# **EthicsCommittee**of the
# **Sarojini Naidu Medical College**

STANDARDOPERATINGPROCEDURES

**InAccordancewithThe Declaration ofHelsinki (2000)**

**&**

**TheICH GCP (E6)Guideline&**

**ICMR Guideline forBiomedicalResearch onHuman Participants (2007)**

**&**

**Schedule 'Y'**


**IssueDate: 10-06-2020**
**EffectiveDate: 10-06-2020**
**Version: 1.0**

**Reviewed By:**

**Acceptedby:**

Dr.A.S Sachan Dr. Chandra Prakash Pal
**ChairmanEthicsCommittee(EC)MemberSecretary Ethics Committee**

## Table of Contents

## 1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committees (EC). The SOPs 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.

## 2. SCOPE

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ethics committee.

## 3. RESPONSIBILITY

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

**Secretariat of Ethics Committee**

- Assist Chairperson to formulate an SOPTeam
- Co-ordinate activities of writing, reviewing, distributing and amendingSOPs
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according tocurrent
- Version of SOPs maintains an up-to-date distribution list for each SOP distributed to the ECmembers.
- Maintain a register to record the names of investigators to whom SOPs aredistributed
- Maintain a file of all current SOPs and the list ofSOPs
- Maintain a file of all past SOPs of theEC

**SOP Team**

- Assess the request(s) for SOP/s revision in consultation with the Member Secretary and Chairperson
- Propose new / modified SOP/ s asneeded
- Draft the SOP/s in consultation with the IEC members and involved administrativestaff
- Review the draftSOP
- Submit the draft for approval toChairperson

**Chairperson of the ethics committee:**

- Reviews and approves theSOPs
- Signs and dates the approvedSOPs

## 4. FLOWCHART

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

## 5. Detailed instructions

***Chairperson ofEC***

- Appoint one or more SOPTeams
- Approve theSOPs
- Sign and date the approvedSOPs

•***5.2 List all relevantprocedures***

- Write down step by step all the procedures of the IEC that are to be standardized in the form of anSOP
- Organize, divide and name eachprocess

***Format andlayout***

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

XX - Two digit numbers assigned specifically to the SOP.
VV - version with one digit number identifying the version of the SOP
W is a one digit number identifying the version of SOP with minor changes in the SOP.
The number of version should be started from 01 and the W should be started with 0, for example, SOP 01/V7.0 is the SOP number 1 version 1 with one minor revision i.e. V7.0.
Each SOP will be prepared according to the standard template.

***Write and approve newSOP***

- A draft will be written by the member secretary/ member of the SOPteam
- The draft SOP will be discussed with the other members of the SOPteam

- The final version will be passed to the Chair person for review andapproval.

***Implement, distribute and file allSOPs***

- The approved SOPs will be implemented from the effectivedate.
- The approved SOPs will be distributed to the EC members and the relevantstaff by the *Secretariat.* When revised version is distributed, the old version will be retrieved from the members and destroyed. However, one copy of the old version will be retainedat theSecretariat.

***Review and request for a revision of an existingSOP***

- Any member of the ethics committee, secretariat or administrative staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form (Annex-2) in to make arequest.
- If the SOP Team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the person who made the request of thedecision.
- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section5.4).

***Manage and archive supersededSOPs***

- SupersededSOPsshouldberetainedandclearlymarked"superseded"andarchivedinthe historical file by the *secretariat***.**

**6. Glossary**

| | |
|---|---|
| SOP (StandardOperating Procedure) | Detailed, written instructions, in a certain format, describe all activities and action undertaken by an organization toachieve uniformity of the performance of a specificfunction.<br><br>The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice. |
| IECmembers | Individuals serving as regular and alternate members onthe Institute's Ethical Committee. These committees are constituted in Accordance with the EC membership requirements set forth in ICH GCP and Schedule Y |
| SOP Team | A selected committee of the members of S.N Medical College, Agra Ethics Committee and administrative staff who oversee the creation, preparation, review and periodic revision of the instituteSOPs. |
| MasterSOP files | An official collection of the institute standard operating procedures (SOP) accessible to all staff, IEC members, auditors and government inspectors as a paper copy with an official stamp on first and last page and the approvalsignatures. |

## 7. References

WHO Operational Guidelines for Ethical Review Committee That Review Biomedical Research (Geneva 2000www.who.int/tdr/publications/publications/-accessed 11 February 2005)

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## 8. ANNEX

| | | |
|---|---|---|
| ANNEX 1 | List of SOPs | EC/01/V7.0 |
| ANNEX 2 | Template for SOP | EC/02/V7.0 |
| ANNEX 3 | Document History | EC/03/V7.0 |
| ANNEX 4 | Log of SOP Recipients | EC/04/V7.0 |
| ANNEX 5 | Request for Revision of an SOP | EC/05/V7.0 |

**ANNEXURE1** **AF/EC/01/V1.0**

**LIST OF STANDARD OPERATING PROCEDURES VERSION-7.0**

**INDEX**

**ANNEXURE2** AF/EC/02/V1.0

Page 1 of 2

**Standard Operating Procedures Template**

Ethics Committee, S.N Medical College, Agra

*Title:* Title which is self-explanatory and is easilyunderstood
SOPCode: *SOP/xx/vv.w* EffectiveDate:
Page:… of ….

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

---

Supersedes:

Authors: Date:……
*(Name).*

Reviewers:

Approved by:
*(Name)*

Chairperson

Signature withDate

---

**Table of CONTENTS**

---

**ANNEXURE-2** AF/EC/02/V1.0

**Main Text:**

1. **Purpose:** summarizes and explains the objectives of theprocedure.
2. **Scope** – states the range of activities that the SOP appliesto.
3. **Responsibility** – refers to person(s) assigned to perform the activities involved in theSOP
4. **Flow chart** – simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for eachactivity
5. **Detailed instructions** – describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorterones.
6. **Glossary** – clarifies uncommon or ambiguous words or phrases byexplanation.
7. **Reference** – lists sources of the information given in theSOP.
8. **Annexure-** documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard tounderstand.

**ANNEX3** AF/EC/03/V1.0

**Document History**

(The final version is the version after the approval by the Chairperson which is V1.0)

| **Author –** | **Version** | **Date** | **Describe the main change** |
|---|---|---|---|
| Name | V7.0 | dd-mm-yy | final version |
| Name | V7.0 | dd-mm-yy | Minor changes |
| Name | V7.0 | dd-mm-yy | Major changes |
| Name | V7.0 | No change | (routine review) |

**ANNEX4** EC/04/V7.0

**Log of SOP Recipients**

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

**ANNEX5** AF/EC/05/V1.0

**Request for Revision of an SOP**

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

*SOP/01/V7.0*

Title:

Details of problems or deficiency in the SOP:

Identified by: Date (D/M/Y):

Discussed with:

SOP revisionrequired: ☐☐Yes ☐☐No

If yes, to be carried out bywhom?

If no, why not?

Date SOP re-finalized:

Date SOP approved:

Date SOP becomes effective:

## Table of Content

The Ethics Committee, S.N Medical College is constituted by The Head of the Instuitios S.N Medical College

## 1. Purpose

The Ethics Committee, S.N Medical College was established on 2020 in order to formalize and specify the Institution's commitment to promotion of high ethical standards in patient care, professional education, clinical research, and community interests.Applicable to all clinical trials including Bioavailability / Bioequivalence (BA/BE) studies, Phase I,II,III,IV studies, Non Therapeutic and Non interventional studies, other than research projects conducted at S.N Medical Hospital .

All Research involving human subjects should be conducted in accordance with ethical principles, which includes,

- Voluntarinism
- InformConsent
- Privacy
- Confidentiality
- Riskminimization
- Professionalcompetence

EC will have both scientists and non-scientists which are appointed by the Head of the Institute of S.N Medical College and Hospital.

## 2. Scope

The SOP applies to the functioning of all activities under the Ethics Committee; S.N Medical CollegeThis includes the basic responsibilities of the EC, composition, appointment of the members and conduct of the meeting.

## 3. Responsibility

- The EC shall allow inspectors or officials authorized by the CDSCO to enter itspremises to inspect records, data or any documents related to clinical trials and provide adequate replies to any query raised by such inspectors orofficials.
- The EC will apply to the CDSCO/ Drug Controller General (India) office to renewthe registration, 3 months prior to the expiry of the awardedregistration
- The EC would regularly inform the CDSCO/ Drug Controller General (India) officeof change in the membership / constitution of the ethicscommittee.
- The EC will respond to the CDSCO / Drug Controller General (India)within 90 daysof receipt of any suspension or cancellation registrationintimation.
- Toensurethecompetentreviewandevaluationofallethicalaspectsofresearch Projects received to ensure compliance with the appropriate laws and safeguard welfare ofsubjects.
- Education of professional, administrative, and support staff about ethical issues Creation, developing revising and implementing ethical guidelines(SOPs)

- Initiate studies in ethics continuing education and training programs to ensure that EC members are qualified to perform their specificduties.

**4. Flowchart**

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Ethical basis and mandate | EC Members, Secretariat |
| 2 | Composition of the EC | Head of the Institute of S.N Medical College and Hospital. |
| 3 | Appointment of EC members | Head of the Institute of S.N Medical College and Hospital. |
| 4 | Membership Requirements | EC Members and Secretariat |
| 5 | Resignation, Disqualification, Replacement of Members | Head of the Institute of S.N Medical College and Hospital. EC Members and Secretariat |
| 6 | Independent Consultants | Head of the Institute of S.N Medical College and Hospital. |
| 7 | Conditions of Appointment | EC chairman and Secretariat |
| 8 | Secretariat includingsupportive staff | Head of the Institute of S.N Medical College and Hospital.Charge in consultation with the EC Secretary. |
| 9 | Quorum Requirements | EC Members and Secretariat. |

**** Please note that EC members includes the Chairperson for all practical purposes unless otherwise specified.***

**5. Detailed Instructions**

- **Ethical basis andMandate**
  - The IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations.
  - Ethics Committee (EC) will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. To ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner, the EC may refer to the SOPs and Guidelines of the EC – S.N Medical College .It will ensure that universal ethical values and international scientific standards are followed in terms of local community values andcustoms.
  - It is a dictum that the goals of research, however important, should never be permitted to override the health and well being of the researchparticipants.

EC will only review the research proposals (clinical trials, basic research, socio- behavioural or operational studies), which are conducted at theInstitute.

- EC is entrusted not only with the initial review of the proposed research proposals prior to initiation of the projects but also have a continuing responsibility of regular monitoring of the approved projects to foresee the compliance of the ethics during the period of the project. Such an ongoing review shall be in accordance with the international guidelines whereverapplicable.
- EC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objectivemanner.

- **Composition of the EC :** Appendix VIII of Sch- Yof Drugs and cosmetics Act, 1940 and rules 1945

| S.No | Name of members | Address | Qualification | Current Designation | Affiliation | Role | Gender |
|---|---|---|---|---|---|---|---|
| 1. | Dr. A.S.Sachan | Department of TBCD,SNMC, Agra | MD T.B.C.D | Prof &ex H.O.D. T.B.C.D. | **No** | **Chairman** | **Male** |
| 2. | Dr.Raj Kamal | National JALMA Institute for leprosy and other Mycobacterium Disease, Tajganj, Agra | M.D Paediatrics and Neonatology | DY. Director **Scientist E ,** Head of Department of Clinical Medicine, National JALMA Institute for leprosy and other Mycobacterial Diseases | **No** | **Basic Medical Scientist** | **Male** |
| 3. | Dr. Arti Agarwal | Department of Microbiology, SNMC, Raja mandi, Agra | M.D Microbiology | Head of Department of Microbiology | **Yes** | **Basic Medical Scientist** | **Female** |
| 4. | Dr. Santosh Kumar | Department of T.B and Chest Disease , S.N.M.C., Raja Mandi, Agra | M.D Chest Medicine | Professor and Head of Department of T.B and Chest Disease | **Yes** | **Clinician** | **Male** |
| 5. | Dr. Ajeet Singh Chahar | Department of Medicine S.N.M.C., Raja Mandi, Agra | M.D Medicine | Assistant Professor Department of Medicine | **Yes** | **Clinician** | **Male** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6. | Dr. RuchikaGarg | Department of Obstetrics and Gynaecology , S.N.M.C., Raja Mandi, Agra | M.D Obstetrics and Gy-naecology | Associate Professor Department of Obstetrics and Gynaecology | **Yes** | **Clinician** | **Female** |
| 7. | Dr. Amrita Gupta | Department of Anaesthesia S.N.M.C., Raja Mandi, Agra | M.D. Anaesthesia | Associate Professor Department of Anaesthesia | **Yes** | **Clinician** | **Female** |
| 8. | Dr. NituChauhan | Department of Transfusion S.N.M.C., Raja Mandi, Agra | M.D Pathology | Head of Department of Transfusion Medicine | **Yes** | **Basic Medical Scientist** | **Female** |
| 9. | Dr. Vipin Kumar Mangal | Department of Pharmacology , S.N.M.C., Raja Mandi, Agra | M.D. Pharmacology | Head of Department of Pharmacology | **Yes** | **Pharmacologist** | **Male** |
| 10. | Sri Om Prakash Singh | H.No 351 ,Sec-9 AwasVikasColony,Sikandra –Agra | B.A | LIC | **No** | **Lay Person** | **Male** |
| 11. | Dr. Rajshree Bhargava | Samadhan Kendra 20/4, Maruti Tower(near Shaheed Smarak), Sanjay Place, Agra-282002 | PhD in psychology | Director, samadhan kendra, centre for psychological assessment, councelling, special education | **No** | **Member – Philosopher & Social Scientist** | **Female** |
| 12. | Dr. S.S Roy | Law department, Agra college | Assistant Professor | Law Department ,Agra College | **No** | **Legal Expert** | **Male** |
| 13. | Dr.ChandraPrakash Pal | Department of orthopaedics, S.N.M.C., Raja Mandi, Agra | M.S Orthopaedics | Head of Department of Orthopaedics | Yes | **Member Secretary** | Male |

**Alternate members:**

- The EC should nominate alternate Chairperson who can be selected from the non-institutional EC members. The alternate Chairperson can oversee / conduct the meeting in the absence of theChairperson.
- Considering the fact that there may be conflict of interests when the Member Secretary is the Principal Investigator/ co-investigator or is absent from the meeting, the EC may consider appointing alternate Member Secretary who should be the institutional EC member.
- The alternate member of required speciality (Legal Expert, Clinical Pharmacologist, Community Member) can be selected for fulfilling the quorum, in case the present member is not able to attend the meeting due to unprecedented prior commitments and the meeting is to be held on the sameday.

- Alternate members are suggested by the EC and nominated by the Head of the Institute of S.N Medical College and Hospital

- Membership requirements

In the interest of the Institute's research program, the EC members including the Chairperson, Member Secretary will be selected by the Head of the Institute of S.N Medical College and Hospital / Officer-in- Charge taking into consideration their expertise, research interests and experience in ethics.

- ❖ Selected members should possess the necessary research experience- scientific knowledge and expertise; knowledge of ethics, and their commitment and willingness to volunteer the necessary time and effort for the IECwork.
- ❖ Community members will be selected based on the basis that they are willing to publicize full name, profession and affiliation. Their Curriculum Vitaes should be submitted to the EC office forrecords.
- ❖ The Chairperson and the EC members should be informed of the potential members by the Member Secretary in the meeting and their concurrence should beobtained.
- ❖ Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal underconsideration.
- ❖ The EC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision, Refer to SOP/03/V1.0 - Confidentiality / Conflict of InterestAgreement.
- ❖ Members will be required to sign a confidentiality agreement at the start of theirterm. Members are appointed for a period of 3 years and the theMember Secretary will also serve the tenure for 3 years. On completing the tenure of the Member Secretary, he/she will be appointed as a member for a period of 6 months for ensuring smooth transition and the necessary help to the Member Secretary as per the decision of the Head of the Institute of S.N Medical College and Hospital
- ❖ The new member secretary should be affiliated member for at least six months before taking up thecharge.Their appointments may be renewed by the Head of the Institute of S.N Medical College. S.N Medical College of the Ethics Committee, S.N Medical College for up to two consecutive terms or as required by the Head of the Institute of S.N Medical College
- ❖ The Ethics Committee will include some rotation in appointment of new members after a period of 03-years, but it will also strive to ensure continuity within the EC. At no point of time will more than 25% of members bereplaced.
- ❖ For institutional Ethics Committee members, it is mandatory that the new members will act as observers for at least three meetings prior to their induction into theEC.

- **Resignation, Disqualification, Replacement ofMembers**

 Membersmayresigntheirpositionsbysubmittingaletterofresignationtothe Chairperson.

 Members may also be disqualified from continua nce in the followingcircumstances:

  - Absence for three consecutivemeetings
  - Should the Chairperson provide written arguments to the (other) members and there is unanimousagreement
  - Member does not comply to the responsibilities set for the members (stubborn- sets up stage for argument/ non-punctual/ not thorough with the jobassigned)
  - Relocate to another city or any suchmatter.

 Members that have resigned or have been disqualified may be replaced by Head of the Institute of S.N Medical College/ Officer-in-Charge.

- **Independent Consultants–**

- The EC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.

- Independent Consultants are suggested by the Chairperson of the EC in consultationwith the Member Secretary and appointed by the Head of the Institute of S.N Medical College/ Officer-in- Charge.
- Their professional qualifications may be in the areas of community and/or patient representation, or subject experts unique to the study proposal under ethics review. Subject experts could be invited to offer their views, based on the requirement of research area, for example HIV, genetic disorders *etc*. it is desirable to include a member from specific patient groups in the Committee. Independent Consultants are appointed only for the review of the study sought. They will not be able to vote or be involved in decision-making.
- Independent Consultants may attend the meeting via teleconference /Vidioconference

- **Conditions of Appointment**
- Chairperson, Member Secretary, Members, Alternate Chairperson, Alternate Members and Independent Consultants are appointed to the EC under the followingconditions:
- Willingness to abide by the requirements laid in theSOP
- Willingness to publicize his/her full name, profession, andaffiliation;
- All financial accountability, reimbursement for work and expenses, if any, within or related to the EC should be recorded and made available to the public uponrequest;
- All EC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants and relatedmatters
- An investigator can be a member of the IEC; however, the investigator-as-member cannot participate in the review and approval process for any project in which heor she has presence as a PI, Co-PI or CI or potential conflict ofinterest.

- **Officers and theirresponsibilities**

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

**Chairperson:**

He/She is responsible to chair the meetings and liase directly with the Head of the Institute of S.N Medical College/Officer-in Charge of the Institute, report the meeting outcomes to the Head of the Institute of S.N Medical College, invite independent consultants to provide special expertise to the EC on proposed research protocol. He/She should work in close co-ordination with the Member Secretary, review and sign along with the member secretary all the minutes, proposals and work towards the smooth function of the EC.

**Alternate Chairperson** :

He/She should be a highly respected individual preferably from outside the institution, fully capable of managing the EC and the matters brought before it with fairness and impartiality, in absence of the Chairperson.

**Member Secretary**:
He is responsible for the administrative aspect of the EC (see 5.8 - below)

**Alternate Member Secretary**:
He is responsible for the proceedings of the meeting in the absence of the member secretary/ if member secretary has conflict of interest for a study under review.

**The EC Administrative Staff: Working Rules**

1. There will be administrative officer/s and attendant/s /helper/s who will helptheEC Chairperson and Member Secretary in executing functions of the EC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the EC. The eligibility criteria for new staff to be appointed will belaid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications may be recommended by EC members duringregularEC meeting and will be recorded in minutes; these are forwarded to the Head of the Institute of S.N Medical College
2. The administrative staff will be appointed by conducting formal interviews (to be conducted by panel of experts appointed by Head of the Institute of S.N Medical College
   a. Duties of the administrativeofficer/s/staff
   b. Correspondence with the EC members and externalexperts
   c. Correspondence with theinvestigators
   d. Pre and post arrangements of ECmeetings
   e. Preparing agenda and minutes of the ECmeetings
   f. Answering queries of theinvestigators
   g. Filing study relateddocuments
   h. Archiving and maintaining the studyfiles

3. Duties of the attendant/s/helper/s
   a. Assisting the secretariat in arranging the ECmeetings
   b. Dispatching sets of study documents to EC members and externalexperts
   c. Receiving the study related documents from and dispatching the ECletters to theinvestigators
   d. Filing study relateddocuments
   e. Archiving and maintaining the studyfiles
   f. Correspondence with the EC members and externalexperts
4. The administrative staff will report to the Chairperson and/or MemberSecretary.
5. The office timing for the administrative staff will be as per S.N Medical College
6. The administrative staff will avail leave as per S.N Medical College.

**Secretariat**

7. The Secretariat is composed of the Member Secretary and the administrative supporting staff which includes a full time peon, ethics analyst and lower division clerk. It is mandatory that the clerical assistant and peon should be a permanent employees to ensure efficient record keeping and retrieval of documents. The supporting staff are appointed by the Head of the Institute of S.N Medical College

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

- Organizing an effective and efficient tracking procedure for eachproposal received
- Preparation, maintenance and distribution of studyfiles
- Allocation of project reviews to specific members to facilitate efficient dispensation of theprojects.
- Organizing EC meetingsregularly
- Preparation and maintenance of meeting agenda andminutes
- Receive and check for the completeness of the documents for review by theEC.
- Co-ordinate with the investigators for the translation (English-Hindi) of the PIS andICDdocuments.

**Maintaining the EC's documentation and Archival**

- Communicating with the IEC members and investigatorapplicants
- Arrangement of training for personnel and IECmembers
- Organizing the preparation, review, revision and distribution of SOPs (see SOP/01/V1.0)
- Work in unison with the EC members and the investigators to reduce the turn-around time of the study proposals sent to the EC forreview.
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committeemembers.

- **Roles and Responsibilities of EC members**
- Regularly attend and actively participate in the ECmeetings
- Review, discuss and consider research proposals submitted for evaluation. Reveiwers for each proposal will review the study. Later, if any other issues the other EC members can voice theircomments/suggestions.
- Monitor serious adverse event reports and recommend appropriate action(s) Review the progress reports and monitor ongoing studies asappropriate.
- Evaluate final reports andoutcomes
- Maintain confidentiality of the documents and deliberations of EC meetings. Declare any conflict ofinterest
- Participate in continuing education activities in biomedical ethics and biomedical research
- If deemed necessary, should suggest any changes that may be necessary to be included in the SOPs of theEC.
- Conduct monitoring visits for any research proposal, ifneeded.

- **QuorumRequirements:**
  - A minimum of five members or one third of the total members must be present at a meeting besides Member Secretary and Chairperson in order to issue a valid advice and/or decision, provided quorum is met.
  - Professional qualifications of the quorum requirements should consistof:
  - One legalexpert
  - OneClinician
  - One socio-behaviouralscientist/ one basic scientist depending on the projectsto

- bediscussed
- At least one member who is independent of the institution/researchsite.
- At least one member whose primary area of expertise is in a non-scientific area i.e. lay person or communitymember
- As per revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials should have in the quorum at least one representative from the followinggroups:
  - ❖ One basic medical scientist (preferably onepharmacologist).
  - ❖ Oneclinician
  - ❖ One legalexpert
  - ❖ One social scientist/ representative of non-governmental organisation/ philosopher/ ethicist/ theologian or a similarperson
  - ❖ One lay person from thecommunity.

- **Dissolving of theEC**
  - At any point in time, should the Institute cease to exist, the EC is automatically dissolved.
  - The EC may also be dissolved at any time by the the Head of the Intuition /Officer-in-Charge of the S. N Medical College following written notification to each of the members

**6. Glossary**

**Confidentiality:** Prevention of disclosure, to other than authorized individuals, of EC/IRB's Information and documents

**IEC:** InstitutionalEthicsCommittee is an independent body (either a review board or committee) whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.

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

**7. References**

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP)1996.
- Schedule Y 2005 and2013.
- Forum for Ethical Review Committees in Asia and the Western PacificSOPs2006
- ICMR Ethics Guidelines2006

**8. ANNEX**

ANNEX 1 Document History EC/01/02/V7.0

**ANNEX1** **EC/01/02/V7.0**

**Document History**

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

## Table of Content

**1. Purpose andApplication:**

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

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

- Ethics Committeemembers;
- Permanent, temporary and part time employees of EthicsCommittee;
- Contractedstaff;

**2. Scope**

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the Ethics Committee,S.N Medical College-Agra

**3. Responsibility**

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

**4. Flowchart**

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

**5. Detailed instructions:**

It will be the policy of the Ethics Committee, S.N Medical College, Agra that every member including the Chairperson, the alternate Chairperson and the alternate members sign the Confidentiality/Conflict of Interest Agreement with date. Even though the member discontinues being a part of the Ethics Committee, S.N Medical College, Agrafor Clinical Studies, he/she will have to maintain confidentiality which will be valid for all the protocol related information for which he/she had accessto.

**Observation of Ethics Committee, KLE University for Clinical Studies meetings / Departmental visit by Guest Attendees**

Permission to observe the Ethics Committee, S.N Medical college, Agra meetings/ visit to the Office of Ethics Committee, S.N Medical College, Agrawill be given only after a formal written request addressed to the Chairman/ Member Secretary.

Permission will be granted for academic purposes and other reasons at the discretion of the Chairman / Member Secretary.

- They will be requested to sign a Confidentiality Agreement Form for Guest Attendees to Ethics Committee, S.N Medical College, AgraMeetings/ Departmentalvisit.
- They will be escorted by staff of the Ethics Committee, S.N Medical College, Agrafor Clinical Studies.
- Care will be taken to see only the necessary documents are given access to while proposals will be stored under lock andkey.

**Read the text carefully andthoroughly:**

- Newly appointed members obtain two copies of the Agreement FormAF/EC/01/03/V1.0
- The member is expected to read through the text of the form verycarefully.\

**Ask questions, if any.**

- Direct questions to the Secretariat, if any part or sentences is notclear.
- Let the Member Secretary explain or clarify the contents of thedocument.

**Sign withconsent.**

- Sign and date both copies of the document before a member of theSecretariat.
- Give the forms back to a Member Secretary/ Secretariat to sign anddate.
- The members keep a copy as theirrecords.

## 6. Glossary

**Confidentiality:** The nonoccurrence of unauthorized disclosure of information:

**Confidentiality Agreement:** (Secrecy or Nondisclosure agreements).

An agreement designed to protect, information, data and expertise from being misused by those who have learned about them. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.

**Conflict of Interest:** A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

Conflict of interest is present and interferes with ability to make an objective evaluation when ethics committee members

- Have their own research projects under review by the Ethics Committee, when they are a investigator, co-investigator, or when they are in a supervisory or mentoring relationshipwith a Principal Investigator.
- A member whose spouse is a Principal Investigator, co-investigator, for any project under review is also considered to have conflict ofinterest.
- Members may also be in a conflict of interest situation when they have interpersonal or financial relationships with the researchers, or personal or financial interests in a company, organization that may be the sponsor of the research project, or that may be substantially affected by theresearch.

To maintain the independence and integrity of research ethics review, members must identify, eliminate, minimize or otherwise manage real, potential or perceived conflicts of interest. If a member has a personal or financial conflict of interest the members must disclose the nature of the conflict and absent themselves from any discussion or decision regarding that research project. In the event that a member's conflict of interest and necessary withdrawal from the meeting will threaten the maintenance of quorum, the Committee can ensure that an alternate member be in attendance to maintain quorum. There are three key elements in this definition: financial interest; official duties; professional interest.

**Strategies to manage Conflict of Interest:**

- Disclose conflict ofinterest
- Document the conflict of interest in attendance register /minutes of themeeting

- Refrain from taking part in any discussion/review/ debate about theproposal;
- Refrain from participating in the review process of project proposal by leaving the meeting room.

## 7. References


1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.
3. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapter7/
4. http://www.cancerinstitute.org.au/media/64618/CINSW_POLICY-conflict-of-interest.pdf
5. http://www.iecindia.org/pdf/sop20_m.pdf


## 8. ANNEX

| | | |
|---|---|---|
| **ANNEX 1** | **AF/EC/ 01/03/V1.0** | Confidentiality Agreement Form for Ethics committee members |
| **ANNEX2** | **AF/EC/ 02/03/V1.0** | Conflict of Interest Agreement Form for Ethics committee members |
| **ANNEX3** | **AF/EC/ 03/03/V1.0** | Confidentiality Agreement Form for Guest Attendees to IEC- S.N Medical College Meetings |
| **ANNEX4** | **AF /EC/ 04/03/V1.0** | Confidentiality Agreement Form for Independent consultants |
| **ANNEX5** | **AF /EC/ 05/03/V1.0** | Confidentiality Agreement for Non-members Requesting Copy (ies) of IEC Documents |
| **ANNEX 6** | **AF /EC/ 06/03/V1.0** | Log of Requests for Copies of IEC Documents |
| **ANNEX7** | **AF /EC/ 07/03/V1.0** | Log of Requests for Original Documents |

**ANNEX1** **AF/EC/01/03/V1.0**

**Confidentiality Agreement Form for Ethics Committee members**

In recognition of the fact, thatI ..... *member's name,and his/her affiliation*……..herein referred to as the "Undersigned", have been appointed as a member of the Ethics Committee S.N Medical College, Agrafor Clinical Studies has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the fundamental duty of an Ethics Committee S.N Medical College, Agramember is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions underreview;

Whereas, the Ethics Committee S.N Medical Collegefor Clinical Studies must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of humansubjects;
This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the Ethics Committee S.N Medical College . Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

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

**Agreement on Confidentiality**

*Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the S.N Medical College,* AgraEthics Committee. *A copy will be given to you for your records.*

In the course of my activities as a member of the Committee, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committeemember.

I also understand that as a member I will be given copies of the study proposals/necessary documents to be evaluated. These will be duly returned by me to the Ethics Committee during the meetings/as and when requested for. I also understand that these documents are confidential; hence every effort will be taken to prevent access to any other person other than me or the office staff of the Ethics Committee. At times documents/proposal in soft copy format will be given/send to me. I will assure that these documents/proposals will be passwordprotected.

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

UndersignedSignature Date

ECchairman/Membersecretary Date:
Signature

**ANNEX2** **AF/EC/ 02/03/V1.0**

## Conflict of Interest Agreement Form for Ethics committee members

It is recognized that the potential for conflict of interest will always exist but has faith in the Ethics Committee and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.
It is the policy of the Ethics Committee University that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the Ethics Committee S.N Medical College, Agra for Clinical Studies.

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

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the Ethics Committee S.N Medical College, Agrareview or approval except to provide information requested by theCommittee.

**Agreement on Conflict of Interest**

*Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the* S.N Medical College, AgraEthics Committee*. A copy will be given to you for your records.*

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

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

_____ _____

UndersignedSignature Date

_____ _____

MemberSecretarysignature Date

**ANNEX3** **AF/EC/ 03/03/V1.0**

**Confidentiality Agreement Form**

**For Guest Attendees to Ethics Committee, S.N Medical College for Clinical Studies Meetings**

I,……from .....understand thatI am allowed to attend the Ethics Committee, S.N. Medical College, Agra meeting as a guest or an observer. In the course of the meeting of the Ethics Committee, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information asConfidential.

Indicate the details (date and number) of **the S.N Medical College, Agra Ethics Committee** Meeting attended:

……

……

……

_____ _____

Signature of the Guestor Observer Date

_____ _____

MemberSecretary Date

Ethics Committee, S.N Medical College-Agra

_____ _____

Signature oftheChairperson Date

**ANNEX4** **AF/EC/04/03/V1.0**

**Confidentiality Agreement/Conflict of interest Form for independent Consultants**

I,…….,..,., from……..as a non-member of Ethics Committee, S.N medical College, Agrafor Clinical Studies, understand that the copy(ies) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Ethics Committee**,** S.N Medical College, Agraand shall not duplicate, give or distribute these documents to any person(s) without permission from the S.N Medical College, AgraEthics Committee. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information asConfidential.

**Agreement on Conflict of Interest**

*Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the* Ethics Committee. *A copy will be given to you for your records.*

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

Signature of theIndependentconsultant Date

**MemberSecretary** Date
Ethics Committee, S.N medical College, Agra

Signature oftheChairperson Date
Ethics Committee, S.N medical College, Agra

**ANNEX5** **AF/EC/05/03/V1.0**

**Confidentiality Agreement Form**

**for Non-members Requesting Copies of IEC Documents**

I,……..,..,., from…….as a non-memberof Ethics Committee S.N medical Collegefor Clinical Studies, understand that the copy (ies) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Ethics Committee and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC/IRB. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IEC documents:

……

……

……

_____ _____

Signature oftherecipient Date

_____ _____

MemberSecretary, Date

Ethics Committee, S.N Medical College –Agra

_____ _____

SignatureofChairperson Date

**ANNEX6** **AF/EC/06/03/V1.0**

## Log of Requests for Copies of IEC Documents

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

**ANNEX7** **AF/EC/07/03/V1.0**

## Log of Requests for Original Documents

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

## Table of Contents

**1. Purpose**

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

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

**2. Scope**

The SOP applies to all personnel of the IEC.

**3. Responsibility**

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

**4. Flowchart**

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

**5. Detailed instructions**

**Topics fortraining**

Ethics committee members should have knowledge of:

- Good Clinical Practice (GCP) including ScheduleY
- Declaration of Helsinki and other International guidelines like CIOMS,WHO
- EthicalIssues
  - Ethical Guidelines for Biomedical Research on Human Participants , ICMR ,2006
  - E6 Good Clinical Practice: Consolidated Guidance, April 1996, ICH –GCP
  - WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants ,2011
  - Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006
  - Relevant laws andRegulations.

An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics will be attempted. Efforts would be made to collect information on overseas trends and to attend international specialist meetings organized for the exchange of experience and information.

**How to gettrained**

- Get information about training courses, workshops, conferences, etc. which are periodically announced onwebsites.
- Select the ones youneed.
- Take approval from the IEC and theChairman
- Register toattend.
- Keep thereceipt.

Reimburse the training expense as approved by the Chairman of S.N Medical, Ethics Committee, S.N medical College, Agra Ethics Committee as perrules.

**Keeping the trainingrecords**

- Fill in the form to record the training/workshop/conference activities inchronological order.
- Make a copy of theform.
- Keep the original form as yourrecord.
- Give the copy to the administrative staff to keep in the IEC member training record file.
- Keep the copy of the documents received at the time of training (soft and hard copy) for referral purpose by the other IEC members at the Ethics Committeeoffice.

## 6. Glossary

| | |
|---|---|
| Conference | A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of commoninterest. |
| Meeting | Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition ofbusiness. |
| Workshop | A group of people engaged in study or work on a creative project orsubject |

## 7. References

i. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.
ii. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996
iii. Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## 8. ANNEX

**Annex 1** Training Record Form

**ANNEX 1**

**AF/EC/01/04/V1.0**

**Training Record Form**

Firstname: Last name:

Department Name / Affiliation

Staff /Membershipsince: Status:

EducationBackground:

Professional Qualification

1. Legalexpert
2. BasicScientist
3. Clinician
4. Public healthExpert
5. SocialScientist
6. Community member/Layperson
7. Any other

WorkExperience:

| S.N | Courses/ Workshops/ Conferences/Meetings attended | Organized by: | Venue | Duration with dates | Source of Funding |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |

**No. TableofContent** **PageNo.**

**1. Purpose**

The purpose of this SOP section is to provide procedures for engaging the expertise of a professional as a consultant to the Ethics Committee Medical College-Agra.

**2. Scope**

If the Chairperson or the Ethics Committee, S.N Medical College –Agra for clinical studies determines that a study will involve procedures or information that is not within the area of expertise of the committee members, Chairperson of the committee in consultation with the Member Secretary suggests individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the committee and appointed by the Chairman.

**3. Responsibility**

Upon the advice or recommendation of the Secretariat, Chairperson or any member of the Ethics Committee, S.N Medical College, Ethics Committee, S.N medical College, Agrafor clinical studies, it is the responsibility of the Ethics Committee, S.N Medical college, Agrato nominate and approve the name of the special consultants to be endorsed by the Chairman.

**Detailed instructions**

**Selection and Appointment of Independent Consultants(ICs)**

- Identify the experts from the list of the independent consultants/roster maintained by the secretariat or by the Ethics Committee Members, Secretariat andChairperson
- Invite theconsultants.

| **No.** | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Maintaining a speciality-wise list/roster of independentConsultants | Secretariat |
| 2 | Suggestions of Independent Consultants | IEC Members / Secretariat or Chairperson |
| 3 | Appointment of Independent Consultants | Chairman |
| 3 | Consultation Services | IEC/IRB Secretariat/ Consultant |
| 4 | Termination of the Services | Consultant / IEC/IRB |

The Chairperson/ Member Secretary on behalf of the Ethics committee will invite IC(s) selected by the committee in writing to assist in the review of the project and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through any mode of communication.

- Make decision based on expertise, availability and independencecriteria
- Get approval from the EthicsCommittee.
- Contact theconsultant.
- Invite the consultant to attend the meeting by sending an appointment letter signed by the Chairman of the EthicsCommittee.

- The Secretariat will request IC to declare competing interests, if any and sign a confidentiality agreement. The Secretariat will maintain and provide a specialty-wise roster ofConsultants.

**Co-ordination with Independent Consultants for fulfilling administrative requirements**

The Secretariat will forward a copy of the Confidentiality Agreement and Conflict of Interest Agreements to IC(s) (See ANNEX 4 AF/EC/04/03/V1.0) for careful reading, understanding andsigning.

The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the Independent Consultant(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert Ethics Committee Members

**Reading, understanding and signing the Conflict of Interest document and ConfidentialityAgreement**

- The IC(s) will sign and date the Confidentiality and Conflict of InterestAgreement document.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it toChairperson.
- The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements.Theoriginalcopiesoftheseagreementswillberetainedbytheir Secretariat and photocopies will be sent to IC (s).
- The Independent Consultant is expected to implement the clauses of the signed Confidentiality/Conflict of interest Agreement Form AF/EC/04/03/V7.0

### 4.4. Consultation Services

IEC provides study protocol documents to the appropriate consultant for review. In case the project has been presented to the Ethics Committee and has further modifications/ revisions/amendment the project has to be submitted alongwith the Review Report Form for comments purpose. The consultant will review the study protocol, attend the Ethics committee meeting, and participate in the discussion but *cannot vote*. Reimbursement will be given to the Consultant as per rules of theInstitute.

The Review Report Form will be filed with the project proposal in the respective file.

### 4.5 Termination of the Services

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

### 5. Glossary

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

### 6. Reference

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## Table of Content

**1. Purpose**

This standard operating procedure is designed to describe how the Secretariat of the Institutional Ethics Committee (IEC) manages protocol submissions to the IEC.

**2. Scope**

Protocol submissions include:

- Submission for Initial Review
- Resubmission of Protocols withCorrections
- ProtocolAmendment
- Continuing Review of ApprovedProtocols
- ProtocolTermination

**3. Responsibility**

It is the responsibility of the IEC secretariat to receive, record, distribute for review and get the project proposals approved by the IEC, as well as to deliver the review results by the way of discussion with / Minutes to the PrincipalInvestigators

**4. Flow chart**

| No. | Activity | Responsibility |
|---|---|---|
| **1** | Receive Submitted project proposals ↓ | IEC Secretariat |
| **2** | Check for submission items:<br>• Initial Review Application<br>• Resubmission of Protocols withCorrections<br>• ProtocolAmendment<br>• Continuing Review of ApprovedProtocols<br>• ProtocolTermination<br>↓ | IEC Secretariat |
| **3** | Complete the submission process ↓ | IEC Secretariat |
| **4** | Store the received documents | IEC Secretariat |

**5. Detailedinstructions**

**Receive submitted documents**

**Initial Review Application**

Go to5.2.

**Resubmission of Protocols with Corrections**

Go to5.2.1.2

**ProtocolAmendment**

Go to 5.2.1.3

**Continuing Review of ApprovedProtocols**

Go to5.2.1.4

**ProtocolTermination/Completion**

Go to5.2.1.5.

**Check for submissionitems**

**Check the receiveddocuments**

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

**InitialReview**

- Check for contents of a submitted project proposal as per Checklist, form AF/EC/01/06/V7.0 (see ANNEX1),
- Review Report form AF/EC/02/06/V7.0 (see ANNEX2),
- Go to step5.2.2

**Resubmission of Protocols withcorrections**

- Check for contents of a submitted project proposal as per Checklist, form AF/EC/01/06/V7.0 (see ANNEX1),
- Review Report form AF/EC/02/06/V7.0 (see ANNEX2),
- Go to step5.2.2

**ProtocolAmendments**

- Check for contents of a submitted project proposal as per Checklist, form AF/EC/01/06/V7.0 (see ANNEX1),
- Review Report form AF/EC/02/06/V7.0 (see ANNEX2),
- Go to step5.2.2

**Annual Continuing Reviews of ApprovedProtocols**

- Check the Annual Report with the template AF/EC/03/06/V7.0 (see ANNEX 3) for all the pointscovered.
- Take out the relevant file and check for the information given in report is same as mentioned in thefile.
- If any point/information is missing, provide Template (soft copy) to the Principal Investigator and request them to give information as per the templateonly.
- Go to step5.2.2.

**Protocol Termination/Completion**

- Check for contents of a submitted package, as per the format of final review AF/EC/04/06/V7.0 (see ANNEX4),
- Study Assessment form AF/EC/02/06/V7.0 (see ANNEX2),
- Go to step5.2.2

**Fill in theforms:**

- Tick marks the points on the Checklist AF/EC/01/06/V7.0 (see ANNEX1).
- Attach the Study Assessment form AF/EC/02/06/V7.0 (see ANNEX2)

**Verify contents of submitted projectproposal**

Title Page should be complete in following respects

- ProjectTitle:
- Name of the PrincipalInvestigator:
- Name of the Co- Investigator/ Collaborator:
- Enclosures with pagenos.

Face Sheet should be complete as per the Checklist (ANNEX 1 AF/EC/01/06/V7.0)

Participant Information Sheet: refer (ANNEX 5 AF/EC/05/08/V7.0)
To see that all the question are included in the Participant Information Sheet as per the given format
Informed Consent Document refer (ANNEX 6 AF/EC/06/08/V7.0)
Summary of Study Protocol and Detailed Protocol should include the following points refer (ANNEX 3 AF/EC/03/08/V7.0)

**Complete the submissionprocess**

- Check for completeness of the submitteddocuments
- Notify the applicants if the package isincomplete.
- State clearly the items missing in thepackage.
- Fill up the related parts and the missingdocuments.
- If the documents found to be complete, put ‘Received’ stamp on the Covering letterand the first page of the documents
- Initial the receiver’s name on the receiving documents. Put date, time and inward number for receiving thedocuments.
- Attach the filled checklist (ANNEX 1 AF/EC/01/06/V7.0) with the copy of the Study Assessment form (ANNEX 2 AF/EC/02/06/V7.0) to the Research Protocoldocuments.

**Processing the submitteddocuments**

- After review of the project by the Secretariat, invite the Internal IEC members for review of project proposal and hand over the proposals for checking along with Checklist and Review Report form to internal reviewers.
- If the internal IEC members find the project to be technically sound and complete in all respect to be placed before the Full Board/ERC, the Principal Investigator will be informed to make multiple copies as required. If the project is to be put forth to the meeting, it will be assigned number and the file of the project with that number will be made. The entry will be made in the 'Project Register' for writing further information. If the project is found to be incomplete, the Principal Investigator will be asked to make the corrections in theproposal.

**Create a Protocol Specific File (for InitialReview)**

- Create the 'Project'file.
- Record the name of the Principal Investigator, title and assign number to theproject.
- Keep the copy of the submitted documents with original signatures in the respective file.

**Store the receiveddocuments**

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

## 6. References

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Associated SOPs: SOP/08/V7.0.

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

## 7. ANNEX

| | | |
|---|---|---|
| ANNEX 1 | (AF/EC/01/06/V7.0) | Checklist |
| ANNEX 2 | (AF/EC/02/06/V7.0) | Study Assessment Form |
| ANNEX 3 | (AF/EC/03/06/V7.0) | Annual Report Templates |
| ANNEX 4 | (AF/EC/0406/V7.0) | Study Report form for protocol termination/ completion |
| ANNEX 5 | (AF/EC/05/06/V7.0) | Document Histories |

**ANNEX1** **(AF/EC/01/06/V7.0)**

**Checklist for Principal Investigator**

| SN | Particulars | | |
|---|---|---|---|
| 1 | Covering letter | Yes | No |
| 2 | Copy of the latest Minutes | Yes | No |
| 3 | Title Page | | |
| | Project Title: | Written | Not Written |
| | Name of the Principal Investigator: | Written | Not Written |
| | Name of the Co- Investigator/ Collaborator: | Written | Not Written |
| | Enclosures with page nos. | Written | Not Written |
| 4 | Face Sheet | | |
| | 1) Project Title | Written | Not Written |
| | 2) Principal Investigator / Co-ordinator | Written | Not Written |
| | - Name,<br>- affiliation,<br>- official postaladdress,<br>- telephonenos.,<br>- e-mailaddress | | |
| | 3) Name, address of the Institution / Orgn. responsible for conduct / coordination of project. | Written | Not Written |
| | 3a) Name & address of the Officer responsible for institutional supervision | Written | Not Written |
| | 4) Name & address of the Funding / Sponsoring Institution/CRO | Written | Not Written |
| | 4(a) Name & address of the Officer-in-Charge of the Funding/Sponsoring institution/CRO | Written | Not Written |
| 5 | Monitor of the Project:<br>- Name<br>- Address | Written | Not Written |
| 6 | Comments/Recommendations of the SAC/ SRC/ ICSCRT/ Technical Experts (Attach Minutes/Letter)<br>If attached, mention page no. | Attached | Not attached |
| **7** | Comments / Recommendations of the Statistician:<br>If attached, mention page no. | Attached | Not attached |
| 8 | To be answered / responded by the PI / Co-ordinator | Complete | Incomplete |
| | a) Does the protocol fall under exempt category?<br>(If yes, give reasons on separate sheet) | Given | Not given |
| | b) Is request made for obtaining waiver from informed | Given | Not given |

| | | | |
|---|---|---|---|
| | consent?<br>(If yes, give reasons on separate sheet) | | |
| | c) ) Does the protocol involve Human participants<br>(If yes, will it include) | Yes | No |
| | i) drawing of blood, body fluids, tissues etc. | Yes | No |
| | ii) Administration of an investigational substance / implantation of a device<br>(if yes, provide name of the drug / substance / device etc. and its manufacture's name and address)<br>(Also, clearance from the DCGI, if relevant) | Yes | No |
| | iii) exposure to ionizing radiation | Yes | No |
| | iv) Use of genetically engineered products (if yes, give details of the product, and appropriate clearances from the DBT, GEAC, DCGI, etc.) | Yes | No |
| | d) Does the protocol involve inclusion of vulnerable participants (if yes, special precautions proposed to safeguard their rights and interests shall be documented on separate sheet) Page No. | Yes | No |
| | Signature of Principal Investigator/coordinatorresponsible for conduct of study with mention of date & place | Complete | Incomplete |
| | Signature of HOD / Chairperson of the Department with mention of date and place | Complete | Incomplete |
| | Signature of Head of the Institution/ Authorized person with mention of date and place | Complete | Incomplete |
| 9 | Undertaking by Investigators & Collaborators Signature, Date | Complete | Incomplete |
| 10 | Brief Bio-data of Investigators | Complete | Incomplete |
| 11 | Role of various Investigators | Complete | Incomplete |
| 12 | Participant Information Sheet: | Complete | Incomplete |
| 13 | Informed Consent Document | Complete | Incomplete |
| 14 | Participant Record Sheet | Complete | Incomplete |
| 15 | Summary of Study Protocol | Complete | Incomplete |
| 16 | Detailed Protocol | Complete | Incomplete |
| 17 | Data Collection tools/ questionnaire | Attached | Not attached |
| 18 | GCP Training Certificate of Principal Investigator/Co-Investigators/Collaborators | Attached | Not attached |

**ANNEX2** **(AF/EC/02/06/V1.0)**

**Study Assessment Form for New Projects**

ProtocolNumber: Date(D/M/Y):

Protocol Title:

Name of Principal Investigator:

Reviewer's name:

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

| | | |
|---|---|---|
| 1 | Objectives of the Study<br>☐ Clear ☐ Unclear | What should be improved? |
| 2 | Background and Rationale<br>☐ Sufficient ☐ insufficient | Comment: |
| 3 | Methodology<br>☐ Clear ☐ Unclear | What should be improved? |
| 4 | Need for diagrammaticrepresentation<br>☐ Yes ☐ No | Comment : |
| 5 | If diagrammatic representation given:<br>☐ Clear ☐ Unclear | What should be improved? |
| 6 | Study Design and Sample size<br>☐ Appropriate Inappropriate | Comment: |
| 7 | Inclusion Criteria<br>☐ Appropriate ☐ Inappropriate | Comment: |
| 8 | Exclusion Criteria<br>☐ Appropriate ☐ Inappropriate | Comment: |
| 9 | Statement for protection of rights and interests of Vulnerable Participants<br>☐ Clear ☐ Unclear | Comment: |
| 10 | Voluntary, Non-Coercive Recruitment of Participants | Comment: |

| | | |
|---|---|---|
| | ☐ Yes ☐ No | |
| 11 | Are Qualification and experience of the Participating Investigators appropriate?<br>☐ Yes ☐ No | Comment: |
| 12 | Disclosure or Declaration of Potential Conflicts of Interest<br>☐ Yes ☐ No | Comment: |
| 13 | Facilities and infrastructure of Participating Sites<br>☐ Appropriate ☐ Inappropriate | Comment: |
| 14 | Involvement of Local Researchers and Institution in the Protocol Design, Analysis and dissemination of Results<br>☐ Yes ☐ No | Comment: |
| 15 | Contribution to Development of Local Capacity for Research and Treatment<br>☐ Yes ☐ No | Comment: |
| 16 | Community consultation where needed<br>☐ Yes ☐ No | Comment: |
| 17 | Benefit to Local Communities<br>☐ Yes ☐ No ☐ Notapplicable | Comment: |
| 18 | Are blood/tissue samples sent abroad?<br>☐ Yes ☐ No | Comment: |

| | **Participation Information Sheet and Informed Consent Documents** | |
|---|---|---|
| S N | **Points** | **Comments** |
| 1 | Are procedures for obtaining Informed Consent appropriate?<br>☐ Yes ☐ No | |
| 2 | Contents of the Informed Consent D o c u m e n t<br>☐ Clear ☐ Unclear | |

| | | |
|---|---|---|
| 3 | Language of the Informed Consent Document<br>☐ Clear ☐ Unclear | |
| 4 | Risks/ inconveniences mentioned clearly<br>☐ Yes ☐ No | |
| 5 | Mention about tests to be performed if any<br>☐ Yes ☐ No | |
| 6 | Period of storage of biological samples<br>☐ Yes ☐ No | |
| 7 | Are possible benefits mentioned<br>☐ Yes ☐ No | |
| 8 | Contact Persons for Participants<br>☐ Yes ☐ No | |
| 9 | Privacy & Confidentiality<br>☐ Yes ☐ No | |
| 10 | Inducement for Participation<br>☐ Unlikely ☐ Likely | |
| 11 | Provision for Medical / Psychosocial Support<br>☐ Appropriate ☐ Inappropriate | |
| 12 | Provision for Treatment of Study Related Injuries<br>☐ Appropriate ☐ Inappropriate | |
| 13 | Provision for Compensation<br>☐ Appropriate ☐ Inappropriate | |

Signature with date:

**ANNEX3** **(AF/EC/03/06/V1.0)**

**Annual Report Template**

ProjectNo: Principal Investigator:

Name of theproject:

Name of the Co-Investigator:

Collaborators:

Duration of thestudy:

Presented to EC–date: Approval date:

Study initiation -date

Amendments if any:

Approval given for the Amendment:

Financial Status

Objectives:

Sample size:

Number of study participants enrolled:

Number of drop outs/ withdrawn:

Summary of the work done (preferably in 1-2 paragraphs):

Number on study/follow-up:

Number of AE/SAE:

Completion/Termination of the study – date

Any protocol deviation and violations:

Publication:

Signature of the Principal Investigator with date

**ANNEX4** **AF/EC/04/06/V1.0**

Study Report Form for Protocol Termination/ Completion

ProtocolNo.:

PrincipalInvestigator:

Protocol Title:

Date of EC Approval

Phone number: E-mail address:

Sponsors /Funding Agencies Name

Address:

Phone: E-mail:

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

Study Design and SampleSize:

Objectives:

Methodology:

Duration of the study:

Total Number of study participants:

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

Studydose(s):

Reasons for termination (if any):

Provision for follow-up of patients:

Whether the study samples are being retained for future use:

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

Outcome and Implications of the Study:

Publications (If any):

Presentations (If any):

SignatureofP.I.: Date:

**ANNEX5** **AF/EC/05/06/V1.0**

**Document History**

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

## Table of Contents

**Expedited review:**

A review process by minimum of 5 Ethics Committee members and Chairperson who report the decision to the Ethics Committee during full board. The proposals with minor*changes to the approved study proposals and those* presenting no more than minimal risk to research participants may be subjected to expeditedreview.

**1. Purpose**

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

**2. Scope**

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

**3. Nature of Study Proposals considered for expedited reviewprocess:**

The study proposals considered for the ERC include

1. Study proposals approved with minor modifications before finalapproval
2. Minor deviations from originally approved research during the period of approval (usually of one year duration). Examples: addition/relieving of acollaborator.
3. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to dataanalysis.
4. Research activities that involve only procedures listed in one or more of the following categories:
   - Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable populationor
   - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature isreported.
5. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical)purposes.
6. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilotstudy.

**4. Flowchart**

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Receive the submitted documents. | IEC Secretariat |
| 2 | Determine protocols for expedited | Members with consultation and |

| | | |
|---|---|---|
| | Review.<br>Agenda will be tabulated with titles of study proposals and reasons for ERC referral asheading ↓ | concurrence from the Chairperson. |
| 3 | Expedited review process | EC members and secretariat |
| 4 | Communicate with the IEC- full board and the Investigator. | Member Secretary and IEC Secretariat |

**5. Detailed instructions**

**Receive the submitteddocuments.**

- Receive the application documents submitted byinvestigators.
- Fill the relevant checklist to check itemsreceived.
- Inward Stamp which includes the receiving date on the letter and thedocuments.
- Sign the receiver's name on the receivingdocuments.
- Hand over the received documents to the IEC/IRBsecretariat.

**Determine protocols for expeditedreview.**

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

Modification /amendment of protocol with minimalchanges

- *Administrative revisions*, such as correction oftypes
- Addition or deletion of *non-procedural items*, such as the addition or deletion of study personnel names, laboratories,etc.
- *Non-significant risk* researchactivity

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

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

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

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

Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and *no additional risks* have been *identified.*

Health Systems Research with no more than minimal risk such as collecting the information on health problems with non-identifying personal informationetc.

If the protocol satisfied any of the criteria for expedited review, the secretariat will send the protocol to Chairperson and the members of the ERC.

**Expedited Process**

**Nomination procedure for expedited reviewers**

- The study proposal will be reviewed by the reviewers who had initially reviewed the proposal in case of amendments and resubmittedproposals.
- In case of new proposals, the member secretary in consultation with the Chairperson will decide the reviewers only in case of emergency, depending on the nature of protocol and the expertise in thecommittee.
- The secretariat sends the revised protocol to the selected ECmembers.
- Carry out the expedited review on the complete proposal (study protocol with all the attached documents as mentioned in the guidelines for submission ofproposals).
- The expedited review should not take longer than 2weeks.
- Inform the IEC- full board of the proposals approved by expedited review at its regularmeetings.
- If any committee member raises concern about any of the proposals presented to itas expedited review, then that proposal shall undergo a regularreview.

**Communicate with the IEC and theinvestigator.**

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

## 6. Glossary

Expedited approval - An IEC approval granted only by the Chairman of the IEC (not the full Board) for minor changes to current IEC approved research activities and for research which involves no more than minimal risk.

## 7 References

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Code of Federal Regulation (CFR)21.

Ethical Guidelines for Biomedical Research on Human Participants, ICMR,2006

## 8.ANNEX

| | | |
|---|---|---|
| ANNEX 1 | AF/EC/01/07/V7.0 | Document History |
| ANNEX 2 | AF/EC/02/07/V7.0 | Checklist |

**ANNEX1** **AF/EC/01/07/V1.0**

**Document History**

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

**ANNEX2** **AF/EC/02/07/V7.0**

**Checklist of Documents for Expedited Review**

| S. No. | Documents | Y/No/NA |
|---|---|---|
| 1 | Covering letter | |
| 2 | Study proposal | |
| 3 | Justification for consideration under Expedited Review (Refer to Point 7.2 Pg.5) | |

## Table of Contents

## 1. Purpose

This SOP describes how the Ethics Committee, S.N Medical College, Agrafor Clinical Studies will review the initially submitted project proposal for approval by the Ethics Committee by using Checklist (see Annex 1 AF/EC/01/06/V1.0) and the Study Assessment Form (see Annex 2 AF/EC/02/06/V1.0).

## 2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. It also applies to the comments regarding the protocol to be written on the project copy itself and to be given to the internal members and thereafter to the Member Secretary for further checking with respect to scientific and ethical aspects for the project. The internal members and the Member Secretary will provide their suggestions. Relevant points made during discussion and deliberation about a specific protocol should be recorded.

## 3. Responsibility

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

The Member Secretary has to check the project proposal and write comments and if necessary discuss for clarification/ correction purpose/ project copy given to the Principal Investigator for further action.

## 4. Flowchart

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Check the points as per checklist | Secretariat/Member Secretary |
| 2 | Provide project copy along with Checklist | Secretariat/ Member Secretary |
| 3 | Final checking of the project | Member Secretary |
| 4 | Receive suggestions from affiliated members | Secretariat/Member Secretary |
| 5 | Inform Investigators about the comments and suggestions of affiliated members | Secretariat /Member Secretary |
| 6 | Checking of submitted study proposals for suggested changesincorporated | Secretariat, affiliated members and MemberSecretary |
| 7 | Send the copies of study proposals to external experts with study assessment form for reviewers at least 8 days prior to the meeting | Secretariat / Member Secretary |

| | | |
|---|---|---|
| | ↓ | |
| 8 | Place the study proposal in the IEC meeting for approval ↓ | Secretariat affiliated members and member Secretary |
| 9 | Record the IEC's Decision | IEC Secretariat |

**5. Detailed instructions**

The secretariat will mark the points on Checklist (as per ANNEX 1AF/EC/01/06/V1.0)

**Placing the proposal before the Ethics CommitteeMeeting**

- After the incorporation of the comments in the project done by the Principal Investigator and the project is made presentable for the meeting with respect to technical and scientific aspects, the Principal Investigators are asked to submit the project files for the circulation to the members at least two weeks before the meeting. The Protocol will be sent to the Members as per the Agenda of the meeting. The English, Hindi and versions(If any other language as per the protocol) of the Participant Information Sheet and Informed consent documents will also be sent to all theMembers.

- Principal investigator will be invited to present the protocol and all EC members will deliberate and provide inputs/suggestions ifany.

**Conveying decision regardingproject:**

The EC members will discuss and clarify the comments and suggestions. The Member secretary shall record the discussions and minute it.

- The final decision on the project as i) approved ii) minor modification for expedited review iii) major modification for full board review iv)Disapprove
- Member(s) of the committee who is/are listed as investigator(s) on a research proposal and having conflict of interest shall declare conflict of interest and will not vote on the proposal and will opt out from all deliberations on the proposal by leaving the meeting room.
- An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of thecommittee.
- An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision making procedures of thecommittee.
- IftheECdecisionis'Approved',itimpliestheapprovalofthestudyasitispresented with no modifications and the study can be initiated.
- If the EC decision is minor modification for expedited review, it implies that the items noted at the convened meeting will be reviewed through expedited review process as per SOP /07/V1.0.

- If the EC decision is major modification for full board, the proposal will have to be re-submitted for the full boardmeeting.
- If the EC decision is disapprove the committee should give reasons for the same and the Principal Investigator should submit justification for thereasons.
- If the study is approved, the Committee will determine the frequency of continuing review from each investigator. Usually approval is given for oneyear.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the ECmembers.

**Final communication of the Ethics Committee decision taken on the project to the Principal Investigator**

- The Secretariat will prepare an approval letter to be sent to the Principal Investigator when the project is approved at an Ethics Committeemeeting.
  The letter will be dated and will contain:
  - Project No. Project title,Date
  - Name of thePI
  - Dates of the meeting when the project is placed before the meeting and approved and version numbers of theproject
  - List of EC members present at the meeting when the project wasapproved.
  - The Chairperson or the Member Secretary will sign the approval letter and the Secretariat will send it to the PrincipalInvestigator.

**Storage ofDocuments**

- The Secretariat will keep a project proposal, Approval letter, copy of the Minutes in the project file along with all the reviewed documents in respectivefile
- The file will be stored in an appropriate shelf in the designatedcabinet.

Timelines for procedures will be as follows:

Initial submission to initial review – 15-21 days
Initial review to full board – 15 days
Minutes given to PI after full board meeting – Within 7 working days
Corrections submitted by PI – Expected within 15 days; maximum upto 90 days
Approval letter – 7-10 days (after submission of final approved copy by Principal Investigator to the Ethics Committee office)

**6. Glossary**

**StudyAssessment Form** An official record that documents the protocol reviewprocess.

**Document** may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

## 7. Reference

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

SOPs Ethics Committee for Research on Human Subjects, Seth G S Medical Collegeand K.E.M. Hospital, Mumbai - August 2013

## 8. ANNEXURE:

ANNEX1: Face SheetFormat
ANNEX2: Undertaking by investigators and co-investigators
ANNEX3: Format for Summary and DetailedProtocol
ANNEX 4: Guidelines for reviewing Participant Information Sheet and Informed Consent Documents
ANNEX5: Participant information sheet
ANNEX6: Informed Consent Form
ANNEX7 : Assent form template
ANNEX8: Guide to PlaceboJustification
ANNEX9 : Guidance of Protocol Submission
ANNEX 10 : Use of Study Assessment Form
ANNEX 11 : Approvalletter

**ANNEX1** **AF/EC/01/08/V1.0**

Title, version no. date , Principal Investigator's name

***Project for approval by S.N Medical College , Agra***

***Project Title :***

***Principal Investigator:***

**Co- Investigator/s:**

**Clinical Collaborator/s:**

| ***S. No.*** | ***Enclosures:*** | ***Page Nos.*** |
|---|---|---|
| 1 | Face sheet | |
| 2 | Undertaking of Principal, Co-investigator and Collaborators | |
| 3 | Brief Bio-data of investigators | |
| 4 | Role of Investigators | |
| 5 | Certification regarding conflict of interest, if applicable | |
| 6 | Summary of study protocol | |
| 7 | Detailed protocol | |
| 8 | Participant Information sheet | |
| 9 | Informed Consent Document | |
| 10 | Funding Agency / sponsor's letter | |
| 11 | GCP Training Certificate of Principal Investigator/ Co-Investigators/Collaborators | |
| 12 | Any other relevant documents | |

*Title, version no. date, Principal Investigator's name (Put as header on all pages)*

## 'FACE SHEET' of the Protocol

1. Title of theProject
*(It should be concise & self-explanatory)*

| To be filled by office |
|---|
| • ProjectNo. |
| • Date ofReceipt |
| • Date/s ofReview |
| • Status - New/Revised/Amendment |
| • Date ofStart |
| • Duration of thestudy |

*2.* Name, affiliation, official postal address, telephone nos., e-mail address of the Principal Investigator / Co-ordinator. *(If it is a multicentricstudy,*
*- who would be responsible for implementation of the protocol)*

| | | | |
|---|---|---|---|
| 3. | **Name and address of the Institution / Organization responsible for conduct / coordination of the protocol.** | 3(a) | **Name and address of the officer responsible for Institutional Supervision** |
| | | | |
| 4. | **Name and address of the Funding / Sponsoring Institution/CRO** | 4(a) | **Name and address of the Officer-in-charge of the funding / Sponsoring Institution / CRO** |
| | | | |

5. Name and address of the auditor / monitor of theProtocol:
*Title, version no. date , Principal Investigator's name*

6. Comments / Recommendations of the SAC / SRC / TechnicalExperts:
(Attach Minutes / Letter, PageNo.)

7. Comments / Recommendations of the Statistician (IfApplicable):
   (Attach letter, PageNo.)

8. To be answered by the PI /Co-ordinator

| | | | |
|---|---|---|---|
| a. | Does the protocol fall under exempt category?<br>*(If yes, give reasons on separate sheet)* | Yes | No |
| b. | Is request made for obtaining waiver from informed consent?<br>*(If yes, give reasons on separate sheet, Page No.)* | Yes | No |
| c. | Is request made for expedited review?<br>*(If yes, give reasons on separate sheet, Page No.)* | Yes | No |
| d. | Does the protocol involve Human participants<br>*(If yes, will it include)* | Yes | No |
| | *i)* body fluids *(if yes, givedetails)*<br>*i)* Control –<br>*ii)* Study group– | Yes | No |
| | ii) Administration of an investigational substance / implantation of a device<br>*(if yes, provide name of the drug / substance / device etc. and its manufacture's name and address) (Also, clearance from the DCGI, if relevant)* | Yes | No |
| | iii) exposure to ionizing radiation | Yes | No |
| | iv) Use of genetically engineered products (if yes, givedetails of the product, and appropriate clearances from theDBT, GEAC, DCGI, etc.) | Yes | No |
| e. | Does the protocol involve inclusion of vulnerable participants<br>*(If yes, special precautions proposed to safeguard their rights and interests shall be documented on separate sheet)* | Yes | No |

It is certified that the statements made herein are true, complete and accurate to the best of my/our knowledge. I am aware that false, fictitious or fraudulent statements or claims may subject me/us to criminal, civil or administrative penalties. I/we agree to accept responsibility for the scientific conduct of the project and to provide required progress reports if the permission is granted as a result of thisapplication.

*Title, version no. date , Principal Investigator's name*

Signature of Investigator:

Date:

Place:

1. 4 copies of all the documents, neatly typed, numbered and should be submitted in bound files.
2. Title of the project should be put as a header with the name of Principal Investigator. Versions if any, and date should be incorporated. e.g. all new proposals will bear Version No anddate.
3. All pages must be serially numbered and put as footer on the right side of thepage.
4. Any incomplete proposal will not be considered for the meeting. Any blank left in the study proposal (example: signatures), should bejustified.
5. All the PIs are instructed to read the ICMR guidelines for Biomedical Research on Human Participants – 2006 before filling theform.

**ANNEX2** **AF/EC/02/08/V1.0**

## UNDERTAKING BY INVESTIGATORS AND CO-INVESTIGATORS

Study Proposalentitled“ ..... ”

1. We have read the ICMR’s Guidelines for ethical conduct of research involving human participants, and are familiar with our duties / obligations to ensure safety, welfare of participants enrolled in the study and confidentiality of the data. The study would start only after obtaining the approval of Institutional Ethical Committee. We have also read the guidelines for good clinical practice issued by DGHS, Government of India and will follow them in our research on human participants. We would be responsible for obtaining the informed consent of participants before enrolling them in thestudy.

2. The Principal investigator, Co-investigators and the Clinical Collaborators will take the full responsibility for the safety of the study participants. Also, the patient care and clinical management will be the joint responsibility of the collaborator, principal investigator and co-investigator.

3. We will follow all the restrictions, if any, laid down by the Ethics Committee; and seek its approval, if there is any deviation in the protocol / procedure of consent. We will report all adverse events, which are required to be reported, and will maintain all records as required. We will honor all obligations as accepted in the consentform.

4. There is no conflict of interest of any kind in carrying out the proposed study. We will not receive any personal, direct or indirect financial benefit from the conduct of thisstudy

5. It is also certified that the statements made herein are true, complete and accurate to the best of my/our knowledge. I am aware that any false, fictitious or fraudulent statements or claims may subject us to criminal, civil, or administrative penalties. We agree to accept responsibility for the scientific conduct of the project and to provide required progress reports if the permission is granted as a result of thisapplication.

Signature ofPrincipalInvestigator

Date: _____

Name:……

Address:…….
……..

Signature of Co-Investigator

Date: _____

Name:……..…….

Address:

**ANNEX3** **AF/EC/03/08/V1.0**

## Format for Summary and Detailed Protocol

**Summary of Protocol**
Introduction:
Rationale:
Objectives of the study:
Inclusion criteria:
Exclusion criteria:
Methodology (including Study Duration):
Implications of the study:
Expected Outcome:
**……**

**Detailed Protocol**
Introduction and Rationale:
Objectives of the study:
Overall and Specific:
Participants enrolled for this study:
Exclusion criteria:
Methodology (including Study Duration):
Study Design, Sample Size, Study Setting
Expected Outcome:
References:

**ANNEX4** **AF/EC/04/08/V1.0**

**Guidelines for reviewing Participant Information Sheet and Informed Consent Document**

The following points should be considered while reviewing the Participant Information Sheet and Informed Consent Document

**1) Participant Information Sheet Process**

- The EC Members should check whether the Participant Information Sheet and Informed Consent Document are as per the norms provided to the Principal Investigator (ANNEX 3 AF/EC/03/08/V7.0). The Participant Information Sheet (PIS) and Informed Consent Document (ICD) should be congruent with the Application and the researchstudy.
- ToseewhethertheinformationintheconsentformisareflectionofInvestigator's communication with the study participant.
- Final comprehensive information of the study may also be given to theparticipants.
- Information provided in Participant Information Sheet is in simple language (easily understood by lay person), with no scientific jargon and yet complete and updated. Informed consent documents should be written using language at the reading level and technical level of theparticipant.
- Consent document is written at the 8th grade readinglevel.
- Because research participants come from a variety of backgrounds and educational levels and are frequently under physical and emotional stress, it is important that Participant Information Sheet/consent form is easy to understand. If a medical term is essential, lay language definition is included . .
- No informed consent, whether oral or written, may include any language through which the research participant or the representative is made to waive or appear to waive any of the research participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability fornegligence.
- Investigator/Co-Investigator has to obtain consent from the potentialparticipants.
- The individual taking the consent should be well versed, sufficiently trained and knowledgeable about the study to answer any questions or appropriately refer questions that may exceed their expertise put forth by the potential studyparticipants.
- The individual obtaining consent can unintentionally influence a research participants decision to participate in research, hence every effort should be taken to avoid undueinfluence.
- Maintaining privacy and the place/setting in which the consent is obtained is of paramount importance. The consent process should be conducted individually and in areas where the discussion is not overheard, there is no peer pressure and or/inattention and no unwanted stress oranxiety.
- The timing of the consent process may have a negative impact on the potentialresearch participant's ability to make a considered decision.
- All research participants must be given the Participant Information Sheet and the Informed Consent Document to take it home (If they desire's so)to discuss it with their family members, doctor and friends. Allowing the research participants sufficient time may improve the quality of the informed consent process. In case of studies pertaining to delivery/labor, informed consent should be obtained in the prenatal visit and reconsent may betaken.

- Investigator, study co-ordinator, social worker or any other team member of the research study should sit face-to-face with the potential participant read/discuss the Participant Information Sheet/Informed Consent Document

**Telephone surveys/interveiw**

- Describe how personal information will remain confidential. In the case where the data collected contains identifying information (e.g., interview tapes, contact information for follow up studies, clinical history with age and name and other identifiable information), describewith whom, for how long, how the data will be stored, and that when the data is no longer required the data will be appropriately destroyed. If the data are anonymous, this statement may be omitted.
  All records identifying the participants will be kept confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available. The study doctor and research team will use personal information about you to conduct this study. This may include your name, address, medical history and information from your study visits. However, this personal information is not included in the study data that will be forwarded to the sponsor or sponsor representatives. You will be identified by a coded number in any reports of publications produced from this study (study data).
  This is important in studies like in Reproductive tract infections, gene studies etc.
- Describe who has access to the data, where the data is and how it will be storedsecurely.
  To confirm that the study data collected about you is correct and related to you, selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. **By signing this document, you are authorizing suchaccess.**

**2) Informed ConsentProcess**

The actal **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 alloptions.
- **Answer all questions** of the participants before making decision toparticipate.
- Explain **risks or concerns** to theparticipants**.**
- Make sure that all information is **understood and satisfies theparticipants**.
- Make sure the participants understand the study and the consentprocess.
- Obtain **voluntary** informed **consent** toparticipate.
- Make sure the participants can **freely consent without coercion, pressure or other undue influences.**
- Consent should be **informally verified on a continuingbasis.**
- **Continue to inform** the participants throughout thestudy.
- **Continue to re -affirm** the **consent/assent** to participate throughout thestudy.
- CRC should write the entire narration of the complete informed ConsentProcess.
- **Procedures or methods** used in the informed consentprocess for recruitment of study participants include:A consentform
- Brochures, Pamphlets or other reading materials (i.e., letters to participants, phone pre-screening questionnaires, phone holdmessages)

- Internetinformation
- Instructionsheets
- Audio-visualpresentations
- Charts, diagrams orposters
- Discussions
- Consultation withothers
- Duration of sample storage and itsdisposal

**Techniques to improve the readability** of consent forms:

- Use short sentences and paragraphs
- Limit to one thought or topic in a sentence, avoid run-onsentence
- Use simple words, less syllables in aword.
- Use common words, remove technical jargon and medicalterms.
- Try to use correct basic grammar andform.
- Use "gene **transfer**" instead of "gene **therapy**" (less impliedeffectiveness).
- Use"**agent**" instead of "**drug**" or "**medicine** " (less impliedeffectiveness).
  Try to avoid the use of "**treatment**", "**therapy**" or "**therapeutic**" in studies involving gene transfer (because these words imply effectiveness)

**ANNEX5** **AF/EC/05/08/V1.0**

## Participant Information Sheet

Title ofProject:_____

Principal Investigator: Name,
Designation,
Contactdetails_____

Co- Investigator(s): Name,
Designation,
Contactdetails_____

Collaborators: Name,
Designation,
Contactdetails_____

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in thestudy.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in thisstudy.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your futurereference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is this research studyabout?
2. What information is known about this type of researchstudy?
3. Why is this research study beingdone?
4. Who can take part in this researchstudy?
5. How many participants will be included for this researchstudy?
6. What do you have to do if you agree to take part in the researchstudy?
7. **What are the possible benefits to you by being in the researchstudy?**
8. How will the research study bedone?
9. What are the tests that will be performed on the participant/ biologicalsample?
10. **How long will you be in the researchstudy?**
11. **How long the biological samples will be stored and how will it bedisposed?**
12. Under what conditions will your Participation in the study beterminated?
13. What are the possible risks and inconveniences that you may face by being in the research study?
14. What happens if you are injured since you took part in this researchstudy?
15. What are the other treatment options/alternatives toparticipation?
16. What will happen if you change your mind about participation in this researchstudy?
17. How will your privacy and confidentiality bemaintained?
18. Will you have to bear any Expenses or Costs by participating in the researchstudy?
19. Whom do you call if you have questions orproblems?
    a. Researchrelated
    b. Regarding rights as aParticipant

Please note that some questions may not be applicable to your research study, hence can be marked as Not Applicable, example Q.12 is applicable for clinical trials, Q.10 may not be applicable for basic research studies wherein the biological samples are taken at a point time.

Please contact the researchers listed below to:
Obtain more information about the study
Ask a question about the study procedures or treatments

Dr. …….
Scientist.....
Depatment.....
Phone…..

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

Name of the Member Secretary Ethics
Committee,S.N Medical College
Moti Katra, Agra-282002
Tel.No.: 05622260353
Fax No.: 05622260965
Email **: ecsnmc20@gmail.com**

Time to contact- Office Hours

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people (non scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records

**ANNEX6** **AF/EC/06/08/V1.0**

## Informed Consent Form

I_____haveread/havehadreadtheparticipantinformationsheetversion no. ……..dated……bearing page numbers 1-….. of the research study entitled ……

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

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

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

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

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

**Signature of Impartialwitness/LegalAuthorised Representative (wherever relevant)with date**

**Signature/Thumb impressionof Study Participant withdate**

Name oftheWitness

Name of the StudyParticipant

Signature ofPrincipalInvestigator withdate

Signature of Person administering theconsent withdate

Name of thePrincipal Investigator

Name of the Person administering theconsent

**ANNEX7** **AF/EC/07/08/V1.0**

**Informed Consent Form**
**(For future use of storedsamples)**

I_____give/do not give permission to preserve my samples to be used for any extension / modification of thisstudy.

If any other studies planning to use these left over stored samples, are decided in future, with the appropriate permission of the Ethics Committee.

I hereby give my consent willingly for use of my samples for future studies as mentioned above.

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

**Signature ofImpartialwitness with date**

Name oftheWitness

**Signature/Thumb impressionof Study Participant with date**

Name of the StudyParticipant

Signature ofPrincipalInvestigator withdate

Name of thePrincipal Investigator

Signature of Person administeringthe consent withdate

Name of the Person administeringthe consent

**ANNEX8** **AF/EC/08/08/V1.0**

## Assent Form

I ……have read /have had read the participant information sheet version no. ……..dated……bearing page numbers 1-….. of the research study entitled ……

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

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

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

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

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

**Signature ofImpartialwitness with date**

**Signature/Thumb impressionof Study Participant withdate**

Name oftheWitness

Name of the StudyParticipant

**Signature/Thumb impression of Mother/Father with date**

Name of the Parent

Signature ofPrincipalInvestigator withdate

Name of thePrincipal Investigator

Signature of Person administering the assent withdate

Name of the Person administering theassent

**ANNEX9** **AF/EC/09/08/V7.0**

## Guide to Placebo Justification

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

**I. Benefits of standardtreatment**

1) Is there a standardtreatment?
2) Is the standard treatment widelyaccepted?
3) Has efficacy of the treatment been consistentlyproven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed orother)?
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 orrefractory)?

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

**II. Risks ofplacebo**

1) Is the risk of using placebo instead of treatment lifethreatening?
   **If yes, placebo is not acceptable.**
2) Is the use of placebo instead of treatment likely to lead to permanantdamage?
   **If yes, placebo is not acceptable**
3) Is the risk of using palcebo 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 acuteemergency?
5) Is the risk of using placebo instead of treatment the persistence of distressingsymptoms?
6) Is the risk of using placebo instead of treatment severe physical discomfort orpain?
   **If the answer of (4) to (6) are"yes", placebo is not acceptable unless risk management is adequate.**

**III. Risk management**

1) Is there benefit in the overall management of thesubject?
   - Yes, considerplacebo
   - No, placebo not recommend.
2) Will the discontinuation of provious treatment put the participant in danger of acute relapse when transferred toplacebo?
   - No, consider placebo
   - Yes, placebo not recommend.
3) Are subjects at high risk for the use of placeboexcluded?
   - Yes, considerplacebo
   - No, placebo not recommend.
4) Is the duration of the study the minimum necessary in relation to the action of thedrug?
   - Yes, considerplacebo
   - No, placebo not recommend.
5) Are there clearly defined stopping rules to withdraw the subject in case he/she does not improve?

- Yes, consider placebo
- No, placebo not recommend.

6) Is risk monitoring adequate to identify progression of the disease before the subject experience severe consequences?
   - Not applicable.
   - Yes, consider placebo
   - No, placebo not recommend.
7) Are there clearly defined stopping rules to withdraw the subject before the advent of severe diseaseprogression?
   - Yes, consider placebo
   - No, placebo not recommend.
8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?
   - Not applicable.
   - Yes, consider placebo
   - No, placebo not recommend.
9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control themallowed?
   - Not applicable.
   - Yes, consider placebo
   - No, placebo not recommend.
10) If the risk of placebo is severely physical discomfort or pain, is there rescuemedication?
   - Notapplicable.
   - Yes, consider placebo
   - No, placebo not recommend.

**IV. Risk disclosure in the consentform**

1) Are the risks of getting placebo instead of active treatmentfullydisclosed?
   - Yes, considerplacebo.
2) Are the risks of the testdrugdisclosed?
   - Yes, considerplacebo.

2) Are the advantages of alternativetreatmentsexplained?
   Yes, considerplacebo.

**Conclusions** :

1. The use of placebo is ethically acceptablebecause:
   - Subjects are not exposed to severe or permanent harm by the use of placebo.
   - Subjects under placebo will benefit from the overall treatment of thedisease.
   - Risks of the use of placebo areminimized.
   - Risks are adquately disclosed in the consent form.

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

……..…
……..…

3. The use of placebo in this study is ethically unacceptablebecause:
   - Subjects are exposed to severe or permanent harm by the use of placebo instead of active treatment.
   - Due to the nature of the disease, the risks of placebo can not be minimized.

**ANNEX10** **AF/EC/10/08/V1.0**

## Guidance of Protocol Submission

The IEC is currently following the version 2 dated 24th September 2014 of the Standard Operating Procedures (SOPs), which are individual activity based and are 24 innumber.
The SOPs are available on the institutional LAN and the institute website.

The templates and forms are available on the Institute LAN for submission to the Ethics Committee

### I Prior to approval of a researchstudy

**Submission of a New StudyProposal**

- The study proposals will be circulated after receiving at EC office to the internal members. They will provide feedback (comments and suggestions) to the PIs within 2weeks.
- The PIs will make the corrections within a week and submit the required number of copies to the ECsecretariat.
- The secretariat will send the copies at least 8 days in advance of the full board meeting to the externalmembers.
- The project will be reviewed at the IECmeeting.
- An investigator is expected to be present at the time of full board meeting and will be invited (telephonically) to the IEC meeting to discuss issues related to the studyproposal.
- After the full board, the minutes will be given within 15days.
- An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 180 days of date of receipt of the letter. In the absence of any response, the project will be declared closed for the IEC officerecords.

### II Once approval for a study isgranted

- An approval will be granted for usually one year studyperiod.

- It is the responsibility of the principal investigator that for studies which will continue for more thanayear,acontinuingreviewreportneedstobesubmitted(within1monthoftheduedate i.e. 11 months from the date of approval)

- PI is responsible to submit continuing review report for the studies which will continue for more than a year (within 1 month of the due date i.e. 11 months from the date ofapproval)

- Submission of Study Related Documents for IECreview

- Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations) will be accepted during the office hours specified above. Only one set of the above stated study related documents need to be submitted for the IEC review as per theformat.

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

A covering letter should be submitted and the template for it is available on the LAN.

**III Once a study isover**

**Submission of Study Completion Report**

- For studies which are completed within the IEC approval period, a study completion report as per the format should be submitted to the IEC, by theinvestigator.
- The study completion report is expected for review within 2 months of completion of the study at the site. A brief study report containing data analysis from all centres should be submitted once available from thesponsor.

**IV In case a study is not initiated orterminated**,

- The same should be communicated to the IEC stating reasons for the same. The report of premature termination of the study should be given as performat.

**ANNEX11** **AF/EC/11/08/V1.0**

**ETHICS COMMITTEE, S.N Medical College-Agra**
Tel:05622260353, Fax No. 05622260965
E-mail: **ecsnmc20@gmail.com**



Ref.: Date

Dr. ……
Department ……..

Subject: Name of the project Title which was approved in meeting, Version 1.0 dated June 2020

ProjectNo.: …… PI: Dr……..

DearDr.....,

This is with reference to the above mentioned research study proposal, Version No. dated (reviewed in the meeting) which was reviewed and approved with minor modifications/ with amendments/ with revision along with the Participant Information Sheet and Informed Consent Documents (English and/ or Hindi) by the Ethics Committee, S.N Medical College for clinical Studies on …(meeting date)……..
with Dr. ….(Chairperson Name)… as the Chairperson. The Ethics Committee acknowledges the receipt and approves the Participant Information Sheet and Informed consent documents (English) / Hindi/on …(final copy received date)….

Please note that any changes to the proposal / Participant Information Sheet / informed consent form should have prior approval by the ethics committee before being implemented. The approval for this proposal is valid for a period of one year only. You are requested to submit the study report for a continuing review at least 2 months before the next re-approval period / on completion of the study.

Ethics Committee approval of the …… collaborating centers shouldbe obtained.

Due date for submission of Continuing review/Completion Report:……

Sincerely,

**ANNEX12** **AF/EC/12/08/V1.0**

**Document History**

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

## Table of Contents

**The Declaration of Helsinki** states that 'Medical research involving a underprivileged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of that population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.'

**1. Purpose**

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

**2. Scope**

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

**3. Responsibility**

It is the responsibility of the EC members to identify study proposals including vulnerable population and ensure that these are considered for full board. The EC will ensure that measures for safeguarding rights and interests of vulnerable participants are mentioned in the face sheet, study proposal, Participant /Assent Information Sheet/ and informed consent/assent form. They have the responsibility to ensure that the vulnerable population is not exploited and they will guide the investigators to design protocols and describe the process of informed consent in such a manner that this will be done.

**4. Flow chart**

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Receive the submitted documents ↓ | IEC Secretariat |
| 2 | Determine protocols including vulnerable population | IEC members and Chairperson |
| 3 | Review of protocol by appropriate reviewes and assess whether their inclusion is justified ↓ | IEC members and Chairperson |
| 4 | Ensure measures for protecting rights and interests of vulnerable population are described in the face sheet ↓ | IEC members and Chairperson |
| 5 | Review the Participant /Assent Information Sheet/ and Informed Consent/Assent form | IEC members and Chairperson |

**5. Detailedinstructions**

**Determine protocols including vulnerablepopulation**

Project proposals presented before the Ethics Committee Meeting which includes vulnerable population: It is the responsibility of the EC to see whether the inclusion of vulnerable populations in the study is justifiable or the population is just being exploited to generate clinical data. In such cases, appropriate reviewers will assess the risk and ensure

measures for protecting their rights. Review of risk assessment will be documented in IEC minutes.

**Vulnerable groups:** Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equallydistributed.

**a.** Research on genetics should not lead to **racialinequalities**;
**b.** Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off thanthem;
**c.** Rights and welfare of **mentally challenged and mentally differently able persons** who are incapable of giving informed consent or those with behavioural disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properlydocumented;
**d.** Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compellingreasons.
**e.** Persons, who are terminally ill, have incurable disease and mentalillness.

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

**i.** ***Children*****:**

**Before undertaking research/trial in children the investigator must ensure that –**

**a.** Children will not be involved in research that could be carried out equally well withadults;
**b.** The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of thechildren;
**c.** A parent or legal guardian of each child has given proxyconsent;
**d.** The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18years.;
**e.** Research should be conducted in settings in which the child and parent can obtain adequate Medical and psychological support;
**f.** Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits tosociety;
**g.** The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents /guardian;
**h.** Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternativeinterventions;
**i.** The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to begained.

***ii. Pregnant or nursingwomen:***

Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation.
As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

**a.** The justification of participation of these women in clinical trials would be that they **should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits.**
Example of such trialsis,

- To test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother tochild,
- Trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancyetc.
- Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in suchinstances.

**b. Research related to termination of pregnancy:** Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI,1971.

**c. Research related to pre-natal diagnostic techniques:** In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of thefoetus.

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

**6. Glossary**

**Vulnerability**

- The Council for International Organizations of Medical Sciences **(CIOMS)** defines **vulnerability** as "Substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchicalgroup."
- **Vulnerable (research) participants:** Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a researchstudymaybeundulyinfluencedbytheexpectation,whetherjustifiedornot,

of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. (WHO)

**7. References**

1. Ethical Guidelines for Biomedical Research on Human Participants , ICMR ,2006
2. E6 Good Clinical Practice: Consolidated Guidance, April 1996, ICH–GCP
3. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants ,2011

**8. ANNEX**

ANNEX1 Documenthistory AF/EC/01/09/V1.0

**ANNEX1** AF/EC/01/09/V1.0

**Document history**

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

## Table of Contents

## 1. Background

As per the DCGI office order dated 19thNovember 2013, Audio Visual (AV) recording of the informed consent process was made mandatory for regulatory clinical trials. This office order is in support to order dated 21stOct 2013 from the Honorable Supreme Court of India. The main idea & purpose behind AV recording of the consent process is to ensure that the clinical trial participants are adequately informed about all aspects of the clinical trial including risks and benefits and chances of failure of the Investigational Medicinal Product (IMP) to give intended therapeutic effect and to ensure that they have understood the details of the study including their right so that individual's voluntary participation is ensured.

## 2. Purpose

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

## 3. Scope

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

1. AV recording of the entire informed consent process is mandatory for all clinical trials approved by the DCGI, provided that they come under the followingcategories.
2. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure providing information to the subject and his understanding of such consent, shall be maintained by the investigator forrecord.
3. In case of clinical trial of anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator forrecord.

## 4. Responsibilities

Principal investigator, Co-Investigator or any other medically qualified member of staff in the team, as delegated by the Principal Investigator, who have the responsibility of obtaining an informed consent, will also be responsible for ensuring AV recording of the informed consent process, storing and archiving without violating the participant confidentiality.

## 5. Applicable rules, regulations andguidelines

- Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F.No. GCT/ 20/SC/Clin./2013 DCGI dated 19th November2013
- Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F.No. X.11014/1/2012-DFQC dated 31st July2015
- Schedule Y (Jan2005)

- Ethical Guidelines for Biomedical Research on Human Participants,ICMR2006
- International Conference on Harmonization; Good Clinical Practice Guidelines: May1996
- Indian GCP2001

## 6. DetailedInstructions

All basic principles and procedures for the administration and documentation of the informed consent process is described in SOP Initial review of submitted protocol.

1. If the participant is unable to give consent for medical or legal reasons, the consent should be taken from the legally acceptable representative (LAR) and the process recorded.
2. If the participant/LAR is illiterate then an impartial witness is needed. This person should also be in the frame for the entire duration of the consentprocess.
3. AV recording should be done of assent whereverapplicable
4. Ensure the following infrastructure is available **prior to** counseling of potential participant:
   a. The informed consent process should be carried out in the designated area when the following conditions should be met) that is-
      i. Free fromdisturbance
      ii. Well lit
      iii. Ensures privacy for theparticipant
      iv. Participant should becomfortable
   b. Camera having video facilitywith
      - ✓ Good resolution (at least1280x720pixels)
      - ✓ Sufficient memory (at least 4GB)
      - ✓ Sufficient battery backup (at least 2hours)
      - ✓ Show non-editable date & time on video(preferably)

      b. Mikesystem
      c. Computer/laptop with CD/DVDwriter
      d. Blank CDs/DVDs withcover
      e. External Hard disk (at least 500 GB to 1TB)
5. Before starting the informed consent process (and the AV recording of thesame)
   - Ensure that all the necessary equipment mentioned above isfunctional.
   - The potential participant/LAR/ Impartial witness should be informed that the whole process of taking the consent is being recorded as per Govt. of India notification to ensure that he/she has understood all the potential risks and benefits involved in the study including failure of the IMP, study details and his/her rights for the purpose of documentation and the confidentiality of the same isassured.
   - The potential participant/LAR/ impartial witness should be made aware that his/her recording may be shown to government agencies or members from the IEC and independentauditors.
   - His/her consent should be documented in a separate ICD that states the same. The process of obtaining signatures of the potential participant/LAR/ impartial witness & Principal Investigator or her designee on this Audio-video consent form should be carried out as per specified in Annexure AF/EC/04/08/V1.0 of SOP/08/V1.0.

**6. Actual AV recordingprocess**

- The PI/Co-I/medically qualified person delegated by the PI and the potential participant/LAR (and if need be the impartial witness) should sit comfortably facing each other / side-by-side in such a way that their faces will be captured in the framesimultaneously.
- The PI/Co-I/medically qualified person delegated by the PI should introduce himself/herself by name, designation and his/ her role in the research, and state the current date andtime.
- Participant/LAR should be requested to introduce his/her name, age and address and in case of LAR, he/she should clearly state relation to actual participant as well as the reason why the participant cannot give consent. Participant/LAR should also state the language he/she understands best and is literate in. The PI/Co-I/medically qualified person delegated by the PI may facilitate this process to ensure all above points are captured in the recording.
- In case participant/LAR is illiterate and an impartial witness is needed, the impartial witness should be requested to introduce himself/herself, give his/her address and state the language that he/she is literatein.
- The Participant/LAR should state that he has been informed about the fact that the entire consent process is being recorded and that he/she has agreed for thesame.
- The Informed Consent Process should be carried out as per SOP 08/V7.0: Administering and documenting informedconsent.
- The participant should be allowed to read the consent document (and this process should berecorded)
- The PI/Co-I/medically qualified person delegated by the PI should explain all the elements of the approved ICF in the language best understood by the potentialparticipant
- Explanation or narration given by the PI/Co-I/medically qualified person delegated by the PI, all the questions asked by the potential participant/LAR and answers given to them should be clearly audible andrecorded.
- At any point during the consent process, if the participant wishes to take more time to read/ understand the consent document, including, for example, take it home to discuss with relatives the recording shall be stopped mentioning the time of stopping. When he/she returns, the recording from the point where it was stopped before shall be resumed as mentioned before stating clearly again the date and time ofrecording.
- The participant/LAR (wherever applicable) should be invited to sign the consent form only after satisfactory answers (in the investigator's judgement) have been given by the participant/ LAR to all the above mentionedquestions.
- Participant/LAR should read out all the statements mentioned in ICF as per Schedule-Y and state whether he/she agrees or not for each statement and affix signature/thumb print at theend
- The actual signing process should berecorded.
- The impartial witness should be requested to enter the name and details of the participant and the date the consent is documented. The impartial witness will also be requested to sign and date the consentform.
- The PI/Co-I/medically qualified person delegated by the PI will also sign and date the consent form at the end of theprocess.

- The recording will be stopped after thanking theparticipant.

7. The recording should be checked for completeness and clarity of both audio and video recording.
8. No editing should be done on the recording so as to maintainauthenticity.
9. The computer/laptop should be password protected. The password will be known only to the PI and members of the study team as designated by the PI.A register should be maintained wherein, each time the data is accessed, the details of who accessed the data, date and reasons for the same this should be entered into the designatedregister.
10. The recording should be then transferred to a CD labeled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings (applicable during re-consenting ) and archived in the external Hard drive. The CD should be filed in the participantbinder.
11. The study participants should be informed that there is possibility of failure of investigational product to provide intended therapeuticeffect.
12. In case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeuticeffect.
13. Archival
    a. The CDs will be archived with each participant binder as per SOP/22/V7.0 Archival and retrieval ofdocuments
    b. The soft copies of the recordings will also be stored in a password protected external hard drive.
    c. The original recording in the computer/laptop will be deleted when study is closedout.

## 7. References:

1. Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F.No. GCT/ 20/SC/Clin./2013 DCGI dated 19th November2013.
2. Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), Gazette of Indian New Delhi, dated 31st July 2015No.489.
3. Draft Guidelines on Audio-Visual Recording of Informed Consent Process in Clinical Trial, CDSCO, MOHFW, 9th Jan2014.
4. FERCAP guidelines for Audio-Visual consentprocess.

**ANNEX1** **AF/EC/1/10/V1.0**

## Document History

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

## Table of Contents

**1. Purpose**

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

**2. Scope**

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

**3. Responsibility**

It is the responsibility of the IEC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the IEC forreconsideration.

A re-submitted protocol may be reviewed and approved by either the Chairperson or some IEC members/reviewers, or full IEC. Decision for the review of the protocol should be determined by the IEC at the time of the initial review and mentioned in the minutes of the Ethics Committee meeting in which the proposal wasdiscussed.

**4. Flowchart**

| **No.** | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Receive resubmitted protocol package ↓ | Secretariat |
| 2 | Review the revised protocol ↓ | Affiliated Members |
| 3 | Sending the protocol to external members/ reviewers ↓ | Secretariat |
| 3 | IECMeeting ↓ | IEC Members |
| 4 | Communicate the IEC decision | IEC Secretariat |
| 5 | Document the decision | IEC Secretariat |

**5. Detailed instructions**

**Receive protocol resubmittedpackage.**

***Check the received packages for:***

Minutes of previous EC meeting

- Response to the comments byInvestigators
  Checklist (AF/EC/01/06/V1.0, see ANNEX 1 of SOP/06/V1.0)

- Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets, etc are included as part of thepackage.
- Changes made to the documents should be bold and the deleted matter should be made strikethrough for easy verification of the corrections done by theinvestigators.

- Put the stamp, write date and acknowledge the receipt of theprotocol.

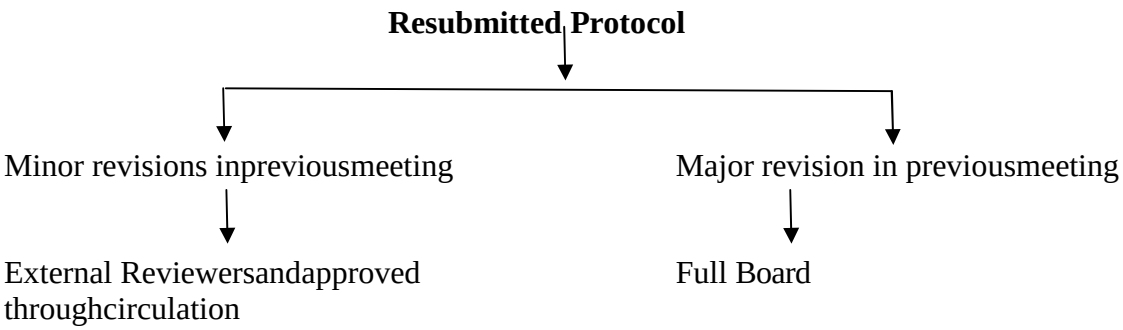
**Review the revised protocol –AffiliatedMembers**

- Check the received protocol as per Checklist(AF/EC/01/06/V1.0)
- Refer to the meeting minutes as guidance for thereview.
- Ensure that the response to comments of EC members as mentioned in the minutes is given by the investigator and page numbers where changes are made are mentioned in theproposal.
- Make further comments if the response is not satisfactory and the changes have not been incorporated in the studyproposal.
- Internal reviewer's will write the comments on the Project Review Report form andwill put signature with date.
- Notify the IECSecretariat.
- Ask the Principal Investigator to make the necessaryrevisions.
- Send the resubmitted proposal with incorporated changes to reviewers /full board as per the decision in theminutes.
- If the proposal has only minor modifications as decided in the previous full board meeting, the proposal with incorporated changes is sent to externalreviewers.
- The Secretariat to receive the package and inform the Member Secretary. Follow instructions in 5.4respectively.

**IECmeeting**

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

- The primary reviewer presents a brief oral or written summary of the study design and his/her comments to the IECmembers.
- The Chairperson entertains discussion on the protocolrevision.
- Further recommendations for modifications to the protocol, consent form, as requested by the Committee are noted in the meeting minutes as 'with modifications made by IEC and will be communicated to theinvestigator.
- The Chairperson takes a consensus of the EC members on the revision toeither:
  - Approve the study to start as presented with no modifications =*Approved*
  - Minor modifications for expeditedreview
  - Major modification for full boardreview
  - *Disapproved*
  - *Flowchart for managing proposals with major and minormodifications*



**Written Communication of theDecision**

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

**6. Glossary**

Document All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or videotape.

**7. References**

World Health Organization, Operational Guidelines for Ethics Committees thatReview Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

**8. ANNEX**

ANNEX1 DocumentHistory AF/EC/01/11/V1.0

**ANNEX1** **AF/EC/01/11/V1.0**

**Document History**

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

## Table of Contents

**1. Purpose**

The purpose of this standard operating procedure is to describe how protocol amendments are managed and reviewed by the IEC

**2. Scope**

This SOP applies to previously approved study protocols but later being amended and submitted for approval by the IEC. Amendments made to protocols may not be implemented until reviewed and approved by the IEC.

**3. Responsibility**

It is the responsibility of the IEC Secretariat to manage protocol amendments. Investigators may amend the contents of protocols from time to time. Amendments may be submitted for either "expedited" review by the Chairperson / Secretariat /members / reviewers or full IEC review.

**4. FlowChart**

| **No**. | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Receive the Amendment Package ↓ | IEC Secretariat |
| 2 | Check for completeness ↓ | IEC Secretariat |
| 3 | Provide it to the affiliated members ↓ | IEC Secretariat |
| 4 | Send it to external experts and Chairperson after incorporation of suggestions ↓ | IEC Secretariat |
| 5 | Determine whether Expedited or Full Review ↓ | IEC Secretariat / Chairperson |
| 6 | Amendment Review Process ↓ | IEC Secretariat/EC Members /Chairperson |
| 7 | Inform the Principal Investigator ↓ | IEC Secretariat |
| 8 | Store Documents | IEC Secretariat |

**5. Detailed instructions**

**Manage the Amendment Documents/Package**

- The amendment documents are prepared by the PrincipalInvestigator.
- Upon receipt of the amendment documents, the Secretariat of the IEC should follow the receiving procedure in SOP/06/V1.0 (Management of Protocol Submission) and SOP/23/V1.0 (Maintaining Confidentiality of IECDocuments).

- Request for Amendment of the Protocol by the Principal Investigator on an existing and previously approved protocol should be made in the covering letter to the chairperson. The request should:
  - State/describe the list of amendments
  - Provide the reason/justification for theamendment

- **Protocol and RelatedDocuments**

- The amended version of the protocol and related documents should be provided to the affiliated members and MemberSecretary.
- The suggestions given by them should be incorporated in the proposal and the changes or modifications should be in bold lettering and the deleted matter should be retained with strikethrough.

**Send the documents to External experts and Chairperson of theIEC**

- After review of the materials, the Member Secretary in consultation with Chairperson will determine whether the protocol requires expedited or fullreview.
- The Secretariat should send the documents to external experts of the IEC.
- Keep "Sent" and "Received" acknowledgement on hard copy (Signature for received) related to the notification of the Chairperson in the protocol file under the Correspondence section.
- Follow IEC SOP/23/V1.0 in preparing and distributing thedocuments.

**Determine whether expedited or fullreview.**

- Refer to SOP/07/V1.0 for ExpeditedReview.
- Refer to SOP/08/V1.0 for Initial Review.
- Protocol amendments which increase risk to study participants, as judged by the Chairperson, such as a change in study design, which may include but is not limitedto:
  - additional treatments or the deletion oftreatments
  - any changes in inclusion/exclusioncriteria
  - change in method of dosage formulation, such as, oral changed tointravenous
  - significant change in the number of subjects (Increase: if there are <20 subjects enrolled, change of 5 is significant; if there are >20 subjects enrolled, a change of 20% is significant – Decrease: if the decrease in the number of subjects alters the fundamental characteristics of the study, it issignificant)
  - significant decrease or increase in dosageamount
    - If the Chairperson decides, the protocol requires full IEC approval, the Chairperson will indicate this decision on the Checklist, sign and date theform.
    - The Secretariat places the protocol amendment request on the agenda for the next convenedmeeting.

**The following documents are distributed to each IEC member:**

- The amendment's revision documents to clearly identify eachchange.
- Requested changes to the consent form, ifapplicable

**ExpeditedReview**

- Refer to SOP/07/V1.0 for expedited reviewprocedure.

**Full Review by the IEC**

- Refer to SOP/08/V1.0 for InitialReview.

- See section5.6

**Protocol Amendment Review Process**

**Review amendedprotocols**

- Use the process outlined in the Study Assessment Form (see SOP/06/V1.0) to review amended protocols and protocol-relateddocuments.
- Note recommendations for changes to the protocol and/or informed consent requested by IEC Members in the minutes as "with modifications made by EC' and will be communicated to theinvestigator.

**The Chairperson and the EC members can give the following decisions:**

- Approve the protocol amendment as is with no modification in the Participant Information Sheet and Informed Consent Document.
- Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IECreview
- Suspend the study, until further information isobtained
- Not suspend the study as currently approved, but request further information regarding the amendment and the effects of the amendments on the approvedstudy
- Not approve the amendment request, stating the reason – but allow the study to continue as previouslyapproved
  - If the IEC approves the protocol amendment, the Secretariat staff communicates this decision to theinvestigator.
  - If the IEC does not approve the protocol amendment, the Chairperson notifies the investigator in writing of the decision and the reason for not approvingthe amendment.
  - Keep the minutes of the meeting relevant to the discussion and the decision reached by the IEC as the official records of the amendment reviewprocess.

**Notify the PrincipalInvestigator.**

- Send a signed and dated Minutes copy to the Principal Investigator for theirrecords.
- The Principal Investigator should then provide a copy with bold and strikethrough which would be checked by Secretariat and internal members and external reviewers as mentioned in the Minutes. Further a "clean" copy (Without bold and strikethrough) of the protocol and related documents should be submitted by the Principal Investigator to the Secretariat of the IEC.

**Storedocuments.**

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

**6. Glossary**

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

Clinical trial office: An institute or an office where the study takes place and where the principal investigator and/or his/0her staff may be reached.

Expedited approval: An IEC approval granted only by the Chairperson of the .... *INSTITUTE* …. IEC or a designated .... *INSTITUTE* …. IEC member (not the full IEC) for minor changes to current IEC approved research activities and for research which involves no more than minimal risk, as stated in the SOP/08/V1.0.

**7. References**

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Code of Federal Regulation (CFR), 21 §56.110, The United States of America,1998

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

**8. ANNEX**

**ANNEX1 DocumentHistory AF/EC/01/12/V1.0**

**ANNEX1** **AF/EC/01/12/V1.0**

**Document History**

| Author | Version | Date | Description of the Change |
|---|---|---|---|
| | Version 1.0 | June 2020 | |

## Table of Contents

## 1. Purpose

.The purpose of the continuing review is to monitor the progress of the entire study, to ensure continuous protection of the rights and welfare of research participants.

Continuing review of the study may not be conducted through an expedited review procedure,unless

1. The study was eligible for, and initially reviewed by, an expedited review procedureor
2. The study has changed such that the only activities remaining are eligible for expeditedreview.

## 2. Scope

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

## 3. Responsibility

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

## 4. Flowchart

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Determine the date of continuing review | EC Secretariat |
| 1 | Remind PI for continuing review submission ↓ | EC Secretariat |
| 2 | Manage continuing review package upon receipt ↓ | EC Secretariat |
| 3 | Notify the affiliated members of the EC& Member Secretary ↓ | EC Secretariat |
| 4 | Incorporate the reports in the Agenda of the forthcoming meeting ↓ | EC Secretariat |
| 5 | Protocol Continuing review process in EC Meeting ↓ | EC Secretariat, EC Members and Chairperson |
| 6 | Approvalofminutes ↓ | Chairperson |
| 7 | Providing Minutes to PI regarding approval | EC Secretariat |

**5. Detailed Instructions:**

**Determine the date of continuingreview**

- The Secretariat will look through the master file of projects approved by the EC for the due dateof continuingreviews.
- The Secretariat will plan for continuing review of annual progress reports to be reviewed atleast one month ahead and as close as possible to the due date (i.e. one year after the date of original approval) of theprotocol.

- The Member Secretary will consult the Chairperson whether to include the annual project report/s in the forthcoming EC meeting for discussion or to review by Member Secretary/ Chairpersonand inform the members at the full board meeting or to send to two EC members nominated by Chairperson forreview.

**Notify the PI or the studyteam**

- The Secretariat will inform the PI at least two months of the due date for the continuing review in writing, (AX17-V1/SOP 01/V1.0) requesting for 2 copies of the annual / periodic progress report to allow the Study Team sufficient time to collate the information and to prepare a reportpackage required for the continuingreview.
- The Secretariat will provide a Continuing Review Application Form (AX16-V1/SOP 13/V1.0) (available at the EC Secretariat) to the Study Team and file the acknowledgement in the masterfile of the researchprotocol.
- Any PI who fails to submit the report for review within the stipulated time, will haveto Clarify the delay in writing, this will be forwarded to the Chairperson,EC.

**Remind Principal Investigator for continuing review submission**

If the report is not received within one month, the secretariat will remind the Principal Investigator. At the end of three months, if no report is received the study will be suspended.

**Manage continuing review document uponreceipt**.

- TheSecretariatwillreceiveapackagesubmittedbytheStudyTeamofcontinuingreviewforeach approved protocol.
- Upon receipt of the package, the Secretariat of the EC should perform thefollowing:

**a Initial and date the submissionpackage**

- See SOP/06/V7.0 for procedures on receipt of submittedpackages.

**Verify the contents of thedocument**

- The Secretariat will verify that the contents of the package include thefollowing documents:

**1)** Continuing Review Application Form (AX16-V1/SOP13/V1.0).

**2)** The Progress Report with: Information about the number of participants enrolled to date andsince the time of the last review, an explanation for any "yes" (ticked on the Continuing Review Application Form (AX16-V1/SOP 13/V1.0) answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to researchparticipants.

- The progress report summary of the protocol since the time of the last review (1copy).
- Request letter for extension of approval of the project, if the project isongoing.
- The Secretariat will check for complete information and for the presence of therequired
- signatures of the Principal Investigator in the Continuing Review ApplicationForm.

**Filing the continuing review document**

The Administrative Officer will file the continuing review original package in the protocol specific master file of the research

**Prepare meetingagenda**

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

**Protocol ReviewProcess**

The EC Chairperson/ Member Secretary/ members will use the Continuing ReviewApplication Form (AX16-V1/SOP 13/V1.0) to guide the review and deliberation process. The ECmembers could arrive at any one of the following decisions at the ECmeeting:

a) Noted and the project can be continued without anymodifications
b) Modifications recommended - Protocols for which modifications have been suggested by the EC may not proceed until the conditions set by the EC in the decision have been met. Protocols should be amended and submitted to the EC within one month for re-review. Protocols that have been approved with recommendations by the EC may not proceed until the conditions set by the EC in the decision have been met. Protocols should be amended and submitted to the EC within one month for rereview
c) Disapproved.

- This decision is recorded by the Member Secretary onAX18-V1/SOP01/V1.0
- The IEC Chairperson will sign and date the EC decision on Continuing ReviewReport after a decision has been reached.
- The completed EC decision on Continuing Review Report is the official record ofthe decision reached by the EC for theprotocol.
- The EC Secretariat will maintain and keep the EC decision forms and minutes ofthe meeting relevant to the continuing review as part of the official record of the review process.

**Store original documents** Place the original completed documents with the other documentsin the Continuing Review Package in the protocolfile

**Communicate the EC Decision to thePI**

The Secretariat will notify the PI of the decision. If the decision is to recommend modifications, the recommendations will be notified to the PI and he/she will be requested to resubmit the protocol/protocol related documents as amendment within 1 month for approval. Till then the project is suspended. These letters must be sent to the PI within Seven working days.

## 6 Glossary

**Approved Protocols** Protocol that have been *approved without stipulations* or*approved with recommendations* by the EC may proceed. Protocols that have been *approved with stipulations* by the EC may not proceed until the conditions set by the EC in the decision have been met. Protocols should be amended and submitted to the EC within *one* month for re-review.

## 7 References

World Health Organization, Operational Guidelines for Ethics Committees that ReviewBiomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH-GCP) 1996.

ICMR guidelines for clinical research.(http://icmr.nic.in/ethical_guidelines.pdf)

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006.

## 8. ANNEX

**ANNEX1** **AF/EC/01/13/V1.0**

**Document History**

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

## Table of Contents

**1. Purpose**

The purpose of this SOP is to provide instructions on the review and follow up, if appropriate, of Final Reports for any study previously approved by the Ethics Committee KLEUniversity.

**2. Scope**

This SOP applies to the review and follow-up of the Final Report which is an obligatory review of each investigator's activities presented as a written report of studies completed to the EC. The Institutional Ethics Committee for Clinical Studies provides a Study Report Form for Protocol Termination/ Completion refer ANNEX 4 (AF/EC/04/06/V1.0) of SOP/06/V1.0 which is to be followed by the investigators for submission of Final report.

**3. Responsibility**

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

**4. Flowchart**

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

**5. Detailed instructions**

**Before each ECMeeting**

- See SOP/06/V1.0 (Management of Protocol Submission) for receiving and checkingthe reportpackages.
- The Member Secretary and affiliated members will review the submitted report and the Principal Investigator will make the changes if needed.
- The Principal Investigator to make sufficient number of hard copies with the incorporatedchanges.
- The Secretariat to send the copies to the external members andChairperson.

**During the ECMeeting**

- Each EC member reviews and gives their comments on a copy of the FinalReport.
- The Chairman entertains any discussion of thestudy.
- If appropriate to the discussions, an IEC member may call for consensus on whetherto request further information or to take other action with theinvestigator.
- Summarize what action should betaken.

**After the ECMeeting**

- Notify the investigator of thedecision.
- Accept and file the Final Report, if no action istaken.
- Note the decision in the meetingminutes.
- Consider the study asclosed.
- Send the approved minutes to theinvestigator.
- Archive the entire study protocol and thereport.

**6. References**

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## Table of Contents

## 1. Purpose

The purpose of this SOP is to provide instructions on the review and follow-up reports of serious adverse experience and unexpected events for any active study approved by the Ethics Committee, Ethics Committee, S.N Medical College –Agrafor Clinical studies. The Serious Adverse Events must be reported by the investigators to the EC within 24 hours after the incident. The unexpected events should be included in the continuing review report submitted to EC.

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

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

## 2. Scope

This SOP applies to the review of SAE reports submitted by Investigators to EC members or other concerned parties.

## 3. Responsibility

The primary responsibility of the EC is to review and address SAE and unexpected events involving risks to participants.

- EC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements of SAE and unexpectedevents.
- The Principal Investigator should submit within 24 hours SAE report or the unexpected adverse event report to the Sponsor, EC, DCGI and Head of the Institution Or byemail.
- The report of SAE of due analysis shall be forwarded by the Investigator to EC, DCGI, sponsor and Head of the institution within 14 calendar days of occurrenceSAE.
- The report should be accompanied by detailed narrative of the SAE and appendix XI form of theCDSCO
- It should be submitted as per checklist detailed by LicensingAuthority.

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

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

**4. Flow chart**

| S.No | Activity | Responsibility |
|---|---|---|
| **1** | SAE related activities before an ECmeeting | EC Secretariat, members |
| **2** | Review and determine the review channel | EC Secretariat, members |
| **3** | Decide the criteria for the review | EC Secretariat, members |
| **4** | Review and discuss during the IEC meeting ↓ | EC members and Chairperson |

| | | |
|---|---|---|
| **5** | Decide what action should be taken | EC members and Chairperson |
| **6** | Inform investigator**,** regulatory authorities and head of institution within 30 days of receipt of the SAE | Secretariat and Chairperson |

**5. Detailedinstructions**

**Before each EC meeting**

**Review and determine the reviewchannel**

EC Secretariat or members review the reporter's assessment to determine whether the report requires review by full Board or by the Chairperson or other qualified EC member(s).

**Criteria for thereview**

The **review criteria** are as follows:

- Assessment of adverse experience is unknown orunlikely
- Report is forwarded to the Chairperson for review and determination if report should be reviewed at the convened meeting by fullBoard.
- Assessment of relatedness of the SE as per the criteria of GSR 52 with amendments of 12th June2015.
- The report is added to the agenda for review at a convened meeting by fullBoard.
- An adverse experience/Investigational New Drug safety Report has been previously seen by full Board but being resubmitted by another investigator participating in the multi-study site (as part of a multi-center/sitestudy).
  - This notification does not require full Boardreview.
  - Reviewed by the Chairperson or other qualified IEC members andsecretariat

**During the ECmeeting**

**Review and discuss**

- After reading and reviewing the report, the Chairperson or designee entertains discussion on the study and similar adverse experiences oradvisories.
- If appropriate to the discussions, the Chairperson or another EC member may call for a consensus on whetherto:

- *Request an amendment to the protocol or the consentform.*
- *Request furtherinformation.*
- *Suspend or terminate thestudy.*

**Decide what action should betaken**

- If any of the above *actions are taken*, the EC Secretariat or designee notifies the investigator of the actiontaken.
- If the EC *takes no action*, a notation is made in the minutes and the study is allowed tocontinue.

**Inform investigator or clinical trialoffice**

- The EC secretariat member drafts a formal letter to the investigators or the clinical trial office to notify them of the action they should take according to the ECdecision.
- Get the Chairperson to approve, sign and date theletter.
- Send the letter and record the deliverydate.

**6. Glossary**

**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, whether or not related to the product.

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

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

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

**Death** - Report if the patient's death is suspected as being a direct outcome of the adverse event.

**Life-Threatening** - Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.
*Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.*

**Hospitalization** (initial or prolonged) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverseevent.
*Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.*

**Disability** - Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life.
*Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.*

**Congenital Anomaly** - Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.
*Examples: Vaginal cancer in female offspring from diethylstilbestrol duringpregnancy; malformation in the offspring caused bythalidomide.*

**Requires Intervention to Prevent Permanent Impairment or Damage** –

Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.
*Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardwareto prevent malunion of a fractured long bone.*

**Unexpected ADR** Unexpected Adverse Drug Reaction is an adverse reaction, the nature or severity of which is not consistent with the informed consent /information sheets or the applicable product information (e.g., investigator's brochure for the unapproved investigational product or package insert / summary of product characteristics for an approved product.

## 7. References

World Health Organization, Operational Guidelines for Ethics Committeesthat Review Biomedical Research,2000.
International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.
Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## 8. ANNEX

ANNEX 1 AF/EC/ 01/15/V7.0 Serious Adverse Event Report
ANNEX2 AF/EC/02/15/V7.0 Unexpected Adverse Event Summary Report
ANNEX3 AF/EC/03/15/V7.0 Document History

**ANNEX1** **AF/EC/01/15/V1.0**

## Serious Event Report

**ProjectNo.:** **PrincipalInvestigator:**

**Study Title:**

**Name of the study medicine/device:**

**Report Date:**

☐**initial** ☐**follow-up**

**Onsetdate:**

Subject'sinitial/number: : Age: ….. Yrs. ☐ Male ☐Female

Subject's history: Laboratory findings: ----------

SAE: Treatment: ----------

Outcome: ☐ resolved ☐ on-going

Seriousness:

☐Death
☐ Life Threatening
☐Hospitalization–○ initial○ prolong
☐ Disability / Incapacity
☐ Congenital Anomaly
☐Other……

Relationto○ Drug○ Device ○ study

☐Notrelated ☐Possibly ☐Probably ☐Definitelyrelated ☐Unknown

Changes to the protocol recommended?☐No ☐ Yes , attachproposal

Changes to the informed consent form recommended?

☐ No ☐ Yes, attach proposal

Reviewedby:……

Comment:…….

Date:……
Action:……

**ANNEX2** **AF/EC/02/15/V1.0**

## Unexpected Adverse Event Summary Report

Principal Investigator:…….

StudyTitle:……...

Name of the studiedmedicine/device……..

Sponsor:……...

| # | Description of Unexpected Adverse Events | Date of Event (D/M/Y) | Date start and end of Tx (D/M/Y) | F or M | Initial | Age (Y) | Serious Yes/No | Related to Study Yes No | Concomitant medication | Inter-vention |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

**Comment:**

Reviewed by**:……**

Date:

**ANNEX3** **AF/EC/03/15/V1.2**

**Document History**

| Author | Version | Date | Description of the Change |
|---|---|---|---|
| | Version 7.0 | | |
| | | | |

## Table of Contents

**1. Purpose**

To provide instructions for taking action and maintaining records that identify Investigators/Institutes who fail to follow the procedures written in the approved Protocol or to comply with National / International guidelines for the conduct of Human research, including those who fail to respond to the IEC requests.

**2. Scope**

This SOP applies to all IEC approved research Protocols involving Human participants.

**3. Responsibility**

1.EC Secretariat is responsible for receiving deviations /violations/waiver reports as per (AF20–V1/SOP01/V1, (AF/EC/01/16/V1.0) submitted by the PI and placing it onagenda of the meeting. Reporting of deviation/ non-compliance/ violation/ waiver in any other reporting format will not be accepted.

2. EC members should review and take action on suchreports.

**4. Flowchart**

| **No**. | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Noting Protocol deviation / noncompliance /violation ↓ | IEC members and Chairperson |
| 2 | Ethics Committee's discussion and decision | IEC members and Chairperson |
| 3 | Notify the Investigator ↓ | IEC Secretariat, members and Chairperson |
| 4 | Keep records and follow up | IEC Secretariat |

**5. Detailed instructions**

**Protocol deviation / non-compliance / violation/waiver has beenobserved:**

- Ensure that the project in which non-compliance has been observed is included in the agenda of the ECmeeting.
- Maintain a file that identifies projects that are found to be non-compliant with National / International regulations or Investigators who fail to follow Protocol approval stipulations or fail to respond to the EC request forinformation/action.

**Detection of Protocol deviation/ non-compliance/violation/waiver**

**5.1.1a)** The IEC members performing monitoring of the project at trial site candetect Protocol deviation/non-compliance / violation, if the project is–

- Not conducted as per Protocol / National / Internationalregulations
- When scrutinizing annual / periodic reports / SAEreports

- Any other communication received from the Investigator / trial site / Sponsor/ Study monitor /CRO

**5.1.1 b**) The Secretariat can detect Protocol deviation / non-compliance / violationfrom Failureto

- Comply with statutoryrequirements
- Respond to requests from EC within reasonable timelimit
- Respond to communication made byEC

**5.1.1. c)** The PI himself / herself may forward the Protocol deviation / non- compliance / Violation / waiver reports to inform to the EC.

Protocol Waiver is analogous to a Protocol Deviation, except that prior IRB approval must be obtained before implementing the necessary departures from the Protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not.

**E.g**. Protocol Waiver means a prospective decision by a Sponsor or Investigator to permit approval of a subject who does not satisfy the approved inclusion / exclusion criteria for enrollment.

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

**5.1.1. E)** Any report / communication brought to the notice of Member Secretary / Chairperson of EC

**5.1.1. F**) Communication received from any source, informing EC about an Alleged Protocol violation / non-compliance / Protocol deviation

Noting Protocol deviation / non-compliance / violation / waiver by theSecretariat

- The EC members who have performed monitoring of a particular trial site anddetect Protocol deviation / non-compliance / violation will inform the Secretariat in writing **Within 24** hours [One workingday].
- Whenever Protocol deviation / non-compliance / violation has been observed,the Secretariat will ensure that the issues as well as the details of non-compliance involving Research Investigators are included in the agenda of the ECmeeting.
- The deviations / violations will be scrutinized for gravity and implications inthe formal full board EC meeting. The EC decision will be communicated to thePI.

- *Note*: The Ethics Committee shall withhold at their discretion the approval of current studies or refuse subsequent applications from the Investigators cited. Such decisions are recorded inminutes.

**The EC Discussion, Decision andAction**

The Chairperson notifies the Investigator regarding the EC's action in writing,

- If the Protocol deviation / non-compliance / violation is detected by any EC member During the monitoring visit, he/she will present the Protocol deviation / noncompliance /violationinformation.
- If detected by Secretariat / forwarded by PI, the Secretary will present theProtocol Deviation / non-compliance / violation / waiverinformation.
- The Chairperson / EC members will review the information available and takea decision depending on the seriousness of theviolation.
- The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus and if no consensus is arrived at, voting will be conducted. The actions taken by EC could include one or more of thefollowing:

* Inform the PI that EC has noted the violation / noncompliance / deviation and inform the PI to ensure that deviations / noncompliance / violations will not occurin the future and follow ECrecommendations.
* Enlist measures that the PI would undertake to ensure that deviations/ noncompliance /violations do not occur infuture.
* Call for additionalinformation.
* Suspend the study till additional information is made available and isscrutinized.
* Suspend the study till recommendations made by the EC are implemented by thePI and are found to be satisfactory by the EC. Suspend the study for a fixed duration of time.
* Revoke approval of the currentstudy.
* Inform DCGI / Other relevant regulatory authorities ifapplicable.
* Keep other research proposals from the PI/ Co-PI underabeyance.
* Review and / or inspect other studies undertaken byPI/Co-PI.

**Notify theInvestigator**

- The IEC Secretariat members record the EC's decision.
- Draft and type a notificationletter.
- Request the Chairperson to sign and date theletter.
- Make two copies of the notificationletter.
- Send the Original copy of the notification to theInvestigator.
- The IRB Secretariat sends a copy of the notification to the relevantNational authorities.

**Keep records and follow up**

- Keep a copy of the notification letter in the "non-compliance"file.
- Store the file in the shelf with an appropriatelabel.
- Follow up the action after a time period as suggested by the EthicCommittee.

## 6. Glossary

**Deviation / Non - compliance / Violation** : The IEC monitors whether Investigators do not perform the study in compliance with the approved Protocol, ICH GCP, FDA regulations and/or fail to respond to the IECs request for information/action.

## 7. References

World Health Organization, Operational Guidelines for Ethics Committees thatReview Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP)1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## 8. ANNEX

ANNEX1 AF/EC/01/16/V1.1 Deviation/Non-Compliance/Violation RecordANNEX 1 AF/EC/01/16/V1.0

Deviation / Non-Compliance / Violation Record

Application Number: □□□ / □□-□□ Date…

StudyTitle:

Investigator

Contact No.:

Institution:

Contact No.:

Sponsor:

Contact No.:

□□DeviationfromProtocol □□Non-Compliance

◯Major ◯Minor □□Violation

Description:

IEC Decision:

Actions taken:

Outcome:

Reported by:……..

Date……..

**Table of Contents**

## 1. Purpose

Since the Ethics Committee, S.N Medical College, Agraconsiders protection of the rights and welfare of the human subjects participating in a clinical investigation/research approved by the EC as its primary responsibility, Informed Consent documents reviewed by the EC may routinely contain the statement, "Questions regarding the rights of a participant/patient may be addressed to the Member Secretary with the Ethics Committee, S.N Medical, Agrafor Clinical Studies.On some occasions, the first contact with the participant/patient would be the EC Secretariat.
This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant in any approved research study.

## 2. Scope

This SOP applies to all responses to requests from participant concerning their rights and well-being while participating in studies approved by the EC.

## 3. Responsibility

The Institute's policy designates the Member Secretary of the EC as the person responsible for communicating with participants/patients regarding their rights as study participants. Delegation of this responsibility to another EC member is acceptable as long as the delegation is documented (in writing).

## 4. Flowchart

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Receive the request | EC Members and Secretariat |
| 2 | Take action ↓ | EC Members and Chairperson |
| 3 | File the request document | EC Secretariat |

## 5. Detailed instructions

### 5.1 Receive therequest.

- The EC member receives the inquiry or requests from researchparticipants/patients.
- Record the request and information in the request record form (Form AF/EC/01/17/V1.0 see ANNEX1)
- Communicate with the EC about study participant rights for instruction (ifrequired).
- Refer the inquiry to the EC Chairperson in writing (ifrequired).
- Staff of the institute may provide assistance in contacting the Member Secretary, but will not provide comments/opinions about theinquiry.

### 5.2 TakeAction

- Investigate thefact.
- Record information and any action or follow-up taken in the formAF/01/17/V1.0.

- Take signature of the Chairperson and the Member Secretary and date theform.
- Report to the EC about the action taken and theoutcomes.
- Communicate the reply with the participant and keep therecord.

**5.3 File the requestdocument**

- Keep the record form in the "response"file.
- Keep a copy in the studyfile.
- Store the file in the appropriately labeledshelf.

**6. References**

**1)** World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

**2)** International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

**3)** Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

**7. ANNEX**

ANNEX1 AF/EC/01/17/V1.0 Request RecordForm

**ANNEX1** **AF/EC/01/17/V1.0**

**Request Record Form**

| | |
|---|---|
| Date Received: | |
| Received by : | |
| Request by : | ☐ Telephone callNo……..……...<br>☐ FaxNo…….….<br>☐ Mailed letter / Date…….…….<br>☐ E-mail /Date…….……<br>☐ Walk-in / Date /Time…….……..<br>☐ Other, specify……..……. |
| Participant's Name: | |
| Contact Address: | |
| Phone: | |
| Title of the Participating Study | |
| | |
| Starting date of participation : | |
| What is the request? | |
| Action taken: | |
| Outcome: | |

**Signature ofMemberSecretary** **Signature of theChairperson**

## Table of Contents

**1. Purpose**

This procedure describes how an EC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the EC, Data Safety Monitoring Board (DSMB), sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of thestudy.

**2. Scope**

This SOP applies to any study approved by Ethics Committee, S.N Medical college, Agra that is being recommended for termination before its scheduledcompletion.

**3. Responsibility**

It is the responsibility of the EC Chairperson to terminate any study that the EC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process.

**4. Flowchart**

| **No.** | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Receive recommendation for study termination ↓ | EC Secretariat |
| 2 | Review and Discuss the Termination Package ↓ | EC Secretariat and Chairperson |
| 3 | Notify the Principal Investigator | EC Secretariat |
| 4 | Store the Protocol Documents | EC Secretariat |
| 5 | Inactivate the Protocol Document | EC Secretariat |

**5. Detailed instructions**

**5.1 Receive recommendation for studytermination.**

- Receive recommendation and comments from IEC members, ScientificDirector, Sponsor or other authorized bodies for study protocol termination.
- Inform the principal investigator to prepare and submit a protocol termination package.
- Receive the study protocol termination package prepared and submitted by the principalinvestigator
- Verify the contents of the package for inclusion of: Request for Termination Memorandum (AF/EC/04/06/V1.0 see ANNEX 4 of the SOP06/V1.0.)

- The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data as listedbelow
  - Original Continuing Review Application Form (AF/EC/03/06/V1.0), see ANNEX 3 of SOP/06/V1.0.
  - Termination is indicated under “ActionRequest”.

* Completeness of the information, including accrual data since the time of the last continuingreview.
* Presence of the required signatures (Principal Investigator) - Initial and date the package uponreceipt.

**5.2 Review and discuss the TerminationPackage.**

- Notify the Chairperson regarding the recommendation for study protocoltermination.
- Send a copy of the termination package to the Chairperson within one working day uponreceipt.
- The Chairperson reviews the results, reasons and accrualdata.
- The Chairperson calls for an emergency meeting to discuss about therecommendation.
- The Chairperson signs and dates the Protocol Termination Application Form in acknowledgment and approval of thetermination.
- The Chairperson returns the form back to the Secretariat within 5 working days of receipt of thepackage.
- The Secretariat reviews, signs, and dates the Protocol Termination Application Form indicating that the termination process iscomplete.

**5.3 Notify the PrincipalInvestigator.**

- Make a copy of the completed Continuing Review ApplicationForm
- Send the copy to the principal investigator for their records within 7 workingdays.

**5.4 Store the protocoldocuments.**

- Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocolfile.
- Send the file toarchive.
- Store the protocol documents for five years.

**5.5 Inactivate the protocoldocuments.**

- Place the study protocol into the ***inactive*** protocolfolder.

**6. GlossaryNil**

**7. References**

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

**ANNEX1** **AF/EC/1/18/V1.0**

**Document History**

| Author | Version | Date | Description of |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

## Table of Contents

**1. Purpose**

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored for its performance or compliance toGCP.

**2. Scope**

This SOP applies to any visit and/or monitoring of any study sites as stated in the EC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

**3. Responsibility**

It is the responsibility of the EC to perform or designate some Ethics Committee Members to perform on its behalf on-site inspection of the research projects it has approved.
The EC members or Secretariat in consultation with the Chairperson may initiate an onsite evaluation of a study site for a cause or for a routine audit.

**4. Flowchart**

| **No**. | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Selection of study sites ↓ | EC members and Chairperson |
| 2 | Procedures before the visit ↓ | EC members and/or representative |
| 3 | Procedures during the visit ↓ | EC members and/or representative |
| 4 | Procedures after the visit ↓ | EC members and/or representative |
| 5 | Present the findings to the Full Board | EC members and/or representative |

**5. Detailed instructions**

**5.1 Selection of study sites**

- Review periodically the files of the submitted/approved studyprotocols.
- Selection of the study sites should be donerandomly
- Select study sites needed to be monitored based on the followingcriteria:
    - New study sites whereverнecessary
    - Reports of remarkable serious adverseevents
    - Number of studies carried out at the studysites.
    - Non-compliance or suspiciousconduct
    - Failure to submit annual reports periodically as decided byEC.

- For cause – site for a reason, too many SAEs, in response to somecomplaints
- Not for cause – No reason, choose anysite

**5.2 Before thevisit**

The EC Members only will

- Contact the site to notify them that they/ their representative will be visiting them. At that time, the monitor and the site will coordinate a time for the site evaluationvisit.
- Make the appropriate travelarrangements.
- Review the EC files for the study andsite,
- Make appropriate notes,or
- Copy some parts of the files for comparison with the sitefiles.

**5.3 During thevisit**

- Get a checklist AF/EC/01/19/V1.0 (ANNEX1).
- The EC representativeswill
  - Review the informed consent document to make sure that the site is using the most recentversion,
  - Review randomly the subject files to ensure that subjects are signing the correct informedconsent,
  - Observe the informed consent process, ifpossible,
  - Observe laboratory and other facilities necessary for the study at thesite.
  - Review the EC files for the study to ensure that documentation is filedappropriately.
  - Collect views of the study participants, ifpossible
  - Brief the full board visit report/comments.
  - Get immediatefeedback.

**5.4 After thevisit**

- The EC representativewill
  - write a report/comment (use the form AF/EC/01/19/V7.0, see ANNEX 1) within 2 weeks describing the findings during theaudit
  - forward a copy of the site visit to theSecretariat
- The Secretariatwill
  - include this report in the Agenda of the Full Boardmeeting
  - Send a copy of the approved report to the site for their files,and
  - Place the report in the correct sitefiles.

## 6. Glossary

**IEC representatives:** Many EC rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to EC.

**Monitoring visit:** An action that EC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

**7. References**

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

**8. ANNEX**

| | | |
|---|---|---|
| ANNEX1 | AF/EC/01/19/V1.0 | Checklist of a MonitoringVisit |
| ANNEX2 | AF/EC/02/19/V1.0 | Document Histories |

**ANNEX1** **AF/EC/01/19/V1.0**

**Checklist of a Monitoring Visit**

Application No.: ☐☐☐/ ☐☐-☐☐ Date of the Visit:

StudyTitle:

Study Site:

PrincipalInvestigator: Phone:

Institute: Address:

Sponsor: Address:

Total number ofexpectedsubjects: Total subjects enrolled:

Are sitefacilitiesappropriate? Comment:

☐ Yes ☐No

Are the InformedConsentdocuments approved by EC areused Comment:

☐ Yes ☐No

Any adverseeventsfound? Comment:

☐ Yes ☐No

Any protocolnon-compliance/violation? Comment:

☐ Yes ☐No

Are all Case Record Forms uptodate? Comment:

☐ Yes ☐No

Are storage of dataandinvestigational products under lock andkey? Comment:

☐ Yes ☐No

Are the facilities for data storagearelocked Comment:

☐ Yes ☐No

How well areparticipantsprotected? Comment:

☐ Good ☐ Fair ☐ Not good

How isconfidentialitymaintained? Comment:

☐ Yes ☐No

Infrastructure relevanttostudy Comment:

☐ Yes ☐No

Resultsofvisit? Givedetails:

☐Yes

Duration ofvisit:…….hours startingfrom: Finish:

**Name of IEC member and accompanion:**

Completedby: Date:

**ANNEX2** **AF/EC/02/19/V1.0**

**Document History**

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

## Table of Contents

**1. Purpose**

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of Ethics Committee, SNMC, Agra.

**2. Scope**

This SOP applies to administrative processes concerning the preparation of the agenda for all regular EC meetings, divided into three stages: before, during and after the meeting.

**3. Responsibility**

It is the responsibility of the Secretariat staff to prepare the agenda for the EC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the agenda and the minutes sent to him/her.

**4. Flowchart**

| **No**. | **Activity** | **Responsibility** |
|---|---|---|
| 1 | Before each Ethics CommitteeMeeting | EC Secretariat |
| 2 | During the Meeting | EC Secretariat, Members and Chairperson |
| 3 | Voting ↓ | EC Members without Conflict of Interest/ Chairperson |
| 4 | After the Meeting | EC Secretariat/ Chairperson |
| 5 | Preparing the Minutes | EC Secretariat/ Chairperson |

**5. Detailed Instructions**

**5.1 Before each Ethics Committeemeeting**

**Check for filled up forms for completeness -Secretariat**

- Reviews the new study application forcompleteness.
- Documents the review by completing the appropriate Checklist (see Annex1 AF/EC/01/06/V1.0). If incomplete, the secretariat staff attempts to obtain the information from the investigators who submitted the application package and gets rectificationdone.

**Consider the appropriate review channel of eachprotocol**

Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel-

- ❖ SOP for Expedited Review -SOP/07/V1.0
- ❖ SOP for Initial Review of Submitted Protocols –SOP/08/V1.0

The protocol will be checked by EC members and Member Secretary with the help of Checklist (see Annex 1 AF/EC/01/06/V10) in which they will assess whether the project will be considered for Review of submitted Protocols, Review of Protocol Amendments, Continuing Review of Study Protocols, Review of Final Reports and Management of Study Termination. The Principal Investigator will mention the type of review in the covering letter and will submit the documents accordingly. Principal Investigator will incorporate the suggestions given by EC members and submit multiple copies as required to the secretariat.
The copies will be sent to the EC Members for their comments and suggestions.

**Prepare meetingagenda**

- Schedule the review as soon as possible after submission, at the time of the next scheduledmeeting.
- Consult the Chairperson to schedule the meetingdate.
- Prepare the meeting agenda, according to the format shown in ANNEX 1 (AF/EC/01/20/V1.0).
- Schedule protocols in the agenda on a first-come first-servebasis.
- **Inform to the EC members regarding the meeting for confirmation purpose.**
- Allow at least 2 weeks for the reviewprocess.
- Specify the due date for the return ofcomments.
- Include a Study Assessment Form see Annex 2 (AF/EC/02/06/V1.0).with the protocol package along with the invitation letter and the meetingagenda.
- Write down the running number of the protocol in the square boxes at thebottom right corner of the form Annex 1 AF/EC/01/20/V1.0
- Sign the second page of the form Annex1AF/EC/01/20/V1.0
- Prepare the package fordelivery.
- Record the name of the EC Members in the agenda for each project to be reviewed.

**Distribution of Protocol Packages(Dossiers Form) to the ECMembers**

- Keep in mind Procedure for Maintaining Confidentiality of EC documents when preparing and distributingdocuments.
- Distribute copies of the protocol submission packages to the EC members personally 8 days prior to EC meeting by post/ hand given materials in the Correspondence section of the respective protocolfile.
- Verify verbally with the members whether the protocol packages arereceived.

**5.2 During the Ethics Committee meeting**

- The EC may allow investigators, clinical collaborators, and guest attendees etc., to attend the portion of the EC meeting related to theirstudies.
- At the discretion of the Chairman, guest attendees (potential client, students, etc.) may be allowed to observe the Boardmeetings.
- Guest Attendees are required to sign a confidentiality agreement form (AF/EC/03/04/V1.0)

- The Secretariat reports on the minutes of the previous meeting and presents the agenda fordiscussion.
- The Secretariat records the discussions and the decisions made during themeeting.
- The Chairperson may inform members and attendees of the rules being followed duringmeetings.
- The meeting proceeds in the order organized in the agenda; however, the Chairperson may allow some switching depending on thesituation.

- The EC Members give their comments right after the presentation and the discussion about the study takesplace.
- Investigators may be allowed to present their projects in brief and clarify any questions the EC members mayhave.

**Voting**

- Voting will be held only in cases where there is a lack of consensus on an issue/protocol.
- Voting will be either by show ofhands.
- In order to avoid conflict of interest, only those EC members who are independent of the investigator and the sponsor of the trial will vote on the research-relatedmatters.
- All voting will take place after the observers / presenters / EC members with a conflict of interest leave the meetingroom.
- The Chairman determines if the number of voting Board members is sufficient to constitute a quorum and proceedsaccordingly.
- An EC member makes a motion to recommend action on a protocol or issue beingdiscussed.

**5.3 After the Ethics CommitteeMeeting**

- As soon as possible after each meeting, a copy of the minutes is sent to EC members for quality control andreview.
- The EC members indicate review by signing and dating theminutes.
- Following staff review, the minutes are given to the Chairperson for review and approval.
- The Chairperson indicates approval by signing and dating theminutes.
- The Secretariat maintains the official copies of the minutes in accordance with the archivingprocedures.

**5.4 Preparing the Minutes and the Approvalletters**

**Assembling the meeting minutes and the decisionform**

- Use the format as shown in ANNEX 2 (Form AF/EC/02/20/V1.0) to write the minutes.
- Compose the summary of each meeting discussion and decision in a concise and easy-to-readstyle.
- Make sure to cover all contents in each particularcategory.
- Check spelling, grammar, and context of the writtenminutes.

- Finish the minutes within two weeks after themeeting.

**Contents of the EC/IRB MeetingMinutes**

- ***The official minutes of the Board meeting consist of, but are not limited to, the following:***
  - ❑ Name of person preparing theminutes
  - ❑ Location where the meeting was held (city,state)
  - ❑ Meetingdate
  - ❑ Attending Ethics Committee members andguests
  - ❑ Agendaitems
  - ❑ Individual serving as Chairperson of themeeting
  - ❑ Determination of a duly constituted quorum by the Chairperson toproceed with themeeting

- ***Requirements for each study or activity requestingApproval:***
  - ❑ Principal Investigator'sName;
  - ❑ Protocol number/date/version of protocol, whenavailable;
  - ❑ Name of EC Members for eachprotocol
  - ❑ Discussion as deemed appropriate by theChairperson
  - ❑ Number of members voting 'yes', 'no', or 'abstention' only whereverapplicable
  - ❑ Number of abstentions and the reason for theabstention;
  - ❑ Reference to the investigator approval letter that lists all changes requested by the ECmembers
  - ❑ Determination of the next requested continuingreview.

- ***Requirements for each study or activity requesting ExpeditedReview:***
  - ❑ Principal Investigator'sName
  - ❑ Protocolnumber
  - ❑ Justification by Principal Investigator for consideration of expeditedreview

- ***Required for each continuing Review Report:***
  - ❑ Principal Investigator'sname;
  - ❑ Protocol number /title
  - ❑ Approval letter for the project
  - ❑ Lists of recommendations or actions to be taken up with the investigator, if applicable.

- ***Required for each Adverse Event notification and FinalReport:***
  - ❑ Principal Investigator'sname;
  - ❑ Sponsor'sname;
  - ❑ Protocol number/title
  - ❑ Actions deemed appropriate by the Ethics Committeereview.

- ***Required for Termination ofApproval:***

- SponsorName's;
- Protocol Number /title
- Principal Investigator's name; reason fortermination

**Approval of the minutes and the decision**

- Check the correctness and completeness of theminutes.
- Send the minutes to the Chairperson/ Member Secretary of theEC
- Request the Chairperson/Member Secretary to approve, sign and date the minutes of the EC meeting and approval letter.

**Filing theminutes**

- Place the original version of the signed minutes by Chairperson/ Member Secretary in the EC files for the specificprotocol.
- Place all correspondence in the appropriatefile.
- Place a copy of the approval letter in the "minutes" file to inform the EC Members of theapproval.

**Distributing the minutes and thedecision**

- Send a copy of the relevant sections of the minutes and the decision form to the Principal Investigators for their records and for them to make the suggested rectifications by the ECmembers.
- Send the approved minutes to the ECmembers.

## 6. Glossary

**Agenda:** A list of things to be done; a program of business at ameeting
**Minutes:** An official record of the business discussed and transacted at a meeting, conference,etc.
**Quorum:** Number of EC members required to act on any motion presented to the Board for action.
**Majority vote**: A motion is carried out if one half plus one member of the required quorum vote in its favor.

## 7. References

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.
International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996.
Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## 8. Annexure

| | | |
|---|---|---|
| ANNEX1 | AF/EC/01/20/V7.0 | Format of an Agenda |
| ANNEX2 | AF/EC/02/20/V7.0 | Format of IEC Meeting Minutes |
| ANNEX3 | AF/EC/03/20/V7.0 | Document History |

**ANNEX1** **AF/EC/01/20/V1.0**

## Format of an Agenda

**Ethics Committee, S.N Medical College**

Day, Date, Timing

**Venue: Site management Office**

The agenda will include:

1. **Declaration of Conflict ofInterest**
2. **Mention of Previous meetingminutes**
3. **Review of New ProjectProposals:**
   i. Title of theStudy
   ProjectNo.: Name of thePI
   Reviewers:
4. **Review of Revised ProjectProposals:**
   i. Title of theStudy
   ProjectNo.: Name of thePI
   Reviewers:

**4. Review of Proposals with Revision andAmendments:**

   i. Title of theStudy
   ProjectNo.: Name of thePI
   Reviewers:

5. **Review of AnnualReport**
   i. Title of theStudy
   ProjectNo.: Name of thePI
   Reviewers:
6. **SAEreporting**
   i. Title of theStudy
   ProjectNo.: Name of thePI
   Reviewers:

**7. Protocol deviation/violation/termination**

   i. Title of theStudy
   ProjectNo.: Name of thePI
   Reviewers:

**8. Details of Site visit done**

9. **Approval of project bycirculation**

10. **Any other matter with the permission of thechair**

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Member Secretary

**ANNEX2** **AF/EC/02/20/1.0**

## Format of IEC Meeting Minutes

- Meeting , date, time from .. to..
- Venue:
- Members Present:
- If absent, justification for the same and quorumavailability
- Name of the members:
- Mention of conflict of interest, if any:
- Review of projects as per Agenda items:
- Any other matter with the permission of the chair:
- Thanking the Chair and closure of the meeting:
- Signature of Member Secretary and the Chairperson on FinalMinutes:

**ANNEX3** **AF/EC/02/20/V1.0**

**Document History**

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

## Table of Contents

**1. Purpose**

To provide instructions for preparation and maintenance of active study files and other related documents approved by the EC of S.N Medical College

**2. Scope**

This SOP applies to all active study files and their related documents that are maintained in the ECoffice.

**3. Responsibility**

It is the responsibility of EC Secretariat to ensure that all study files are prepared, maintained and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

**4. Flowchart**

| No. | Activity | Responsibility |
|---|---|---|
| 1 | Organize the contents of the active study files | EC Secretariat |
| 2 | Maintain the active study files | EC Secretariat |

**5. Detailed instruction**

**Organize the contents of the active studyfiles**

- Get the original documents/copy of the studyfiles.
- Gather, classify and combine all related documentstogether.
- Check if a study file contains, at a minimum, the followingdocuments:
  - Original applications and any updates received during thestudy.
  - Investigator's brochures or similardocuments
  - Approval letters and other correspondence sent to theinvestigator.
  - Approved documents (protocols, amendment, informed consent form, advertising materials,etc.)
  - Adverse experience reports or Investigational New Drugs safety reportsreceived
  - Continuing reviewreports
- Use a folder with the following on thecover:
- The name of the principal Investigator/sponsor
- The protocolnumber
- The number assigned by the ECSecretariat

**Put the following into each folder with the following information:**

- Sponsor with address and contact phone/e-mail id of contact person, protocol number, investigator name (with address, e-mail, telephone and fax) andtitle
- Application form of the EC Protocol, Case Report Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data, any other material submitted by theinvestigator.
  - Correspondence
  - Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
  - Revisions/Amendments

- AdverseEvents
- Continuing Review, ifapplicable
- Finalreport

**Maintain the active studyfiles**

- Assign the approved study files with unique identifiers (on a sheet of paper) established by a member of the ECSecretariat
- Combine related documents of the approved study filesappropriately.
- Attach an identity Label to thepackage.
- Indicate date when Annual Review isdue
- Keep all active and potential study packages in a secure filecabinet.
- Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by theEC.
- Send all closed study files toarchive.
- Store the closed study files for ***at least 5 years*** after the studyclosure.

***Note****:* For studies with multiple study sites, a member Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.

**6. Glossary**

| | |
|---|---|
| Active Study File | Any approved protocol, supporting documents, records containing Communications and reports that correspond to each currently approved study. |
| CRF | Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant. |
| IND | Investigational New Drug is a drug that has never been seen in the market because itisunderinvestigationofitsefficacyandsafetyandnotyetbeenapprovedfor marketing by the local authorities. The drug is therefore approved for used only at some certain study sites |
| ICD | Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. |
| Master file | A file for storage of the originally signed and dated documents |

**7. Reference:**

ICMR guidelines for clinical research.(http://icmr.nic.in/ethical_guidelines.pdf)
Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## Table of Contents

**1. Purpose**

To provide instructions for storing inactive study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors.

**2. Scope**

This SOP applies to archiving the study files and administrative documents that are retained for at least fifteen years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

**3. Responsibility**

It is the responsibility of EC Secretariat for maintaining inactive study files and administrative documents.

**4. Flowchart**

| No. | Activity | Responsibility |
|---|---|---|
| **1** | After receiving the final report | EC members, secretariat |
| **2** | Archiving administrative documents | EC secretariat |
| **3** | Retrieving Documents | EC secretariat |

**5. Detailed instructions**

**After receiving the finalreport**

- EC Secretariat and Members will review the Final Report of thestudy.
- A member of the Secretariatshould
  - ✓ Remove the contents of the entire file from the active study filingarea.
  - ✓ Verify that all documents are present in an organizedmanner.
  - ✓ Place the file in a storagecontainer
- Keep the files of the multi-center studies active, until all the study sites areclosed.
- Place in Archivalroom.

**When archiving administrativedocuments**

A staff of the EC Secretariat should

- Perform inventories of miscellaneous administrativedocuments
- Place the documents in the appropriate storage container so that it may be easilyretrieved.

**RetrievingDocuments**

- Keep in mind the SOP/23/V1.0 (Maintaining Confidentiality of Ethical Review Committee Documents)
- Retrieval of documents can only be done with a request form (AF/EC/01/22/V1.0, see ANNEX 1) signed and dated by the EC Chairperson or the MemberSecretary.
- The requestor must also sign and date the log of request (AF/EC/02/22/V1.0, see ANNEX2)

- The Secretariat retrieves archived documents and documents in the inventory (register) kept by Ethics Committee SN Medical College, Agra for Clinical Studies at Archivalroom.
- Return the file back to itsplace.
- Record, sign and date when the document has been returned andkept.

**6. Glossary**

| | |
|---|---|
| Administrative Documents | Documents include official minutes of EC meetings (as described in SOP/13/V1.0) and the Standard Operating Procedures, both historical files and Master Files as described in SOP/01/V1.0. |
| Inactive Study Files | Approved and supporting documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the Ethics Committee S.N Medical College for Clinical Studies Board for which a final report has been reviewed and accepted. |

**7. References**

World Health Organization, Operational Guidelines for Ethics Committeesthat Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good ClinicalPractice (ICHGCP)1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

**8. ANNEX**

ANNEX 1 AF/EC/01/22/V1.0 Document Request Form

ANNEX 2 AF/EC/02/22/V1.0 Log of Requested IECDocuments

**ANNEX1** **AF/EC/01/22/V1.0**

**Document Request Form**

| | | |
|---|---|---|
| Name of Document requested: | | Code: |
| Requested by: | | Date: |
| ☐Chairperson | ☐Secretariat | ☐ IEC Member |
| ☐Secretariatstaff | ☐Authority | ☐Others…….. |
| Purpose of the request: | | |

| | |
|---|---|
| Retrieved by: | Date: |
| Returned by: | Date: |
| Archived by: | Date: |
| Approved by: | Date: |

**ANNEX2** **AF/EC/02/22/V1.0**

**Log of Requested IEC Documents**

| # | Document | Requester | Date Requested | Retrieved by | Archived by | Returned Date |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**Page No…….**

**Table of Contents**

**1. Purpose**

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle original documents and copies of documents in order to protect confidentiality of documents.

**2. Scope**

This SOP applies to maintaining confidentiality while handling, distribution and storage of submitted study protocols, EC documents, and correspondence with experts, auditors and the general public.

**3. Responsibility**

Confidentiality of study protocols, EC documents, and correspondence with experts and auditors is mandatory. EC members and staff have signed confidentiality agreements with the institute that enforces confidentiality. If non-members of the EC need copies of documents, it is the responsibility of the EC member/staff to maintain confidentiality of documents.

**4. Flowchart**

| No. | Activity | Responsibility |
|---|---|---|
| **1** | Access to EC documents ↓ | EC members and Secretariat |
| **2** | Classify confidential documents ↓ | EC members and Secretariat |
| **3** | Copy confidential documents ↓ | EC Secretariat |
| **4** | File Log of Copies | EC Secretariat |

**5. Detailed instructions**

**Access to ECDocuments**

The EC members and the staff of the Secretariat of the EC, who must read, understand and agree to the following:

**Members and Member Secretary of theEC**

- Sign a confidentiality agreement (see ANNEX 1 AF/EC/01/03/V1.0) with Ethics Committee S.N Medical College –Agra for Clinical Studies institute before the start of any activity for theEC.
- Shall have access to all ECdocuments.
- Are free to request and to use original documents or copies of originaldocuments.

**Secretariat of theEC**

- The Secretarial Assistant of the EC is a staff member of the Ethics Committee S.N Medical College for ClinicalStudies
- Sign a confidentiality agreement with Ethics Committee, S.N medical College for Clinical Studies Have access to any document issued by or to theEC.

**Classify confidentialdocuments**

**- Types of documents**

**The types of documents reviewed by EC members include:**

- Study proposals and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions orreviews)
- EC documents (SOPs, meeting minutes, advice anddecisions)
- Correspondence (experts, auditors, study participants,etc.)

*Note: Copies of all versions of documents, including draft and sequential definitive versions, are to be kept private and confidential with the exception of those made according to the followingsections.*

**Copy confidentialdocuments**

Copies of documents, including draft and sequential versions, are considered to be confidential and are not permitted to be brought out except when a document is needed for day-to-day operations.

**CopyAuthorization**

- Only members of the EC are allowed to ask forcopies.
- Only staff members of the Secretariat of the IEC are allowed to make suchcopies.
- The Secretary of the EC may ask for help, but is responsible formaintaining Confidentiality of alldocuments

**Log ofCopies**

- A Log of Copies (see ANNEX 1 Form AF/EC/01/23/V1.0) must be kept by the Secretariat.
- The log should include: the name and signature of the individual receiving the copy; the initial of the IEC Secretary who made the copy; the number of copies made and the date that the copies weremade.

**Copies requested by non-members of theEC**

- Copies of EC's documents requested by non-members of the EC (including the Secretary) can only be given after the permission from the Member Secretary and the person requesting for the document signs a confidentiality agreement form (AF/EC/03/03/V1.0).
- Copies made for non-members of the EC must be recorded in both the Log of Requests for Copies of IEC's documents (AF/EC/01/16/V710) and the log of Copies of the Original Documents(AF/EC/02/23/V1.0).

**File Log ofCopies.**

- The Log of Copies of Original Documents must be stored with the originaldocuments.
- The Log of Copies of Original Documents is *not* a confidential document and can be reviewed uponrequest.
- A Log of Copies of Original Documents must bemaintained.

## 6. Glossary

| | |
|---|---|
| Document | Documents mean the followings:<br><br>- Study Protocols and related documents (such ascase report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews)<br>- EC documents (SOPs, meeting minutes, adviceand decisions)<br>- Correspondence (experts, auditors, studyparticipants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc. |
| Non-members of the EC | Any relevant person/persons who presently is/are not a member/members of the IEC such as authorities, monitors, auditors, subjects, etc. |

## 7. References

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research,2000.

International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996.

Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## 8. ANNEX

ANNEX 1 AF/EC/01/23/V1.0 Log of Requests for Copies of IEC's Documents

ANNEX 2 AF/EC/02/23/V1.0 Log of Copies of Original Documents

**ANNEX1** **AF/EC/01/23/V1.0**

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

| No. | Documents requested | No. of Copies | Name of Recipient | Signature of Recipient | Secretariat Initials | Date |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**ANNEX2** **AF/EC/02/23/V1.0**

**Log of Copies of Original Documents**

***Title of the Document*** :……..…….
……..

| No. | Name of Recipient | No. of Copies | Reasons of the Request | Signature of Recipient | Secretariat Initials | Date |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

*Note*: *This log should be attached to the original documents*

**Table of Contents**

**1. Purpose**

The purpose of this SOP is to guide how to prepare for an audit or inspection of the EC processes.

**2. Scope**

This SOP applies to *Ethics Committee, S.N Medical College*

**3. Responsibility**

It is the responsibility of the Secretariat, the Members, and the Chairperson of the EC to perform all tasks according to the SOPs and to be well-prepared and available to answer questions during evaluation, audit or inspection visits of authorities.

**4. Flowchart**

| No. | Activity | Responsibility |
|---|---|---|
| **1** | Have an Audit / Inspection ↓ | EC Chairperson / Medical Director of the Institution |
| **2** | Prepare for the audit / Inspection ↓ | EC Secretariat / Members and Chairperson |
| **3** | Meet the Auditor / Inspection ↓ | EC Secretariat / Members and Chairperson |
| **4** | Discuss the Issues ↓ | EC Secretariat / Members and Chairperson |
| **5** | Record the Event | EC Secretariat |

**5. Detailed instructions**

**Receive a Call for an Audit /Inspection**

- Receive a notice of Audit/Inspection
- The Member Secretary / Chairperson inform the Director or Head ofInstitution.
- The Chairperson should inform ECmembers.

**Prepare for the audit /Inspection**

- Get a checklist AF/EC/01/24/V1.0 (see ANNEX1).
- Go through all steps on thelist.
- Check if all documents are labeled and kept in the right order for easy andquicksearch.
- Check for any missing or disorganizedrecords.
  - ✓ Background and training records of EC members
  - ✓ Application SubmissionRecords
  - ✓ Protocol AssessmentRecords
  - ✓ CommunicationRecords
  - ✓ AmendmentApproval

- ✓ Meeting Agenda, Minutes, Approvalletters
- ✓ Activefiles
- ✓ Continuing and Finalreports

- Review the ECSOPs.
- Make sure that no omission or deviationexists.
- Make sure to have good reasons for any omission ordeviation.
- Inform EC members about the inspection date so that they are able to attend the audit/inspectionmeeting.

**During the Audit /Inspection**

- The Chairperson or the Secretariat welcomes and accompanies theauditors/inspectors tothe reserved meetingroom.
- Members and some key staff must also be present in the meetingroom.
- The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data areneeded.
- Answer questions of the auditors/inspectors clearly, politely and truthfully withconfidence and straight to thepoint.
- Find and get all information and files requested by theauditors/inspectors.
- Take note of the comments, recommendation of theauditors/inspectors.

**Discuss theIssues**

- Review comments and recommendations of theauditors/inspectors.
- Write a report and have it approved by theChairperson.
- The Chairperson calls for the correction.
- Allow appropriate time for correction and improvementprocess.
- Carry an internal follow-upaudit.
- Evaluate theoutcome.
- Report the outcome to theChairperson.

**Record the Audit/InspectionEvent**

- Keep record of the report on the audit/inspection meeting in theaudit/inspectionfile.
- Record also the findings from the internal follow-up audit in the internal auditfile.

## 6. Glossary

Audit — A systematic and independent examination of research trialapproval activities and documents to determine whether thereview and approval activities were conducted and data wererecorded and accurately reported according to the SOPs, GCP,Declaration of Helsinki and applicable regulatoryrequirements

Inspection — The act by a regulatory authorities of conducting an officialreview of documents, facilities, records, and any other resourcesthat are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor'sand/or contract research organizations (CRO) facilities, Office ofEthics Committees, or at other establishments deemed appropriateby the regulatory

authorities

## 7. References

World Health Organization, Operational Guidelines for Ethics Committees that review Biomedical Research,2000.
International Conference on Harmonization, Guidance on Good ClinicalPractice (ICHGCP)1996.
World Health Organization, Surveying and Evaluating EthicalReviewPractices, Feb. 2002
Forum for Ethical Review Committees in Asia and the Western Pacific SOPs2006

## 8. ANNEX

ANNEX 1 AF/EC/01/24/V1.0 Audit and Inspection Checklist

ANNEX1 AF/EC/01/24/V1.0

**Audit and Inspection Checklist**

| | |
|---|---|
| □InternalAudit □External □AuditInspection | Date: |
| The date(s) which the audit/inspection has been agreed for: | |
| Review the SOPs and note details of any omissions or deviations, with reasons | |
| Check the files for the presence of allsigned documents. Note any that aremissing and actions taken.<br>✓ Background and training recordsofIECmembers<br>✓ Application SubmissionRecords<br>✓ Protocol AssessmentRecords<br>✓ CommunicationRecords<br>✓ AmendmentApproval<br>✓ Meeting Agenda, Minutes, Approvalletters<br>✓ Activefiles<br>✓ Continuing and Finalreports | |
| Are any documents known to be missingfrom the study master file? | |
| Which personnel and members will be available? Give details of times anddates. | |
| What arrangements are there in the event the auditor/inspector needs to makecopies of documents? | |
| Completed by: ……<br><br>Name and Signature | Date:…….. |