Standard Operating Procedures (SOP) of University Ethics Committee (UEC), Kerala University of Health Sciences (KUHS).

Version 2

Dated: 25th October 2019

Kerala University of Health Sciences
Medical College PO,
Thrissur, Kerala 680596

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Introduction

Kerala University of Health Sciences (KUHS) is a medical University, set up under the Kerala University of Health Sciences Act 2010, to ensure proper systematic instructions, teaching, training and research in Modern Medicine, Homoeopathy, Ayurveda, Siddha, Unani and other Allied Health Sciences and to have uniformity in the various academic programmes in medical and allied subjects in the State of Kerala. The headquarters of the University is situated adjacent to Govt. Medical College, Thrissur. The territorial jurisdiction of the University extends to the boundaries of the state. The mandate of the University is to affiliate all colleges and institutions imparting professional education in health care, conduct examinations, and award degrees to the eligible candidates. There are more than 300 Institutions affiliated to the University now and it offers more than 138 courses as on Dec 2019.

KUHS being an affiliating University, has no constituent colleges and hence no University faculty as such. During the first five years, construction of the Head Quarters building at Thrissur and establishment of its office was completed. In the next five years, KUHS tried to establish itself as a Professional University that spreads knowledge in the field of Health Sciences, to address health issues of Kerala and disseminate it, design an efficient and equitable health system which integrates traditional knowledge with modern science and technology and to create competent and compassionate health professionals of high standard, who are heirs to the rich traditions of the world of science and ancient wisdom that enriches the art and science of health care through research and quality education. The strength of this University is the harmonious co-existence with a clear vision for the future shared by all the Health Science streams under seven faculties namely Medicine, Dental Science, Pharmaceutical Sciences, Nursing, Ayurveda, Siddha & Unani, Homeopathy, Paramedical &Allied Health Sciences.

Kerala University of Health Sciences has the mandate to generate and disseminate knowledge in the field of health Sciences in the State. For this, it is important to establish schools and centres under KUHS. There are 3 Schools one Academic Staff College and 8 Research Centres, under KUHS.

They are,

1. School of Health Policy and Planning Studies, Thiruvananthapuram.
2. Academic Staff College, KUHS Campus, Thrissur.
3. School of Fundamental Research in Ayurveda, Thripunithura.
4. School of Family Health Studies, Kozhikode.

Research Centres, under KUHS are,

1. Centre for Basic Sciences Research and Bio-ethics.
2. Centre for Gerontological Studies.
3. Centre for Disability Management Studies.
4. Centre for Health Care Counselling.
5. Centre for Inter-disciplinary, Allied Health Sciences and Technology.
6. Centre for Studies in Medical Simulation.
7. Centre for Studies on Health of Young Adults.
8. Centre for History of Medicine and Health Humanities.

All the schools are established at the KUHS Campus, Thrissur. All these Schools and centres have research projects sanctioned by the University. University ethics committee looks after the ethical issues and scientific rigor of the Research projects done directly by the University through these Schools and Centres. Affiliated institutions have their own Institutional Ethics Committees as per the minimum requirements prescribed for starting different courses.

Brief History of University Ethics Committee (UEC)

As per chapter IV, clause 37 of Kerala University of Health Sciences Act 2010 the University Ethics Committee (UEC) was constituted vide order No. 6431/Ac.B/2014/KUHS on 31.07.2014. It was a nine (9) member committee with Justice M. R. Hariharan Nair, Former Judge, High Court of Kerala as Chairman.
The nine Members were,

1. Justice M R Hariharan Nair, Former Judge, High Court of Kerala (Chairman)
2. Dr. Ajithkumar K, Dean Research (Member Secretary)
3. Dr K. Praveenlal, Principal, Govt. Medical College, Cochin.
4. Dr.K.R Girija, Vice Principal, Govt. Medical College, Thrissur
5. Dr.Jayaprakash Mulayil, Former Principal & Prof. of Community Medicine, CMC Vellore.
6. Dr.Nandini K Kumar Former, Deputy Director General –ICMR
7. Dr.Bhanumathy, Association for Mentally Handicapped Adults (AMHA)
8. Dr.Anad Zakariah Professor, Medicine, CMC Vellore.
9. Dr.K.R Janardanan, Thekkemadom Road, Thrissur.

The 23rd Governing Council of 11.02.2015 ratified the constitution of the University Ethics Committee as above with a suggestion to include four more members. Hence the University Ethics Committee was reconstituted with 13 (thirteen) members under the chairmanship of M. R. Hariharan Nair, Former Judge,

High Court of Kerala vide University Order No. 6431/Dean R/KUHS/2014 dated 17.03.2015.
The thirteen Members were:

1. Justice M R Hariharan Nair, Former Judge, High Court of Kerala (Chairman)
2. Dr. Ajithkumar K, Dean Research (Member Secretary)
3. Dr K. Praveenlal, Principal, Govt. Medical College, Cochin
4. Dr. K.R Girija, Vice Principal, Govt. Medical College, Thrissur
5. Dr. Jayaprakash Mulayil, Former Principal & Prof. of Community Medicine, CMC Vellore
6. Dr. Nandini K Kumar Former Deputy Director General – ICMR
7. Dr. Bhanumathy Association for Mentally Handicapped Adults (AMHA)
8. Dr. Anad Zakariah Professor, Medicine, CMC Vellore.
9. Dr. K.R Janardanan, Thekkemadom Road, Thrissur.
10. Dr. Jayakrishnan T, Associate Professor of Community Medicine, Govt. Medical College, Kozhikode
11. Ms. Saibala M, Nursing Director, Amrita Institute of Medical Sciences, Cochin
12. Dr. K Manoj, Professor, Kayachikitsa, VPSV, Kottakkal
13. Dr. Muneer Ahammed, Director, College Development Council, Rajiv Gandhi University of Health Sciences, Bangalore.

Vide University Order No. 6431//Dean R/KUHS/2014 dated 02.11.2017, the committee was reconstituted once again as Dr. K. Ajithkumar, the member secretary of UEC was relieved from the post of Dean Research, KUHS and Prof (Dr) Harikumaran Nair G S, Professor, Department of Radiodiagnosis, Govt. T D Medical College, Alappuzha was appointed as the new Dean (Research). Thus, Prof (Dr) Harikumaran Nair G S became Member secretary of UEC, consisting of 15 members.
The existing fifteen Members as per latest order are as follows,

1. Justice M.R. Hariharan Nair, Former Judge, High Court of Kerala (Chairman)
2. Dr. Harikumaran Nair G S, Dean Research, KUHS (Member Secretary)
3. Dr. K. Ajithkumar, Associate Professor of Dermatology of Govt. Medical College, Thrissur.
4. Dr. George Varghese, Principal, Pushpagiri Dental College
5. Dr. Gopinath S, Scientist IV, National Homoeopathic Research Institute for Mental Health, Kurichi, Kottayam
6. Dr. Surya Prakash, Al Shifa College of Pharmacy, Perinthalmanna

7. Dr. Gopakumar, Associate. Prof., Govt. Ayurveda College, Thiruvananthapuram
8. Dr.K.R.Girija, Vice Principal, Amrita Institute of Medical Sciences, Cochin
9. Dr. Nandini K Kumar, Former Deputy Director General ICMR
10. Dr. Bhanumathy, Association for Mentally Handicapped Adults (AMHA), Karattukkara, Elthuruth, Thrissur-11
11. Dr. K.R.Janardanan, Thekkemadom Road, Thrissur
12. Dr. Jayakrishnan. T, Associate Professor of Community Medicine, Government Medical College, Manjery.
13. Ms. Saibala.M, Nursing Director, Amrita Institute of Medical Sciences, Cochin
14. Dr. Praveenlal Kuttichira, Principal, Jubilee Mission Medical College, Thrissur
15. Dr. Sujith Chandi, Professor of Pharmacology, CMC, Vellore.

It is this committee that felt the need to have a fresh version incorporating the substantial changes that came in the field of regulatory mechanisms governing medical research after issue of Version I, went through the Draft of the 2nd version of the SOP given hereunder, and approved the same for publication and for immediate use after due approval from the Hon. Vice Chancellor as per decision taken in its Meeting held on 25-10-2019

List of Abbreviations used in this version of SoP

Abbreviation/Acronym	Full Title/Description
ADR	Adverse Drug Reaction
AE	Adverse Event
CDSCO	Central Drugs Standard Control Organization
CFR	Code of Federal Regulations
CIOMS	Council for International Organisations of Medical Sciences
CLA	Central Licensing Authority
COI	Conflict of Interest
Co-I	Co-Investigator
CRF	Case Record Form
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
DCGI	Drug Controller General of India
DCR	Drugs and Cosmetic Rules (1945)
DGFT	Directorate General of Foreign Trade
DSMB	Data Safety Monitoring Board
ELSI	Ethical, Legal and Social Issues
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FERCAP	Forum for Ethical Review Committees in Asia & Western Pacific Region
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HMSC	Health Ministry's Screening Committee
IB	Investigator's Brochure
ICD	Informed Consent Document
ICF	Informed Consent Form
ICH	International Committee on Harmonization
ICMJE	International Committee of Medical Journal Editors
ICMR	Indian Council of Medical Research
IND	Investigational new drug
LAR	Legally Acceptable/Authorized Representative
MoU	Memorandum of Understanding

MTA	Material Transfer Agreement
NIH	National Institutes of Health
NOC	No-objection Certificate
OHRP	Office for Human Research Protections
PI	Principal Investigator
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
UEC	University Ethics Committee
WHO	World Health Organization
WMA	World Medical Association

Glossary

1) **Active Study File:** A file containing protocol, supporting documents, records, communications and reports that correspond to an ongoing approved study.

2) **Adverse Drug Reaction:** All noxious or unintended responses to a medicinal product is an adverse drug reactions having causal relationship between the product and the adverse event with reasonable possibility.

3) **Adverse Event**: Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavourable or unintended sign or experience associated with the use of the investigational product (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the product.

4) **Amendment protocol:** Amended parts and related documents of the protocol, previously approved by the UEC, KUHS. In the course of the study, the PI may decide to make changes in the protocol.

5) **Ancillary care:** Ancillary care refers to providing investigation and treatment for conditions that occur during the course of trial that are unrelated to the original condition/study for which the study participant was enrolled.

6) **Appellate authority:** If the study participant is not satisfied with the decision of the IHEC, s/he may appeal to the Vice-Chancellor, KUHS for remedial action, who is the appellate authority.

7) Archival: Storage of closed study files.

8) **Assent:** To agree or permit to participate in research generally used in the context of child participant of more than 7 - 18 years of age who are old enough to understand the implications of any proposed research but not legally eligible to give consent. For children from more than 7-12 years, it will be oral assent and from more than 12 – 18 years, it will be written assent. Informed consent of parent/LAR is necessary except in certain circumstances, e.g. risky behaviour of adolescents.

9) **AYUSH Intervention:** Includes any existing/new intervention with drug, therapeutic or surgical procedure or device in the recognized traditional systems of India as per Ministry of AYUSH, GOI (including Ayurveda, Yoga, Naturopathy, Unani, Siddha, Homoeopathy, SOWARIGPA).

10) Beneficence: To try to do good or an action, which weighs the risks against benefits to prevent, reduce or remove harm for the welfare of the research participant(s) in any type of research.

11) **Clinical trial:** Clinical trial in relation to a new drug or investigational new Drug, Bio Medical and health research, Academic clinical trial etc are all defined in Section 2 of the New Drugs and Clinical trials Rules 2019 and they are binding on the UEC. Plainly put, a clinical trial is any research/study that prospectively assigns human participants or groups of humans to one or more health-related intervention(s) to evaluate the effects on health outcomes. The intervention could be drugs, vaccines, biosimilars, biologics, phytopharmaceuticals, radiopharmaceuticals, diagnostic agents, public health interventions, socio-behavioural interventions, technologies, devices, surgical techniques or interventions involving traditional systems of medicine, etc. As per amended Schedule Y (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetics) and/or adverse effect with the objectives determining safety and/or efficacy of a new drug. The academic clinical trial as per GSR 313 (e) dated 16 March 2016 is a clinical trial using intervention falling under the definition of 'New Drug' but intended only

for academic purposes and not marketing purposes.

12) **Closed Study File**: A file corresponding to a study, which has been completed, terminated, discontinued, suspended, not initiated is considered a closed file.

13) **Confidentiality:** Keeping information confidential, which an individual has disclosed in a relationship of trust and with the expectation that it shall not be divulged to others without permission. In addition, it means prevention of disclosure of information and documents related to UEC by stakeholders to other than authorized individuals.

14) **Conflict of Interest (COI)**: It is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like financial or non-financial (personal, academic or political) gain.

- Types of COI
  1. A personal COI is said to exist when -
     a) there is immediate family relationship (spouse/partner, parent or parent of spouse, child or child of spouse/partner, sibling or sibling of spouse/partner, or a dependent who resides with an UEC member or consultant or who receives 50% or more support from an UEC member, regardless of age) or other close current personal relationship ("step" relationships included) with the investigator, or with co-investigators;
     b) UEC member or her/his immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff
     c) Research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest, if applicable).
  2. A professional COI means the UEC member or her/his immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.
  3. A financial COI for UEC members and immediate family exists when the UEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual

property rights (e.g., patents, copyrights, product or service being evaluated).

15) **Compensation**: Provision of financial payment to the research participants or their legal heirs when temporary or permanent injury or death occurs due to participation in research approved by ethics committee as per KUHS policy.

16) **Continuing Review:** Periodic review of the progress of the approved protocols. Generally, this is done once in a year from the date of start of the project for the duration of the study. It may be done earlier depending on the risk involved in the study.

17) **Document:** Document may be of any form, e.g., paper, electronic mail (e-mail), faxes, audio, video tape or images, etc., which falls under the purview of UEC

18) Exemption from review: A research study is said to be exempt from review when the proposals with less than minimal risk with no linked identifiers are submitted and requires only approval of member-secretary in consultation with the Chairperson if necessary. Such proposals are to be reported to the full committee during its meeting.

19) **Expedited review/meeting:** An expedited review is an accelerated review process for proposals having minimal risk, revised document with minor changes for approval by a sub-committee comprising Chairperson, member-secretary and 1 or 2 designated members of UEC. The decision is reported to the full board in its subsequent meeting.

20) **Full Committee Review:** Review of initial, resubmitted, continuing review, amendments of protocols and or informed consent documents and any other documents, which are tabled in the meeting of the full UEC committee for detailed discussion and decisions. This has to be on regular basis or in emergency/urgent situations this can be reviewed during unscheduled meeting.

21) **Independent Consultants**: Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed.

22) **Informed Consent Document**: Written signed and dated paper confirming a participant's willingness to voluntarily participate in a particular research, after

having been informed of all aspects of the research that are relevant for the participant's decision to participate.

23) **Initial Review:** The first-time review of the protocol done during a meeting.

24) **Investigator's brochure**: The Investigator's Brochure (IB) is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human participants.

25) **Investigational New Drug(s) (IND)**: IND means a new chemical entity or a product having therapeutic indication but which has never been tested earlier on human beings.

26) **Justice:** Pertains to fairness in the way people are dealt with, indicating fair selection and distribution of benefits and risks to participants who should be fully apprised about them.

27) **Lay person:** A literate person who has not pursued a medical science/health related career in the last 5 years and is aware of the local language, cultural and moral values of the community.

28) **Legal Expert**: A person with a basic degree in law from a recognized university conversant with current affairs in law related to health care.

29) **Legally Acceptable Representative (LAR):** A person who will give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the Ethics Committee (EC).

30) **Legally Authorized Representative (LAR):** A person who, under applicable law or judicial authority, can give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the EC.

31) **Less than minimal risk:** Research in which there is no known physical, emotional, psychological, or economical risk to the study participant. This research qualifies as exempt if it does not involve special populations (i.e.,

minors, prisoners, pregnant women, etc.).

32) **Malfeasance**: It is the doing of any act that is criminal or wrongful, which gives rise to, or somehow contributes to the causing of injury to another person. It is not a distinct crime; but is an affirmative act that is illegal or wrongful. It is distinct from misfeasance, which is an act not illegal, but only performed improperly. It is intentional conduct and illegality that makes it malfeasance.

33) **Master SOP files**: A collection of the Standard Operating Procedures (SOP) of UEC, KUHS with the necessary signatures on first page accessible to all staff, UEC members, auditors and government inspectors as an original paper copy in the filing system of the UEC secretariat. When a copy of this is provided to members of UEC or others, it is termed controlled copy, which has to be returned to UEC office when next revision to SOP is to be issued or the purpose of reference is over.

34) **Minimal risk:** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, study of case records as retrospective study, etc. (National Ethical Guidelines, 2017). Exception will be surgery, chemotherapy or radiation therapy, where great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current daily life.

35) **Less than minimal risk**: Research, in which there is no known physical, emotional, psychological, or economical risk to the study participants. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.)

36) **Minutes:** An official written record of proceedings of an UEC meeting.

37) Non-compliance: Failure or refusal to act in accordance with approved study protocol, national guidelines/regulations.

38) **Past SOPs of the UEC**: A collection of previous official master versions of SOPs and relevant information regarding changes.

39) Primary Reviewer: A member of IHEC to whom review of a given study is assigned to do the technical and ethical review from the time of submission till the completion of the study. For each protocol, there will be two primary reviewers – one for scientific/technical and ethical review and the other for review of ICF. They complete the protocol review form and present their observations before the board.

40) **Protocol Deviation/Violation/Non-compliance**: Any change, divergence, or departure from the study design or procedures of a research protocol as approved by the UEC or Investigators not performing the study in compliance with the approved protocol, current guidelines/regulations/UEC policies and/or fail to respond to the UEC request for information/action. A protocol deviation is a less serious non-compliance with the approved study protocol.

41) **Protocol Waiver**: Protocol Waiver is analogous to a Protocol Deviation, except that prior UEC approval has been obtained before implementing the necessary departures from the protocol.

42) **Quorum:** Minimum number and/or kind of EC members required for decision making during a meeting.

43) **Adverse drug reaction:** An adverse drug reaction is a response to a drug which is noxious and unintended and which occurs at doses normally used for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.

44) **Serious Adverse Event (SAE):** An adverse event is serious when the research outcome for the participant is any untoward medical occurrence that at any dose results in death, life-threatening injury requiring hospitalisation, prolongation of hospitalisation, significant disability/incapacity, congenital anomaly.

45) Social Scientist: A person who is an expert on societal and social behaviour with specialization/experience in the area.

46) **SOPs (Standard Operating Procedures)**: Detailed, written instructions, in a

certain format, describing activities and actions undertaken by the UEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify and standardize the functioning, whilst maintaining high standards of Good Clinical Practice

47) **SOP Effective date**: The date of implementation of SOPs after acceptance by the Vice Chancellor, KUHS following signed and dated approval of the Chairperson, UEC.

48) SOP Manual: A collection of (all the) SOPs (and their Annexures) put together in book format.

49) **SOP Team**: A team of members including the Member Secretary and any other member of UEC identified by the chairperson, which prepares or revises SOPs of the UEC of KUHS.

50) Status Report: Report summarizing the progress of the approved study as of a stated period.

51) **Study Assessment Form**: An official record that documents the protocol review process.

52) **Study protocol**: A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial.

53) **University Ethics Committee (UEC)**: It is an independent body responsible for ensuring the protection of the rights, safety, dignity and well-being of human participants involved in a clinical research under the aegis of KUHS and to provide public assurance of their protection.

54) **UEC members**: Individuals serving as regular members of the UEC, KUHS.

55) **Vulnerable participants:** Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.

56) **Violation**: The act of doing something that is not as per the approved study protocol, which violates ethical principles and/or human rights. The UEC monitors whether investigators conduct the study in compliance with the approved protocol, national regulations or not and/or fail to respond to the UEC request for information/action.

57) **Protocol Deviation**- A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the UEC. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the UEC using the standard reporting form.

58) **Protocol Violation**- A protocol violation is a deviation from the UEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data. If the deviation meets any of the following criteria, it is considered a protocol violation. Example list is not exhaustive.

I. The deviation has harmed or posed a significant or substantive risk of harm to the research participant. For example,
   - Receiving the wrong treatment or incorrect dose.
   - Withdrawal criteria met during the study but was not withdrawn.
   - Receiving an excluded concomitant medication.

II. The deviation compromises the scientific integrity of the data collected for the study. For example,
   - A research participant who was enrolled does not meet the protocol's eligibility criteria.
   - Failure to treat research participants as per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)
   - Changing the protocol without prior UEC approval.
   - Inadvertent loss of samples or data.

III. The deviation is a wilful breach of human participant protection regulations, policies, or procedures on the part of the investigator(s). For example,
   - Failure to obtain informed consent prior to initiation of study-related procedures

- Falsifying research or medical records.
- Performing tests or procedures beyond the individual's professional scope or privilege status (credentials)

IV. The deviation involves a serious or continuing noncompliance with central, state, local, or institutional human participant protection regulations, policies, or procedures. For example,
- Working under an expired professional license or certification
- Failure to follow central and/or local regulations, and intramural research or CC policies
- Repeated minor deviations.

V. The deviation is inconsistent with the Human Research Protection requirements in research ethics principles. For example,
- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

59) **Minor Protocol Deviation**- A minor protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the UEC and which DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

60) **Serious Adverse Event:** Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect

61) **Serious Adverse Event or Serious Adverse Drug Reaction:** An AE or ADR that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

62) **Adverse Event:** An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated

with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

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12. The Belmont Report, Ethical Principles and Guidelines for the protection of human subjects of research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research April 18, 1979, Department of Health, Education, and Welfare.
13. NABH Guidebook to standards for accreditation of Ethical Committees (1st ed., 2015).
14. Global Code for Research in Resource-Poor Settings. European Commission, 2018.
15. GSR 227(E) dt. 19.3.2019, New Drugs and Clinical Trials Rules, 2019.

Standard Operating Procedures

The Standard Operating Procedures (SOP) listed below are part of the UEC SOP Manual Version 2 dated 25.10.2019

SOP Prepared by:

Name and Position on the UEC	Signature with date
Dr. Ajithkumar K.	
Dr. Harikumaran Nair G. S.	

Reviewed by:

Name and position on UEC	Signature with date
Dr. Nandini K Kumar	

Approved by:

Name and Position on the UEC	Signature with date
Justice Hariharan Nair (Chairperson, UEC)	

Accepted by:

Name and Position on the UEC	Signature with date
Dr. M K C Nair, Vice Chancellor, KUHS	

Format of SOP Content

SOP Title: Preparation of Standard Operating Procedures for University Ethics Committee

List of SOP with Code:

Effective Date:

Table of Contents:

Page numbers of SOP manual will be on continuous basis.

1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the University Ethics Committee (UEC). The SOP provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national, and international ethical guidelines.

1.2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the UEC.

1.3. Responsibility

It is the responsibility of the Chairperson of the UEC to appoint a SOP team to formulate a new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures, format and coding system as per the contents in the checklist provided that is used while drafting or editing any SOP of the UEC. All members of UEC will review the SOPs and approval will be given by Chairperson of UEC. The SOPs shall then be accepted by the Vice Chancellor, KUHS.

1.3.1 Secretariat of the UEC will:

- Assist Chairperson to formulate a SOP Team
- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Ensure that all the UEC members and involved administrative staff have access to the SOPs
- Ensure that all the UEC members and involved staff are working according to current version of SOPs
- Maintain an up-to-date distribution list for each SOP distributed to the UEC members.
- Maintain a register to record the names of investigators to whom SOPs are distributed
- Maintain a file of all current SOPs and the list of SOPs
- Maintain a file of all past Master SOPs of the UEC.

1.3.2 SOP team will

- Assess the request(s) for SOPs revision in consultation with the Secretariat, Member Secretary and Chairperson
- Propose new/modified SOPs as needed

- Draft the SOPs giving step by step process details in consultation with the designated UEC members and involved administrative staff
- Make a list of SOPs with coding reference
- Review the draft SOPs
- Submit the draft for approval to Chairperson

1.3.3 Chairperson of the UEC will

- Appoint one or more SOP Teams
- Approve the SOPs
- Sign and date the approved SOPs

1.3.4 UEC members and involved administrative staff (if any) will

- Sign and date the approved SOPs when they receive it
- Maintain a file of all SOPs received

1.4. Detailed instructions

1.4.1 Identify the need for new or amendment of current SOP

Any member of the UEC or Secretariat who would feel the requirement of a revision or notices an inconsistency/discrepancy/has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by writing to the UEC Chairperson either as an email/letter/verbal request in a meeting. The Chairperson will inform all the UEC members about this request at a regular full-board UEC meeting. If the UEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson to proceed with the revision process of the SOP. If the UEC members do not agree, no further action will be taken. The Chairperson will inform the member of the UEC or Secretariat who made the request for modification of the SOP.

1.4.2 Appoint the SOP Team(s)

- The Chairperson will constitute a SOP Team(s) consisting of the member-secretary and members of the UEC who have a thorough understanding of the ethical review process.
- The SOP writing team will carry out the subsequent steps as described in sections 1.4.3 to 1.4.7. and their term will be for a period of one year.

1.4.3 List all relevant procedures

- Write down step by step all the procedures of the UEC that are to be standardized in the form of a SOP.
- Organize, divide and name each process.

1.4.4 Write and review a new SOP

- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson.
- Each SOP should be given a number and a title that is self-explanatory and easily understood. A unique code number with the format SOP xx/Vy will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP. "V" refers to version of the SOP and "y" will be a number identifying the version, e.g. the first SOP of the second version would be SOP01/V_2 i.e. it is SOP number 01 with version 2.
- Each SOP may have annexure(s), which are forms to be filled in by various stakeholders [Reviewers, UEC Chairperson/Member Secretary/Secretariat or Principal Investigator (PI)]. Each annexure will be given a unique code number with the format AX pp/SOPXX/Vy. AX refers to annexure form, pp is a two-digit number identifying specific number of the annexure, while XX/Vy refers to the SOP number and its version. For example, AX01/SOP01/V_2, means annexure number 1 belongs to SOP01/V_2.
- Each SOP will be prepared according to the standard template in AX01/SOP01/V_2. Each page of the SOP will bear the header which will have the effective date (aa/bb/cccc) i.e. the date of implementation after release. The SOP number will be on the right hand corner with the title of the SOP while the footer will bear the page number as page p of q (total) pages. The logo of the Institution/Hospital may be put in the header.
- The draft SOP written by one or more members of the SOP team will be reviewed by the designated members of the UEC. After incorporating the suggestions put forth by the reviewing members, a copy of the revised draft SOP will be sent to the Member-Secretary to circulate it to all the UEC members for comments.

1.4.5 Write and review a revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form (AX02/SOP01/V_2) along with description of the main change/s.
- The rest of the steps are as described in Section 1.4.4.

1.4.6 Pagination and blank pages

- All pages, including blank pages in this SOP Manual will be continuously numbered.

- In this SOP Manual, each Section/SOP will start on a right-hand side page. If the SOP ends on right-hand side, the following left-hand side page will be left blank but will be included for page numbering. This is to enable the next SOP to start from the right-hand side page.

1.4.7 Prepare and submit final draft

The SOP Team will submit the reviewed SOP to the UEC Members who will review it at a meeting.

- The suggestions that are agreed upon by the UEC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- The SOP team would stand automatically dissolved once the UEC takes final decision regarding the SOP.

1.4.8 Approve the new/revised SOP

The final version will be presented to the Chairperson for review and approval. The authors (SOP team members), reviewers and the Chairperson will sign and date the SOP on the first page of the SOP document followed by acceptance by Vice-Chancellor of KUHS on the same page. The date of implementation following the release of the SOP will be declared as the effective date for the SOP manual. The same will apply to revised SOP too.

1.4.9 Implementation, distribution and filing of SOPs

1.4.9.1 The approved SOP will be implemented from the effective date.

1.4.9.2 The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.

1.4.9.3 A hard copy of the approved SOP (termed controlled copy) will be distributed to the UEC members as controlled copy and a log will be maintained as per the annexure - *AX03/SOP01/V_2*.

1.4.9.4 The UEC members and Secretariat will review the SOPs at least once in every 5 years.

1.4.9.5 One complete set of current SOPs will be filed in the SOP Master file by the UEC Secretariat in the UEC office.

1.4.9.6 Photocopies made from the official paper version of the SOP can be considered as controlled copies, if stamped and signed by Member Secretary for distribution to UEC members.

1.4.9.7 SOPs should be made available to all Investigators on Institute website.

1.4.9.8 When the revised version is distributed, all the UEC members will be requested to return or destroy their copy of earlier version and their action taken in this regard has to be documented.

1.4.9.9 Only one copy of the earlier version will be clearly marked 'Superseded/Obsolete' and filed in the file entitled 'Past SOPs of the UEC' by the UEC Secretariat in the UEC office.

1.4.9.10 The process of evolution of previous SOPs of the UEC will be documented in defined format as per *AX 04/SOP01/V_2*.

1.5. Flow Chart

No.	Activity	Responsibility
1	Identify the need for new or amendment of current SOP	Any member of UEC, secretariat or administrative staff
2	Appoint the SOP Team(s)	Chairperson
3	List all relevant procedures	SOP Team
4	Write a new/revised SOP	SOP Team
5	Review a revised SOP	SOP Team and/UEC members
6	Prepare and submit final draft	SOP Team
7	Approve the new/revised SOP	Chairperson
8	Acceptance of the new/revised SOP	Head of the institution (VC, KUHS)
9	Implement, distribute and file SOPs	UEC members and Secretariat

1.6. Annexures

Annexure 1: *AX01/SOP01/V_2*- Template for SOPs

Annexure 2: *AX02/SOP01/V_2*- Documentation of History of the SOPs

Annexure 3: *AX03/SOP01/V_2*- Log of the UEC members receiving SOP

Annexure 4: *AX04/SOP01/V_2*- List of SOPs of the UEC

Annexure 1: AX01/SOP01/V_2

Main Text:

1. **Purpose**: *Summarizes and explains the objectives of the procedure.*
2. **Scope:** S*tates the range of activities that the SOP applies to.*
3. **Responsibility**: *Refers to person(s) assigned to perform the activities involved in the SOP*
4. **Detailed instructions**: *Describes procedures step by step in short and clear sentences*
5. **Flow chart:** *Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*
6. **Annexure**: *Forms to capture information pertaining to the SOP instructions*

Annexure 2: AX02/SOP01/V_2

Documentation of History of the SOPs with Details of superseded SOP

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)

Annexure 3: AX03/SOP01/V_2

Log of the UEC members receiving SOPs

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date

Annexure 4: AX04/SOP01/V_2

List of SOPs of the University Ethics Committee

No	Title of the Standard Operating Procedures (SOPs)	SOP No.
1	*Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing and Amending SOPs*	*SOP 01*
2	*Constitution of University Ethics Committee (UEC), Selection, Roles and Responsibilities of Members of the UEC*	*SOP 02*
3	*Handling Conflict of Interest among Ethics Committee Members*	*SOP 03*
4	*Selection and Responsibilities of Independent Consultants*	*SOP 04*
5	*Procedures for allowing Guest/Observer to visit University Ethics Committee or attend UEC meeting*	*SOP 05*
6	*Management of Submission of Research Study Protocol and Study Related Documents*	*SOP 06*
7	*Categorization of Submitted Protocols for Ethics Review*	*SOP 07*
7A	*Initial Full-Board Review of Research Study Protocols*	*SOP 7 A*
7B	*Expedited Review of Research Study Protocols*	*SOP 7 B*
7C	*Exemption from Ethics Review of Research Study Protocols*	*SOP 7C*
8	*Agenda Preparation, Meeting Procedures and Recording of Minutes*	*SOP 08*
9	*Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol*	*SOP 09*
10	*Continuing Review of Study Protocols*	*SOP 10*
11	*Review of Protocol Deviations/Violations/Non-compliance*	*SOP 11*
12	*Review of Serious Adverse Events (SAE) Reports*	*SOP 12*
13	*Review of Study Completion Reports*	*SOP 13*
14	*Management of Premature Termination/Suspension/Discontinuation of the Study*	*SOP 14*
15	*Request for Waiver of Written Informed Consent and Waiver of Consent*	*SOP 15*
16	*Site Monitoring and Post-Monitoring Activities*	*SOP 16*
17	*Dealing with Participants' Requests and Complaints Coming to Ethics Committee*	*SOP 17*
18	*Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents*	*SOP 18*
19	*Reviewing Proposals involving Vulnerable Populations*	*SOP 19*
20	*Preparing for Ethics Committee Audit/Inspection*	*SOP 20*
21	*Training and Assessment of Ethics Committee Members*	*SOP 21*

2.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe frequency of Ethics Committee Meeting and the terms of reference (TOR) of members, which provide the framework for constitution, selection, roles and responsibilities of the University Ethics Committee (UEC) and procedures for maintaining confidentiality of all activities and documents.

2.2. Scope

This SOP applies to the constitution of the UEC, selection, roles and responsibilities of members of the UEC and maintenance of confidentiality of all activities and documents.

2.3. Responsibility

The Head of the Institution will appoint the Chairperson, Member Secretary and UEC members. The letter issued by the Chairperson will specify the Terms of Reference especially about the role and responsibility specific to each member, duration and conditions of appointment. It is the responsibility of the Chairperson, Member Secretary and UEC members and the Secretariat to read, understand, follow and respect this SOP.

2.4. Detailed Instructions

2.4.1 Composition of the University Ethics Committee (UEC)

2.4.1.1 The UEC will be established by the Vice Chancellor, KUHS in compliance with the provisions in S. 37 of the KUHS Act 2010 and as per guidelines of ICMR.

2.4.1.2 The Chairperson of UEC may help in identifying the person as Alternate/Co-Chairperson, Member Secretary, Joint Secretary and UEC members for appointment based on their qualification, experience in the domain field, interest, ethical and/or scientific knowledge and expertise. The UEC members can also suggest names of potential members to be the Chairperson. The Vice-Chancellor will make the final decision regarding the appointment.

2.4.1.3 It is the responsibility of the Chairperson and Member Secretary to ensure that the functioning of Ethics Committee is independent and as per current ethical guidelines and regulatory guidelines.

2.4.2 **Introduction**

It is necessary that UEC reviews all research proposals, on regulatory biomedical and health Science areas, involving human participants, their biological material and data to be reviewed and safeguard the dignity, rights, safety and well-being of all research participants. UEC is entrusted with the initial review of research proposals prior to their initiation, and have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research. The UEC should be competent and independent in its functioning.

2.4.2.1 The University is responsible for establishing and ensuring an appropriate and sustainable system for quality ethical review and monitoring.

2.4.2.2 The University is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and protected time for the Member Secretary to run the UEC functions.

2.4.2.3 The UEC is responsible for both scientific and ethical review of research proposals. It shall, however, be open to the Chairperson to entrust the work of preliminary scientific assessment to an appropriate person or committee taking into account the nature of the work. Although UEC may obtain documentation from a prior scientific review, it must determine that the research methods are scientifically sound to address the ethical implications of the chosen research design or strategy.

2.4.2.4 All types of biomedical and health research (non-regulatory clinical trials, Academic trials, basic science, social, behavioral, public health research, etc.) must be reviewed by UEC before it is initiated.

2.4.2.5 Its hierarchical position in the organization and authority under which it is established will be clearly indicated (*AX02/SOP02/V_2*)

2.4.2.6 The UEC will be multi-disciplinary and multi-sectorial in composition. The UEC shall follow the provisions of the new Drugs and Clinical Trial Rules 2019, Good Clinical Practices Guidelines and other regulatory requirements prevailing from time to time to safeguard the rights, safety and well-being of trial subjects.

2.4.2.7 The UEC will be composed of minimum 7 members and a maximum of 15 members as per current requirement of ethical guidelines, 2017 and New Drugs & Clinical Trials, dated19.3. 2019.

2.4.2.8 The members will -

a. Include a combination of medical and non-medical, scientific and non-scientific persons including laypersons to represent the different points of view to promote adequate review of research.

b. Have the required qualifications as prescribed by applicable guidelines and regulations from time to time.
c. Members should have the expertise, be committed and willing to volunteer the necessary time and effort for the UEC activity.
d. Members should not have any known record of professional misconduct.
e. Conflict of interest will be avoided, but where unavoidable, there will be transparency with regard to such interests (SOP03/V_2).

2.4.2.9 The UEC will have representation that is balanced in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community/society'.

2.4.2.10 The committee should include at least one member whose primary area of expertise is in a non-scientific area.

2.4.2.11 The UEC should have members comprising clinician, basic medical scientist with mandatory inclusion of at least a layperson, one woman member, one legal expert, one independent member - social scientist or representative of NGO/voluntary agency/philosopher/ethicist/ theologian.

2.4.2.12 The UEC should have 50% non-affiliate members.

2.4.2.13 The UEC may invite member(s) of specific patient groups or other special interest groups for an UEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (*AX03/SOP02/V_2*) and declare in writing, conflicts of interest (COI), if any, prior to attending the meeting (*AX02/SOP03/V_2*). They will attend the meeting and will not have the right to vote.

2.4.2.14 The Composition shall be as follows:

a. Chairperson, well respected person from any background in society with prior experience (must not be affiliated to the institution).
b. Alternate or Co-Chairperson, well respected person from any background in society with prior experience (if appointed, must not be affiliated to the institution).
c. One Member Secretary, having knowledge and experience in clinical research and ethics, be motivated and have good communication skills (must be affiliated to institution).
d. One Joint Member Secretary of same requirement as above (if appointed, must be affiliated to institution).
e. One or more Basic Medical or Non-Medical Scientist having post graduate qualification in medical (preferably clinical Pharmacologist for

reviewing proposals on new drug as defined in New Drug & Clinical Trial Rules, dated 19.3.2019) or biological sciences and adequate experience of minimum 2 years (affiliated or non-affiliated).

f. One or more clinicians having post graduate qualification, adequate training and experience of minimum 2 years (at least one should be affiliated to institution)
g. One legal expert or retired judge conversant with current related regulations (affiliated or non-affiliated)
h. One social scientist/representative of non-governmental agency/One philosopher, ethicist or theologian, intellect, educationist (affiliated or non-affiliated)
i. One or more literate lay persons from the community (not to be affiliated to the institution) who should be aware of local, social and cultural norms of the particular area. If person is of medical or health science background, they should not have pursued that career in the past 5 years. Desirable criteria would be experience of involvement in social and community welfare activities.

2.4.3 Composition of SAE subcommittee under UEC

The UEC Chairperson will delegate SAE review to subcommittee members constituted from among members of UEC. Primarily clinician, basic medical scientists (preferably pharmacologist), will be part of the sub-committee along with member secretary. Delegation of some responsibility to any other ethics committee member e.g. legal expert (if required) would be done at the discretion of Chairperson or Alternate Chairperson. This subcommittee will review the SAEs submitted by PI (on site) and will report to the UEC for the purpose of reimbursement and compensation etc. which will further review and forward that information to CLA (Central Licensing Authority).

2.4.4 Agreement regarding Maintenance of Confidentiality

2.4.4.1 It is the responsibility of each UEC member to sign the agreement contained in the confidentiality Agreement Form (*AX03/SOP02/V_2*) when accepting to be a member for reviewing research projects.

2.4.4.2 The staff of the secretariat will also sign a confidentiality agreement (*AX04/SOP02/V_2*).

2.4.4.3 The Secretariat will obtain the signature of the UEC Chairperson on the Confidentiality form.

2.4.4.4 The Secretariat will provide UEC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them

and UEC Chairperson) and acknowledge the receipt of agreement with their signature and date.

2.4.4.5 The Secretariat will keep the original copies of the signed Agreements in the UEC office in the file entitled 'Confidentiality Agreement' file for members and photocopies of the agreement in the individual members' files.

2.4.5 Tenure of Membership

The tenure of UEC will be for a term of 3 years from the date of appointment. Chairperson and all members shall serve on the committee for a maximum of two terms. Under exceptional circumstances, extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human research. This may be decided as two incremental extensions for two years at a time. Normally after serving for these terms a member could be re-appointed after a break of a term.

2.4.6 Appointment of New Members

2.4.6.1 The UEC members will be appointed by the Head of the Institution.

2.4.6.2 New members will be appointed under the following circumstances:

a. When a regular member completes her/his tenure.
b. If a regular member resigns before the tenure is completed.
c. If a regular member ceases to be a member for any reason including death or disqualification.
d. If the Vice Chancellor thinks that there is need for more members, provided, the total number does not exceed 15.

2.4.7 Conditions to be fulfilled by a member after appointment

2.4.7.1 Members to be appointed in the UEC will need to submit the following:

a. A recent CV signed and dated.
b. Training certificates in Ethics and/or GCP and SOP. In case training certificates are not available at the time of induction as member in the UEC, the member must submit these within 6 months of appointment.

2.4.7.2 Members must be willing to:

a. Publicize her/his full name, profession and affiliation.
b. Sign the Confidentiality Agreement (*AX3/SOP02/V_2*) and maintain confidentiality regarding meeting, deliberations, applications, information on research participation and related matters.
c. Read, understand, accept and follow the Conflict of interest policy and sign the Conflict of interest agreement form (*AX1/SOP03/V_2*).

d. Be committed and understanding to the need for research and for imparting protection to research participants in research.

2.4.8 Resignation and Disqualification of Members

2.4.8.1 **Resignation:**

a. An UEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Vice Chancellor to whom the resignation will be transmitted by the Chairperson.
b. If the Chairperson resigns, she/he is required to inform the Vice-Chancellor 30 calendar days in advance. When an emergency warrants resignation for which prior notice could not be given in time, the resignation may be accepted by the Vice-Chancellor. The same applies to a member as well.

2.4.8.2 **Disqualification for conduct unsuitable of an UEC member**:

a. UEC Chairperson or Member-secretary will initiate the process on receipt of a written communication provided by UEC member or a member of the public alleging misconduct by a member.
b. The Chairperson will satisfy herself/himself that a *prima facie* case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of UEC could be questioned, the Chairperson may suspend the membership of the concerned UEC member till the final decision is taken by UEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an UEC member and will not perform any duties as UEC member.
c. The Chairperson may call for a meeting of the UEC specifically to discuss this issue or the matter will be taken up for discussion during full committee review meeting. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the UEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend herself/himself.
d. The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd majority of members present in the meeting). The Chairperson will convey the disqualification to the concerned member through a written communication.

2.4.8.3 Disqualification for not attending UEC meetings:

A member may be disqualified from UEC membership if the member fails

to attend more than 3 consecutive UEC meetings without prior intimation. The process concerned will be as follows:

a. The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the UEC without prior intimation to the UEC or is on long leave extending for more than six months without valid reasons.
b. The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next UEC meeting.
c. A written communication will be sent to the concerned UEC member informing her/him that the issue of disqualification would be discussed at the meeting, inviting the member to be present at the meeting to clarify her/his position. Alternatively, the concerned UEC member will be allowed to explain in her/his absence in a letter addressed to the Chairperson, which will be read and reviewed at the meeting.
d. The Chairperson or Member-Secretary will inform the other UEC members about the cessation of membership of the member, in consultation with the Chairperson, by written communication or during the next meeting of UEC. The same will be communicated to the Vice Chancellor by the Chairperson.

2.4.9 Hierarchy

a. Chairperson, Alternate/Co-Chairperson, Member Secretary and Joint Member Secretary may be appointed from amongst the members.
b. The Chairperson will head the committee. Alternate Chairperson will head the committee in the absence of Chairperson.
c. The Member Secretary and the Joint Member Secretary (whenever applicable) will be in-charge of all documents and funds in the possession of the committee.
d. Other UEC members will be regular committee members with equal ranking.

2. 4.10 Functions of Chairperson

2.4.10.1 The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals and be accountable for independent and efficient functioning of the committee

2.4.10.2 Ensure active participation of all members (particularly non-affiliated, non-medical/non- technical) in all discussions and deliberations.

2.4.10.3 Ratify minutes of the previous meetings

2.4.10.4 In case of anticipated absence of both Chairperson and Alternate/Co-Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson (or the members present may elect an Acting Chairperson on the day of the meeting). The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.

2.4.10.5 Seek COI declaration from members and ensure quorum and fair decision-making.

2.4.10.6 Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

2.4.10.7 Preside over all elections as well as administrative and financial matters pertinent to the committee's functions.

2.4.10.8 Represent the UEC at various meetings and forums.

2.4.10.9 The Chairperson will sign documents and communications related to UEC functioning.

2.4.10.10 The Chairperson will delegate her/his responsibilities to the Alternate/Co-Chairperson in accordance with UEC SOPs.

2.4.11 Functions of Alternate/Co-Chairperson

To act as Chair in the absence of Chairperson and to perform all functions of Chairperson.

2.4.12 Member secretary

2.4.12.1 Signs documents and communications related to UEC functioning.

2.4.12.2 Communicates with the UEC members and applicants/investigators.

2.4.12.3 Notifies the Principal Investigator regarding UEC decisions related to the submitted research proposal.

2.4.12.4 Provides necessary administrative support for UEC related activities to the Chairperson.

2.4.12.5 Provides updates on relevant and contemporary issues on ethics in health research as well as relevant contemporary literature to the committee members.

2.4.12.6 Receives ethics committee review processing fees and issue official receipts for the same.

2.4.12.7 Delegates various responsibilities to appropriate and authorized individuals.

2.4.12.8 Ensures adherence of UEC functioning as per SOPs.

2.4.12.9 Prepares and makes available annual reports/annual financial statements of the UEC, if any, for scrutiny by auditors/inspectors.

2.4.13 Functions of the Joint Member Secretary

The Joint Member Secretary, if any, will perform the same functions of Member Secretary in her/his absence

2.4.14 Functions of UEC members

2.4.14.1 Accept appointment letter in writing with dated signature

2.4.14.2 Attend UEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.

2.4.14.3 Review, discuss and consider research Proposals submitted for evaluation.

2.4.14.4 Monitor Serious Adverse Event reports and recommend appropriate action(s).

2.4.14.5 Review the progress reports and monitor ongoing studies as appropriate.

2.4.14.6 Do on-site monitoring visits whenever needed.

2.4.14.7 Evaluate final reports and outcomes.

2.4.14.8 Maintain confidentiality of the documents and deliberations of UEC meetings.

2.4.14.9 Declare any conflict of interest in writing to the Chairperson, if any, at each meeting.

2.4.14.10 Participate in continuing education activities in bioethics related to biomedical and health research and provide the training certificate to the UEC secretariat for filing.

2.4.14.11 Provide an updated CV when requested for by the UEC secretariat.

2.4.14.12 Carry out work delegated by Chairperson, Member-secretary/Joint Member-secretary.

2.4.14.13 Assist Chairperson/Co-Chairperson, Member-secretary/Joint Member-secretary, in carrying out UEC work as per SOPs.

2.4.14.14 Be updated on guidelines, relevant laws and regulations.

2.4.15 Quorum requirements – Any decision taken in the UEC meeting either by the Chairperson/Alternate Chairperson will not be valid without fulfillment of the quorum requirements as given below:

2.4.15.1 As per ICMR Guidelines

a. Minimum any five members in the meeting room including medical, non-medical or technical and/or non-technical members
b. Presence of one non-affiliate member.

2.4.15.2 As per CDSCO's specific requirement

a. medical basic scientist (preferably a clinical pharmacologist)
b. clinician
c. legal expert
d. social scientist or representative of non-governmental voluntary agency/philosopher/ethicist/theologian/a similar person
e. lay person.

2.4.16 Secretariat

2.4.16.1 The Secretariat will be composed of the administrative supporting staff

2.4.16.2 The Secretariat will support the Member Secretary and Joint Member Secretary (if applicable) in all their functions

2.4.16.3 All the staff of the Secretariat will sign a confidentiality agreement, which should be filed with the UEC (*AX04/SOP02/V_2*)

2.4.16.4 The working rules for the Secretariat are stated in (*AX01/SOP02/V_2*)

2.4.17 Types of projects reviewed by UEC

The UEC will act as the IEC for University's own Schools, Centres, Academic staff College, Departments and Constituent Colleges till they constitute their own IECs. The UEC will review scientific and ethical aspects of all types of research studies involving human participants.

2.4.18 Honorarium to the Members

Reimbursement of travelling expenses and/or reasonable honorarium for attending the UEC meetings may be given to the UEC members.

2.4.19 Preparing an annual activity report of the UEC for submission to the Head of the Institute

The Member Secretary will make a yearly activity report for submission to the Head of the Institute, which will include the following elements:

a. Number and dates of the UEC meetings of full committee
b. Number of SAE subcommittees and any other subcommittee, as applicable
c. Number and type of proposals reviewed in a year, status of each study proposal whether completed/ongoing/terminated
d. Number of approvals for full board review/expedited review with decisions
e. Brief details about workshops, training programs and other activities undertaken by the UEC and those attended by UEC members
f. Any other matter

2.4.20 Training of the UEC Members in Research Ethics

a. An individual selected as a new member of the UEC can attend at least one meeting as an 'Observer' before being inducted as a member of the UEC.
b. Member Secretary or an UEC member may provide introductory training in Research, Research Ethics, Human Protection and GCP to the new members and also before implementation of new or revised version of SOP.
c. Other alternative for training certificate in ethics and GCP could be by online method or by attending workshops.
d. Training in SOP will have to be in-house by member secretary or an UEC member.
e. A newly inducted member should submit a certificate of training in 6 months.
f. All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in workshop, conference and/or re-training program related to research ethics, as a delegate, faculty or facilitator, etc.
g. The UEC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update or assess the UEC Members and Institutional faculty members.
h. The UEC may nominate and/or sponsor (as applicable) an UEC member for attending conference, continuing education session workshop and/or training program etc.

2.5. Reference to other applicable SOPs

SOP03/V_2 - *Conflict of Interest Policy for University Ethics Committee*
SOP08/V_2 - *Agenda Preparation, Meeting Procedures and Recording of Minutes*

2.6. Flowchart

S. No.	Activity	Responsibility
1.	Composition of the Institutional Ethics Committee	Head of the Institute
2.	Selection and appointment of Chairperson	Head of the Institute
3.	Appointment and conditions of appointment of new members	Head of the Institute
4.	Initiation of the process of appointment	Secretariat
5.	Resignation and disqualification of members	Head of the Institute, Chairperson and UEC Members

6.	Quorum requirements	Chairperson, Member Secretary and Secretariat

2.7. Annexures

Annexure 1: *AX01/SOP02/V_2* - UEC Administrative Staff: Working rules

Annexure 2: *AX02/SOP02/V_2* - Organizational Chart of the Institution

Annexure 3: *AX03/SOP02/V_2* - Confidentiality Agreement Form for UEC Members /Member Secretary

Annexure 4: *AX04/SOP02/V_2* - Confidentiality Agreement Form for Staff of Secretariat

Annexure 5: *AX05/SOP02/V_2* - List of Ethics Committee Members

Annexure 6: *AX06/SOP02/V_2* – List of SAE Subcommittee Members

Annexure 1: AX01/SOP02/V_2

The UEC Secretariat/Administrative Staff: Working Rules

There will be employees in the UEC secretariat to assist Member Secretary for smooth functioning of UEC. Administrative officers/assistants with support staff of attendants/helpers may be appointed as and when deemed necessary by the UEC. This staff will help the UEC Chairperson and Member-Secretary in the discharge of their functions. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of eligible leaves may be recommended by UEC members and discussed during regular UEC meeting and will be recorded in minutes.
The administrative staff will report to the Chairperson and/or Member Secretary.

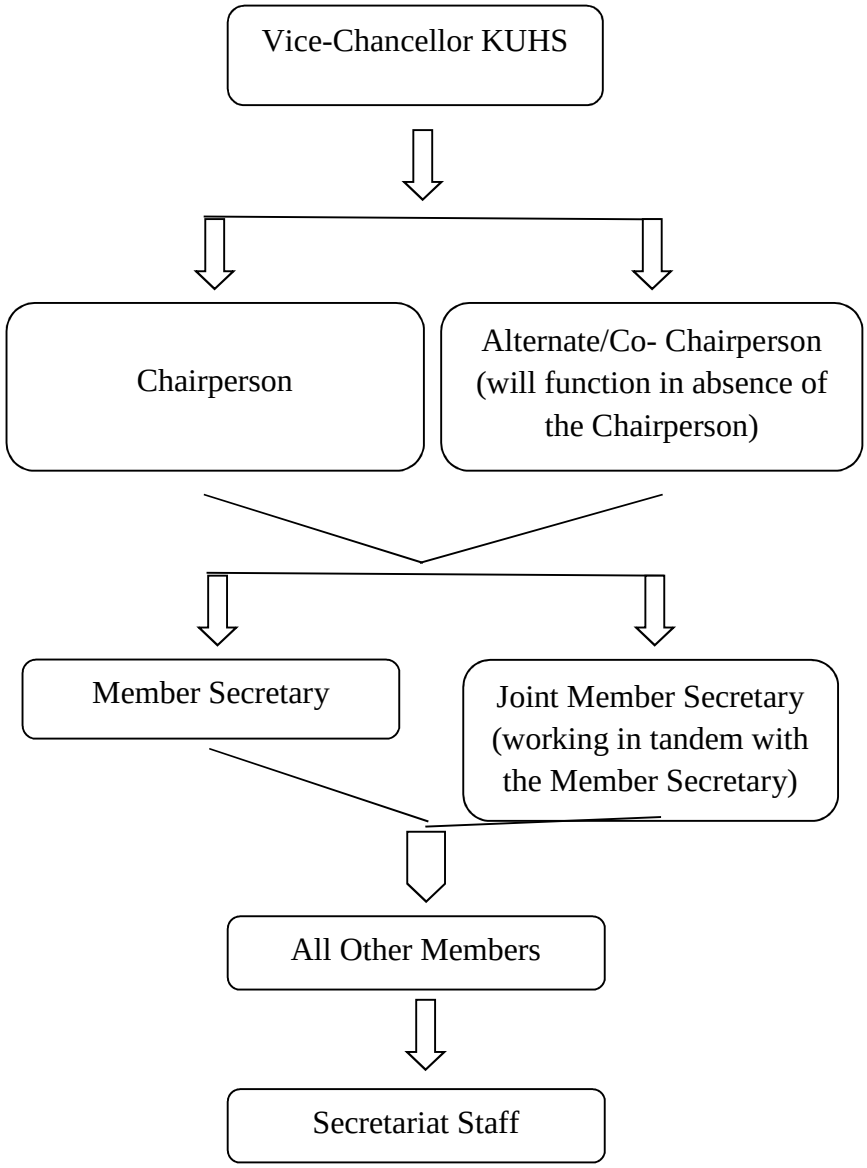
Duties of UEC Secretariat

1. Correspondence with UEC members and external experts
2. Correspondence with the investigators
3. Preparing agenda and minutes of the UEC meetings
4. Answering queries of the investigators
5. Filing study related documents
6. Archiving and maintaining the study files, SOPs, all correspondences
7. Maintaining electronic database of the UEC records with access limitation.

Duties of the attendant/s/helper/s

1. Assisting the secretariat in arranging the UEC meetings
2. Dispatching sets of study documents to UEC members and external experts
3. Receiving the study related documents from and dispatching the UEC letters to the investigators
4. Filing study related documents
5. Archiving and maintaining the study files
6. Assisting the Secretariat during the meetings

Annexure 2 : AX02/SOP02/V_2



Annexure 3 : AX03/SOP02/V_2

Confidentiality Agreement Form for UEC Members/Member Secretary

I_____ (UEC Member's name) have been appointed as a member of the UEC to assess research involving human participants in order to ensure that they are conducted in a humane and ethical manner, and complying with the national guidelines/regulations (international regulations in addition, if applicable) and institutional policies.

I agree to hold all the information deemed Confidential, Proprietary or Privileged in trust or confidence. This information provided to me for research review whether explicit or implied, verbal or documentary, incorporated in computer software or held in electronic storage media/device or otherwise shall be used only for contemplated purposes and not for any other purpose. As written confidential information including any copies and notes thereof, provided for review is sole property of the UEC it shall not be copied or retained, and will be promptly returned or properly handled in the manner required by the UEC, including destruction of the same.

I agree to take reasonable measures to protect the information, unless legally compelled to disclose, from use by third parties, including denial of access to it under Right to Information Act; not to use the Confidential Information for any purpose outside the Committee's mandate or which would result in a benefit to me or any third party; and upon termination of my functions as a Committee member, will destroy all Confidential Information including any minutes or notes I may make or keep as reference.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature of UEC Member **Date**

_____ _____

Chairperson's Signature **Date**

I acknowledge that I have received a copy of this Agreement signed by the UEC Chairperson and me.

Signature of the UEC member **Date**

Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept in file in **UEC** Office. A copy will be given to you for your records.

Note:

Legal compulsion to disclose

In the event that the member becomes legally compelled to disclose any Confidential information, the member shall give prompt notice in writing of such facts to the UEC, so that UEC has an opportunity to seek a protective order or legally appropriate remedy. In the event that such protective order or other appropriate remedy is not sought by the UEC, or is sought, but is not obtained; the member will, nevertheless, disclose only that portion of the Confidential Information as is necessary to comply with its obligations under law and shall use reasonable endeavors to obtain any appropriate court order or other reliable assurance that Confidential treatment will be accorded to Confidential Information so disclosed.

Governing Law:

This agreement shall be governed and construed in accordance with the application of Indian laws, and that the local courts shall have exclusive jurisdiction in respect of disputes over subject matter of this Agreement.

Annexure 4: AX 04/SOP03/V_2

Confidentiality Agreement Form for Staff of UEC Secretariat

I, _____ (Name and Designation) as a non-member of UEC understand that the documents and information related to UEC activity assigned to me as staff of UEC office are confidential. I shall use the information only for the indicated purpose as required by the UEC and shall not duplicate, give or distribute these documents/information to any person(s) without permission from the UEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information confidential.

_____ _____

Name and Signature of staff of UEC Secretariat
with Date

_____ _____

Name and Signature of Chairperson of UEC
with Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, UEC and me.

_____ _____

Name and Signature of the recipient
with Date

Annexure 5: AX05/SOP02/V_2

Ethics Committee Membership List

Name of the Ethics Committee: University Ethics Committee (UEC) of KUHS
DHR Reg No…… Address:
Membership List Dated:

S. No.	Member Name	Role in Ethics Committee	Highest Degrees Earned	Gender	Primary Scientific or Non-Scientific Specialty	Affiliation With Institution
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Note: The Ethics Committee membership list is of current date. It will get updated whenever there is change in membership.

Annexure 6: AX06/SOP02/V_2

SAE Sub-Committee Members List

S. No.	Member Name	Role in SAE Subcommittee	Highest Degrees Earned	Gender	Specialty	Affiliation with Institution
1						
2						
3						
4						
5						

3.1. Purpose

The purpose of this SOP is to describe the process to maintain confidentiality and to identify and manage conflict of interest among University Ethics Committee (UEC) members.

3.2. Scope

This SOP covers the policy applicable to all UEC members, which is related to maintaining confidentiality and identification, declaration and management of conflict of interest

3.3. Responsibility

All UEC members (regular and alternate) are responsible for understanding definition of conflict of interest (COI) and for self-identifying and disclosing these. The Chairperson would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

3.4. Detailed Instructions

- Voluntary disclosure regarding COI by UEC member_- The UEC member should determine whether she/he has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.
- UEC members should not participate in discussing or decision making while reviewing research proposal applications at any level (exempt, expedited, or full-committee) if they have conflicts of interest, except to provide information requested by the UEC.
  a) At the time of becoming a UEC member, she/he should sign a confidentiality and COI agreement.
  b) If an UEC member has a COI with regard to a proposal as a primary reviewer, she or he should inform the UEC Secretariat and return the documents (hard copies), so that the review is re-assigned to other members.
  c) If an UEC member has a COI for review of research study at a meeting, she or he should inform the Chairperson and leave the meeting room while decision about the study is being taken. She/he may stay in the meeting room only to answer questions about the research. This is applicable also for UEC meetings at which discussion on serious adverse

events, deviations/violations, amendments/ continuing review reports related to studies are discussed.

d) Recusal - UEC member who declares COI and leaves the meeting does not count as part of the quorum for the decision making process either by consensus/vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence, which should be recorded in the minutes of the meeting.

e) If an UEC member finds/identify, that she/he has developed a COI during the conduct of a research project approved by UEC, she/he shall inform the same to the secretariat who will communicate this information to the Chairperson for appropriate action and report that to the UEC at the next UEC meeting.

- At the beginning of each meeting, the UEC Chairperson asks the members to disclose any COI concerning any of the items in the agenda.
- During the meeting, UEC member having conflict discloses that just before the review of the relevant item begins.
- If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chairperson/Vice-Chairperson/Co-Chairperson appointed should take over, for discussion on such a project.
- When existence of COI is uncertain, more information is gathered from other relevant sources and determination is done by UEC member with the help of UEC, or by UEC Chairperson/Member Secretary (as applicable)
- The UEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
- The UEC shall not approve a research study proposal where a COI is not managed or eliminated.
- Management of COI
    - UEC members
        - will disclose the COI as discussed above
        - will not serve as reviewers
        - will not influence the discussion and decision making of the concerned study despite staying away during the UEC meeting.
    - Experts/consultants – Proposal will not be sent to them or will be retracted if COI is declared.

- UEC Member Secretary and the Secretariat will record the points related to disclosure and management of COI in the minutes of the meeting of the UEC.

3.5 Flow Chart

No.	Activity	Responsibility
1	Determination of Conflict of Interest (COI)	UEC Member
2	Disclosure and management of COI	UEC Member
3	Ensuring declaration and management of COI during review process	UEC Chairperson
4	Recording of COI in minutes of UEC meeting	UEC Member Secretary/ Secretariat

3.6. Annexure

Annexure 1: *AX01/SOP03/V2*-Conflict of Interest Declaration for UEC members, when joining as members.

Annexure 2: AX02/SOP03/V2-Conflict of Interest Declaration Form for UEC Members, when attending a meeting (if applicable).

Annexure 1: AX01/SOP03/V2

Conflict of Interest Declaration Form for UEC Members

I am aware of the policy of the UEC regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which she/he has actual/potential conflict of interest except to provide information as requested by the UEC.

☐ I declare that I have no conflict of interest to report.

☐ I have the following conflict of interest to report

i. Personal
ii. Professional
iii. Financial

In accordance to the policy of the UEC, I will also immediately disclose to the Chairperson/Member Secretary of the UEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee. I shall abstain from participating in decision-making process related to such proposals and inform the committee that I cannot be a part of the quorum for consensus or voting.

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

I, _____(name) have read and accept the terms and conditions as explained in this Agreement.

Name and Signature of the UEC Member _____Date_____

Name and Signature of the Chairperson _____Date_____

Description of conflict of interest:

i. Any relationships, transactions, positions you or your spouse hold (volunteer or otherwise), or circumstances that you believe would constitute a conflict of interest.
ii. Positions you or your spouse or an immediate family member hold in non-profit and for-profit boards/businesses (as an officer or director, or a majority shareholder, get speaking fees or own any related businesses by yourself or a family member).

Annexure 2: AX02/SOP03/V2

Conflict of Interest Declaration Form for UEC members when attending meeting

I _____declare (actual or potential COI) in relation to the proposal titled "_____" submitted for review to the UEC.

The reason for COI is personal/professional/financial
(describe).

I will refrain from the review process and/or discussion at the UEC meeting/and will not take part in ongoing and periodic review and monitoring of this study.

Name and Signature of UEC Member _____
with Date

Counter signed

Name and Signature of Chairperson _____
with Date

4.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging expertise of professionals as Reviewer(s)/Independent Consultant(s) (IC) to the University Ethics Committee (UEC).

4.2. Scope

This SOP covers the procedures for selecting, appointing Reviewers/ICs and getting their expert opinion during the UEC review process. It also defines the responsibilities of IC.

4.3. Responsibility

It is the responsibility of the Chairperson/Member Secretary/UEC member(s) to nominate the name of one or more Reviewers/IC(s). The Chairperson is responsible for endorsing the choice of Reviewer/IC nominated by UEC Member Secretary/UEC member(s). The administrative procedures regarding selection, confidentiality agreement and maintenance of roster of Reviewers/ICs will be carried out by UEC secretariat.

4.4. Detailed instructions

4.4.1 Recommendation of names of Reviewers/ICs and making a roster of Reviewers/ICs for the UEC

- Chairperson/Member Secretary/UEC members will nominate the names of ICs from different disciplines.
- A list of discipline wise Reviewers/ICs will be maintained by the Secretariat in the UEC records with details like (Name, designation, affiliation, contact details, and updated curriculum vitae) besides listing them in the SOP with name and discipline.
- Member Secretary, in consultation with Chairperson will select a panel of Reviewers/IC(s) for the UEC.
- Member Secretary will issue an appointment letter to the Reviewers/IC(s) after confirming their willingness through telephonic/electronic communication and receive a written confirmation from them by email/fax,

4.4.2 Consulting a Reviewer/IC during UEC review process

- The Chairperson/Member Secretary/an UEC member may suggest that the opinion be sought from one or more Reviewers/IC(s) and may suggest the name of a particular Reviewer/IC from the roster of Reviewers/ICs maintained by the UEC or from outside the roster, if during the review

process of any given research study it is felt that the study involves procedures or information that is not within the area of collective expertise of the UEC members.

- If deemed necessary the Member Secretary, in consultation with Chairperson or during committee meeting will identify and select the Reviewer/IC(s) outside the roster based on area of expertise and independence to provide her/his independent opinion in writing. This may be done after seeking concurrence and confirming availability of the Reviewer/IC through telephonic/electronic communication.

4.4.3 Communication with Reviewers/ICs

- The Secretariat may request a copy of the updated curriculum vitae of the Reviewer/IC (those outside roster) for UEC records and future reference.
- The Member Secretary will request Reviewer/IC to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the Confidentiality Agreement and Conflict of Interest Agreement (*AX01/SOP04/V_2*) for careful reading, understanding, and signing.
- The Member Secretary will provide explanations/clarifications (telephonically or in writing) to the Reviewers/IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/Legal expert/UEC members.

4.4.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The Reviewers/IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to Reviewers/IC(s).

4.4.5 Review of research study proposal

- The Secretariat will provide study protocol documents along with the Study Assessment Form for Reviewer/IC (*AX02/SOP04/V_2*) to the Reviewers/IC(s) who may be provided with a copy of 'Guidelines for Reviewers'.
- The Reviewers/IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within two weeks.
- The assessment report provided by the Reviewers/IC(s) becomes a permanent part of the study file.
- The assessment report will be presented by Member Secretary in the UEC meeting when the concerned study is being discussed.
- If deemed necessary, the Chairperson or Member-secretary may seek additional information or clarifications from the Reviewer/IC in writing.
- Additional Information provided by the Reviewer/IC will be considered as a part of the Assessment Report.
- If deemed necessary, the Chairperson or Member-secretary may invite the Reviewers/IC(s) to attend an UEC meeting for providing additional information or clarifications that may be sought by UEC members or Chairperson.
- Reviewer/IC will not participate in the decision making process on the research study.
- Reviewer/IC may be reimbursed for expenses related to travel (if invited to attend the meeting), time spent for review, documents referred to in the library/internet or any other incidental expenses, etc.

4.4.6 Tenure of Services of Reviewer/IC

- The roster of Reviewers/ICs maintained at the UEC office will be updated every 3 years or as may be required.
- For Reviewer/IC appointed for a particular study, the services of Reviewer/IC get automatically terminated once the final decision regarding the study is taken by the UEC.
- The UEC will document the termination of the services of Reviewer/IC through appropriate intimation.

4.4.7 Responsibilities of Reviewer/IC

- If Reviewer/IC agrees to review a research proposal, she/he will comply with UEC requirements of signing confidentiality and conflict of interest agreements.

- Reviewer/IC will review the research study and complete the Assessment Form (duly signed and dated) within a stipulated time period/date specified.
- Reviewer/IC will attend an UEC meeting for providing additional information or clarifications, if invited by Member Secretary in consultation with the Chairperson.
- Reviewer/IC will not participate in the decision making process on the research study.
- Reviewer/IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

4.5. Flow Chart

No.	Activity	Responsibility
1	Recommendation of a name of one or more Reviewers/IC(s)	UEC Member, Member Secretary or Chairperson
2	Selection and Appointment of Reviewers/IC(s)	Member Secretary in consultation with Chairperson
3	Invitation to Reviewers/IC(s) on behalf of UEC	Chairperson/Member-Secretary
4	Co-ordination with Reviewers/IC(s) for fulfilling administrative requirements	UEC Secretariat
5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	Reviewer/IC, Chairperson
6	Maintenance of a discipline-wise list/roster of Reviewers/ICs	UEC Secretariat
7	Reviewing documents pertaining to research project	Reviewer/IC

4.6. Annexures

Annexure 1: *AX01/SOP04/V_2* - Confidentiality and Conflict of Interest Agreement for an IC

Annexure 2: *AX02/SOP04/V_2* - Study Assessment Form for a Reviewer/IC

Annexure 01: AX01/SOP04/V_2
Confidentiality and Conflict of Interest Agreement Form for a Reviewer/Independent Consultant

Agreement on Confidentiality

I, _____
_____ (Name and Designation) as a non-member of University Ethics Committee (UEC) of KUHS understand that the document(s) sent to me by the UEC is/are confidential. I shall use the information only for the indicated purpose described by the UEC and shall not duplicate, give, convey or distribute these documents to any person(s) without prior permission from the UEC of KUHS. I agree to take full responsibility to keep the information confidential.

Agreement on Conflict of Interest

In accordance with the policy of the UEC regarding conflict of interest that no reviewer may undertake to review, comment or participate in decision making of any activity in which she/he has actual/potential conflict of interest, I will immediately disclose to the Chairperson of the UEC any actual or potential conflict of interest that I may have, in relation to any particular proposal submitted for review by the committee.

I, _____(name) have read and accept the terms and conditions as explained in this Agreement.

Name and Signature _____ Date _____
(Incorporate the capacity of the declarant as Reviewer/Consultant)

Name and Signature of the Chairperson_____ Date _____

I acknowledge that I have received a copy of this Declaration signed by the UEC Chairperson and me.

_____ _____
Signature Date

[The original signed and dated Declaration will be kept in file in UEC Office. A copy will be given to Reviewer/IC for records]

Annexure 2: AX02/SOP04/V_2

Study Assessment Form for a Reviewer/Independent Consultant

UEC Protocol Number:	
Protocol Title: _____ Comments on the scientific aspects of the protocol (rationale, sample size, inclusion and exclusion criteria, alternatives):- _____ _____ Comments on the ethical aspects of the protocol (benefit –risk assessment, vulnerability, compensation etc.) _____ _____ _____ Informed Consent Document: _____ _____ _____ Comments on any other issues/aspects: _____	
Remarks:	• Recommend approval • Recommend approval after incorporation of suggested changes • Recommend disapproval (Please state Reasons) • Any other (Please specify with reasons)
Name of the Reviewer/Independent Consultant reviewing the project: Signature with Date:	_____

5.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by University Ethics Committee (UEC) when a Guest/Observer visits the UEC Office or attends an UEC full board meeting, in order to ensure adequate protection of confidentiality of information related to research studies.

5.2. Scope

This SOP covers the procedures for allowing guest/observer to visit the UEC Office and/or observe a meeting in progress.

5.3. Responsibility

- It is the responsibility of Member Secretary in consultation with Chairperson to decide whether a guest/observer may be allowed to visit the UEC Office or attend an UEC meeting.
- It is the responsibility of the guest/observer(s) intending to attend an UEC meeting to read, understand, accept and sign the agreement contained in the Confidentiality form prior to visiting UEC/attending an UEC meeting.
- The Secretariat will ensure that the Confidentiality and Conflict of Interest Form (*AX01/SOP05/V_2*) is duly signed and dated by the guest or observer for visit to UEC Office/UEC meeting and will file it in UEC records.

5.4. Detailed instructions

5 4.1 Receiving request from guest/observer to visit UEC office or attend UEC meeting

- On receiving a written or verbal request, the UEC Member/Member Secretary/Secretariat will obtain permission from Chairperson.
- The date and time of the visit will be informed to the guest/observer in writing/email.
- The request letter/email will be filed in UEC records by the secretariat.

5.4.2 Filling up of Confidentiality Agreement Form

- Confidentiality Agreement Form (*AX01/SOP05/V_2*) will be provided to the guest attendee/observer on the day of visit/at the time of meeting.
- The guest/observer will read the form carefully before visit/before commencement of the meeting and fill the details in the form with signature and date.

5.4.3 Ask questions, if any

- If there are any doubts, the guest/observer will seek clarifications or additional information from the Secretariat.
- The Member Secretary will provide explanations, additional information and/or clarifications.

5.4.4 Signing of Confidentiality Agreement Form

- The guest/observer will sign and date the document before a member of the Secretariat.
- She/he will return the signed form to the Secretariat.
- The Secretariat will obtain the signature of the UEC Chairperson on the Confidentiality/Agreement Form.
- The secretariat will provide guest or observer a photocopy of the Confidentiality Agreement Form for their records (duly signed and dated by them and UEC Chairperson) and acknowledge the receipt of agreement by their signature.
- The Secretariat will keep the original copy of the signed Agreements at the UEC office in the files entitled 'Confidentiality Agreement file for guests/observers'.
- The Secretariat will store the file in a secure cabinet with controlled access.

5.4.5 Keep the Agreement in mind

The guests/observer must follow the clauses of the signed Confidentiality Agreement Form.

5.5. Flow chart

No.	Activity	Responsibility
1.	Receiving request from guest/observer	UEC Secretariat/Member/ Member Secretary
2.	Allowing a Guest/Observer	Chairperson
3.	Informing guest/observer about visit/meeting date and time	UEC Secretariat
4.	Read the text carefully and thoroughly, sign the confidentiality agreement and COI declaration	Guest/Observer
5.	Filing of signed confidentiality form in UEC records	UEC Secretariat

5.6. Annexure

Annexure 1: *AX01/SOP05/V_2* - Confidentiality and Conflict of Interest Agreement Form for Guest/Observer visiting UEC office or attending an UEC Meeting.

Annexure 1: AX01/SOP05/V_2

Confidentiality and Conflict of Interest Agreement Form

For Guest/Observer Attendees to UEC/UEC Meetings

I, _____ (name), understand that I am being allowed to visit UEC office facility/attend the UEC meeting on _____ at _____am/pm as a Guest/Observer at _____ (Venue).

I understand that I may become aware of some confidential information during my visit to UEC office/during the course of the UEC meeting.

Upon signing this form, I agree to take full responsibility to keep the information confidential unless I am legally compelled to disclose and disclose only that portion of the Confidential Information necessary, as part of my duty.

I do not have conflict of interest, personal, professional or financial, but in the event of my having it related to my visit/during the course of UEC meeting I will inform UEC of the same for it to take appropriate action in the matter accordingly.

_____

Name and Signature of the Guest/Observer attendee,
with date

Counter signed by,

_____

Name and Signature of Chairperson of UEC,
with date

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the UEC -Chairperson and me.

_____

Name and Signature of the Guest/Observer attendee,
with Date

6.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Institutional Ethics Committee (IEC) should manage submitted protocol and other documents.

6.2 Scope

The scope of this SOP includes submission of research proposal and related documents for Initial Review; resubmission of research proposal with corrections; protocol amendments; and submissions of written communications related to continuing review of approved protocols

6.3 Responsibility

It is the responsibility of the UEC Secretariat to receive, record and distribute the received protocols and any other documents for review, act as per instructions given in this SOP and ensure that the communication reaches the concerned recipient.

6.4 Detailed Instructions

6.4.1 Receive study protocols/documents

The Principal Investigator (PI) will submit a research proposal to the UEC office for review and decision under any of the following sections within the specified time:

- New Proposals for Initial Review/Re-submission of Protocols with Corrections/Amended Protocols and related documents:
- Documents related to continuing review of approved protocols such as-
    - Protocol progress and final reports
    - Protocol completion/Termination
    - Protocol deviations/violations/non-compliance
    - Serious Adverse Events (SAE) initial/follow up/final reports
- All other documents for consideration at the full committee meeting (except those related to participant safety, which may be submitted at any time) must be submitted at least 15 days in advance of the meeting to be considered in the next meeting agenda.

    Note: In urgent situations, non-clinical student proposals may be submitted 72 hours in advance of the meeting. In such situations, the urgency should be well explained.

6.4.2 Initial Review Application

6.4.2.1 The Secretariat will check the hard and soft copies to ensure the availability and full compliance of the following items:

1. Fifteen (15) sets of hard copies of the proposal (One original and 14 sets of Photostat copies) and a labelled CD/DVD
   (Soft copy can be uploaded to the server with security, if so, instructed).
2. A completely filled UEC Project Submission Application Form for Initial Review *AX1/SOP06/V_2*
3. The marked checklist (*AX02/SOP06/V_2)*
4. Duty Delegation Log of the Study team (*AX03/SOP06/V_2)*
5. Document Receipt Form (*AX04/SOP06/V_2)*
6. Verify contents of Submitted Documents: The Secretariat will use the checklist (*AX02/SOP06/V_2)* to confirm whether all the ticked documents are there in the application docket/package
   - Project submission application form for initial review
   - Covering letter to Member Secretary/Chairperson duly signed by PI
   - Protocol as per the requirements of the current guidelines and regulations. (*AX01/SOP06/V_2/*New Format as applicable)
   - Amendments to protocol (if any)
   - Informed consent document (ICD) in English (as per sample format in page 50 of ICMR's National Guidelines) or Waiver of Consent form as per SOP15/V_2
   - ICD in Regional languages (if applicable)
   - Back translations of ICDs (if applicable)
   - Translation and Back translation certificates (if applicable)
   - Amendments to the ICD (if any)
   - Case Record Form
   - Recruitment procedures: advertisement, notices, letters to investigators (if applicable)
   - Patient instruction card, identity card, diary etc. (if applicable)
   - Investigator's Brochure (if applicable for Drug/Device trials)
   - Applicable Regulatory permissions/approvals of DCGI (CLA) approval, FDA marketing/manufacturing license for herbal drugs, Health Ministry Screening Committee (HMSC) approval, Bhabha Atomic Research Centre (BARC)
   - Investigator's Undertaking to DCGI, if applicable
   - Applicable administrative sanction from the head of the Institution or Memorandum of Understanding in case of studies involving collaboration with other institutions
   - A copy of Administration sanction from the head of the Institution or Memorandum of Understanding for sending the samples to laboratories outside the Institution. (if applicable)

- Brief Curriculum Vitae of all the study team members
- GCP training certificate (within 1 year) of Principal Investigator, Co-investigator/s and Study Coordinator/s. (if applicable)
- Research Methodology training certificate of Principal Investigator, Co-investigator/s and Study Coordinator/s within past 5 years
- List of ongoing research studies undertaken by researcher as Principal Investigator and/or Co-investigator.
- Undertaking to comply with national and international ethical guidelines, GCP protocols and relevant regulations
- Details of Funding agency/Sponsor and fund allocation
- Clinical Trial Agreement between the sponsors, investigators and the head of the institution(s) (if applicable)
- Insurance policy (if applicable) with the insurance certificate for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk
- Indemnity policy clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk.
- Ethics Committee clearance of other centres (if applicable)
- Institutional Stem Cell Research Committee approval (if applicable)
- Clinical Trial registration, (if applicable).
- Processing fee payment receipt *(if applicable from time to time)*
- Any additional document(s), as required by UEC
- The Secretariat will then ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing by the UEC Secretariat).

***6.4.2.2 Complete the submission process*:** The Secretariat will:

1. Complete the checklist of submission
2. Stamp the receiving date on the first page of the covering letter and initial it.
3. Make a photocopy of the completed document receipt form *AX04/SOP 06/V_2* and return the original copy of the *AX04/SOP06/V_2* to the applicants for their records.
4. Keep the copies of the submitted documents with original signatures in the protocol "Submission" file.
5. Number the project file as UEC/Number (00)/year (00)

6.4.2.3 Dispatch and Store the received Documents: The Secretariat will

- Prepare 2 sets of a protocol package containing completed application form *AX01/SOP06/V_2*, protocol related documents along with checklist *AX02/SOP06/V_2* and send 1 set to the UEC members along with a copy of Project Assessment Form for Initial Review after the last day of submission is over, ensuring at least 7 days for review before the next meeting.
- Store the appropriately labelled original protocol documents in the designated storage area in the UEC office.
- If the UEC members prefer to receive and review soft copies, these are sent in a CD/Pen drive/Flash drive/email along with a copy of Project Assessment Form for Initial Review.

6.4.3 Resubmission of Protocols with corrections and Amendments of protocol/related documents

1. For resubmitted protocol, the PI will submit one soft copy and one hard copy of the amended Protocol and related documents (SOP09/V_2) with list of comments and clarifications with changes duly highlighted at relevant pages
2. The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier submitted protocol mentioning the justification for the amendment.
3. The protocol related documents, which do not require to be changed and are already submitted for the UEC office during initial review, are not required to be submitted again.
4. The Secretariat will present the docket to the Member Secretary.
5. The Member Secretary will determine whether all steps as for Initial review are followed and place the same before the next meeting of UEC for appropriate consideration.

6.4.4 Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Progress Reports, Study completion/termination, SAE report, Protocol deviations

The UEC will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, Study completion/termination/SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

6.4.5 Processing Fees for UEC review

The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non-refundable are as given in the following table:

Sr. No.	Category of review	Pharma industry sponsored Research	Government sponsored/ NGO Research	Academic or Investigator initiated Research
1.	New study protocol	Rs. ……../-	Rs. ……./-	Rs. ……./-
2.	Continuing review (per review)	Rs. ……../-	Rs. ……./-	Rs……../-
3.	Protocol Amendment (per amendment review) (if applicable)	Rs. ……../-	Rs. ……./-	Rs. ……./-
4.	Providing one photocopy of submitted study documents lost by the investigator (amount for 10 pages' document) (over 10 pages, Re. 1 per page)	Rs. ……../-	Rs. ……./-	Rs. ……./-

6.5 Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages	UEC Secretariat
2	Initial Review Application	UEC Secretariat
3	Resubmission of Protocols with Corrections	UEC Secretariat
4	Protocol Amendments	UEC Secretariat
5	Annual Continuing Review of Approved Protocols	UEC Secretariat
6	Protocol Completion	UEC Secretariat

6.6 Annexures

Annexure 1: AX01/SOP06/V_2- Project submission application form for initial review for academic (non-regulatory) studies.

Annexure 2: AX02/SOP06/V_2-Checklist of protocol submission

Annexure 3: AX03/SOP06/V_2- Duty Delegation Log of Study team

Annexure 4: AX04/SOP06/V_2- Document Receipt Form

Annexure 1: AX01/SOP06/V_2

Project Submission Application Form for Initial Review for Academic (non-regulatory) Studies

- Please fill in the details in legible handwriting/Typed/Computer printed
- Tick √ in the box for the appropriate answer
- Write NA if question is not applicable

Incompletely filled form will not be accepted.

UEC Protocol no.				
Title of the project				
	Name	Designation	Department and Institution	Signature
Principal Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				

(For additional collaborators attach details and letter of Consent by the collaborator(s) on a separate page)
Please attach brief curriculum vitae of the study team members
(Principal Investigator, Co-Investigator, study co-ordinator)
Attached Yes ☐ No ☐

Non-sponsored study ☐ Sponsored study ☐

If Non-Sponsored Study
Type of study:
Thesis/Dissertation ☐
ICMR Study ☐
Other Academic Study ☐
Duration of study _____
Approx. Completion date (MM/YY) _____

If sponsored,
Total Budget: Rs. _____
From where is the study being funded_____
Research fund is being utilized from in-house funding authority ☐
Any other ☐
If any other, please give details _____
Allocation of budget heads (Please attach separate sheet if needed)
_____

1.Type of Study: Study Design

- Prospective ☐
- Retrospective ☐
- Cross sectional ☐

Is the study Observational/Interventional? ☐
_____
If interventional, does the study involve testing of
a new drug or of care practices?
Yes ☐ No ☐
Not applicable

2. Does the study meant for academic trial involve use of:
marketed Drug/Vaccine/Device/Traditional/Herbal Medicine/
New Technique (surgical/PT/OT/Psychotherapy etc.)/
Diagnostic Kit/Investigations
If other, please specify……

i) Is the test drug/device marketed in India?
Yes ☐ No ☐ NA ☐
Please attach copy of package insert/product insert.

ii) Does the test drug involve a change in use, dosage, route of administration?
Yes ☐ No ☐ NA ☐

iii) **If yes**, please attach copy of DCGI permission/medicine insert.

3. Subject selection
i) Number of subjects at this centre
if multi-centric, total number of subjects

ii) Vulnerable subjects Yes ☐ No ☐

(tick the appropriate boxes)

pregnant women/illiterate/seriously ill/terminally/Children/Neonates/ Mentally challenged/Elderly/Handicapped/Economically backward/Socially backward/Institutional employees/Students/any other

If any other, please specify_____

4. Does the study involve use of i) Foetal tissue or abortus	Yes	No
ii) Organs or body fluids	Yes	No
iii) Gene therapy **If yes**, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.	Yes	No
iv) Ionizing radiation/Radioisotopes **If yes**, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission	Yes	No
v)Infectious/biohazardous specimens	Yes	No
vi)Will pre-existing/stored/left over samples be used?	Yes	No
vii)Will samples be collected for banking/future research	Yes	No
viii) Will any sample collected from patients be send abroad? **If yes,** Please submit a copy of Director General of Foreign Trade (DGFT) permission.	Yes	No
ix) Is there any collaboration with any foreign Laboratory, Clinic or Hospital? **If yes,** Please submit a copy of Health Ministry Screening Committee (HMSC)/ICMR permission or Approval (as applicable for foreign collaborations).	Yes	No
5.Will any advertising be done for recruitment of subjects (like Posters, flyers, Brochures etc.)? **If Yes,** Attach a copy of UEC review.	Yes	No
6. Is there any compensation for participation? (travelling allowance) **If Yes,** Monetary ☐ In kind ☐ Please specify the amount/type……	Yes	No

7. Are there any arrangements for compensation/treatment of trial related injury? **If Yes,** By Sponsor □ By Investigator □ By Insurance Company □ By others □ Please submit a copy of Insurance Policy (if applicable)	Yes	No
8. Do you have any conflict of interest in the present study? (financial/non – financial/any other) **If yes,** Please specify……	Yes	No
9. Is any other department involved in participant recruitment/investigation? **If yes,** Please specify…… Name and signature of concerned Head of Department	Yes	No

We hereby declare the information given above is true.
A copy of the study report will be submitted at the end of the study.

Name and Signature of Principal Investigator: _____

Name and Signatures of Co- investigators:

1._____

_____

2._____

_____

3._____

_____

4. _____

_____

Forwarded by Heads of Department(s)/Institution

_____ Stamp/Seal of the Department(s)

Annexure 2: AX02/SOP06/V_2

Check List for Protocol Submission

Check List of Documents for Protocol Submission to UEC be filled in by the study team

Protocol submission for initial review

(Tick accordingly; compulsory documents have to be submitted by ticking in the box marked as 'Yes') * Compulsory documents for initial review.

Sr. No.	Document	Yes	No	Date by which it will be submitted, if pending	NA
1	*Project submission application form duly filled				
a.	Covering Letter				
b.	Project proposal – 5 hard copies				
c.	Project proposal – soft copy sent by e-mail/CD/DVD/Flash drive/by uploading				
d.	CV of all investigators				
e.	Fee for review				
2	Approval of Institutional Review Board (IRB) (for thesis/dissertations proposals)				
3	*Letter to Member Secretary/Chairperson				
4	*Summary of protocol (not more than 500 words)				
5	*Protocol				
6	*Informed consent document in English				
7.	*Informed consent documents in Regional languages (Total No:-)				
8.	Back translation of Informed Consent Documents (if available)				
9	Translation and Back translation certificates (if available)				

10	*Case Record Form				
11	*Research participants' recruitment procedures: advertisement, notices (If applicable)				
12	*Patient instruction card, identity card, diary etc.				
13.a	*Research Participants Questionnaire/s (If applicable)				
13.b	Research participants confidentiality statement				
14	*Investigator Brochure				
15	*Insurance certificate and policy (if applicable)				
16	*Investigator's undertaking to DCG(I)/CLA (if applicable)				
17	DCG(I)/CLA approval [if DCGI approval is awaited, the same should be mentioned in the covering letter to the UEC] (if applicable)				
18	* Trial Agreement for drug trial/Memorandum Of Understanding/Copy of clinical trial protocol Material Transfer Agreement (MTA), as applicable, for collaborator& Government sponsored trials (draft if final not ready)				
19	FDA marketing/manufacturing license for herbal formulations/nutraceuticals				
20	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ionizing radiations				

21	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy				
22	a) Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions/foreign agencies (one copy) Or Memorandum of Understanding (as applicable) b) Administrative sanction from the Head of the Institution for the samples to be sent to outside institution (one copy) Or Material Transfer Agreement (if applicable)				
23	*Budget Sheet for the Proposed Study (Format for budget sheet stated below)				
24	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) (one copy only)				
25	*Ethics Committee clearance of other centres (Total No _____) (if applicable)				
26	*Log of delegation of responsibility of the study team members - Sample Format Enclosed) *AX03/SOP06/V_2*)				
27	*Document Receipt Form (one copy only)				
28	*Current Status of Ongoing Studies approved by UEC conducted by principal investigator (information may be submitted separately)				

29	Documentation of clinical trial registration (in Clinical Trial Registry of India)/any other WHO platform registry (if applicable)				
30	*GCP training certificates of principal investigator, co-investigator(s), study coordinator(s) for interventional clinical trial sponsored by pharmaceuticals companies of training taken in last 5 years (one copy only)				
31	Any other Documents submitted				

Budget Sheet for the Proposed Study

1	Title of the Project:	
2	Name of Principal Investigator (PI) with signature	
3	Designation and address of the PI	
4	Names of Co-investigators with department/Institution and signature:	
5	Source of funding	
	Government:	Central ☐ State ☐ Local ☐
	In-house	
	Private Foundation:	Indian ☐ Foreign ☐
	Non-profit agency/trust funded	
	Pharma/industry sponsored (if applicable)	
	Other:	
	No funding required	

	Address, phone, fax. E-mail of sponsor with the name of the contact person	
6	Total Budget for the entire project in Rs…….	
7	Duration of the Project in months	
8	Proposed date of starting the project	
9	Direct payments to investigators, if any	
10	Any other benefits to the investigators/department/institution	
11	Conflict of Interests, if any	
Name of PI:		**Signature & Date:**

Annexure 3: AX03/SOP06/V_2

Delegation of Responsibilities of Study team

Study title: _____

_____

No.	Name	Role
1		Principal Investigator
2		Co-Investigator
3		Co-Investigator
4		Co-investigator
5		Co-Investigator
6		Co-investigator
7		Study co-ordinator *
8		Laboratory Technician
9		
10		

**Study coordinator may preferably be a person specifically appointed for coordinating the trial/Research; other than the staff member (assistant/associate professor)*

(Please place tick marks against assigned duties for each member in the following table)

Code	TASKS	Role Played by Each Study Team Member									
		1	2	3	4	5	6	7	8	9	10
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/Screening										
C	Obtain informed consent										
D	Evaluate inclusion/exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										
M	Review & sign of the lab reports										
N	Receive the study drug, document drug dispensing, storage & accountability										

O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										

Annexure 4: AX04/SOP06/V_2

Document Receipt Form for initial review

Protocol Number:	**Received number:**	**Submitted date:**
Protocol Title:		
Principal Investigator:		
Department/ Institution		
Communication with the UEC:	E-mail address…… Phone…… Fax……	
For office use only		
Documents submitted:	**Complete** □ **Incomplete** □ will submit on_____	
Documents to be submitted later:	• final signed clinical trial agreement (if applicable) • informed consent form (English & in vernacular language) • study budget • CLA approval • CTRI Registration • GCP Training certificate • Other sites EC permission • Others……	To verify and tick whether documents received. • final signed clinical trial agreement (if applicable) • informed consent form (English & in vernacular language) • study budget • CLA approval • CTRI Registration • GCP Training certificate • Other sites EC permission • Others…… □ Research methodology Training certificate
Received by (Name and signature):		
Date on which documents received:		

Note: Please bring this receipt with you when you visit the office of the University Ethics Committee.

7.1. Purpose

The purpose of this SOP is to describe the procedure to categorize new research study protocols submitted by investigators for initial review by full committee/expedited review committee or for exemption from review process.

7.2. Scope

This SOP covers the process of categorization of new research study protocols submitted to University Ethics Committee (UEC) for initial review. It does not cover subsequent submissions.

7.3. Responsibility

It is the responsibility of the Member Secretary [in consultation with Chairperson, if necessary, to categorise the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants, i.e. full committee review, expedited review and exemption from review.

7.4. Detailed Instructions

7.4.1New proposals received for initial review

- New research study proposals received on or before the date specified will be considered for review in the next meeting of the UEC.
- The Secretariat will ensure that application of the research proposal is complete in terms of required documents.
- If any essential document is not available, an explanation must be sought in writing for the UEC to review. (SOP06/V_2).

7. 4.2 New proposals forwarded to Member Secretary

- The Secretariat will forward the soft copy of the research proposal to the Member Secretary for initial screening within 2 working days of receiving the proposal.
- The Member Secretary will screen the research proposals and categorise the proposals as elaborated in Section 7.4.3 within 3 working days of receipt.

7.4.3 Categorisation of New proposals for review by UEC

The Member Secretary, in consultation with Chairperson, if required, will categorise the proposals into three types of review processes, based on the ICMR's National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 as explained below:

7.4.4 Full Committee Review: When new research proposals and other related documents are tabled in a formally convened meeting of the Ethics

Committee for detailed discussion and decision, this is called Full Committee Review.

- All research proposals presenting more than minimal risk that are not covered under exempt, emergency or expedited review should be subjected to full committee review. Some examples are,
  - Research involving vulnerable populations, even if the risk is minimal.
  - Research with increase over minimal risk (please see table 2.1 of ICMR guidelines 2017 for further details).
  - Studies involving deception of participants (see section 5.11 of ICMR guidelines 2017 for further details).
  - Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken.
  - Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk.
  - Proposal with major deviations and violations in the protocol.
  - Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment.
  - Research during emergencies and disasters either through an expedited review/scheduled or unscheduled full committee meetings may be decided by member secretary depending on the urgency and need, in consultation with the Chairperson.
- Prior approval of research on predictable emergencies or disasters for implementation later when the actual emergency or disaster occurs.

7.4.5 Expedited Review: When new research proposals and related documents undergo a speedy review process by only two or three Ethics Committee members designated by the Chairperson, it is called Expedited Review. This may be sufficient, if the research study involves not more than minimal risk as defined in the ICMR guidelines.

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

- Research involving documentation materials that are non-identifiable (e.g. data, documents, records etc.).
- SAEs/unexpected Adverse Drug Reaction (ADR) of minor nature is reported if they are not evaluated separately by SAE subcommittee.
- For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site-specific requirements in addition to the full committee common review.
- Research during emergencies and disasters covered by section 12 of ICMR guidelines 2017.

➢ The following are examples of documents that will undergo Expedited Review but are NOT in the category of INITIAL review,

- Revised proposals previously approved through expedited review, or with minor modifications to the previously approved through full review or continuing review of approved proposals.
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors or change in researcher(s).
- Minor deviations from originally approved research causing no risk or minimal risk.
- Progress/annual reports where there is no additional risk (e.g. activity limited to data analysis).

7.4.6 Exemption from review: The UEC may grant an exemption from review, when research fulfils the following criteria,

- Research that does not involve live identifiable human participants,
- Research on data in the public domain,
- Research on anonymised data derived from records of participants and the research has less than minimal risk to participants.

Examples include:

✦ Research conducted on data available in the public domain for systematic reviews or meta-analysis.

- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person.
- Quality control and quality assurance audits in the institution.
- Comparison of instructional techniques, curricula, or classroom management methods.
- Consumer acceptance studies related to taste and food quality.
- Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

7.5 Reference to other applicable SOPs:

- SOP06/V_2: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review
- SOP7A/V_2: Initial Full Committee Review of New Research Study Protocols
- SOP7B/V_2: Expedited Review of New Research Study Protocols
- SOP7C/V_2: Exemption from the Ethics Review of Research Study Protocols

7.6. Flow Chart

No.	**Activity**	**Responsibility**
1	Receiving new research study proposal and related documents by a fixed date of the month	Secretariat
2	Verifying completeness of submitted research study documents	Secretariat
3	Forwarding of new proposals to Member Secretary UEC	Secretariat
4	Categorization of the Protocols into 3 categories: full committee, expedited review and exemption from review process	Member Secretary/ Member Secretary in consultation with the Chairperson (if required)

7A1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the University Ethics Committee (UEC) members will perform an initial review of new research proposals using the Assessment Form.

7A2. Scope

This SOP applies to the initial review and assessment of all research study protocols submitted for review and approval from the UEC. All research studies presenting with minor increase over minimal risk (or low risk) and more than minimal risk (or high risk) and which do not qualify for exemption (SOP07C/V_2) or expedited review (SOP07B/V_2).

7A3. Responsibility

7A.3.1. The Member Secretary is responsible, after categorisation of the studies (SOP07/V_2), to forward the studies to the Secretariat.

7A.3.2. The UEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the UEC members for review (If the study is categorised for Full committee review), and communication of the review results to the investigators.

7A.3.3. Primary reviewers/UEC members will be responsible for reviewing the research proposals and related documents and sending their comments within 7 working days of receiving the package.

7A.3.4. It is the responsibility of the primary reviewer/designated UEC members to fill the Assessment form along with comments and recommendation they have, after reviewing each study protocol. assigned to them.

7A.3.5. The UEC members are responsible for attending and participating actively in the discussion at the full Committee Meeting.

7A.3.6. The Member Secretary is responsible for organising the Full Committee Meeting.

7A.3.7. The UEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

7A.3.8. The Chairperson is responsible to sign and date the decision in the UEC Decision Form *AX03/SOP07A/V_2.*

7A4. Detailed instructions

7A.4.1. Appointment of primary reviewers

The Member Secretary/Chairperson will appoint two or more primary reviewers for each study on the basis of expertise in the related field and experience. They may include one clinician and one non-technical person to the extent possible. More than two may be appointed, if necessary.

7A.4.2. Distribute the protocol package

- The Secretariat will fill in the required details in the covering letter to the Primary Reviewers/UEC Members requesting initial review (*AX01/SOP07A/V_2*) and in the study assessment form *AX02/SOP07A/V_2*.
- The Secretariat will send a packet *(hard or soft copy)* containing the following to the UEC members.
  i. Letter to primary reviewer(s)/designated UEC Members requesting Initial Review (*AX01/SOP07A/V_2).*
  ii. Study assessment form to UEC member (*AX02/SOP07A/V_2)* for their comments
  iii. Investigator's Study Submission Application Form
  iv. Protocol and related documents
  v. Study assessment form *AX02/SOP07A/V_2* in case it is to the Primary reviewer.

7A.4.3. Receive the distributed protocol package

- The UEC members will receive the protocol package with the Study Application Form, as soft copy and/or hard copy (if desired so).
- Designated primary reviewers will also receive the Study Assessment Form for Initial Review AX02/SOP07A*/V_2*.

7A.4.4. Verify the contents of the package

- The UEC member will verify all the contents.
- The UEC member will check the meeting date to see if it is convenient for the member to attend the meeting.
- The UEC member will notify the UEC Secretariat, if any documents are missing or if the specified date of the UEC meeting is not convenient to attend.

7A.4.5. Review by the **UEC members**

***7A.4.5.1*. Review of the protocol**

- The proposal will be reviewed by each member as per guidelines to review a research proposal described in *AX05/SOP 07A/V_2*.

- The UEC member will consider the following criteria when performing the review of the study protocol and the study related documents:

i. Scientific design and conduct of the study
ii. Risks and potential benefits
iii. Selection of study population and recruitment of research participants
iv. Inducements, financial benefits and financial costs
v. Protection of research participants' privacy and confidentiality
vi. Procedures for voluntary, informed consent
vii. Risk to participants
viii. Needs of dependent persons
ix. Community considerations
x. Qualifications of Investigators and assess adequacy of study sites
xi. Disclosure or declaration of potential conflicts of interest
xii. Ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.
xiii. Permission for access to participants from other institutions or bodies

7A4.5.2 The UEC member will consider the following criteria when performing the review of the Informed Consent Document.

- Voluntary, non-coercive recruitment, participation/withdrawal
- Procedures for obtaining informed consent
- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document which should be plain and easy to understand. by general public
- Translation of the informed consent document in the local languages
- Privacy and confidentiality
- Risks and discomforts – physical/mental/social
- Alternative treatments
- Benefits – to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/psychosocial support

- Treatment and compensation for study related injuries as per applicable regulations
- Provision for audio-visual recording of consent process in case of regulatory clinical trials (if applicable)
- Use of biological materials
- Contact persons with address and phone numbers for questions about the research project, participants' rights and injury
- Check for provision for signatures with dates of participant, person conducting informed consent process [investigator/investigator designee and witness (if applicable)]

7A.4.6. *Use of study assessment form for reviewers*

- The assessment form is designed to standardise the review process.
- All reviewers will fill out the assessment form (AX02/SOP07A/V_2) - form) with their comments related to review of the research proposal to ensure that all elements of research study are reviewed and are accordingly documented during the discussion at the meeting.
- The duly filled, signed and dated assessment forms will be returned along with the research proposals to the Secretariat within 7 working days from receiving the package.

7A.4.7. ***Gather the assessment reports***

The UEC Secretariat will collect the Assessment Forms and file in the original study file and convert it into a soft copy, if necessary, for discussion at the meeting. If the comments come as a soft copy these will be collated for discussion at the meeting.

7A.4.8. ***UEC meeting***

- At the commencement of the meeting itself members having conflict of interest related to the proposals shall disclose the same and be absent at the time when the particular proposal is taken up for consideration.
- Such absentees shall not be considered for the required quorum for the particular proposal. The minutes of the meeting shall also include details of such abstention.
- During the discussion at the meeting, the primary reviewer shall brief the members about summary of the study proposal and read out the comments and evaluation provided on the assessment form.
- The comments of independent consultant (if applicable) will be discussed by the member secretary.
- The other UEC members shall give their comments right after the presentation.

- The Principal Investigator/Co-investigator may be called in to provide clarifications on the study protocol that she/he has submitted for review to the UEC.
- The UEC members will discuss and clarify the comments and suggestions.
- The Member secretary (assisted by the Secretarial staff) shall record the discussions
    - The final decision on the study will be recorded as: Approved/Approved with recommendations/Revision with minor amendments/Revision with major amendments/Not approved either by broad consensus or by voting (majority considered as >50%), which will be recorded in the UEC Decision Form AX03/SOP07A/V_2 by the Member Secretary.
    - The following will not be eligible to participate in decision making or vote -
        - Absentee members who have declared conflict of interest
        - Member(s) of the committee who is/are listed as investigator(s) on a research proposal
        - An investigator or study team member invited for the meeting.
        - An independent consultant invited for the meeting to provide opinion
        - Specific patient groups invited for the meeting will not vote or participate in the decision-making procedures of the committee.
- In the case of decision to raise any query as a prelude to further consideration of the proposal, the Committee will specify whether the query responses and revised proposal, if applicable, will go only to the Chairman, Member Secretary, a specified subcommittee, to primary reviewers or to Full Committee before final approval. In case the sanction is granted taking into account the response by the Chairman or Member Secretary, this will be reported to the UEC at the next meeting.
- The response and changes carried out may be considered for discussion at a future UEC meeting.
- The Secretariat will obtain the signature of all the members and of the Chairperson of the UEC on the UEC Decision Form (AX03/SOP07A/V_2).
- If the study is approved, the Committee may, in appropriate cases, recommend monitoring of the study depending on the degree of risk involved.

- The Member Secretary shall prepare the minutes of the meetings of the UEC, with all relevant details including the list of participating members, and get it approved by the Chairman.
- The Secretary shall implement the decisions taken by the UEC and maintain all required registers and records.

7A.4.9. ***Final communication of the UEC decision taken on the study to the Principal Investigator***

- When the study is approved by the UEC, the Secretariat will prepare an approval letter *AX04/SOP07A/V_2* in the prescribed format, which is to be sent to the Principal Investigator within 14 working days of the meeting.
- If the UEC decision is disapproval or if it requires further details, clarifications or documents, the decision shall be communicated in writing by the Secretary through appropriate letter within 14 working days of the meeting.
- A notifying letter to the investigator should state the following:

  "If you are aggrieved by this decision, you may address the Chairman pointing out specific reasons, if any, for concluding that the decision was erroneous or that it requires re-review. This should be done within four (4) weeks of the receipt of the committee's decision."
- If the Committee has directed modifications, the Principal Investigator shall provide such additional details within six weeks.

7A.4.10. ***Storage of Documents***

1.1. Records can be maintained in hard copies as well as soft copies.
1.2. All records must be archived for a period as specified in SOP for archiving after the completion/premature termination of the study.
1.3. Documents related to regulatory clinical trials must be archived for 5 years after the completion/premature termination of the study or as per existing regulations.
1.4. Records may be archived for a longer period, if required by the sponsors/regulatory bodies or the subject matter is involved in litigation.

***7A.*5. Flow Chart**

No.	Activity	Responsibility

1	Receive package or research proposal and research related documents package	UEC Secretariat
2	Verify contents and distribute	UEC Secretariat
3	Appointment of primary reviewers	Member Secretary/Chairperson
4	Initial review of documents, Fill review assessment form	UEC members
5	UEC board meeting, discussion and decision	UEC members, Member Secretary, Chairperson
6	UEC decision communicated to PI	UEC Secretariat
7	Storage of study related documents with relevant correspondence	UEC Secretariat

7A.6. Annexures

Annexure 1:AX01/SOP07A/V_2- Letter to Primary Reviewers/UEC Members requesting Initial Review

Annexure 2: AX02/SOP07A/V_2-Study Assessment Form

Annexure 3: AX03/SOP07A/V_2-Decision Form for Full Committee

Annexure 4: AX04/SOP07A/V_2-Format of Full Committee/Expedited Committee

Approval letter

Annexure 5: AX05/SOP07A/V_2-Guidelines for reviewing a study protocol

Annexure 1:*AX01/SOP07A/V_2*

Letter to Primary Reviewers/UEC Members requesting Initial Review

Dear member,
The ……(no.) meeting of the UEC will be held on …….
at …….. in…….

You are requested to review the proposals in the package especially the ones marked to you as primary reviewer. Please review the proposal and related documents and fill the study assessment form (*AX02/SOP07A/V_2*) provided with the package with your comments, within 7 days of receiving the package. Kindly confirm your availability for the meeting.

Name of Member	Date of Receipt	Signature	Attending meeting (Y/N)

Protocol Number: (as per UEC records)	Date of receipt at UEC office after review by UEC member (DD/MM/YY):	
Protocol Title:		
Name of the Principal Investigator	Designation	Department/Institution/Address
Name of the Reviewer:		
Signature of Primary Reviewer/UEC member reviewing the study with date:		Attending the meeting: Yes ☐ No ☐

Annexure 2: *AX02/SOP07A/V_2*

Study Assessment Form

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

Mark and comment on relevant items applicable to the study

	Items	**Comments**
1	Objectives of the Study ( ) Clear ( )Unclear	
2	Need for Human Participants ( ) Yes ( ) No	
3	How many participants? • at the site ( ) • total including other sites ( )	
4	Study design and methodology ( ) Appropriate and clear ( ) Need changes	
5	Background Information applicable to rationale of objectives ( ) Sufficient ( ) Insufficient	
6	Risks and Benefits Assessment Level of risk • Less than minimal • Minimal • Minor increase over minimal risk or low risk • More than minimal risk or high risk	
7	Benefit to risk ratio ( ) Acceptable ( ) Unacceptable	

8 Inclusion Criteria ( ) Appropriate ( ) Inappropriate	
9 Exclusion Criteria ( ) Appropriate ( ) Inappropriate	
10 Discontinuation and Withdrawal Criteria ( ) Appropriate ( ) Inappropriate	
11 Involvement of Vulnerable Participants * ( ) Yes ( ) No If yes, mechanism to protect vulnerable participants	
12 Sufficient number of participants (sample size)? ( ) Yes ( ) No	
13 Control Arms (placebo, if any) ( ) Yes ( ) No If yes, justification for the use of placebo	
14 Are qualification and experience of the Investigators appropriate? ( ) Yes ( ) No	
15 Disclosure or Declaration of Potential conflicts of Interest ( ) Yes ( ) No	
16 Facilities and infrastructure of Participating Site ( ) Appropriate ( ) Inappropriate	
17 Compliance to Regulations ( ) Yes ( ) No	

18 Community Consultation if applicable * ( ) Yes ( ) No	
19 Contribution to Development of Local Capacity for Research and Treatment ( ) Yes ( ) No	
20 Availability of similar studies/Results ( ) Yes ( ) No	
21 Benefit to Local Communities ( ) Yes ( ) No	
22 Are blood/tissue samples being sent abroad? ( ) Yes ( ) No	
23 Need for informed consent/Assent * ( ) Yes ( ) No	
24 Are procedures for obtaining Informed Consent appropriate? ( ) Yes ( ) No	
25 Contents of the Informed Consent Document * ( ) Complete ( ) Incomplete	
26 Language of the Informed Consent Document ( ) Clear ( ) Unclear	
27 Details of contact Person(s) for Participants ( ) Yes ( ) No	
28 Privacy & Confidentiality * ( ) Yes ( ) No	

29 Provision for Medical and or/Psychosocial Support * ( ) Appropriate ( ) Inappropriate	
30 Provision for Treatment of Study-Related Injuries * ( ) Appropriate ( ) Inappropriate	
31 Provision for Compensation * ( ) Appropriate ( ) Inappropriate	
32 If applicable, mention of storage of biological materials and/or data ( ) Appropriate ( ) Inappropriate	
33 Will biological samples and/or data send abroad? ( ) Yes ( ) No If yes, is it being submitted for HMSC?	
34 Involvement of Researchers and Institution in Publication of Results ( ) Yes ( ) No	

Comments on science, ethics and informed consent documents:

_____

_____

_____

Note: Points for comment by non-scientist/bioethicist reviewer
Recommendation: approval/revision/non-approval of project

Name and Signature of reviewer
with date

Annexure 3: *AX03/SOP07A/V_2*

Decision Form for Full Committee

Date of UEC meeting: _____

UEC Protocol number: _____	
Title:	
Principal Investigator:	Department/Institution Address:
Final Decision at the meeting	• Approved (AP) • Approved with modifications (AM) • Revision with minor/major amendments (RS) • Disapproved with reasons (DA) • Monitoring required • Reason:_____
	Comments: _____ _____

No.	Names of Members present	AP	AM	RS	DA	Signature

Note: *AP: Approved; AM: Approved with modification [(either primary reviewer/full committee). If reviewed by full committee again one more decision form has to be filled; RS: Resubmission; DA: Disapproved*

If voting is resorted to:

- No. of members voting for the decision:
- No. of members voting against the decision:

- No. of members abstaining from voting:

Name and Signature of Chairperson
with Date

Annexure 4:*AX04/SOP07A/V_2*

Format of Full Committee/Expedited Committee Approval letter

Date.....

To,
Dr/Mr./Mrs/Smt.....
Dept. of.....
Ref: The study no. EC/……/20……..
titled, "……".
Sub: Letter no……..

Dear Dr/Mr/Mrs/Smt……

The meeting of the University Ethics Committee (UEC) was held on..... at.....in the..... with..... as Chairperson.

The list of members who attended the meeting is as follows.

Name of Members	Position on UEC	Designation & Affiliation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The UEC reviewed the above mentioned Research study and approved the following documents submitted for this clinical study at the meeting.

1. ……
2. ……

……

The UEC hereby approves the proposal through broad consensus/voting for the entire duration of the study. The starting date should be intimated to the secretariat. It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the

committee. The UEC functions in compliance with applicable guidelines and regulatory requirements and will monitor the research from time to time.

It is the policy of UEC that it be informed about any onsite serious adverse event or unexpected adverse event within 24 hours of knowing its occurrence as per the formats specified in SOP through telephone call or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to chairman of the UEC and the head of the institution where the trial is being conducted at the earliest, and in any event, within 14 calendar days of SAE or death.

No changes/amendments in the proposal and Informed Consent Document should be initiated without prior written approval of UEC, which expects that the investigator should promptly report to UEC any such deviations or changes of the protocol or about any new information that may affect adversely the safety of the research participants or the conduct of the Research.

For any amendment to the protocol kindly inform the UEC the exact alteration that has been made in the original project indicating it by highlighting it along with a list of changes with Page no. Clause no. etc.). Any alteration in the budgetary status should be clearly indicated and submitted for approval.

For studies, which will continue for more than a year, approval is valid only up to completion of one year from the date of initiation. For continuing review, a progress report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval)

On completion of the project a copy of the final report with summary of findings with publications, if any, should be submitted to the UEC for review. If research needs to be continued beyond the approved total duration of research, fresh approval has to be obtained for extension of the period.

Sincerely yours,

Member Secretary-
(Signed and dated by the Member Secretary)

Date of approval of the study: dd/mm/20…

Annexure 5: AX05/SOP07A/V_2

Guidelines for reviewing a study protocol

Reviewers should make use of the following points while reviewing research studies which relate to scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.

1. How will the knowledge, result or outcome of the study contribute to human well-being?
2. How will the Knowledge from the basic research may possibly benefit?
   - Will the study design be able to give answers to the objectives?
   - Whether the end points are appropriately selected?
   - The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - The control arm is appropriately selected for best comparison.
   - The placebo when used is justified.
   - The number of study participants in non-treatment (or placebo) arm is minimized.
   - Unbiased assignment (e.g. randomization, etc.) is in practice or not?
   - Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - The sample group size appropriate with the given statistical assumptions.
   - Predictable risks are minimized.
   - The tests and procedures that involve more than minimal risk are cautiously used or
   - The tests and procedures could be replaced by those, which have lesser risk without compromising the scientific logic.
   - Deception of Research participants is avoided except when necessitated by design of the research e.g. sensitive topics pursued in social and behavioural sciences.
   - Instruction and support systems such as counselling for study participants are included (if needed) when deception is integral to the study design.
   - The study participants are adequately assessed and provided follow-up care, if needed.
   - Who will be the participants in the study?
   - Whether the described population is appropriate for the study?
   - Whether predictable vulnerabilities are considered?

- It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
- There will be secondary participants?
- Do the inclusion and exclusion criteria selectively include participants most likely to serve the objective of the study?
- Is there equitable inclusion of participants?
- Properly exclude participants who can predictably confound the results?
- Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?
- Does the study design have adequate built-in safeguards for risks?
- Appropriate screening of potential participants?
- Does the frequency of visits and biological samplings reasonably monitor the expected effects?
- Are there defined stopping (discontinuation)/withdrawal criteria for participants with worsening condition?
- Is there minimized use of medication withdrawal and placebo whenever possible?
- Will rescue medications and procedures be allowed when appropriate?
- Is there a defined safety committee to perform interim assessments, when appropriate?
- Is appropriate follow-up designed into the study?
  For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.

- Is pre-clinical and/or early clinical studies sufficiently performed before this study?
- The animal study and *in vitro* testing results done if applicable?
- Previous clinical results, if done?
- Is the selected dose of marketed drug based on scientific basis?
- Do the study and the informed consent process include issues of special concern, such as:
  - Waiver or alteration of consent?
  - Delayed consent (e.g., emergency treatment, etc.)?
  - Deception?
  - Sensitive information of participants that may require a confidentiality statement?

Guidelines to review Informed Consent Document/Patient Information Sheet The actual process of informed consent should:

- Give the participants significant information about the study.
- Make sure the participants have enough time to carefully read and consider all options.
- Answer all questions of the participants before making decision to participate.
- Explain risks or concerns to the participants.
- Make sure that all information about the research and consent process is understood to the satisfaction of the participants.
- Make sure the participants understand the study and the consent process.
- Obtain voluntary informed consent to participate.
- Make sure the participants can freely consent without coercion, pressure or other undue influences.
- Consent should be verified on a continuing basis especially when changes in design of the research or new information is available.
- If participant is illiterate than her/his legally authorized/acceptable representative should sign consent on her/his behalf in the presence of impartial witness.
- Permission for access to participants from other institutions or bodies

Guidelines to Placebo Justification, if applicable:

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered.

I. Benefits of standard treatment

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has 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 answers of (1) to (6) are "yes", placebo is not recommended.*
- *If any one or more answers are "no", placebo may be possible.*

7) Are the side effects of the standard treatment severe?
8) Does standard treatment have many uncomfortable side effects?

9) Does standard treatment have contraindications that prevent some research participants from being treated?
10) Is there substantial (25%) placebo response in this disease or symptom?

- *If the answer of* (7) *to* (10) *are "no", placebo is not recommended.*
- *If any one or more answers are "yes", 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 answers 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 research participants?
   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 research participants at high risk for the use of placebo excluded?
   Yes, consider placebo
   No, placebo not recommended.
4) Is the duration of the study at minimum necessary level 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 research participants in case he/she does not improve?

Yes, consider placebo

No, placebo not recommended.

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

Yes, consider placebo

No, placebo not recommended.

7) Are there clearly defined stopping rules to withdraw the research participants 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?

Yes, consider placebo

No, placebo not recommended.

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?

Yes, consider placebo.

No, placebo not recommended.

10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?

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.

3) Are the advantages of alternative treatments explained?

Yes, consider placebo.

Conclusions:

The use of placebo is ethically acceptable when:

- Research participants are not exposed to severe or permanent harm by the use of placebo.
- Research participants 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.

- If it is used for a self-limited disease likely to be of a short duration

Guidelines to review advertisements

- Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:
  - The name and address of the researcher or research facility.
  - The purpose of the research or the condition under study.
  - In summary form, the criteria that will be used to determine eligibility for the study.
  - A brief list of benefits to participants, if any.
  - The time or other commitment required of the participants.
  - The location of the research and the person or office to contact for further information
  - Advertisement can be displayed at patient recruitment areas for the research concerned.

The UEC reviews advertising to ensure that advertisements

DO NOT:

- State or imply a certainty of favourable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type
- Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

	University Ethics Committee, KUHS Title: Expedited Review Process	SOP07A/V_2 Effective from 25-10-2019 Valid till 24-10-2024

7B.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the University Ethics Committee (UEC) members will perform an expedited review of new research proposal and revised proposals with minor amendments/administrative corrections using a prescribed procedure.

7B.2. Scope

This SOP applies to the review and approval of research proposals and related documents, which qualify for expedited review by the UEC, as per ICMR's Ethical Guidelines, 2017. These should carry not more than minimal risk and should fulfil the criteria for expedited review.

7B.3. Responsibility

- The Member Secretary in consultation with the Chairperson (if necessary), will determine if the proposals qualify for expedite review and is responsible to forward them to the Secretariat.
- The UEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the designated UEC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators.
- Designated UEC members will be responsible for reviewing the research protocols and related documents within the given periods.
- It is the responsibility of the designated UEC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The UEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.
- The Chairperson is responsible to sign with date in the decision of the UEC.

7B.4. Detailed instructions

7B.4.1 Appointment of reviewers

After determining that the Proposal/Project qualifies for an expedited review, the Member Secretary (in consultation with Chairperson) will nominate two or more UEC members to review the protocol.

7B.4.2 Distribute the protocol package

- The Secretariat will fill in the required details in the nomination form to the UEC Members requesting initial review.
- The Secretariat will send a packet (hard or soft copy) to the designated UEC members.
    - Nomination letter to UEC Members requesting initial review
    - Study assessment form
    - Project Submission Application Form
    - Protocol and related documents

7B.4.3 Receive the distributed protocol package:

Designated UEC members will receive the protocol package with the Project Application Form, in a soft and/or hard copy.

7B.4.4 Verify the contents of the package

- The UEC member will verify all the contents and will notify the UEC Secretariat if any documents are missing.

7B.4.5 Review by the UEC members

- UEC members will review the protocol within 7 days of receiving the package.
- The comments of the UEC members will be duly recorded.
- If deemed necessary, the proposal may be sent to an expert/independent consultant for review.

7B.4.6 Gather the assessment reports.

The UEC Secretariat will collect the Assessment Forms with the comments from each designated reviewer of UEC and file in the original study file.

7B.4.7 Decision and Communication of decision to PI and UEC full board

- The Member Secretary will discuss the comments of the members with the Chairperson and a decision about the protocol will be taken.
- If there are queries, these will be sent to the PI within 2 working days after receipt of queries, by the Secretariat, in consultation with Member Secretary.

- The reply from the PI will be discussed, by the Member Secretary with the Chairperson or with the designated UEC members and a decision will be reached.
- The final decision will be recorded on the Study Assessment Form for expedited review.
- The final decision by the Chairperson is recorded on the Study Assessment Form for expedited review.
- The decision will be informed to the UEC members at the next full committee meeting.
- If deemed necessary as decided by reviewer(s), Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full committee meeting before final decision.
- The Secretariat will send the Study approval letter to the PI (AX04/SOP7A/V_2).
- If the project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator in writing within 7 working days.
- The reasons for disapproval of a project will be specified in the letter sent to PI.
- The expedited review process should be completed within 14 working days.

7B.5. Flow Chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review	Member Secretary
3.	Approve the Secretary's recommendation regarding the protocols for expedited review.	Chairperson
4.	Expedited process	UEC Members/Chairperson
5.	Decision of UEC	Chairperson
6.	Communicate with the UEC and the Investigator	Member Secretary/ Secretariat

7.B.6. Annexures

Annexure 1: **AX01/SOP7B/V_2** - Form for nomination of IEC members for Review.

Annexure 2: **AX02/SOP7B/V_2** -Study Assessment Form for Expedited Review.

Annexure 1 AX01/SOP7B/V_2

Form for nomination of UEC Members for Review

Date:

To,

…….

Member,

UEC, KUHS

The project no……..

titled……

……

……

Sub: Review of ……

……

……

Dear Sir/Madam/Dr. ……

The following document(s) has/have been submitted to the UEC for review.

1. _____
2. _____
3. _____

For expedited review, you are requested to fill the study assessment form enclosed and send to the UEC office within 7 working days of receiving the package.

_____

Name and Signature of Member Secretary/Chairperson

with date……

Annexure 2: AX02/SOP7B/V_2

Study Assessment Form for Expedited Review

UEC Protocol Number:	Date of receipt at UEC office (……/……/……)
Project Title: _____ _____ __	

Name of the Principal Investigator	Department/Address	Contact number
Total no. of Participants at the site:		
No. of Study sites:		
Sponsor if any:		

Duration of the Study:		
Reviewer's name :		
Type of Study		
Biological material	Stored ☐	Prospective collection ☐
Data collection	Retrospective ☐	Prospective ☐
Scientific Aspects		
Is the sample size justified?	Yes ☐	No ☐
Inclusion/exclusion criteria	Acceptable ☐	Not acceptable: Reasons ☐
Is the proposal scientifically sound?		Yes ☐

Are procedures adequately explained	Yes ☐
Ethical Aspects	
Risk – physical/psycho-social/economic/legal	Acceptable ☐
Is participants are more at risk than benefit? If so, is it justified?	Yes ☐ Yes ☐
Is risk to participants justified	Yes ☐
Benefits	Acceptable ☐ Reasonable ☐
Are vulnerable participants adequately protected?	Yes ☐
Informed consent Document	
Is the language easy to understand with matching local translation?	Yes ☐
Are separate forms attached wherever necessary?	Yes ☐
Is compensation explained well?	Yes ☐
Is withdrawal appropriately addressed?	Yes ☐

Provisional Decision:
Approved □
Approved with modifications □
Resubmission □
Not approved □

Reason for disapproval _____

Name of the UEC member _____

Signature _____

Date _____

Final decision:

Approved □
Approved with recommendations/suggestions □
Further revision with minor or major amendments for Resubmission □

Not approved □

Reasons for disapproval_____
_____

For full committee review □

Name and Signature of the Chairperson: _____
_____

Date:

7C1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for exemption from ethics review and approval of a research protocol.

7C2. Scope

This SOP applies to the review of protocols categorized as qualified for exemption from review by the Member Secretary in consultation with the Chairperson. Any research that carries less than minimal risk and fulfils criteria for exemption from review is covered in this SOP.

7C3. Responsibility

- It is the responsibility of the Member Secretary in consultation with the Chairperson to record the decision in the Exemption Form with reasons.
- The UEC Secretariat is responsible for recording and filing the decision including the reasons for that decision.
- The Chairperson must sign with date, the letter conveying the decision.

7C4. Detailed instructions

7C4.1 Receive the submitted documents.

- The Secretariat will receive the Exemption from Review, through Application Form, Protocol and other documents submitted by the investigators.
- The Secretariat will check that the package is complete and will forward it to the Member Secretary for review.

7C4.2 Determine proposals eligible for exemption from review

- The Member Secretary will screen the research proposal and determine whether the study qualifies for exemption from review, based on the criteria laid down in the Ethical Guidelines of Indian Council of Medical Research (ICMR), for research that involve less than minimal risk.
- In some circumstances, research that appears to meet low risk criteria may need to be reviewed by the UEC. This might be because of requirements of the publisher of the research or the organization providing funding resources and/or existing data or as a condition for access to participants.

7C4.3 Exemption Process

- If the protocol and related documents satisfy the above stated criteria, the Member Secretary in consultation with the Chairperson

will review the brief summary of the project and the Exemption Form.

- The Member Secretary records the decision on the Exemption Form.
- The Secretariat communicates the decision to the Principal Investigator.
- The Member Secretary will place the application for review and decision regarding exemption at the next full committee meeting.

7C4.4 Communication

- The decision regarding request for Exemption from review, signed by the Member Secretary of the UEC, will be forwarded by the Secretariat to the Principal Investigator within 7 working days after the decision regarding the exemption is taken.
- The Member Secretary will inform the UEC members of the decision at the next regular meeting and minute it.

7C5. Flow Chart

No.	Activity	Responsibility
1	Receive the submitted documents.	UEC Secretariat
2	Review of proposal and Exemption Form	Member Secretary
3	Recording the decision on Exemption Form in consultation with the Chairperson	Member Secretary
4	Communicate the decision to the Investigator	UEC Secretariat
5	Informing the decision to the members in the forthcoming meeting	Member Secretary
6	Recording and filing the decision	UEC Secretariat

7C6. Annexures

Annexure 1 - ***AX01/SOP7C/V_2***

Annexure *1 AX01/SOP7C/V2*
Review Exemption Application Form

1. **Principal Investigator's Name:**
   _____
2. **Title of Project:** _____

_____

3. **Name of other participating investigators/students:**

_____

_____

4. **Brief description of the project:**

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants 'description, and procedures/methods to be used in the project:

5. **State reasons why exemption from ethics review is requested?**

- Research on microbes cultured in the laboratory □
- Research on commercially available cell lines □
- Research on cadavers or death certificates provided such research reveals no identifying personal data □
- Research conducted on data available in the public domain for systematic reviews or meta-analysis □
- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person □
- Quality control and quality assurance audits in the institution □
- Comparison of instructional techniques, curricula, or classroom management methods □
- Consumer acceptance studies related to taste and food quality □
- Public health programmes by Government agencies such as programme evaluation, where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)
- Any other,
  ……

(This should include justification for exemption e.g., study does not involve human participants. If exemption is being requested based on low risk involved in the study, please refer to the backside of this annexure)

Name and Signature of the Principal Investigator: _____

_____

_____

Date _____

Forwarded by the Head of the department/Institution:

Name: _____

Signature: _____

Date_____

Recommendations by the UEC Member Secretary:

- Exemption recommended □
- Cannot be exempted □
- Reasons for discussion in full committee meeting

  _____

Name and Signature of the Member Secretary: _____

_____

_____

Date _____

Final Decision at Full Committee meeting held on:

- Exemption allowed □
- Exemption not allowed □

Reasons_____

Name and Signature of the Chairperson: _____

_____

_____

Date _____

NOTE:

No research can be counted as low risk, if it involves:

(i) Invasive physical procedures or potential for physical harm
(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offence
(iii) Personal or sensitive issues
(iv) Vulnerable groups
(v) Cross cultural research
(vi) Investigation of illegal behaviour(s)
(vii) Invasion of privacy
(viii) Collection of information that might be disadvantageous *to* the participant
(ix) Use of information already collected that is not in the public arena which might be disadvantageous *to the* participant
(x) Use of information already collected which was collected under agreement of confidentiality
(xi) Participants who are unable to give informed consent
(xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague, or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
(xiii) Deception
(xiv) Audio or visual recording without consent
(xv) Withholding benefits from "control" groups
(xvi) Inducements
(xvii) Risks to the researcher

(This list is not limited, but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life).

Please check that your application/summary has discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements.

8.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, and minutes.

8.2 Scope

This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all UEC meetings.

8.3 Responsibility

- It is the responsibility of the Member Secretary assisted by the Secretariat to prepare the agenda for the UEC meeting
- The Chairperson will review and approve the agenda
- It is the responsibility of the Member Secretary to ensure proper recording and dissemination of the minutes after the meeting is over.
- It is the responsibility of all members to read and approve the minutes sent to her/him.
- The Chairperson will review and finally approve the minutes

8.4 Detailed instructions

8.4.1 Committee meeting

- The UEC Full Committee meeting will be scheduled once in three months or as per requirements.
- Even if there are no new research proposals for review, the gap between two full committee meetings will not normally exceed three months.
- If there is a long gap between two meetings the reason for the gap should be documented

8.4.2 Preparation of meeting agenda of full committee

The Member Secretary assisted by the Secretariat will prepare the meeting agenda with date, time and venue of the meeting and will include the subtopics as given in *AX01/SOP08/V_2*

- The Secretariat will collect and verify all forms/documents for completeness and make them available in the meeting.
- The Secretariat will schedule protocols in the agenda as per date of receipt.
- The agenda for the UEC meeting is prepared and sent 10 days in advance before the date of meeting.
- Answers to the UEC queries, amended study related documents (Protocol, ICD, CRF) or matter related to safety of participant received

from the investigators in time and any item in emergent and very exceptional included in the additional agenda. The Member Secretary in consultation with the Chairperson would prepare this.

- Any study-related document which is not presented in time will not be considered.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed sufficiently in advance to the UEC members through telephone, SMS/WhatsApp/e-mail or any other electronic means.
- The Secretariat will send the final agenda, list of proposal(s) given exemption and reviewed through expedited process, and minutes of the previous meeting along with notice of the meeting 10 days before the scheduled meeting.

8.4.3 During the meeting

- Meeting will be held as scheduled, provided, the required quorum is available.
- The Secretariat will obtain the signatures of all the UEC members present on the attendance register.
- Experts/independent consultants, if invited, will sign Confidentiality and COI agreement and also if there are guests/observers
- The meeting will begin with a welcome note by the Member Secretary and remarks by the Chairperson
- The Chairperson will initiate the meeting after ensuring that the quorum has been met.
- The Chairperson at her/his discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the Conflict of Interest (*AX02/SOP03/V_2*).
- If a member has declared conflict of interest, the Chairperson will ask the member concerned to leave the meeting room when the concerned issue is being discussed and this will be minuted.
- The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict.
- The fact that a member excused himself from the meeting on the ground of conflict of interest will be specifically noted in the minutes.
- The Chairperson will ask the members whether any points need to be discussed regarding minutes of the previous meeting.
- If no points are raised, the minutes of the previous meeting will be considered as confirmed.

- If applicable, the Chairperson will also ask the members, if there is any issue to be raised regarding the list of proposals exempted and approved through expedited process.
- The Member Secretary will present the agenda of the day's meeting for discussion.
- The meeting shall generally proceed in the order as in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed, if required.
- In case of projects submitted for initial review, the detailed instructions given in this SOP will be followed.
- Investigators who have been asked by the UEC secretariat to provide additional information or clarifications related to their project may do so and attend the UEC meeting, if permitted to do so.
- The discussion amongst UEC members will not be done while the investigator is in the meeting room.
- Any other matter will be presented by the Member Secretary for comments by the members, which will be noted.
- The Member-Secretary assisted by the secretarial staff will record the gist of discussions and decisions arrived at for each item in the agenda and will read it before the decision is taken by the Chairperson.

8.4.4 Decision making

- The final decision on each proposal/issue discussed in the meeting shall be by broad consensus or by voting (more than 50% majority). In case there is absence of consensus for any reason, the majority view recorded as per vote shall be accepted as the decision of the UEC.
- Decisions will include approval, disapproval, revision with minor or major amendments, suspension or termination of an ongoing study.
- The following persons shall not have the right to vote at the meeting:
  - Member(s) of the committee who is/are listed as investigator(s) on a research proposal that comes up for discussion in that meeting.
  - An investigator, special invitee (expert) or study team member invited for the meeting.
  - UEC members attending through telecom/Skype/other software/other media.

8.4.5 After the Committee meeting

- The Secretariat will prepare the minutes of the meeting in a concise and easy-to-read style soon after the meeting.
- The Secretariat will make sure to cover all contents in each particular category to include the following:
  - Venue of the meeting.

- Meeting number, date/duration of the meeting (time of commencement and end)
- Name of the Chairperson of the meeting and UEC members and invitees attending the meeting.
- Details of the study including name of the Sponsors, if any and investigator(s).
- Protocol number/date/version of protocol.
- Name of the Primary and secondary Reviewers, if any.
- Follow-up action, if any.
- Brief summary of minutes highlighting aspects on science, methodology, ethics and informed consent document.
- Reference to the investigator approval letter that lists all changes requested by the UEC.
- Determination of the date for continuing review, if any.

Requirements for each study or activity requesting Expedited Review:

- Sponsor's name, if any.
- Protocol number and UEC number.
- Investigator's name
- Lists of expedited approval requests and outcomes.

Requirements for each Continuing Review Report:

- Sponsor's name, if any.
- Protocol number and UEC number.
- Investigator's name.
- Indication of the Committee's determination to continue, terminate, or amend the study.
- Lists of recommendations or actions to be taken up with the investigator, if applicable.

Requirements for each Adverse Event notification and Final Report:

- Sponsor's name, if any.
- Protocol number and UEC number.
- Investigator's name.
- Report or summary of report provided by the SAE sub-committee.
- Actions deemed appropriate by the UEC.

Requirements for Termination of Approval:

- Name of the Sponsor, if required.
- Protocol number and UEC number.
- Investigator's name and reason for termination.

8.4.6 Approval of the minutes and communication of decision

- The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairperson for review and approval within 7 working days of the meeting day.
- The Chairperson indicates approval by signing and dating the minutes.
- On receipt of approval from the Chairman, the Secretariat will email the minutes of the meeting to the UEC members within 7 working days after approval.
- The decision regarding the proposal shall be communicated to the investigator within 7 working days of receiving approval from the Chairperson.

8.4.7 Filing the minutes

- The Secretariat will place the approved versions of the minutes in the minutes file.
- The Secretariat will file the UEC Decision Forms in the project files and place all correspondence in the appropriate files.

8.4.8 Calling an Emergency Meeting of UEC

- The Member Secretary, in consultation with Chairperson may decide to call an emergency meeting for any one or more of the following reasons:
  - Urgent issues which, if not decided upon early, could adversely affect or have adverse impact on patient safety, public safety or national economy etc.
  - Occurrence of unexpected serious adverse event(s).
  - Other reasons, as deemed appropriate by the Member Secretary with concurrence of the Chairperson.
- The Secretariat will endeavour to contact each UEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting.
- The Secretariat will prepare and send to the members, packets containing the information and documents about the matter(s) or the relevant details.
- During the meeting, the Chairperson will determine, if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of the said 15 minutes; the meeting would be held without a quorum provided at least four members (preferably including one scientific and one non-scientific member) are present, given the urgency of the matter under consideration.

- The members will follow the relevant UEC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making.
- The minutes of the emergency meeting will be prepared, distributed, approved and filed as described in the steps above for regular full committee meeting.

8.4.9 Releasing UEC Decision Letters

- UEC decision letters will be prepared by the secretariat.
- Member Secretary will sign the decision letters and release them to the investigators.

8.5 References to other applicable SOPs

SOP05/V_2: Procedures for allowing Guest/Observer to visit UEC Office or attend UEC meeting.

SOP06/V_2: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review.

SOP07/V_2: Categorization of Submitted Protocols for Ethics Review.

SOP07A/V_2: Initial Full Committee Review of New Research Study Protocols

8.6 Flowchart

No.	Activity	Responsibility
1	Preparation of meeting agenda prior to a Committee meeting	UEC Member Secretary in consultation with the Chairperson
2	During the Meeting	UEC Secretariat, Members and Chairperson
3	After the Committee Meeting preparation and submission of the draft Minutes for approval of the Chairman.	UEC Secretariat/ Member Secretary
4	Approval of minutes	UEC members/Chairperson
5	Filing the minutes	UEC Secretariat
6	Calling an emergency meeting	Member Secretary in consultation with the Chairperson

8.7 Annexures

Annexure 1: ***AX01/SOP08/V_2*** - Agenda format

Annexure 1

AX01/SOP08/V_2

Agenda of the UEC Meeting

Meeting No.

Venue of the meeting:
Meeting Date:
Meeting time:

A. Apologies for absence, if any.
B. Declaration of COI and quorum
   Ratifying minutes of the previous meeting, and if applicable, list of proposals exempted and expedited.
C. New research proposals for Initial Review
D. Resubmitted amended proposals and/or related documents
E. Protocol extensions, deviations, violations, waivers, non-compliance
F. Review of protocols with related documents referred for Full Committee review after expedited review.
G. SAE reports as per 'New Drug and Clinical Trial Rules'/CIOMS forms/Safety letters if any, with minutes of SAE committee (if applicable)
H. Continuing review of approved protocols
I. Review of Study Completion Reports and premature study termination
J. Review of Site Monitoring Visit Reports
K. Any other matter e.g.
    a. Emergency concerns
    b. UEC policies
    c. Training of Members
    d. Revising SOPs
    e. Any other issues raised by Member(s) or issues to be informed to the members.
    f. Report of any other subcommittee or group appointed/designated by Chairperson for any specific or general purpose.

9.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the University Ethics Committee (UEC) manages amended, re-submitted, research study protocols.

9.2. Scope

This SOP applies to the review of research proposals and related documents that have been resubmitted to the UEC, as amended ones, by the Principal Investigator (PI) with clarifications and modifications sought by the UEC in initial review.

9.3. Responsibility

- It is the responsibility of the UEC Secretariat to ensure the completeness of the documents submitted to the UEC.
- Research proposal and related documents revised with minor amendments will normally undergo expedited review and if they are revised with major amendments they will undergo a full committee review.
- Additionally, primary reviewers who had reviewed the initial submission may be asked to review the resubmitted proposal and related documents, if any.
- If the amendment(s) is/are of administrative nature an expedited review will be undertaken, while if the amendment(s) relate to participant safety or data capture, full committee review is recommended. This information would be recorded during the meeting.

9.4. Detailed instructions

9.4.1. Receipt of resubmitted protocol and its distribution

- The Secretariat will verify if the PI has replied to queries of the UEC within 30 days of receipt of the letter of comments from the UEC.
- If PI does not submit the revised proposal and/or clarification called for by the UEC and a reminder will be sent after 30 working days of sending the letter. This will be repeated twice at 10 days' interval with colour code.
- In case of continued non response despite these reminders, all further action regarding the proposal will be dropped and the file will be closed.
- The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat, verified, and appropriate action pursued in the matter.
- The Secretariat will confirm in writing the receipt of request for review of amended Protocol or related documents from the Principal Investigator (PI).

- The verification by the Secretariat will be for the following items:
  - List of point wise reply to the UEC letter of comments indicating page numbers of the changes made in the revised document.
  - Revised version of protocol and/or the informed consent document and/or any other related documents such as, case report forms, diary sheets, etc. submitted with the changes made to the documents either underlined or highlighted.
- The amended proposal and related document will require Full Committee review, if any of the following changes:
  - The Protocol amendment changes the risk-benefit assessment, such as a change in study design,
  - additional treatments or the deletion of treatments.
  - changes in inclusion/exclusion criteria.
  - change in method of dosage formulation, such as change from oral to intravenous.
  - Changes in procedures, number of visits/follow up period or the number of research participants which might alter the fundamental characteristics of the study significantly.
  - Major changes in the Informed consent document.
- For each decision on resubmitted protocol for expedited review, the Secretariat will provide the UEC Decision Form and Assessment Form(s) to-
  - the Chairperson/Member Secretary, if the decision on the protocol was ***'Approved with recommendations subject to review by Chairperson/Member Secretary only'***.
  - the Member Secretary for summarising and including it in the agenda for full committee review in the forthcoming meeting if the decision on the protocol was ***'for discussion at full committee meeting'***.
  - the designated UEC members, if the decision on the proposal was for ***'review by designated UEC members'***.

9.4.2. Review of revised protocol by UEC member/Member Secretary/Chairperson:

- The UEC member/Member Secretary/Chairperson will refer to the query letter/comments as guidance for the review and consider whether the recommendations of the UEC have been addressed adequately and make further comments, if necessary, in the Assessment Form for resubmitted protocol.
- The Secretariat will retrieve the Assessment Form for resubmitted protocol from the members/Member Secretary/Chairperson.

- In case the decision is to discuss the revised protocol at the full committee meeting, the Member Secretary will present a brief summary of the proposal and the comments of the UEC members/Chairperson in the UEC Full Committee meeting.
- The Chairperson shall invite discussion on the protocol revision from all the UEC members.
- The final decision regarding the research project shall be reached by consensus/voting and shall be one of the following:
    - ☐ Approved
    - ☐ Further modifications to items noted at the convened meeting and follow-up by the Chairperson/Member Secretary/UEC members after receipt of the requested modifications for placing in the next meeting
    - ☐ 'Not approved' after giving reasons.
    - ☐ Suspend the study, until further information is obtained.
- In case the revised protocol is already approved through expedited review, the decision is informed to the members at the full committee meeting.
- Primary reviewer/designated UEC members performing the review must sign the form with date, and return this to the Secretariat after the review.

9.4.3 Communication of the Decision to the Principal Investigator

- If the UEC approves the protocol/informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter to the PI within 14 working days of the meeting.
- The decision regarding disapproval (stating reasons) or request for specific modifications shall be communicated in writing to the investigator within 14 working days of the meeting.
- The letter of comments sent to the investigator shall state that the reply to the letter is expected within stipulated time (within 14 days) and in the absence of any response to three reminders at intervals of 10 days, the project will be declared closed.
- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full committee meeting.

9.5. Flowchart

No.	Activity	Responsibility
1.	Receive the Protocol amendment/Resubmitted protocol	UEC Secretariat

2.	Notify the Member Secretary/ Chairperson of the UEC	UEC Secretariat
3.	Determine whether full committee review/review by designated members is needed	UEC Member Secretary/ Chairperson
4.	Designate UEC members for review	UEC Chairperson
5.	Distribution to UEC members	UEC Secretariat
6.	Protocol Amendment/Revised documents Review	UEC Members/ Member Secretary/Chairperson
7.	UEC Decision	UEC Member Secretary/Chairperson
8.	Communication of the Decision to the Principal Investigator	UEC Secretariat
9.	Store documents	UEC Secretariat

9.6 **Annexures**

Annexure 1: **AX01/SOP09/V$_2$** Assessment of Resubmitted Protocol

Annexure 2: **AX02/SOP09/V$_2$** Proposal and/or related documents Amendment Request and Assessment Form

Annexure 3: **AX03/SOP09/V$_2$** Approval letter for Proposal Amendment/ Document Amendment

Annexure 1: AX01/SOP09/V_2

Assessment of Resubmitted Protocol

UEC Protocol Number: Protocol Title:		
Number of review : 2nd Review 3rd Review 4th Review		
Principal Investigator:		
Department/Institution Address:		
Date ofInitial Review by UEC:	Date of Last Review:	
The UEC Decision recorded in the meeting minutes: (meeting held on _____) _____		
Opinion of the reviewer:		
Approved	Yes ☐ No ☐	
If not approved, reasons for that	_____ _____	
Further revision or modification required	Yes ☐ No: ☐ Explain: _____ _____ _____ _____	
To be discussed at the forthcoming full committee meeting	_____ _____ _____ _____	
Any Other	_____ _____ _____	

	___

Name of the Reviewer: 1)
_____

Signature with Date: _____

Name of the Reviewer: 2)
_____

Signature with
Date: _____

Final Decision: Approved YES ☐ NO ☐

If not approved, reasons for that
_____
_____
___
Further revision or modification required for Resubmission

Any Other

Name and Signature of the Chairperson/Member Secretary_____
Date: _____

Annexure 2: AX02/SOP09/V_2

Proposal and/or related documents Amendment Request and Assessment Form

UEC Protocol Number:	
Protocol Title: _____ _____ ____	
Principal Investigator _____ and Department: _____	
Approved date:	No. of amendment:
o State/describe the amendment: type of document/part of document amended o Reasons for the amendment o Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)	
Have the changes/modifications in the amended versions been highlighted/underlined? Yes ☐ No ☐	
Name of Principal Investigator: _____ Signature with Date:_____	

Type of review

- Review by Member Secretary/Chairperson
- Review by designated UEC members
- Full Committee discussion and review

Comments of the reviewer _____

_____

____

Decision:	☐ Approved ☐ Suggested Recommendation(s) ☐ Not approved ☐ Next full committee discussion

Name of UEC Member/Member Secretary/Chairperson reviewing the project: _____

Signature

with Date:_____

Final Decision: Approved Yes ☐ No ☐

If not approved,

Reasons _____

Further revision or modification required:

Any Other

Name and Signature of the Chairperson/Member Secretary: _____

_____

_____

_____

Date:_____

Annexure 3 ***AX03/SOP09/V_2***

Approval Letter for Proposal Amendment/Document Amendment

To

…….

.

…….

(PI)

Department:

……..

UEC No. of Project:

……

Title:

……..

Dear

Sir/Madam/Dr._____

__

We have received from you the following document(s).

1.
2.

At the University Ethics Committee (UEC) meeting held on _____ the above mentioned documents were reviewed in the presence of following members:

1.
2.
3.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the IEC.

After reviewing, the UEC has decided to approve:

(a) The aforementioned study-related documents

OR

(b) the following documents:

1.
2.

After reviewing the documents, the UEC has decided to approve the aforementioned study-related documents.

Yours truly,

_____

Name and Signature of UEC Chairperson/Member Secretary
with Date

10.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how continuing review of previously approved protocols should be managed by the University Ethics Committee (UEC). The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants.

10.2 Scope

This SOP applies to conducting any continuing review of already approved study protocols at pre-specified intervals. All the projects approved by the UEC will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the UEC may choose to review or monitor the protocols more frequently.

10.3 Responsibility

It is the responsibility of the UEC Secretariat to remind the PIs and Member Secretary regarding continued review of protocols at the correct interval. All the approved protocols will be reviewed annually. It is the responsibility of the Member Secretary to ensure, during the UEC meeting in which the project is finally approved, that a decision is taken whether the project needs to be reviewed more frequently or not. This must be recorded in the minutes. A fresh decision to increase frequency of review may be taken if required based on the SAE reports, monitoring reports, or safety concerns. This is the responsibility of the SAE subcommittee and Member Secretary. The UEC is responsible for reviewing the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding UEC communication.

10.4. Detailed instructions

10.4.1 Determining the date of continuing review

- The continuing review will always be done at least once in the year.
- The UEC may recommend more reviews during the approval process depending on the level of risk.
- The Secretariat will inspect the minutes of meeting to set a time table for continuing review.
- The Secretariat will identify and record the due dates for each project.

10.4.2 Notifying the PI or the study team

The Secretariat will send a reminder to the PI as per the prescribed format at least one month prior (if an annual review) or less as appropriate (if any special additional reviews are required) to the due date of continuing review.

10.4.3 Managing the continuing review package upon receipt

The Secretariat will receive one set of a package (soft and hard copy) from the PI as per the prescribed format for continuing review of approved protocol by the UEC.

10.4.4 Verifying the contents of the package

- The Secretariat will ensure that the contents of the package include the following documents:
    - Continuing Review Application in the prescribed Form.
    - The Continuing Review Application Form duly filled with an explanation and a discussion of scientific developments, either through this study or similar research studies that may alter risks to research participants.
    - The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. must be discussed in the attached narrative.
- The Secretariat will confirm that complete information is appended and signed by the Principal Investigator in the Continuing Review Application form.

10.4.5 Review process

- The Continuing review submission may undergo expedited review or full committee review as deemed appropriate by the UEC Chairperson/Member Secretary.
- The Secretariat will send the Continuing Review Application Form to the designated UEC members.
- The UEC Chairperson/Member Secretary/Member(s) will use the Continuing Review Application Form to guide the review and deliberation process to reach one of the following decisions after review:
    1. Noted - The UEC approves the continuation of the project without any modifications.
    2. Modifications recommended: Unless the modifications suggested/recommended by the UEC for the protocol have been met, the study cannot continue. The amendments and the required documents should be appended and submitted to the UEC within one month for re-review.

3. The project cannot be continued: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the Principal Investigator. The Member Secretary shall record this decision.

- The UEC Chairperson/Member Secretary will sign and date the final UEC decision on Continuing Review Report after a decision has been reached.
- The decision on continuing review taken by the Chairperson/Member Secretary/Member(s) will be informed to all UEC members at the next full committee meeting for discussion.
- The UEC Secretariat will maintain and keep the UEC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process in the project file.

10.4.6 Communicating UEC Decision to the PI

- The Secretariat will notify the PI of the decision within 14 days of the meeting at which the report is discussed or of the date of final review by the Chairperson/Member Secretary.

10.4.7 Non-submission of continuing review report by principal investigator before due date.

If a PI fails to submit the continuing review report within two months of the due date (i.e. 10 months from the date of approval, or earlier on the dates as specified), the Secretariat will send a telephonic and/or email reminder thrice at an interval of 10 working days. If there is no response, the UEC secretariat will put up the matter for discussion at the forthcoming full committee meeting for appropriate action. This may consist of, but not limited to, sending:

a) A letter asking explanation for non-submission
b) A letter asking the PI to put recruitment of new participants on hold till report is submitted
c) Any other action as deemed appropriate by UEC

10.5 Flow Chart

No.	Activity	Responsibility
1	Determine the date of continuing review	Member Secretary
2	Notify the Principal Investigator or study team	UEC Secretariat
3	Manage continuing review package upon receipt and verifying its contents	UEC Secretariat
4	Notify the members of the UEC	UEC Secretariat
5	Review of Continuing review report	UEC Secretariat, Members and Chairperson
6	Communicate the UEC decision to the Principal Investigator	UEC Secretariat

10.6. Annexures

Annexure 1: *AX01/SOP10/V_2* Reminder letter from the UEC to the principal investigator

Annexure 2: *AX02/SOP10/V_2* Continuing Review Application Form

Annexure 1: AX1/SOP10/V_2

Reminder letter by the UEC to principal investigator

Date :-

Name of Principal Investigator:

Department/Address:

UEC Project no.

Title_____

The above referenced project was approved by the UEC on _____and is due for Continuing Annual/Periodic Review by the UEC. You are requested to submit an Annual/Periodic status report in the prescribed format enclosed, on or before _____(1-month period)

Signature with date _____

Member Secretary

Annexure 2: AX02/SOP10/V2

Continuing Review Application Form

Project no. _____Date of approval_____

Summary of protocol: No. of participants screened No. of participants approved by UEC No. of participants recruited _____ No. of participants ongoing _____ No. of participants completed ____ No. of refusal to consent Have any participants been withdrawn from this study? Yes ☐ No ☐ If Yes, (state the number and reasons for drop-outs for each participant, attach separate sheet if needed) Have there been any amendments in protocol/Informed Consent Document since the last review? Yes ☐ No ☐ Were these protocol/Informed Consent Document (ICD) amendments approved by UEC? Yes ☐ No ☐ If no, mention the amendments not approved Which protocol amendment (version) is being followed at the site at present _____ Which ICD amendment (version) is being followed at the site at present _____	Has any information appeared in the literature, or evolved from this or similar research that might affect the UEC/UEC's evaluation of the risk/benefit analysis of participants involved in this protocol? Yes ☐ No ☐ If Yes (attach separate sheet if needed) No. of SAEs Causality determined by UEC: Related and not related Compensation given _____ Whether reports of SAEs at other sites have been submitted to the UEC-_____ Have any participating investigators been added or withdrawn since last review? Yes ☐ No ☐ If Yes (Identify all changes in the attached narrative) Is report of interim data analysis available? Yes ☐ No ☐ If Yes (submit as an attachment) Is report of the data safety and monitoring board available? Yes ☐ No ☐ If Yes (submit as an attachment)

	Have any investigators developed COI related to this protocol? Yes ☐ No ☐ If Yes (Append a statement of disclosure)

Signature of the Principal Investigator with Date:

Assessment of Continuing Review Report by the UEC
To be reviewed by

- Chairperson/Member Secretary only and inform the UEC members at Full Committee meeting
- Full Committee meeting
- Any 2 UEC members and inform UEC members at Full Committee

Names of UEC members:
1._____
2._____

Name and Signature with date
Chairperson/Member Secretary

UEC Decision on the Continue Review Report

- Approved for continuation without further modifications with effect from……..
- Revision incorporating modifications to be re-submitted
  (State modifications)
- To be discontinued
  (State reasons)

Date of Full Committee meeting: _____

Signature of reviewer/s with date:

_____

Name and Signature with date

Chairperson/Member Secretary

11.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe action(s) to be taken by the UEC when investigator(s)/trial site(s) fail(s) to:

- follow the procedures written in the approved protocol.
- comply with national and/or international guidelines, statutory provisions, institutional policies or rules or procedures mandated by the University Ethics Committee (UEC) for the conduct of human research
- respond to the UEC requests regarding statutory, ethical, scientific or administrative matters.

11.2 Scope

This SOP applies to all UEC approved research protocols involving human research participants.

11.3 Responsibility

The UEC Secretariat is responsible for receiving deviation/violation reports as per request submitted by the Principal Investigator (PI)/others and placing it on the agenda of the meeting. Reporting of deviation/violation in any other reporting format will not be accepted. The UEC members should review and take action on such reports.

11.4 Detailed instructions

11.4.1 Protocol Deviation: This occurs when there is some deviation in protocol, but it -

a) has no substantive effect on the risk posed to a research subject or others.
b) will not affect the subjects' willingness to participate in the study
c) has no substantive effect on the value of the data collected.
d) does not confound the scientific analysis of the study results
e) did not result from willful or voluntary misconduct on the part of an Investigator or a member of the Investigator's study team.

Examples:

- wrong version of the informed consent form being used
- sample collections at different time points than specified in the

protocol

- patient follow up on days not specified in the protocol

11.4.2 Minor Protocol Deviation: A minor protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol, that has not been approved by the UEC and which does not have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

11.4.3 Protocol Violation: If the deviation reaches any of the following criteria, it is considered as a protocol violation. Examples listed below, are not exhaustive.

I. The deviation has harmed or posed a significant or substantive risk of harm to the research participant. For example,
   - Receiving the wrong treatment or incorrect dose.
   - Withdrawal criteria met during the study but was not withdrawn.
   - Receiving an excluded concomitant medication.

II. The deviation compromises the scientific integrity of the data collected for the study.
   For example,
   - o A research participant who was enrolled does not meet the protocol's eligibility criteria.
   - o Failure to treat research participants as per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)
   - o Changing the protocol without prior UEC approval.
   - o Inadvertent loss of samples or data.

III. The deviation is a wilful breach of human participant protection regulations, policies, or procedures on the part of the investigator(s).
   For example,
   - o Failure to obtain informed consent prior to initiation of study-related procedures.
   - o Falsifying research or medical records.
   - o Performing tests or procedures beyond the individual's professional scope or privilege status (credentials)

IV. The deviation is inconsistent with the Human Research Protection requirements in research ethics principles.

For example,

- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

11.4.4 Action on intentional Protocol deviation: When there is intentional deviation from approved protocol, it has to be reported to the sponsor as well as UEC for prior approval before implementation. The Member secretary/Chairperson of UEC will consider the question of approval or not and inform members of UEC during the full committee meeting for appropriate action.

Examples of such deviations may be:

- in the participant's best medical interest to remain in the study
- exception to inclusion/exclusion criteria (age, concurrent medication)
- visits out of sequence or out of protocol "window"
- injection of study drug in left arm rather than right arm

11.4.5 Non-compliance:

a. Non-serious and non-continuing noncompliance involves isolated incidents.
   - an unintentional mistake, an oversight, or a misunderstanding which is not serious or continuing in nature.

b. Serious non-compliance:
   - an action or omission by an investigator which is non-compliant with national guidelines/regulations or UEC policy, which would have foreseen as increasing risks or compromising the rights and welfare of a participant or other persons.

c. Continuing non-compliance:
   - A pattern of repeated actions or omissions taken by an investigator that indicates a deficiency in the ability or willingness of an investigator to comply with national guidelines/regulations/UEC policy or determinations.
   - Working under an expired professional license or certification
   - Repeated minor deviations.

d. Research Misconduct noncompliance:

This involves callous disregard for the protection of human participants or for the integrity of research which may meet the definition of research misconduct - fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results.

11.4.6 Detection of Protocol deviation/violation/non-compliance

Protocol deviation/violation may be detected in one the following ways (but not limited to those listed below),

a. Reported by Investigator/Sponsor/Contract-Research Organization, to the UEC.
b. Reported by the UEC members monitoring the project if the project has not been conducted as per protocol/national/international regulations or detected it while scrutinizing annual/periodic reports/SAE reports/any other communication received from the Investigator/trial site/sponsor/study monitor/contract research organization.
c. Detected by the Secretariat from failure to comply with statutory requirements/failure to respond to requests from UEC within reasonable time limit/failure to respond to communication made by UEC.
d. The UEC Secretariat and/or UEC members may become aware of a protocol deviation/violation while reviewing study-related documents including reports filed in by the Principal Investigator (PI).
e. Communication/complaint/information received from a research participant who has been enrolled or any individual who has been approached for enrolment.
f. Any report/communication brought to the notice of a Member, Member Secretary/Alternate Secretary/Chairperson of UEC by an independent person.
g. Communication received from the Head of the Institution informing UEC about an alleged protocol deviation/protocol violation

11.4.7 Receipt of protocol deviation/violation/report by the Secretariat

1. The PI will report the protocol deviation/violation in the prescribed form.
2. In case protocol deviation/violation is detected by any other person and reported to the UEC (there is no format for this), the Member Secretary will write to the PI to submit details of protocol deviation/violation, if any, in the prescribed form.
3. The Secretariat will intimate, the Member Secretary, on any protocol deviation/violation report received from the PI/from any source at the earliest and within 2 working days of receipt.

11.4.8 Actions to be taken

1. The action of the UEC will be based on:
    - The nature and seriousness of the deviation/violation.
    - Frequency of deviation/violation in the study in the past.
    - Frequency of deviation/violation in previous studies by the same PI/Co-PI or in the same department.

2. Member Secretary will decide on the impact of the protocol deviation/violation and act accordingly. Depending upon the seriousness, the UEC shall do the following (not limited to these actions)
    - Ask PI for written clarification as soon as the deviation information/report is received
    - If the impact is serious, this report will be shared with the Chairperson and two or more UEC members designated by the Chairperson and the Member Secretary will instruct the Secretariat to schedule a full-committee meeting specifically to discuss the issue within 7 working days of the initial scrutiny.

3. The UEC members will review the information available and deliberate on it.

4. The Chairperson will take a final 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. The decision will be taken by voting if there is no consensus. The decision taken by UEC could include one or more of the following:

- Determine that no further action is required, or take other actions as appropriate.
- Inform the PI that the UEC has noted the violation/deviation, and instruct the PI to ensure that deviations/violations do not occur in future and to follow UEC recommendations.
- Enlist measures that the PI would undertake to ensure that such deviations/violations do not occur in future.
- Observe the research or consent process (depending on the nature and frequency of the deviation).
- Suggest modifications to the protocol.
- Alter the interval for submission of the continuing review/annual project status.
- Ask for additional training of the investigator and study team
- Reprimand the PI.
- Seek additional information from the PI.
- Conduct audit by the UEC.
- Suspend the study till additional information is made available and scrutinized.
- Suspend the study till recommendations made by the UEC are implemented by the PI and found to be satisfactory by the UEC.
- Suspend the study for a fixed duration of time.
- Terminate the study by revoking approval of that ongoing study.
- Inform DCGI/other relevant regulatory authorities, if applicable.
- Keep other research proposals from the PI/Co-PI under abeyance and review and/or inspect other studies undertaken by same PI/Co-PI.
- This final decision will be recorded by the Member Secretary.

11.4.9 Procedure for notifying the PI and other concerned authorities

The Member Secretary will draft a notification letter.

- The signed letter by Member Secretary will be sent to the PI and Department Head(s) (if required on case-to-case basis) and Institutional Officials (if required on case-to-case basis).
- The UEC secretariat will send a copy of the notification to the relevant national authorities (if required on case-to-case basis)

and institutes (if required on case-to-case basis in case of multi-centric trials).

11.4.10 Records and follow up to be kept by UEC secretariat

- The Secretariat will keep a copy of the notification letter in the respective project file.
- If necessary will follow up after a reasonable time.

11.5 Flow Chart

No.	Activity	Responsibility
1	Detection and reporting of Protocol deviation/violation	UEC members/Secretariat/Principal Investigator/external person
2	Receipt of protocol deviation/violation report	Secretariat
3	Review, board discussion, decision and action	UEC Members, Member Secretary and Chairperson
4	Notify the Principal Investigator/concerned authorities of UEC action	Secretariat
5	Maintain records	Secretariat

11.6 Annexure

Annexure1:***AX01/SOP11/V2***-Deviation/Violation/Non-compliance Record

Annexure2:***AX02/SOP11/V2***-Decision form

Annexure 1: AX01/SOP11/V_2

Deviation/Violation/Non-compliance Record

UEC Protocol no.:
Study Title:
Principal Investigator and Department:
Patient no.:
Date of occurrence: dd/mm/yyyy Deviation Violation Non-compliance
Identified by - Principal Investigator/study team/sponsor/monitor/DSMB/IEC
Total number of similar deviations/violations/occurred for the same trial/project/Research:
Description of deviation (s)/violation(s)/Non-compliance Classify (Tick the appropriate box): • Consenting • Enrollment • Laboratory assessment • Investigational Product • Safety Reporting • Source documentation • Staff • Patient non-compliance • Others (Please specify) Corrective Actions Taken by the Principal Investigator: _____ _____ _____

Impact on participant if any: Does it warrant change in protocol?
Reported by (Name of Principal Investigator/Study Team Member): Signature with date: _____

Annexure 2: AX02/SOP11/V2

Action Form for Decision by Member Secretary and/or Chairperson/designated UEC member

Provisional decision by reviewer: Member Secretary and/or Chairperson/UEC member with dated signature.

- Noted the violation/deviation/waiver/non-compliance
- Instruct the PI to ensure such actions do not occur in future and to follow UEC recommendations.
- Suggest modifications to the protocol.
    - Alter the interval for submission of the continuing review/annual project status.
    - Ask for additional training of the investigator and study team
    - Reprimand the PI.
    - Seek additional information from the PI.
    - Suspend the study till additional information is made available and scrutinized.
    - Suspend the study for a fixed duration of time/till UEC recommendations are implemented.
    - Terminate the study by revoking approval of the ongoing study and give reasons.
    - Keep other research proposals from the PI/Co-PI under abeyance and review and/or inspect other studies undertaken by same PI/Co-PI.
    - Refuse further applications from the PI/Co-PI
    - Refer to UEC full committee meeting.

Name of reviewer

Signature with Dtae

Discussion of the protocol deviation/violation at the

Emergency meeting on _____

Next Scheduled full committee meeting on _____

Final decision at the full committee meeting held on_____

_____

Name and Signature with date UEC Chairperson

12.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) reported to the UEC for any study and as part of the oversight of the University Ethics Committee (UEC).

12.2. Scope

This SOP applies to the review of Serious Adverse Event (SAE) reports {SAE onsite as well as SAEs of the multicentre studies occurring at other sites (offsite) submitted to the UEC}.

12.3. Responsibility

The principal investigator is responsible for submitting all the Serious Adverse Event (SAE) occurring to the subjects recruited at the site within 24 hours of occurrence or first information on occurrence of SAE (whichever is earlier) in the format provided by UEC. It is the responsibility of the UEC to receive all safety reports and get them reviewed by SAE subcommittee and UEC in a timely manner.

12.4. Detailed instructions

12.4.1 SAE Subcommittee

- The Serious Adverse Event (SAE) Subcommittee of the University Ethics Committee (UEC) will review all serious adverse events (SAE) at the site/other sites approved by UEC involving human participants.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

12.4.2. Composition of the SAE Subcommittee

- The SAE Subcommittee will be appointed by the Chairperson of UEC
- The SAE Subcommittee will be multi-sectoral in composition.
- The SAE Subcommittee will be composed of members of the UEC.
- The composition shall be as follows:
  - ✓ Chairperson of the SAE Subcommittee
  - ✓ One Member of UEC as Executive Secretary
    - At least one member with Post-Graduate qualification as a Clinician/Clinical Pharmacology/any other relevant clinical specialties in the institution.

- ✓ Two members of UEC including non-scientist of UEC preferably legal person.
- ✓ UEC Member Secretary will be Ex-Officio members of the SAE Subcommittee

- The Head of the SAE Subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.
- In case of anticipated absence, the Head of SAE subcommittee will nominate a SAE subcommittee member as acting head.
- The acting Head will have all the powers of the Head of SAE subcommittee for that meeting.
- For the SAE Subcommittee meeting, a quorum will consist of at least four (4) members as follows - one member (preferably pharmacologist), one member (preferably clinician), Executive Secretary and Head/Acting head of the SAE subcommittee.
- The SAE subcommittee will meet as often as required.

12.4.3 Membership requirements

- UEC Members will be appointed to the SAE Subcommittee, if they show willingness and commitment to perform the role and responsibility as SAE Subcommittee member.
- The Chairperson of the UEC is responsible for appointing the SAE Subcommittee members.
- The tenure of SAE Subcommittee will be for a continuous period of 2 (two) years from the date of appointment.
- The retiring member will be eligible to be appointed for the new tenure consecutively four times.
- SAE Subcommittee member may resign from membership by submitting a letter of resignation to the Executive Secretary of the SAE Subcommittee. The member may or may not assign reasons for resignation.
- SAE Subcommittee member may be disqualified from SAE Subcommittee membership if the member fails to attend consecutively more than 5 (five) SAE Subcommittee meetings without prior intimation and the Head of SAE Subcommittee will inform Chairperson of UEC, in writing, about this.

- The Chairperson will discuss the issue of disqualification at the full committee meeting and allow the concerned SAE Subcommittee member to state reasons for the unauthorized absence.

12.4.4 Functions of the Executive Secretary of the SAE Subcommittee

1. To schedule and organize the SAE Subcommittee meetings.
2. To prepare and maintain meeting agenda and minutes.
3. To convene SAE subcommittee meetings
4. To prepare the communication letters related to the adverse event reports.
5. To communicate with the UEC members, regulatory authorities and investigators in timely manner.
6. To provide necessary administrative support for SAE Subcommittee related activities.
7. To ensure adherence of the SAE Subcommittee functioning as per SOPs

12.4.5. Onsite SAE

12.4.5.1 Receipt of SAE report

- The UEC Secretariat will receive the following documents within the specified time, if a SAE is experienced by any research participant.
  i. Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence as per the format specified in AX01/SOP12/V2.
  ii. Due analysis should be submitted by the PI and sponsor within 14 days from the occurrence of the SAE along with the format specified in AX02/SOP12/V2.
  iii. The follow up reports of all on-site SAE till the event is resolved.
  iv. The UEC Secretariat will ensure that the report is complete in all respects and that it has been received at the UEC office within the specified time limit.
  v. If the report has been received beyond the specified time, it will be considered as a protocol violation and appropriate action will be taken.
  vi. The UEC Secretariat will sign and write the date on which the report is received.
  vii. The Secretariat will forward these reports to the UEC Member Secretary or Executive Secretary of the SAE Subcommittee (if constituted) within two working days.

12.4.5.2 **Review and Decision on SAE Reports and Communication to PI and Regulatory Authority by UEC**

- Executive Secretary of the SAE committee will review the SAE report and present it to the SAE subcommittee (as applicable) for review and opinion.
- At the meeting of UEC or SAE subcommittee, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management, and financial compensation to be given to the research participants. The applicable formulae and guidelines as per regulation will be used for discussion.
- If deemed necessary, a decision to hold emergency UEC meeting may be taken to discuss about financial compensation. An emergency UEC meeting will be scheduled within 7 days for the same.
- The Executive Secretary of the SAE subcommittee may refer the SAE report to full committee for review if deemed necessary.
- The minutes of the SAE Subcommittee/UEC meeting will include the information on SAE at the site along with the opinion on the above points on the onsite SAE.

Participant ID	Letter no./and date of reporting	Type of Report (I/FU)*	Date of onset	whether study drug is withheld	SAE Outcome	Causality in the opinion of PI	Recommendation(s) by the SAE Sub-committee

*I-initial, FU- Follow-Up

The minutes will be circulated to the UEC members *via* email and approval/objection will be sought from the members in a period of 5 working days.

- The UEC secretariat will send a formal letter to the concerned PI and inform the UEC decision.
- This letter will be signed and dated by the Member-Secretary or Chairperson (UEC) and will be sent to the PI within a period of 7 working days from the date of the SAE subcommittee meeting.
- The PI will be requested to reply to the query letter on the SAE report within 7 working days.
- The opinion regarding relatedness, medical management and compensation for research related injury will be communicated by UEC to the Central Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE in case of regulatory clinical trials.
- The Secretariat will file a copy of these letters in the study file.

*12.4.*5.3. Reports of SAE Occurring at other Sites

The investigator will need to submit the report of SAEs occurring at other sites (CIOMS and SUSARS) in the form of soft copies only (CD) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:

Sr. No.	Country.	Type of Report (I/FU)*	SAE event	Date of onset	Date of report	Outcome	Causality	
							Investigator	Sponsor

*I-initial, FU- Follow-Up

- For every SAE term, a separate row of the above table is to be used (the SAE terms should not be combined).
- Causality to be stated as related (R) or not related (NR)
- The SAEs occurring at other sites will be reviewed by the Executive Secretary of the SAE Subcommittee, informed to other members and discussed in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites.

*12.4.*5.4 Onsite AE

The UEC Secretariat will receive the following documents pertaining to AE occurrence related to research proposals approved by the UEC:

1. The PI should submit annual onsite AE reports in the continuing review report.
2. In view of the risk assessment of a given research proposal the UEC will instruct adverse events to be reported (earlier, if deemed necessary) at specified timelines in the project approval letter.
3. The UEC Secretariat will ensure that the report is complete in all respects, and signed and dated by the PI and that it has been received at the UEC office within the specified timelines.
4. If the report has been received beyond that time, it will be considered as deviation.
5. For all the onsite AE reports received at the UEC office, the Secretariat of the institution will forward these reports to the Member Secretary of UEC for review.
6. Member Secretary of UEC will place the AE reports with action taken for discussion at full committee meeting.

7. Queries, if any, on the report will be communicated to the PI by the Member Secretary of UEC, following full committee meeting.
8. The Secretariat will file a copy of these letters in the study file.

***12.4.*5.5 Review During the Full *Committee* UEC meeting.**

- The UEC Member Secretary will read out the minutes of all the SAE subcommittee meetings including the recommendations/decisions of the SAE subcommittee.
- In case of the SAE occurring at the site to be discussed at the full committee meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to give their opinions and ensure free and frank discussion.
- The decision can be arrived at by consensus. If not agreed by consensus, the issue would be put for voting (a majority vote for a decision is 2/3rd majority of the members present and voting)

***12.4.*5.*6 Decision* of UEC on SAE review**

The UEC/SAE Subcommittee (if constituted) may take one or more of the following decisions on review of the SAE reports:

- Note the information about the SAE in records for future reference.
- Request further follow up information and/or additional details.
- Ask for periodic follow-up of the research participant till SAE is resolved
- Depending on complexities of issue, UEC/SAE Subcommittee may decide to seek opinion of outside expert/independent consultant who is requested to respond within 14 working days.
- Provide recommendations regarding/raise queries related to compensation for study related injury and death

Type of Actions Taken by UEC following full Committee review

- Suggest changes/amendments in protocol, Patient Information Sheet/Informed Consent Document/Investigators' Brochure/any other study related documents.
- Suspend the study until additional information is available.
- Suspend the study until review is completed (safety monitoring of ongoing patients to be continued).
- Suspend the study until amendments requested for by the UEC are carried out.

- Suspend enrolment 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.
- 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.
- Terminate the study.
- Any other appropriate action.

The decision shall be recorded in the minutes of the full committee UEC meeting. If the recommendation from the UEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigator's brochure) or re-consenting of research participants, the decision will be conveyed to the PI through telephone, fax or email within 24 hours. UEC Member-Secretary/secretariat will document such a communication in the related study file. A formal letter to the PI informing about the UEC recommendations in such situations will be sent within 5 working days of the IEC meeting having taken place.

12.5. Flowchart

No.	Activity	Responsibility
1	Receipt of SAE report	UEC Secretariat
2.	Submission of SAE report to the SAE Subcommittee	UEC Secretariat
3	Agenda and Minutes of the Subcommittee (if constituted)	Executive Secretary of the SAE Sub-committee (if constituted)
4.	Review and discussion of SAE report at the Subcommittee meeting (if constituted)	SAE Subcommittee members (if constituted)
5.	Review and discussion of SAE report at the full Committee meeting	Member Secretary of UEC

6.	Communication of the UEC decision about SAE review to the Licensing authority	Executive Secretary of the SAE Sub-committee (if constituted)/Member Secretary of UEC.
7.	Communication of the UEC decision about SAE review to the principal investigator	Executive Secretary of the SAE Sub-committee (if constituted)/ Member Secretary of UEC/UEC Secretariat

12.6. Annexures

Annexure 1: ***AX01/SOP12/V2*** – Reporting Serious Adverse Events (As per New Drugs and Clinical Trials Rule 2019)

Annexure 2: ***AX02/SOP12/V2*** - Checklist for Onsite Serious Adverse Event submission

Annexure 3: ***AX03/SOP12/V2*** – *Onsite* Serious Adverse Event Analysis Report

Annexure 1: AX01/SOP12/V_2

Reporting Serious Adverse Events Occurring in a Clinical Trial or Bioavailability or Bioequivalence Study

Patient details	
• Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc.)*	
• Gender	
• Age or date of birth	
• Weight	
• Height	
1. Suspected Drug(s) :	
• Generic name of the drug*	
• Indication(s) for which suspect drug was prescribed or tested.	
• Dosage 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 re-challenge information.	
• Setting (e.g. hospital, outpatient 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*	
• 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 2: AX02/SOP12/V_2
Checklist for Serious Adverse Event (SAE) submission (For Onsite SAE)

Sr. No.	Details		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death, Please tick (✓)**	**Death**	**Other than Death**
		Yes ☐ **No** ☐	**Yes** ☐ **No** ☐
		Give details	**Give details**
3.	**In case of Serious Adverse Event (SAE), please specify if there is any injury to the participant**		
4.	Protocol Title		
5.	Protocol Study No./ID/Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor (Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial/Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	**Patient Details**		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		

c)	Age and/or date of birth	
d)	Weight	
e)	Height	
13.	**Suspected Drug(s)**	
a)	Generic name of the drug	
b)	Indication(s) for which suspect drug was prescribed or tested	
c)	Dosage form and strength	
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)	
e)	Route of administration	
f)	Starting date and time of day	
	Stopping date and time, or duration of treatment	
14.	**Other Treatment(s)**	
	Provide the same information for concomitant drugs (including non-prescription/OTC Drugs) and nondrug therapies, as for the suspected drug(s).	
15.	**Details of the events**	
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.	
b)	Start date (and time) of onset of reaction.	
c)	Stop date (and time) or duration of reaction.	
d)	De-challenge and re-challenge information.	
e)	Setting (e.g., hospital, outpatient clinic, home, nursing home).	
16.	**Outcome**	

a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.	
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.	
c)	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.	
17.	**Details about the Investigator**	
a)	CT Site Number, if any	
b)	Name	
c)	Address	
d)	Telephone/Mobile Number & Email	
e)	Profession (speciality)	
f)	Date of reporting the event to Licensing Authority:	
g)	Date of reporting the event to Ethics Committee overseeing the site:	
h)	Signature of the Investigator	
18.	**Details about the Ethics Committee**	
a)	Name & Address	
b)	Name of Chairperson & Address	
c)	Telephone/Mobile Number	
d)	Email	
19.	Adverse Event Term/Details of SAE	
20.	Causality Assessment (Related/Unrelated) by Investigator.	
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO	

22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :	
23.		
a)	Duly filled SAE Form as per Appendix XI of Schedule Y	
b)	Laboratory investigations report/Discharge summary (if available and applicable)	
c)	Post-mortem report (if applicable)/Any additional documents)	

Note: Information not relevant to a particular SAE should be marked with NA

Annexure 3: AX03/SOP12/V_2
Serious Adverse Event (SAE) Analysis Report
(For Onsite SAE)

Sr. No.	Details		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death,** Please tick (✓)	**Death** **Yes** ☐ **No** ☐	**Other than Death** **Yes** ☐ **No** ☐
3.	**In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant**		
4.	Protocol Title		
5.	Protocol Study No./ID/Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor(Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial/Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	**Patient Details**		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		
c)	Age and/or date of birth		

d)	Weight	
e)	Height	
13.	**Suspected Drug(s)**	
a)	Generic name of the drug.	
b)	Indication(s) for which suspect drug was prescribed or tested.	
c)	Dosage form and strength.	
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).	
e)	Route of administration.	
f)	Starting date and time of day.	
g)	Stopping date and time, or duration of treatment	
14.	**Other Treatment(s)**	
	Provide the same information for concomitant drugs (including non-prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).	
15.	**Details of the events**	
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.	
b)	**Start date (and time) of onset of reaction.**	
c)	**Stop date (and time) or duration of reaction.**	
d)	**De-challenge and re-challenge information.**	
e)	**Setting (e.g., hospital, out-patient clinic, home, nursing home).**	
16.	**Outcome**	
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.	

b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.	
c)	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.	
17.	**Details about the Investigator**	
a)	CT Site Number, if any	
b)	Name	
c)	Address	
d)	Telephone/Mobile Number & Email	
e)	Profession (speciality)	
f)	Date of reporting the event to Licensing Authority:	
g)	Date of reporting the event to Ethics Committee overseeing the site:	
h)	Signature of the Investigator	
18.	**Details about the Ethics Committee**	
a)	Name & Address	
b)	Name of Chairman & Address	
c)	Telephone/Mobile Number	
d)	Email	
19.	Adverse Event Term/Details of SAE	
20.	Causality Assessment (Related/Unrelated) by Investigator.	
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO	

22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :	
23.		
a)	Duly filled SAE Form as per Appendix XI of Schedule Y	
b)	Laboratory investigations report/Discharge summary (if available and applicable)	
c)	Post-mortem report (if applicable)/Any additional documents)	

Details of payment for medical management of SAE?
(please give information who paid how much was paid, to whom, with evidence of the same)

What is the investigator's assessment for compensation amount to be paid?

What is the sponsor's assessment for compensation amount to be paid?

Has the participant made a claim?

Yes □ No □

If yes,
for how much amount _____
If no, please ensure that the participant/nominee have been made aware of his/her' rights regarding compensation. Please submit documentation regarding the same

_____

_____

Signature of the Principal Investigator:
Date:_____

13.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report submitted for studies approved by the University Ethics Committee (UEC).

13.2 Scope

This SOP applies to the review of the Study Completion Report, which is a written report of every completed study submitted by the Principal Investigator (PI).

13.3 Responsibility

It is the responsibility of the UEC Chairperson/Member Secretary/Members to review the study report and act on it.

13.4 Detailed instructions

13.4.1 Receipt of Study Completion Report

- The Secretariat will receive one copy (soft and hard) of Study Completion Report filled as per the format ***(AX01/SOP13/V_2)*** from the PI.
- The study completion report is expected from the investigator within 1 month of completion of the study at the site.
- The Secretariat will follow instructions (Management of Protocol Submission) for receiving and checking the report package.
- It is the responsibility of the UEC Secretariat to review the report for completeness.
- The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form and forward it to the Member Secretary within 7 working days of receipt.
- The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full committee meeting.
- If deemed necessary (e.g. a deviation/violation/non-compliance is noted), the Member Secretary will handle it.
- The Secretariat shall include the Study Completion Report Form in the agenda for UEC members for discussion at the full committee meeting.

13.4.2 Discussion in the Full Committee meeting

- The Member Secretary will present the report and members can discuss as needed.
- Following the discussion, the Chairperson may take one of the following decision:
    - Noted and accepted
    - Request for additional information/clarification

- The Secretariat will note the decision in the meeting minutes
- The Member Secretary will send a letter to the PI conveying decision on the study completion report.
- The study shall be considered as closed if the decision by UEC is "Noted and accepted".
- The Secretariat will accept and file the Report and get the Study Completion Report Form ***(AX01/SOP13/V_2)*** signed by the Chairperson.
- The final report will be placed in the master file and kept in the archival area.
- The Secretariat will archive the entire study for the required period from the date of completion of the project if the decision is noted and closed.

13.5 Flow chart

No.	Activity	Responsibility
1	Receipt of the study completion report	UEC Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	UEC Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to the Member Secretary	UEC Secretariat
4	Review of the Study completion report for completeness and informing members at full-board meeting	Member-Secretary
5	Inclusion of the report/review at full-board meeting	UEC Secretariat
6	Discussion and decision at the full board meeting	Chairperson
7	Noting the decision in the minutes of the Meeting	UEC Secretariat
8	Conveying decision to the Principal Investigator	UEC Secretariat
9	Archiving all the study-related documents along with the Study completion report	UEC Secretariat

13.6 Annexure 1: *AX01/SOP13/V_2* - Study Completion Report

Annexure 1: AX01/SOP13/V_2

Study Completion Report Form

(To be filled by principal Investigator)

UEC Project No.
Project Title: _____ _____
Principal Investigator
Department
Total no. of study participants recruited
Total no. of study participants approved by the UEC for recruitment
Duration of the study
*Results (summary) with Conclusion: (use extra blank paper, if more space is required). _____ _____
*Note: If the final report is not available from sponsor, it may be submitted later to the UEC on
Number of SAEs at our centre:
Whether all SAEs have been intimated to the UEC
No. of patients withdrawn: Reasons for Withdrawal of Patients: _____
Name and Signature of Principal Investigator:

Action taken:

□ Noted and accepted

□ Requires more information/action as follows:

_____

_____

UEC Meeting date (If reviewed in the meeting) _____

Final Decision: _____

Name and Signature of Member Secretary
with date:

14.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the University Ethics Committee (UEC) manages premature termination/suspension /discontinuation of a research study.

14.2. Scope

This SOP applies to any study previously approved by the UEC that has been recommended for termination/suspension/discontinuation before its scheduled completion.

14.3. Responsibility

It is the responsibility of the University Ethics Committee (UEC) to manage the termination/suspension/discontinuation of any study that was previously approved by UEC) recommended for termination by the Data Safety and Monitoring Board, Principal Investigator, Sponsor or other authorized bodies or by the UEC. The Secretariat is responsible for management of the process.

14.4. Recommendation for Termination/Suspension/Discontinuation

14.4.1 By PI/Sponsor

An investigator/Sponsor may put on hold a previously approved research when in the judgment of the investigator/Sponsor this is appropriate to protect the rights or welfare of participants or when new safety information has appeared in the literature, or evolved from this or similar research.

14.4.2 By UEC

UEC can prematurely terminate/suspend/discontinue the study in the following situations:

- Following protocol non-compliance/violation/non-compliance to ethical guidelines and related regulations/UEC policies UEC decides in full committee meeting to terminate/suspend/discontinue the study.
    - SAEs occurring may require the study to be prematurely terminated for the safety of the patients.
    - When research has been associated with unexpected serious harm to participants.
    - Zero accrual or low accrual for 1-2 years.
- Suspended protocols remain open for long time requiring continuing review.
- The UEC may revoke approval and terminate previously approved research protocol, which will now be considered closed no longer requiring continuing review.

14.5. Detailed instructions

14.5.1. Receipt of Recommendation for Study Termination.

The Secretariat will receive the study protocol termination/suspension/discontinuation report and verify the contents of the report for completeness and/or other documents like letter from PI/sponsor.

14.5.2. Review by the UEC

- The Secretariat will inform the Chairperson and Member Secretary regarding the recommendation for premature termination/suspension/discontinuation of study protocol and submit the report within 3 working days of receipt of the same.
- The Chairperson shall review the report and either call for an emergency meeting or discuss the report at the regular full committee meeting and the Secretariat will make arrangement accordingly.
- The Member Secretary in the meeting will inform members the reasons for the premature termination/suspension/discontinuation of the project.
- If the report is unclear or more information is required from the PI, the Chairperson shall instruct the Secretariat to seek clarifications/additional information from the Principal Investigator.
- The Chairperson shall acknowledge by signing with date the study termination/suspension/discontinuation report.
- If the UEC has revoked approval/suspended the study, regulatory authorities and Head of the institution must be informed within 14 working days after the full committee meeting.

14.5.3 Notifying the Principal Investigator

- The Secretariat will prepare a notification letter and send to the PI within 14 working days after the meeting acknowledging the approval of termination/letter seeking clarifications/information regarding the premature termination.
- In case, a letter is sent seeking clarifications/information regarding the premature termination/suspension/discontinuation, the PI shall send a written response within 30 days of receiving the letter.
- If the PI does not comply, the matter will be put to the full committee meeting for discussion.
- The investigator may appeal in person or respond to the convened UEC in writing.

14.5.4 Store the Protocol Documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file for archival.
- The protocol documents will be stored for a period of 3 years for biomedical and health research from the date of project Termination.

14.6. Flowchart

No.	Activity	Responsibility
1	Receive recommendation for study termination/suspension/discontinuation	UEC Secretariat
2	Review and Discuss the Termination/suspension/discontinuation report	UEC members, Member Secretary and Chairperson
3	Notify the Principal Investigator	UEC Secretariat
4	Store the Protocol Documents	UEC Secretariat

14.7. Annexure

Annexure 1: *AX01/SOP14/V_2* - Premature Termination/suspension/discontinuation Report.

Annexure 1: AX01/SOP14/V2
Premature Termination Report

UEC Protocol no.:			
Protocol title:			
Principal Investigator:			
Department:			
UEC approval date:		Date of last Annual/Periodic status report submitted to UEC:	
Date of initiation of Study:		Termination/suspension/discontinuation date:	
No. of participants enrolled:		No. of participants completed:	
No. of ongoing participants:		No. of drop outs: Reason for each drop-out:	
SAEs (total no.): _____	Whether SAEs were timely reported to the UEC? Yes ☐ No ☐		
Brief summary of results: (use extra blank paper, if more space is required) _____			
Reason(s) for termination/suspension/discontinuation: _____			
Signature of Principal Investigator with date: _____			

Discussed at the UEC meeting held on _____

Action taken:

Approval of the Premature Termination/suspension/discontinuation of the project/requires more information/action as follows: _____

_____

Name and Signature of Chairperson, UEC
with date.

15.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the University Ethics Committee (UEC) may grant waiver of written or verbal informed consent.

15.2 Scope

This SOP applies to the all protocols submitted for review by the UEC that ask for consent waiver.

15.3 Responsibility

It is the responsibility of the UEC to review and approve a request for verbal/written consent waiver. The Member Secretary will record the decision in the minutes and in the Application Form. The Chairperson will sign and date letter conveying the decision.

15.4 Detailed instructions

- The Application Form (*AX01/SOP15/V_2*) is designed to standardize the process of applying for waiver of written/verbal consent.
- When a request for waiver of consent is received from the Principal Investigator (PI) to the UEC in the given format, the following steps are taken:
  - The UEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.
  - The UEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- The UEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.
- The final decision whether to grant the waiver is taken at a full committee meeting unless the project is considered under expedited review.
- The decision regarding approval/disapproval of waiver is informed to the PI in writing. If the waiver is not granted, the UEC will provide reasons for the same.

15.5 Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents	UEC Secretariat
2	Review of protocol and application for waiver of consent	UEC Members
3	Decision regarding waiver of consent	UEC Members during full committee meeting
4	Communicate the decision to the Investigator	UEC Secretariat
5	Recording and filing the decision	UEC Secretariat

15.6 Annexure

Annexure 1: *AX01/SOP15/V_2* Application form for requesting waiver of consent

Annexure 1: AX01/SOP15/V_2

Application form for requesting waiver of consent

A request to waive written informed consent must be accompanied by a detailed explanation justifying waiver. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants.

1. **Principal Investigator's name:** _____
2. **Department and Address:** _____
   _____
   _____
3. **Title of project:** _____
   _____
   _____
4. **Names of co-investigator(s) and Department(s) with address:**
   _____
   _____
5. **Request for waiver of informed consent:**

- Please tick the reason(s) for requesting waiver
  1. research cannot practically be carried out without the waiver and the waiver is scientifically justified
  2. retrospective studies, where the participants are de-identified or cannot be contacted
  3. research on anonymized biological samples/data
  4. certain types of public health studies/surveillance programmes/ programme evaluation studies
  5. research on data available in the public domain
  6. Humanitarian emergency situations or disasters as described in ICMR Guidelines
  7. Any other (please specify)

  _____
- Statement assuring that the rights of the participants are not violated

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

  _____

Principal Investigator's signature with date: _____

Final decision at full committee meeting held on: _____

Waiver granted Yes ☐ No ☐

If not granted, reasons

_____

_____

_____

Signature of the Chairperson with Date: _____

16.1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for monitoring and oversight of an UEC approved protocol.

16.2. Scope

This SOP applies to all UEC approved studies for which off-site and a routine or for-cause on-site monitoring may be undertaken by the UEC.

16.3. Responsibility

It is the responsibility of the UEC or Chairperson and Member Secretary to decide to conduct off-site and on-site monitoring. If further required, it is the responsibility of the designated UEC member(s) to perform on-site monitoring of selected study site(s).

16.4. Detailed instructions

The monitoring process involves two major oversight activities as given below:

- Off-site monitoring/oversight - Review done by Ethics Committee during full Committee meetings on quarterly, half yearly and annual progress report depending on the risk involved and duration of the study.
- On-site monitoring/oversight - Review at random done by Member Secretary in consultation with the Chairperson and if deemed necessary, assessed by UEC designated members for on-site routine or 'for-cause' monitoring.

16.4.1. Off-sight Monitoring

This will be done on three (3) monthly basis for protocols of 6 months' duration and on six (6) monthly/annual basis for those of longer duration. The selection of files for review will be picked at random.

- UEC requirements
    - Compliance with approved protocol and conditions if any
    - Maintenance and confidentiality of records
    - Progress reports and completion report
    - Publications if any during period of study
    - Whether information is submitted for -
        - Any proposed changes in protocol

- Any unforeseen events that might ethically be unacceptable for continuing the project and would require amendments
- Any new information positive or negative from related studies

- A report will be prepared addressing any shortcomings and non-conformities observed by suggesting corrective and preventive action. The report will be sent to PI for clarification and correction and submitted to UEC for review and appropriate course of action as continuation/discontinuation/suspension/ termination.
- The report has to be filed for Record.

16.4.2. On site monitoring

Selection of study sites

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Committee, which is recorded in the UEC decision form *and* in the UEC minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the UEC, after approval by the Chairperson.
- The reasons for identifying a particular site for "*for-cause monitoring*" could include any one or more of the following:
    - Large number of Protocol deviations,
    - Protocol violations even after initial warning,
    - Large number of studies carried out at the study site or by the investigator,
    - Large number of Serious Adverse Events (SAE) reports,
    - High recruitment rate,
    - Complaints received from participants or any other person,
    - Frequent failure to submit the required documents,
    - Any other cause as decided by UEC.

16.4.2.1 Before the visit

- Irrespective of the cause for conducting monitoring the following procedure will be followed:
    - The Chairperson will identify and select one or more UEC members (henceforth referred to as monitors) to conduct monitoring of a site.

- The selected members will be given an appointment letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson
- The Secretariat will decide the date of the monitoring in consultation with the monitors and the PI.
- The final date will be communicated to the PI and monitors (with a request to be available).
- The monitor will receive from secretariat the relevant reference material and/or project documents, review them and make appropriate notes/ changes.

- Monitors will carry with them Site Monitoring Visit Report Forms collected from the Secretariat.

16.4.2.2 During the visit

- The Monitor will follow the check list and:
  - check the log of delegation of the team, responsibilities of study team,
  - check if the site is using latest UEC approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
  - observe the informed consent process, if possible,
  - review randomly selected participants' files to ensure that participants are signing the correct informed consent,
  - check if the investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study), storage times, conditions and acceptability of expiry dates and if sufficient supplies are available, wherever applicable,
  - verify that the investigator follows the approved protocol and all approved amendment(s), if any,
  - ensure that for clinical trials the investigator and the investigator's trial staff are adequately informed about the trial,
  - verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the

investigator/institution, and have not delegated these functions to unauthorized individuals,

- verify that the investigator is enrolling only eligible subjects,
- determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events,
- review the project files of the study to ensure that documentation is filed appropriately,
- review the source documents for their completeness, and
- collect views of the study participants, if possible,

- The Monitor will fill the Site Monitoring Visit Report Forms (if applicable), sign with date.

16.4.2.3 After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Forms (if applicable) to the UEC secretariat within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).
- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next UEC full committee meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The UEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
  - Continuation of the project with or without changes,
  - Restrictions on enrolment,
  - Recommendations for additional training,
  - Recruiting additional members in the study team,
  -
  - Revising/ providing qualifications/ experience criteria for members of the study team,
  - Termination of the study,
  - Suspension of the study, etc.
- If the Monitor has findings that impact on safety of the participant, the Monitor will inform the Member Secretary on the same day. The Member Secretary will

discuss with the Chairperson and any one of the actions described above will be taken.

- The final decision taken at the full board UEC meeting will be recorded in the Site Monitoring Visit Report Form.
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

16.5. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	UEC Member Secretary / Chairperson
2	Identification of UEC members for monitoring during meeting	Chairperson
2	Inform Principal Investigator in writing	Secretariat
3	Review of UEC protocol file prior to visit and collect Site Monitoring visit report from UEC office	UEC member(s)
4	Review or monitoring of site	UEC member(s)
5.	Complete the monitoring report and present in UEC meeting	UEC member(s)
6.	Communication of UEC decision to PI	Secretariat

16.6. Annexures

Annexure 1: *AX01/SOP15/V_2* - Site Monitoring Visit Report

Annexure 2: *AX01/SOP15/V_2 - Monitoring* of Audio-visual recording of AV consent Process

Annexure 1: AX01/SOP16/V_2

Site Monitoring Visit Report

(Please tick the box corresponding to the answer)

UEC project no.	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Type of study: ☐ Investigator initiated ☐ Pharma ☐ Thesis ☐ Government agency ☐ Others (Specify)	

Date of UEC approval: Date of Initiation of the study: Duration of study:
Reason for monitoring: ☐ Routine ☐ For-cause (State reason) ☐ Protocol Violations/Deviations ☐ SAE reporting ☐ Recruitment rate ☐ Other _____

Last monitoring done, if any, ☐ Yes __ ☐ No Date of last meeting:
Project Status: 1. Ongoing ☐ 2. Completed ☐ 3. Recruitment Completed ☐ 4. Follow-up, extension study ☐ 5. Suspended ☐ 6. Terminated ☐ In case the response to the above question is option 5 or 6, kindly provide reason(s): _____
Recruit status: _____ Total patients to be recruited_____ Screened _____ Screen failure _____ Enrolled _____ Withdrawn _____ Reason _____ Discontinued_____ Reason _____ Completed Active

Are the present study team members as per the list approved by the UEC? ☐ Yes ☐ No	Comment:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Is the recent version of Informed Consent Document (ICD), after UEC approval, used? ☐ Yes ☐ No	Comment:
Whether appropriate vernacular consent has been taken from all patients? ☐ Yes ☐ No	Comment:
Any other findings noted about the ICDs? ☐ Yes ☐ No	Comment:
Is recent UEC approved version of protocol used? ☐ Yes ☐ No	Comment:
Has the eligibility, inclusion/ exclusion criteria been adhered to? ☐ Yes ☐ No	Comment:
Was informed consent process witnessed?	Comment

Were participants interviewed?	Comment
Any adverse events found? □ Yes □ No	Comment:
Any SAEs found? □ Yes □ No	Comment:
Were the SAEs informed to UEC within timelines specified by CDSCO? □ Yes □ No	Comment:
No. of deaths reported: o Deaths unrelated to participation in the trial: o Deaths possibly related to participation: o Deaths related to participation in the trial: Any other non-death study related injury	 _____ _____ _____ □ Yes □ No □ NA Comments (If Any) _____ _____
Compensation paid for study related injury or death	□ Yes □ No □ NA Comments (If Any)
Are there any protocol non-compliance deviations/violations? □Yes □ No	Comment:

Have the protocol non-compliance deviations/violations been informed to UEC? □ Yes □ No	Comment:
Are all Case Record Forms up to date? □ Yes □ No	Comment:

Are storage of data and investigating products locked? □ Yes □ No	Comment:
How well are the participants protected? □ Good □ Fair □ Not good	Comment:
Any other remarks □ Yes □ No	Give details:
Duration of visit:_____ hours	Starting from: Finish:
Name of the study team member(s) who were present: Signature _____ Date:	
Name of UEC members and representatives who attended monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the UEC meeting held on _____

_____

Signature of Chairperson, UEC with date

Annexure 2: AX02/SOP16/V$_2$

Monitoring of Audio-visual recording of AV consent Process

1. Facility where informed consent process carried out - (well lit, free from noise, privacy ensured):
    - Yes _____ No_____
    - Remarks: _____
2. The consent is taken in a language that participant/LAR understands best and is literate in.
    - Yes _____ No_____
    - Remarks: _____
3. Introduction of each person (one conducting the informed consent, discussing participant/legally acceptable representative (LAR)/impartial witness) involved during informed consent process and information about necessity for audio-visual recording
    - Yes _____ No_____
    - Remarks: _____
4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.
    - Yes _____ No_____
    - Remarks: _____
5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
    - Yes _____ No_____
    - Remarks: _____
6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the UEC.
    - Yes _____ No_____
    - Remarks: _____

7. Explanation or narration by the person conducting the informed consent discussion, specially risk, benefit, compensation, withdrawal, contact details for queries.
    - Yes _____ No_____
    - Remarks: _____
8. Questions asked by the potential participant/LAR are answered satisfactorily.
    - Yes _____ No_____
    - Remarks: _____
9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.
    - Yes _____ No_____
    - Remarks: _____
10. Reading out by the participant/LAR (or having read out by impartial witness), the statements mentioned in Informed Consent and stating whether participant agrees or not with each statement.
    - Yes _____ No_____
    - Remarks: _____
11. Documentation of signatures of all those involved in the Informed Consent Process.
    - Yes _____ No_____
    - Remarks: _____
12. Clarity and completeness of AV recording
    - Yes _____ No_____
    - Remarks: _____
13. Storage of recording in password protected laptop/desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.
    - Yes _____ No_____

- Remarks: _____

17.1 Purpose

The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint(s) related to their participation in research approved by the University Ethics Committee (UEC).

17.2 Scope

This SOP applies to handling of requests for information/complaints made by participants concerning the rights and well-being of the research participants in research studies by the UEC.

17.3 Responsibility

It is the responsibility of the UEC Secretariat and Chairperson/Member Secretary to initiate the process of giving information asked by research participants or to address any injustice that has occurred, if any complaints are received.

17.4 Detailed instructions

1. A request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the UEC Member Secretary after entering into the request record form.
2. The Member Secretary may also receive a request, complaint or query directly from the participant. The Member Secretary will record it in the request record form and notify the Secretariat.
3. The Member Secretary will additionally ascertain details of the request/complaint by examining any relevant documents and by interviewing the participant, if necessary.
4. If required, the Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).
5. The Secretariat will inform the Chairperson about the request, query or complaint received from the research participant.
6. In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairperson, will provide the information herself/himself or will designate one or more UEC member(s) to provide such information.
7. In case of a complaint received from a research participant:
   - The Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the

seriousness of the matter, the Chairperson will direct the Member Secretary to:

- Appoint a sub-committee of two or more UEC members for enquiry in order to resolve the matter.
- Call an emergency meeting of two or more UEC members for discussion
  or
- Consider the matter for discussion at the next full committee meeting.

- The Chairperson/Member Secretary/designated UEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The UEC will insist on factual details to determine gap, if any, between truth and individual perception.
- Opportunity will be given to complainant and the accused to make submissions.
- If the matter is serious, it will be brought to the attention of the Head of the institution who in consultation with the Chairperson will make a decision. For this the Chairperson will provide the following:
  a. the complaint
  b. material reviewed in the Chairperson's investigation
  c. the results of the Chairperson's investigation
  d. any other relevant documentation.

- If the Head of the institution feels that, the matter needs further investigation she/he could set up a panel for that purpose.
- The possible procedures include the following,
  a. Noting on the file about the occurrence of the matter
  b. Requirement for amendments to the project, including increased monitoring by the UEC
  c. Suspension of the project
  d. Termination of the project
  e. Other action to resolve the complaint.

- If the complainant is not satisfied with the outcome of the Chairperson's investigation, then she/he can refer the complaint to the Head of the institution or her/his nominee, or request that the Chairperson do so.
- The information including any action taken or follow-up and final decision will be recorded in the form and signed with date.

- The UEC members will be informed about the action taken and the outcomes in the forthcoming UEC meeting and minuted.
- The Secretariat will place all documents in the relevant study file.

17.5 Flowchart

No.	Activity	Responsibility
1.	Receiving the request/query/complaint from research participant	UEC Member Secretary/Member
3.	Initiating process to identify the problem	UEC Chairperson/Member Secretary
4.	Deliberations to arrive at solution	UEC Chairperson/Member Secretary/Members
5.	Communication with the research participant	UEC Secretariat
6.	File the request document	UEC Secretariat

17.6 Annexure

Annexure 1: **AX01/SOP17/V_2** - Request/Complaint Form

Annexure 1: AX01/SOP17/V_2

Request/Complaint Form

Date:	
Received by :	
Request/Complaint received through:	• Telephone No. _____ • Fax No. _____ • Letter/Date _____ • E-mail/Date _____ • Walk-in/Date/Time_____ • Other, specify _____ _____
Participant's Name:	
Contact details **Address** **Phone:**	
UEC Project no.	
Title of the Project	
Starting date of participation	
Information requested/complaint/query	
Action taken	
Reviewed by	
Final Decision	
Date of UEC meeting (if applicable)	

_____ _____

Name & Signature of Member Secretary **Date**

18.1. Purpose

To provide instructions for preparation and maintenance of active study files and other related approved documents, UEC administrative documents, archival of closed files and retrieval of documents.

18.2. Scope

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and UEC administrative documents by the UEC Secretariat.

18.3. Responsibility

It is the responsibility of Member Secretary with assistance of the Secretariat to ensure that all active study files and UEC records are prepared, maintained during the study period and kept securely for the prescribed period after the closure/termination of the project.

18.4. Detailed instructions

18.4.1. Record/database of new proposals

The UEC secretariat will maintain written and electronic record of each application received in following manner:

a) assign unique project identification number
b) name of the PI(s) and Co-PIs
c) name of the responsible institution or organisation
d) title of the project
e) date of review in UEC meeting and the decision(s) taken at this meeting
f) decision of UEC with date
g) date of re-review of any changes/amendments to the project
h) decision: approval with suggestions, if any, or non-approval with reasons
i) type of approval, whether by expedited or full committee review.

18.4.2 Maintenance of the Active Study Files

- A study master file is prepared comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the UEC office.

• All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of,

- All original research proposals reviewed and approved,
- Reviewer's assessment forms
- Agenda of UEC meetings
- Minutes of the UEC meeting
- Study approval letter
- Reviewed and approved consent documents,
- Amendments and any other correspondence
- Decision of re-submitted proposal with amendments
- Study progress reports, interim reports and final report on completion
- Serious adverse event report forms submitted by investigators,
- DSMB and monitoring reports
- Any other reports and/or publications
- UEC correspondence
- Index page of serially arranged contents to be pasted inside the cover of the file

Note:

- Strict confidentiality will be maintained for the contents of the files
- All active files will be kept secured in a file cabinet with controlled access.
- A logbook for accessing the files by authorized staff & members will be maintained.

18.4.3. Maintenance of the UEC Administrative Records

The UEC records will include the following:

18.4.3.1. UEC members' records

a) Appointment letter of each member with,
   - terms of reference regarding term of appointment,
   - role in UEC
   - acceptance letters/emails or other evidence with receipt by member signed and dated.

b) Signed and dated confidentiality and COI agreements.

c) Updated Curriculum vitae (hard copy or soft copy) with sign and date and evidence of qualifications.

d) Training records for each UEC member (Human research protection, GCP, SOP)
e) Documentation of resignations/terminations

18.4.3.2. UEC membership roster - An UEC roster will be maintained which will contain:

a) Names of UEC members/experts
b) Age and gender
c) Qualifications
d) Role in UEC
e) Status of affiliation to institution (e.g., unaffiliated or affiliated)
f) Regular/Alternate member to the UEC (if applicable)
g) Correspondence related to changes in UEC membership with DCGI (CLA), CDSCO or DHR or any other concerned authority
h) UEC attendance roster
i) Agenda and Minutes of UEC meetings

18.4.4. Other documents

a) Standard operating procedures (SOPs)
b) Progress reports
c) Final reports
d) UEC reference material
e) Incoming and outgoing correspondence register
f) Documents related to Workshops & conferences organized by UEC
g) Continuing education for members & staff
h) SOP training and distribution logs
i) CD of soft copy, if any and related documents of each proposal.

18.4.5. Maintenance of Closed Study Files

- Once the study file is closed (following completion/premature termination), the related study files will be shifted to the UEC Archival room.
- All closed study files will be archived in the UEC archival room for a period of three years/five years/more from the date of closure of the study as per CDSCO/DHR/Sponsor requirement.
- A log book for archival of study documents will be maintained.

18.4.6. Accessibility/Retrieval

- Study files and administrative records will be made available for audit, making photocopies (if requested by investigator) or any other purpose (e.g., research on SAEs) on request if authorized by Member Secretary/Chairperson in the Request Form (AX01/SOP18/V_2).
- Representatives of regulatory authorities may have access at all times.
- A logbook of retrieval of documents will be maintained.

18.4.7. Disposal of Closed Files and Copies of Protocols and Documents Submitted for UEC Review

- At the end of the archival period, the closed files will be shredded and disposed of by authorized UEC personnel.
- Extra copies of protocols and documents submitted for UEC review and any other extra copies, will be shredded by authorized UEC secretariat personnel after the UEC meeting without any notification to PI.
- A formal disposal log will be maintained, providing details of documents that will be disposed.

18.5. Flowchart

No.	Activity	Responsibility
1	Organize the contents of the active study files	UEC Secretariat
2	Maintain the active study files and Administrative Documents	UEC Secretariat
3	Archival of Study files	UEC Secretariat
4.	Authorising retrieval of archived Documents	Chairperson/ UEC Member Secretary
5.	Disposing closed study files and maintaining Document disposal log	UEC Secretariat

18.6. Annexures

Annexure 1: AX01/SOP18/V_2 - Document Request Form

Annexure 2: AX 02/SOP18/V_2- Log for disposal of study documents

Annexure 1: AX01/SOP18/V_2

Document Request Form

Project No.:	
Project Title:	
Name of Principal Investigator (PI) :	
Requested by :	
Documents requested :	
Purpose of the Request	
Signature of Requesting person:	
Signature of PI:	
Signature of Member Secretary/ Chairperson with date:	

Annexure 2: AX02/SOP18/V_2

Log for disposal of study documents

Project No.	Title	Name of Principal Investigator	No. of files	Date of UEC Approval	Date of Study Initiation	Date of Study Closure	Disposed by (Name & Sign) of Authorized Individual

19.1. Purpose

This Standard Operating Procedure (SOP) describes the requirements and process of review of research that involves vulnerable participants.

19.2. Scope

This SOP covers the policies and procedures applied to all research proposals submitted to the UEC that involve vulnerable participants.

19.3. Responsibility

- It is the responsibility of the Member Secretary with Secretariat to maintain up-to-date tools, like checklists, for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines.
- UEC Chairperson/Member Secretary are responsible for ensuring that UEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programmes.
- The Member Secretary/Chairperson is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research and for identifying consultants having expertise for specific review as and when required.
- UEC members are responsible for review of research planned for vulnerable populations, including an assessment of potential for coercion.

19.4. Definition and Mandate

19.4.1 Definition

See in glossary and ICMR Guidelines, 2017

19.4.2 Mandate

Gazette notification dated 19th March, 2019 [G.S.R. 227(E)] has mandated audio-visual recording of informed consent process in case of vulnerable participants in clinical trials of new chemical entity/new molecular entity except for anti HIV and anti-leprosy drug trials, where audio recording would suffice. The UEC should exercise particular care to protect the rights, safety and well-being of all vulnerable subjects participating in the study.

19.5. Detailed instructions

19.5.1. Reviewing protocols with vulnerable participants

- The protocol should be reviewed following the procedure prescribed from time to time.
- Additionally, the protocol should be reviewed to assess whether the following points are addressed:
    - Can the research be performed in any other non-vulnerable participants?
    - Is there justification to use vulnerable population?

- Do the benefits justify the risks?
- Are the participants selected equitably?

- Have the measures to protect Autonomy of the vulnerable population been described?
- UEC members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study.
- The review must address all points in the checklists for different vulnerable populations.

19.5.2. Appointing Reviewers

The Member Secretary/Chairperson will appoint two or more members of the UEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols.

19.5.3 Duties of Secretariat

- Provide a suitable checklist to the investigator depending on the type of participants to be recruited for the study.
- Provide appropriate reference material including National Ethical Guidelines of ICMR, 2017 or help reviewer locate the material relevant to vulnerable populations when specifically requested for, by a reviewing member.

19.5.4. Responsibilities of Reviewers

- UEC Members will review the protocol and the informed consent document or assent form as per SOPs.
- The UEC members will discuss the comments in the UEC meeting.
- The discussion will be documented in the minutes.
- The Member Secretary will ensure that the UEC recommendations have been incorporated in the revised protocol and protocol related documents.

19.5.5. Approval of the protocol

- The final version of the protocol will be approved/recommended for modification/disapproved at a full committee meeting.
- Letter regarding approval/modification/disapproval will be sent to the PI.
- Wherever necessary the UEC approval should state that, if in future the vulnerability status of the participant changes, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant would be re-consented.

19.6. Flow Chart

No.	Activity	Responsibility
1	Appoint reviewers	Chairperson/Member Secretary
2	Review the protocol	UEC members
3	Discussion at UEC meeting	UEC member
4	Communicating the decisions to principal investigator	UEC Secretariat

19.7. Annexures

NOTE: The following annexures apply to some sections of vulnerable participants. These checklists should be filled in by principal investigator and should be reviewed by UEC members. Appropriate modifications should be made as per UEC requirement

Annexure 1*:* AX01/SOP19/V_2 – Checklist: Requirements for Research Involving Children
Annexure 2: AX02/SOP19/V_2 – Checklist: Requirements for Research Involving Pregnant Women & Foetuses
Annexure 3: AX03/SOP19/V_2 – Checklist: Research Involving Cognitively Impaired Adults
Annexure 4: *AX04/SOP19/V_2* – Checklist-Research Involving Students, Employees or Residents
Annexure 5: *AX05/SOP19/V_2* – Checklist: Considerations for Genetic Research

Annexure 1: AX01/SOP19/V_2

Checklist: Requirements for Research Involving Children

Name of Principal Investigator:

Study Title:

For the principal investigator		UEC Office
Risk Determination	**Benefit Assessment**	**UEC Action**
Less than minimal risk	Not identifiable	Approvable
Minimal *	Direct benefit	Approvable
	Indirect benefit to community/society	
Minor increase over minimal risk (low risk)	Potential benefit to child.	Approvable
Greater than minimal risk (high risk)	Indirect benefit, offer knowledge about child's condition/disorder	Approvable on case – by- case basis**

** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life of a healthy individual or occurring during the performance of routine physical or psychological examinations or tests.*

*** Consent of both parents may be needed, as applicable*

	Yes	No	NA
1. Does the research pose greater than minimal risk to children?	☐	☐	☐
If yes: Are convincing scientific and ethical justifications given?	☐	☐	☐
If yes: Are adequate safeguards in place to minimize these risks?	☐	☐	☐
2. Does the study involve healthy children?	☐	☐	☐
If yes: Is the inclusion of healthy children justified?	☐	☐	☐
3. Are the prior studies conducted on animals and adults appropriate and justified?	☐	☐	☐
If No: Is the lack of studies conducted on animals and adults justified?	☐	☐	☐
4. Will older children be enrolled before younger ones?	☐	☐	☐
5. Is permission of both parents necessary?	☐	☐	☐
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" is described?	☐	☐	☐
If Yes: Are the conditions acceptable?	☐	☐	☐
6. Will efforts be made to ensure, that parents' permission to involve their children in research studies to be obtained, is free from coercion, exploitation, and/or unrealistic promises?	☐	☐	☐
7. Are provisions to obtain the oral assent of children over 7 and up to 12 and also honouring their dissent?	☐	☐	☐
8. Are provisions to obtain the written assent of children over 12 and up to 18 and also honouring their dissent?	☐	☐	☐
9. Are provisions to protect participants' privacy and the confidentiality of information regarding procedures?	☐	☐	☐
10. Are there special problems that call for the presence of a monitor/UEC member/legal appointee during consent procedures?	☐	☐	☐
11. Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?	☐	☐	☐

12. Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	☐	☐	☐
13. Does the research involve possibility of findings, which may have implications for other family members? (for e.g. genetic risk, HIV infection, Hepatitis C)	☐	☐	☐
If Yes: Are there adequate mechanisms in place to deal with other members of the family?	☐	☐	☐
14. Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)	☐	☐	☐

Name and Signature of Principal Investigator: _____

Date _____

UEC Office use only	
Comments of Primary Reviewer:	
Primary Reviewer Name and Signature and Date	

Annexure 2: AX02/SOP19/V_2

Checklist: Requirements for Research Involving Pregnant Women and Foetuses

Name of Principal Investigator:

Study Title:

When research involves pregnant women or foetuses	Yes	No	NA
1. Where scientifically appropriate pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted, which provide data for assessing potential risks to pregnant women and foetuses?	☐	☐	☐
2. Is the risk to the foetus not more than minimal?	☐	☐	☐
3. If the risk more than minimal caused solely by interventions or procedures, that hold out the prospect of direct benefit for the woman or the foetus?			
4. Any risk that is the least possible for achieving the objectives of the research.	☐	☐	☐
5. Is the woman's consent or the consent of her legally authorized/acceptable representative, obtained in accordance with the informed consent provisions, unless altered or waived?	☐	☐	☐
6. Is the woman or her legally authorized/acceptable representative, fully informed regarding the reasonably foreseeable impact of the research on the foetus or resultant child?	☐	☐	☐
7. Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?	☐	☐	☐
8. Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?	☐	☐	☐
9. Do individuals engaged in the research have a part in determining the viability of a foetus?	☐	☐	☐

When research involves neonate after delivery	Yes	No	NA
1. Are scientifically appropriate, preclinical, and clinical studies, conducted, which provide data for assessing potential risks to neonates?	☐	☐	☐

2. Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?	☐	☐	☐
3. Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?	☐	☐	☐
4. Do individuals engaged in the research have any part in deciding as to the timing, method, or procedures used to terminate pregnancy?	☐	☐	☐
5. Do individuals engaged in the research have a part in determining the viability of a foetus?	☐	☐	☐
A.Foetuses of uncertain viability	**Yes**	**No**	**NA**
1. Does the research hold out the prospect of enhancing the probability of survival of the particular foetus to the point of viability?	☐	☐	☐
2. Any risk least possible for achieving the objectives of the research?	☐	☐	☐
3. The purpose of the research is development of important biomedical or healthcare knowledge, which cannot be obtained by other means. Will there be a risk to the foetus from the research?	☐	☐	☐
4. Is the legally effective informed consent of either parent of the neonate (or if, neither parent is able to consent because of unavailability, incompetence or temporary incapacity, is the legally effective informed consent of either parent's legally authorized/acceptable representative's consent), obtained?	☐	☐	☐
B.Nonviable foetuses	Yes	No	NA
1. Will vital functions of the neonate be artificially maintained?	☐	☐	☐
2. Is there any risk to the neonate resulting from the research?	☐	☐	☐
3. The purpose of the research is the development of important biomedical and healthcare knowledge that cannot be obtained by other means	☐	☐	☐
4. The legally effective informed consent of both parents of the neonate obtained? (waiver and alteration provisions do not apply here). 5. If either parent is unable to consent because of non-availability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable foetus will meet the requirements.	☐ ☐	☐ ☐	☐ ☐

(a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women and/or foetuses.

(b) The research will be conducted in accordance with applicable regulatory and ethical guidelines.

Name and Signature of Principal Investigator: _____

Date _____

UEC Office use only	
Comments of Primary Reviewer:	
Primary Reviewer's Name and Signature and Date	

Annexure 3: AX03/SOP19/V2

Checklist- Research Involving Cognitively Impaired Adults

Name of Principal investigator:

Study Title:

A. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant** (All items requires "Yes")		
1. Is the recruitment of participants justified considering the rationale and objectives of the study?	Yes	No
2. The risk is justified by the anticipated benefit to the participants.	☐	☐
3. The relation of anticipated benefit to the risk is at least as favourable to the participants as that presented by available alternative approaches.	☐	☐
4. Will the participants be withdrawn, if they appear to be unduly distressed?	☐	☐
5. The proposed plan for the assessment of the capacity to consent is adequate.	☐	☐
6. Consent will be taken from participants capable of being consulted.	☐	☐
7. Does document include provision for the consent a parent(s)/legally authorized/acceptable representative in case participants are not capable of being consulted?	☐	☐

B. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant ((All items requires "Yes")		
	Yes	No
1. Is the recruitment of participants justified considering the rationale and objectives of the study?	☐	☐
2. Are the foreseeable risks to the participants low?	☐	☐
3. Is the negative impact on the participant's well-being minimized and low?	☐	☐
4. Will the participants be more closely monitored?	☐	☐

5. Will the participants be withdrawn, if they appear to be unduly distressed?	☐	☐
6. The proposed plan for the assessment of the capacity to consent is adequate.	☐	☐
7. Consent will be taken from participants capable of being consulted.	☐	☐
8. Does the consent document include provision for a legally authorized/acceptable representative in case participants are not capable of being understanding the implications?	☐	☐

Name and Signature of Principal Investigator: _____

Date _____

UEC Office use only	
Comments of Primary Reviewer	
Primary Reviewer Name and Signature and Date	

Annexure 4: AX04/SOP19/V_2

Checklist: Research Involving Students, Employees, or Residents

Name of Principal Investigator:

Study Title:

	Yes	No
1. Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	☐	☐
2. Have the risks to participants been minimized?	☐	☐
3. Have participants been assured that participation is voluntary (no signs of coercion)?	☐	☐
4. Have participants been assured that privacy and confidentiality will be protected?	☐	☐

Answers to all the above points should be YES for approval

Name and Signature of Principal Investigator: _____

Date _____

UEC Office use only	
Comments of Primary Reviewer	
Primary Reviewer Name and Signature and Date	

Annexure 5: AX05/SOP19/V2

Checklist: Considerations for Genetic Research

Name of Principal Investigator:

Study Title:

	Yes	No
1. Will the samples be made anonymous to maintain confidentiality? If yes, then the following checklist points are not applicable	☐	☐
2. Will the results be disclosed? If yes, has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?	☐	☐
3. Will the results be used in management of current condition of patient?	☐	☐
4. Has the appropriateness of the various strategies for recruiting participants and their family members been considered?	☐	☐
5. Does the proposed study population comprise family members?	☐	☐
6. Will family members be implicated in the studies without consent?	☐	☐
7. Will the samples be destroyed in the future?	☐	☐
8. Will the samples be used for future research	☐	☐
9. Is pre-test and post-test genetic counselling being offered?	☐	☐

Name and Signature of Principal Investigator: _____

Date _____

UEC Office use only	
Comments of Primary Reviewer	
Primary Reviewer Name and Signature & Date	

20.1. Purpose

The purpose of this SOP is to guide Ethics Committee (UEC) to prepare for an audit or inspection of the UEC.

20.2. Scope

The SOP applies to all the UEC members and the Secretariat.

20.3. Responsibility

It is the responsibility of the Member Secretary, Chairperson, UEC Members and the UEC Secretariat to keep UEC documents ready for audit and to be available to answer questions during audit or inspection by administrative and regulatory authorities.

20.4. Definitions and Mandate

20.4.1 *Audit:*

i. A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

ii. Audit of a Trial- A systematic verification of the study, carried out by persons not directly involved, on:

(a) Study related activities to determine consistency with the Protocol

(b) Study data to ensure that there are no contradictions on Source Documents.

(c) The audit should also compare data in the Source Documents with the interim or final report. It should also aim to find out if practices were employed in the development of data that would impair their validity.

(d) Compliance with the adopted Standard Operating Procedures (SOPs).

20.4.2. *Inspection:*

An official review/examination conducted by regulatory authority/authorities of the documents, facilities, records and any other resources that are deemed by the authority/authorities to be related to the study. The inspection may be carried out at the site of the trial, at the sponsor's/or CRO's facilities and Ethics Committee verify adherence to Good Clinical Research Practice.

20.5. Detailed instructions

20.5.1 Receipt of notification of an Audit/Inspection

On receipt of written/mailed communication regarding audit/inspection visit, the Member Secretary will inform the Chairperson, UEC members and if applicable the Head of Institution, about the date and purpose of the audit/inspection.

20.5.2 Preparing for the audit

- On receiving information about the audit/inspection, UEC Member Secretary and/or UEC member/s are given the responsibility by the Chairperson to prepare for the visit with assistance of the Secretariat.
- The Member Secretary and/or designated UEC member/s will make arrangements in accordance with the steps mentioned in the checklist.
- The studies with incomplete/missing documents will be dealt with separately and actions taken will be documented.
- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

20.5.3 On the day/s of Visit

- Chairperson/Member Secretary/designated UEC Member/s should welcome and accompany the auditors/inspectors to the reserved meeting room.
- Designated team members must be present in the meeting room.
- The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information needed.
- The UEC Chairperson/Member Secretary/UEC Members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.
- The information and files requested by the auditors/inspectors should be made available by the Secretariat.
- The Member Secretary/designated UEC member/Secretariat will make note of the comments, recommendation of the auditors/inspectors.

20.5.4 Correction of deficiencies observed at audit/inspection

- Member Secretary/designated UEC member/Secretariat will review comments and recommendations of the auditor/inspector.
- On receipt of Audit/Inspection report, the Chairperson should implement corrective and preventive actions and set the timeline for implementation of corrections as stated by the auditor/inspector.
- The Member Secretary/designated UEC member should communicate to the auditor/inspector the action plan after seeking approval of the Chairperson.
- If deemed necessary, the Chairperson will decide a review date for an internal follow-up audit.

- The Member Secretary/designated UEC member/s should report the outcome of the internal follow-up audit to the Chairperson.

20.5.5 Recording the Audit/Inspection Visit

- The Member Secretary, designated UEC member and the Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.
- The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.

20.6. Flow Chart

No.	Activity	Responsibility
1	Receipt of Audit/Inspection notification	UEC Member Secretary
2	Preparing for the audit	UEC Member Secretary/designated UEC member(s)/Secretariat
3	Presenting information and files to auditor/inspector	UEC Member Secretary/member(s)/ Secretariat
4	Review comments/recommendation of auditor/inspector	UEC Member Secretary/member(s)/ Secretariat
5	Receipt of audit/inspection report	UEC Member Secretary/Member(s)
6	Planning corrective/preventive actions and setting timeline for their implementation	UEC Chairperson
7	Conducting internal follow-up audit	UEC Member Secretary/member(s)
8	Recording the Audit/Inspection Visit	UEC Member Secretary/Secretariat

20.7. Annexure

Annexure 1: *AX01/SOP20/V_2* - Audit and Inspection Checklist

Annexure: AX01/SOP20/V_2

Audit and Inspection Checklist

1. Date of letter of communication regarding audit/inspection:
2. Date(s) on which the audit/inspection has been agreed on:
3. To ensure the UEC members and staff have been informed about the date/s and time.
4. To ensure availability of UEC related information–mandate, terms of reference, organisation chart (in the print form) in the UEC office.
5. To make sure of availability of latest copy/copies of signed SOPs in print form in the office and/or in electronic form.
6. To review the SOPs and note details of any omissions or deviations, with reasons.
7. To ascertain availability of all national and international ethics guidelines and regulations in print form and/or in electronic form in the UEC office.
8. To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/incomplete documentation and actions taken.
    - Records regarding applications of research studies for review including protocols and related documents
    - Record of Protocol Assessment Forms – Comments of UEC members, Meeting Agenda,
    - Minutes (documented in individual study file or separately as meetings file)
    - Communication records with investigator (documented in individual study file)
    - Amendment Approvals (documented in individual study file)
    - SAE reports and SAE related communications with investigator and regulators.
    - Protocol deviation/violation/exception reports (documented in individual study file)
    - Continuing and final completion/termination reports (documented in individual study file)
9. To ensure availability of documents regarding list of members, appointment details like tenure, CVs, baseline and periodic training of UEC members.
10. To ensure availability of documents regarding appointment, CVs and training of staff of secretariat.
11. To ensure measures for maintaining security of electronic database and office records.

12. To make sure that maintenance, retrieval, storage, archival and tracking of the study files is done as per the respective SOPs.
13. To ascertain proper labelling and indexing of study files and storage cabinets.
14. To decide which members will communicate with auditors/inspectors, be available for audit/inspection, prepare action plan and conduct follow-up internal audit (if applicable)
15. To report to UEC members at the full committee meeting about findings in the audit/inspection report received.
16. To make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable.

21.1. Purpose

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the University Ethics Committee (UEC) members and the Secretariat.

21.2. Scope

The SOP applies to assessment of all the UEC members and the Secretariat.

21.3. Responsibility

It is the responsibility of the UEC Chairperson, with the assistance of Member Secretary, to ensure that there is adequate initial and continued training of the UEC members and the staff of the Secretariat. The Chairperson is responsible for assessment of all UEC members and a complete self-assessment exercise at prescribed intervals.

21.4. Detailed instructions

21.4.1. Topics for training

a) UEC members should have knowledge of the following:
   - Relevant ethical guidelines and relevant regulatory requirements/guidelines.
   - Roles and Responsibilities of UEC members.
   - Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy.
   - Recent Developments in relevant Health Science specialities.
   - SOPs of the UEC.

b) Secretariat should have knowledge and relevant skills for conducting the following activities:
   - Competency in working on Microsoft word and similar software, Excel and similar software, UEC office software etc.
   - Maintenance of UEC Database and archiving.
   - Communication skills - written and verbal.
   - Knowledge about the SOPs.

21.4.2. Training of new UEC Members

a) Every time a new committee is constituted, the members must undergo initial training on ethical guidelines, ethics in clinical research and Good Clinical Practice Guidelines and SOPs, unless they are not already trained. Refresher training will be provided at least once in every year.

b) Member Secretary or an UEC member will provide an introductory training to the new members. They would be encouraged to undergo EC training programme too, within six months of joining as members.
c) The Chairperson, UEC Member Secretary, and members will be encouraged to receive continued training by participating in a workshop, conference and/or re-training program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
d) The UEC will conduct workshops on ethical guidelines, ethics in clinical research and Good Clinical Practice Guidelines from time to time to impart training to the UEC Members and the Institutional faculty members.
e) The UEC may sponsor or reimburse the expenses of UEC members for attending conference, continuing education session workshop and/or training program (if applicable).

21.4.3. Training of the Secretariat

- The UEC Member Secretary along with other members will train the Secretariat on SOPs.
- There will be initial training and at least one training session per year on SOPs.
- The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

21.4.4. Assessment of UEC members

- The Chairperson should evaluate the UEC members' performance once a year using an assessment form.
- The Chairperson should also undergo self-assessment once a year.

21.4.5. Maintenance of training records of the UEC Members and the Administrative Staff

- The Secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual UEC members.
- The copies will be filed in the individual members' files.
- Copies of the records regarding training of the Secretariat will also be maintained in their respective files.

21.5. Flow Chart

No.	Activity	Responsibility
1	Training of UEC Members	UEC Chairperson/Member Secretary
2	Assessment of performance of Members including Member Secretary	UEC Chairperson
3	Assessment of performance of Chairperson	UEC Chairperson (self-evaluation)

21.6. Annexures

Annexure 1- AX01/SOP21/V_2*:* Self-Assessment Form for UEC Member Secretary/Member

Annexure 2- AX02/SOP21/V_2*:* Self-Assessment Form for UEC Chairperson

Annexure 1: AX01/SOP21/V_2

Assessment Form for Ethics Committee Members

1. Current tenure.	
2. Terms served.	
3. Training received.	
4. Training given to other members.	
5. Type of training received.	
6. No of meetings attended.	
7. No of projects reviewed per meeting as primary reviewer	
8. No of projects reviewed per meeting as secondary reviewer.	
9. Participation in SAE report review process.	Yes/No
10. Participation in site monitoring visits.	Yes/No
11. Number and type of continuing training workshops organised for UEC members. (applicable to Member Secretary)	
12. Number and type of continuing training workshops organised for staff of the UEC secretariat (applicable to Member Secretary)	
13. Any other significant contribution to the field of research ethics.	
14. Remarks by the Chairperson.	

***Annexure 2:* AX02/SOP21/V_2**

Self-Assessment Form for UEC Chairperson

1. Current tenure	
2. Terms served	
3. Training received	
4. Type of training received	
5. No. of meetings held in current year	
6. No of meetings attended	
7. Whether quorum requirement fulfilment was ensured in UEC meetings	
8. Whether issues related to conflict of interest considered	
9. Whether any other issues of serious consequences addressed	
10. Any significant contribution to the field of research ethics	
11. Any other comments	