Their Curriculum Vitae should be submitted to the IEC office for records.

**7.2.3.** The Chairperson and the IEC members should be informed of the potential members by the Member Secretary in the meeting and their concurrence should be obtained.

**7.2.4.** Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.

**7.2.5.** the IEC shall decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision, [Refer to SOP/03/V-2.0 –Confidentiality /Conflict of Interest Agreement- the members are consented with the same version of Documents]

**7.2.6.** Members will be required to sign a confidentiality agreement at the start of their term.

**7.2.7.** **Terms of Appointment:** The IEC of UPUMS Members can be appointed for a duration not exceeding **05** Years for **02** terms. However, depending on the need and expertise of the member, the term can be extended for further period of five years in an exceptional case with the approval from the Competent authority.

**7.3 Resignation, Disqualification, Replacement of Members:** Members may resign their positions by submitting a letter of resignation to the Chairperson.

***Members may also be disqualified from continuance in the following circumstances:***

- Should the Chairperson provide written arguments to the (other) members and there is unanimous agreement
- Member does not comply to the responsibilities set for the members (stubborn- sets up stage for argument/ non-punctual/ not thorough with the job assigned)
- Members who have resigned or have been disqualified may be replaced with new members by the Vice-Chancellor of UPUMS.

**7.4 Independent Consultants:**

**7.4.1.** The IEC may be further supported in its reflections on specific protocols or requests for advice on methodological/scientific issues by the Independent Consultants.

**7.4.2.** Please refer SOP 05: Selection and Responsibilities of Independent

**7.5 Terms of Appointment:** Chairperson, Member Secretary, Members, Alternate Chairperson, Alternate Members, and Independent Consultants are appointed to the IEC under the following conditions:

**7.5.1.** Willingness to abide by the requirements laid in the SOP

**7.5.2.** Willingness to publicize his/her full name, profession, and affiliation

**7.5.3.** All IEC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants and related matters

- An investigator can be a member of the IEC; however, the investigator-as-member cannot participate in the review and approval process for any clinical trials in which he or she has a presence as a PI, Co-PI, or potential conflict of interest.

**7.6 Members and their responsibilities:**

The following officers through their respective responsibilities contribute to the good functioning of the IEC:

**7.6.7 Chairperson:**

› He/She should be a highly respected individual from outside and not affiliated to the institution.

He/she is responsible to chair the meetings, invite independent consultants to provide special expertise to the IEC on proposed research protocol.

- He/She should work in close co-ordination with the Member Secretary, review and sign along with the member secretary all the minutes, proposals and work towards the smooth function of the IEC.

**7.6.2 Alternate Chairperson**:

- He/She should be a highly respected individual preferably from outside and not affiliated to the institution, fully capable of managing the IEC and the matters brought before it with fairness and impartiality. Act as Alternative chairperson in absence of the Chairperson.

**7.6.3 Member Secretary**:

- He/She is responsible for the administrative activities of IEC Section-8

**7.6.7 Alternate Member Secretary**:

- He/she is responsible for the proceedings of the meeting in the absence of the member secretary/ if the member secretary has a conflict of interest for a study under review.

**7.6.5 Medical scientist:**

- A basic medical scientist should have post-graduate qualifications and adequate experience in his/her respective field. A basic medical scientist should be an MD in one of the basic sciences. Basic sciences include anatomy, physiology, biochemistry, pharmacology, microbiology and pathology.
- He/She should review the protocol with respect to the methodology, design of the study and rationale of the study hypothesis and should review overall protocol.
- He/She can act as a primary scientific reviewer

**7.6.6 Scientific Member:**

- A basic science scientist should have post-graduate qualifications and adequate experience in his/her respective field.
- He/She should review the protocol in accordance to pre-clinical studies and with respect to the methodology, design of the study and rationale of the study hypothesis and should review overall protocol

**7.6.7 Legal Expert:**

- Role of Legal expert is as primary reviewer of the contract to review the insurance, compensation, and trial agreements.
- Law can help physicians and others in decision-making and legalized approaches are similarly said to foster deliberation and careful weighing of evidence as well as playing a fundamental role in tempering subjective discretion and minimizing arbitrariness.
- Should review overall protocol including Clinical trial agreements and insurance in clinical trials.

**7.6.8 Layperson:**

- Represent the interests of the community/participant at large
- Less influenced by the financial and non-financial conflicts of interests
- Reviewing the informed consent process to ensure participant protection
- Evaluating benefits and risks to research participants
- Reviewing protocols helping to ensure that language and other aspects of a study make sense to the layperson

**7.6.9 Clinicians:**

- A basic science scientist should have post-graduate qualifications and adequate experience in his/her respective field.
- He/She should review the protocol in accordance to clinical studies and with respect to the methodology, design of the study and rationale of the study hypothesis and should review overall protocol
- He/She can act as a primary scientific reviewer.

**7.6.10 Representative of Non-Governmental Voluntary agency:**

- A graduate with specialization in social ethics, intercultural ethics, and the ethics of gender and vulnerable population.
- Serve as resource persons to religious beliefs and faith concerning the value dimensions and values of illness and health even if Participants or their families have no apparent religious affiliation.
- Bring expertise in ethical and moral values to the multidisciplinary team in the clinical setting.

**7.6.11 IEC Assistant Coordinator:**

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance, and distribution of study files

- Preparation and maintenance of meeting agenda
- Receive and check for the completeness of the documents for review by the IEC

8. **The IEC Administrator and staff:** There will be administrative officer/s and attendant/s/helper/s who will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned as and when deemed necessary by the IEC. The eligibilitycriteria for new staff to be appointed will be laid down depending on the required job profile. Theadministrative staff will be appointed by conducting formal interviews (to be conducted by a panel of experts appointed by Vice-Chancellor of UPUMS, Saifai-10

- Member secretary will do preliminary review of submitted protocols and determination of primary reviewer in consultation with chairperson if required
- Correspondence with the IEC members and external Members
- Correspondence with the investigators/Sponsors
- Pre and post arrangements of IEC meetings
- Preparing agenda and minutes of the IEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files

**8.1 The Secretariat shall have the following functions:**

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance, and distribution of study files
- Allocation of project reviews to specific members to facilitate efficient dispensation of the projects.
- Organizing IEC meetings regularly
- Preparation and maintenance of meeting agenda and minutes
- Receive and check for the completeness of the documents for review by the IEC.

**8.2 Duties of the attendant/s /helper/s**

- Assisting the secretariat in arranging the IEC meetings
- Dispatching sets of study documents to IEC members and external experts
- Receiving the study related documents from and dispatching the IEC letters to the investigators

**8.3 The office timing for the administrative staff will be as per Uttar Pradesh University of Medical Sciences, Saifai**. The administrative staff will avail leave as per Uttar Pradesh University of Medical Sciences, Saifai Norms. The Secretariat is composed of the Member Secretary and the administrative supporting staff which includes Ethics Committee coordinator, a full-time peon and lower division clerk. It is mandatory that the clerical assistant and peon should be a permanent employee to ensure efficient record keeping and retrieval of clinical trial related documents.

**9. Maintaining the IEC's documentation and Archival**

- Communicating with the IEC members and investigator applicants
- Arrangement of training for personnel and IEC members
- Organizing the preparation, review, revision and distribution of SOPs.
- Work in unison with the IEC members and the investigators to reduce the turn-around time of the study proposals sent to the IEC for review.
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

**10. Roles and Responsibilities of IEC members**

- Regularly attend and actively participate in the IEC meetings
- Review, discuss and consider research proposals submitted for evaluation. Reviewers for each proposal will review the study. Later, if any other issues the other IEC members can voice their comments/suggestions.
- Monitor serious adverse event reports and recommend appropriate action(s) Review the progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports of clinical trials
- Maintain confidentiality of the documents and deliberations of IEC meetings. Declare any conflict of interest
- Participate in continuing education activities in biomedical ethics and biomedical research
- If deemed necessary, should suggest any changes that may be necessary to be included in the SOPs of the IEC
- Conduct ethical review of study protocol and its related documents
- Conduct monitoring visits for any research proposal, if needed

**11. Dissolving of the IEC:**

- At any point in time, should the Institute cease to exist, the IEC is automatically dissolved.
- The IEC may also be dissolved at any time by the Vice-Chancellor, Uttar Pradesh University of Medical Sciences, Saifai/Officer-in-Charge of the Uttar Pradesh University of Medical Sciences following written notification to each of the members

**12. References:**


- New Drugs and Clinical Trial Rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- International Conference on Harmonization, Guidance for Good Clinical Practice E6R2 (ICH-GCP) 2016
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants-2011

IEC SOP 03: Confidentiality/Conflict of Interest Agreement

## IEC SOP 03: Confidentiality/Conflict of Interest Agreement

**1. Purpose and Application:**

The purpose of this section is to provide a form of Confidentiality/Conflict of Interest Agreement and identify who should read, understand, accept, sign and date the form. The procedure provides details when and where to sign as well as how the signed document should be kept.

**The policy principles and procedures contained in this SOPs applies to:**

- Institutional Ethics Committee members
- Permanent, temporary and part-time employees of Ethics Committee
- Guest Attendees i.e Students, EC Assessor-External Members

**2. Scope:**

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai.

**3. Responsibility:**

As it is mandatory to maintain the confidentiality of study protocols, IEC documents, and correspondence with experts, it is the responsibility of all newly appointed IEC of Uttar Pradesh University of Medical Sciences, Saifai members to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form, before beginning their ethical review tasks to protect the rights and safety of study participants. If non-members of the IEC need copies of documents, it is the responsibility of the IEC member/staff to take confidentiality and conflict of interest agreement forms duly signed and dated.

**4. Flow chart:**

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1. | Read the text carefully and thoroughly | IEC members |
| 2. | Ask questions, if any | IEC members |
| 3. | Sign to indicate consent | IEC members |
| 4. | Keep the Agreement in mind | IEC members |
| 5. | Copy Confidential documents | IEC Secretariat |
| 6. | File log of Copies | IEC Secretariat |

## 5. Detailed instructions:

It will be the policy of the IEC of UPUMS, which every member including the Chairperson, the alternate Chairperson, and the alternate members to sign the Confidentiality/Conflict of Interest Agreement with date. Even though the member discontinues being a part of the IEC of Uttar Pradesh University of Medical Sciences, Saifai for the Clinical Studies, He/she will have to maintain confidentiality which will be valid for all the protocol related information for which he/she had access to Observation of IEC, The UPUMS for Clinical Studies meetings/ Departmental visit by Guest Attendees/research students.

- Permission to observe the Institutional Ethics Committee, Uttar Pradesh University of Medical Sciences, Saifai meetings/visits to the Office of Ethics Committee, Uttar Pradesh University of Medical Sciences, Saifai will be given only after a formal written request addressed to theChairperson/ Member Secretary.
- Permission will be granted for academic purposes and other reasons at the discretion of the Chairman/ Member Secretary.
- They will be requested to sign a Confidentiality Agreement Form for Guest Attendees to Ethics Committee, Uttar Pradesh University of Medical Sciences, Saifai Meetings/ Departmental visit.
- They will be escorted by staff of the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai.
- Care will be taken to see only the necessary documents are given access to while proposals will be stored under lock and key.

### 5.1 Read the text carefully and thoroughly

- Newly appointed members obtain two copies of the Agreement Form.
- The member is expected to read through the text of the form very carefully.

### 5.2 Ask questions if any

- Direct questions to the Secretariat if any part or sentences is not clear.
- Let the Member Secretary explain or clarify the contents of the document.

**5.3 Sign with consent**

- Sign and date both copies of the document before a member of the Secretariat.
- Give the forms back to a Member Secretary/ Secretariat to sign and date.
- The members have to keep a copy for their records

**5.4. Strategies to manage Conflict of Interest:**

- Disclose conflict of interest
- Document the conflict of interest in attendance register /minutes of the meeting
- Refrain from taking part in any discussion/review/ debate about the proposal;
- Refrain from participating in the review process of project proposal by leaving the meeting room.

**6. Glossary:**

- **Confidentiality:** The non-occurrence of unauthorized disclosure of information:
- **Confidentiality Agreement:** (Secrecy or Nondisclosure agreements). An agreement designed to protect, information, data and expertise from being misused by those who have learned about them. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
- **Conflict of Interest:** A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.
- Conflict of interest is present and interferes with ability to make an objective evaluation in cases of:
  i. Member of IEC have their own research projects under review by the Ethics Committee, when they are an investigator, co-investigator, or when they are in a supervisory or mentoring relationship with a Principal Investigator.
  ii. A member whose spouse is a Principal Investigator, co-investigator, for any project under review is also considered to have conflict of interest.

iii. Members may also be in a conflict-of-interest situation when they have interpersonal or financial relationships with the researchers, or personal or financial interests in a company, organization that may be the sponsor of the research project, or that may be substantially affected by the research.

iv. To maintain the independence and integrity of research ethics review, members must identify, eliminate, minimize, or otherwise manage real, potential or perceived conflicts of interest. If a member has a personal or financial conflict of interest, then he/she must disclose the nature of the conflict and absent themselves from any discussion or decision regarding that research project. If a member's conflict of interest and necessary withdrawal from the meeting will threaten the maintenance of quorum, the Committee can ensure that an alternate member be in attendance to maintain quorum.

**7. References:**


- Integrated addendum to ich E6(R1): guideline for good clinical practice (E6) R2-2016
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trial Rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


**8. ANNEXURES:**

**AF/IEC/ 01/03/V-2.0** Confidentiality Agreement Form for IEC members

**AF/IEC/ 02/03/V-2.0** Conflict of Interest Agreement Form for IEC members

**AF/IEC/ 03/03/V-2.0** Confidentiality Agreement Form for Guest Attendees to IEC Meetings

**AF/IEC/ 04/03/V-2.0** Confidentiality Agreement Form for Independent consultants

**AF/IEC/ 05/03/V-2.0** Confidentiality Agreement for Non-members Requesting Copy of IEC Documents

**AF/IEC/ 06/03/V-2.0** Log of Requests for Copies of IEC Documents

**AF/IEC/ 07/03/V-2.0** Log of Requests for Original Documents

**ANNEXURE: 01** **AF/IEC/01/03/V-2.0**

**Confidentiality Agreement Form for Ethics Committee Member**

In recognition of the fact, that I_____herein referred to as the "Undersigned", have beenappointed as a member of the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai, has been asked to assess research studies involving human subjects 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 fundamental duty of an IEC-Uttar Pradesh University of Medical Sciences, Saifai member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC- Uttar Pradesh University of Medical Sciences, Saifai for Clinical Studies 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 subjects;

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC-Uttar Pradesh University of Medical Sciences, Saifai. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

The undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietaryinformation belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

I have read and accepted the aforementioned terms and conditions as explained in this Agreement.

| **Undersigned Signature** | **Date** |
|---|---|
| | 18-Aug-2024 |
| **IEC Chairperson/Member secretary** | Date |
| | 18-Aug-2024 |

**ANNEXURE: 02** **AF/IEC/02/03/V-2.0**

**Conflict of Interest Agreement Form for Ethics Committee Members**

It is recognized that the potential for conflict of interest will always exist but has faith in the Ethics Committee and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the IEC of UPUMS that no member may participate in the review, comment or approvalof any activity in which he/she has a conflict of interest except to provide information as requested by the IEC, Uttar Pradesh University of Medical Sciences, Saifai for Clinical Studies.

The Undersigned will immediately disclose to the Chairperson of the Ethics Committee any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations inrespect of such proposals.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC, Uttar Pradesh University of Medical Sciences, Saifai review or approval except to provide the information requested by the Committee.

I,_____have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals.

| Undersigned Signature | Date |
|---|---|
| | |
| IEC Chairperson /Member secretary | Date |
| | |

**ANNEXURE: 03** **AF/IEC/03/03/V-2.0**

**Confidentiality Agreement Form**

**For Guest Attendees to Institutional Ethics Committee, Uttar Pradesh University of Medical Sciences, Saifai for Clinical Studies Meetings**

I .....from .....understand that I am allowed to attend the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai Full board/or SAE Review meeting as a guest or an observer. In the course of the meeting of the Ethics Committee, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information Confidential.

Indicate the details (date and number) of **the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai** Meeting attended:

.....

.....

.....

| Signature of the Guest or Observer | Date |
|---|---|
| | |
| Member Secretary | Date |
| | |
| IEC Chairperson | Date |
| | |

**ANNEXURE: 04** **AF/IEC/04/03/V-2.0**

**Confidentiality Agreement Form for independent Consultants**

I_____from_____

as a non-member of the Institutional Ethics Committee, Uttar Pradesh University of Medical Sciences, Saifai for Clinical Studies, understand that the copy(ies) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the InstitutionalEthics Committee**,** Uttar Pradesh University of Medical Sciences, Saifai and shall not duplicate, give or distribute these documents to any person(s) without permission from the Institutional Ethics Committee, Uttar Pradesh University of Medical Sciences, Saifai. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information Confidential.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

| Signature of the Independent consultant | Date |
|---|---|
| | |
| Member Secretary | Date |
| | |
| IEC Chairperson | Date |
| | |

**ANNEXURE: 05** **AF/IEC/05/03/V-2.0**

**Confidentiality Agreement Form for Non-members Requesting Copies of IEC Documents**

I_____from_____[as a non-member of Institutional Ethics Committee Uttar Pradesh University of Medical Sciences, Saifai for Clinical Studies, understand that the copy (i.es) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Institutional Ethics Committee 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 takereasonable measures and full responsibility to keep the information Confidential.

I have received copies of the following IEC documents:

.....

.....

.....

| Signature of the recipient | Date |
|---|---|
| | |
| Member Secretary | Date |
| | |
| IEC Chairperson | Date |
| | |

**ANNEXURE: 06** **AF/IEC/06/03/V-2.0**

**Log of Requests for Copies of IEC Documents**

| Sr. No | Date | Name of the Receiver | Documents Requested | Sign of the Receiver | Reason for Request |
|---|---|---|---|---|---|
| 1. | | FEFCAP ASSESSOR | Last three Years IEC Approved clinical trial documents | Electronic | Accreditation/Assessment |
| 2. | | FEFCAP ASSESSOR | IEC Membership Files | Electronic | Accreditation/Assessment |
| 3. | | FEFCAP ASSESSOR | SAE Files | Electronic | Accreditation/Assessment |
| 4. | | FEFCAP ASSESSOR | Regulatory documents | Electronic | Accreditation/Assessment |
| 5. | | | | | |
| 6. | | | | | |

**ANNEXURE: 07** **AF/IEC/07/03/V-2.0**

## Log of Requests for Original Documents

| Sr. No | Date | Name of the Receiver | Documents Requested | Signature of the Receiver | Reason for Request |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

# IEC SOP 04: Training Personnel and Ethics Committee Members

## 1. Purpose

The purpose of this section is to inform the Ethics committee personnel and members why trainingis necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information, and ethics.

New IEC members are required to undergo a training program on joining the Committee. It is the responsibility of the IEC Secretariat to give copy of the SOPs of the IEC, ICMR and CDSCO guidelinesto the IEC members for reference and use.

## 2. Scope:

The SOP applies to all personnel of the IEC.

## 3. Responsibility:

It is the responsibility of the IEC members to have them educated and trained periodically.

## 4. Flow chart:

| Sl.No | Activity | Responsibility |
|---|---|---|
| 1 | Topics for training | IEC members / staff |
| 2 | How to get trained | IEC members / staff |
| 3 | Keeping the training record | IEC members /staff |

## 5. Detailed instructions:

**5.1. Topics for training:** Ethics committee members should have knowledge of Good Clinical Practice (GCP) including, Declaration of Helsinki and other National & International guidelines like CIOMS, WHO Ethical Issues:

- Basic Research Ethics
- ICH GCP E6(R2) 2016
- CIOMS-2016
- Latest version of IEC SOP
- Any changes in the recent clinical trial regulations/guidelines

An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics will be attempted. Efforts would be made to collect information on

overseas trends and to attend international specialist meetings organized for the exchange ofexperience and information.

**5.2 How to get trained**

- All the IEC members should attend the training/ workshop organized by Internal IEC as well as external agencies at least once in a year
- Recent SOP trainings

**5.3. Keeping the training records**

- Fill in the form to record the training/workshop/conference activities in chronological order.
- Make a copy of the form.
- Keep the original form (Attendance list) as records with signed and dated.
- Give the copy to the administrative staff to keep in the IEC member training record file
- submission of copy of training certificate

**6. Glossary:**

- **Conference:** A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
- **Meeting:** Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
- **Workshop:** A group of people engaged in study or work on a creative project or subject
- **SOP Training:** IEC member secretary/Chairperson will engage on the summary of SOP changes/SOPs

**7. References:**


› International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016

› WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013

› Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017

› Standard and operational guidance for ethics review of health-related research with human participants-2011

› New Drugs and Clinical Trial Rules, 2019

› ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

**ANNEXURE: 01** **AF/IEC/01/04/V-2.0**

## Training Record Form

Name of the Topic:

Venue:

Mode of Training: Online/Offline

National/International Level:

Date and Time:

Name of the Speakers and professional Details

1. _____
2. _____
3. _____
4. _____
5. _____ Department

Name/Affiliation: Sponsoring Agencies if applicableList of Audiences attended:

Feedback:

Original Attendance list to be attached:

IEC SOP 05: Selection and Responsibilities of Independent consultants

# IEC SOP 05: Selection and Responsibilities of Independent consultants

**1. Purpose:**

The purpose of this SOP section is to provide procedures for engaging the subject expertise of aprofessional as a consultant to the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai.

**2. Scope:**

the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai for clinical trials determines that a study will involve procedures or information that is not within the area of expertise of the committee members, Chairperson of the committee in consultation with the Member-Secretary suggests individuals with competence in special areas to assist in the review ofissues that require expertise beyond or in addition to those available in the committee and appointed by the Chairperson.

**3. Responsibility:**

Upon the advice or recommendation of the Secretariat, Chairperson or any member of the IEC. it is the responsibility of the IEC chairperson and UPUMS to nominate and approve the name of the consultants to be endorsed by the IEC Chairperson.

**4. Flow Chart:**

| Sl.No | Activity | Responsibility |
|---|---|---|
| 1. | Maintaining a specialty-wise list/roster of independent Consultants | Secretariat |
| 2. | Suggestions of Independent Consultants | IEC Members / Secretariat or Chairperson |
| 3. | Appointment of Independent Consultants | Chairperson |
| 4. | Consultation Services | IEC/Secretariat/ Consultant |
| 5. | Termination of the Services | Consultant / IEC |

**5. Detailed instructions:**

**5.1 Selection and Appointment of Independent Consultants (ICs):** Identify the experts from the list of the independent consultants/roster maintained by the secretariat or by the Ethics Committee Members, Secretariat and Chairperson.

- The Chairperson/ Member Secretary on behalf of the Ethics committee will invite IC(s) selected by the committee in writing to assist in the review of the project and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming the availability of the IC through any mode of communication.
- Make decision based on expertise, availability, and independence criteria
- Get approval from the Ethics Committee.
- Contact the consultant.
- Invite the consultant to attend the meeting by sending an appointment letter signed by the Chairman of the Ethics Committee
- The Secretariat will request IC to declare competing interests, if any and sign a confidentiality agreement. The Secretariat will maintain and provide a specialty-wise roster of consultants.
  - Appointment of Independent Consultants: In accordance with the Standard Operating Procedure (SOP) of the **Institutional** Ethics Committee of UPUMS and as per the directions of IEC Members, Member Secretary and chairman the following faculty members of Uttar Pradesh University of Medical Sciences, Saifai, a constituent unit of UPUMS have been appointed as **Independent Consultants** to review the research protocols:
  - In the term of appointment of the aforesaid consultants shall be co-terminus with the of ethics Committee i.e., 02 term of 03-years

**5.2. Co-ordination with Independent Consultants for fulfilling administrative requirements**:

- The Secretariat will forward a copy of the Confidentiality Agreement and Conflict of Interest Agreements to IC(s) for careful reading, understanding, and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the Independent Consultant(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert/ Ethics Committee Members.

**5.3. Reading, understanding, and signing the Conflict-of-Interest document and Confidentiality Agreement:**

- The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement document.
- The Chairperson will sign and date the Confidentiality and Conflict of Interest
- The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC (s).

**5.4. Consultation Services:** Their professional qualifications may be in the areas of community and/or patient representation, or subject experts unique to the study proposal under ethics review. Subject experts could be invited to offer their views, based on the requirement of research area, for example HIV, genetic disorders *etc*. it is desirable to include a member from specific patient groups in the Committee. Independent Consultants are appointed only for the review of the study sought. They will ***not be able to vote*** or be involved in decision-making. The Review Report Form will be filed with the project proposal in the respective file.

**5.5. Termination of the Services:** Consultation services may be terminated by either the consultants themselves or by the IEC. Upon termination of the consultant's services, a member of the Secretariat ensures that all the qualifying documentation and the reason for discontinuation of the services are filed with the administrative documents.

**6. Glossary:**

**Independent consultant:** An expert who gives advice, comments, and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.

**7. Reference:**

- ICMR Guidelines-2017
- New Drugs and Clinical trial rules-2019

**8. Annexure:**

- AF/IEC/01/05/8.2 ICs Review Report Form

**ANNEXURE:01** **AF/IEC/01/05/V-2.0**

## Independent Consultant Review Report Form

| | | | |
|---|---|---|---|
| Protocol Number | | Version and date | |
| PI Name | | ICs Name | |
| Meeting Date (D/M/Y) | | IEC Meeting time | |

**Mark and comment on whatever items applicable to the study**.

| | | |
|---|---|---|
| 1. | Comments on the protocol | |
| 2. | Comments on the informed consent document | |
| 3. | Comments on any other issues/ aspects: | |
| 4. | Any recommendations | |

| **IEC office uses only** | |
|---|---|
| **Name of the reviewer with signature and date** | |

IEC SOP 06: IEC Protocol submission procedures

## 1. Purpose:

This standard operating procedure is designed to describe how the Secretariat of the InstitutionalEthics Committee (IEC) of UPUMS to manage the protocol submissions.

## 2. Scope:

A protocol submission includes:

- Submission for Initial Review and Approval
- Re-submission of Protocols with Corrections
- ICD/Protocol Amendments-Summary of changes
- Continuing Review of Approved Protocols
- Protocol Termination

## 3. Responsibility:

It is the responsibility of the IEC secretariat to receive, record, and distribute for review and get the proposals approved by the IEC, as well as to deliver the review results by the way of discussion with Decision to the Principal Investigator/Co-Investigator.

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1. | Receive Submitted project proposals | IEC Secretariat |
| 2. | Check for submission items<br>• Initial Review Application<br>• Re-submission of Protocols with Corrections<br>• Protocol Amendment-Summary of changes<br>• Continuing Review of Approved Protocols<br>• Protocol Termination | IEC Secretariat |
| 3. | Complete the submission process | IEC Secretariat |
| 4. | Store the received documents | IEC Secretariat |

## 5. Detailed instructions:

### 5.1. Receive submitted documents

#### 5.1.1. Initial Review Application

- Go to SOP/08/V-2.0

**5.1.2. Re-submission of Protocols with Corrections**

- Go to SOP/11/V-2.0

**5.1.3. Protocol Amendment**

- Go to SOP/12/V-2.0

**5.1.4. Continuing Review of Approved Protocols**

- Go to SOP/13/V-2.0

**5.1.5. Protocol Termination/Completion**

- Go to SOP/18/V-2.0

**5.2. Check for submission items**

**5.2.1.1. Check the received documents:** Receive the documents from the Principal Investigator after confirming that they are complete with respect to information, forms, approval letters, enclosures, page nos. on each page etc

**5.2.1.2. Initial Review**

- Check for contents of a submitted project proposal as per Checklist, form AF/IEC/01/06/V-2.0
- Review Report form: AF/IEC/02/06/V-2.0

**5.2.1.3. Re-submission of Protocols with corrections**

- Check for contents of a submitted project proposal as per Checklist, form AF/IEC/01/06/V-2.0
- Review Report form: AF/IEC/02/06/V-2.0

**5.2.1.4. Protocol Amendments**

- Check for contents of a submitted project proposal as per Checklist, form AF/IEC/01/06/V-2.0
- Review Report form AF/IEC/02/06/V-2.0

**5.2.1.5. Annual Continuing Reviews of Approved Protocols**

- Check the Annual Report with the template AF/IEC/03/06/V-2.0 for all the points covered.
- Take out the relevant file and check for the information given in report is same as mentioned in the file.

- If any point/information is missing, provide Template (soft copy) to the Principal Investigator and request them to give information as per the template only.
- Go to step 5.2.2.

**5.2.1. Protocol Termination/Completion**

- Check for contents of a submitted package, as per the format of final review AF/IEC/04/06/V-2.0 and AF/IEC/05/06/V-2.0
- Study Assessment form AF/IEC/02/06/V-2.0

**5.2.2 Fill in the forms:**

- Tick marks the points on the Checklist AF/IEC/01/06/V-2.0
- Attach the Study Assessment form AF/IEC/02/06/V-2.0

**5.2.3 Verify contents of submitted clinical trial protocol:** Title Page should be complete in following respects

- Protocol Title/No:
- Name of the Principal Investigator:
- Name of the Co- Investigator/ Collaborator:
- Enclosures with page nos.
- Face Sheet should be complete as per the Checklist (AF/IEC/01/06/V-2.0)
- Participant Information Sheet: refer (AF/IEC/05/08/V-2.0)
- To see that the entire questions are included in the Participant Information Sheet as per the given format Informed Consent Document refers (AF/IEC/06/08/V-2.0). Summary of Study Protocol and Detailed Protocol should include the following points refer: (AF/IEC/03/08/V-2.0)

**5.3 Complete the submission process**

- Check for completeness of the submitted documents
- Notify the applicants if the package is incomplete.
- State clearly the items missing in the package.
- Fill up the related parts and the missing documents.
- If the documents found to be complete, put 'Received' stamp on the Covering letter and the first page of the documents

- Initial the receiver's name on the receiving documents. Put date, time and inward number for receiving the documents.
- Attach the filled checklist (AF/IEC/01/06/V-2.0) with the copy of the Study Assessment form (AF/IEC/02/06/V-2.0) to the Research Protocol documents.

**5.4 Processing the submitted documents**

- After review of the Protocol by the Secretariat and give the IEC protocol code [eg: IEC-01-2022 first protocol in the year of 2022] to the respective protocol.
- IEC Secretariat will check for the completeness of the Ethics Committee dossier.
- Complete IEC dossier will be circulated to IEC members along with the checklist [including primary reviewers] through University-UPUMS personnel.
- Will Call/ invite the IEC members for full board review of new protocols as per the agenda.
- The submitted protocol is technically sound and reviews from the members and the same will be approved
- If the clinical trial protocol is found to be incomplete, the Principal Investigator will be asked to make the corrections in the proposal

**5.5 Create a Protocol Specific File (for Initial Review)**

- Create the 'Clinical trial protocol' file.
- Record the name of the Principal Investigator, title and assign number to the trial recorded in the XLS format
- Keep the copy of the submitted documents with original signatures in the respective file.

**5.6 Store the received documents**

- Bind the documents together appropriately.
- Store the dated and initial original protocol documents on the IEC submission shelf for review in chronological order.

**6. References:**

› International Conference on Harmonization of technical requirements for pharmaceuticals for human use E6R2-(ICH)-2016
› Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

- WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trial Rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

## 7. ANNEXURES:

(AF/IEC/01A-01AF/06/V-2.0) IEC forms and other formats for Investigator

(AF/IEC/02/06/V-2.0) Study Assessment Form for New protocol

(AF/IEC/03/06/V-2.0) Annual Report Templates

(AF/IEC/04/06/V-2.0) Study Report form for protocol termination

(AF/IEC/05/06/V-2.0) Study Report form for protocol completion

(AF/IEC/06/06/V-2.0) Clinical Trial Agreement Checklist

(AF/IEC/07/06/V-2.0) Study Principal Investigator CV Format

(AF/IEC/08/06/V-2.0) Contents of the proposed protocol for the Conducting Clinical Trail

**Annexure: 01A** (AF/IEC/01A/06/V-2.0)

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY Institutional ETHICS COMMITTEE OF UPUMS, Saifai

Submit one (1) hard copy of the Research Proposal along with Covering letter, a CD/DVD of the proposal and a 'soft copy' along with the following information to the Member Secretary, Institution Ethics Committee at the IEC office, UPUMS, Saifai.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the IEC with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant/LAR, covering all the points given,** before it can be considered for placing before the IEC. Also ensure that all the pages are numbered.

**PROJECT SUBMISSION TIME**: SUBMISSIONS WILL BE RECEIVED ON ALL WORKING DAYS. PROPOSALS RECEIVED TILL specified date WILL BE PROCESSED IN THE COMING INSTITUTION ETHICS COMMITTEE MEETING AND THOSE RECEIVED AFTER WILL BE PROCESSED IN THE NEXT INSTITUTION ETHICS COMMITTEE MEETING. ALL MEETINGS OF INSTITUTION ETHICS COMMITTEE WILL BE HELD Quarterly AS FAR AS POSSIBLE. THE FREQUENCY WILL CHANGE DEPENDING UPON THE NUMBER OF PROPOSALS AND WILL BE UPDATED accordingly.

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC Moreover if the approval is required in a particular format, the same may be submitted in a CD/DVD.

**Amendment Submission:** While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

**(Kindly read the instructions carefully and do abide by the above.)**

FORM TO BE FILLED BY THE PRINCIPAL INVESTIGATOR/Research Scholar (UG/PG/PhD/Super Specialty) FOR SUBMISSION TO
INSTITUTIONAL ETHICS COMMITTEE (IEC), UPUMS, Saifai

(FOR ATTACHMENT TO EACH COPY OF THE PROPOSAL)

Serial No of IEC Management Office:

TITLE OF THE PROJECT:
……...

……

| Strike off which is not applicable | **Name, Designation, Department** | **Mobile No. Email ID** | **Number of Projects already with Investigator** | **Signature** |
|---|---|---|---|---|
| **Principal Investigator/ Research Scholar** (UG/PG/PhD/Super Specialty) | | | | |
| **Co-PI/Guide** | | | | |
| **Co-PI/Co-Guide** | | | | |
| **Co-PI/Co-Guide** | | | | |
| | | | | |
| | | | | |
| | | | | |

**Name, Mobile Number and Email ID should be clearly written.**

| | | | |
|---|---|---|---|
| **Sponsor Information** :<br>1. Indian a) Government ☐<br>b) Private ☐ | Central ☐ | State ☐ | Institutional ☐ |
| 2. International Government ☐ | Private ☐ | | UN agencies ☐ |
| 3. Industry National ☐ | Multinational ☐ | | |
| **Contact Address of Sponsor:** | | | |
| **Total Budget**: | | | |
| Who will bear the cost of investigation / implants drugs / contrasts? | 1.Patient | 2.Project | 3. Exempted |
| | 4. Other Agencies | | |

**1.Type of Study :** Cross sectional case control cohort Clinical Trial Review

Participating Centre : Single center Multi-centric Others (Specify)

**2. Status of Review:** New ☐ Revised ☐

Clinical Trials:

**Drug /Vaccines/Device/Herbal Remedies:**

i. Does the study involve use of:

Drug ☐ Devices ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐

**ii.** Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

| | | |
|---|---|---|
| **iii.** Does it involve a change in use, dosage, route of administration? | Yes | No |
| **If yes**, whether DCGI's /Any other Regulatory authority's Permission is obtained? | Yes | No |
| **If yes,** Date of permission : | | |

| | | |
|---|---|---|
| **iv.** Is it an Investigational New Drug?<br><br>**If yes,** IND No: | Yes | No |
| a). Investigator's Brochure submitted | Yes | No |
| b). *In vitro* studies data | Yes | No |
| c). Preclinical Studies done | Yes | No |
| d). Clinical Study is : Phase I Phase II Phase III Phase IV | | |
| e). Are you aware if this study/similar study is being done else-where?<br><br>**If Yes**, attach details | Yes | No |

**4. Brief description of the proposal** – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures,

statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

**5. Subject selection:**

| | | | |
|---|---|---|---|
| ii. | Duration of study : | | |
| iii. | Will subjects from both sexes be recruited | Yes | No |
| iv. | Inclusion / exclusion criteria given | Yes | No |
| v. | Type of subjects Volunteers Patients | | |
| vi. | Vulnerable subjects Yes No | | |

(Tick the appropriate boxes)

| | | | | | |
|---|---|---|---|---|---|
| pregnant women | ☐ | children | ☐ | elderly | ☐ |
| Fetus | ☐ | illiterate | ☐ | handicapped | ☐ |
| Mental | ☐ | terminally ill | ☐ | seriously ill | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| i. | Special group subjects | Yes | ☐ | No | ☐ |

(Tick the appropriate boxes)

| | | | | | |
|---|---|---|---|---|---|
| captives | ☐ | institutionalized | | employees | ☐ |
| students | ☐ | nurses/dependent | | armed | ☐ |
| any other | ☐ | staff | | forces | ☐ |

**6. Privacy and confidentiality**

| | | | |
|---|---|---|---|
| i. | Study involves - | Direct Identifiers | ☐ |
| | | Indirect Identifiers/coded | ☐ |
| | | Completely anonymised | ☐ |

| | | | |
|---|---|---|---|
| ii. | Confidential handling of data by staff | Yes | No |
| **7. Use of biological/ hazardous materials** | | Yes | No |
| ii. | Use of organs or body fluids | Yes | No |
| iii. | Use of recombinant/gene therapy | Yes | No |
| **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained? | | Yes | No |
| iv. | Use of pre-existing/stored/left over samples | Yes | No |
| v. | Collection for banking/future research | Yes | No |
| vi. | Use of ionizing radiation/radioisotopes | Yes | No |
| **If yes,** has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? | | Yes | No |
| vii. | Use of Infectious/bio hazardous specimens | Yes | No |
| viii. | Proper disposal of material | Yes | No |
| ix. | Will any samples collected from the patients be sent abroad? | Yes | No |
| **If Yes, justify with details of collaborators** | | | |

| | | |
|---|---|---|
| a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? | Yes | No |

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐

Facility in India inaccessible ☐

Facility available but not being accessed. ☐

If so, reasons…

**8. Consent :** *Written ☐ Oral ☐ Audio-visual ☐

i.CONSENT FORM : (TICK THE INCLUDED ELEMENTS)

| | | | |
|---|---|---|---|
| Understandable language | | Alternatives To participation | |
| Statement that study involves research | | Confidentiality Of records | |
| Sponsor of study | | Contact information | |
| Purpose and procedures | | Statement that Consent is voluntary | |
| Risks & Discomforts | | Right to withdraw | |
| Benefits | | Consent for future use of biological material | |
| Compensation for participation | | Benefits if any On future commercialization eg. genetic basis for Drug development | |
| Compensation for study related injury | | | |

*if written consent is not obtained, give reasons.

| | |
|---|---|
| ii. Who will obtain consent? PI/Co-PI | Nurse/ Counsellor |

| | | | |
|---|---|---|---|
| Research staff | Any other | | |
| **9. Will any advertising be done for recruitment of Subjects?**<br>(posters, flyers, brochure, websites – if so kindly attach a copy) | | Yes | No |
| **10. Risks & Benefits:**<br>i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? | | Yes | No |
| ii. Is there physical / social / psychological risk / discomfort?<br>**If Yes,** Minimal or no risk<br>More than minimum risk<br>High risk | | Yes | No |
| iii. Is there a benefit<br>a) to the subject?<br>Direct<br>Indirect<br>b) Benefit to society | | | |
| **11. Data Monitoring**<br>i. Is there a data & safety monitoring committee/ Board (DSMB)? | | Yes | No |
| ii. Is there a plan for reporting of adverse events?<br>**If Yes,** reporting is done to :<br>Sponsor Ethics Committee DSMB | | Yes | No |
| iii. Is there a plan for interim analysis of data? | | Yes | No |
| iv. Are there plans for storage and maintenance of all trial database?<br>**If Yes,** for how long? | | Yes | No |
| **12. Is there compensation for participation?**<br>**If Yes,** Monetary In kind | | Yes | No |

| | | |
|---|---|---|
| **13. Is there compensation for injury?**<br>**If Yes,** by Sponsor | Yes | No |
| **14. Do you have conflict of interest?**<br>**(financial/non-financial) If Yes, specify :** | Yes | No |
| Conflict of interest for any other investigator(s) (if yes, please explain in brief | 1_____Yes<br>2_____Yes | |
| 15. Participant Information Sheet<br>*(mark √ if yes)* | Attached English version<br>Attached Hindi version | |
| 16. **Participant Informed Consent Form**<br>*(mark √ if yes)* | Attached English version<br>Attached Hindi version | |
| 17. Whether any work on this project has started or not? | *(mark √ if yes, X if no) (Please Separate certificate to this effect).* | |
| 18. In case of clinical trials CTRI status | | |

# CHECKLIST FOR ATTACHED DOCUMENTS

*Covering letter, through proper channel forwarded by Head of Department . . . . . ☐

*Project proposal – 01 Copy . . . . . ☐

*Curriculum Vitae of Investigators . . . . . ☐

*Brief description of proposal . . . . . ☐

*Patient information sheet (PIS) . . . . . ☐

*Patient Informed Consent form (PICF). . . . . ☐

*Soft Copy of the Proposal . . . . . ☐

Investigator's brochure . . . . . ☐

Copy of advertisements/Information brochures . . . . . ☐

Copy of clinical trial protocol and/or questionnaire . . . . . ☐

HMSC/DCGI/DBT/BARC clearance (if required) . . . . . ☐

*Undertaking that the study shall be done in accordance with ICMR and GCP guidelines . . . . . ☐

*Undertaking that Left over blood will be disposed off in controlled & regulated manner . . . . . ☐

*Undertaking of responsibility in case of adverse event . . . . . ☐

In case of multi-centric study, IEC clearance of other centres must be provided . . . . . ☐

Definite undertaking as to who will bear the expenditure of injury related to the project . . . . . ☐

If an insurance cover is intended . . . . . ☐

Insurance certificate must be provided (as per ICMR guidelines) . . . . . ☐

Permission to use copyrighted Questionnaire / Perform . . . . . ☐

Investigator should provide undertaking what they will do with the leftover sample tissue . . . . . ☐

Certificate/undertaking as mentioned in column 17 . . . . . ☐

Others . . . . . ☐

[NOTE: REQUIRED DOCUMENTS MARKED WITH [ * ] ARE MANDATORY]
Please do not submit without required documentation.

**Annexure: 01B** (AF/IEC/01B/06/V-2.0)

## PATIENT INFORMATION SHEET

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in **English and Hindi, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points**:

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample (quantity in tea spoon full) to be taken
11. Costs and source of investigations, disposables, implants and drugs/ contrast media
12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
13. In case of a drug trial:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug/ references should be provided
14. Self-certification should be given that the translation to vernacular language is correct

# रोगी सूचना पत्र

नाबालिग के मामले में परियोजना रोगी या प्रतिभागी या अभिभावक / अभिभावक को संबोधित प्रतिभागी सूचना पत्र के साथ होना चाहिए। प्रतिभागी सूचना पत्र तैयार करते समय, जांचकर्ता को निम्नलिखित सामान्य जानकारी वाले विषयों को अंग्रेजी और हिंदी में एक साधारण आम आदमी की भाषा में प्रदान करना होगा  जिसे उनके द्वारा समझा जा सकता हैए एक कथा रूप में, प्रतिभागी / एलएआर को निर्देशित किया गया, जिसमें सभी बिंदु शामिल हैं।

1. अध्ययन शीर्षक
2. अनुसंधान अध्ययन के लक्ष्य और तरीके
3. भागीदारी की अपेक्षित अवधि
4. अनुसंधान से प्रतिभागी या दूसरों के लिए अपेक्षित लाभ
5. अध्ययन से जुड़े प्रतिभागी को कोई जोखिम या असुविधा
6. अभिलेखों की गोपनीयता का रख-रखाव
7. अनुसंधान से संबंधित चोट के लिए नि शुल्क उपचार की व्यवस्था
8. ऐसी चोट से होने वाली विकलांगता या मृत्यु के लिए विषयों का मुआवजा
9. किसी भी समय जुर्माना या लाभ के नुकसान के बिना व्यक्तिगत रूप से भाग लेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिसके लिए विषय अन्यथा हकदार होगा
10. रक्त नमूना की मात्रा (चाय चम्मच में मात्रा पूर्ण) लेने के लिए
11. जांच, निपटान, प्रत्यारोपण और दवाओं / विपरीत मीडिया की लागत और स्रोत
12. प्रत्येक पृष्ठ के शीर्ष पर सिद्धांत जांचकर्ता और सह.जांचकर्ता का टेलीफोन नंबर / संपर्क संख्या
13. दवा परीक्षण के मामले में:

    ए) दवा का रासायनिक नाम, इसके विनिर्माण और बैच संख्या की तारीख का उल्लेख किया जाना चाहिए

    ख) दवा / संदर्भों का प्रारंभिक बायोइक्विलेंस अध्ययन प्रदान किया जाना चाहिए

14 आत्म-प्रमाणीकरण दिया जाना चाहिए कि स्थानीय भाषा का अनुवाद सही है

**Annexure: 01C** (AF/IEC/01C/06/V-2.0)

## PARTICIPANT INFORMED CONSENT FORM

Patient Identification Number (PIN) for this study:_____

**(Title of the project)**

Name of Principal investigator:……

Designation……., Department .....,

Tel.No(s)……email ID……

The contents of the information sheet dated..... that was provided have been read carefully by me/ explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks/ benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw from the study at anytime, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from UPUMS, Saifai. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:

(Signatures /Left Thumb Impression) Place:

Name of Participant:_____Son/Daughter/spouse of:_____ Complete postal address:_____

This is to certify that the above consent has been obtained in my presence.

---------- Date:

Signatures of the Principal Investigator Place:

| **1) Witness–1 (Subject's relative)** | **2)Witness–2** |
|---|---|
| ---------- | ---------- |
| Signature | Signature |
| Name: | Name: |
| Address: | Address: |

**NB: Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution**

**(Investigators are advised to prepare the translation in simple understandable Hindi on their own)**

## सहभागी सुचित सहमति प्रपत्र

इस जांच के लिए सहभागी पहचान नम्बर.....
अनुसंधान शीर्षक .....
मुख्य अन्वेषक का नाम.....
पद .....
फोन नं0.....
मैने दिनांक ..... के सूचना पत्र में दिये गये सभी तथ्यों को पढ़ लिया है। मुझे समझ आने वाली भाषा में विस्तारपूर्वक बता दिया गया है और मैने तथ्यों को भलीभाँति समझ लिया है। मै पुष्टि करता/करती हूँ कि मुझे प्रश्न पूछने का अवसर दिया गया है।
मुझे अध्ययन की प्रकृति, उद्देश्य तथा इसके सम्भावित लाभ/जोखिमों और अध्ययन की सम्भावित अवधि एवं अन्य प्रासंगिक जानकारी के बारे में विस्तारपूर्वक समझा दिया गया है। मैं समझता हूँ कि इस अध्ययन में मेरी भागेदारी स्वैच्छिक है और इस अध्ययन से किसी भी समय बिना कोई कारण बताए, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हुए मै अपना नाम वापस ले सकता/सकती हूँ।
मै समझता/समझती हूँ कि इस अनुसन्धान में मेरी सहभागिता से मेरे बारे में एकत्र जानकारी और चिकित्सा नोटों को यूपीयूएमएस, सैफई अस्पताल के जिम्मेदार लोगो द्वारा देखा जायेगा। मै इन व्यक्तियों को अपने रिकार्ड देखने की अनुमति प्रदान करता/करती हूँ।
मैं उपर्युक्त अध्ययन में भाग लेने के लिये अपनी सहमत प्रदान करता/करती हूँ।
सहभागी के हस्ताक्षर/बाएं अंगूठे का निशान दिनांक स्थान
सहभागी का नाम
पिता/पति का नाम
पूरा पता
यह प्रमाणित किया जाता है कि उपर्युक्त सहमति मेरी उपस्थति में ली गई है
मुख्य अन्वेषक के हस्ताक्षर दिनांक स्थान

1. गवाह के हस्ताक्षर (रिश्तेदार)

नाम
पता

2) गवाह के हस्ताक्षर

नाम
पता

**Annexure: 01D** (AF/IEC/01D/06/V-2.0)

# UNDERTAKING

IEC-UPUMS, Saifai Serial No and Date: ……..…….

Title of the Proposal: ……..……
……

I,…….....…..... (Name of PI/Research Scholar), ……..…… (Designation)…… (Dept.) do hereby solemnly state and affirm that the above mentioned project shall be done in accordance with the guidelines of ICMR and GCP.

……
(Signature of Principal Investigator/Research Scholar)

Date: ……

**Annexure: 01E** (AF/IEC/01E/06/V-2.0)

# UNDERTAKING

IEC-UPUMS, Saifai Serial No and Date: ……..

Title of the Proposal: ……..
……

I,…….. (Name of PI/Research Scholar),

…….. …… (Designation)……

(Dept.) do hereby solemnly state and affirm as under.

1. The above mentioned project shall be done in accordance with ICMR and GCP Guidelines.
2. ……
   (Name and Address of the Institute/Sponsor/Individual)
   will be responsible in case of any adverse event caused due to deviation in above mentioned guidelines.

Signature of the Individual/ Head of the Institute/ Sponsor with Seal

(Signature of Principal Investigator/Research Scholar)

Name and Mobile No. of the person to be contacted in case of adverse event.

1.
2.
3.
4.
5.

**Annexure: 01F** (AF/IEC/01F/06/V-2.0)

# UNDERTAKING

IEC- UPUMS, Saifai Serial No and Date: ……..

Title of the Proposal: ……..
……

I, ……..…..... (Name of PI/Research Scholar), ……..…… ..…… (Designation)…….
(Dept.) do hereby solemnly state and affirm as under:
We are taking ……..…… (ml) of Blood to conduct the below mentioned test in accordance

with the stated project/research.

A.

B.

C.

D.

E.

Once all the necessary tests are done and completed, the left over blood samples are trashed in biohazard bins which are specially tagged for incineration process and then the leftover Blood are disposed-off in a very controlled and regulated manner.

……
(Signature of Principal Investigator/Research Scholar)

Date: ……

**ANNEXURE: 02** **(AF/IEC/02/06/V-2.0)**

**Study Assessment Form for Reviewer**

Protocol Number: Date (D/M/Y):

Name of Principal Investigator:

Protocol version and date:

Primary Reviewer's name with Designation:

| Sl. No | Particulars | Appropriate | Not Appropriate | N/A | Comments |
|---|---|---|---|---|---|
| 1. | **Scientific related issues** | | | | |
| | Rationale | | | | |
| | Objectives | | | | |
| | Study design | | | | |
| | Study population | | | | |
| | Inclusion Criteria | | | | |
| | Exclusion Criteria | | | | |
| | Withdrawal criteria | | | | |
| | Procedures used in research | | | | |
| | The use of placebo | | | | |
| | The use of medical device | | | | |
| | Method of Research Assessment<br>- Assessment of efficacy<br>- Assessment of safety | | | | |
| | Monitoring Complications and solutions | | | | |
| | Blood or specimens [Frequency & Amount] | | | | |
| | Duration and number of follow up | | | | |
| | Statistics used in analysis | | | | |
| 2. | **Ethical issues** | | | | |
| | Involvement of Vulnerability | | | | |
| | - Identification of Vulnerability<br>- Justification for the use of Vulnerable population<br>- Protection of Vulnerable groups | | | | |
| | Risk to the health of participants | | | | |
| | - Identify the risk: physical, | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | psychological, economic, legal risk or risk due to invasion of privacy and confidentiality | | | | |
| | Sufficient measures to prevent or minimize the risks | | | | |
| | Risk to the health of the embryo or the unborn child or spouse | | | | |
| | Risk to the research community | | | | |
| | Direct benefits to participants<br>-During and after the study | | | | |
| | Benefits to Society | | | | |
| | Favorable benefits/risk ratio | | | | |
| **3.** | **Informed consent issues** | | | | |
| | a. Person who obtained informed consent<br>b. Time when informed consent was conducted<br>c. Place where informed consent was obtained | | | | |
| | Objective of the research | | | | |
| | Voluntary | | | | |
| | Right to withdraw from the study | | | | |
| | Alternatives in case of non-participation | | | | |
| | Rationale of the study | | | | |
| | Study procedure and participant's responsibilities | | | | |
| | Risks or discomforts to the participants | | | | |
| | Benefits to the participants or others | | | | |
| | Medical care during the study | | | | |
| | Payment/reimbursement/compensation | | | | |
| | Privacy and confidentiality | | | | |
| | Name, contact address, and telephone number of the investigator | | | | |
| | Contact address and telephone number of | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | the ethics committee | | | | |
| | Certificate of informed consent form/Assent form | | | | |
| | Language used in the informed consent form | | | | |
| **4.** | **Qualification of Investigator** | | | | |
| | Expertise of investigator(s) | | | | |
| | Training of the investigator(s) (GCP for clinical trials or Human Participant Protection) | | | | |
| | Conflict of interest of the investigator(s) | | | | |

**For medical device protocols:**

Non-significant risk ☐

Significant risk ☐

- Registered with USFDA/MDD approval with supporting document of registration ☐
- Not yet registered with USFDA/MDD or no evidence or information for risk determination ☐

**Risk assessment of the protocol:**

- Research not involving more than minimal risk ☐
- Research involving greater than minimal risk but presenting the prospect of direct benefit to the participants ☐
- Research involving greater than minimal risk and no prospect of direct benefit to individual participant, but likely to yield generalizable knowledge about the participant's disorder or condition ☐

**Duration of progress report:**

**06**-Months ☐ **12** Months ☐

**Opinion of the Reviewer**:

Approve ☐

Minor modification(s) ☐

Major modification (s) ☐

Disapprove, ☐

please provide reason(s): _____

**Reviewer Name signature and date**

**ANNEXURE: 03** **AF/IEC/03/06/V-2.0**

## Study Report Form for Protocol Termination

Protocol No.: Protocol

Title: Principal

Investigator:

Date of IEC Approval with reference NumbersPhone

number/E-mail address:

Sponsors /Funding Agencies Name:

Address:

Phone/E-mail:

Study site(s): No. of Participants as each site:Study

Design and Sample Size:

Objectives:

Methodology:

Duration of the study:

Total Number of study participants:

No.of Study Arms (If any):

Number of participants in each of the Study Arms:

Study dose(s):

Reasons for termination (if any):

Provision for follow-up of patients:

Whether the study samples are being retained for future use:Results:

(Use extra blank paper, if more space is required.)Outcome

and Implications of the Study:

Presentations (If any):

Signature of P.I.: Date:

**ANNEXURE: 04** **AF/IEC/04/06/V-2.0**

**Study Report Form for study Completion**

Protocol No.: Principal Investigator:

Protocol Title:

Date of Final IEC Approval Phone

number: E-mail address:

Sponsors /Funding Agencies Name:

Address:

Phone: E-mail:

Study site(s): No. of Participants as each site:Study

Design and Sample Size:

Objectives:

Duration of the study:

Total Number of study participants:

No. of Study Arms (If any): Number of participants in each of the Study Arms:Study

dose(s):

Provision for follow-up of patients:

Whether the study samples are being retained for future use:Outcome

and Implications of the Study:

Presentations (If any):

Signature of P.I.: Date:

**ANNEXURE: 05** **AF/IEC/05/06/V-2.0**

**Clinical Trial Agreement Checklist**

| Sl. No | Description | Yes | No |
|---|---|---|---|
| 1. | **Protocol Number and Title** | | |
| 2. | **Effective date** | | |
| 3. | **Parties Involved** - (Sponsor / CRO, Principal Investigator, Institution and or SMO) **Bipartite** | | |
| | **Tripartite** | | |
| | **Quadra parted** | | |
| 4. | **Agreed terms** - Definition, Conduct of the study, Responsibility of the company, Principal investigator, Institution | | |
| 5. | **Study drug and Materials** | | |
| 6. | **Study and Protocol** | | |
| 7. | **The Study Schedules** | | |
| 8. | **Monitoring and audit by the company** | | |
| 9. | **Inspection by the regulatory authorities** | | |
| 10. | **Payment Details**- Budget and Payment scheduled, Payment of cost outside budget and payment schedule, Payment terms, payment recipient and address, Reimbursement, Payment for screen failure, payment for study Coordinator. | | |
| 11. | **Obligations of the institution and Principal Investigator** - EC Approval, Performance of the study, Key personnel, sponsor Visit, Supplies | | |
| 12. | **Study Records , reports and Data** - Study records , Case report form, Annual reports, Final Reports , **(In case of PI is no longer associated with the institute, Institute head or authorized designee will be responsible for maintenance and retention of study records)** , Reporting of SAE( Sponsor, EC, DCGI and head of institution ), 14th day PI analysis Report ( Sponsor, EC,DCGI and head of institution ). | | |
| 13. | **Confidentiality** | | |
| 14. | **Publications** | | |
| 15. | **Ownership of materials, data, inventions and discoveries.** | | |
| 16. | **Representations, warranties and covenant**.- Of the PI, Of the Sponsor, No other Representations or warranties, Of the Institutions | | |

| | | | |
|---|---|---|---|
| **17.** | **Governing Law -**This agreement and any dispute or claim out of or in connections with it or its subject matter (including non- contractual disputes or claims ) shall be governed by and constructed in accordance with the laws of India without regard to the conflict of law principles thereof. The parties irrevocably agree that the courts of India shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this agreement or its subject matter (including non-contractual disputes or claims). | | |
| **18.** | **Indemnification** - Sponsor Indemnification, Institution Indemnification, Notification, Claims, Representation, subject injury. | | |
| **19.** | **Insurance** - Sponsor insurance, Institution Insurance | | |
| **20.** | **Compliance, Transparency, Anti - bribery, Anti- corruption and Conflict of Interest**. | | |
| **21.** | **Term and Termination** | | |
| **22.** | **Miscellaneous** | | |
| **23.** | **Agreed by the parties** - Sponsor/ CRO, PI, Institution, SMO ( if involved) | | |
| **24.** | **Witness details** | | |
| **25.** | **Payee Details of the Hospital:** Head of the Institution:<br>Fund Transfer in the Name of Research Cell -UPUMS, Saifai for clinical trial **-**Institutional overhead charges: 10% | | |
| **26.** | **Payee Details of the Ethics Committee of UPUMS**<br>Fund Transfer to Research Cell -UPUMS, Saifai | | |
| **27.** | **Research funds to be paid in the name of Research Cell -UPUMS, Saifai**<br>**For the Non- Global study/ Global study** | | |
| **Name and sign of the reviewer** | | | |
| | | | |

**ANNEXURE:06** **AF/IEC/06/06/V-2.0**

**Study Principal Investigator CV Format**

| | |
|---|---|
| **Name:** | |
| **Present affiliation (Job title, department, and organisation):** | |
| **Address (Full work address):** | |
| **Telephone number:** | **Email address:** |
| **Qualifications:** | |
| **Professional registration (Name of body, registration number and date of registration):** | |
| **Previous and other affiliations (Include previous affiliations in the last 5 years and other current affiliations):** | |
| **Clinical trials undertaken in the last 03 years:** | |
| **Relevant research training/experience in the area:** | |
| **Relevant publications** *(Give references to all relevant publications in the last three years)*: | |
| | |
| | |
| **Signature and date** | |

**ANNEXURE: 07** **AF/IEC/07/06/V-2.0**

## Contents of the proposed protocol for the conducting clinical trial

a. Full title of the clinical study,
b. Protocol, Study number, and protocol version number with date.
c. The Investigational New Drug (IND) name/number of the investigational drug.
d. Complete name and address of the Sponsor and contract research organization if any.
e. List of the investigators who are conducting the study, their respective institutional affiliations and site locations
f. Name of clinical laboratories and other departments and/or facilities participating in the study.

**Table of Contents**

1. Background and introduction
    a. Preclinical experience
    b. Clinical experience:

        Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends existing data should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.
2. Study rationale: This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.
3. Study objective (primary as well as secondary) and their logical relation to the study design.
4. Study design
    a. **Overview of the study design:** Including a description of the type of study (i.e., double-blind, multicentre, placebo controlled, etc.), a detail of the specific treatment groups and number of study Subjects in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.
    b. Flow chart of the study
    c. A brief description of the methods and procedures to be used during the study.

d. Discussion of study design: This discussion details the rationale for the design chosen for this study.

5. Study population: the number of subjects required to be enrolled in the study at the investigative site and by all sites along with a brief description of the nature of the subject population required is also mentioned.
6. Subject eligibility

a. Inclusion criteria

b. Exclusion criteria

7. Study assessments-plan, procedures and methods to be described in detail.
8. Study conduct stating the types of study activities that would be included in this section would be: medical history, type of physical examination, blood or urine testing, electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review, etc.

   Each visit should be described separately as Visit 1, Visit 2, etc.

   *Discontinued subjects:* Describes the circumstances for Subject withdrawal, dropouts, or otherreasons for discontinuation of Subjects. State how dropouts would be managed and if they wouldbe replaced describe the method of handling of protocol waivers if any. The person who approvesall such waivers should be identified and the criteria used for specific waivers should be provided. Describes how protocol violations will be treated, including conditions where the study will beterminated for noncompliance with the protocol.
9. Study treatment-
   a. Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of
   b. Placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drug(s),
   c. Their doses, frequency, and duration of concomitant treatment should be stated.
   d. Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations Details of the product stability, storage requirements and dispensing requirements should be provided. Dose modification for study drug toxicity:

Rules for changing the dose or stopping the study drug should be provided Possible druginteractions

e. Concomitant therapy: The drugs that are permitted during the study and the conditions under which they may be used are detailed here. Describe the drugs that a Subject is not allowed to use during parts of or the entire study. If any washout periods for prohibited medications are needed prior to enrolment, these should be described here.

f. Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the Investigator and/or the Subject

g. Un-blinding procedures: If the study is blinded, the circumstances in which un-blinding may be done and the mechanism to be used for un-blinding should be given

10. Adverse Events:

Description of expected adverse events should be given. Procedures used to evaluate an adverse event should be described.

11. Ethical considerations: Give the summary of:

a. Risk/benefit assessment:

b. Ethics committee review and communications

c. Informed consent process

d. Statement of subject confidentiality including ownership of data and coding procedures.

e. Vulnerability

f. Privacy and Confidentiality

12. Study monitoring and supervision

13. Investigational Product Management:

a. Give investigational product description and packaging (stating all ingredients and the formulation of the investigational drug and any placebos used in the study)

b. The precise dosing required during the study

c. Method of packaging, labeling and blinding of study substances

d. Method of assigning treatments to subjects and the subject identification code numbering system

e. Storage conditions for study substances

f. Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed, and returned or destroyed.

g. Describe policy and procedure for handling unused investigational products.

14. Data Analysis: Provide details of the statistical approach to be followed including sample size, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints (primary as well as secondary) and safety endpoints.

    *Statistical analysis:* Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used, and the methods used for missing data; method of evaluation of the data for treatment failures, non-compliance, and Subject withdrawals; rationale and conditions for any interim analysis if planned.

    Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable.

15. Undertaking by the Investigator

16. Appendices: Provide a study synopsis, copies of the informed consent documents (patient information sheet, Informed consent form etc.); Case Record Form (CRF) and other data collection forms; a summary of relevant preclinical safety information and any other documents referenced in the clinical protocol.

    1. Protocol- if any amendments- Summary of changes
    2. Investigator brochure
    3. CRF
    4. Patient materials Diaries if applicable
    5. Final/Draft Clinical Trial Agreement
    6. CV, MRC and GCP of PI
    7. CTRI
    8. DCGI Approval Letter/Submission letter
    9. Sponsoring agent Details
    10. Study or site-specific insurance
    11. ICDs –all vernacular languages – Translation and back translation certificates

# IEC SOP 07: Expedite Review Process

**1. Expedited review:**

A review will be processed by minimum of 5 Institutional Ethics Committee members and Chairperson. the proposals with minor changes to the approved study proposals and those presenting no more than minimal risk to research participants may be subjected to expedited review

**2. Purpose:**

The purpose of this SOP is to provide criteria for determination of which study *proposals* can be reviewed through expedited process as well as instructions on composition of ERC (Expedited reviewCommittee), appointment of members, management, review and approval of the expedited review.

**3. Scope:**

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments, changes in the Participant Information Sheet and/ or Informed Consent Document of currently approved studies as per National and International guidelines

**4. Nature of Study Proposals considered for expedited review process:**

The study proposals considered for the ERC include

- **a.** Where there is no additional risk or activity is limited to data analysis.
- **b.** Research activities that involve only procedures listed in one or more of the following categories:
  - Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
  - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
- **c.** Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
- **d.** When in required situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

**4. Flow chart:**

| Sl.No. | Activity | Responsibility |
|---|---|---|
| **1.** | Receive the submitted documents. | IEC Secretariat |
| **2.** | Determine protocols for expedited review. Agenda will be tabulated with titles of study proposals and reasons for ERC referral as heading | Members with consultation and concurrence from the Chairperson. |
| **3.** | Expedited review process | IEC members and secretariat |
| **4.** | Communicate with the IEC- full board and the Investigator. | Member Secretary and IEC Secretariat |

## 5. Detailed instructions

### 5.1 Receive the submitted documents.

- Receive the application documents submitted by investigators.
- Fill the relevant checklist to check items received.
- Inward Stamp which includes the receiving date on the letter and the documents.
- Sign the receiver's name on the receiving documents.
- Hand over the received documents to the IEC secretariat.

### 5.2 Determine protocols for expedited review.

IEC Secretariat determines whether a study is qualified for expedited review according to the following criteria:

#### 5.2.1 Modification /amendment of protocol with minimal changes

- Administrative revisions, such as correction of types
- Addition or deletion of non-procedural items, such as the addition or deletion of study personnel names, laboratories, etc.

- Non-significant risk research activity

**5.2.2** Proposals involve interviewing of a non-confidential nature (not of a private e.g. relate to sexual preference etc.), not likely to harm the status or interests of the individual and not likely to offend the sensibilities of the people involved.

**5.2.3** Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use.

Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However, procedures involving the *use of x*-rays or microwaves are NOT recommended for expedited review.

**5.2.4** Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.

**5.2.5** No additional risks have been identified.

**5.2.6** Health Systems Research with no more than minimal risk such as collecting the information on health problems with non-identifying personal information etc. If the protocol satisfied any of the criteria for expedited review, the secretariat will send the protocol to Chairperson and the members of the IEC of UPUMS.

**5.3 Expedited Process: Selection procedure for expedited reviewers**

- The study proposal will be reviewed by the at least 2 Reviewers based on expertise & a Layperson if there's informed consent forms
- The member secretary in consultation with the Chairperson will decide the reviewers only in case of when required, depending on the nature of protocol and the expertise in the committee.
- Carry out the expedited review on the complete proposal (study protocol with all the attached documents as mentioned in the guidelines for submission of proposals).
- Reviewers' fill-up the Assessment Form & submit or return back to IEC office within 05 working days
- The expedited review should not take longer than 2 weeks.

- If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review.

**5.4 Communicate with the IEC and the investigator.**

- Full Board notification of items approved through expedited review by the Chairperson or the designee is accomplished by providing notification and source documentation of the items in the meeting agenda / notes.
- Decision will be documented as Approved/ Referred for Regular full Review. The IEC Secretariat communicates the decision to the investigator signed by the Member Secretary and the Chairperson/Alternate Chairperson.

## 6. Glossary:

**Expedited approval** - An IEC approval granted only by the Chairman of the IEC (not the full Board)for research which involves no more than minimal risk.

## 7. References:


› International Conference on Harmonization of technical requirements for pharmaceuticals for human use E6R2(ICH)-2016

› Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

› WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013

› Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017

› Standard and operational guidance for ethics review of health-related research with human participants-2011

› ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


## 8. ANNEXURE

AF/IEC/01/07/V/8.2 Document HistoryAF/IEC/02/07/V/8.2

Checklist

**ANNEXURE: 01** **AF/IEC/01/07/V-2.0**

**Document History**

| Author | Version | Date | Description of the Change |
|---|---|---|---|
| | | | |

**ANNEXURE: 02** **AF/IEC/02/07/V-2.0**

## Checklist of Documents for Expedited Review

| Sl. No. | Documents | Y/No/NA |
|---|---|---|
| **1.** | Covering letter | |
| **2.** | Study proposal | |
| **3.** | Justification for consideration under Expedited Review | |

IEC SOP 08: Initial Review Procedures

# IEC SOP 08: Initial Review Procedures

## 1. Purpose:

This SOP describes how the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai for Clinical trial Protocols will review the initially submitted protocol proposal/Community related subject proposals for approval/review by the Ethics Committee.

## 2. Scope:

This SOP applies to the review and assessment of all protocols submitted for initial review and decision from the IEC. the 02 primary reviewers and layperson will review the Ethics Committee dossier prior to full board meeting and thereafter to the IEC members for further checking with respect to scientific and ethical aspects for the clinical trial proposals. The IEC members and the Member Secretary will provide their suggestions. Relevant points made during full board discussion and deliberation about a specific protocol should be documented.

## 3. Responsibility:

It is the responsibility of the Secretariat to check for the completeness of the documents and mark the points on the checklist and write the comments they might have after reviewing each study protocol. The Secretariat checks the protocol proposal submitted by the Principal Investigator and marks the points in the Checklist.

PI should submit the Protocol Presentations to Secretariat Two days prior of scheduled meeting. The following contents to be included in the Presentation:

- Study Title(Includes Phase, Version, Methodology)
- Sponsoring agency Details
- Objectives of the study
- Inclusion/Exclusion Criteria
- Methodology
- Risk-Benefit analysis
- Study Plans
- Study Material details if needed
- Any challenges

The Member Secretary shall check the protocol proposal and write comments necessary for clarification/ correction purpose.

**4. Flow chart:**

| SL.NO. | ACTIVITY | RESPONSIBILITY |
|---|---|---|
| **1.** | Check the points as per checklist | Primary reviewers/Member Secretary |
| **2.** | Provide protocol and study related documents along with Checklist | Primary reviewer/Layperson |
| **3.** | Final checking of the dossier | Member Secretary |
| **4.** | Receive suggestions from IEC members and/or Primary reviewers in the full board meeting | IEC Members |
| **5.** | Inform Investigators about the comments and suggestions of IEC members during full board meeting | IEC Member Secretary/IEC Administrator |
| **6.** | IEC Decision letter given to the Principal Investigator or study designee | Member Secretary/IEC Admin |
| **7.** | Record the IEC's Decision in the minutes | IEC Secretariat |

**5. Detailed instructions:**

**5.1.** The primary reviewers will mark the points on the Checklist (as per AF/IEC/01/06/V-2.0)

5.1.1. Two primary reviewers and layperson review the PI submitted protocol & its related documents i.e informed consent document, IB, insurances', questionnaire, patient's diary and PIS & ICF

translations etc. by using check list [New Study Assessment Checklist] and the samechecklist/remarks discussed in the full board meeting

**5.2.** **Placing the proposal before the Ethics Committee Meeting:**

5.2.1. The study investigator will submit dossier [14 hard + 01 soft copy] to IEC secretariat-15-21 days prior to schedule the meeting.

5.2.2. The clinical trial dossiers will be sent to the Members as per the agenda of the meeting.

5.2.3. Two primary reviewers and layperson will review the PI submitted proposals by using check list [New Study Assessment Checklist] and same will be discussed in the full board meeting

5.2.4. Principal investigator will be invited to present the protocol and all IEC members will deliberate and provide inputs/suggestions if any.

**5.3.** Conveying decision regarding study protocol: The IEC members will discuss and clarify the comments and suggestions. The Member Secretary shall record the discussions and minute it. The decision letter is given to the principal investigator/study designee

5.3.1. The Decision on the protocol is:

- **a.** Approved – with or without suggestions or comments;
- **b.** Revision with minor modifications/amendments
- **c.** Revision with major modifications for resubmission
- **d.** Disapproved

5.3.2. Explanation for the above each IEC decision:

- Approved – with or without suggestions or comments;
- Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
- Revision with major modifications for re-submission – this will be placed before the full committee for reconsideration for approval; or
- Disapproved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission

5.3.3. Member(s) of the committee who is/are listed as an investigator(s) on a research proposal and having conflict of interest shall declare conflict of interest and will not vote on the proposal and will opt out from all deliberations on the proposal by leaving the board meeting room.

5.3.4. An investigator or study team member invited for the meeting will not vote or participate in the decision-making procedures of the ethics committee.

5.3.5. An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision-making procedures of the committee.

*5.3.6.* If the study is approved, the Committee will determine the frequency of continuing review from each investigator. Usually, approval is given for *one year*.

5.3.7. The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.'

**5.4. Final communication of the Ethics Committee decision taken on the protocol to the Principal Investigator:** The Secretariat will prepare an approval/decision letter and to be sent to the Principal Investigator when the protocol is approved at an Ethics Committee full board meeting.

**5.5. The letter contains:**

- Protocol No./Protocol title version and Date
- Name of the PI/Department
- Timings and location
- Dates of the meeting when the protocol is placed before the meeting and approved and version numbers of the protocol
- List of IEC members present/absent at the meeting when the protocol was approved.
- Approval period
- The Chairperson or the Member Secretary will sign the approval letter and the Secretariat will send decision letter to the Principal Investigator.

**6. <u>Storage of Documents:</u>**

- The Secretariat will keep a protocol proposal, Approval letter, PI communications, DCGI correspondences, hospital administrators/Sponsors communications and IEC notification by the PI
- The file will be stored in an appropriate shelf in the designated cabinet.

**7.** **Timelines for procedures will be as follows:**

- PI/study designee: submission of dossier/protocol proposals to IEC office/secretariat– within **15-21** days
- the IEC dossier circulation done Prior to **14 days** of the scheduled meeting
- IEC Decision given to PI after the full board meeting – Within **07** working days
- An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 90 days of date of receipt of the letter. In the absence of any response, the protocol will be declared closed for the IEC office records.

**8.** **Glossary:**

- Study Assessment Form: An official record that documents the protocol review process.
- Document: Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

**9.** **Reference:**


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use (ICH)-2016
- Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trial Rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


**10.** **Annexures:**

1. Guidance for Protocol Submission
2. Format for Summary and Detailed Protocol
3. Undertaking by investigators
4. ICD Review format for layperson
5. Guide to Placebo Justification
6. IEC approval letter format
7. IEC Decision Letter format

**ANNEXURE:01** **AF/IEC/01/08/V-2.0**

Guidance of Protocol Submission to IEC of UPUMS

The IEC is currently following the V-2.0 dated Aug-2024 of the Standard Operating Procedures (SOPs), which are individual activity based and are 24 in number.

The SOPs are available on the institutional Ethics Committee institute website and 02 no's hard copies available at IEC of UPUMS office.

The templates and forms are available on the University's website -www.upums.ac.in

for submission to the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai

I. **Prior to approval of a research study**:

- Submission of a New Study Proposal
  - PI/study designee Submission of ethics committee dossier to IEC office/secretariat– within **15-21** days
  - The secretariat sends the copies at least **14 days** in advance of the full board meeting to the IEC members
  - The protocol will be reviewed at the IEC full board meeting
  - An investigator is expected to be present at the time of full board meeting and will be invited (telephonically) to the IEC meeting to discuss issues related to the study proposal.
  - After the full board, the approval letter will be given within **07 working days.**
  - An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 90 days of date of receipt of the letter. In the absence of any response, the protocol will be declared closed for the IEC office records.

**II. Once approval for a study is granted**

- An approval will be granted for usually one year study period.
- It is the responsibility of the principal investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within 2 months of the due date i.e. 10 months from the date of approval)
- Submission of Study Related Documents for IEC review or notifications.
- Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations or any other notifications) will be accepted during the office hours. Two set of the above stated study related documents need to be submitted for the

IEC review/notification as per the format and one copy will be returned to after being acknowledged by the member secretary/Chairperson/or IEC secretariate.

- No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants.

**ANNEXURE: 02** **AF/IEC/02/08/V-2.0**

Format for Summary and Detailed Protocol

Protocol Title: PI/CoI-Name:

Sponsor/CRO Name:

| Sl. No. | Enclosures: | Page Nos. |
|---|---|---|
| 1. | Face sheet | |
| 2. | Undertaking of Principal, Co-investigator and Collaborators | |
| 3. | Brief Bio-data of investigators | |
| 4. | conflict of interest, if applicable | |
| 5. | Summary of study protocol, if the protocol amended Summary of Changes version and date | |
| 6. | Detailed protocol version and date | |
| 7. | Participant Information sheet version and date | |
| 8. | Informed Consent Document version and date | |
| 9. | Translation and Back translation certificates | |
| 10. | Funding Agency / sponsor's letter | |
| 11. | Investigator Brochure version and date | |
| 12. | Final CTA/Draft | |
| 13. | GCP Training Certificate of Principal Investigator/ Co-Investigators/Collaborators | |
| 14. | CTRI | |
| 15. | DCGI submission/Approval letter | |
| 16. | Investigator Undertaking | |
| 17. | Study/site Specific Insurance [ Who it covers and validity] | |
| 18. | Any other relevant documents | |

**ANNEXURE: 03** **AF/IEC/03/08/V-2.0**

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator).
2. Name and address of the medical college, hospital or another facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:

i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study-related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

xi. I will maintain the confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

xii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

xiii. Declaration of Conflict of Interest

**8.** Signature of Investigator with date

**ANNEXURE: 04** **AF/IEC/04/08/V-2.0**

Review of Informed consent document by Layperson

| Name of the reviewer: | | | |
|---|---|---|---|
| Name of the PI | | Protocol No | |
| IEC meeting date: | | Protocol Version and Date | |

| **Sl.No** | **Guidelines for reviewing Participant Information Sheet and Informed Consent Documents** | **Comments** |
|---|---|---|
| 1 | **Essential elements:** | |
| | Statement that the study involves research and explanation of the purpose of the research. | |
| | Expected duration of the participation of subject. | |
| | Description of the procedures to be followed | |
| | any reasonably foreseeable risks or discomforts to the Subject. | |
| | Description of any benefits. If no benefit is expected Subject should be made aware of this. | |
| | Disclosure of specific appropriate alternative procedures or therapies available to the Subject. | |
| | Confidentiality statement | |
| | Trial treatment schedule | |
| | Statement describing the financial compensation and the medical management | |
| | In the event of a trial related injury or death, the sponsor or his representative or the investigator or center | |

| | | |
|---|---|---|
| | Study team and Ethics Committee contact details | |
| | Responsibilities of subject on participation in the trial. | |
| | Statement that participation is voluntary | |
| | Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect. | |
| | Any other pertinent information. | |
| **2** | **Additional elements, which may be required:** | |
| | Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent. | |
| | Additional costs to the subject that may result from participation in the study. | |
| | The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject. | |
| | A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable. | |
| 3 | Format of informed consent form for Subjects participating in a clinical trial – | |
| | Signature of LAR/Participant/Impartial witness and PI and study team details | |
| | Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant. | |
| Reviewer signature | | |

**ANNEXURE: 05** **AF/IEC/05/08/V-2.0**

Guide to Placebo Justification

Name of the PI:

Protocol Version and Date:

IEC meeting Date:

Background conditions, such as benefits of standard treatment, risk of using placebo, risk managementand disclosure should be considered. The followings are some guides to ease Board decision.

I. Benefits of standard treatment (Yes/No)

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has the efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

If the answer of (1) to (6) are "yes", placebo is not recommended.If any one or more answers are "no", placebo may be possible.

II. Risks of placebo

1) Is the risk of using placebo instead of treatment life threatening?
   If yes, placebo is not acceptable.
2) Is the use of placebo instead of treatment likely to lead to permanent damage?
   If yes, placebo is not acceptable
3) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?
   If yes, placebo is not acceptable.
4) Can the use of placebo instead of treatment lead to an acute emergency?
5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?
6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?

   If the answer of (4) to (6) are"yes", placebo is not acceptable unless risk management is adequate.

III. Risk management

1) Is there benefit in the overall management of the subject?

   □ Yes, consider placebo

□ No, placebo not recommended.

2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?

□ No, consider placebo

□ Yes, placebo not recommended.

3) Are subjects at high risk for the use of placebo excluded?

□ Yes, consider placebo

□ No, placebo not recommended.

4) Is the duration of the study the minimum necessary in relation to the action of the drug?

□ Yes, consider placebo

□ No, placebo not recommended.

5) Are there clearly defined stopping rules to withdraw the subject in case he/she does not improve?

□ Yes, consider placebo

□ No, placebo not recommended.

6) Is risk monitoring adequate to identify the progression of the disease before the subject experience severe consequences?

□ Not applicable.

□ Yes, consider placebo

□ No, placebo not recommended.

7) Are there clearly defined stopping rules to withdraw the subject before the advent of severe disease progression?

□ Yes, consider placebo

□ No, placebo not recommended.

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?

□ Not applicable.

□ Yes, consider placebo

□ No, placebo not recommended.IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?

□ Yes, consider placebo.

2) Are the risks of the test drug disclosed?

□ Yes, consider placebo.

2) Are the advantages of alternative treatments explained?

□ Yes, consider placebo.

Conclusions:

1. The use of placebo is ethically acceptable because:

□ Subjects are not exposed to severe or permanent harm by the use of placebo.

□ Subjects under placebo will benefit from the overall treatment of the disease.

□ Risks of the use of placebo are minimized.

□ Risks are adequately disclosed in the consent form.

2. The use of placebo in this study could be reconsidered if the following conditions are met:

.....

3. The use of placebo in this study is ethically unacceptable because:

□ Subjects are exposed to severe or permanent harm by the use of placebo instead of active treatment.

□ Due to the nature of the disease, the risks of placebo cannot be minimized.

| IEC OFFICE USE ONLY | |
|---|---|
| IEC Member Secretary/IEC Chairperson name and Signature | |

## IEC approval letter Template -01

**To**

*«Name_of_the_Candidate»*
*«Designation»*
Department of ***«Department»***
UPUMS, Saifai.

**From,**

Member Secretary
Institutional Ethics Committee,
Uttar Pradesh University of Medical Sciences,
Saifai-206130, Etawah (UP)

Ethical Committee Approval No.: **«Sl_No_»**/-------

**Study Title:** ***«Title»***

**Subject:** Institutional Ethics Committee approval for the above referenced study at UPUMS, Saifai.

This is with reference to the above referenced research project/study/synopsis topic "***«Title».***" produced by **«Name_of_the_Candidate»**, Department of ***«Department»*** Uttar Pradesh University of Medical Sciences, Saifai, Etawah, all the submitted documents for the study were reviewed and discussed. The Ethics Committee approved the study as discussed in the meeting held on …….

**Note:** You are requested to check the Approval Letter thoroughly. If any Discrepancy is noted, it may be brought to the notice of the undersigned not later than one week (7 days) after issue of the letter. No correspondence regarding discrepancies will be accepted after one week (7 days) of issue of letter.

**Approval Authority:**
**Institutional Ethics Committee Member Secretary:**

| | |
|---|---|
| **Name:** | |
| **Signature & Date:**<br><br>**Stamp** | |

## IEC approval letter Template -02

**To,**

_____
_____
_____

**From,**

Chairperson/Member Secretary
Institutional Ethics Committee,
Uttar Pradesh University of Medical Sciences,
Saifai-206130, Etawah (UP)

**Protocol No:** _____

**Study Title:** _____

**Subject:** Institutional Ethics Committee approval of the above referenced clinical trial study at UPUMS, Saifai.

This is with reference to your submission letter dated _____for the clinical trial study no. _____ the Institutional Ethics Committee meeting dated _____, the below mentioned study documents for the study no. _____ were reviewed and discussed.

Submission letter dated _____contains following Documents:

| SN | Name of Documents | Version And Date |
|---|---|---|
| 1 | Study Protocol | Protocol Number: _____<br>_____ |
| 2 | DCGI Approval Letter (CT NOC) | File No.- _____<br>Dated _____ |
| 3. | Investigator's Brochure | IB No: _____<br>Version: _____ |
| 4. | File Note to the study protocol | Version: _____ |
| 5. | Informed Consent Document (Subject information sheet & Informed consent form) | |
| | • English | Version _____ |
| | • Hindi | _____ |
| 6. | Translation certificate of Informed Consent Document (ICD Version 03 dated 04-10-22) | |
| | | |
| | • English to Hindi | _____ |
| 7. | Back Translated Informed Consent Document (Subject information sheet &Informed consent form) | |
| | • Hindi to English | _____ |
| 8. | Back Translation certificate of Informed Consent Document (ICD Version 03 dated 04-10-22) | |
| | • Hindi to English | _____ |
| 9. | Assent Form | |
| | • English | _____ |
| | • Hindi | _____ |
| | | |
| 10. | Translation Certificate of Assent Form Version _____ | |

| | | |
|---|---|---|
| | • English to Hindi | _____ |
| 11. | Back Translated Assent Form | |
| | • Hindi to English | _____ |
| 12 | Back Translation Certificate of Assent Form Version _____ | |
| | • Hindi to English | _____ |
| 13 | Subject Diary Cards | |
| | • English | _____ |
| | • Hindi | _____ |
| 14 | Translation certificate of subject diary card | |
| | • English to Hindi | _____ |
| 15 | Back Translated Subject Diary Cards | |
| | • Hindi to English | _____ |
| 16 | Back Translation Certificate of subject diary cards | |
| | • Hindi to English | _____ |
| 17 | Clinical Trial Agreement (Draft) | Enclosed |
| 18 | Investigator Undertaking | Dated: _____ |
| 19 | CV, MRC & GCP of Principal Investigator | Dated _____ |
| 20 | CDL release | Dated _____ |
| 21 | CTRI number | _____ |
| 22 | Insurance Policy | Policy Number: _____<br>From _____ |
| 23 | Case Report Form template | _____ |

The following members were present during the **meeting** held on _____at_____at _____.

| SN | Name | Role in the EC | Designation | Gender |
|---|---|---|---|---|
| 01 | | | | |
| 02 | | | | |
| 03 | | | | |
| 04 | | | | |
| 05 | | | | |
| 06 | | | | |
| 07 | | | | |
| 08 | | | | |
| 09 | | | | |
| 10 | | | | |
| 11 | | | | |

\

The Ethics Committee approved the study as discussed in the meeting held on ……

**Remarks/Suggestion:**

1. The IEC hereby approved the research proposal to be conducted in it's presented form only.
2. The IEC expects to be informed immediately (within 24 hrs) in case of any Serious Adverse Events (SAEs).
3. The IEC expects to be informed about study related information (new or changed or updated) that may affect safety of subjects and /or conduct of the study.
4. PI /study team/ Member are not a part of voting process.
5. Changes to protocol in PICF cannot be initiated without approval of IEC.
6. Copy of final study report has to be provided to IEC.
7. The IEC expects to be informed about the progress of the study at six (6) months once from date of its first approval letter and case basis for pharmacodynamic study, pharmacokinetics study, etc.
8. Member of IEC will have right to monitor study site and conduct of study with prior intimation.
9. Notification letter regarding initiation, on-going and completion of the study should be informed.
10. Our ethics Committee operates in accordance with applicable ICMR guidelines for Biomedical Research on Human Subejcts-2017, India GCP & ICH-GCP guidelines which govern GCP & IEC operations, declaration of Helsinki (Brazil, 2013) and 21 CFR Part 56 and 21 CFR part 50 and New Drugs and Clinical Trial Rules 2019.

**Note:** You are requested to check the Approval Letter thoroughly. If any Discrepancy is noted, it may be brought to the notice of the undersigned not later than one week (7 days) after issue of the letter. No correspondence regarding discrepancies will be accepted after one week (7 days) of issue of letter.

**Approval Authority:**
**Institutional Ethics Committee Chairperson/Member Secretary:**

| | |
|---|---|
| **Name:** | _____ |
| **Signature & Date:**<br><br>**Stamp** | |

**ANNEXURE:07** **AF/IEC/07/08/V-2.0**

IEC Decision Letter format

IEC Protocol Code:

| |
|---|
| Protocol Title: |
| Protocol Version and Date: |
| Name of the investigator: |
| Name of affiliation/Department: |
| Status of Review Process<br>New Review ☐ Revised Review ☐ Expedite Review ☐ |
| Date of IEC Meeting:<br>Venue: |
| Decision on the Protocol:<br>**e.** Approved – with or without suggestions or comments; ☐<br>**f.** Revision with minor modifications/amendments ☐<br>**g.** Revision with major modifications for resubmission ☐<br>**h.** Disapproved ☐ |
| Any suggestion or remarks: |
| Approved for the period of _____ |
| |

**You are requested to report to the Ethics Committee the following:**

- Progress of the study periodically [Biannual* and Annual report]
- During the course of this investigation, any significant deviations from the approved protocol and/or serious adverse events should immediately be brought to the attention of the Ethics Committee.
- Submit the continuing letter at least 2 months prior to the end of -the approval period

**Signature of Member Secretary**

IEC SOP 09: Vulnerable Populations

# IEC SOP 09: Vulnerable Populations

## Introduction:

The IEC of Uttar Pradesh University of Medical Sciences, Saifai takes special consideration in protecting the welfare gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, pregnant women, and individuals with consent capacity impairment. The IEC carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards measures for vulnerable subjects. The IEC may require additional safeguard measures to protect potentially vulnerable population. For instance, the IEC may require that the investigator submit each signed informed consent form to the IEC, that someone from the IEC oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time to allow the subject time for family discussion and query resolution, family discussion and questions. IEC expects to follow the principles laid down in the ICMR-Ethical Guidelines for Biomedical Research on Human Participants.

### 1. Purpose:

The purpose of this SOP is to describe how the IEC will ensure that the rights and interests of vulnerable population are safeguarded. The IEC will ensure that individuals or communities included for research are selected in such a way that the burdens and benefits of the research areequally distributed.

### 2. Scope:

This SOP applies to the process by which the IEC will protect the rights and interests of vulnerable population. Additional protection will be ensured depending upon the risk of harm and the likelihood of benefit.

### 3. Responsibility:

It is the responsibility of the IEC members to identify study proposals including vulnerable population and ensure that these are considered for full board. The IEC will ensure that measures for safeguarding rights and interests of vulnerable participants are mentioned in the face sheet, study proposal, Participant /Assent Information Sheet/ and informed consent/assent form. They have the responsibility to ensure that the vulnerable population is not exploited and they will

guide the investigators to design protocols and describe the process of informed consent in such a manner that this will be done.

**4. Detailed instructions:**

4.1 **Determine protocols including vulnerable population:** Project proposals presented before the Ethics Committee Meeting which includes vulnerable population: It is the responsibility of the IEC to see whether the inclusion of vulnerable populations in the study is justifiable or the population is just being exploited to generate clinical data. In such cases, appropriate reviewers will assess the risk and ensure measures for protecting their rights. Review of risk assessment will be documented in IEC minutes.

**4.2 Vulnerable groups: 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.**

a. 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 participants such as prisoners, students, subordinates, and employees, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.
e. Persons, who are terminally ill, have an incurable disease and mental illness.

**4.2.1 Consideration issues and protection of specific vulnerable groups:**

1. **Children:** Before undertaking research/trial in children the investigator must ensure that –

a. Children will not be involved in research that could be carried out equally well with adults.
b. 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. It can be studied earlier only if the drug has atherapeutic value in a primary disease of the children.

c. A parent or legal guardian of each child has given proxy consent.
d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
e. Research should be conducted in settings in which the child and parent can obtain adequate Medical and psychological support.
f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society.
g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian.
h. 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.
i. 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.

2. Pregnant or nursing women: 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 foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant, or nursing would not be suitable participants.

- The justification of 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 is, To test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, Trials for detecting foetal abnormalities and for conditions associated with or 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.

4. **Research related to termination of pregnancy:**

   Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could bemade participants for such research as per The Medical Termination of Pregnancy Act, GOI,1971.

5. **Research related to pre-natal diagnostic techniques:**

   In pregnant women such research should be limited to detect the foetal 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 foetus.

6. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record:
7. Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

5. **Glossary:**

- Vulnerability: The Council for International Organizations of Medical Sciences (CIOMS) defines vulnerability as "Substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group."
- Vulnerable (research) participants: 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. Individuals whose willingness to volunteer in a research study may

be unduly influenced by the expectation, whether justified or not, of benefits associated withparticipation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. (WHO).

## 6. References:


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use (ICH)-2016
- Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- National ethical guidelines for biomedical research involving children-2017
- New Drugs and Clinical Trial Rules,2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


## 7. ANNEXURE:

AF/IEC/01/09/V-2.0 Checklist for assent form

AF/IEC/02/09/V-2.0 Participants who are students, employees and special considerationsAF/IEC/03/09/V-2.0 Assent Form

**ANNEXURE: 01** **AF/IEC/01/09/V-2.0**

**Checklist for review of Assent Form**

Protocol No: PI Name:

**IEC Meeting Date:**

I. 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 the occurrence of serious harm or an adverse event (AE) is unlikely.

II. Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

III. Approval to proceed with this category of research must be made by the IEC with input from selected experts.

| SL.NO | IF, YES PLEASE JUSTIFY | Y | N | NA |
|---|---|---|---|---|
| 1. | Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises? | | | |
| 2. | Are provisions made to obtain the assent of children?<br>**Oral ASSESENT**:7 to < 12 years **Written Consent**: 12 to < 18 years | | | |
| 3. | Are provisions made to protect participants' privacy and the confidentially of information regarding procedures? | | | |
| 4. | Are there special problems that call for the presence of a monitor or IEC member during consent procedures? | | | |
| 5. | Does the research involve implications for other family member?<br>(for example, genetic risk , HIV infection, Hepatitis C) | | | |
| 6. | Should parents be required to be present during the conduct of the research? Are the procedures involved painful? Must subject stay overnight in the hospital when they otherwise would not have to? ) | | | |

| **IEC OFFICE ONLY** | |
|---|---|
| Reviewer name signature and date | |
| Member Secretary/Chairman signature and date | |

**ANNEXURE: 02** **AF/IEC/02/09/V-2.0**

**Participants who are students, employees require special considerations**

Study Title/No:

Investigator Name:

IEC# Meeting Date:

| PARTICULARS | YES | NO |
|---|---|---|
| The proposed plan for the assessment of the capacity to consent is adequate. … | | |
| Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not? … | | |
| Have the risks to participants been minimized? | | |
| Have participants been assured that participation is voluntary (no signs of coercion)? … | | |
| Have participants been assured that confidentiality will be protected or maintained? | | |

| **IEC OFFICE USE ONLY** | |
|---|---|
| Reviewer name signature and date | |
| Member Secretary/Chairman signature and date | |

**ANNEXURE: 03** **AF/IEC/03/09/V-2.0**

**Assent Form**

I ……have read /have had read the participant information sheet version no. ……..dated……bearing page numbers ….. of the research study entitled

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my assent willingly to participate in this research study.

For Limited or non-readers: (Illiterate participants) I have witnessed the assent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individualhas given assent freely.

| Signature Of Impartial Witness/LAR | Signature/Thumb Impression Of Representative & Date |
|---|---|
| | |
| Name of the witness | Name of the study participant |
| | |
| Signature/thumb impression of mother/father | Signature of the person administering the assent & date |
| | |
| Signature of principal investigator | Signature of person administering the consent |

IEC SOP 10: AV- Recording of Informed consent Process

# IEC SOP 10: AV- Recording of Informed consent Process

**1. Background:**

As per the DCGI office order dated 25-Aug-2015, G.S.R. 611. (E) 31st July 2015 and New Drugsand Clinical Trial Rules, 2019.

**2. Purpose:**

The purpose of this SOP is to describe the procedures for Audio-Visual (AV) recording, storage and archival of the informed consent and assent process for regulatory studies.

**3. Scope:**

This SOP applies to all those regulatory clinical trials approved by the DCGI, which require documenting of the written informed consent and assent process.

**3.1.** An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record:

**3.2.** Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

**3.3.** Statement that there is a possibility of failure of IP to provide an intended therapeutic effect

**3.4.** Statement that in case of Placebo-controlled trials, the placebo administered to the subjects shall not have any therapeutic effect

**3.5.** Any other pertinent information

**4. Responsibilities:**

**4.1.** IEC will ensure that Principal investigator will conduct AV recording of the informed consent process, store and archive without violating the participant confidentiality as detailed below in section 6.

**4.2.** IEC will specifically ask for consent for AV Consenting in addition to the ICF

**4.3.** AV recordings may be reviewed periodically by IEC members

**5.** **Applicable rules, regulations and guidelines:**

i. New Drug and Clinical Trial Rules 2019.

ii. Ethical Guidelines for Biomedical Research on Human Participants, ICMR2017.

iii. International Conference on Harmonization; Good Clinical Practice Guidelines: E6(E2)-2016

**6.** **Detailed Instructions for PI to follow:** All basic principles and procedures for the administration and documentation of the informed consent process are described in SOP Initial review of the submitted protocol.

**6.1.** if the participant is unable to give consent for medical or legal reasons, the consent should be taken from the legally authorized representative (LAR) and the process recorded.

**6.2.** If the participant/LAR is illiterate then an impartial witness is needed. This person should also be in the frame for the entire duration of the consent process.

**6.3.** AV recording should be done of assent wherever applicable

**6.4.** Ensure the following infrastructure is available prior to counseling of potential participant:

**a.** The informed consent process should be carried out in the designated area when the following conditions should be met) that is -

i. Free from disturbance

ii. Well lit

iii. Ensures privacy for the participant

iv. Participant should be comfortable

**b.** Camera having video facility with

- Good resolution
- Sufficient memory (at least 4 GB)
- Sufficient battery backup (at least 2 hours)
- Show non-editable date & time on video (preferably)

a. Mike system

b. Computer/laptop with CD/DVD writer

c. Blank CDs/DVDs with cover

d. External Hard disk (at least 500 GB to 1 TB)

1) Before starting the informed consent process (and the AV recording of the same)

i. Ensure that all the necessary equipment mentioned above is functional.

ii. The potential participant/LAR/ Impartial witness should be informed that the whole process of taking the consent is being recorded as per Govt. of India notification to ensure that he/she has understood all the potential risks and benefits involved in the study including failure of the IMP, study details and his/her rights for the purpose of documentation and the confidentiality of the same is assured.

iii. The potential participant/LAR/ impartial witness should be made aware that his/her recording may be shown to government agencies or members from the IEC and independent auditors.

iv. His/her consent should be documented in a separate ICD that states the same. The process of obtaining signatures of the potential participant/LAR/ impartial witness & Principal Investigator or her designee on this Audio-video consent form should be carried out as per specified in Annexure AF/IEC/04/08/V-2.0 of SOP/08/V-2.0.

**7. Actual AV recording process:**

**7.1.** Participant/LAR should read out all the statements mentioned in ICF as per New Drugs and Clinical Trial Rules,2019 and state whether he/she agrees or not for each statement and affix signature/thumb print at the end

**7.2.** The actual signing process should be recorded.

**7.3.** The impartial witness should be requested to enter the name and details of the participant and the date the consent is documented. The impartial witness will also be requested to sign and date the consent form.

**7.4.** The PI/Co-I/medically qualified person delegated by the PI will also sign and date the consent form at the end of the process.

**7.5.** The recording will be stopped after thanking the participant.

**7.6.** The recording should be checked for completeness and clarity of both audio and video recording.

**7.7.** No editing should be done on the recording so as to maintain authenticity.

**7.8.** The computer/laptop should be password protected. The password will be known only to the PI and members of the study team as designated by the PI. A register should be maintained wherein, each time the data is accessed, the details of who accessed the data, date and reasons for the same this should be entered into the designated register.

**7.9.** The recording should be then transferred to a CD labeled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings (applicable

during re-consenting) and archived in the external Hard drive. The CD should be filed in theparticipant binder.

**8. Archival**

**8.1.** The soft copies of the recordings should be stored in a password protected external hard drive for a minimum of five years.

**8.2.** The original recording in the computer/laptop will be deleted when study is closed out.

**9. References:**


- Draft Guidelines on Audio-Visual Recording of Informed Consent Process in Clinical Trial, CDSCO, MOHFW, 9th Jan 2014.
- FERCAP guidelines for Audio-Visual consent process
- New Drugs and Clinical Trial Rules,2019

IEC SOP 11: -Review of resubmitted Clinical trial protocol

# IEC SOP 11: -Review of resubmitted Clinical trial protocol

## 1. Purpose:

This SOP describes how resubmitted study protocols are managed, re-reviewed and approved bythe IEC.

## 2. Scope:

This SOP applies to study protocols that have been reviewed earlier with recommendations from IEC for some corrections in the initial review process.

## 3. Responsibility:

It is the responsibility of the IEC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol with conditions for revision has been resubmitted to the IEC for reconsideration. A re-submitted protocol may be reviewed and approved by the Chairperson/member secretary**.** IEC members/reviewers, or full IEC, Decision for the review of the protocol should be determined by the IEC at the time of the initial review and mentioned in the minutes of the Ethics Committee meeting in which the proposal discussed.

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1. | Receive resubmitted protocol package | Secretariat |
| 2. | Review the revised protocol | Members |
| 3. | Sending the protocol to Primary reviewers | Secretariat |
| 4. | IEC Meeting | IEC Members |
| 5. | Communicate the IEC decision | IEC Secretariat |
| 6. | Document the decision | IEC Secretariat |

## 5. Detailed instructions:

### 5.1 Receive protocol resubmitted dossier:

5.1.1 check the received dossier for: Minutes of previous IEC meeting

5.1.2 Response to the comments by Investigators Checklist (AF/IEC/01/06/V-2.0)

5.1.3 Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets, etc are included as part of the package.

5.1.4 Changes made to the documents should be bold and the deleted matter should be made strikethrough for easy verification of the corrections done by the investigators.

5.1.5 Put the stamp, write date and acknowledge the receipt of the protocol.

### 5.2 Review the revised protocol

5.2.1. Check the received protocol as per Checklist (AF/IEC/01/06/V-2.0)

5.2.2. Refer to the meeting minutes as guidance for the review.

5.2.3. Ensure that the response to comments of IEC members as mentioned in the minutes is given by the investigator and page numbers where changes are made are mentioned in the proposal.

5.2.4. Make further comments if the response is not satisfactory and the changes have not been incorporated in the study proposal.

5.2.5. Internal reviewers will write the comments on the clinical trial protocol Review Report form and will put signature with date.

5.2.6. Notify the IEC Secretariat.

5.2.7. Ask the Principal Investigator to make the necessary revisions.

5.2.8. Send the resubmitted proposal with incorporated changes to reviewers /full board as per the decision in the minutes.

5.2.9. If the proposal has only minor modifications as decided in the previous full board meeting, the proposal with incorporated changes is sent to external reviewers.

5.2.10. The Secretariat to receive the package and inform the Member Secretary. Follow instructions in 5.4 respectively.

**5.3 IEC meeting:**

if the IEC previously decided that major modifications to be made in the proposal, then the revision will be processed as:

1.1.1. the primary reviewer presents a brief oral or written summary of the study design and his/her comments to the IEC members.

1.1.2. The Chairperson entertains discussion on the protocol revision.

1.1.3. Further recommendations for modifications to the protocol, consent form as requested by the Committee are noted in the meeting minutes as 'with modifications made by IEC and will be communicated to the investigator.

1.1.4. The Chairperson takes a consensus of the IEC members on the revision to either:

1.1.5. The decision on the protocol as:

- Approved – with or without suggestions or comments.
- Revision with minor modifications/amendments
- Revision with major modifications for resubmission
- Disapproved

1.1.6. Member(s) of the committee who is/are listed as investigator(s) on a research proposal and having conflict of interest shall declare conflict of interest and will not vote on the proposal and will opt out from all deliberations on the proposal by leaving the meeting room.

1.1.7. An investigator or study team member invited for the meeting will not vote or participate in the decision-making procedures of the committee.

1.1.8. An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision-making procedures of the committee.

1.1.9. If the IEC decision is 'Approved', without implies the approval of the study as it is presented with no modifications and the study can be initiated.

1.1.10. If the IEC Decision is approved with or without suggestions, it implies that the study can be initiated only after PI responses is reviewed and approved by the member secretary of IEC.

1.1.11. If the IEC decision is minor modification, it implies that the Approval is given after receiving supportive documents/Clarifications and Examination by member secretary or expedited review of the case may be.

1.1.12. If the IEC decision is major modification for resubmission, it implies the PI should resubmit with the major modification for reconsideration of proposal by full board review.

1.1.13. Member(s) of the committee who is/are listed as investigator(s) on a research proposal and having conflict of interest shall declare conflict of interest and will not vote on the proposal and will opt out from all deliberations on the proposal by leaving the meeting room.

1.1.14. An investigator or study team member invited for the meeting will not vote or participate in the decision-making procedures of the committee.

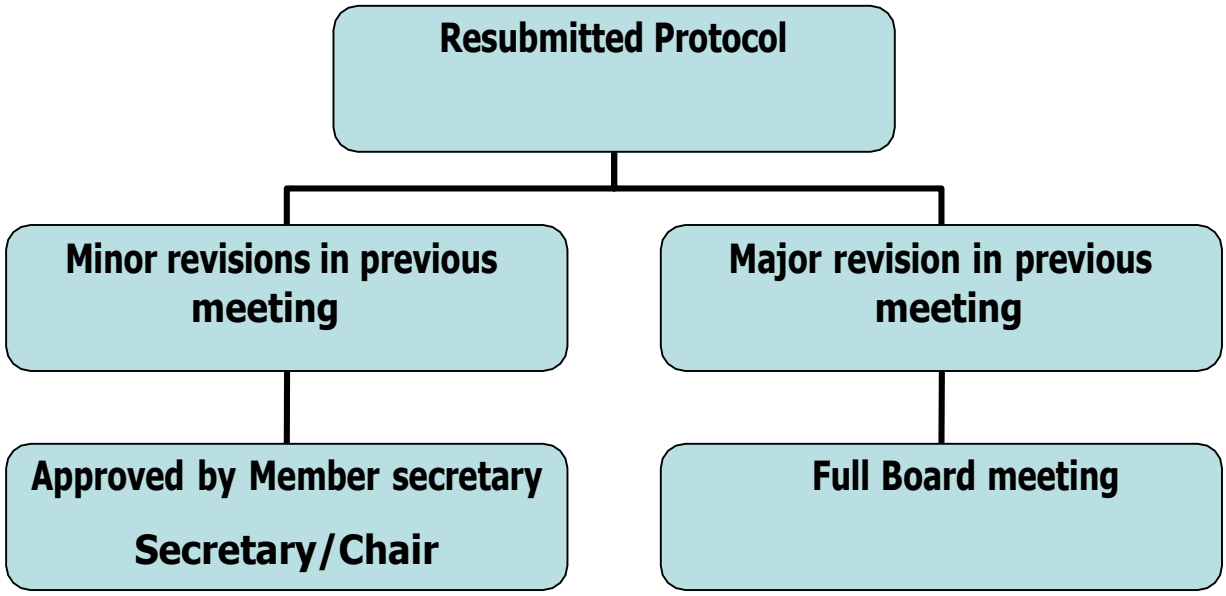
1.1.15. An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision-making procedures of the committee.

1.1.16. If the IEC decision is 'Approved', without implies the approval of the study as it is presented with no modifications and the study can be initiated.

1.1.17. If the IEC Decision is approved with or without suggestions, it implies that the study can be initiated only after PI responses is reviewed and approved by the member secretary of IEC.

1.1.18. If the IEC decision is minor modification, it implies that the Approval is given after receiving supportive documents/Clarifications and Examination by member secretary or expedited review of the case may be.

1.1.19. If the IEC decision is major modification for resubmission, it implies the PI should resubmit with the major modification for reconsideration of proposal by full board review.



**5.4 Written Communication of the Decision:**

- The Secretariat then prepares the Approval letter and gets the member Secretary's or Chairperson's signature.
- If the study is approved, the Committee determines the frequency of Continuing Review for each study site (usually it should be once a year).
- The Secretariat sends an Approval letter to the investigator the IEC decision and schedule of continuing review.
- The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- If the Committee requires modifications to any of the documents, the Secretariat sends a written request of the specific changes to the investigator to make the necessary changes and resubmit the documents to the IEC.

## 6. Glossary:

**Document:** All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio orvideo tape.

## 7. References:


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use E6R2 (ICH)-2016
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical trial Rules,2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

# IEC SOP 12: Review of Amended Study Protocols

## 1. Purpose:

The purpose of this standard operating procedure is to describe how protocol amendments/ICF Amendments/data forms are managed and reviewed by the IEC of UPUMS, Saifai

## 2. Scope:

This SOP applies to previously approved study protocols but later being amended any study related documents and submitted for approval by the IEC. Amendments made to protocols may not be implemented until reviewed and approved by the IEC. Amended Documents for notifications with minor/Administrative changes are acknowledged by the Member Secretary or Chairman of IEC.

## 3. Responsibility:

It is the responsibility of the IEC Secretariat to manage protocol amendments/ICD/Data forms. Investigators may amend the contents of protocols from time to time. Amendments may be submitted for either "expedited" review by the Chairperson and or Member secretary review.

## 4. Flow Chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1. | Receive the Amendment Package | IEC Secretariat |
| 2. | Check for completeness | IEC Secretariat |
| 3. | Provide it to the members & Primary reviewers | IEC Secretariat |
| 4. | Determine whether Expedited or Full Review | IEC Member secretary / Chairperson |
| 5. | Amendment Review Process | IEC Secretariat/Members /Chairperson |
| 6. | Inform the Principal Investigator | IEC Secretariat |
| 7. | Store Documents | IEC Secretariat |

## 5. Detailed instructions:

**5.1** Manage the Amendment Documents/ Package: The Principal Investigator will submit Amended Protocol of an existing and previously approved protocol should be made in the covering letter to the chairperson/Member-Secretary. The request should:

- State/describe the list of amendments [ including summary of changes]
- Provide the reason/justification for the amendment
- If Minor administrative changes are reviewed and approved by Member-Secretary.

- Upon receipt of the amendment document form the PI, the Secretariat of the IEC should follow the receiving procedure in SOP/06/V-2.0 (Management of Protocol Submission) and SOP/23/V-8.3 (Maintaining Confidentiality of IEC Documents).
- After review of the materials, the Member Secretary/secretariat will determine whether the protocol requires expedited or full review.
- The amended version of the protocol and related documents should be provided to the IEC members.
- Keep "Sent" and "Received" acknowledgment on hard copy (Signature for received) related to the notification of the Chairperson/Member Secretary in the protocol file under the Correspondence section-Follow IEC SOP/23/V-2.0 in preparing and distributing the documents.

**5.2 Full Review by the IEC:**

- Refer to SOP/08/V-2.0 for Initial Review.

**5.3 Protocol Amendment Review Process:**

### 5.3.1 Review amended protocols:

- Use the process outlined in the Study Assessment Form (see SOP/06/V-2.0) to review amended protocols and its related documents.
- Note recommendations for changes to the protocol and/or informed consent requested by IEC Members in the minutes as "with modifications made by IEC' and will be communicated to the investigator.

**5.3.2 The Chairperson and the IEC members can give the following decisions:**

-Approve
-Minor modification to the amendment,
-Major modification to the amendment
-Disapprove

- Expedited review at the level of the Member Secretary;
- Not approve the amendment request, stating the reason – but allow the study to continue as previously approved
- If the IEC approves the protocol amendment, the Secretariat staff communicates this decision to the investigator.
- If the IEC does not approve the protocol amendment, the IEC Secretariat notifies the investigator in writing of the decision and the reason for not approving the amendment.
- Keep the minutes of the meeting relevant to the discussion and the decision reached by the IEC as the official records of the amendment review process.

**5.4 Notify the Principal Investigator:**

- "Decision letter" to PI and if further amendments are decided PI should again changeversion no. and date.

**5.5 Store documents:** Place the original completed documents, the "clean" version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

**6. Glossary:**

**Amendment protocol**: A package of the amended parts and related documents of Package, the protocol, previously approved by the IEC. In the course of the study, the Principal Investigator may decide to make changes in the protocol.

-**Major:** there is a change in the Protocol title and methodology any other modification in theICDs

-**Minor:** there is changes in the administrative aspects

**Clinical Research department:** An institute or an office where the study takes place and where the principal investigator and/or his/her staff may be reached.

## 7. References:


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016
- WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trial Rules, 2019


## 8. Annexure:

Checklist for amended study protocol

**ANNEXURE: 01** **AF/IEC/01/12/V-2.0**

## Submission of Amended study proposal Template

**Protocol title:**

**Name of the PI:**

**Amended Version and Date:**

| | | |
|---|---|---|
| **Date of EC approval:** | | |
| **Date of start of study:** | | |
| **1** | Details of amendment(s) | |
| **2** | Impact on benefit-risk analysis<br>Yes ☐ No ☐ If yes, describe in brief: | |
| **3** | Type of review requested for amendment:<br>Expedited review (No alteration in risk to participants)<br>☐<br>Full review by EC (There is an increased alteration in the risk to participants)<br>☐ | |
| **4** | Version number of amended Protocol/Investigator's brochure/ICD: | |
| Signature of the PI | | |

**ANNEXURE: 02** **(AF/IEC/02/12/V-2.0)**

**Study Assessment Form for Amended Document**

Protocol Number: Meeting Date (D/M/Y):

Name of Principal Investigator: Protocol Version & Date

Reviewer's name with Designation:

Mark and comment on whatever items applicable to the study.

| Sl. No | Particulars | Comments |
|---|---|---|
| | **Details of Amended Protocol (If Applicable)** | |
| **1.** | Summary of Changes<br>☐ Clear Unclear ☐ | |
| **2.** | Inclusion Criteria<br>☐ Appropriate Inappropriate ☐ | |
| **3.** | Exclusion Criteria<br>☐ Appropriate Inappropriate ☐ | |
| **4.** | Vulnerability assessment (If Applicable)<br>☐ Yes No ☐ | |
| **5.** | Are blood/tissue samples will be sent to Abroad?<br>☐ Yes No ☐ | |
| **6.** | DCGI submission/Approval Letter<br>☐ Yes No ☐ | |
| **Participant Information Sheet and Informed Consent Documents (If Applicable)** | | |
| **1.** | Contents of the ICD Translation and back translation certificates<br>☐ Clear Unclear ☐ | |
| **2.** | Language of the ICD: Kannada, Hindi, English and Marathi<br>☐ Clear Unclear ☐ | |
| **3.** | Risks/ inconveniences mentioned clearly<br>☐ Yes No ☐ | |
| **4.** | Period of storage of biological samples<br>☐ Yes No ☐ | |
| **5.** | Privacy & Confidentiality<br>☐ Yes No ☐ | |
| **6.** | Provision for Compensation per subjects in ICFs-TA(INR)<br>☐ Appropriate Inappropriate ☐ | |

Reviewer Signature

IEC SOP 13: Continuing review of clinical trials

# IEC SOP 13: Continuing review of clinical trials

## 1. Purpose:

The purpose of the continuing review is to monitor the progress of the entire study, to ensure continuous protection of the rights and welfare of research participants. Continuing review of the study may not be conducted through an expedited review procedure, unless

- The study was eligible for, and initially reviewed by, an expedited review procedure or
- The frequency for study progress report is for every biannual and or annually.
- * Biannual report to be submitted short duration studies i.e. PK/PD studies and or which studies have <6-8 months of study duration.

## 2. Scope:

This SOP applies to conducting any continuing review of study protocols involving human participants at intervals appropriate to the degree of risk but at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently (more than once a year).

## 3. Responsibility:

It is the responsibility of the Principal Investigators to submit the study protocols for continuing review as mentioned in the approval letter. The Ethics Committee is responsible for determining the date of continuing review. The period is usually one year as provided in the approval letter. The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of enrolment of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate. The IEC has the same options for decision making on a continuing review package as from initial review protocol.

**4. Flow chart:**

| Sl.No. | Activity | Responsibility |
|---|---|---|
| **1.** | Determine the date of continuing review | IEC Secretariat |
| **2.** | Remind PI for continuing review submission or study progress report to IEC | IEC Secretariat |
| **3.** | Manage continuing review upon receipt | IEC Secretariat |
| **4.** | Notify to the members of the IEC | IEC Secretariat |
| **5.** | Incorporate the reports in the agenda of the forthcoming meeting | IEC Secretariat |
| **6.** | Study progress report review in the full board meeting | IEC Secretariat, IEC Members and Chairperson |
| **7.** | Approval of minutes | Chairperson |
| **8.** | Providing Decision letter to the PI for the period of ONE Year | IEC Secretariat |

## 5. Detailed Instructions:

### 5.1. Remind Principal Investigator for continuing review submission:

**5.1.1.** IEC Secretariat Remind the Investigator within 1 month of expiry of approval

**5.1.2.** It is the responsibility of the principal investigator that for studies which will continue for more than a year, a request for continuing approval and progress report needs to be submitted (within 2 months before the due date i.e. 10 months from the date of approval)

**5.1.3.** If the request and report is not received within two months of due date, the secretariat will remind the Principal Investigator. At the end of two months, if no report is received the study will be suspended and same will be communicated to PI

**5.1.4.** any study related data during the lapse period (between the due date and the late submission date) will be considered null and void

**5.2 Manage continuing review document upon receipt:** The Secretariat will receive a package submitted by the Study Team of continuing review for each approved protocol.

**5.2.1.** IEC members will monitor the subject's safety and well-being

**5.2.2.** IEC members will monitor For-cause assessments for the followings Non – compliance/and or complaints of the approved study

**5.2.3.** IEC members will involve the identification of opportunities for improvement.

**5.2.4.** Upon receipt of the package, the Secretariat of the IEC should perform the following:

**5.2.5. Verify the contents of the document:** The Secretariat will verify that the contents of the package include the following documents:

- Continuing Review Application Form
- The Progress Report with: Information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" (ticked on the Continuing Review Application Form answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants.
- The progress report summary of the protocol since the time of the last review (1 copy).
- Request letter for extension of approval of the project, if the project is ongoing.
- The Secretariat will check for complete information and for the presence of the required
- Signatures of the Principal Investigator in the Continuing Review Application or study progress report.

**5.3. Filing the continuing review document:**

- The study designee or PI of the study submit Annual progress report with request letter for the continuing of study protocol
- that if further amendments are decided PI should again change version no. and date

**5.4 Prepare meeting agenda:**

The Secretariat will follow for procedures on the preparation of meeting agenda and place the forwarded Annual Progress Report on the agenda for the meeting of the IEC as (AF/IEC/01/13/V-2.0), if deemed necessary by the Chairperson/ Member Secretary, on the datewhich is as close as possible to the due date (i.e. one year after the date of original approval)of the protocol.

**5.5 Continuing Protocol Review Process:**

The IEC Chairperson/ Member Secretary/ members will use the Continuing Review Application Form to guide the review and deliberation process. The IEC members could arrive at any oneof the following decisions at the IEC meeting: Continuation of approval for one year

**5.6 Store original documents**:

Place the original completed documents with the other documents in the Continuing ReviewPackage in the protocol file

**6. Glossary:**

**Approved Protocols** Protocol that has been *approved without stipulations* or *approved with recommendations* by the IEC may proceed. Protocols that have been *approved with stipulations* 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 *one* month for re-review.

**7. References:**


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use E2R2(ICH)-2016
- Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- WMA Declaration of Helsinki-Ethical principal for Medical Research involving human subjects-2013
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trial Rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


**8. Annexure:**

Annual Report Template (AF/IEC/01/13/V-2.0)

**Annexure: 01** **(AF/IEC/01/13/V-2.0)**

## Annual Report Template

| Sl.No | Particulars | Filled by the Investigator) |
|---|---|---|
| **1.** | Protocol No: and Version & date | |
| **2.** | Protocol Title: | |
| **3.** | Principal Investigator: | |
| **4.** | Name of the Co-Investigator: | |
| **5.** | Duration of the study: | |
| **6.** | PI Presented to IEC Meeting – date: | |
| **7.** | Approval date: | |
| **8.** | **Study initiation: - date** | |
| **9.** | **Amendments if any:** | |
| **10.** | Approval given for the Amendment: | |
| **11.** | Financial Status: | |
| **12.** | Objectives: | |
| **13.** | Sample size | |
| **14.** | Number of study participants enrolled | |
| **15.** | Number of Drops outs: | |
| **16.** | Number of screen failures: | |
| **17.** | Number of ongoing: | |
| **18.** | **Summary of the work done (preferably in 1-2 paragraphs):** | |
| **19.** | Number on study/follow-up: | |
| **20.** | Number of AE/SAE: | |
| **21.** | Completion/Termination of the study – date | |
| **22.** | Any protocol deviation and violations: | |
| **23.** | Next due for the study Approval: | |
| **24.** | Signature of the Principal Investigator with date | |

IEC SOP 14: Review of clinical trial final report

# IEC SOP 14: Review of clinical trial final report

## 1. Purpose:

The purpose of this SOP is to provide instructions on the review and follow-up, if appropriate, of Final Reports for any study previously approved by the Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai.

## 2. Scope:

This SOP applies to the review and follow-up of the Final Report which is an obligatory review of each investigator's activities presented as a written report of studies completed to the IEC. The Institutional Ethics Committee for Clinical Studies provides a Study Report Form for Protocol Termination/ Completion (AF/EC/04/06/V-2.0) of SOP/06/V-2.0 which is to be followed by the investigators for submission of the Final report.

## 3. Responsibility:

It is the responsibility of the IEC secretariat to review the report for completeness before making copies for the IEC meeting.

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1 | Activities before the IEC meeting | IEC Secretariat |
| 2 | Activities during the IEC meeting | IEC Secretariat / Members / Chairperson |
| 3 | Activities after the IEC meeting | IEC Secretariat |

## 5. Detailed instructions:

### 5.1 Before each IEC Meeting

- See SOP/06/V-2.0 (Management of Protocol Submission) for receiving and checking the Final study completion report.
- The Member Secretary and affiliated members will review the submitted report and the Principal Investigator will make the changes if needed.
- The Secretariat to send the copies to the IEC members and Chairperson. If needed.

### 5.2 During the IEC Meeting

- IEC member reviews and gives their comments on a copy of the Final Report.
- The Chairman entertains any discussion of the study.

- If appropriate to the discussions, an IEC member may call for consensus on whether to request further information or to take other action with the investigator.
- Summarize what action should be taken.

**5.3 After the IEC Meeting**

- Notify the investigator of the decision.
- Accept and file the Final Report, if no action is taken.
- Note the decision in the meeting minutes.
- Consider the study as closed.
- Send the approved minutes/Decision to the investigator.
- Archive the entire study protocol and the report.

**6. References:**


› Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants-2011

› International Conference on Harmonization, Guidance on Good Clinical Practice E2R2(ICH GCP) 2016.

› Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017

› New Drugs and Clinical Trial Rules, 2019

› ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2021

IEC SOP 15: Review SAE reports from the PI/study designee

# IEC SOP 15: Review SAE reports from the PI/study designee

**1. Purpose:**

The purpose of this SOP is to provide instructions on the review SAE initial and follow-up reports of serious adverse events and unexpected events for any active study approved by the Institutional Ethics Committee, UPUMS. The Serious Adverse Events must be reported by the investigators to the IEC within 24 hours after the incident. The unexpected events should be included in the continuing review report submitted to IEC.

Unanticipated risks are sometimes discovered during studies. Information that may impact the risk/benefit ratio should be promptly reported to and reviewed by the IEC to ensure adequate protection of the welfare of the study participants.

The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare, or safety of the participants in the study.

**2. Scope:**

This SOP applies to the review of SAE reports (on site) submitted by Investigators to IEC of UPUMS.

**3. Responsibility:**

**3.1.** It is the responsibility of the IEC to review all the Clinical trial SAEs occurred at site in a Timely manner

**3.2.** The researcher is responsible for reporting all SAEs to the EC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days

**3.3.** The report of SAE of due analysis shall be forwarded by the Investigator to IEC, DCGI, and sponsor or its representative within 14 calendar days of occurrence SAE.

**3.4.** The UPUMS Ethics Committee for clinical trial shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the said sponsor or its representative, who has obtained permission from the Central Licencing Authority for conduct of clinical trial or bioavailability or bioequivalence study, as the case may be, to the

Central Licensing Authority within a period of thirty days of receiving the report of the seriousadverse event of death from the investigator.

**3.5.** The report of SAE of due analysis shall be forwarded by the Investigator to IEC, DCGI, and sponsor or its representative within 14 calendar days of occurrence SAE.

**3.6.** The report should be accompanied by detailed narrative of the SAE and Annexure-1 form of the CDSCO

**3.7.** SAE review members/IEC members review the PI submitted SAE Documents and submitted in the Full board Meeting and IEC opinion/Minutes be communicated with the DCGI and PI within 30 days of SAE Occurrence.

**3.8.** In the case of other site SAEs consider for information

**3.9.** The sponsor or his representative shall pay the compensation in case of clinical trial related Injury or death within 30 days of the receipt of such an order from Licensing Authority.

**3.10.** The IEC Secretariat is responsible for initial screening of the reports and assessing / seeing whether they need a review of full Board, Chairperson, other qualified IEC members or experts.

**4. Flow chart:**

| Sl.No | Activity | Responsibility |
|---|---|---|
| 1. | SAE related activities before an IEC meeting | IEC Secretariat, SAE Sub-committee members |
| 2. | Review and determine SAE relatedness in the SAE Review sub-Committee | IEC Secretariat, SAE Sub-committee members and subject Expert |
| 3. | Decide the criteria for the review | IEC Secretariat, members |
| 4. | Review and discuss during the IEC meeting | IEC members and Chairperson |
| 5. | Decide what action should be taken | IEC members and Chairperson |
| 6. | Inform investigator, regulatory authorities within 30 days of receipt of the SAE | Secretariat and Chairperson/Member Secretary |

**5. Detailed instructions:**

**5.1. Composition of the Committee:** The SAE sub-Committee members appointed/Selected by the Chairperson of IEC from the Members and subjects' experts.

- The composition shall be as follow:
    - Chairman of Sub-Committee
    - Member-Secretary
    - IEC Administrator
    - Subject Experts- if Needed
    - Physician if Needed
- The SAE sub-Committee may invite legal expert of IEC of UPUMS to provide opinion on the (if any) legal implication of Serious adverse event.
- The chairperson of the SAE sub-Committee responsible for the conducting of SAE sub-Committee meetings, and lead all discussions and deliberations pertinent to the review of SAEs
- The chairperson of the SAE sub-Committee/Member-secretary of IEC approve the minutes of meetings.
- In the event of report of SAEs, the IEC secretariat convenes meeting (as many as necessary) after receiving the SAE related documents.

5.2 The SAE sub-Committee may be constituted within IEC of Uttar Pradesh University of Medical Sciences, Saifai. If the institutions have large number of SAE reports.

5.3 The Serious adverse Event (SAE)- sub-committee of IEC of UPUMS review all SAEs occurred atsite/ academic studies, which have been approved by the IEC.

5.4 The committee consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse events involving the human participants.

**5.5 Criteria for SAE Review**: **As per the WHO Causality assessment scale the criteria for SAE review as follow: (1) off site – on site; (2) SUSAR – Non SUSAR; (3) Related – Non related**

- Report is forwarded to the SAE members for review and determination if report should be reviewed at the convened meeting and same report is added to the agenda for review at a convened meeting by full Board. An adverse experience/Investigational New Drug Safety Report has been previously seen by full Board but being resubmitted by another investigator participating in the multi-study site (as part of a multi-center/site study).
- The SAE follow up notification does not require full Board review

› Reviewed by the Chairperson/Member Secretary or SAE review committee members and secretariat

**5.6 Functions of the Member-Secretary of the SAE Sub-committee**

- To schedule, organize and conduct SAE sub-committee meetings.
- To prepare and maintain meeting agenda and minutes.
- To prepare the communication letters related to the adverse event reports.
- To communicate with the IEC members, regulatory authorities and investigators in timely manner.
- To provide necessary administrative support for SAE sub-committee related Activities.
- To ensure adherence of the SAE Sub-committee functioning as per SOPs.
- reporting SAE to CDSCO through Sugam portal within 30 days

**5.7 During the full board review meeting:**

- Ask PI for the uploading of SAE initial report in the SAE Sugam portal
- Member-Secretary read out the minutes of the SAE sub-committee meetings including the recommendations/decisions of the SAE sub-committee.
- In case se of the SAE occurring at the site to be discussed in full review at the meeting, the member-Secretary also provide the relevant information including updates on SAE have occurred earlier at the site.
- The Decision be recorded in the minutes of the meeting and circulated.

5.8 **Decision of IEC of UPUMS on SAE review:** The SAE sub-committee/IEC may take one or more of the following decisions on review of the SAE reports:

- Type of Actions Taken by IEC/ SAE Sub-committee on Review of SAE Report: Following detailed review of the SAE reports and related documents, the IEC/ SAE Subcommittee can suggest one of the following actions:
- SAE Assessment by using WHO Causality Assessment scale
- IEC Decision is :
  - No further action required;
  - Request information,
  - Recommend further action
- The detailed narration/ report of SAE be communicated to DCGI ( As per New CDSCO rules
- Note the information about the SAE in records for future reference
- Request further follow-up information and/or additional detail

- Ask for periodic follow-up of the research participant till SAE is resolved
- Depending on the complexities of issue, IEC/ SAE sub-committee may decide to seek opinion of outside expert consultant who be requested to respond within 14 working days
- Provide recommendations regarding/raise queries related to compensation for study-related Death

**5.9 Type of actions taken by the IEC: if the SAEs repeatedly occur in the same study/trials**

- Suspend the study till additional information is available.
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).
- Suspend enrollment of new participants.
- Suspend certain activities under the protocol. Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial. Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations etc. as prescribed in the amendment. Any other appropriate action. the decision shall be recorded in the minutes of the IEC meeting. The decision of the IEC requiring immediate action from the PI be conveyed to the PI through Letter/telephone, fax or email within 24 hours. Such a communication be documented by the IEC Member-Secretary in the study file.
- Formal letter to the PI informing about the IEC recommendations in such situations be sent within 5 working days of the IEC meeting having taken place.

## 6. Glossary:

**Adverse Drug Reaction:** In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not establish all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases orfor modification of physiological function.

## IEC SOP 15: Review SAE reports from the PI/study designee

**IND:** Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.

**SAE :( Serious Adverse Event)** The adverse event is SERIOUS and should be reported when the patient outcome is:

**Death** - Report if the patient's death is suspected as being a direct outcome of the adverse event. **Life-Threatening** - Report if the patient was at substantial risk of dying at the time of the adverseevent or it is suspected that the use or continued use of the product would result in the patient'sdeath.

Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusionpump failure which permits uncontrolled free flow resulting in excessive drug dosing.

**Hospitalization** (initial or prolonged) - Report if admission to the hospital or prolongation of ahospital stay results because of the adverse event.

Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.

**Disability** - Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities orquality of life.

Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.

**Congenital Anomaly** - Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.

Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.

**Requires Intervention to Prevent Permanent Impairment or Damage** –

Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.

Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to

Prevent malunion of a fractured long bone.

**Unexpected ADR** Unexpected Adverse Drug Reaction is an adverse reaction, the nature or severity of which is not consistent with the informed consent /information sheets or the applicable product information (e.g., investigator's brochure for the unapproved investigational product or package insert / summary of product characteristics for an approved product.

## 7. References:


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016
- WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trials, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


## 8. ANNEXURE:s

**AF/IEC/ 01/15/V-2.0** Data elements for reporting serious adverse events occurring in a clinical trial or bioavailability or bioequivalence study

**AF/IEC/02/15/V-2.0** SAE Reporting Template

## Table:05

**DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL**

**1.** Patient Details:

Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)*Gender

Age or date of birthWeight

Height

**2.** Suspected Drug(s):

Generic name of the drug*

Indication(s) for which suspect drug was prescribed or testedDosage

form and strength

Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)Route of

administration

Starting date and time of day

Stopping date and time, or duration of treatment

**3.** Other Treatment(s): Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).

**4.** Details of Serious Adverse Event: Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*

Start date (and time) of onset of event.

Stop date (and time) or duration of event DE

challenge and rechallenge information.

Setting (e.g., hospital, out-patient clinic, home, nursing home)

**5.** Outcome: Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

**6.** Details about the Investigator*

## IEC SOP 15: Review SAE reports from the PI/study designee

Name and Address Telephone

number\ Profession (specialty)\

Date of reporting the event to Central Licencing Authority:

Date of reporting the event to ethics committee overseeing the site:Signature of the

Investigator or Sponsor

**Note:** Information marked * must be provided

**ANNEXURE: 02** **AF/IEC/02/15/V-2.0**

**Principal Investigator (Name, Designation and Affiliation)**

**Title of study**

| | | | | |
|---|---|---|---|---|
| **1.** | **Participant details :** | | | |
| | Initials and Case No./Subject ID | Age at the time of event | Gender<br>Male ☐<br>Female ☐ | Weight: (Kgs)<br>Height: (cms) |
| **2.** | Report type: Initial ☐ Follow-up ☐ Final ☐<br>If Follow-up report, state date of Initial report<br>What was the assessment of relatedness to the trial in the initial report?<br>By PI- Related ☐ By sponsor - Related ☐ By EC - Related<br>☐ Unrelated ☐ Unrelated ☐<br>☐ Unrelated ☐ ☐ | | | |
| **3.** | Describe the event and specify suspected SAE diagnosis: | | | |
| **4.** | Date of onset of SAE: | | Date of reporting: | |
| **5.** | Onset lag time after administration of intervention: | | Location of SAE (Clinic/Ward/Home/Other) | |
| **6.** | Details of suspected study drug/device/investigational procedure causing SAE: | | | |
| | I. Suspect study drug (include generic name) device/intervention: | | | |
| | II. Indication(s) for which suspect study drug was prescribed or tested: | | | |
| | III. Route(s) of administration, daily dose and regimen, dosage form and strength: | | | |
| | IV. Therapy start date: Stop date: | | | |
| **7.** | Was study intervention discontinued due to event?<br>Yes ☐ No ☐ | | | |
| **8.** | Did the reaction decline after stopping or reducing the dosage of the study drug / procedure?Yes ☐ No ☐<br>If yes, provide details about the reduced dose. | | | |
| **9.** | Did the reaction reappear after reintroducing the study drug / procedure?<br>Yes ☐ No ☐ NA ☐ | | | |

☐ ☐ ☐

| | | | | |
|---|---|---|---|---|
| | If yes, provide details about the dose. | | | |
| **10.** | Concomitant study drugs history and lab investigations:<br>I. Concomitant study drug (s) and date of administration:<br>II. Relevant test/laboratory data with dates:<br>III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc) | | | |
| **11.** | Have any similar SAE occurred previously in this study? If yes, please provide details.<br>Yes ☐ No☐ yes | | | |
| **12.** | Seriousness of the SAE: | | | |
| | Death<br>Life threatening<br>Hospitalization-initial or prolonged<br>Disability | ☐<br>☐<br>☐ | Congenital anomaly<br>Required intervention to prevent permanent impairment / damage<br>Others (specify) | ☐<br>☐<br>☐ |
| **13.** | Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom). | | | |
| **14.** | Outcome of SAE: | | | |
| | Fatal<br>Continuing<br>Recovering | ☐<br>☐<br>☐ | Recovered<br>Unknown<br>Other (specify) | ☐<br>☐<br>☐ |
| **15.** | Was the research subject continued on the trial?<br>Yes ☐ No ☐ NA ☐ | | | |
| **16.** | Provide the details about PI final assessment of SAE relatedness to trial. | | | |
| **17.** | Has this information been communicated to sponsor/CRO/regulatory agencies?Yes ☐ No ☐<br>Provide details if communicated (including date) | | | |
| **18.** | Does this report require any alteration in trial protocol? | | | |

| | |
|---|---|
| | Yes ☐ No ☐ |
| **19.** | Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom)<br>Signature of PI: |

IEC SOP 16: Site Monitoring Visit

# IEC SOP 16: Site Monitoring Visit

## 1. Purpose:

The purpose of this SOP is to provide procedures as to when and how a study Protocol should bemonitor for its performance or compliance to GCP and IEC of UPUMS.

## 2. Scope:

This SOP applies to any visit and/or monitoring of any clinical trials which is approved by the IEC ofUPUMS.

## 3. Responsibility:

It is the primary responsibility of the IEC to visit or designate some Ethics Committee Members toperform the monitoring of the clinical trials which is approved by the IEC of UPUMS

The IEC members or Secretariat in consultation with the Chairperson may an evaluation of a studyprotocol for a cause or for a routine monitoring

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1 | Selection of study Protocol based on for cause or routine | Secretariat IEC members and Chairperson |
| 2 | Sending of Monitoring visit to the Study designee/Investigator of the study | IEC Secretariat/Member Secretary/IEC member |
| 3 | Procedures during the visit as per the monitoring agenda | IEC Secretariat/Member Secretary/IEC member |
| 4 | Procedures after the visit report is submitted to full board meeting | IEC Member/Chairperson/Member secretary |
| 5 | Present the findings to the Full Board | IEC member secretary |

## 5. Detailed instructions:

### 5.1 Selection of study Protocol based on the for cause and or routine

- **For cause:** there is any frequent reporting of Protocol deviation/SAEs/AEs or any complaints from the study participants
- **For Routine:** Selection of the study Protocol should be done randomly

**5.2 Before the visit: The IEC Members only will**

5.2.1 Contact the study team to notify them that they/ their representative will be visiting them. At that time, the monitor and the study team will coordinate a time for the Protocol evaluation visit.

5.2.2 Review the IEC files for the study and any other correspondence

5.2.3 Make appropriate notes, or copy some parts of the files for comparison with the Protocol files.

5.2.4 PI may inform about IEC monitoring visit through Mail. If needed or they Will select the random study from the different sponsor/PI/CRO to be Monitored by the IEC members.

**5.3 During the visit: Get a checklist AF/IEC/01/19/V-2.0**
**The IEC representatives will**

5.3.1. Review the informed consent document to make sure that the study team is using the most recent version of ICD.

5.3.2. Review randomly the subject files to ensure that subjects are signing the correct informed consent.

5.3.3. Observe the informed consent process, ICF and ICF Documentation.

5.3.4. Source documents monitoring

5.3.5. Observe laboratory and other facilities necessary for the study.

5.3.6. Review the IEC communication documents of the study to ensure that documentation is filed appropriately.

5.3.7. Collect views of the study participants, if possible

5.3.8. Brief the full board visit report/comments.

5.3.9. If needed Investigator site file(ISF) with all the logs

5.3.10. Checking of T/A of the subject

**5.4 After the visit: The EC representative will**

5.4.1. write a report/comment (use the form AF/IEC/01/19/V-2.0) within 2 weeks describing the findings during the visit forward a copy of the study team visit form to the Secretariat

5.4.2. The Secretariat will Include this report in the Agenda of the Full Board meeting

5.4.3. Send a copy of the approved report to the study Investigator for their files, and Place the report in the correct study files.

5.4.4. Retain one more copy of the approved report in the IEC files

5.4.5. IEC Monitoring report submitted to the study investigator/study designee.

## 6. Glossary

**IEC representatives:** Many IEC rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to IEC.

**IEC Monitoring visit:** An action that IEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects,recording data and reporting their observations, especially serious adverse events found during the studies. Also, source documents monitoring to know how the subjects are kept informed on the risk and benefit and also (in amended ICF), how the continued consenting process is documented, capturing the need for reconsenting. Normally monitoring visit will be arranged in advance withthe intimation to the principal investigators.

## 7. References:


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016
- Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants-2011
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- International Ethical Guidelines for Health-related Research Involving Humans-CIOMS-2016


## 8. ANNEXURE

AF/IEC/01/19/V-2.0 Checklist for IEC members Monitoring Visit

**ANNEXURE: 01** **AF/IEC/01/19/V-2.0**

## Site monitoring visit report

| **Protocol Number** | **PI Name** | **Date of visit** |
|---|---|---|
| | | |
| **Study CRCs** | Site ID | Phone No: |
| | | |
| **CROs/Sponsors Name** | | |
| Subject Details: | | |
| **No. of Participants Screened:** | No of Participants enrolled | No of Participants Ongoing: |
| **No. of Participants drop out:** | No. of Participants completed | |
| Subject interview (if planned) | | |
| Awareness of the rights | | [Y/N]-Comments |
| Satisfied with the process | | |
| **Study protocol and related documents:** | | |
| Use of recent (IEC approved) version of protocol | | |
| Use of recent (IEC approved) version of informed consent document | | |
| Informed consent process complete (including source documentation) | | |
| Is the delegation proper (as respect to qualification and experience) | | |
| SAE reporting timely and complete (if any) | | |
| Weather appropriate vernacular consent have been taken | | |
| Investigational Medicinal Products | | |
| Logs up to date | | |
| Safekeeping with controlled access and temperature maintenance | | |
| Clear delegation | | |
| **Ethical concerns:** | | |
| Grievance handling explained and the same documented | | |

| | |
|---|---|
| Subject/s remuneration done as due | |
| Is there any involvement of vulnerable population (if Yes Please write the type of Vulnerability) _____ | |
| Is the study team conducting repeated education/information about research, benefits, risks and alternatives for vulnerable persons? | |
| Justification for the inclusion of vulnerable population in the research | |
| Corrective and preventive action submitted by PI<br>Within 10 days of the recipient | |

**Study status**: Enrolling/Follow up/Data cleaning**:**

I. **SUMMARY:**

| **Protocol Number** | **PI Name** | **Date of visit** |
|---|---|---|
| | | |
| Site ID | Phone No: | |
| | | |
| CROs/Sponsors Name | | |
| Subject status: | | |
| No. of Participants Screened: | No of Participants enrolled | No of Participants Ongoing: |
| No. of Participants drop out: | No. of Participants completed | |
| Key Dates | | |
| IEC Approval | Study initiation | First Participant screened |
| | | |
| Latest versions and date: | | |
| Protocol | ICF | Investigator Brochure |
| | | |
| Study team member qualification, ICH-GCP, training etc., | Co-Investigator | Study CRCs |

## II. Documents Reviewed:

- ☐ Signed Informed Consents:
- ☐ Source Documents:
- ☐ Monitoring/ auditing reports:
- ☐ Investigational Product use, storage & reconciliation records:
- ☐ Delegation of Responsibilities Log:
- ☐ Subject Enrolment Log (equitable distribution):
- ☐ Clinical trial Agreement, Indemnity & Insurance:
- ☐ Investigator's File & Communications fileOther
- ☐ information attached-Findings

## III. **If any suggestions:**

IEC Members/Member Secretary Signature:

IEC SOP 17: Intervention in Protocol Deviation and Violation

# IEC SOP 17: Intervention in Protocol Deviation and Violation

**1. Purpose:**

To provide instructions for taking action and maintaining records that identify Investigators/Institutes who fail to follow the procedures written in the approved Protocol or tocomply with National / International guidelines for the conduct of Human research, including those who fail to respond to the IEC requests.

**2. Scope:**

This SOP applies to all IEC approved research Protocols involving Human participants.

**3. Responsibility:**

IEC Secretariat is responsible for receiving deviations /violations/waiver reports as per SOP01/V-2.0, (AF/IEC/01/16/V-2.0) submitted by the PI and placing it on agenda of the meeting. Reporting ofdeviation/ non-compliance/ violation/ waiver in any other reporting format will not be accepted. IEC members should review and take action on such reports.

**4. Flow chart:**

| Sl.No | Activity | Responsibility |
|---|---|---|
| 1. | Protocol deviation and or Violation notified to IEC | PI of the study |
| 2. | Review of PD and Violation | IEC Secretariat |
| 3. | Inclusion of PD and Violation into Agenda | IEC Secretariat |
| 4. | Review and discuss during the IEC meeting | IEC members and Chairperson |
| 5. | Decide what action should be taken | IEC members and Chairperson |
| 6. | Inform investigator/study designee | Secretariat and Chairperson/Member Secretary |

## 5. Detailed instructions:

### 5.1. Protocol deviation / non-compliance / violation/waiver have been observed:

- Ensure that the project in which non-compliance has been observed is included in the agenda of the IEC meeting.
- Maintain a file that identifies projects that are found to be non-compliant with National / International regulations or Investigators who fail to follow Protocol approval stipulations or fail to respond to the IEC request for information/action
- The PI himself / herself may forward the Protocol deviation/non- compliance/ Violation /waiver reports to inform 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 approval of a subject who does not satisfy the approved inclusion / exclusion criteria for enrollment.

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

**b.** Communication received from any source, informing IEC about an Alleged Protocol violation / non-compliance / Protocol deviation

**c.** Noting Protocol deviation / non-compliance / violation / waiver to the Secretariat

**d.** PI/Study Monitors who have performed monitoring of a particular trial site and detect Protocol deviation / non-compliance / violation will inform to the Secretariat in writing **Within 15 Days**.

**e.** Whenever Protocol deviation/non-compliance/violation has been observed, the 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.

**f.** The deviations/violations will be scrutinized for gravity and implications in the formal full board IEC meeting. The IEC decision will be communicated to the PI.

***Note*:** The Ethics Committee shall withhold at their discretion the approval of current studies or refuse subsequent applications from the Investigators cited. Such decisions are recorded inminutes.

**5.2 Detection of Protocol deviation/ non-compliance/ violation/waiver:**

The IEC members performing monitoring of the project at trial site can detect Protocoldeviation/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 / trial site / Sponsor/CROs

**5.3 The IEC Discussion and Action:** The Chairperson/Member secretary notifies the Investigator regarding the IEC's action in writing,

- If the Protocol deviation /non-compliance/violation is detected by any IEC member
  During the monitoring visit, he/she will present the Protocol deviation / non-compliance /violation information.
- If detected by Secretariat / PI, the Secretary will present the Protocol Deviation/non-compliance/violation/waiver information
- The Chairperson/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 and rights of the research participants are safeguarded.
- **IEC Decision is**
  1. No further action required;
  2. Request information,
  3. Recommend further action
- Inform the PI that IEC has noted the violation / non-compliance / deviation and inform the PI to ensure that deviations / non-compliance / violations will not occur in the future and follow IEC recommendations.
- Enlist measures that the PI would undertake to ensure that deviations / noncompliance /violations do not occur in future.
- 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 are found to be satisfactory by the IEC. Suspend the study for a fixed duration of time.

- Revoke approval of the current study.
- Inform DCGI / Other relevant regulatory authorities if applicable.
- Keep other research proposals from the PI/ Co-PI under abeyance.
- Review and / or inspect other studies undertaken by PI/Co-PI

### 5.4 Notify the Investigator

- The IEC Secretariat members record the IEC's decision.
- Request the Chairperson/Member-Secretary to sign and date the letter.
- Make two copies of the notification letter
- Send the Original copy of the notification to the Investigator.

### 5.5 Keep records and follow up

- Keep a copy of the notification letter in the "non-compliance" file.
- Store the file in the shelf with an appropriate label.
- Follow up the action after a time period as suggested by the Ethic Committee.

## 6. Glossary

**Deviation / Non - compliance / Violation**: The IEC monitors whether Investigators do not perform the study in compliance with the approved Protocol, ICH GCP, FDA regulations and/or fail to respond to the IECs request for information/action.

**Protocol Deviation:** Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the subject, researcher, or research staff. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of a researcher.

Examples of a deviation include:

- A rescheduled study visits
- Failure to collect an ancillary self-report questionnaire
- Subject's refusal to complete scheduled research activities

**Protocol Violation:** Intentional change to, or non-compliance with the IEC approved protocol without prior sponsor and IEC approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data.

**Examples of protocol violations:**

- Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form)
- Loss of laptop computer that contained identifiable, private information about subjects
- Accidental distribution of incorrect study medication or dose
- Not following inclusion/exclusion criteria

**7. References:**


› International Conference on Harmonization of technical requirements for pharmaceuticals for human use (ICH)-2016

› Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017

› New Drugs and Clinical Trail rules,2019

› ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


**8. ANNEXURE:**

| | |
|---|---|
| AF/IEC/01/16/V-2.0 | Deviation/Non-Compliance/Violation Record |

**ANNEXURE: 01** **AF/IEC/01/16/V-2.0**

## Deviation/Non-Compliance/Violation notification

Study Title:

Investigator

Sponsor:

Contact No.:

Protocol Deviation/Violation ☐ Violation ☐ Deviation

| | | | | |
|---|---|---|---|---|
| 1. | Is the deviation related to (Tick the appropriate box) : | | | |
| | Consenting | ☐ | Source documentation | ☐ |
| | Enrolment | ☐ | Staff | ☐ |
| | Laboratory assessment | ☐ | Participant non-compliance | ☐ |
| | Investigational Product | ☐ | Others (*specify*) | ☐ |
| | Safety Reporting | ☐ | | |
| 2. | Total number of deviations /violations reported till date in the study: | | | |
| 3. | Deviation/Violation identified by: Principal Investigator/study team ☐<br>Sponsor/Monitor ☐<br>SAE Sub Committee/EC ☐ | | | |
| 4. | Provide details of Deviation/Violation: | | | |
| 5. | Corrective action taken by PI/Co-PI: | | | |
| 6. | Impact on (if any):<br>Study participant ☐<br>Quality of data ☐ | | | |

Reported by: …….

Date……..

# IEC SOP 18: Response to Complaints, Queries & Requests

## 1. Purpose:

Since the Institutional Ethics Committee of UPUMS considers protection of the rights and welfare ofthe human subjects participating in a clinical investigation/research approved by the IEC as its primary responsibility, Informed Consent documents reviewed by the IEC may routinely contain the statement, "Questions regarding the rights of a participant/patient may be addressed to the Member Secretary with the IEC of Uttar Pradesh University of Medical Sciences, Saifai for Clinical Studies address and/or phone number. On some occasions, the first contact with the participant/patient would be the IEC Secretariat.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant in any approved research study.

## 2. Scope:

This SOP applies to all responses to requests from participant concerning their rights and well-being while participating in studies approved by the IEC.

## 3. Responsibility:

The Institute's policy designates the Member Secretary of the IEC as the person responsible for communicating with participants/patients regarding their rights as study participants. Delegation of this responsibility to another IEC member is acceptable as long as the delegation is documented (in writing).

## 4. Flow Chart:

| Sl.No | Activity | Responsibility |
|---|---|---|
| 1. | Complaints, Queries and request from the stakeholders | IEC Secretariat |
| 2. | Taken up in the full board meeting | IEC Secretariat |
| 3. | Action on complaints and any request from the trial stakeholders | IEC members and Chairperson |

## 5. Detailed instructions:

### 5.1 Receive the request:

- The IEC member receives the inquiry or requests from research stakeholders
- Record the request and information in the request record form (Form AF/IEC/01/17/V-2.0)
- Communicate with the IEC about study participant rights for instruction (if required).
- Secretariat may provide assistance in contacting the Member Secretary, but will not provide comments/opinions about the inquiry.

### 5.2 Take Action:

- SOP related
- Record information and any action or follow-up taken in the form AF//IEC01/17/V-2.0.
- Take signature of the Chairperson and/or the Member Secretary and date the form.
- Report to the IEC about the action taken and the outcomes.
- Communicate the reply with the participant and keep the record.
- Trial participants/PI's complaints & action taken by the IEC to notify the head of the Institution.
- All the Quires and complaints has to be received by the IEC. response and action for the same may be based on the Queries or complaints.

### 5.3 File the request document

- Keep the record form in the "response" file.
- Keep a copy in the study file.
- Store the file in the appropriately labeled

## 6. References:


- International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016
- WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trials, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

## 7. ANNEXURES:

| | |
|---|---|
| AF/IEC/01/18/V-2.0 | Participant's Request/Complaint Form AF/IEC/02/18/V-2.0 |
| | Patient's Rights and Responsibilities [Hindi] |
| AF/IEC/03/18/V-2.0 | Patient's Rights and Responsibilities [English] |

**ANNEXURE: 01** **AF/IEC/01/17/V-2.0**

**Participant's Request/Complaint Form**

| | |
|---|---|
| DATE RECEIVED: | |
| Received by : | |
| Request by : | |
| Name of the stakeholders | |
| Contact<br>Address:<br>Phone: | |
| Study No | |
| Name of Study Principal<br>Investigator/CRC/Phlebotomist | |
| What is the request/Complaints? | |
| Action taken: | |
| Outcome: | |

| | |
|---|---|
| Initial/Signature | |
| IEC member Secretary of IEC | |

IEC SOP 19: Management of study termination

# IEC SOP 19: Management of study termination

## 1. Purpose:

This procedure describes how an IEC proceeds and manages the termination of IEC Approval for the research studies. Protocols are usually terminated at the recommendation of the IEC, Data SafetyMonitoring Board (DSMB), sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

## 2. Scope:

This SOP applies to any study approved by IEC of UPUMS that is being recommended for termination of IEC approval before its scheduled completion.

## 3. Responsibility:

It is the responsibility of the IEC Chairperson/Member-secretary to terminate IEC approval of anystudy that the IEC has previously approved when the safety or benefit of the study participants isdoubtful or at risk. The Secretariat is responsible for management of the termination process.

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1. | Receive recommendation for the study termination | IEC Secretariat |
| 2. | Review and Discuss the Termination of the study protocol | IEC Secretariat and Chairperson/Member Secretary |
| 3. | Notify the Principal Investigator | IEC Secretariat |
| 4. | Store the Protocol Documents | IEC Secretariat |
| 5. | Place it in the Inactivate the Protocol Document | IEC Secretariat |

## 5. Detailed instructions:

**5.1 Receive recommendation for study approval termination.**

5.1.1 Receive recommendation and comments from IEC members, Sponsor/CROs or other authorized bodies for study protocol termination.

5.1.2 Inform the principal investigator to prepare and submit a protocol study termination letter

5.1.3 Receive the study protocol study termination prepared and submitted by the principal investigator.

5.1.4 The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data

5.1.5 Termination is indicated under "Action Request".

5.1.6 Completeness of the information, including accrual data since the time of the last continuing review.

5.1.7 Presence of the required signatures (Principal Investigator) - Initial and date the package upon receipt. Find the Termination form in SOP/06/V-2.0.

**5.2 Review and discuss the Study termination.**

5.2.1. Notify the Chairperson/member secretary regarding the recommendation for study protocol termination.

5.2.2. Provide information about any required participant follow-up visits during a suspension/termination

5.2.3. Notify of the termination or suspension of new enrollments and/or all ongoing research activities

5.2.4. The Chairperson/IEC Members reviews the results, reasons and accrual data.

5.2.5. The Secretariat calls for a meeting of full board to discuss about the recommendation. If needed

5.2.6. The Chairperson/Member Secretary signs and dates the Protocol Termination Application Form in acknowledgment and approval of the termination

5.2.7. After reviewing the all required information about study protocol and their participant safety only IEC had to take action on protocol Suspension/Termination

**5.3 Notify the Principal Investigator:** The Secretariat/Member secretary reviews, signs, and dates the Protocol Termination Application Form indicating that the termination process is complete.

**5.4 Store the protocol documents:**

- Keep the original version of the request letter for termination and the original version of the Continuing Review Application Form in the Protocol file.

- Send the file to archive.

- Store the protocol documents for five years

**6. <u>References:</u>**


› WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013

› Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017

› New Drugs and Clinical trial Rules, 2019

# IEC SOP 20: Agenda and Minutes of Meeting Preparation

## 1. Purpose:

The purpose of this procedure is to identify the administrative process and provide instructions forthe preparation and circulation of meeting agenda, Meeting proceedings, invitation and notification letters of institutional Ethics Committee.

## 2. Scope:

This SOP applies to administrative processes concerning the preparation of the agenda for all regular IEC meetings, divided into three stages: before, during and after the meeting.

## 3. Responsibility:

It is the responsibility of the Secretariat staff to prepare the agenda for the IEC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson/MemberSecretary should review and approve the agenda and the minutes sent to him/her.

## 4. Detailed Instructions:

### 4.1 Submission of Clinical trials related documents/Dossier to IEC

- Check the completeness of the EC Dossier by IEC secretariate
- Reviews the new study submission letter/EC Dossier for completeness by secretariate
- Special meeting may conduct based on the IEC Chairperson/Member Secretary discretion
- Consider the appropriate review channel of each protocol: Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel procedures
  - Submission of ethics committee dossier to IEC office/secretariat– within **15-21** days
  - the IEC dossier circulation done Prior to **14 days** of the scheduled meeting
  - IEC Decision given to PI after the full board meeting – Within **07** working days

### 4.2 Before the full board meeting:

4.2.1. Schedule the review as soon as possible after receiving the IEC dossier

4.2.2. Consult the Chairperson and other IEC members to schedule the meeting date and time

4.2.3. Inform to the IEC members regarding the meeting for confirmation

4.2.4. Schedule protocols in the agenda on a first-come first-serve basis.

4.2.5. Prepare the meeting agenda, according to the format shown in ANNEX 1 (AF/EC/01/20/V-8.3).

4.2.6. Include a Study Assessment Form see Annex 2 (AF/EC/02/06/V-2.0) by the Primary reviewers and ICD Assessment checklist by Layperson/Ngo representatives and IEC dossier along with the meeting agenda.

4.2.7. Allow IEC members at least **14 days** for the review process.

4.2.8. Write down IEC protocol Code as per IEC of UPUMS in the square boxes at the bottom right corner

4.2.9. Assign the Primary reviewers and Layperson to review the Ethics Committee dossier and Informed consent documents respectively

4.2.10. IEC Dossier circulated to each IEC member

4.2.11. The Principal Investigator will mention the type of review in the covering letter and will submit the documents accordingly.

4.2.12. The Dossier will be sent to the IEC Members for their comments and suggestions will be discussed in the IEC full board meeting

4.2.13. Place the new clinical trials/agenda in the full board meeting

>SOP for Expedited Review - SOP/07/V-2.0

>SOP for Initial Review of Submitted Protocols – SOP/08/V-2.0

**4.3 During the Ethics Committee meeting:**

4.3.1 The Meeting is conducted in physical mode and Virtual mode partially and all the meeting proceedings are recorded and stored securely

4.3.2 Present meeting agenda approval from all the members and Member secretary read the previous meeting minutes with the approval from the chairperson

4.3.3 At the discretion of the Chairman, guest attendees (potential client, students, etc.) may be allowed to observe the Board meetings.

4.3.4 The Chairperson may inform members and attendees of the rules being followed during meetings.

4.3.5 The IEC may allow investigators, clinical collaborators, and guest attendees/students etc., to attend the portion of the EC meeting related to their studies by filling confidentiality agreement and approved by member secretary/Chairperson

4.3.6 Decide the degree of risks

4.3.7 Consider whether or not the study should be approved.

4.3.8 The IEC administrator/Secretariate records the Proceedings/discussions and the decisions made during the meeting.

4.3.9 The IEC Members give their comments right after the presentation and the discussion about the study takes place.

**4.3.10 Decision Making Procedure:**

- Voting will be held only in cases where there is a lack of consensus on an issue/protocol.
- Voting will be by hand rising.
- In order to avoid conflict of interest, only those IEC members who are independent of the investigator and the sponsor of the trial will vote on the research-related matters.
- All voting will take place after the observers / presenters / IEC members with a conflict of interest leave the meeting room.
- The Chairman determines if the number of voting Board members is sufficient to constitute a quorum and proceeds accordingly.
- If a quorum is not met then the meeting will be deferred
- An IEC member makes a motion to recommend action on a protocol or issue being discussed.

**4.4 <u>After the Ethics Committee Meeting:</u>**

4.4.1. IEC secretariat prepares the meeting proceeding of the minutes report after completion of meeting of the PI presented protocols.

4.4.2. As soon as possible after each meeting, a copy of the minutes is sent to IEC members for records/information.

4.4.3. The Secretariat sends an IEC decision letter along with the approved documents to the investigator. The letter contains, at a minimum, a listing of each document approved, the date set by the IEC for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.

4.4.4. If the IE votes not to approve the study, the Chairperson or Secretariat immediately notifies the investigator in writing of the decision and the reason for disapproving the study. If the investigator wishes to appeal this decision, he or she may do so by contacting IEC office. This process is stated in the action letter provided to the investigator

**4.4.5.** If the IEC/IRB votes to require modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific **changes**

**to** the investigator asking him or her to make the necessary changes and resubmit thedocuments to the IEC Secretariat.

4.4.6. The Chairperson/Member secretary indicates approval by signing and dating the minutes.

4.4.7. The Secretariat maintains the official copies of the minutes in accordance with the archiving procedures.

**4.5 Distributing the minutes and the decision**

- Send a copy of the IEC decision letter to the Principal Investigators for their records and for them to make the suggested rectifications by the IEC members.
- Send the approved minutes to the IEC members.

**5 Glossary:**

**Agenda:** A list of things to be done; a program of business at a meeting

**Minutes:** An official record of the business discussed and transacted at a meeting, conference, etc. **Quorum:** Number of EC members required to act on any motion presented to the Board for action. **Majority vote**: A motion is carried out if one half plus one member of the required quorum votes initsfavor.

**6 References:**

› New Drugs and Clinical Trial Rules 2019.
› Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
› Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
› ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

**7 Annexure:**

| | |
|---|---|
| AF/IEC/01/20/V-2.0 | Format of an Agenda |
| AF/IEC/02/20/V-2.0 | Format for IEC meetings |

**ANNEXURE: 01** **AF/IEC/01/20/V-2.0**

## Format of an Agenda

**Type of Meeting**: Full Board Meeting

**Venue:**

Date of issuance:

To,

**NOTICE OF MEETING:**

### IEC Members:

Member 1 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 2 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 3 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 4 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 5 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 6 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 7 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 8 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 9 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 10 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 11 (name, position, science/non-science, affiliated/non-affiliated, male/female)Member 12(name, position, science/non-science, affiliated/non-affiliated, male/female) Member 13 (name, position, science/non-science, affiliated/non-affiliated, male/female)Member 14 (name, position, science/non-science, affiliated/non-affiliated, male/female)

**AGENDA**

1. CALL TO ORDER
2. DETERMINATION OF QUORUM
3. DISCLOSURE OF CONFLICT OF INTEREST
4. APPROVAL OF THE AGENDA
5. APPROVAL OF THE MINUTES OF THE LAST MEETING
6. PROTOCOL REVIEW

**6.1. FULL BOARD REVIEW**

**6.1.1. Protocols for Initial Review**

| | |
|---|---|
| **Protocol Code** | |
| **Submission date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.2. Protocols for Modification or Resubmissions

| | |
|---|---|
| **Protocol Code** | |
| **Re-Submission date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.3. Amendments

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |
| **Submission date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.4. Protocol Non-Compliance (Deviation or Violation) Reports

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |

| | |
|---|---|
| **Report date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.5. SAE Reports

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |
| **Report date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.6. Requests, Queries, and Complaints

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.7. Site Visit Reports

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |

| | |
|---|---|
| **Protocol Title** | |
| **Site Visit date** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.8. Study Termination

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.9. Continuing and Progress Reports

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

### 6.1.10. Final Reports

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |

| | |
|---|---|
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |

**7. OTHER MATTERS:**

**8. ADJOURNMENT:**

Kindly make it convenient to attend and bring these relevant documents for your ready reference.Yours sincerely,

Member Secretary

**ANNEXURE: 02** **AF/IEC/02/20/V-2.0**

## Format of IEC Meeting Minutes

**Type of Meeting**: Full Board Meeting

**Venue:**

Date of issuance:

**Attendance:**

## Present:

Member 1 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 2 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 3 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 4 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 5 (name, position, science/non-science, affiliated/non-affiliated, male/female)

**Absent:**

Member 1 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 2 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 3 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 4 (name, position, science/non-science, affiliated/non-affiliated, male/female) Member 5 (name, position, science/non-science, affiliated/non-affiliated, male/female)**Subject Expert/Intendent Consultant:**

**Member 1 -**Name, Designation -Department-Affiliation, male/female

**Others:**

Staff (name, position)

Guest (name, position)

1. **CALL TO ORDER**

   <Title, First name, surname> Chair, called this meeting to order at. Time>

2. **DETERMINATION OF QUORUM**

   Quorum was declared with the presence of members, inclusive of the presence of medical, non-medical/lay, noninstitutional, and female members, as confirmed by the Member Secretary, .

3. **DISCLOSURE OF CONFLICT OF INTEREST**

<Title, surname of chair>called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting. The following member/s inhibited from participation in the deliberations during the full board meeting for the following reasons:

<Title, Name, surname > as Investigator for the study entitled, "TITLE" (PROTOCOL NUMBER)

**4.** APPROVAL OF THE AGENDA

<Title, surname of chair > presided over the discussion of the agenda of the meeting for

(Date of current meeting). The agenda was corrected during the discussion and approved asamended.

**5. APPROVAL OF THE MINUTES OF THE LAST MEETING:**

**5.1.** Corrections in the Meeting Minutes

**5.2.** Approval of the Meeting Minutes

**5.3.** Matters Arising from the Minutes of the Last Meeting requiring EC action

**6. PROTOCOL REVIEW:**

**6.1. FULL BOARD REVIEW**

**6.1.1. Protocols for Initial Review**

| | |
|---|---|
| **Protocol Code** | |
| **Submission date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Quorum status** | |
| **Conflict of Interest** | |
| **Assessment of Scientific Issues** | 1. Rationale and literature review<br>2. Objectives/Expected output<br>3. Research/Study design<br>4. Study population, sampling design, and sample size<br>5. Inclusion criteria<br>6. Exclusion criteria<br>7. Withdrawal criteria<br>8. Control arms (placebo or less effective intervention, |

| | |
|---|---|
| | if any)<br>9. Study procedures and tools<br>10. Data management and analysis |
| **Assessment of Ethical Issues** | 1. Risks<br>2. Benefits<br>3. Vulnerability |
| **Assessment of Informed Consent Issues** | 1. Completeness of patient information sheet (PIS) and informed consent form (ICF)<br>2. Language and translation of PIS and ICF<br>3. Voluntary participation<br>4. Insurance and medical care<br>5. Cost, compensation, and reimbursement<br>6. Privacy and confidentiality<br>7. Assent and parental consent<br>8. Informed consent process |
| **Assessment of the Qualification of the Investigator** | 1. Expertise<br>2. Training<br>3. Conflict of interest |
| **Conclusion and Recommendations** | |
| **Action Taken** | 1. Approved – with or without suggestions or comments;<br>2. Revision with minor modifications/amendments<br>3. Revision with major modifications for resubmission<br>4. Disapproved |
| **Approval Expiration Date (if applicable)** | |
| **Frequency of Continuing Review (in case of approval and minor revision)** | |
| **Other Comments (if ANY)** | |

### 6.1.2. Protocols for Modification or Re-submissions

| | |
|---|---|
| **Protocol Code** | |
| **Re-Submission date** | |

| | |
|---|---|
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Quorum status** | |
| **Conflict of Interest** | |
| **Assessment of PI Response to Initial Review** | |
| Conclusion and Recommendations | |
| Action Taken | 1. Approved<br>2. Minor modification to the amendment,<br>3. Major modification to the amendment<br>4. Disapprove<br>Expedited review at the level of the Member Secretary; |
| Approval Expiration Date | |
| Frequency of Continuing Review (in case of approval and minor revision) | |
| Other Comments (if applicable) | |

### 6.1.3. Amendments

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |
| **Submission date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Time allotment** | |
| **Quorum status** | |
| **Conflict of Interest** | |

| | |
|---|---|
| **Assessment of Amendment** | |
| Conclusion and Recommendations | |
| Action Taken | **1.** Approved<br>**2.** Minor modification to the amendment,<br>**3.** Major modification to the amendment<br>**4.** Disapprove<br>Expedited review at the level of the Member Secretary; |
| Other Comments (if applicable) | |

**6.1.4.** Protocol Non-Compliance (Deviation or Violation) Reports

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |
| **Report date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Quorum status** | |
| **Conflict of Interest** | |
| Assessment of Protocol Non-Compliance Report | |
| Conclusion and Recommendations | |
| Action Taken | **Decision**<br>No further action required;<br>Request information,<br>Recommend further action |
| Other Comments (if applicable) | |

**6.1.5.** **SAE Reports**

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |

| | |
|---|---|
| **Report date** | |

| | | |
|---|---|---|
| **Protocol Title** | | |
| **Principal Investigator** | | |
| **Reviewers** | | |
| **Sponsor or CRO** | | |
| **Quorum status** | | |
| **Conflict of Interest** | | |
| **Assessment of SAE** | Submission Date | |
| | Date of SAE | |
| | Onsite or offsite | |
| | Country (if offsite) | |
| | SUSAR or Non-SUSAR | |
| | Related or Non-Related to the Study | |
| | SAE Status | |
| Conclusion and Recommendations | | |
| Action Taken | **Decision**<br>No further action required;<br>Request information,<br>Recommend further action | |
| Other Comments (if applicable) | | |

### 6.1.6. Requests, Queries, and Complaints

| | |
|---|---|
| **Protocol Code** | |
| **Approval date** | |
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| Assessment of Request, Query or | |

| | |
|---|---|
| Complaint | |
| Conclusion and Recommendations | |
| Action Taken | **Decision**<br>No further action required;<br>Request information,<br>Recommend further action |
| Other Comments (if applicable) | |
| Conclusion and Recommendations | |

### 6.1.7. Site Visit Reports

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |
| **Protocol Title** | |
| **Site Visit date** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Quorum status** | |
| **Conflict of Interest** | |
| Assessment of Site Visit Report | |
| Action Taken | **Decision**<br>No further action required;<br>Request information,<br>Recommend further action |
| Other Comments (if applicable) | |
| Conclusion and Recommendations | |

### 6.1.8. Study Termination

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |

| | |
|---|---|
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Quorum status** | |
| **Conflict of Interest** | |
| Assessment of Risks from Study Termination | |
| Action Taken | **Decision**<br>No further action required;<br>Request information,<br>Recommend further action |
| Other Comments (if applicable) | |
| Conclusion and Recommendations | |

### 6.1.9. Continuing and Progress Reports

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Quorum status** | |
| **Conflict of Interest** | |
| Assessment of Continuing and Progress Report | |
| Action Taken | **Decision**<br>No further action required; |

| | |
|---|---|
| | Request information,<br>Recommend further action |
| Other Comments (if applicable) | |
| Conclusion and Recommendations | |

### 6.1.10. Final Reports

| | |
|---|---|
| **Protocol Code** | |
| **Protocol Approval date** | |
| **Application date** | |
| **Protocol Title** | |
| **Principal Investigator** | |
| **Reviewers** | |
| **Sponsor or CRO** | |
| **Quorum status** | |
| **Conflict of Interest** | |
| Assessment of Final Report | |
| Action Taken | **Decision**<br>No further action required;<br>Request information,<br>Recommend further action |
| Other Comments (if applicable) | |
| Conclusion and Recommendations | |

**5. OTHER MATTERS:**

**6. ADJOURNMENT:** This meeting was adjourned at

| | | |
|---|---|---|
| **Prepared by** | **SECRETARIAT STAFF-Name** | **Date and signature** |
| **Checked by** | **Member Secretary-Name** | **Date and signature** |
| **Approved by** | **Chairperson-Name** | **Date and signature** |

IEC SOP 21: Maintenance of Active Clinical Trials

# IEC SOP 21: Maintenance of Active Clinical Trials

## 1. Purpose:

To provide instructions for preparation and maintenance of active study files and other related documents approved by the IEC of UPUMS.

## 2. Scope:

This SOP applies to all active clinical trial files and their related documents that are maintained inthe IEC office in the Data management system [Which is established by the Uttar Pradesh University of Medical Sciences, Saifai]

## 3. Responsibility:

It is the responsibility of IEC Secretariat to ensure that all study files are prepared, maintained and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1 | Organize the contents of the clinical trial files | IEC Secretariat |
| 2 | Maintain the clinical trial files in the UPUMS's Data management system including In/Outward, Protocol Status and Membership files | IEC Secretariat |

## 5. Detailed instruction:

### 5.1 Organize the contents of the active study files

5.1.1. Get the original documents/copy of the study files.

5.1.2. Gather, classify and combine all related documents together.

5.1.3. Use a folder with the following on the cover

- The name of the principal Investigator /sponsor
- The protocol numbers as per IEC of UPUMS (eg-First Protocol in the year 2022 i.e 01-2022]
- The number assigned by the IEC Secretariat

5.1.4. Check if a study file contains, at a minimum, the following documents:

- Original applications and any updates received during the study.
- Investigator's brochures or similar documents
- Approval letters and other correspondence sent to the investigator.
- Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
- Adverse experience reports or Investigational New Drugs safety reports received
- Continuing review reports

**5.2. Put the following into each folder with the following information:**

5.2.1 Maintenance of internal log for the record of submission letter, approval letter and other notification from the study investigator.

5.2.2 Sponsor with address and contact phone/e-mail id of contact person, protocol number, investigator name and title/no

5.2.3 Application form of the IEC Protocol, Case Report Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data, any other material submitted by the investigator.

- Correspondence
- Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
- Revisions/Amendments
- Adverse Events
- Protocol deviation
- Continuing Review, if applicable
- Completion reports (Final report)

**5.3 Maintain the active study files**

5.3.1. Inward/outward register/ log is maintained in the UPUMS's Data management System

5.3.2. Assign the approved study files with unique identifiers (on a sheet of paper) established by a member of the IEC Secretariat

5.3.3. Combine related documents of the approved study files appropriately.

5.3.4. Indicate date when Annual Review is due

5.3.5. Keep all active and potential study files in a secure file cabinet.

5.3.6. Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the IEC.

5.3.7. Store the closed regulatory study files for at least 5 years and **non-**regulatory research (3 years) or as required by sponsor after the study closure

5.3.8. Regular [every 6 months] back up to be taken for the Soft copies of IEC related documents on external hard drive with mention of dates on the backup [ Which is stored in the PC-at IEC Office]

**5.4 Maintain IEC records:**

- Maintain all the IEC records such as Agenda/minutes of the meeting, Membership files, Attendance registers etc.

  ***Note:*** For studies with multiple study sites, a member Secretariat should maintain the filesto allow cross-referencing without unnecessary duplications.

**6 Glossary:**

| | |
|---|---|
| Active Study File | Any approved protocol, supporting documents, records containing Communications and reports that correspond to each currently approved study. |
| IND | Investigational New Drug is a drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites |
| ICD | Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. |
| Master file | A file for storage of the originally signed and dated documents |

**7. Reference:**


› ICMR guidelines for clinical research- October, 2017

› Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

› NDCT Rules, 2019

IEC SOP 22: Archival and Retrieval of clinical trials documents

# IEC SOP 22: Archival and Retrieval of clinical trials documents

## 1. Purpose:

To provide instructions for storing inactive study files and completed IEC study documents in a secure manner while maintaining access for review by auditors and inspectors or any external Accreditation Assessors [Clinical Trials].

## 2. Scope:

This SOP applies to archiving the study files and completed IEC documents that are retained for at least five years (or more for some particular cases) after completion of the research so that the records are accessible for auditors, inspectors and Assessors. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

## 3. Responsibility:

It is the responsibility of IEC Secretariat for maintaining inactive study files and IEC completed studies of IEC-Uttar Pradesh University of Medical Sciences, Saifai

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1 | After receiving the final report | IEC members, secretariat |
| 2 | Archiving IEC Completed documents | IEC secretariat |
| 3 | Retrieving Documents | IEC secretariat |

## 5. Detailed instructions:

### 5.1 After receiving the final report

5.1.1. IEC Secretariat and Members will review the Final Report/study completion report of the study.

5.1.2. A member of the Secretariat should

- Remove the contents of the entire file from the active study filing area.
- Verify that all documents are present in an organized manner.
- Place the file in a store compactor with particular rack number

5.1.3. Keep the files of the multi-center studies active, until all the study sites are closed.

5.1.4. Study closure notification should be as per the IEC-UPUMS-SOP

5.1.5. Place in Archival room with biometric Lock

5.2 **When archiving administrative documents, A staff of the IEC Secretariat should:**

- Essential IEC Documents are those documents which individually and collectively allow the evaluation of the conduct of a study and quality of the data generated.
- Essential IEC documents are needed for the sponsor's independent audit function and inspection by the Regulatory Authority.

5.3 **Retrieving Documents**

5.3.1 Keep in mind the SOP/23/V-2.0 (Maintaining Confidentiality of Ethical Review Committee Documents)

5.3.2 Retrieval of documents can only be done with a request form (AF/IEC/01/22/V-2.0) signed and dated by the IEC Chairperson or the Member Secretary/secretariat staff.

5.3.3 The requestor must also sign and date the log of request (AF/IEC/02/22/V-2.0) The Secretariat retrieves archived documents and documents in the inventory (register) kept by Institutional Ethics Committee UPUMS for Clinical Trials at Archival room.

5.3.4 Return the file back to its place.

5.3.5 Record, sign and date when the document has been returned and kept.

**6. Archival Storage Conditions:** Archives to storage in conditions which is dry and seasonally stable with minimum exposure to natural or artificial light and protection from pests, pollution and access by authorized person

- It is a clean and Dry Place
- The doors are lockable and secure.
- CCTV Surveillance
- Fire Extinguisher
- Pest control

**7. Disposal/ Shredding of closed files and copies of protocols and documents submitted for ethical review**

7.1 At the end of the prescribed period, the documents from the protocol file will be shredded and properly disposed by authorized IEC/ administrative staff, without any notification to PI, keeping environment protection at the foremost.

7.2 Extra copies of protocols and documents submitted for ethical review and any other extra copies will be shredded by authorized IEC, UPUMS personnel after the IEC meeting without any notification to PI.

Soft copies of protocol related documents stored in the external hard disk drive will be deleted at the time of shredding of the hard copy.

7.3 A formal disposal log will be maintained (AF/IEC/03/22/V-2.0), providing details of documents that will be disposed.

- Disposing Inactive protocols aside from those with Final Reports

## 8. Glossary:

| | |
|---|---|
| **Administrative Documents** | Documents include official minutes of IEC meetings (as described in SOP/13/V-2.0) and the Standard Operating Procedures, both historical files and Master Files as described in SOP/01/V-2.0. |
| **Inactive Study Files** | Those studies are approved and or approved with suggestion which is/or not initiated at site level |
| **Closed study files** | After completion of all study related activity at site with study closure study notification |

## 9. References:


- International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) E6R2-2016
- National Ethical guidelines for biomedical and health research involving research participants guidelines -2017
- New drugs and Clinical Trial Rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020


## 10. ANNEXUREs

AF/IEC/01/22/V-2.0 Document Request Form AF/IEC/02/22/V-2.0 IEC Documents Retrieval Record FormAF/IEC/03/22/V-2.0 Log for disposal of study documents

**ANNEXURE: 01** **AF/IEC/01/22/V-2.0**

**Document Request Form**

| | |
|---|---|
| Name of Document requested: | |
| Requested by: | |
| Date: | |
| ☐ Chairperson ☐ Secretariat ☐ IEC Member | |
| ☐ Secretariat staff ☐ Authority ☐ Others…….. | |
| Purpose of the request: | |
| Retrieved by: | Date: |
| Returned by: | Date: |
| Archived by: | Date: |

**ANNEXURE: 02** **AF/IEC/02/22/V-2.0**

## IEC Documents Retrieval Form

| | | | | | | |
|---|---|---|---|---|---|---|
| **Sl.No** | | | | | | |
| **Protocol No** | | | | | | |
| **PI Name** | | | | | | |
| **Shelf No** | | | | | | |
| **Archived on** | | | | | | |
| **Archived at (Shelf No)** | | | | | | |
| **Retrieved by** | | | | | | |
| **Retrieved on** | | | | | | |
| **Return by** | | | | | | |
| **Returned on** | | | | | | |
| **Disposal on** | | | | | | |

**ANNEXURE: 03** **AF/IEC/03/22/V-2.0**

## Log for disposal/Shredding of study documents

| Project No/Title | Name of PI | No of Files | Date of IEC approval | Date of Study Initiation | Date of study closure | Disposed By Name and Sign |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

IEC SOP 23: Maintaining of Confidentiality of IEC Documents

# IEC SOP 23: Maintaining of Confidentiality of IEC Documents

**1. Purpose:**

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle original documents and copies of documents in order to protect confidentiality of documents.

**2. Scope:**

This SOP applies to maintaining confidentiality while handling, distribution and storage of submitted study protocols, IEC documents, and correspondence with experts, auditors and thegeneral public.

**3. Responsibility:**

Confidentiality of study protocols, IEC documents, and correspondence with experts and auditorsis mandatory. IEC members and staff have signed confidentiality agreements with the institutethat enforces confidentiality. If non-members of the IEC need copies of documents, it is the responsibility of the IEC member/staff to maintain the confidentiality of documents.

**4. Flow chart:**

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1 | Access to IEC documents | IEC members and Secretariat |
| 2 | Classify confidential documents | IEC members and Secretariat |
| 3 | Copy confidential documents | IEC Secretariat |
| 4 | File Log of Copies | IEC Secretariat |

**5. Detailed instructions:**

**5.1 Access to IEC Documents:** The IEC members and the staff of the Secretariat of the IEC, who must read, understand and agree to the following: **Members and Member Secretary of the IEC**

5.1.1 Sign a confidentiality agreement (AF/IEC/01/03/V-2.0) with Institutional Ethics Committee UPUMS for Clinical Study Protocols institute before the start of any activity for the IEC.

5.1.2 Shall have access to all IEC documents.

5.1.3 Are free to request and to use original documents or copies of original documents.

**5.2 Secretariat of the IEC**

- The Secretarial Assistant of the IEC is a staff member of the Ethics Committee UPUMS for Clinical Studies

- Sign a confidentiality agreement with Ethics Committee of KHER for Clinical Studies Have access to any document issued by or to the IEC.

**5.3 Classify confidential documents**

- **Types of documents**

- **The types of documents reviewed by IEC members include:**

  - Study proposals and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions, or reviews)
  - EC documents (SOPs, meeting minutes, advice, and decisions)
  - Correspondence (experts, auditors, study participants, etc.)

**Note:** Copies of all versions of documents, including draft and sequential definitive versions are to be kept private and confidential except for those made according to the following sections.

**5.4 Copy confidential documents:** Copies of documents, including draft and sequential versions, are considered to be confidential and are not permitted to be brought out except when a document is needed for day-to-day operations.

**5.5 Copy Authorization:**

- Only members of the IEC are allowed to ask for copies.
- Only staff members of the Secretariat of the IEC are allowed to make such copies.
- The Secretary of the EC may ask for help, but is responsible for maintaining
- Confidentiality of all documents

**5.6 Log of Copies**

- A Log of Copies (see AF/IEC/01/23/V-2.0) must be kept by the Secretariat.
- The log should include: the name and signature of the individual receiving the copy; the initial of the IEC Secretary who made the copy; the number of copies made and the date that the copies were made.

**5.7 Copies requested by non-members of the EC**

- Copies of IEC's documents requested by non-members of the IEC (including the Secretary) can only be given after the permission from the Member Secretary and the person requesting for the document signs a confidentiality agreement form (AF/IEC/03/03/V-2.0).

- Copies made for non-members of the EC must be recorded in both the Log of Requests for Copies of IEC's documents (AF/IEC/01/16/V-2.0) and the log of Copies of the Original Documents (AF/IEC/02/23/V-2.0).

**5.8 File Log of Copies.**

- The Log of Copies of Original Documents must be stored with the original documents.
- The Log of Copies of Original Documents is *not* a confidential document and can be reviewed upon request.
- A Log of Copies of Original Documents must be maintained.

**6. Glossary:**

| | |
|---|---|
| Document | Documents mean the followings:<br>- Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews)<br>- IEC documents (SOPs, meeting minutes, advice and decisions)<br>- Correspondence (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc. |
| Non-members of the IEC | Any relevant person/persons who presently is/are not a member/members of the IEC such as authorities, monitors, auditors, subjects, etc. |

**7. References:**


- International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) E6R2-2016
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trial Rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

## 8. ANNEXURES:

AF/IEC/01/23/V-2.0 Log of Requests for Copies of IEC's Documents

AF/IEC/02/23/V-2.0 Log of Copies of Original Documents

**ANNEXURE: 01** **AF/IEC/01/23/V-2.0**

## Log of Requests for Copies of IEC's Documents

| No. | Documents requested | No. of Copies | Name of Recipient | Signature of Recipient | Secretariat Initials | Date |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**ANNEXURE: 02** **AF/IEC/02/23/V-2.0**

## Log of Copies of Original Documents

***Title of the Document:*** ……..

……

……..

| Sl.No. | Name of Recipient | No. of Copies | Reasons of the Request | Signature of Recipient | Secretariat Initials | Date |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

*Note*: *This log should be attached to the original documents*

IEC SOP 24: Audit and Inspection of the IEC of UPUMS

# IEC SOP 24: Audit and Inspection of the IEC of UPUMS

## 1. Purpose

The purpose of this SOP is to guide how to prepare for an audit or inspection of the IEC processes.

## 2. Scope

This SOP applies to Institutional Ethics Committee of Uttar Pradesh University of Medical Sciences, Saifai.

## 3. Responsibility

It is the responsibility of the Secretariat, the Members, and the Chairperson of the IEC to perform all tasks according to the SOPs and to be well-prepared and available to answer questions during evaluation, audit or inspection visits of authorities.

## 4. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1 | call for an audit an Audit / Inspection | IEC Chairperson / Head of the Institution |
| 2 | Prepare for the audit / Inspection | IEC Secretariat / Members and Chairperson |
| 3 | Meet the Auditor / Inspection | IEC Secretariat / Members and Chairperson |
| 4 | Discuss the Issues | IEC Secretariat / Members and Chairperson |
| 5 | Record the Event | IEC Secretariat |

## 5. Detailed instructions:

### 5.1 Receive a Call for an Audit / Inspection

- Receive a notice of Audit /Inspection
- The Member Secretary / Chairperson inform the Director or Head of Institution.
- The Chairperson/member secretary should inform IEC members.

### 5.2 Prepare for the audit / Inspection

- Get a checklist AF/IEC/01/24/V-2.0
- Go through all steps on the list.
- Check if all documents are labeled and kept in the right order for easy and quick search.
- Check for any missing or disorganized records.

- Background and training records of IEC members
- Application Submission Records
- Protocol Assessment Records
- Communication Records
- Amendment Approval
- Meeting Agenda, Minutes, Approval letters
- Active files
- Continuing and Final reports

- Review the IEC SOPs.
- Make sure that no omission or deviation exists.
- Make sure to have good reasons for any omission or deviation.
- Inform IEC members about the inspection date so that they are able to attend the audit/inspection meeting.

**5.3 During the Audit / Inspection**

- The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room.
- Members and some key staff must also be present in the meeting room.
- The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data are needed.
- Answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the point.
- Find and get all information and files requested by the auditors/inspectors.
- Take note of the comments, recommendations of the auditors/inspectors.

**5.4 Discuss the Issues**

- Review comments and recommendations of the auditors/inspectors.
- Write a report and have it approved by the Chairperson.
- The Chairperson calls for the correction.
- Allow appropriate time for correction and improvement process.
- Carry an internal follow-up audit.
- Evaluate the outcome.
- Report the outcome to the Chairperson.

**5.5 Record the Audit/Inspection Event**

- Keep record of the report on the audit/inspection meeting in the audit/inspection file.
- Record also the findings from the internal follow-up audit in the internal audit file
- CAPA should be provided to Auditor or inspector within timelines mentioned by the authority in the audit/inspection report.

## 6. Glossary:

| | |
|---|---|
| **External audit** | A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki, and applicable regulatory requirements |
| **Internal Audit** | A systematic examination of IEC membership files and other IEC approved study protocol and clinical trial participant related information by Internal members selected by head of institute/Member secretary |
| **Inspection** | The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsors and/or contract research organizations (CRO) facilities, Office of ethics Committees, or at other establishments deemed appropriate by the regulatory authorities |

## 7. References:


- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants-2011
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- New Drugs and Clinical Trial Rules, 2019


## 8. ANNEXURES:

AF/IEC/01/24/V-2.0 Audit and Inspection Checklist

AF/IEC/02/24/V-2.0 Confidentiality Agreement Form for Auditors/inspectors

**ANNEXURE: 01** **AF/IEC/01/24/V-2.0**

**Audit and Inspection Checklist**

| | |
|---|---|
| Internal Audit<br>External Audit<br>Regulatory Inspection | **Date:** |
| The date(s) which the audit/inspection has been agreed for: | |
| **Review the SOPs and note details of any omissions or deviations, with reasons** | |
| **Check the files for the presence of all signed documents. Note any that are missing and actions taken.**<br>› Background and training records of EC members<br>› Application Submission Records<br>› Protocol Assessment Records<br>› Communication Records<br>› Amendment Approval<br>› Meeting Agenda, Minutes, Approval letters<br>› Active files<br>› Continuing and Final reports | |
| Are any documents known to be missing from the study master file? | |
| Which personnel and members will be available? Give details of times and dates. | |
| What arrangements are there in the event the auditor/inspector needs to make copies of documents? | |
| **Completed by: .....**<br><br>**Name and Signature** | Date: ..... |

**ANNEXURE: 02** **AF/IEC/02/024/V-2.0**

## Confidentiality Agreement Form for Auditors/inspectors

I,_____from_____as an **Auditors/inspectors** of Ethics Committee of UPUMS for Clinical trials, understand that the copy (ies) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Ethics Committee 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:

……

……

……

| **IEC office use only** |
|---|
| Signature of the recipient and date |
| |
| Member Secretary/Chairperson signature and date |
| |

IEC SOP 25: Subject recruitment strategies

# IEC SOP 25: Subject recruitment strategies

## 1. INTRODUCTION & PURPOSE:

This standard operating procedure (SOP) describes the processes for developing a recruitment plan and provides recommended recruitment definitions, strategies and activities covering the entire recruitment period, screening and rescreening at UPUMS, Saifai

## 2. SCOPE:

This SOP covers the study recruitment process starting from a base population of patients or healthy volunteers through to enrolled study participants.

## 3. APPLICABLE REGULATIONS AND GUIDELINES:

3.1 International Conference on Harmonization of technical requirements for pharmaceuticals for human use (ICH)-2016

3.2 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

3.3 WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013

3.4 Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017

3.5 New Drugs and Clinical trial rules, 2019

3.6 ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

## 4. RESPONSIBILITY:

This SOP applies to all clinical study team personnel involved in conducting clinical trialactivities at the UPUMS site.

## 5. Flow chart:

| Sl.No. | Activity | Responsibility |
|---|---|---|
| 1 | Patient recruitment strategies | IEC Secretariat / Members and Chairperson |

| | | |
|---|---|---|
| 2 | Submission of Approval for Patient recruitment methods by the PI | IEC Secretariat / Members and Chairperson |
| 3 | Board meeting for the approval of advetisement materials or any other to recruit the study partticippansts | Approved by the IEC member/Chairperson |

## 6. PROCEDURES: Development and Implementation of a Recruitment Plan:

**6.1.** Identify potential recruitment methods or strategies related to each area of the recruitment process.

- In patient
- Out patient
- Referral in the institution
- Advertisements (web site – internets)
- Health camps
- Private clinics
- Paediatrics

- Select the most suitable recruitment activities. Several recruitment methods may be used throughout the study rather than depending on one single method for recruitment.
- Formalise and document the recruitment plan and strategies including timelines.
- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, vulnerable population and ethnicity)
- 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 participants or their representatives

### i. <u>OUTPATIENT RECRUITMENT PROCESS</u>

**Outpatient Recruitment Process**

↓

Hospital Registration

↓

Get a Registration Code/number number

↓

PI OPD/Ward

↓

Screening as per Inclusion/Exclusion criteria

↓

After informed consent Process

↓

Screening

↓

Enrolment

**ii. IN PATIENT RECRUITMENT PROCESS:**

**Inpatient Recruitment Process**

↓

Hospital Registration counters/Causality-Emergency

↓

Get Unique Registration code/ number

↓

PI OPD/ICU/Ward

↓

Inclusion/Exclusion criteria

↓

After informed consent Process

↓

Screening

↓

Enrolment

**iii. REFERRALS:**

OPD/IPD basis

↓

Subjects- Referred by Investigator/Clinician within the hospital

↓

## IEC SOP 25: Subject recruitment strategies

[By using IEC of UPUMS approved Protocol-ICDs-Pamphlet]

↓

Check the Inclusion and Exclusion criteria

↓

Send to the study Principal investigator

↓

Again check the Inclusion/Exclusion criteria

↓

After informed consent Process

↓

Screening

↓

Enrolment

**iv. <u>ADVERTISEMENTS:</u>**

Sponsor/CRO develop recruitment material

↓

Principal Investigator/Study designee submit to Ethics Committee

↓ ➔IEC Review

After IEC of Uttar Pradesh University of Medical Sciences, Saifai approvals- Advertisements and Poster

↓

Recruitment Material will be used for the study

↓

OPD/IPD Basis

↓

Check the Inclusion/Exclusion criteria

↓

After informed consent Process

↓

Screening

↓

Enrolment

**v. HEALTH CAMPS:**

The institution will conduct health camps in rural areas

↓

**If- IEC approved only**-By using Recruitment material-Inclusion/exclusion criteria checklist

↓

Refereed to the site

↓

OPD Basis

↓

Re-Check the Inclusion/Exclusion criteria

↓

After informed consent Process

↓

Screening

↓

Enrolment

**vi. PEDIATRICS:**

Hospital Delivery birth data base

↓Or

Immunization clinics

↓Or

Community health centre awareness

↓Or

Referrals

↓

Inclusion exclusion criteria After informed consent Process

↓

Screening

↓

Enrolment

**vii. Private Clinics:**

PI of the study can refer private clinic same patient to Hospital OPD

↓

OPD registration as per the Hospital policy

↓

Inclusion exclusion criteria After

informed consent Process

↓

All the inclusion criteria's are met

↓

Enrolled into the clinical trials

- Review recruitment goals and recruitment strategies periodically during the trial.
- Obtain Institutional Ethics Committee of UPUMS approval of recruitment methodsand materials.
- Implement the recruitment methods.
- The Investigator must schedule a meeting prior to enrolment, in order to secure the co-operation of study team to obtain a sufficient number of subjects.
- **In pediatric study subjects should be enrolled 05 subjects/Day**
- Enrolling eligible participants into the study using the protocol specified enrolment procedures.

**7. Applicable staff**

This SOP applies to all the personnel of the clinical research team and others who may beresponsible for subject recruitment in the study. These include the following:

- Investigator
- Research Team (listed in the delegation log)
- CRC
- Sponsors/CRO
- SMOs

**8. References**

- 21 CFR 312.60 – General Responsibilities of Investigators
- 21 CFR 50.20 – General Requirements for Informed Consent
- 21 CFR 50.25 – Elements of Informed Consent
- Guidelines on Good Clinical Practice
- ICH Guidelines for Good Clinical Practice (E6)
- New Drugs and Clinical Trial rules, 2019
- ICMR-National Guidelines for ethics Committees reviewing biomedical and Health research during COVID-19-April-2020

IEC SOP 26: Continuous improvement: a corrective and preventive action-CAPA

## IEC SOP 26: Continuous improvement: a corrective and preventive action-CAPA

1. **PURPOSE:** To document the procedure for managing and addressing research-related risks as referred to in ICH E6 R2-2011 section 5.20 and Good Clinical Practice.

2. **RESPONSIBILITY AND SCOPE:** This standard applies to all Trials Conducting/ted at UPUMS, which are approved by the IEC of UPUMS, Saifai

3. **APPLICABILITY:** Principal Investigator/ Investigator, Sub-Investigator(s) research coordinators and others (study Participants)

4. **BACKGROUND:** A Corrective and Preventive Action Plan (CAPA) is a quality system plan used to address a research-related issue that has occurred. It incorporates:
   - Identifying the root cause of the issue;
   - Identifying actions to prevent recurrence of the issue (corrective action) or, identify actions to prevent an issue from occurring (preventive action);
   - Documenting that the required actions were completed.
   - Some examples of research-related issues include: injury of clinical trial participants or a high potential for this to occur; repeated violations of the protocol; serious breaches of privacy and significant data integrity problems.
   - The CAPA process is an important part of ensuring quality and ethical research practice and ensuring that systems used in research are continuously improved.

5. **PROCEDURE**

**5.1. Identification of an issue:** Potential and/or actual issues that arise during the conduct of research can be identified through several sources.

For example:

- A specific incident has occurred.
- Observations/concerns are made by a research staff member about a potential issue.
- Concerns are raised during/after monitoring, auditing, external/third party audits, or regulatory authority inspection of the research.
- A concern raised by another body such as a data safety monitoring committee, IEC of Uttar Pradesh University of Medical Sciences, Saifai.
- A concern/issues raised by the clinical trial participants

Please note that these may or may not be a deviation from the protocol.

**5.2. Assessing the risk:** A CAPA is required in cases where a corrective action and/or preventive action is necessary to appropriately address a risk. Risk assessments improve quality and compliance. They are a proactive, anticipatory approach to improve quality management. The risk should be determined by assessing

(i) The impact on patient rights/safety and the study objectives, and

(ii) The likelihood of occurrence/recurrence.

**5.3. Developing the CAPA plan The steps involved are:**

5.3.1. **Initiation of CAPA:** The concerned clinical research study team/PI shall identify and decide who will take overall responsibility for the CAPA plan. This includes development of the CAPA plan, its implementation, training of staff on the CAPA plan, and evaluation of the results of the CAPA plan within 10 working days.

5.3.2. Evaluate the extent of the problem: identify/characterize the problem; determine the scope and impact; investigate data, process, operations, and other sources of information; investigate the impact of the issue on the overall research.

5.3.3. Focus on determining the root cause(s): investigate how/why the incident occurred (i.e. are there specific causes or sources of the problem; why is this problem occurring; is the problem due to training, design, manufacture, management, documentation, etc.)

5.3.4. After identifying the root cause(s), break the solution into discrete, measurable actions that address the root cause(s) - actions items should include:

a. What will be done – identify action(s) needed to correct and prevent recurrence (e.g. amending documents, changing systems, staff training)

b. Who will make amendments/perform the corrective actions and when?

c. Establishing an achievable target date for completion. Describe the procedures implemented to resolve the problem and indicate who is responsible for the procedure. Indicate an achievable date for the corrective action.

5.3.5. Track progress towards completion of all required actions and evaluate whether the implemented actions have successfully addressed the issues.

5.3.5. For Preventive Actions, describe the preventive actions or planned, and who is responsible. Create a list of all tasks that must be completed to prevent the problem.

**5.4. Documenting and reporting the CAPA**

5.4.1. CAPAs should be documented using the CAPA template (Attached below). a copy of the CAPA should be sent to the Study Investigator and same CAPA should be reviewed by the PI and Ethics Committee members and stored with other trial related documents in the Trial Master File.

5.4.2. Each issue requires a separate CAPA. All CAPAs should be reviewed, signed and dated by the individual preparing the form and the member Secretary of IEC, UPUMS, Saifai-10

5.4.3. If the CAPA is required in response to a protocol deviation, a copy of the CAPA should be submitted to the approving IEC of UPUMS in accordance with the sponsors or its repressive requirements for addressing protocol violations, deviations, and complaints

5.4.4. If the CAPA is unacceptable, the PI will be notified and will need to provide an appropriate response within the given timelines.

5.4.5. A summary of all CAPAs (in progress and completed) should be maintained in a CAPA tracking log and stored with other trial related documents in the Ethics Committee Correspondence file Individually. The CAPA Person must ensure that corrective and/or preventive actions are managed, documented, completed, modified, verified as effective, and closed as required per this procedure.

## 6. GLOSSARY

- Corrective and Preventive Action (CAPA) Plan – actions taken to collect information and identify a problem, determine root cause, identify and implement a corrective and/or preventive action to prevent further recurrence.
- Correction – immediate remedial actions taken to repair, rework or adjust the effect of an existing deviation or other undesirable situation.
- Corrective Action – immediate action to a problem that has already occurred or has been identified.
- Preventive Action – taken to eliminate the root cause of a potential problem, including the detection/identification of problems.
- Root Cause – factor that caused a non-conformance and should be permanently eliminated through process improvement.
- Root Cause Analysis – a class of problem-solving methods used to identify the root causes of

IEC SOP 26: Continuous improvement: a corrective and preventive action-CAPA problems or events.

## 7. REFERENCES

- Note for Guidance on Good Clinical Practice
- CDSCO rules and regulations

## 8. APPENDICES

- **Annexure 1: Corrective and Preventive Action Plan Template**
- **Annexure 2: CAPA Tracking Log**

**ANNEXURE: 01** **AF/IEC/01/26/V-2.0**

**Corrective and Preventive Action Plan Template**

A CAPA is written to identify a discrepancy/ problem in the conduct of a clinical research study, note the root cause of the identified problem, identify the corrective action to prevent the recurrence of the problem, and document that the corrective action has resolved the problem. In general, the tone ofCAPA should be forward-looking and not seek to explain an error discovered in the conduct of a clinical research study.

| | |
|---|---|
| Date: | *Date that the CAPA is written* |
| To: | Principal Investigator |
| From (Person responsible for overall CAPA): | Name, Title, the site/institutional affiliation of the person authoring the CAPA, including their signature |
| Protocol Title / Research Study: | |
| IEC protocol Number | |
| Issue / Deficiency Identified: | Brief description or outline of the topic/process/problem being documented. This can be formatted as a paragraph, numbered list, or bulleted items. |
| Root Cause: | The reason(s) that the issue arose. Root-cause analysis is a class of problem solving methods used to identify the root causes of problems or events. |
| Corrective Action Plan: | Description of the correction action(s) taken or planned by the site. If the site was instructed to perform these corrective actions (i.e. by the sponsor or monitor), indicate by whom and as of what date. If status of reports, records or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed. |
| Implementation: | Description of the procedures used to document resolution of the problem, the persons who are responsible for the procedures, etc. |
| Effective Date of Resolution: | Effective date for corrective action |
| Preventive Action: | Description of the preventive actions taken or planned by the site. If the site was instructed to perform these preventive actions, indicate by whom and as of what date. Preventive actions are taken to eliminate the root-cause of a |

| | |
|---|---|
| | potential problem, including the detection/identification of problems |
| Evaluation/Follow up: | Any plan/procedure to evaluate the implementation and completion, persons who are responsible for the evaluations, timeframe for the evaluation, etc. |
| Comments | Any additional comments or information not noted above. Document any relevant observations here. |

Ethics Committee Member Signature

**ANNEXURE: 02** **AF/IEC/02/26/V-2.0**

| CORRECTIVE ACTION REPORT NO. | OPEN DATE | ISSUED TO | DESCRIPTION | DUE DATE | CLOSEOUT DATE |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

Verified By: _____

Date: _____

# IEC SOP 27: Review of Biomedical and Health Research and CDSCO-Clinical trials During COVID-19 Pandemic

**1. Purpose:**

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC of UPUMS will function and conduct ethics review in an emergency situation with restrictions asimposed by social distancing requirements during COVID- 19 outbreak.

**2. Procedure and Responsibilities**:

| Sl. No | Procedure | Responsibilities |
|---|---|---|
| 1. | Submission of study documents for review as per IEC SOP-Initial submission of protocol | Study designee/Principal investigator |
| **2.** | Receive, record, verify completeness and allot reference no. | IEC Secretariat |
| **3.** | Categorize depending on risk (Exempt/ Expedited, Full committee), identify need for review by experts/ independent consultants/ patient/ others, designate reviewers | IEC Secretariat/ Member secretary |
| **4.** | Perform Initial review of documents by the IEC Primary reviewers | Primary reviewers |
| **5.** | Schedule virtual Meeting, Prepare Agenda, invite members (Independent Consultants/ Subject Experts/ PI/ Member secretary of local IEC/ in consultation with Chairperson) | IEC Secretariat/ IEC-Member |
| **Virtual IEC Meeting** | | |
| **6.** | Open the meeting, determine quorum (section 4.8.4 of ICMR National Ethical Guidelines), COI declaration, Summaries Agenda through Go To Meeting Application | IEC Chairperson |
| **7.** | Brief presentation and/ or address queries on the research proposal and leave meeting prior to decision | IEC Secretariat/ IEC-Member |
| **8.** | Present observations on item reviewed | Primary reviewers |

| | | |
|---|---|---|
| **9.** | Discuss further on the item and reach consensus | IEC Members |
| **10.** | Record Decision and rejoin member who had declared COI before moving on to subsequent item on agenda | IEC Secretariat/IEC-Member |
| **11.** | Record minutes of meeting, ratify approved decisions of exemption/ expedited review before closing meeting | IEC Chairperson/member Secretary |
| **12.** | Communication of decision and maintaining records. | IEC Secretariat |
| **13.** | Follow up/monitoring/ analysis of SAE / handling of issues related to non-compliance, violation, complaints etc. | member Secretary consultation with chairperson |

**3. Detailed Instructions:**

**3.1.** The Research Proposal should be submitted with supporting documents (Informed Consent, Brief CV of PI/ Co PIs, Questionnaire/ Case report form, Approval/ Comments of scientific committee, CTRI/ CDSCO / HMSC/ MTA/ MoU/ Insurance coverage) as applicable.

**3.2.** Once received, the secretariat will verify protocol for completeness (if not ask PI) and number.

**3.3.** Member secretary to categorize research into full review, expedited review or exemption from review.

**3.4.** Member Secretary (in consultation with Chairperson) will identify need for review by subject experts, independent consultants, special invitees, patient representatives, others for prior review or to present views during the meeting.

**3.5.** The project for full review will be included in agenda of virtual full-committee meeting to be scheduled at the earliest (48 hrs.) by the Member Secretary in consultation with Chairperson.

**3.6.** The member will be briefed about the technological requirements and virtual platform used for the conduct of the meeting.

**3.7.** Quorum requirements for review will be applicable as per section 4.8.4 ICMR National Ethical Guidelines, 2017 and New Drugs and Clinical Trial Rules, 2019.

**3.8.** Review procedures as per ICMR National Ethical Guidelines will also hold good for the virtual web ethics meeting.

**4. References:**

- Review of Biomedical and Health Research and CDSCO-Clinical trials During COVID-19 Pandemic