STANDARD OPERATING PROCEDURES

for

INSTITUTIONAL HUMAN ETHICS COMMITTEE

Chettinad
Academy of Research & Education
(Deemed to be University Under Section 3 of the UGC Act 1956)

CHETTINAD ACADEMY OF RESEARCH AND EDUCATION

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Registration No.-ECR/212/Inst/TN/2013

2016

Prepared by	Reviewed & Approved by
Dr.E.Malligai Member Secretary	Capt.Dr.B.Santhakumar Chairperson

1. Introduction:

Chettinad Academy of Research & Education (CARE), a deemed to be University under section 3 of the UGC Act, 1956, offers inter-disciplinary and multi-disciplinary high quality innovative programmes in the broad fields of Life Sciences and related technologies and promotes clinical research in areas of national and local health problems.

The need for Institutional Human Ethics Committee in medical and research establishments resulted from the realization that affirms human rights as a prerogative of all members of society. The CARE faculty, research scholars and post graduate, under graduate students conduct several biomedical research projects which involves patients and healthy human volunteers. This involves a number of ethical issues which needs to be addressed. The Institutional Human Ethics Committee(IHEC) plays the vital role of guiding researchers in the ethical issues associated with their research.

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Dr.E.Malligai Member Secretary	Capt.Dr.B.Santhakumar Chairperson

	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	Authority and constituting the IHEC		
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1. **Purpose:**
   To Establish and constitute the Institutional Human Ethics Committee (IHEC) for Chettinad Academy of Research and Education (CARE)

2. **Scope:**
   Applicable to Chettinad Academy of Research and Education

3. **Responsibility:**
   Vice chancellor is responsible for implementing this standard Operating Procedure (SOP)

4. **Procedure:**

   4.1 Vice Chancellor will select and nominate the Chairperson and Member Secretary for CARE, IHEC. The IHEC will be constituted by the Vice Chancellor in consultation with the Chairperson.

   4.2 Vice Chancellor will invite the members to join ethics committee by sending the official request letter (Document 1)

   4.3 Members will confirm their acceptance to the Vice Chancellor by providing all the required information for membership (Document 2)

   4.4 The Vice Chancellor will ensure that the IHEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve (Document 3)

   4.5 Vice Chancellor will designate and instruct Chairperson of IHEC or his representative to conduct the regular proceedings of IHEC for the institute at regular intervals, Vice Chancellor will review the functioning of IHEC

Prepared by	Reviewed & Approved by
Dr.E.Malligai Member Secretary	Capt.Dr.B.Santhakumar Chairperson

1. **Purpose:**
   To appoint suitable members for the IHEC, CARE

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   Vice chancellor and Chairperson are responsible for implementing this standard Operating Procedure (SOP)

4. **Procedure:**

   4.1 Vice Chancellor in consultation with Chairperson will nominate the members of IHEC, who have the qualification and experience to review and evaluate the scientific, medical and ethical aspects of the proposed study.

   4.2 When needed, IHEC will invite subject experts to offer their views.

   4.3 The appointment of an IHEC member will be for 3 years.

   4.4 IHEC will have minimum of 10 to maximum of 15 members

   4.5 It is mandatory to have the following categories of members to represent multidimensional structure.

   a. Chairperson from outside the institution
   b. 1-2 Basic medical scientist (preferably one pharmacologist)
   c. 1- 2Clinician
   d. 1 Legal expert
   e. 1 Social Scientist / Representative of NGO
   f. 1 Philosopher / ethicist / theologian
   g. 1 lay person from the community
   h. Member secretary

   4.6 **Quorum Requirements:**

   4.6.1 At least one person from all the above 5 representation are required to compose a quorum.

   4.6.2 All decisions should be taken in meetings and not by circulation of project proposal

4.6.3 The attendance register / log will be filled to document the quorum of the meetings.

4.7 Vice Chancellor may renew the appointment on the basis of the member's contribution.

4.8 During the term, Vice Chancellor in consultation with the Chairperson can disqualify any member if, the contribution is not adequate and/ or there is long period of (member) non-availability.

4.9 Member will have the right to discontinue from membership of IHEC after giving written notice at least one month in advance.

4.10 Vice Chancellor can replace the member of IHEC as and when required.

4.11 Each member is required to sign the declaration and confidentiality agreement regarding IHEC activities (Document 2)

4.12 Vice Chancellor can nominate IHEC members to undergo orientation programme in national and international developments in ethics.

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1. **Purpose:**
   To define the general responsibilities of the members of IHEC including training requirement.

2. **Scope:**
   Applicable to IHEC Members, CARE.

3. **Responsibility:**
   Vice chancellor, Chairperson and Members of the IHEC are responsible for implementing this standard Operating Procedure (SOP)

4. **Procedure:**

   4.1 IHEC members are expected to show their full commitment, responsibility, professionalism and availability, regarding the science and ethics of research, respect for divergent opinions and ability to maintain confidentiality.

   4.2 IHEC members are expected to attend all the IHEC meetings. Information should be provided at least one week before, if a member is unable to attend an IHEC meeting.

   4.3 IHEC members will be offered ongoing opportunities for enhancing their capacity for ethical review, including participation at the periodic Research Ethics and GCP workshops conducted by the Institute.

   4.4 All IHEC members must familiarize with the ICMR guidelines for research involving human participants, Schedule Y of the Drugs and Cosmetics Act, the Declaration of Helsinki, ICH-GCP guidelines, CONSORT and other relevant guidelines for the design, conduct and reporting of various types of research designs.

   4.5 All the members will be given training on the above mentioned guidelines and rules yearly basis. A training record would be maintained for the same.

   4.6 Every new member will get trained on all of the above mentioned guidelines and rules at the time of appointment.

   4.7 When a new rule/ guideline/ sop revision has happened, all the members

would be trained and training records would be maintained for the same.

4.8 IHEC members are expected to assess in detail the proposals allotted to them and attend the convened meetings with their prepared report that highlights the deficiencies and suggest improvements in design or execution of the study

4.9 All IHEC members are expected to declare competing conflicts of interest with respect to research proposals or investigators, if any, before commencement of each meeting.

4.10 IHEC members are expected not to be present during presentation of proposals in which they are co-investigators, unless requested to answer clarifications; they may present proposals if they are principal investigators, but in both situations should leave the room before IHEC discussions and decisions

4.11 Members should not make copies of any material provided to them and ensure destruction or return of all materials sent for review (Soft copy containing research proposals and supporting documents) after the IHEC meetings.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	CONVENING AND CONDUCTING IHEC MEETINGS		
IHEC/ SOP/ 06	Version No:03	Issue Date: 17-03-2016	PAGE 1 OF 1

1. **Purpose:**
   To hold regular Ethics Committee meetings

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   Chairperson and Member Secretary of the IHEC are responsible for implementing this standard Operating Procedure (SOP)

4. **Procedure:**

   4.1 The Member Secretary in consultation with the Chairperson may convene the IHEC meeting once in every three months.

   4.2 Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.

   4.3 All the IHEC meetings will be held regularly on scheduled dates that are announced and notified in advance.

   4.4 All the proposals will be received at least three weeks before the meeting, checked for completeness as per the check list initially by the office clerk (Form I), subsequently by the member secretary (through a nominated person) using the evaluation form (Form II)

   4.5 Members will be given not less than 10 days time in advance to review study proposals and the relevant documents.

   4.6 Minutes of the IHEC meetings, all the proceedings and deliberation will be documented.

   4.7 Signatures of the Chairperson and the Member Secretary will be obtained on the minutes of the meeting document. The minutes will be circulated to all the guides / HODs in case of student proposals.

   4.8 Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	INDEPENDENT CONSULTANTS		
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1. **Purpose:**
   To call upon subject experts for specialized views

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   Chairperson and Member Secretary of the IHEC are responsible for implementing this standard Operating Procedure (SOP)

4. **Procedure:**

   4.1 IHEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/ AIDS positive persons or ethnic minorities.

   4.2 They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IHEC.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	POLICY FOR RESIGNATION, REMOVAL AND REPLACEMENT OF MEMBERS		
IHEC/ SOP/ 08	Version No:03	Issue Date: 17-03-2016	PAGE 1 OF 1

1. **Purpose:**
   Resignation, Removal and Replacement of members

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   Vice Chancellor CARE is responsible for implementing this standard Operating Procedure (SOP)

4. **Procedure:**

   4.1 A member can submit resignation to Chairperson of the IHEC with a minimum notice period of one month, mentioning the valid reason for the resignation. It can be approved by the head of the Institution in consultation with chairperson / Member Secretary.

   4.2 In case of resignation of a member, Vice Chancellor of institution will appoint a new member falling in the same category of membership. Appointment may be made in consultation with the chairperson / Member Secretary.

   4.3 A member may be removed/ terminated of his/ her membership in case of failure of attending the last 3 consecutive ethics committee meetings.

   4.4 The respective communication shall be maintained at the Ethics committee records.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	DOCUMENTS REQUIRED FOR SUBMISSION OF RESEARCH PROPOSAL FOR IHEC APPROVAL		
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1. **Purpose:**
   To submit research proposal for review by IHEC

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   All Investigators are responsible for implementing this SOP.

4. **Procedure:**

   4.1 The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IHEC (Form No: A or B). All research proposals must be submitted in English language only.

   4.2 Application can be submitted to the office of the Member Secretary, IHEC, CARE on any working day.

   4.3 All the proposals and documents must be submitted to the IHEC, CARE on or before the last date of submission of the proposal.

   4.4 Ten copies of study proposal (with all documents) must be submitted for Regular Ethic Committee review. A soft copy of the proposal must also be submitted through email (ihec@chettinadhealthcity.com).

   4.5 Receipt of the application will be acknowledged by the IHEC office over the Email after the last date of submission.

   4.6 Every application will be allotted an IHEC registration number to be used for all future correspondence and reference

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	INITIAL SCRUTINY OF PROPOSALS FOR COMPLETENESS		
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1. **Purpose:**
   To check the research proposals submitted by the investigators for completeness

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   The office of the Member Secretary is responsible for implementing this SOP

4. **Procedure:**

   4.1 Every proposal will be collected and compiled by the Institute Ethics Committee office.

   4.2 An office staff nominated by the Member Secretary will verify the proposals for completeness as per the checklist (Form II).

   4.3 In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary corrections and to resubmit

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	REVIEW OF RESEARCH PROPOSALS BY IHEC		
IHEC/ SOP/ 11	Version No:03	Issue Date: 17-03-2016	PAGE 1 OF 1

1. **Purpose:**
   To review the research proposals submitted by the investigators both scientifically and ethically.

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   All the members of IHEC are responsible for implementing this SOP

4. **Procedure:**

   4.1 Every proposal will be sent not less than 10 days before the meeting to all members of IHEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IHEC review.

   4.2 All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

   4.3 Informed consent form should mention the rights of the research participants to claim compensation in case of research related injuries and whom to contact for such claims.

   4.4 The IHEC review will be done through formal meetings and will not resort to decision through circulation of proposal.

   4.5 Expert opinion of additional members would be obtained if necessary.

   4.6 In cases where a conflict of interest is determined that may damage the scientific integrity of a project or cause harm to research participants, the members would take decision carefully after a thorough review. In case of decision to approve, appropriate advise must be given to the investigators (to declare such conflicts of interest to the ethics committee and future publications) and verify if the participants are informed of the sponsorship of the research as applicable.

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1. **Purpose:**
   To review the research proposals submitted by the investigators which involves vulnerable population both scientifically and ethically

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   All the members of the IHEC are responsible for implementing this SOP

4. **Procedure:**

   4.1 Vulnerable research participants are individuals whose willingness to volunteer in a research trial may be duly influenced by the expectation (whether justified or not), benefits associated with participation, retaliatory response from higher authority in case of refusal to participate, and whose consent may not be valid for various reasons. They include infants, children and adolescents, pregnant and lactating women, students and employees, mentally challenged patients, critically ill patients etc.

   4.2 All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

   4.3 Vulnerable group can become participants only if the study is designed to protect or advance the health of this population and for which the non-vulnerable group would not be suitable participants

   4.4 In case of trials involving children, the assent of the child should be obtained from the age of seven to eighteen years unless there is no medically accepted alternative to the therapy (provided consent has been obtained from parents/ guardian)

   4.5 Rights and welfare of people who are unable to give informed consent must be protected. Informed consent should be obtained from legally authorized representatives in the presence of impartial witness with adequate explanation of risks and benefits.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	EXPEDITED REVIEW OF RESEARCH PROPOSAL BY INSTITUTE ETHICS SUB-COMMITTEE		
IHEC/ SOP/ 13	Version No: 03	Issue Date: 17-03-2016	PAGE 1 OF 1

1. **Purpose:**
   To provide expedited review and approval of a research proposal

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   All the members of the Institute Ethics Sub-committee are responsible for implementing this SOP

4. **Procedure:**

   4.1 IHEC will receive and consider the proposals for expedited review and approval for the studies having/ involving:
   i. No or minimum risk to the trial participants.
   ii. Re examination of a proposal already examined by the IHEC.
   iii. Study of minor nature like the examination of case records.
   iv. Similar study proposal for which IHEC had already given approvals earlier.
   v. An urgent proposal of national interest having minimum risk.
   vi. All ICMR student projects and post graduate proposals with minimal risk.
   All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.

   4.2 All expedited approvals will be given in a meeting of the Sub-Committee of four members (nominated by the Chairperson). All the four members including the Member Secretary should be present for the meeting.

   4.3 Decision taken by the Sub-Committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the IHEC.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	DECISION MAKING REGARDING THE RESEARCH PROPOSAL		
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1. **Purpose:**
   To make a decision regarding approval of the submitted research proposal

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   All the members of IHEC are responsible for implementing this SOP

4. **Procedure:**

   4.1 In making decision on application for the ethical review of any research proposal, IHEC will consider the following:

   4.1.1. Member having a conflict of interest will indicate to the Chairperson prior to the review of application and same will be recorded in the minutes.

   4.1.2. Where there is a conflict of interest, member will withdraw from the decision making procedure.

   4.1.3. A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non members (e.g. Investigator) from the meeting.

   4.1.4. Decision will only be taken at meetings where a quorum (5 in a committee of 11) is complete.

   4.1.5. Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.

   4.1.6. Only IHEC members who participated in review and discussion will participate in decision making.

   4.1.7. Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.

   4.1.8. Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.

   4.1.9. Rejection of proposal will be supported by clearly stated reasons.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	COMMUNICATING THE DECISION OF IHEC TO THE INVESTIGATOR		
IHEC/ SOP/ 15	Version No: 03	Issue Date: 17-03-2016	PAGE 1 OF 1

1. **Purpose:**
   To communicate the decision of IHEC to the applicant

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   Member Secretary of IHEC is responsible for implementing this SOP

4. **Procedure:**

   4.1 A decision of the IHEC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format (Document-4). A certificate of approval will be sent to the applicant within 2 weeks (Document-5). All the approvals will be valid for only three years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.

   4.2 The communication of the decision will include:
   - Name and address of IHEC.
   - The date and place of decision.
   - The name and designation of the applicant.
   - Title of the research proposal reviewed.
   - The clear identification of protocol no., version no., date, amendment no., date.
   - A clear statement of decision reached.
   - Any advice by the IHEC to the applicant.
   - In case of conditional decision, any requirement by IHEC, including suggestions for revision, and the procedure for having the application re-reviewed.
   - In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
   - Signature of the member secretary with date.

Prepared by	Reviewed & Approved by
Dr.E.Malligai Member Secretary	Capt.Dr.B.Santhakumar Chairperson

1. **Purpose:**
   To carry out follow up of the research proposals

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   All Members of IHEC are responsible for implementing this SOP

4. **Procedure:**

   4.1 IHEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.

   4.2 Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IHEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.

   4.3 All the requirements and procedures for follow up review will be similar to that of initial and main review.

   4.4 Following instances and events will require the follow-up review:

   4.4.1. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.

   4.4.2. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.

   4.4.3. Any event or information that may affect the benefit/ risk ratio of the study.

   4.5 A decision of a follow up review will be issued and communicated to the applicant indicating modification/ suspension/ termination / continuation of the project.

   4.6 In case of premature suspension / termination, the applicant must notify the IHEC of the reasons for suspension/ termination with a summary of results.

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4.7 Applicant must inform the time of completion of study and must send the result summary to IHEC. IHEC must receive a copy of final summary of study completed from the applicant.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	TYPES OF CLINICAL RESEARCH REVIEWING BY IHEC		
IHEC/ SOP/ 17	Version No: 03	Issue Date: 17-03-2016	PAGE 1 OF 1

1. **Purpose:**
   Reviewing of Types of Clinical research

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   Chairperson, Member Secretary and all Members are responsible for implementing this SOP

4. **Procedure:**

   The Ethics Committee will review Pharmaceuticals studies, epidemiological studies, retrospective studies, herbal studies and studies for devices.

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1. **Purpose:**
   To carry out follow up of the research proposals with respect to serious adverse events

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   All Members of IHEC and the investigators are responsible for implementing this SOP

4. **Procedure:**

   4.1 IHEC will monitor the Serious Adverse Events related to the study or product/ device in the follow up of the research proposal

   4.2 IHEC will review the exact nature of Serious Adverse Event and the time of reporting by the investigators and whether the Investigator followed the procedure regarding the medical and financial management of Serious Adverse Event as mentioned in the research protocol.

   4.3 The following events should be reported as 'Serious Adverse Events' by the investigator.

   4.3.1 The death of a study subject, whether or not related to an investigational agent

   4.3.2 A life-threatening adverse drug event

   4.3.3 Inpatient hospitalization or prolongation of existing hospitalization for >24 hours (excluding elective hospitalization for conditions unrelated to the study)

   4.3.4 A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions

   4.3.5 A birth defect in an offspring of a study participant, regardless of the time after the study the congenital defect is diagnosed

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4.4 Important Medical Events (IME) that [not resulting in death, be life threatening, or require hospitalization] may be considered an SAE when, based upon medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent these events listed in the definition.

4.5 Any Serious Adverse Event should be reported to the sponsor within 24 hrs and to the IHEC within 7 days (in the format given in Schedule Y, Appendix XI). In case of death, it should be reported to the IHEC within 24 hrs.

4.6 All other Adverse Events that are not fatal or life threatening must be filed within 14 calendar days. The details will be evaluated and discussed in detail in the final report of the study

4.7 A decision of this follow up review will be issued and communicated to the applicant indicating modification/ suspension/ termination/ continuation of the project

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1. **Purpose:**
   To archive the study related documents, proceedings and communications.

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   The Member Secretary is responsible for implementing this SOP.

4. **Procedure:**

   4.1 All the documents and communications of IHEC will be dated, filed and archived in a secure place.

   4.2 Only persons, who are authorized by the Chairman of IHEC will have the access to the various documents.

   4.3 All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion / termination of the study.

   4.4 No document (except agenda) will be retained by any IHEC member.

   4.5 At the end of each meeting, every member must return all the research proposals and documents to IHEC office staff. They will archive one copy in IHEC office and other copies will be destroyed after one year.

   4.6 Following documents will be filed and archived with proper label on the top of file for easy identification of proposal.

   4.6.1. The constitution, written standard operating procedures of the IHEC, and regular (annual) reports.

   4.6.2. The curriculum vitae of all IHEC members.

   4.6.3. A record of all income and expenses if any, of the IHEC, including allowances and reimbursements made to the secretariat and IHEC members.

   4.6.4. The published guidelines for submission established by the IHEC.

   4.6.5. The agenda of the IHEC meetings.

4.6.6. The minutes of the IHEC meetings.

4.6.7. One copy of all material submitted by an applicant.

4.6.8. A copy of the decision and any advice or requirements sent to an applicant.

4.6.9. All written documentation received during the follow-up.

4.6.10. The notification of completion, premature suspension, or premature termination of study.

4.6.11. The final summary or final report of the study.

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	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	POLICY TO PREVENT CONFLICT OF INTEREST		
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1. **Purpose:**
   To prevent conflict of interest.

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   The Chairperson, Member Secretary and members are responsible for implementing this SOP.

4. **Procedure:**

   4.1 The ultimate interest of Ethics committee is to prevent conflict of interest.

   4.2 It has been recognized that the potential for conflict of interest will always exist but Chairperson is capable to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

   4.3 The Members shall voluntarily withdraw from the IHEC meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairperson prior to the review and be recorded so in the minutes.

   4.4 All Members shall sign a declaration on conflict of interest.

Prepared by	Reviewed & Approved by
Dr.E.Malligai Member Secretary	Capt.Dr.B.Santhakumar Chairperson

	CHETTINAD ACADEMY OF RESEARCH AND EDUCATION		INSTITUTIONAL HUMAN ETHICS COMMITTEE
	SAMPLE STORAGE AND DISCARD		
IHEC/ SOP/ 21	Version No: 03	Issue Date: 17-03-2016	PAGE 1 OF 1

1. **Purpose:**
   Storing and discarding of samples

2. **Scope:**
   Applicable to CARE.

3. **Responsibility:**
   The Investigators and Guide are responsible for implementing this SOP.

4. **Procedure:**

   4.1 Storage period of biological sample should be clearly indicated by an investigator. Any related data of participants if the investigator likes to use in future should get proper consent from the participants.

   4.2 If Investigator wants to store the sample for future use he/ she has to get the consent from the participant. If he/ she refuses then that particular sample should not be used.

   4.3 Samples should be discarded as per Biomedical Guidelines (Management & Handling) 1988, as amended to date and should be documented with Signature of Investigator and Guide.

Prepared by	Reviewed & Approved by
Dr.E.Malligai Member Secretary	Capt.Dr.B.Santhakumar Chairperson

Chettinad
Academy of Research and Education

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Submission Date	
Serial No.	

PROPOSAL SUBMISSION FORM FOR INSTITUTIONAL HUMAN ETHICS COMMITTEE– CARE**

FOR DM / M.Ch/ M.Sc./ MBBS/ Ph.D STUDENTS

FORM - A

1. Title of the proposed research	
2. Name of the Candidate: a. Department b. Degree / Course c. Batch of admission to the course d. Month & year of submission of Thesis e. Email ID of the Candidate f. Email ID of the Guide g. Mobile No. of the Candidate	 a. b. c. d. e. f. g.
3. Institute where the research will be conducted:	
4. Name of the external institutes associated with the study (if any)	
5. Name of guide:	
6. Name of co – guide:	
7. Study proposal in the given format including the a. PROFORMA (**Annexure 1**) b. Necessary supportive documents like i.Questionnaire(**Annexure 2**) ii. Assessment scales (**Annexure 3**) iii.Others if any (**Annexure 4**)	 a. b. i. ii. iii.

ChettinadHealthCity, Rajiv Gandhi Salai, Kelambakkam,Kancheepuram Dist. Tamil Nadu 603103.
Ph – 91(0)44 47428417 / Mobile: +919094038000/ Fax – 91(0)44 47411011
Email: ihec@chettinadhealthcity.com

Chettinad
Academy of Research and Education

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Submission Date	
Serial No.	

8. Informed consent document with a. Participant information sheet (**Annexure 5**) b. Participant informed consent form (**Annexure 6/ 6a**) c. Investigator declaration (**Annexure 7**)	 a. b. c.
9. Ethical issues that could be identified by the investigator and plans to address them: (**Annexure 8**)	
10. Details of sponsorship if any: (**Annexure 9**)	
11. Authorization letter from HOD stating that the research has not been started (**Annexure 10**)	
12. Signature of the Candidate:	
13. Signature of the guide:	
14. Signature of the head of the department:	

**** No thesis work shall be/ can be started unless ethics clearance / approval is obtained. Kindly note that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the ethics committee.**

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PROPOSAL SUBMISSION FORM FOR INSTITUTIONAL HUMAN ETHICS COMMITTEE- CARE * *

OTHER THAN STUDENTS

FORM - B

1. Title of the proposed research	
2. Name of the Principal Investigator: a. Department b. Designation c. Email ID d. Mobile No.	 a. b. c. d.
3. Name of the Co - Investigator I: a. Department b. Designation c. Email ID d. Mobile No.	 a. b. c. d.
4. Name of the Co - Investigator II: a. Department b. Designation c. Email ID d. Mobile No.	 a. b. c. d.
5. Institute where the research will be conducted:	
6. Name of the external institutes associated with the study (if any)	

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Academy of Research and Education

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Submission Date	
Serial No.	

7. Study proposal in the given format including the a. PROFORM A (**Annexure 1**) b. Necessary supportive documents like i.Questionnaire(**Annexure 2**) ii. Assessment scales (**Annexure 3**) iii.Others if any (**Annexure 4**)	 a. b. i. ii. iii.
8. Informed consent document with a. Participant information sheet (**Annexure 5**) b. Participant informed consent form (**Annexure 6/ 6a**) c. Investigator declaration (**Annexure 7**)	 a. b. c.
9. Ethical issues that could be identified by the investigator and plans to address them: (**Annexure 8**)	
10. Details of sponsorship if any: (**Annexure 9**)	
11. Authorization letter from HOD stating that the research has not been started (**Annexure 10**)	
12. Total Budget (approx. in Rs.) Who will bear the cost of investigation / implant drugs / contrasts?	Rs. _____ ☐Project ☐ patient ☐Other Agencies
13. Signature of the Principal Investigator:	
14. Signature of the Co-investigator(s):	1. 2.
15. Signature of the head of the department:	

**** No thesis work shall be/ can be started unless ethics clearance / approval is obtained. Kindly note that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the ethics committee.**

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Form I

IHEC – CARE

Initial Check list to verify completeness of documents submitted

For official use only Proposal S.No._____ Date _____

1. Ten copies of the proposal for regular ethics committee & soft copy to be sent through E.Mail

2. Proforma and consent forms (English) matching with those given in IHEC, CARE web site

3. Proforma completely filled with all the questions answered in complete sentences

4. Proforma duly signed by the investigator(s), guides, co-guides and Head of concerned departments, with date

5. Consent forms Annexure 6 and 6a in both English language and the local language (Tamil)

6. Complete address and phone number of the investigator/guide provided in the appropriate place in consent form Annexure 6

7. Appropriate Consent form Annexure 6a enclosed for adults and children (less than 18 years)

Form II

Check list for verification of proposals submitted to Institute Ethics committee (Human studies)

For official use only *Proposal No.*

	Yes	No	NA	Comments
Is all the documentation provided?				
Scientific importance and validity				
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2. If the study is a replication of a previous study, is it justified?				
3. Can the intervention studied be practically implemented?				
4. Is there provision for dissemination of results of the research?				
5. Has the research protocol been approved by a competent body?				
6. Should the study be referred to a technical expert, policy maker or statistical expert? (If YES, please inform the Secretary/ERC as soon as possible, suggesting a suitable person)				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Are the investigators qualifications, competence and experience appropriate to conduct the study?				
10. Are the facilities at the site adequate to support the study?				
11. Is the manner in which the results of research will be reported and published ethical?				
Assessment of Risks/Benefits				
1. Is the involvement of human participants necessary to obtain the necessary information?				
2. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
3. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
4. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
5. Is there provision for compensation for participants who sustain injuries?				

	Yes	No	NA	Comments
6. Have adequate provisions been made for dealing with and reporting adverse effects?				
7. Have adequate provisions been made for safety monitoring and termination of the research project?				
Respect for the dignity of the research participants				
Informed consent				
1. Is the process for obtaining informed consent appropriate?				
2. Are the participants competent to give consent?				
3. Is the justification adequate for the intention to include individuals who cannot consent?				
4. Will dissent be respected?				
5. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
6. Do you approve the incentives offered?				
7. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
Confidentiality				
1. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
Rights of the participants				
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?				
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
3. Is there provision for the subjects to be informed of results of clinical research?				
Fair participant selection				
1. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
3. Does the selection of participants stigmatize any group?				
4. Does selection of subjects favour any group?				

	Yes	No	NA	Comments
5. Is the research conducted on vulnerable individuals or groups?				
6. Is the research externally sponsored?				
7. Is the research a community research?				
8. Is the research a clinical trial?				
Responsibilities of the researcher				
1. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher obtained permission from the relevant authorities?				
3. Are there any conflicts of interest, including payments and other rewards?				
4. Are there any other ethical / legal/ social /financial issues in the study?				

Additional Comments:

.....

.....

.....

Recommendation: Approve [ ] Reject [ ] Conditional Approval (please state the conditions)

.....

.....

.....

Name of Reviewer:
Signature :
Date :

Date:

From
Vice Chancellor
CARE, Kelambakkam
Kancheepuram Dist.

To

_____

_____

Sub: Constitution of Institutional Human Ethics Committee (IHEC) – Reg.,

Dear Sir / Madam

On behalf of Chettinad Academy of Research & Education, I request your concurrence for possible appointment as a member of Institutional Human Ethics Committee (IHEC) of this institute. Kindly send your consent in the enclosed format and provide the necessary information requested.

Yours sincerely

Signature:

Name:

Consent to be a member of IHEC

Date:

To
The Vice Chancellor
Chettinad Academy of Research & Education
Rajiv Gandhi Salai, Kelambakkam
Kancheepuram Dist. - 603 103

Sub: Consent to be a member of IHEC

Sir,

I accept the invitation to become a member of IHEC of Chettinad Academy of Research & Education, Rajiv Gandhi Salai, Kelambakkam, Kancheepuram Dist - 603 103

I shall regularly participate in the IHEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing to publicize my full name, profession and affiliation.

I shall make available to the public on request, all reimbursement for work and expenses if any related to IHEC.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV. Thanking You,
Yours sincerely,

Signature ----------

Name of Member ---------- Date:

Address and Telephone No:

Document 3

Ref: Date:

List of members of IHEC - CARE

The Institutional Human Ethics Committee is reconstituted as per ICMR guidelines with the following members

The tenure of the members will be three years from _____

Chair Person:

1. _____

Member secretary:

2. _____

Members:

Basic Medical Scientists:

3. _____
4. _____
5. _____

Clinicians:

6. _____
7. _____

Social Scientists:

8. _____

Philosopher:

9. _____

Legal Expert:

10. _____

From Public:

11. _____

Vice Chancellor - CARE

Minute of the Meeting IHEC - CARE

To

_____

_____

The _____meeting of the Institutional Human Ethics committee (IHEC) for the year _____ was held in _____, CARE on _____ under the Chairpersonship of _____. Besides the Chairperson, _____ Member Secretary _____ Member_____ attended the meeting.

After the proceedings, the proposals listed for the meeting were taken up for discussion. After deliberations, the following decisions were arrived.

No. of Proposals reviewed _____

No. of Proposals approved _____

No. of Proposals approved subject to corrections_____

The recommendations made by the committee are given below.

The investigators whose proposals need minor modifications are required to send three copies of revised proposals to _____, Member Secretary. If the revision is satisfactory, the approval certificate will be issued after consulting the Chairperson of the Committee.

The recommendations of the committee to each proposal are detailed below:

Department_____

S.No.	Proposal S.No.	Name of the student/Principal Investigator	Title of the proposal	Name of Guide / Co-guide	Recommendations of the committee

Any Change, modification or deviation in the protocol, or any serious adverse event must be informed to ethics committee within fourteen days. Any protocol modification or amendment must receive IHEC approval. Investigator should conduct the study as per the recommended FCP/GLP guidelines.

It is also confirmed that our ethics committee is constituted and functions as per GCP guidelines issued by DCGI and ICMR.

Member Secretary IHEC- CARE

Chairperson IHEC - CARE

Chettinad
Academy of Research and Education

Chettinad Academy of Research and Education
Institutional Human Ethics Committee

Document 5

Proposal S.No.:_____ Date:_____

CERTIFICATE

This is to certify that the Proposal S.No._____, entitled "_____" Submitted by _____Department of _____ has been approved by the Institutional Human Ethics committee, at the meeting held on _____under the following terms and conditions.

a. This approval is valid for three years or the duration of the project whichever is less.
b. Any change in the study procedure/ site/ investigator should be informed to the IHEC

Member Secretary
IHEC, CARE

To
The Principal Investigator
Co-investigators

Annexure - 5

PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in English and Tamil, in a simple layman's language, in a narrative form, directed to Participant / Legally Authorised Representative (LAR), covering all the points given on the website, which can be understood by them:

1. Title of the study / project
2. Aims and the methods of the research
3. Expected duration of the subject participation
4. The benefits to be expected from the research to the subject or to others
5. Any risk to the subject associated with the study
6. Maintenance of confidentiality of records.
7. Provision of free treatment for research related injury
8. Compensation of Subjects for disability from or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
10. Amount of blood sample in quantity, in Tea spoon full, to be taken should be mentioned
11. Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned.
12. Telephone number / contact number of principal investigator and Co-investigator at the top of each page
13. In case of drug trials:
    a. The chemical name of the drug
    b. Initial Bio Equivalent study of the drug / references should be provided
14. Self-certification should be given that translation to vernacular is accurate.

Annexure - 6

PARTICIPANT INFORMED CONSENT FORM (PICF)

IHEC Proposal S.No.: _____ Date: _____

Title of the project:

_____

_____

Name of the Principal Investigator: Mobile No.:

The contents of the information sheet dated _____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from CARE. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

Date:
Place:

_____
(Signatures / Left Thumb Impression)

Name of the Participant: _____
Son / Daughter / Spouse of: _____
Complete Postal Address: _____

This is to certify that the above consent has been obtained in my presence.

Date:

Place:

_____
Signature of the principal Investigator

1. Witness - 1

_____
Signature

Name & Address

2. Witness - 2

_____
Signature

Name & Address

Note: Three copies should be made, for (1) Participant, (2) Researcher, (3) Institution
(Investigators are advised to prepare the translation in simple understandable Tamil on their own)

Annexure - 6a

Consent form (for participants less than 18 years of age)

Parent/ Legally accepted representative(LAR)

Participant's name: Address:

Parent/ LAR's name:

Title of the project:

_____

_____

The details of the study have been provided to me in writing and explained to me it my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my child's/ ward's participation in the study is voluntary and that I am free to withdraw my child/ ward at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent for the participation of my child/ ward in the above study.

Assent of child/ ward obtained (for participants 7 to 18 years of age)

Signature of parent/ LAR: _____ Date: _____

Signature of the Witness: _____ Date: _____

Signature of the investigator: _____ Date: _____

Annexure – 7

Investigator's Declaration

Certified that....

1. The research is not duplicative of previously reported research
2. All investigators working on this proposal are aware of the ICMR ethical guidelines
3. I / we have reviewed the pertinent scientific literature
4. The study shall be initiated only upon review & approval of IHEC
5. I / we will obtain approval from IHEC before initiating any deviation / Changes in the study
6. Informed consent will be obtained & confidentiality of the subject will be maintained.

Place:

Date: Chief Investigator

Annexure – 10

Letter of Authorisation

This letter hereby states that the candidate named _____

pursuing his/her _____, has not officially started his/her Research titled

_____

_____

_____in our Department. He/she will be starting her research activity after the ethics committee approval.

Guide HOD

Date:

1. Proposal Submission form for students – A
2. Proposal Submission form other than students Form – B
3. Initial Check list to verify completeness of documents submitted Form – I
4. Check list for verification of proposals submitted to IHEC Form – II
5. Invite letter for members Document – 1
6. Consent of IHEC members Document – 2
7. List of members of IHEC Document – 3
8. Minutes of the IHEC Meeting Document – 4
9. IHEC approval certificate Document – 5
10. Participant Information Sheet – Annexure 5
11. Participant informed consent – Annexure 6
12. Participant informed consent (<18yrs) – Annexure 6a
13. Investigator Declaration form – Annexure 7
14. Authorization letter – Annexure 10

Prepared by	Reviewed & Approved by
Dr.E.Malligai	Capt.Dr.B.Santhakumar