SOP of the Institutional Ethics Committee

National Institute of Ayurveda, Jaipur

SOP No. 2010/July./01, Revision No. 01. November 2011/18, Revision No. 02. June 2017/20, Revision No 03. Mar 2018/15

Supersedes: All Previous SOPs

OFFICE OF THE ETHICS COMMITTEE (EC), NATIONAL INSTITUTE OF AYURVEDA & ATTACHED HOSPITALS, JAIPUR

Contents

1. Goals of Ethical committee

1.1 Primary Goal of Ethical Committee

The primary goal of the Ethical Committee is to ensure that, in research involving human subjects at National Institute of Ayurveda and its attached Hospitals the rights and welfare of human subjects are adequately protected. To achieve this goal, the Ethical Committee will verify whether the research projects are designed in a manner to minimize potential harm to human subjects, review all planned research involving human subjects prior to initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ascertain that human subjects are indeed protected.

1.2 Secondary Goals of Ethical Committee

Secondary goals of the Ethical Committee are to inform and assist researchers of National Institute of Ayurveda and its attached Hospitals on ethical and procedural issues related to the use of human subjects in research, to facilitate compliance with relevant regulations of the drugs and cosmetics (2nd amendment) rules 2005 of the ministry of health and family welfare or Indian Council of Medical Research (ICMR) or the published guidelines of the AYUSH-GCP

2. Region of Supervision of Ethical Committee

The following categories of research involving human subjects may be initiated only after review and approval by the Ethical Committee:

a. Research that is to take place on the premises of National Institute of Ayurveda and attached hospitals or collaborating hospitals.
b. At its discretion, the Ethical Committee may accept for review, and approve research projects that are to take place elsewhere on or off the premises of National Institute of Ayurveda, but only with the involvement of at least one member of the staff of National Institute of Ayurveda as an investigator.

2.1 Authority of Ethical committee in Overseeing Research Involving Human Subjects

Ethical Committee is mandated to review and monitor any and all types of research, in which human subjects are involved. No research involving human subjects at National Institute of Ayurveda Hospitals will be given exemption from Ethical Committee review. The authority conveyed to the Ethical Committee includes the following:

a. To review all research projects involving human subjects.

b. To approve new research projects, and review continuation of previously approved projects and require from investigators revisions in research protocols and informed consent documents if needed.
c. To disapprove the initiation of a new research project and suspend or terminate a previously approved project.
d. To monitor the activities in approved projects, in any way deemed necessary, including regularly scheduled continuing review at least every twelve months, and verification of compliance with approved research protocols and informed consent procedures.
e. To ensure prompt reporting to the Ethical Committee of any planned changes in approved projects, and to ensure that no material changes occur without prior approval of the Ethical committee.
f. To ensure prompt reporting to the Ethical Committee of any serious adverse events or severe drug reactions occurring in approved projects, or in other projects related in context to the approved projects.

3. Composition of the Ethics Committee:

As per order number: F.10 (12)/ 2017-NIA/ACA/1428-33 dated 03.11.2017 from the office of the Director, National Institute of Ayurveda, Jaipur the Institutional Ethics Committee has been re-constituted as follows:-

S.No.	Name & Address	Contact Details	Category	Status
1	**Vaidya Prof. Banwari Lal Gaur**	Former Vice –Chancellor Dr. S.R. Rajasthan Ayurveda University Jodhpur and Ex-Director, National Institute of Ayurveda Mb. 9829077697	Academician	Chairman
2	**Prof. Kamlesh Kumar Sharma**	Head, Deptt of Swastha vritta, NIA Jaipur Mb.94133345633	Medical scientist	Member
3	**Prof.V Nageshwar Rao**	Deptt of Rasa Shastra, NIA Jaipur Mb.9828066878	Medical scientist	Member
4	**Prof. Smt Sushila Sharma**	Deptt of Prasuti tantra NIA, Jaipur Mb.9660843984	Medical scientist	Member
5	**Prof. Pawan Kumar Godatwar**	Head Deptt. Of Roga Nidan & Vikriti Vigyan, NIA, Jaipur Mb.9314502834	Medical scientist	Member
6	**Prof Hemant Kumar Kushwaha**	Retd. Prof, NIA 80/100 , Nilgiri Marg, Patel Marg, Agrawal farm, Mansarovar, Jaipur Mb.9983176279	Clinician	Member
7	**Prof Arun Chougule**	Dean, Paramedical sciences and HOD Radio Diagnoses, SMS Medical College, Jaipur & Dean, Raj health University Mb.9928140113	Basic Medical scientist	Member
8	**Prof. Smt Monika jain**	HOD Pharmacology, SMS Medical College Mb.9828786533	Basic Medical scientist	Member
9	**Dr. Kamal Kanta Dadhich**	Retd. Professor of Sanskrit Deptt. Of College Education Govt. of Rajasthan Mb.9414227881	Common men Representative	Member
10	**Shri Anil Shukla**	Sangthan Mantri Sewa Bharti, Jaipur Mb.9460060029	Non Govt Voluntary agency	Member
11	**Shri Om Prakash Rangjika**	Advocate Rajasthan High court 5, Guru Gorakshak Colony, Near Nagar Nigam stadium, Sanganer, Jaipur Mb.9414079691	Legal Profession	Member
12	**Dr Sumit Nathani**	Assissstant prof, Deptt of Dravyaguna, NIA,Jaipur Mb.7665809886	Medical Scientist	Member Secretary

4. Ethical committee Meetings

The Ethical Committee will meet approximately every year, earlier if needed, at a day decided by the Chairman, Secretary and the members at the last meeting. The quorum of Ethical Committee shall be at least 5 members with the following representations:

a) Basic Medical Scientists
b) Clinicians
c) Legal Expert (Advocate)
d) Social worker or NGO volunteer or Philosopher or Ethicist or Theologian
e) Lay Person

4.1 Ethical Committee Meeting Agenda

The Ethical Committee will have an agenda for each of its meetings. The agenda will include listing and identifiers for all research project applications awaiting action by the Ethical Committee. At least seven days in advance of the scheduled meeting date, the agenda will be made available by email or post for review by members of the Ethical Committee. All documents relating to a study submitted by an investigator will be distributed as electronic/paper copies and sent to the members of the Ethical Committee scheduled to conduct the full review.

4.2 Ethical Committee Meeting Procedures

The Ethical Committee will meet 6 months, to review the research project applications submitted for approval. With the exception of applications eligible for expedited review (Section 8), the Ethical Committee membership will determine the outcome of its review of research project applications at meetings, where quorum has been established. A quorum requires the presence of a minimum of 5 members at meeting and a vote that includes at least one lay member. Except when an expedited review procedure is used, the Ethical Committee will review proposed research at convened meetings at which a majority of the members of the Ethical committee are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Ethical Committee has the authority to define the approval granted for a study as invalid or expired**.** The chairperson, or in his absence, another member of the Ethical Committee will chair the meetings. Whenever a research project application is being reviewed, in which a member of the Ethical Committee may have a conflict of interest, that member may leave the site of the Ethical Committee meeting for the duration of the review of that application. If the member with conflict of interest is present will only provide required study related information and will not be a part of decision making process.

4.3 Ethical Committee Meeting Minutes

The Secretary of Ethical Committee will prepare minutes of each meeting of the Ethical Committee, during which research projects are being reviewed. The minutes will be in sufficient detail, and will include the followings:

a. Date and venue of the meeting
b. Attendance of members and reason of absence of primary members. If primary members are absent, the presence of alternate members
c. Decisions reached on each research project application reviewed
d. Distribution of membership votes on the decisions, documenting the number of votes for, against and abstaining
e. Reasons for requiring changes in a project, or disapproving, suspending or terminating a project
f. If vulnerable groups of subjects were included in the research, the justification for their inclusion, and adequacy of special precautions taken to minimize risks
g. Summary of the discussion of disputed issues and their resolution
h. Date of next scheduled continuing review of a project, and the perceived level of risk on which the time of next review was based

The minutes will be made available for review by the Ethical Committee members by email and/or post.

4.4 Ethical Committee Notification of Meeting Decisions and issuing of the certificate of approval

Upon completion of the review of a research project application, the Secretary of Ethical Committee will prepare a notification document, to inform the applicant principal investigator of the outcome of the review. This document will include the following information:

a. The outcome of the review by the Ethical Committee, and the date of decision for approved projects and the reporting requirements for the principal investigator.
b. For disapproved, suspended or terminated projects, the reasons for these decisions, and the rights of the investigators for rebuttal of the decision.
c. The list of members present in the decision taking meeting and the members who voted for and against the study. These are listed in the Ethical Committee Decision Letter send to investigator.

5. Review of the Projects Requiring Waiver for Informed Consent Process and Documentation

5.1 Projects Eligible for Waiver of the Written Informed Consent Process

The Ethical Committee will consider waiving the requirement of obtaining written informed consent from a subject of research, if the nature of the research meets one of the following definitions:

a. Does not violate the privacy of the subject
b. is not invasive and
c. Does not involve risks to the subjects that are more than minimal.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests, i.e. the nature of the research meets one of the following definitions:

i. Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the investigator records the information in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects, or if the sources of the information are publicly available.
ii. Research involving normal educational practices.
iii. Research involving use of educational tests, survey procedures, interview procedures or observation of public behavior without revealing subjects' identity, placing them at risk of criminal or civil liability, or damaging their financial standing, employability or reputation.
iv. Research that anticipates but lacks definite plans for involvement of human subjects, such as institutional-type center or training grants; any study involving human subjects under the umbrella of such grants will have to be reviewed subsequently by the Ethical Committee, prior to its initiation.
v. Research that cannot practicably be carried out, if informed consent were to be obtained in advance, provided that the rights and welfare of the subjects will not be adversely affected; in this instance, arrangements shall be made to provide pertinent information to the subjects after their participation.

5.1.2 In emergency situations, the Ethical Committee has right to make exceptions to informed consent requirements after appropriately reviewing such protocols.

5.2 Projects Eligible for Waiver of the Requirement for Documentation of the Informed Consent

The Ethical Committee may waive the requirement for documentation of the informed consent (a signed Subject Consent Form), but not that of obtaining informed consent, under one of the following circumstances:

a. The principal research risk is potential harm resulting from a breach of confidentiality, and the only record linking the subject and the research is the consent document.

b. The research presents no more than minimal risk of harm to subjects, and does not include any procedure, for which written consent would be required, if it were to be performed for clinical management. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

In cases where the Ethical Committee will waive the requirement for documentation of informed consent, the investigators shall still provide the subject with the written Subject Information Sheet the text of which shall be reviewed and approved by the Ethical Committee. Based on this information, the investigator shall obtain oral consent to participate, but the granting of the consent will not be documented in writing.

6. Ethics committee Fees

6.1. **Sponsored projects-** The fees of Ethics Committee for sponsored projects, per Clinical Trial will be Rs. 10,000 per project & this will be in the name of "**Secretary (Ethics)"** which is the account of the institution, National Institute of Ayurveda for this purpose. The rest of the funding for the trial shall be in the name of Principal Investigator. Both the cheques shall be submitted in the office of Account Office of Ethics Committee and account office of Ethics Committee shall distribute the cheque to Principal Investigator after obtaining receipt.

6.2. MD/MS/PhD- For **Investigator initiated trials** without private funding, non - drug trial, trials by PG/PhD. Towards thesis/original research, and processing charges for Research sanctioned by AYUSH, NIA, CCRAS, DST, Central DTS,ICMR, CSIR, etc., no Ethics Committee fees shall be charged. However a fix amount of Rs one thousand (Rs 1000/-) will be charged towards registration of the research work. This will be payable in the name of "**Dean Research**" which is the account of the Institution, National Institute of Ayurveda.
Any other project/research /study of regional or national importance approved and with directions for the Ethical committee fees waiver by The Director, NIA would also be entertained.

7. Initial Review by Ethical Committee of Human Subject Research

Before being submitted to the Ethical Committee for clearance, all projects will have to be presented and cleared by the Institutional research review board (IRRB) National Institute of Ayurveda & Hospital Clinical Trials Screening Committee under the Office of the Director and Controller, National Institute of Ayurveda Jaipur.

The plan proposals of M.D/M.S. and PhD students would be routed through the Departmental research committee (DRC) and Institutional Research Review Board respectively.
The reports of the DRC and IRRB will be discussed in Institutional Ethics Committee.
In case an issue needs further elaboration then the plan may again be taken up in the Institutional Ethics Committee meeting for the needful.

No aspect of use of Human subjects in research may begin, until Ethical Committee has granted the approval.

7.1 Documents Required for Initial Review

To apply for initial review and approval of a new project, the principal investigator should submit all documents necessary for an orderly review of the project, particularly those aspects involving human subjects. The application shall be accompanied by hard and soft copies each of:

1. One page synopsis of the study protocol.
2. Protocol Version <Version No.> dated <Date>.
3. Power point presentation of overview of project (maximum 5 slides) on CD.
4. Investigator's Brochure Version <Version No.> dated <Date> containing all details of the chemistry, animal studies, toxicology and available clinical data of the trial drug with adequate bibliography.
5. Subject Information Sheet and Informed Consent Form <Version No.> dated <Date> in Hindi and English, with version numbers and dates. The ICF should be approved by Ethical committee before its use in the trial.
6. Proposed methods of subject accrual including advertisement(s) etc
7. Principal Investigator's current CV
8. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
9. Investigator's Agreement with the Sponsor- Copy of the Clinical Trials Agreement (CTA) between the investigator and the Clinical Research Organization/ Sponsor of the research project/trial and institution (proforma party).
10. Investigator's Undertaking- Undertaking by the Investigator as per set format published in the Drugs and Cosmetics (IInd Amendment) Rules,2005 of the Ministry of Health &Family Welfare (copy of the same may be obtained from the Office of the Ethics Committee) stating the number of trial he/she is presently actively engaged in and that he/she has the time and the resources to undertake the present study.
11. Other documents such as subject diary, subject emergency card, quality of life questionnaires, Copyright permissions etc.

7.2 EC Criteria for Approval of New Research

In consideration of approval of a new research project involving human subjects, the Ethical Committee will review the application to determine if all of the following criteria are met:

a. Risks to subjects are minimized
b. Risks to subjects are reasonable in relation to anticipated benefits
c. Selection of subjects is equitable
d. The study is scientifically designed and the sample size has been justified
e. Appropriate informed consent will be sought from prospective subjects or their legally acceptable representatives
f. Informed consent will be appropriately documented
g. There are adequate provisions for monitoring data collected to ensure the safety of subjects (when appropriate)
h. There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data (when appropriate)
i. Whenever subjects are considered to be vulnerable to pressure or undue influence (such as children, fetuses, prisoners, pregnant women, mentally ill, intellectually disabled, cognitively impaired persons, economically or educationally disadvantaged persons), their use is adequately justified and additional safeguards have been included in the study to protect the rights and welfare of these subjects.

7.3 Ethical Committee Process of Initial Review

Upon receipt of the documents for an initial review, the Secretary of the Ethical Committee will notify all members. Members would receive a copy of the full protocol and will review the proposal against the nine criteria for approval of research listed in Section 7.2, and include additional items on the following:

Proposed interval until next continuation review, to be based on the estimated extent of risks;

whether or not the written informed consent document is sufficiently informative and includes all elements of informed consent, and whether and what kind of revisions in the protocol or consent document have been or need to be obtained for the application to be approved.

Prior to the Ethical Committee meeting to discuss the project, all Ethical Committee members will have the authority to request from the applicant Investigator, via the Secretary of Ethical Committee, revisions or additional information or documents. Upon completing his/her review, a member could present his / her comments to the Ethical Committee via the Secretary. After sufficient discussion, the members attending the Ethical Committee meeting will vote on the application, to approve it, disapprove it, or defer a decision until revisions are implemented, additional information is provided, or

further expert review is obtained. The decisions will be based on the votes of all members present. Only those members will vote who are independent the sponsor and are not part of the study team.

Under certain circumstances, if minor revisions in the submitted documents are required or a missing document of minor importance is to be obtained, the Ethical Committee may delegate the chairperson or the primary reviewer to approve the project on behalf of the Ethical Committee. The decision of the primary reviewer will be ratified in the next full Ethical Committee meeting.

Depending upon degree of risk involved, the Ethical Committee may consider monitoring the data and trial activities to ensure the adequate protection of safety, rights and well-being of participants.

The outcome of any review conducted by the Ethical Committee will be sent directly to the appropriate Investigator

In case of disagreement between the Ethical Committee and the investigators of a project under review with regard to requested revisions or a decision to disapprove the project, the Ethical Committee will provide the opportunity of rebuttal for the investigators, either in writing, or by appearing at a meeting of the Ethical Committee, to defend their cases. Under no circumstances will any subject be admitted to the trial before the Ethical Committee issues its written approval/favorable opinion of the trial.

7.4 Review of External Sites (whenever applicable)

If investigator plans to conduct research at external sites that are engaged in research, the following information regarding these sites should be submitted to Ethical Committee for review:

a. Contact information for the site
b. Site's permission for the research to be conducted
c. Periodic review of documents pertaining to the satellite sites

Investigator will follow all Ethical Committee requirements when conducting research at satellite sites.

8 Ethical Committee Monitoring of Human Subject Research in Progress

The Ethical Committee will monitor all active research projects involving human subjects, to ascertain that the subjects are being protected adequately from research risks and from any other breaches of human rights. Regular monitoring of all previously approved projects will be in the form of continuing reviews scheduled at the time of most recent Ethical committee approval of the project. The frequency of the scheduled continuation reviews will be appropriate to the degree of risk, but not less than once per year and the schedule of the continuing review will be decided upon approval. In addition, the Ethical Committee will ensure that the investigators of active research projects carry out the following, as needed, as a condition of approval of their projects:

a. Report to the Ethical Committee any planned change in the study, and do not implement any change without receiving prior approval, except to eliminate immediate hazard.
b. Report to the Ethical Committee any unanticipated problems involving risks to subjects.
c. Report to the Ethical Committee any new information on the project that adversely influences the risk/benefit ratio.

8.1 Amendment Requests

Investigators of a previously approved project may request from the Ethical Committee approval to make amendments to various aspects of the project. No amendment may be implemented without the notification to the Ethical committee . An amendment may be in the content or the form of documentation. Types of amendments include the following:

a. Amendment to the study protocol
b. Amendment to the investigator's brochure describing a test article
c. Amendment to the informed consent document
d. Amendment to the Investigators involved

Different types of amendments may be requested individually or in combination. Particularly, a change in the study protocol or investigator's brochure may require a change in the informed consent document. The Ethical Committee will scrutinize the amended documents to determine the degree to which risks to human subjects may have changed, if there is any need to revise the consent document, and if changes in the consent document are adequate. A copy of the current or revised informed consent document shall accompany the amendment application. Administrative changes to the form of documents may not require full committee approval (see section 9.3).

8.2 Adverse Event Reports

Investigators of a previously approved project are obligated to report to the Ethical Committee, any unexpected adverse event involving human subjects of research. Adverse events occurring at National Institute of Ayurveda hospital or at other study sites in a multi-centre study must be reported (if requested by the sponsor of a study) to the Ethical Committee within a week and all SAEs must be reported to Ethical Committee within 7 working days.

Adverse events include the following:

a. Expected or unexpected harmful effects of an investigational or approved drug, biologic or device, observed in the approved project, or in other research settings similar to that of the approved project
b. Physical or emotional harm to the subject during the execution of the experimental protocol

c. An event occurring in the premises of the institution housing the research project, not as a direct result of the research, but in conjunction with it.

The Ethical Committee will scrutinize the adverse event documents to determine the degree to which risks to human subjects may have changed, if there is any need to revise the consent document, and if changes in the consent document are adequate. A copy of the current or revised informed consent document shall accompany the adverse event report.

8.3 Notifications to Institutional Authorities

The notification documents will be made available for review by the Ethical Committee members.

If the study is approved by Ethical Committee, it will ensure notification to the appropriate institutional authorities of:

a. Any unanticipated problems involving risks to human subjects or others
b. Any instance of serious or continuing noncompliance with the regulations or the requirements or determination of the Ethical Committee : or
c. Any suspension or termination of Ethical Committee approval while protecting the rights and welfare of the study subjects.

8.4 Additional Measures of Ethical Committee to Monitor Active Research Projects

Additional monitoring of approved projects may occur at the discretion of the Ethical Committee, in targeted or random form

a. Requests for progress reports from investigators.
b. Examinations of research records.
c. The Ethical Committee may consider visiting the institution at any point of study period including a physical observation of consent process based on the degree of risk involved.
d. Verification from sources other than investigators that no material changes in the study have occurred. In targeting research projects to be subjected to these additional monitoring activities, the Ethical Committee will consider the level of risks of harm, the frequency and nature of adverse events, the vulnerability of the subjects of research, and any complaints received from the subjects.

If the information gained during its monitoring process indicates that human subjects of a research project are exposed to unexpected serious harm, or the requirements of the Ethical Committee are not being met, the Ethical Committee will suspend or terminate the research. In such instances, the Ethical Committee will provide the opportunity of rebuttal for the investigators, either in writing, or by appearing at a meeting of the Ethical Committee to defend their cases.

In most instances, the act of obtaining consent shall be validated on the written document that contains the information needed to give informed consent, i.e. the Subject Consent Form. The validation shall be implemented by the signatures of the subject or the subject's legally acceptable representative or impartial witness, and of the investigator obtaining the consent. In the case of a child being recruited as a subject of research, an assenting signature of the subject of an age (7 or above) sufficient to comprehend the nature, risks and benefits of the study, shall be obtained on the Subject Consent Form, in addition to the signature of the legally acceptable representative.

The documentation shall be executed on a single consent form and this original signed form will be maintained in the study site file. A copy of the executed document shall be given to the subject or subject's legally acceptable representative. All these information will be verified by the Ethical committee , while performing on site visit as additional monitoring in targeted or random form.

9. Research Projects Eligible for Expedited Review and Approval

Certain types of research project applications submitted to the Ethical committee for initial or scheduled continuing review, requests for amendments, or adverse event reports will be eligible for "expedited review". The basic element determining the eligibility for expedited review is the magnitude of the risks to which the human subjects of the research will be exposed.

Only projects involving no more than minimal risk will be considered for expedited review. If the subjects of the research include children, fetuses, pregnant women, mentally ill, intellectually disabled, cognitively impaired persons or prisoners, the project will not be eligible for expedited review, regardless of the risk.

9.1 Ethical committee Process for Expedited Review

Expedited review of a new project or previously approved project may be requested by the principal investigator at the time of submission of the application, by indicating the applicable criterion for expedited review. Alternatively, the chairperson may choose to process an application by expedited review. Expedited review will be carried out by the chairperson or another experienced member of the Ethical committee designated by them. The reviewer will have the authority to approve the project, without a vote of the Ethical committee membership. If the reviewer believes that there is reason for disapproval, or the nature of the project is not suitable for expedited review, the reviewer will defer any decision, and submit the project to a full review by the Ethical committee . Upon approval, based on expedited review, the Ethical committee membership will be informed of the approval at the time of a regularly scheduled meeting, and it will be recorded in the minutes of that meeting.

9.2 Research Considered by Ethical committee as Suitable for Expedited Review

The following types of research, considered having no more than minimal risk, and not involving children, fetuses, pregnant women, prisoners, mentally ill or cognitive impaired or intellectually disabled persons have been explicitly identified as eligible for expedited review:

a. Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth, and permanent teeth if subject care indicates a need for extraction.
b. Collection of excreta and external secretions including sweat, and uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labour.
c. Recording of data from subjects, using non-invasive procedures routinely employed in clinical practice (including use of physical sensors applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's privacy; procedures such as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echocardiography, and electroretinography, not including exposure to electromagnetic radiation outside the visible range, such as X-rays and microwaves).
d. Collection of blood samples by venipuncture, in an amount not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects, who are in good health and not pregnant.
e. Collection of supra-gingival and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and is accomplished in accordance with accepted prophylactic techniques.
f. Voice recordings made for research purposes, such as investigations of speech defects.
g. Moderate exercise by healthy volunteers.
h. Study of existing data, documents, records, pathological specimens, or diagnostic specimens.
i. Research on individual or group behavior or characteristics of individuals, such as perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
j. Research on drugs or devices for which an investigational new drug exemption or investigational device exemption is not required.

9.3 Previously Approved Research Eligible for Expedited Review

Research approved previously by expedited review will be considered eligible for expedited review at the time of its regular continuing review, if during the course of the study; the risks of the study have not increased. Prior to the scheduled date of regular continuing review, changes may have to be implemented in an approved project. Amendments to a previously approved research protocol of administrative or logistical

nature, revisions in the text of an informed consent document, or corrections in text of documents, all of which are minor in nature and do not increase the risks involved, will be considered eligible for expedited review.

10. Ethical committee Records

The Ethical committee will retain all relevant documents related to studies submitted to Ethical committee for at least five years after completion of the research. These records will be accessible for inspection and copying by authorized representatives of the regulatory agencies at reasonable times and in a reasonable manner. The documents are maintained in a safe and confidential manner. No identifiable information or information that fall within the preview of Intellectual property rights will be given to others in right to information act. Any information that is released will be only after the approval of the committee.

10.1 Ethical committee Documentation

The Ethical committee will maintain an archive file of all of the following documents:

- The Constitution and composition of the Ethical committee ;
- The curriculum vitae of all Ethical committee members;
- Current national and international guidelines;
- Meeting Records
- SOPs and Related Documents

10.2 Ethical committee Research Projects

The Ethical committee will maintain an archive of files for all research projects approved by the Ethical committee . Such files will be retained for at least five years after completion of the research. Each project folder will include the following types of documents, as conventional hard copy:

a. Copies of the Protocol, data collection formats, CRFs, investigational brochures etc. submitted for review;
b. All correspondence with Ethical committee members and investigators regarding application, decision and follow-up;
c. Agenda of all Ethical committee meetings;
d. Minutes of all Ethical committee meetings with signature of the Chairperson;
e. Copies of decisions communicated to the applicants;
f. Record of all notification issued for premature termination of a study with a summary of the reasons;
g. Progress reports
h. Investigator's short CV
i. Insurance and Indemnity policy statement
j. Texts of advertisements for subject recruitment
k. Notifications of Ethical committee decisions
l. Reports on amendments and adverse events

m. Statements on significant new findings
n. Correspondence between Ethical committee and investigators of the project.
o. Statement of total funding received from the sponsors and the details of receipts of institution dues /Ethical committee fees deposited by the PI for and in relation with trial.
p. List of project purchases and the relevant records.
q. Final trial closure report of the study.

11. Submission of the final trial closure report

Principle investigator/ sponsor / concerned party needs to submit final trial closure report along with the settlement of all pending payments within two month of the trial closure failing which the Ethical committee approval/ sanction/ permission of the project concerned will be deemed cancelled/ withdrawn.

The investigator/s will submit in writing at the time of trial closure a statement of total funding received from the sponsors and the details of receipts of institution dues /Ethical committee fees deposited by the PI for and in relation with trial. Besides this the PI shall also provide a list of project purchases and the relevant records to the Ethical committee office.