ANIL NEERUKONDA
INSTITUTE OF DENTAL SCIENCES

SANGIVALASA, BHEEMUNIPATNAM, VISAKHAPATNAM – 531 162
Email Id: office.anids@gmail.com, principal.anids@gmail.com
Ph.No. 8008901247& 8008901278, Website : www.anids.edu.in

Standard Operating Procedure (SOP)

For

Institutional Ethics Committee (IEC)

ANIL NEERUKONDA
INSTITUTE OF DENTAL SCIENCES

SANGIVALASA, BHEEMUNIPATNAM, VISAKHAPATNAM – 531 162
Email Id: office.anids@gmail.com, principal.anids@gmail.com
Ph.No. 8008901247& 8008901278, Website : www.anids.edu.in

SOP FOR IEC COMMITTEE IN GENERAL

CODE NO: RANIDS 03

VERSION: IEC ANIDS/2.0.1

PREPARED BY: DR ANIL CH – MEMBER SECRETARY – IEC ANIDS

APPROVED BY: DR L VAMSI KRISHNA REDDY – PRINCIPAL - ANIDS

DR S SREEDHAR REDDY – CHAIR PERSON – IEC ANIDS

EFFECTIVE DATE: 21st JANUARY 2025

EFFECTIVE UPTO: 21st JANUARY 2030

INDEX

SNO	CONTENT
1.	PURPOSE
2.	SCOPE
3.	NAME, FORMATION AND REGISTARTION
4.	OBJECTIVES AND RESPONSIBILITIES
5.	FUNCTIONS & OPERATIONS
6.	APPLICATION FORM FOR CLEARANCE OF RESEARCH PROJECT BY IEC
7.	PROCEDURE FOR DOCUMENT RECEIPT AND HANDLING
8.	DOCUMENTS CIRCULATION
9.	ELEMENTS OF REVIEW
10.	SAFETY INFORMATION – AE , SAE & ADR PROTOCOL
11.	RESPONSIBILITIES OF EXPERT COMMITTEE
12.	CRITERIA FOR RESEARCH APPROVAL
13.	IEC MEETING PROTOCOLS
14.	DECISION MAKING PROTOCOLS
15.	APPROVAL PROTOCOLS
16.	ETHICAL EXEMPT STUDIES PROTOCOL
17.	REVIEW OF ONGOING STUDIES
18.	ANNUAL PROGRESS REPORT POLICY
19.	RECORDS RETENTION AND ARCHIVAL POLICY
20.	HANDLING OF SUBJECT QUERIES

ANIL NEERUKONDA
INSTITUTE OF DENTAL SCIENCES
SANGIVALASA, BHEEMUNIPATNAM, VISAKHAPATNAM – 531 162
Email Id: office.anids@gmail.com, principal.anids@gmail.com
Ph.No. 8008901247& 8008901278, Website : www.anids.edu.in

SOP FOR IEC COMMITTEE IN GENERAL

Code No: RANIDS 03 **Version: IECANIDS/2.0.1**

Effective Date: 21st JANUARY 2025

Title: SOP TO BE FOLLOWED BY IEC IN GENERAL

PREPARED BY	REVIEWED BY	APPROVED BY	
Dr. CH. ANIL (IEC MEMBER SECRETARY)	Dr. BADARI RAMAKRISHNA (IEC MEMBER)	Dr. L. VAMSI KRISHNA REDDY (PRINCIPAL)	Dr. S SRIDHAR REDDY (IEC CHAIRMAN)

THE STANDARD OPERATING PROCEDURE TO BE FOLLOWED BY THE COMMITTEE IN GENERAL:

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the Standard Operating Procedure to be followed by committee in general

2. Scope

This SOP applies to IEC ANIDS for general guidelines, selection of studies and responsibilities of members of IEC ANIDS

3. Name, Formation & Registration:

This Ethics Committee is known as **Institutional Ethics Committee,** Anil Neerukonda Institute of Dental Sciences, in short IEC, ANIDS.

Anil Neerukonda Institute of Dental Sciences Seal Sangivalasa

4. Objectives and Responsibilities:

The primary objective of this committee will be:

1. To protect the right, safety and wellbeing of the research subject and assist in welfare and benefit of the society.
2. To review the qualifications of all investigators participating in the proposed research study.
3. To keep all information submitted to them confidential
4. To review all research proposals submitted to the committee within the specified time

and maintain clear documentation of it.

5. To review the progress of each research project at appropriate and specified intervals and also review the summary of final report of the studies approved by them

Functions & Operations:

Submission of the Research Proposals

1. All communications with the Committee will be documented in Physical or electronic databases.
2. Before receiving the review materials, it is advisable to obtain Conflicts of Interest (COI), declaration and CA (Confidentiality Agreement) from the Member Secretary, Chairperson & Members.
3. If it is required by Sponsor/Contract Research Organization (CRO)/ Investigator/Institution. A copy of this agreement will be filed with the official records of the Committee and another copy will be returned to the Sponsor / Contract Research Organization (CRO)/ Investigator / Institution.
4. The Committee will require the submission in Printed (member copies + 1 Principal Investigator Reference copy (if required) + Guest Member copy (if any) & electronic copy of documents of study as listed for every research proposal.
5. All the relevant revised documents which are resubmitted for review should be submitted in two copies (Committee reference copy + one copy), if the resubmission involves only those changes which are suggested by the Committee with no other modifications.
6. The documents required for submission are the following:

- Study proposal with covering letter.
- Protocol along with compensation details and any amendments to it, Informed Consent Form (ICF), and its translation(s) into regional language (s) with translation certificates.
- Written information to be provided to the subjects {e.g., Patient Information Sheets (PIS), if applicable}.
- Investigator's Brochure (IB).
- Subject recruitment procedures (e.g., advertisements), if applicable.
- Available safety information.
- Information about payments and compensation available to the subjects.
- Investigator's current Curriculum Vitae indicating qualification and experience.
- Approval from competent regulatory authorities.

7. The Committee will require the submission in Printed (member copies + 1 Principal Investigator Reference copy (if required) + Guest Member copy (if any) & electronic copy of documents of study as listed for every research proposal.
8. All the relevant revised documents which are resubmitted for review should be submitted in two copies (Committee reference copy + one copy), if the resubmission involves only those changes which are suggested by the Committee with no other modifications.
9. The documents required for submission are the following:

Seal

a) Study proposal with covering letter.
b) Protocol along with compensation details and any amendments to it, Informed Consent Form (ICF), and its translation(s) into regional language (s) with translation certificates.
c) Written information to be provided to the subjects {e.g., Patient Information Sheets (PIS), if applicable}.
d) Investigator's Brochure (IB).
f) Subject recruitment procedures (e.g., advertisements), if applicable.
g) Available safety information.
h) Information about payments and compensation available to the subjects.
i) Investigator's current Curriculum Vitae indicating qualification and experience.
j) Approval from competent regulatory authorities.

Prescribed Application Form for Clearance of Research Project by IEC:

a) Name of the Investigator/co-investigator with designation.
b) Name of the Department where research will be conducted.
c) Protocol of the proposed research involving human subjects / participants
d) Ethical issues in the study and plans to address these issues.
e) Copies of Proforma / Case Report Forms / Questionnaires / Follow-up Cards, etc.
f) Details of Informed Consent Process, including patient information sheet and the Informed Consent Form in local language Telugu/English / Hindi.
g) For any drug / device trial, all relevant publications / pre-clinical data and clinical trialdata from other institutions within the country / other countries, if available.
h) Curriculum Vitae of all the investigators with relevant publications during the last five years.
i) Regulatory clearances (other than IEC,ANIDS), if required
j) Details of Funding agency/sponsors and fund allocation for the proposed work.
k) An agreement to report only Serious Adverse Events (SAE) to IEC.
l) Statement of conflicts of interest, if any.
m) A statement specifying pecuniary risks involved and the measures taken to provide compensation to the research participants.
n) Plans for publication of results – positive or negative - while maintaining the privacy and confidentiality of the study participants.
o) Any other information relevant to the study.
p) Copies of Proforma / Case Report Forms / Questionnaires / Follow-up Cards, etc.
q) Details of Informed Consent Process, including patient information sheet and the Informed Consent Form in local language Telugu/English / Hindi.
r) For any drug / device trial, all relevant publications / pre-clinical data and clinical trialdata from other institutions within the country / other countries, if available.
s) Curriculum Vitae of all the investigators with relevant publications during the last five years.
t) Regulatory clearances (other than IEC,ANIDS), if required
u) Details of Funding agency/sponsors and fund allocation for the proposed work.

Anil Neerukonda Institute of Dental Sciences Seal Sangivalasa

v) An agreement to report only Serious Adverse Events (SAE) to IEC.
w) Statement of conflicts of interest, if any.
x) A statement specifying pecuniary risks involved and the measures taken to provide compensation to the research participants.
y) Plans for publication of results – positive or negative - while maintaining the privacy and confidentiality of the study participants.
z) Any other information relevant to the study.

Signature of Principal Investigator (PI)
Place:
Date:

Signature of Co-investigator(s):
Place:
Date:

The protocols should include among other things the following:

- Inclusion and exclusion criteria for entry of subjects in the study.
- Precise description of methodology of the proposed research, including intended dosages of drugs or materials, planned duration of treatment and details of invasive procedure, if any.
- A description of plans to withdraw or withhold standard therapies in the course of research.
- The plans for statistical analysis of the study.
- Safety of proposed intervention to be tested, including results of relevant laboratory research.
- Storage and maintenance of all data collected during the trial.
- Agreement to comply with national and international GCP protocols for clinical trials.

Procedure for Document Receipt & Handling:

1. Receiving the Study Documents
   The Member Secretary will receive the study documents and other related documents in hard copies at the Ethics Committee office, submitted by the Principal Investigator / Institution / Sponsor / CRO.
2. Checklist for Submitted Documents
   The Member Secretary will check the following:
   1. A Submission Letter addressing the Ethics Committee.
   2. Total number of copies of all documents.

Anil Neerukonda Institute of Dental Sciences Seal Sangivalasa

Circulating the Documents:

1. Study documents will be circulated to the members along with a Document Circulation Log.
2. The Document Circulation Log will be filed by the person receiving the documents.
3. After the documents have been circulated, Document Circulation Log will be checked for completeness and will be documented.

ANIL NEERUKONDA
INSTITUTE OF DENTAL SCIENCES
SANGIVALASA, BHEEMUNIPATNAM, VISAKHAPATNAM – 531 162
Email Id: office.anids@gmail.com, principal.anids@gmail.com
Ph.No. 8008901247& 8008901278, Website : www.anids.edu.in

IEC, ANIDS

DOCUMENT CIRCULATION LOG

Protocol No.:

S. No	Member's Name	Receiver's Name	Date	Signature

Return of the Documents:

- On the meeting day, the members will bring their hard copies of the study documents to be reviewed.
- After taking the decision for the proposed study, the members return their copies atthe office.
- All the returned copies will be discarded if not asked to be returned by the Investigator / Institution / Sponsor / CRO, except for two copies, one Committee reference copy and one copy to be kept with the Chairperson.
- Out of the two copies, one Committee reference copy will be archived at the Committee office and the Archival Log will be updated accordingly and the second copy will be kept with the Chairperson.
- Archival will be done as described in Archival Policy, p-28.
- In case a member is not able to attend the meeting by that time, it will be the member's responsibility to return the documents to the Committee.

Elements of Review:

The submitted proposal shall be reviewed both for scientific content and ethical principles. The Committee members shall review the proposal with reference to the following:

- Scientific design of the study
- Justification / Rational of the study
- Selection criteria for subjects
- Potential benefits to the study subjects, predictable risks to the study subjects
- Criteria for discontinuation

Anil Neerukonda Institute of Dental Sciences Seal Sangivalasa

- Monitoring of serious adverse events
- Compensation to the subjects for participating in the study
- Subject recruitment procedures (e.g., advertisements), if applicable
- Protection of privacy and confidentiality and plans for publication of results(positive or negative)
- Statistical analysis
- Informed consent document in English and regional languages
- Competence of the Investigators, supporting staff and infrastructure facilities
- Approval of regulatory authorities wherever applicable.

Safety Information:

Adverse Event/ Serious Adverse Event reporting may be required for

1. The protection of the subject
2. Proper use of drug once it is marketed.

Adverse Event (AE): Any untoward medical occurrence in a Patient or Clinical Investigation Subject administered the pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with the use of the Investigational Product, whether or not related to that. Expected adverse event may be known to occur and is listed in the Investigational Brochure, Informed Consent, or General Investigational Plan; whereas Unexpected adverse event may not be listed in Investigational Brochure, Informed Consent, or General Investigational Plan, also not listed in a drug package insert.

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) is any untoward medical occurrence that at any dose:

1) Is life-threatening: If subject was at substantial risk of dying at the adverse event time, or continued use of the device or other medicinal product which might have resulted in the death of the subject.
2) Requires admission to the hospital or prolongation of hospitalization was a result of adverse event.
3) Results in persistent or significant disability/ incapacity: If the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., significant, persistent or permanent change, impairment or damage or disruption in the person's body function/ structure/ physical activities and/or quality of life.
4) Result in a Congenital Anomaly/ Birth Defect: If exposure to a medicinal product

during pregnancy may have resulted in an adverse outcome in the child.

5) Important medical event like allergic bronchospasm, blood disorders, seizures/ convulsions, the development of drug dependence or drug abuse.
6) Required medical or surgical intervention (treatment) to prevent permanent impairment of a body function or damage to a body structure as a result of medicinal product usage.

Timeline for reporting of SAE

To	Within 24 hours of identifying the event	Within 14 days of Occurrence of SAE	Within 21 days	Within 30 days

NOTE:

1. In case if the sponsor fails to provide medical management/ financial compensation to the subject, the Licensing Authority (DCGI) may after giving an opportunity to show cause why such order should not be passed and/or may suspend or cancel the clinical trial and/or restrict sponsor to conduct any further clinical trials in the country.
2. For SAE other than Death, trial subject will get the compensation.
3. For Death, nominee of the subject will get the compensation.

Responsibility of Ethics Committee:

Shall forward its report after due analysis on SAE with its opinion on the financial compensation (if any) to be paid by the sponsor to:

Responsibility of Expert Committee (CDSCO Office) & Licensing Authority (DCGIOffice):

- The Expert Committee shall examine the report of SAE and gives its recommendations (including quantum of compensation) to the Licensing Authority within 30 calendar days of receiving the report from the Ethics Committee.
- After considering the recommendations of the expert committee, the Licensing Authority shall decide the quantum of compensation and issue an order (shall be paid by Sponsor) within 3 months of receiving the report of SAE.

Criteria for the Approval of Research:

In order to approve the research proposal, the Committee shall determine that all of the following requirements are satisfied:

Anil Neerukonda Institute of Dental Sciences Seal Sangivalasa

1. Risks to subjects, if any, are reasonable in relation to anticipated benefits. In evaluating risks and benefits, the Committee should consider only those risks and benefits that may result from the research.
2. Selection of subject is equitable. In making this assessment, the Committee should take into account the purposes of the research and the setting, in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children prisoners, pregnant women, mentally disabled persons, or economically or educationally or educationally disadvantaged persons.
3. Informed consent will be sought from each prospective subject or the Legally Authorized Representative of the subject.
4. When appropriate, the research plan makes adequate provision for monitoring the datacollected to ensure the safety of subjects.
5. When appropriate, there are adequate provisions to protect the privacy of subjects andto maintain the confidentiality of data.
6. In case, in which the documentation requirement is waived, the Committee may require the Investigator to provide subjects with a written statement regarding the research.
7. The Committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reason /s for the Committee's action and shall be reported promptly to the Investigator, appropriate institutional officials, the department or agency head.

Meetings:

1. The Committee will hold regular meeting, depending on the number of research proposals for review. However the committee will meet at least once every 3-4 months.
2. A maximum of 5 proposals can reviewed at each meeting if the proposals are of the different molecules and different study designs; However, if proposals require urgent review, the same can be done irrespective of number of protocol. In case, the proposals are with the similar molecule and/or similar study design they can be reviewed in the same meeting.
3. The Member Secretary will check the availability of the members for the meeting and shall invite the members for the same accordingly.
4. Primary reviewer could be assigned by the chairperson to conduct a detailed review of a research protocol and provide a report at the meeting
5. All regular members will receive notification of meeting schedules at least five (5) days in advance.
6. The proposal may be sent to a subject expert for his/ her assessment and opinion of the research proposal. The subject expert may be invited for the meeting if deemed

necessary by the Committee.

7. The Investigator and / or Co- Investigator may be invited to the meeting to provide clarifications on the study protocol if deemed necessary by the Committee.

8. Specific patient group representatives may also be invited for the meeting based on the requirement of the research area if deemed necessary. e.g. Subjects with HIV/AIDS or genetic disorders etc.

9. Meeting will be held only if quorum is met. A quorum will be defined as a minimumof 5 (five) members including one basic scientist (preferably a pharmacologist), one clinician, one legal expert, one social worker/ representative of a non-governmental organization / theologian or a similar person, one lay from the community.

Minutes:

The proceeding of the meeting will be recorded in English and in the form of minutes. The Members Secretary will be responsible for coordination, recording and circulation of the meeting minutes.

Decision Making:

1. Decision for each proposal / study shall be individual voting.
2. All members present at the meeting will vote on the research proposal.
3. The decision will not be declared until the consensus is reached amongst all the members regarding the opinion to the proposal/ study under consideration.
4. The queries, comments or suggestions from the member(s) not in favour of the approval, shall be forwarded to the Sponsor / CRO/ Principal Investigator and reply received from their end will be discussed with members. After all the members(s), are satisfied with the reply, the chairperson shall take the final decision regarding further action on the protocol depending on the opinion / decision which is favoured by majority of the quorum members present at the meeting.
5. Absent members will not have a right to vote. However, if absent members have been a part of the entire discussion via any electronic media from (e .g. telecom, webcam etc.). They will be eligible to vote.
6. Member(s) of the Committee who is/ are listed as investigator(s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.
7. An investigator or study team member invited for the meeting will vote or participate in the decision making procedures of the Committee.
8. The Committee shall notify the Investigation/ Sponsor / CRO in writing of its decision to approve or disapprove the proposed research activity. If the Committee decides to disapprove a research activity, it shall include in its written notification, a statement of the reasons for its decision and give the Investigator / Institution /Sponsor /CRO an opportunity to respond in person or in writing.

Seal

Review Outcome:

The Committee will document its view as the following:

1. Approval – Unconditional or Conditional
2. Request for Modification or Information
3. Disapproval
4. Termination/ Suspension of the research proposal / ongoing study

Notification of Review Outcome:

The outcome of the Committee review will be recorded and conveyed to the Investigator / CRO/Sponsor Within 7 (seven) Working day from the date review.

Approval Period:

All projects will be given approval for a period of 1 (one) year from the date on which the project was approved and for the projects continuing for longer than one year annual renewal will be mandatory.

Procedures for Appeal after Protocol Rejection:

For research proposals rejected by the Committee, the applicant may appeal for a repeat review in writing, within Twelve (12) weeks of the receipt of the Committee's decision. While doing so, the applicant shall give justification relevant to the issues / objections raised by the Committee.

Amendments to the Approved Research Proposal and Informed Consent Documents:

1. All amendments to the approved research proposal shall be submitted to the Committee immediately for its review.
2. No changes in the protocol and/ or Informed Consent Documents shall be initiated without prior written approval from the Committee, except when necessary to eliminate immediate harm s to the subjects, or when the change(s) involve only logistical or administrative aspects of the trial [e.g. change of monitor , telephone numbers].

Research studies that are Exempt Ethical approval:

Within the definition of research, the following are not considered to be 'research' and would be exempt:

1. Service evaluation
2. Performance reviews

Anil Neerukonda Institute of Dental Sciences Seal Sangivalasa

3. Literary or artistic criticism
4. Testing within normal education requirements
5. Quality assurance/audit projects that do not involve access to or collection of private or sensitive data.

Research Studies that are "Exempt Ethical Approval*

The following types of research do not require ethical approval from IEC, ANIDS (unless approval is specifically required by an external funding body or other external body) and should be submitted to IEC, ANIDS only for 'Exempt', stating clearly the clause under which the exemption is sought:

S.No	Research Type	Example
1	Research involving information freely available in the public domain.	Published biographies, newspaper accounts of an individual's activities and published minutes of a meeting which would not be considered 'personal data'
2	Research involving anonymized records and data sets that exist in the public domain.	Datasets available through the offices of National and State agencies where appropriate permission have already been obtained and it is not possible to identify individuals from the information provided.
3	Studies of public behaviour that are purely observational.	All non-invasive and non-interactive studies where the recorded observations do not identify individuals (names, photographs) which could place them at risk of harm, stigma or prosecution.
4	Research involving the use of nonsensitive, completely anonymous studies.	All anonymous educational tests, survey and interview procedures when the participants are not defined as "vulnerable"and participation will not induce undue psychological stress or anxiety.
5	Research involving the use of education tests,survey and interview procedures on human participants in the public arena.	All elected or appointed officials, candidatesfor public office, artists.

Anil Neerukonda Institute of Dental Sciences Seal Sangivalasa

Expedited Review:

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member-Secretary and the Chairperson of the of the IEC or designated member of the Committee or Subcommittee of the IEC does expedited review only if the protocols involve:

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposals 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 data analysis.
3. Research activities that involve only procedures like Clinical studies of drugs and medical devices only when: Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. 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 trial that may be initiated later based on the findings of the pilot study.

Review of On-going Studies:

The Committee will conduct continuing review of each on-going Study at intervals appropriate to the degree of risk to the subjects, but not less than once a year, and can also have authority to observe or have a third party observe the research activities.

The investigator should promptly report the following to the Committee:

i. Deviations from or changes to the protocol to avoid immediate hazards to the trial subjects.
ii. Deviations / changes that increase the risk to subjects and / or affect significantly the conduct of the trial.
iii. All serious and/ or Unexpected Adverse Events should be reported to the Committee by the Investigator within 24 hours of their occurrence as per applicable regulatory guidelines. The report of the serious adverse event of that or severe adverse event other than that after due analysis should be submitted within 10 (ten) calendar days of occurrence.
iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Seal

Annual Progress Report:

1. For the study continuing for longer than the period of one year, the first report shall be submitted within thirty (30) days of completion of one year following the date of the first approval.
2. Subsequent report shall be submitted at one year intervals following the first report.
3. The Committee can recommend termination of ongoing clinical trials for the reasons like patient's safety, breach of any condition of approval, non-compliance on part ofthe Investigator, goal of the study achieved midway, complaint from the subject etc.

Records Retention:

The Committee will retain the following records;

1. Standard Operating Procedures (SOPs) in effect at the time of review and the previous SOPs.
2. Membership list at the time of review and the previous membership records.
3. Occupation/ affiliations of the members at the time of review with CVs and training records of the members as well as CV of guest expert members.
4. Agenda of meetings, minutes of meetings and all correspondence with the Principal Investigator.
5. Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by the Investigators etc.
6. Registration details of the Ethics Committee.

Archival Policy:

1. The Committee reference study documents and other related documents will be archived for 5 (five) years after the completion of the study. And after 5 (five) years, the respective Principal Investigator / Sponsor/ CRO will be informed about the end of archival period and the documents will be returned or discarded as instructed by therespective authority.
2. The Archival Log will be updated accordingly.
3. The documents will be archived within a secure place in a locked cupboard with restricted access.
4. The documents of the completed study can be archived at a separate facility and the details for the same will be maintained in the archival log.

Handling of Subject Queries:

- The subjects can call on the Committee Office number which is given in the Informed Consent Document.
- Subject's queries shall be documented by the Member Secretary and the same shall be conveyed to the Chairperson. The reply of the Chairperson will be conveyed back to the concerned subject.
  - In case the subjects want to talk directly to the Chairperson, the Chairperson's numbershall be provided from the Committee Office.