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An ISO 9001:2015 certified institution

CODE OF ETHICS POLICY

POLICY NO.	ISSUE/REVISION NO.	DATE OF REVISION	NEXT REVISION
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PREPARED BY	VERIFIED BY	APPROVED BY
R&D HEAD/COORDINATOR	IQAC COORDINATOR	PRINCIPAL

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INSTITUTIONAL ETHICAL COMMITTEE
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INSTITUTIONAL ETHICAL POLICY

Objectives and Responsibilities

The primary objective of this committee will be:

. 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 especially, the proprietary information.

4. To review all research proposals submitted to the committee within the specified time limits.

5. To maintain concise but clear documentation of its use on the research proposals.

6. 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

I. All communications with the Committee will be in writing (Physical or electronic)

2. Before receiving the review materials, it is advisable to obtain COI declaration and CA (Confidentiality Agreement) from the Member Secretary, Chairperson & members. If it is required by Sponsor/CRO/ Investigator/1Institution. A copy of this agreement will be filed with the official records of the Committee and another copy will be returned to the Sponsor/ CRO / Investigator/ Institution.

3. The Committee will require the submission in Printed (member copies + 1 PI Reference copy (if required) + Guest Member copy (if any) & electronic copy (whenever possible) of study dossier as listed for every research proposal.

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4. 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 modification.

5. In case of any amendment to the research proposal or any modification which is not suggested by the Committee and is not administrative, submission should be as directed in sub-clause 3 above.

6. The documents required for submission are the following:

a) Study proposal with covering letter.

b) Protocol along with compensation details and any amendments to it, Informed Consent Form (ICF), including any amendments and its translation(s) into regional language (s) with translation certificates.

e) Written information to be provided to the subjects {e.g, Patient Information Sheets (PIS), if applicable).

d) Investigator's Brochure (IB).

e) Undertaking by Investigator.

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.

k) Copy of the Insurance Certificate.

l) DCG () clearance (whenever applicable).

m)Investigator's agreement with the Sponsor / CRO.

n) Health Ministry Screening Committee (HMSC)/ Bhabha Atomic Research Centre (BARC)/ Genetic Engineering Advisory Committee (CEAC)/ Director General of Foreign Trade (DGFT) clearance wherever applicable.

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o) Food and drug Administration (FDA) marketing / manufacturing license for herbal drug wherever applicable.

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. Details of Informed Consent Process, including patient information sheet and the Informed Consent Form in local language /English /Hindi.

g) For any drug // device trial, all relevant publications/ pre-clinical data and clinical trial data 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, EIDS), 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 measure(s) taken to provide compensation to the research participants, the human subjects involved as participants in research (as defined in the guidelines of various national agencies), the researchers themselves, and such other persons who may be directly or indirectly at risk in the conduct of the research.

n) Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.

o) Agreement to comply with the relevant national guidelines for research in human genetic transplantation etc. as and when applicable.

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p) 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:

a) Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.

b) Subject recruitment procedures.

c) Inclusion and exclusion criteria for entry of subjects in the study.

d) Precise description of methodology of the proposed research, including intended dosagesof drugs, planned duration of treatment and details of invasive procedure, if any.

e) A description of plans to withdraw or withhold standard therapies in the course of research.

f The plans for statistical analysis of the study.

g) Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.

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h) Storage and maintenance of all data collected during the trial.

i) Agreement to comply with national and international GCP protocols for clinical trials.

Procedure for Document Receipt & Handling:

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:

a. A Submission Letter addressing the Ethics Committee.

b. Total number of copies of all documents.

Circulating the Documents

1. Study documents will be circulated to the members along with a Document Circulation Log to maintain the record of the same and the template of Document Circulation Log is given below.

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 archived in master log file.

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Return of the Documents

On the meeting day, the members will bring their hard copies of the study

documents to be reviewed.

I. After taking the decision for the proposed study, the members return their copies at

the office.

II. 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.

V. 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.

V. Archival will be done as described in Archival Policy.

VI. In case a member is not able to attend the meeting, 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

a) Scientific design of the study

b) Justification/ Rational of the study

c) Selection criteria for subjects

d) Justification for use of placebo, if any

e) Potential benefits to the study subjects, predictable risks to the study subjects Criteria for discontinuation / withdrawal of the subjects

g) Monitoring of serious adverse events

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h) Compensation to the: bjects for participating in the study

i) Subject recruitment procedures (e.g, advertisements), if applicable

j) Patient retention activities

k) Compensation for study related injury or death

l) Post trial benefits

m) Protection of privacy and confidentiality and plans for publication of results (positive or negative)

n) Statistical analysis

o) Informed consent document in English and regional languages

P) Competence of the Investigators, supporting staff and infrastructure facilities

q) 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 Medicinal (Investigational) Product, whether or not related to the Medicinal (Investigational) Product. 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:

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1. Results in death

2. 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.

3. Requires inpatient hospitalization or prolongation of existing hospitalization: If subject requires admission to the hospital or prolongation of hospitalization was a result of adverse event.

4. 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.

5. 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.

6. Important medical event like allergic bronchospasm, blood disorders, seizures/convulsions, the development of drug dependence or drug abuse.

7. 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.

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:

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 (as distinguished from risks and benefits of therapies subjects would receive even if not participating in 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 data collected to ensure the safety of subjects.

5. When appropriate, there are adequate provisions to protect the privacy of subjects and to 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. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

8. 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 protocols. In case, the proposals are with the similar molecule and/or similar study design they can be reviewed in the same meeting.

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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. In case of molecule/ combination of molecules which has already been discussed earlier by the Committee and/ or the molecule/ active ingredient that have been in case for considerable period of time, review meeting for such protocols studies can be scheduled well within five(5) days or short notice as per availability of members. Towards the same, a list of molecules reviewed will be updated on regular basis for ready reference.

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 minimum of 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.

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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 reserve the right to withhold favorable opinion/approval on a research proposal when the Committee does not have reasonable assurance about the qualification of the Investigator(s), the site facilities, the Sponsor/CRO or the research protocol itself.

9 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.

Review Outcome

The Committee will document its view as the following:

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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 hazards to the subjects, or when the change(s) involve only logistical or administrative aspects of the trial le.g. change of monitor (s), telephone number(s)].

Research studies that are Exempt Ethical approval:

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

1. Service evaluation
2. Performance reviews
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, EIDS (unless approval is specifically required by an external funding body or other external body) and should be submitted to IEC, EIDS only for "Exempt, stating clearly the clause under which the exemption is sought:

Clause Research Type Example

Research involving information Published biographies, newspaper freely available in the public accounts of an individual's activities and domain. published minutes of a meeting which would not be considered 'personal data'

Datasets available through the offices

State agencies where appropriate permission have already been obtained and it is not possible to identify individuals from the information provided. All non-invasive and non-interactive

Research involving anonymized records and data sets that exist in the of National and public domain.

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3 Studies of public behaviour that are purely observational. 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 All anonymous educational tests, nonsensitive, completely survey and interview procedures when the anonymous studies. participants are not defined as "vulnerable" and participation will not induce undue psychological stress or anxiety.

Research involving the use of All elected or appointed officials, education tests, survey and candidates for public office, artists. interview procedures on human participants in the public arena.

Taste and food quality evaluation & Studies where the food consumed is: acceptance studies. a) wholesome without additives or b) consumer Exempt' doesn't apply to food contains a food ingredient, agricultural, evaluation studies where ethical chemical or enviro mental contaminant, issues related to local socio-religious for a purpose and at a level declared safe and cultural practices of the studied by the relevant National/State food safety agency population may be a concern.

In accordance with the above criteria, IEC.EIDS will have to make the final judgement as to whether a particular activity should be submitted to 1EC, EIDS for a formal Ethics committee approval or just an 'Exempt Note that exemptions above do not apply to research involving vulnerable participant.

For example, children and young people, those with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship.

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 listed in one or more of the following categories:

a. Clinical studies of drugs and medical devices only when studying drug

i. Research is on already approved drugs except when interaction or conducting trial on vulnerable population or Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

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.

a. Research on interventions in emergency situation when proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, drug physicians may use new intervention as investigational (IND)/devices/vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients

i. When consent of person/patient/responsible relative or custodian/team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCF1;

iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data.

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b. Research on disaster management: A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may als0 be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations. Disaster affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed. The research undertaken should provide direct or indirect benefits to the participants, the disaster affected community or future disaster affected population and a prior agreement should be reached on this, whenever possible, between the community and the researcher.

v. All international collaborative research in the disaster affected area should be done with a local partner on equal partnership basis.

vi. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

Expedited Review Procedures

I. The Committee may use expedited review procedure in case of minor changes in the previously approved research. The expedited review may also be used when the amendments appear to involve no more than minimal risk to the study subjects.

2. Under the expedited review procedure, the review may be carried out by the Chairperson, or by one or more experienced reviewers designated by the Chairperson from amongst the

members of the Committee. The reviewers may exercise all the authorities of the Committee except that the reviewers may not disapprove the research.

3. An On-going research activity may be disapproved only after review in accordance with non-expedited review procedure as mentioned. The members will be informed about the expedited review proposal in next full board meeting.

4. Only the Chairperson shall make the decision to allow an expedited review.

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 human 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.

ii. 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.

iii. New information that may affect adversely the safety of the subjects or the conduct of the trial.

2. In addition, the Investigator should submit the progress report of the study at intervals appropriate to the degree risk to the human subjects or as directed by the Committee.

3. In case of serious adverse event of death or other serious adverse events, the Committee will meet as and when required, in the view of recent amendment by CDSCO. The Committee may also invite an expert for his / her opinion on the same. The Committee will generate the report after due analysis and submit the same to the applicable authority within timelines specified in the applicable regulatory guidelines.

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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 of the Investigator, goal of the study achieved midway, complaint from the subject etc.

Annual Renewal Process

For studies, whose duration is more than one year, an extension of approval shall be given, after the status report and all other relevant reports mentioned are reviewed and approved by the Committee by the Annual Renewal Process. The approval for extension for study will be given for a period of one year.

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. Invitation Letter, Consent Letter and CDA signed by members and guest expert members and Resignation Letters of the members who have resigned.

5. Agenda of meetings, minutes of meetings and all correspondence with the principal Investigator.

6. Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by the Investigators, reports of injuries to the subjects etc.

ble regulatory guidelines.

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8. Registration details of the Ethics Committee.

Archival Policy

The Committee reference study documents and other related documents will be archived for5 (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 the respective 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.

Reports to the Relevant Regulatory Authorities.

The Committee will make a yearly activity report for submission to the Relevant Regulatory Authorities upon request, which would include the following elements;

1. A quantitative evaluation of the activities of the Committee and list of proposals reviewed.

2. Status of each study proposal.

3. Statements of significant new findings provided to subjects.

Handling of Subject Queries

1. The subjects can call on the Committee Office number which is given in the Informed Consent Document.

2. 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.

3. In case the subjects want to talk directly to the Chairperson, the Chairperson's number shall be provided from the Committee Office.

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