INSTITUTIONAL HUMAN ETHICS COMMITTEE

Standard Operating Procedures – Version 1.0

(Effective from January 2014)

1.0 Jurisdiction

The Institutional Human Ethics Committee (IHEC) of Avinashilingam Institute for Home Science and Higher Education for Women shall monitor all research activities undertaken in the Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore – 641 043.

This includes funded and non-funded projects and also student studies involving any kind of human subjects.

2.0 Objectives

The IHEC fully embodies the letter and spirit laid out in the „Ethical Guidelines for Biomedical Research on Human Participants‟ of the Indian Council of Medical Research (ICMR).

The IHEC specifically intends to:

2.1 Ensure a competent review of scientific and ethical aspects of the project proposals received by it in an objective manner.

2.2 Provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through an appropriate scientific review committee of the IHEC.

2.3 All protocols MUST meet Avinashilingam Institute for Home Science and Higher Education for Women ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, maintenance of confidentiality, choice of sample size and protection of vulnerable populations).

3.0 Composition

Given below is the composition of the Institutional Human Ethics Committee.

3.1 Voting members

i. Chairman – Not affiliated with the Institution
ii. One clinician from the Institution
iii. One clinician not affiliated with the Institution
iv. At least one person from basic sciences
v. One representative from each faculty involved in human studies
vi. One lay person representing the Community
vii. One legal expert
viii. One person from a non-scientific background
ix. Member-Secretary

3.2 Non-voting members

3.2.1 Technical Advisor to IHEC on Adverse Events Monitoring

The Technical Advisor shall remain a non-voting member in the IHEC, unless s/he is a member of the IHEC.

3.2.2 Members of the Scientific Review Committee of IHEC

The members of the Scientific Review Committee of IHEC who reviewed the application for review from PIs shall be permitted to be present in the IHEC Full Panel Review meetings when the relevant study/studies is/are being presented. Their presence in the IHEC shall be as non-voting members, unless they are members of the IHEC. (Also see paragraphs 4.3.4 & 9.1).

4.0 Selection of members

4.1 Chairperson

4.1.1 The Chairperson will be selected by the Head of the Institution. The Chairperson will not be affiliated with the institution. Due consideration to merit and awareness to research and ethical issues will be given during the selection of the candidate.

4.1.2 The term of office will be for a period of 36 months with provisions for renewal with the permission of the Committee.

4.2 Member Secretary

4.2.1 The Member Secretary will be appointed by the Chairperson. The term of office will be for 36 months, with provisions for renewal with the permission of the Committee.

4.3 Members

4.3.1 The members will be appointed by the Chairperson for a period of 36 months, with provision of renewal.

4.3.2 A new member will be chosen if an incumbent leaves.

4.3.3 A member will be removed from membership of the IHEC if

(i) s/he abstains from the meeting for more than three consecutive times without intimating the IHEC secretariat (either in writing or over the phone);

(ii) violates NDA (confidentiality);

(iii) hides conflict of interest;

(iv) resorts to professional misconduct.

5.0 Quorum for Review Meeting

5.1 Six members of whom AT LEAST one will be from among those members not affiliated to the Institute.

6.0 Authority under which IHEC is constituted

6.1 The Head of the Institute constitutes the IHEC and selects the Chairperson giving due consideration to merit and research expertise.

6.2 After this, the Committee will be vested with the rights to uphold its own autonomous function.

7.0 Responsibility

7.1 Responsibilities of IHEC

The IHEC ensures that the research protocols that are carried out at Avinashilingam Institute for Home Science and Higher Education for Women:

7.1.1 Do not compromise the safety, rights and well-being of the volunteers participating in the research study

7.1.2 Are conducted under the supervision of investigators with the required experience / expertise

7.1.3 Include only volunteers with the due and valid process of informed consent being gone through and completed (i.e., the subject‟s informed consent is obtained before entering them in research proposals. The subjects are informed of their rights to withdraw from the research at any stage and also of the consequences (if any), of such withdrawal. The subjects are assured that their refusal to participate or withdrawal from participation will not compromise their access to the organization‟s services).

7.1.4 Are sound in scientific design, and are conducted according to Director General of Health Services, Ministry of Health and Family Welfare as well as local regulatory requirements.

7.1.5 Are reviewed within six weeks of submission

7.1.6 Will be maintained confidentially and all the members will sign a confidentiality form.

7.1.7 The Committee will review all new research projects and also the ongoing research projects at intervals appropriate to the degree of risk to the study subjects.

7.1.8 The committee will maintain a list of projects submitted, approved / disapproved and the outcome of each project.

7.2 Responsibilities of Member-Secretary, IHEC

In consultation with the Chairperson, the Member Secretary will be responsible for the following functions:

7.2.1 Receiving all research proposals submitted to the IHEC for Panel Review

7.2.2 Numbering the proposals

7.2.3 Forwarding all proposals to committee members for review

7.2.4 Preparation of agenda for all committee meetings

7.2.5 Inviting experts from relevant areas to the scheduled meetings

7.2.6 Notification of review outcome to investigators of research proposal

7.2.7 Preparation of circulation of minutes (within 14 days of the meeting)

7.2.8 Retention and safekeeping of all records and documentation

7.3 Responsibilities of the Technical Advisor (TA) to IHEC on Adverse Events Monitoring

S.No.	Area	Job Responsibilities of Technical Advisors in brief	Remarks
1	Internal Auditing of Adverse Events / Serious Adverse Events	Scan through AERs, Monitor AEs/SAEs and report to IHEC, prepare month-wise report, to be tabled during IHEC Panel Review meeting	If necessary, the TA is encouraged to consult the Biostatistician before the audit report is finalized. In such cases, both the TAs should sign the report

The TA has been empowered to direct the PIs to withhold trials, if situation warrants, and shall issue a Determination Letter to the concerned PIs accordingly.

A. PRE-REVIEW PROCEDURE

8.0 How to apply for review of study proposal

8.1 Application for approval should be made in the prescribed format. All items must be filled in, and no items should be left blank as otherwise, it might result in summary rejection of the application.

8.1.1 How to obtain a copy of the application format for submission?

Soft copies of application forms are available from the Avinashilingam University website (www.avinuty.ac.in). Hard copies can be obtained from the Member Secretary.

8.1.2 **What should be submitted, how many copies in what format and when?**

Please see paragraph 8.5 below

8.2 Who should apply for approval of the proposal by the IHEC?

The Principal Investigator (PI) of the proposed study applies on behalf of the team of researchers.

8.3 Whom to be addressed to?

All proposals must be addressed to the Member Secretary, IHEC, Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore, with a request to review the proposal for its ethical soundness.

8.3.1 **Where to submit the application?**

All applications for review by the IHEC must be handed over / sent by courier to the Member Secretary of the IHEC.

8.4 The journey of a proposal

8.4.1 All study proposals (with the necessary enclosures (please see paragraph 8.5 below for details) for review must be submitted to the Member Secretary, IHEC with a request to review it and ensure that the submitted proposal complies with all the requirements.

8.4.2 If not found suitable for forwarding to IHEC, either the proposal will be returned with suggestions and / or queries to the PI by the Member Secretary, or the PI will be invited for a personal discussion by the Member Secretary, or the Primary Reviewers of the proposal concerned.

8.4.3 If forwarded to the IHEC, the proposal is then included in the list of projects to be reviewed by Members of IHEC in a full Panel Review meeting.

8.4.3.1 If the proposal was reviewed under the „**Exempt Review**" clause, it will then be listed in the list of projects to be cleared in the Agenda of the IHEC full Panel Review meeting. In this case, the PI is not required to present the proposal before the IHEC full Panel Review meeting.

8.4.3.2 If the proposal was reviewed under the „**Expedited Review**" clause, the PI will be invited for a discussion by the reviewers of the proposal. It will then be listed in the

list of projects to be cleared in the Agenda of the IHEC full Panel Review meeting. In this case, the PI is not required to present the proposal before the IHEC full Panel Review meeting.

8.4.3.3 Copies of the proposals along with annexures are sent to the Members of IHEC for review using a model review check-list prepared by the ICMR. This will be sent at least 10 days before the scheduled date of the IHEC full Panel Review meeting.

8.4.3.4 The PI will be intimated about the date for IHEC Panel Review meeting.

8.4.3.5 On the day of IHEC full Panel Review meeting, the PI shall come to the venue with a PowerPoint presentation of the study proposal, and offer clarifications or answer queries raised by the members.

8.4.3.6 If the proposal is approved unconditionally by the members of IHEC in the IHEC full Panel Review meeting, then, the letter of approval for the study will be issued by the Member Secretary, IHEC on behalf of the Chairman, IHEC within a week.

8.4.3.7 If the proposal is approved conditionally by the members of IHEC in the IHEC full Panel Review meeting, then, the Member Secretary, IHEC shall send a letter to the PI stating the conditions to be fulfilled if the study is to be fully approved by the IHEC.

8.4.3.8 A letter of approval for the study will be issued by the Secretary, IHEC on behalf of the Chairman, IHEC only after the PI complies with all the requirements.

8.5 List of documents to be submitted by the PI to the Secretary, IHEC for review of the study proposals:

The PIs are requested to submit 3 hard copies and one soft copy on CD and by e-mail in portable document format (pdf) as attachment files of all the relevant documents at least 30 days before the scheduled date of the IHEC meeting. The PI should send by e-mail the soft copy of the application set to the Member-Secretary, IHEC by e-mail from the PI‟s own, currently used e-mail ID.

The e-mail ID of IHEC is: ihec_auw@gmail.com

The hard copies must be accompanied with an affidavit from the sponsor of the company to the effect that the contents of the soft copy being sent by e-mail are the true copy of the hard copy being submitted to the IHEC. It is the PI‟s responsibility to submit this affidavit from the sponsor and address it to the Secretary, IHEC. Without this affidavit, the application will not be considered as valid, and therefore, will not be reviewed by the IHEC.

The IHEC full Panel Review meeting is normally convened once in every three months, OR, as and when required. After the receipt of all the proposals, a minimum of two weeks is required for review by Members of the IHEC and to complete administrative procedures before it can be placed before a full Panel Review of the IHEC. Review of proposals is a time consuming process, and last minute submissions with request to include them for review during a particular month will not be entertained as it will result in compromising in the quality of the review process.

8.5.1 Application for review of study proposal in the prescribed format

8.5.2 Processing fee of Rs. 500/= to IHEC (applicable only to sponsored projects) / Rs.1000/- (applicable only to non-institutional PIs)

8.5.3 Detailed budget including source of funding and financial requirements for the project.

8.5.4 Final Protocol with all amendments

8.5.5 Investigator‟s Brochure and any other safety-related information available

8.5.6 Feasibility assessment form

8.5.7 Nil Disclosure Agreement (NDA)

8.5.8 Clinical Trials Agreement (CTA)

8.5.9 Investigator‟s agreement with sponsor

8.5.10 **Informed Consent Form**:

8.5.10.1 Informed Consent From in English
8.5.10.2 The relevant translated language versions of the Informed Consent Form
8.5.10.3 Back-translated versions of Informed Consent Form
8.5.10.4 Appropriate translation certificates for Informed Consent Form

8.5.11 **Subject Information Sheet**:

8.5.11.1 Subject (or participant) Information Sheet in English
8.5.11.2 Subject Information Sheet in the relevant translated languages
8.5.11.3 Back-translations of Subject Information Sheet
8.5.11.4 Appropriate translation certificates for Subject Information Sheet

8.5.12 Case Record Form / Questionnaire

8.5.13 Insurance Policy, wherever applicable (if not for the entire duration of the study period, PI to enclose a statement explaining the reasons and an assurance to the effect that it will be renewed in due course. If it is not renewed and communicated to IHEC in time, validity of approval for the study automatically ceases)

8.5.14 Ethics Committee clearance of other centers (if the proposed study is a multi-centre study)

8.5.15 CTRI Registration number

8.5.16 Investigator‟s undertaking to DCGI

8.5.17 Clearance Certificate(s) from the following agencies, wherever applicable:

8.5.17.1 Drug Controller General of India (DCGI)
8.5.17.2 Health Ministry Screening committee (HMSC)
8.5.17.3 Bhabha Atomic Research Centre (BARC)
8.5.17.4 Genetic Engineering Advisory Committee (GEAC)
8.5.17.5 Director General of Foreign Trade (DGFT)

8.5.18 Food and Drug Administration (FDA) marketing/manufacturing license for herbal drugs, where applicable

8.5.19 Current CV of the Principal Investigator

8.5.20 For any drug / device trial, all relevant pre-clinical animal data

8.5.21 For any drug/device all previous data from the clinical trial, if one has taken place

8.5.22 Statement of conflicts of interest, if any.

8.5.23 A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

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

8.5.25 Any other information relevant to the study.

* PIs are not supposed to recruit study volunteers until and unless the CTRI number is obtained and the same transmitted to the IHEC in writing by quoting the relevant study name, number, name of PI etc., in the communication. The PI should wait for the final approval letter from IHEC to start recruiting study volunteers.

8.6 Student Research proposals and studies that fall under the purview of Exempt Review

Student Research proposals and studies falling under the purview of Exempt Review by the IHEC should fill the format exclusively for these categories of proposals. List of documents to be attached are much less compared to Clinical Trials, and they are listed in the application form itself. They are exempted from adhering to clauses 8.5.3, 8.5.5, 8.5.6, 8.5.7, and 8.5.12 to 8.5.20 listed above.

While students may be designated as PIs, there must be a faculty member from the institution to guide their research work, and the details of that faculty-member must be mentioned clearly in the application form, failing which it will not be taken up for review by the IHEC.

B. REVIEW PROCEDURE

9.0 Review Procedure

9.1 The ICMR „Ethical Guidelines for Biomedical Research on Human Participants" suggests that the institutional ethics committees (IEC) "should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee. In institutions where this is lacking, the IEC may take up the dual responsibility of review of both, the scientific content and ethical aspects of the proposal. It is advisable to have separate Committees for each, taking care that the scientific review precedes the scrutiny for ethical issues. The scientific evaluation should ensure technical appropriateness of the proposed study. The IECs should specify in writing the authority under which the Committee is established."

Accordingly, the IHEC of Avinashilingam Institute for Home Science and Higher Education for Women has designated a sub-committee comprising of the Member Secretary,

the Deputy Chair, and one chosen member as the „Primary Reviewers" as well as the „Scientific Review Committee" of IHEC, which shall look into the scientific merit of all the study proposals submitted for review by the IHEC. The Member Secretary is empowered to nominate one or more persons from the IHEC as reviewers of study proposals with clearly defined portfolios. This arrangement is done with the concurrence of the Chairman, IHEC.

Though the ICMR recommends separate mechanisms for scientific and ethical review, the IHEC will look into not only the scientific aspects, but also ethical aspects of the study proposals. In other words, the IHEC will work closely with the researcher to ensure that the protocol is appropriately written, that there is sound science, and ethics. In the event of these found wanting in the protocols submitted, IHEC will raise specific queries and seeks resolution of these before the protocol moves for full Panel Review of the IHEC. This makes certain that researchers do make changes that are deemed necessary, and are in full cognisance of them and are involved in developing the required amendments as well.

In order to function as the Primary Reviewer as well as the Scientific Review Committee of the IHEC, the IHEC shall sign a tripartite agreement with the PIs and sponsors to this effect. The members shall sign a „Nil Disclosure Agreement (NDA) with the IHEC to assure and maintain confidentiality of the study proposal submitted to it and intellectual property arising out of the proposed work.

The Member Secretary will allocate individual Primary Reviewership on an year-to-year basis to specific Core Group Members with portfolios on Clinical Trials, Genetic Studies, PG Dissertation Proposals, Problem Solving for Better Health (PSBH) Student Research Proposals, and ICMR Short-Term Studentship (ICMR-STS) proposals.

The Biostatistician will look only into the statistical aspects like sample size estimation, analysis plan etc. S/he will have a check-list to look for these elements. All proposals for review for conducting Clinical Trials will be reviewed by the Biostatistician and other Core Group Members within seven days of receipt of the study proposal. Other proposals will be referred to the Biostatistician based on the felt-need by the Primary Reviewers in IHEC.

When the PI is invited to present her / his proposal to the IHEC Full Panel Review Meeting, the Primary Reviewer(s) who reviewed the proposals will be present in the meeting as members without voting rights.

They will offer appropriate clarifications, answer queries raised by members and participate in the discussion.

9.1.1 Pre-requisites for being designated as individual Primary Reviewers in IHEC

Individual Primary Reviewers in IHEC need to be thorough in basic Principles of Epidemiology, Research Methods (including study designs) and Biostatistics. Those who had participated in the advanced-level training programmes in Research Methods and Biostatistics conducted by the ICMR or any other equivalent, reputed research oriented Institution, are eligible to be the individual Primary Reviewers, provided they are a member of the IHEC.

9.2 The committee will meet ONCE in three months OR as and when required.

9.3 Advance notice, 10 days before each meeting will be sent out to the IHEC members, along with the Agenda and copies of study proposals mentioned in the Agenda.

9.4 The Chairperson will conduct all meetings of the IHEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from among the members by the members present. The Alternate Chairperson will then conduct the meeting.

10.0 Elements of review

10.1 The following elements of review will be taken into consideration while reviewing study proposals:

10.1.1 Scientific design and conduct of the study.

10.1.2 Approval of appropriate scientific review committees.

10.1.3 Examination of predictable risks/harms.

10.1.4 Examination of potential benefits.

10.1.5 Procedure for selection of subjects in methodology including inclusion/ exclusion

10.1.6 Withdrawal criteria and other issues like advertisement details.

10.1.7 Management of research related injuries, adverse events.

10.1.8 Compensation provisions.

10.1.9 Justification for placebo in control arm, if any.

10.1.10 Availability of products after the study, if applicable.

10.1.11 Patient information sheet and informed consent form in local language.

10.1.12 Protection of privacy and confidentiality.

10.1.13 Involvement of the community, wherever necessary.

10.1.14 Plans for data analysis and reporting

10.1.15 Adherence to all regulatory requirements and applicable guidelines

10.1.16 Competence of investigators, research and supporting staff

10.1.17 Facilities and infrastructure of study sites

10.1.18 Criteria for withdrawal of study subjects, suspending or terminating the study

10.1.19 Approval of regulatory authorities wherever applicable

10.2 There will be primarily three types of review viz.,

10.2.1 **Panel Review (an all-member IHEC meeting)**

10.2.2 **Expedited Review**

10.2.3 **Exempt Review**

10.3 Full Panel Review

The Panel Review of IHEC means the review of the study proposals received by the Member Secretary of the IHEC. Copy each of study proposal and relevant document(s) will be made available to each and every Member of the IHEC by the IHEC secretariat at least 10 days before the IHEC Panel Review meeting is scheduled to be held. The Panel Review Meeting of the IHEC, thus, is the meeting of all the members of IHEC before whom the PI makes a PowerPoint presentation of the study. Questions / clarifications will be raised by the members with the PI.

The Primary Reviewers of the study proposals submitted for review by the IHEC are expected to be present during the presentation and discussion of the study proposal. However, they will not have voting rights, unless they are Members of the IHEC.

10.4 Expedited review

10.4.1 All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making.

10.4.2 Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.

10.5 Expedited review procedures may be used when ALL of the following criteria are true:

10.5.1 The research presents no more than minimal risk to participants.

10.5.2 The identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

10.5.3 The research is not classified.

10.5.4 The research falls into one or more of the following categories:

10.5.4.1 Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows from healthy, non-pregnant adults.

10.5.4.2 Prospective collection of biological specimens for research purpose by non invasive means.

10.5.4.3 Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared / approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications)

10.5.4.4 Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non research purposes (such as medical treatment or diagnosis)

10.5.4.5 Collection of data from voice, video, digital, or image recordings made for research purposes.

10.5.4.6 Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communications, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation , human factors evaluation, or quality assurance methodologies.

10.5.4.7 Continuing review of research previously approved by the convened IRB as follows

10.5.4.7.1 Where (i) the research is permanently closed to the enrollment of new subjects

(ii) all subjects have completed all research -related interventions; and

(iii) the research remains active only for long-term follow up of subjects; or

10.5.4.7.2 where no subjects have been enrolled and no additional risks have been identified; or

10.5.4.7.3 Where the remaining research activities are limited to data analysis

10.6 Expedited Review Committee of the IHEC – Composition, authority

The composition of the Expedited Review Committee of IHEC is as shown below:

Member Secretary, IHEC

Deputy Chairman, IHEC

One chosen faculty member, who is also a member of the IHEC

10.7 Exempt Review

10.7.1 Educational Research

10.7.1.1 Research conducted in established educational settings, involving normal educational practices, such as:

10.7.1.1.1 Research on regular and special education instructional strategies, or

10.7.1.1.2 Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

10.7.1.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behaviour UNLESS

10.7.1.2.1 information is recorded in such a manner that subject can be identified (either directly or indirectly) AND

10.7.1.2.2 subjects responses could place subjects at risk (e.g., criminal or civil liability, financial standing, employability or reputation)

10.7.1.3 Research involving educational tests, surveys, interviews, or observation of public behaviour if:

10.7.1.3.1 The subjects are elected or appointed public officials or candidates for public office; or

10.7.1.3.2 Federal statute requires confidentiality of identifiable information to be maintained permanently

10.8 Research based on Secondary Data

10.8.1 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. Sources must either be publicly available or information must be recorded in such a manner that subject cannot be identified (either directly or indirectly)

10.9 Exempt status shall not be granted when:

10.9.1 Research involves vulnerable population

10.9.2 Research involves Human Embryonic Stem Cells

10.9.3 The project involves significant physical invasions or intrusions upon the privacy of participants.

10.10 Exempt Review Committee of the IHEC – Composition, authority

The composition of the Exempt Review Committee of IHEC is as shown below:

Member Secretary, IHEC

Deputy Chairman, IHEC

Institutional Senior Member of IHEC

11.0 Minutes

The Member Secretary, designated by the Chairperson, will record the Minutes of the meeting and circulate the same to the members within two weeks of the meeting. Principal Investigator or Co-Investigator may be called to the meeting to present the study or answer specific queries. However, the Presenter will not participate in the decision making / voting process of that study even if he / she is a regular member of the IHEC.

A Study Team member including the Principal Investigator will be deemed an interested party with regard to the review.

The Study Team Member‟s non-participation in the decision making / voting process will be recorded in the response letter from the IHEC.

12.0 Decision making

The decision of the committee will be taken by a majority vote after the quorum requirements are fulfilled to recommend / reject / suggest modifications for a repeat review or advise appropriate steps. If subject experts are invited to offer their views, they will not take part in the voting process.

13.0 Independent Consultant

IHEC will call upon Independent consultant as experts who will provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific disease or methodology, represent specific community, patient groups or special interest group (like HIV positive subjects, ethnic minorities).

In case of a study planned with alternative systems of medicine, it should include investigators from those systems as well as from modern medicine. A copy of animal study reports will be required in the case of herbal drugs that are not marketed. Non member experts will not be allowed to vote.

14.0 Validity of Approval

Validity of the approval is for one year from the date of the meeting on which the project was approved, after which the PI will seek re-approval for its continuation. The PI shall contact the IHEC in advance and the IHEC shall remind the PI in advance. Renewing the tenure in time is a shared responsibility of both the parties.

15.0 Review Outcome

The Committee will give its opinion on the project in one of the following ways:

a. Approval

b. Disapproval

c. Modification before Approval

d. Discontinuation of a previously Approved project

16.0 Communication of Review Outcome

In all cases, the study will be unambiguously identified by protocol title and number.

All documents reviewed will be listed in the response letter, which will also list the number of members present and date of the meeting at which the study was reviewed.

List of the members who attended the meeting will not be provided by the IHEC.

The Chairman / Member-Secretary will convey the decision of the committee to the Principal Investigator in writing.

C. POST-REVIEW PROCEDURE

17.0 Review of the modified Proposal

When modifications to the proposal, as recommended by the committee are minor, the revised documents may not be re-circulated. The revised proposal shall be reviewed by either Chairperson, Member Secretary or by one or more experienced reviewers designed by the Chairperson from among the members of IHEC. An approval may then be issued if the revised documents are found satisfactory. The committee will keep all members of the committee informed of these approvals.

18.0 Procedure for Appeal

For research proposals rejected/disapproved by IHEC, the applicant may appeal for a repeat review within 12 weeks of receipt of committee‟s decision to IHEC. While doing so, the applicant shall give justification relevant to the issues/ objections raised by the committee.

19.0 Review of Amendments to the Approved Research Proposal

19.1 Should an amendment to a study-related document be administrative in nature and not involving study design or safety criteria, it may be provisionally approved in writing, by the Chairman / member-secretary of the Committee without calling a full meeting.

19.2 The Chairman / Member Secretary will inform other members of the Committee of the amendment and his / her decision during the subsequent regular meeting of the committee. The decision will be ratified and minuted.

19.3 If the amendment involved changes to study-design and safety criteria, a full review is needed.

20.0 Review of Study Volunteer Recruitment Procedure

All advertisements, letters to doctors, posters, notices to be used for recruitment of subjects shall be reviewed and approved by the committee prior to their implementation in the study

21.0 The Principal Investigator, after obtaining the approval of IHEC, submits:

21.1 a report of the research project being carried out, every 6 months or as and when directed by the IHEC

21.2 a report of each serious adverse event with regard to the study

21.3 amendments / revisions to any study-related document as well as patient safety related information

21.4 report of completion of the project or its discontinuation with reasons

All communication to IHEC should be in writing; study title, study proposal number (if approved), CTRI numbers (wherever applicable) must be quoted in all correspondence.

22.0 Correspondence by PI with the IHEC

22.1 Before approval of the study

All correspondence by the PI before the review process is completed (i.e., before approval is granted) must be addressed to the Member Secretary, IHEC. The Study title, study number and CTRI number (wherever applicable), must be quoted in all correspondence.

22.2 After approval of the study

All correspondence by the PI after the review process is completed (i.e., after approval is granted) must be addressed to the Member Secretary, IHEC. The Study title, study number and CTRI number (wherever applicable), must be quoted in all correspondence.

23.0 Record keeping and archiving

23.1 Curriculum Vitae (CV) of all members of IHEC.

23.2 Copy of all study protocols with enclosed documents, progress reports, and SAEs.

23.3 Minutes of all meetings duly signed by the Chairperson.

23.4 Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

23.5 Copy of all correspondence with members, researchers and other regulatory bodies.

23.6 Final report of the approved projects.

23.7 All documents should be archived for 15 years. On-going study-related documents will be kept in the lockers in the IHEC Secretariat for a period of three years or till the closure of the study, whichever is latter, while study documents older than three years and closed study related documents will be shifted to the lockers in the IHEC Archives Room.

24.0 Amendments to the Standard Operating Procedure

24.1 Amendments to the Standard Operating Procedure of IHEC, Avinashilingam Institute for Home Science and Higher Education for Women shall be proposed in writing.

24.2 The proposal for amendment shall be to the Member Secretary.

24.3 It shall be presented to the regular members at a scheduled committee meeting

24.4 Only regular members shall vote to accept or reject the proposed amendment.

24.5 If the amendments are minor the changes on a final version will be indicated as version 1.1, version 1.2 etc. If there are major amendments, the version will be indicated as Version 2.

25.0 Location and Business address

Institutional Human Ethics Committee
Avinashilingam Institute for Home Science and Higher Education for Women
Coimbatore – 641 043, India

E mail: ihec_auw@gmail.com

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