Standard Operating Procedures

Institutional Human Ethics Committee

Version No. 1

Authors

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Dr.N.Pandiyan

CHENNAI FERTILITY CENTER

Chennai Fertility Centre and
Research Institute

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Foreword

Dr. VM. Thomas
Chairman and Institute Director,
Chennai fertility center and Research Institute

It is human nature to become curious about what is happening around us and how we can attach meaning to it. Also due to our inquisitive nature, we explore a lot of possibilities that can give answers. In the pursuit of finding answers, we have found answers to some of the daunting human issues through research. Research is essential to take our journey as a human race forward. It is this journey that is going to help humans solve some of the biggest mysteries in the human body. In pursuit of research sometimes we can go overboard on our curiosity, and that's where it is essential to know the limits which we should never cross.

We at Chennai Fertility Center and Research Institute have believed in the importance of the Institutional Ethics Committee's role in ensuring scientifically and ethically sound research. This Book of Standard Operating Procedure is a step in the formidable direction and ensures that we do our job justly. We believe this book will also be a guiding light for all others seeking guidance. I acknowledge the tremendous effort of Dr. L. Krishnavignesh (Member Secretary, IHEC, CFC & RI / Head, Learning, Research and Development, Chennai Fertility Center and Research Institute, Chennai), and Dr. N. Pandiyan (Chairperson, IHEC, CFC & RI / Cheif Consultant in Andrology and Reproductive Medicine, Head, Department of Reproductive Medicine, Chettinad Hospital and Research Institute, Chennai) for preparing this book of standard operating procedures with high ethical standards.

CFC
CHENNAI FERTILITY CENTER

Preface

Ethics and morality are human inventions. They are not instincts or dictates of Nature. Nature is merciless and is never concerned about individual survival or well being. On the other hand, Ethics and Morality are concerned about the welfare of everyone, the rich and the poor, the weak and the strong, the ruler and the ruled. It is primarily meant to protect the weak and the vulnerable from the exploits of the strong and the dominant.

Medical ethics are following ethical principles in the practice of medicine. This of course changes from time to time and from place to place. It is important to understand the current guidelines in the ethical practice of medicine and follow it diligently.

Assisted Reproduction is a relatively new branch of medicine. Unlike all other medical fields, the decision we make may well affect, not only the mother and father but also the future - the child and their offspring. Therefore, abundant caution must be exercised in the practice of this field.

In vitro fertilization and Embryo Transfer was the first Assisted Reproductive Technique invented by Professor Robert G Edwards, Mr Patrick Steptoe and their team to help women with irreparable tubal Infertility have a baby. The team was then widely criticized by many, including Nobel laureates, that they were engaged in unethical work and would create a Frankenstein monster. The birth of Louise Brown and more than 5 million babies world over has to a large extent assuaged these criticisms and fears. However, even today, fear and criticism of Assisted Reproduction have not entirely disappeared.

The last 3 decades have seen a further rapid increase in the indications and the techniques of Assisted Reproduction with attendant huge ethical issues.

Research forms the backbone of learning. Research is re- searching for truth again. Even so-called established truth should be questioned and confirmed or refuted. Truth, after all, is relative and is based on currently available evidence. Research in Reproduction is fraught with several dangers and pitfalls.

In the search for truth, researchers in their enthusiasm may breach the boundaries of ethical conduct of research. The Researcher and the Ethical Committee, which has the responsibility of evaluation of the Research protocol and permitting it, need to understand the nuances of Research and the Standard Operative Procedures. Finally we would like to thank Dr. Sudha Ramalingam (Director - Research and Innovation, PSG Institute of Medical Sciences & Research, Coimbatore), Dr. S. Swarnalakshmi (IRB Manager, YRG CARE, Chennai), Dr. C.B. Tharani (Head & Professor, Meenakshmiammal Dental College, Chennai) and G. Anuja (IHEC, CFC & RI, Secretariat staff for their continous support. We also acknowledge ICMR for setting the highest ethical standards in protecting the human participants in the conduct of Research.This book addresses and offers guidance to the Ethical Committee for the evaluation of Research proposals and guides in the Ethical Conduct of Research. We hope you will find it useful. We would be happy to have your feedback which will help us improve future editions.

Dr. L. Krishnavignesh
Member Secretary, IHEC, CFC & RI / Head, Learning, Research and Development, CFC & Research Institute, Chennai.

Dr. N. Pandiyan
Chairperson, IHEC, CFC & RI / Cheif Consultant in Andrology & Reproductive Medicine, Head, Department of Reproductive Medicine, Chettinad Hospital & Research Institute, Chennai.

TABLE OF CONTENTS

List of Abbreviations / Acronyms

Abbreviation/Acronym	Full Title/Description
ADR	Adverse Drug Reaction
AE	Adverse Event
BA	Bio-availability
BE	Bio-equivalence
CDSCO	Central Drugs Standard Control Organization
CFR	Code of Federal Regulations
CFC & RI	Chennai Fertility Centre and Research Institute
CIOMS	Council for International Organizations of Medical Sciences
CIMS	Chennai Institute of Medical Sciences
CoI	Conflict of Interest
Co-I	Co-Investigator
CRF	Case Record Form
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
DBT	Department of Biotechnology
DCGI	Drug Controller General of India
DCR	Drugs and Cosmetic Rules, 1945
DGFT	Directorate General of Foreign Trade
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
ELSI	Ethical, Legal and Social Issues
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FERCAP	Forum for Ethical Review Committees in Asia and the Western Pacific Region
FWA	Federal wide Assurance
GCP	Good Clinical Practice

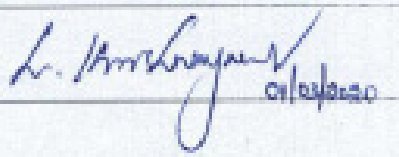
Abbreviation/Acronym	Full Title/Description
HMSC	Health Ministry's Screening Committee
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Committee on Harmonization
ICMJE	International Committee of Medical Journal Editors
ICMR	Indian Council of Medical Research
IMA	Indian Medical Association
IND	Investigational New Drug
IHEC	Institutional Human Ethics Committee
IRB	Institutional Review Board
IORG	IRB Organization
ISI	Indian Standards Institute
LAR	Legally Acceptable/ Authorized Representative
MoU	Memorandum of Understanding
MTA	Material Transfer Agreement
NCE	New Chemical Entity
NDA	New Drug Application
NIH	National Institutes of Health
NOC	No-objection Certificate
OHRP	Office for Human Research Protections
PI	Principal Investigator
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
WHO	World Health Organization
WMA	World Medical Association

Approval of SOPs with signatures

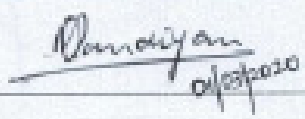
The below mentioned SOPs are part of IHEC SOP Manual V 1.0

SOP 01-V 1.0
SOP 02-V 1.0
SOP 03-V 1.0
SOP 04-V 1.0
SOP 05-V 1.0
SOP 06-V 1.0
SOP 07-V 1.0
SOP 08-V 1.0
SOP 09-V 1.0
SOP 10-V 1.0
SOP 11-V 1.0
SOP 12 V 1.0
SOP 13-V 1.0
SOP 14-V 1.0
SOP 15-V 1.0
SOP 16-V 1.0
SOP 17-V 1.0
SOP 18-V 1.0
SOP 19-V 1.0
SOP 20-V 1.0
SOP 21-V 1.0
SOP 22-V 1.0
SOP 23-V 1.0
SOP 24-V 1.0
SOP 25-V 1.0
SOP 26-V 1.0
SOP 27-V 1.0
SOP 28-V 1.0
SOP 29-V 1.0
SOP 30-V 1.0
SOP 31-V 1.0
SOP 32-V 1.0
SOP 33-V 1.0
SOP 34-V 1.0

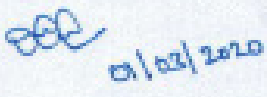
Prepared by:

Name and Position in the IHEC	Signature with date
Dr. L. Krishnavignesh (Member-Secretary, IHEC)	

Reviewed and Approved by:

Name and Position in the IHEC	Signature with date
Dr. N. Pandiyan (Chairperson, IHEC)	

Accepted by:

Name and Position in the IHEC	Signature with date
Dr. VM. Thomas, Chairman & Institute Director	

List of Members of the IHEC

S.no.	Name of the Member of IHEC	Area of Expertise	Affiliated to CFC & RI or not	Sex
1	Dr. N. Pandiyan (Chairperson)	Reproductive Medicine, Clinician (Obstetrics &Gynaecology)	Non-Affiliated	M
2	Dr. L. Krishnavignesh (Member-Secretary, IHEC)	Embryologist	Affiliated	M
3	Dr. Smisha Sridev Barathan (Clinician)	Reproductive Medicine, Clinician (Obstetrics &Gynaecology)	Affiliated	F
4	Dr. S. Swarnalakshmi (Social Scientist)	Ethicist / NGO representative	Non-Affiliated	F
5	Dr. C.B. Tharani (Basic Medical Scientist)	Pharmacologist	Non-Affiliated	F
6	Dr. R. Satishkumar (Basic medical scientist)	Plant Molecular Biology, Biotechnology	Non-Affiliated	M
7	Dr. ChitraRamanathan (Clinician)	Clinician (Obstetrics & High-risk pregnancies)	Affiliated	F
8	Dr. T. Puvithra (Clinician)	Reproductive Medicine, Clinician (Obstetrics &Gynaecology)	Non-Affiliated	F
9	Dr. Malar K.T (Clinician)	Reproductive Medicine, Clinician (Obstetrics & Gynaecology)	Affiliated	F
10	O. Deepa (Scientific Member)	Embryologist	Affiliated	F
11	Dr. N. Punithavathi (Clinician)	Clinician (Obstetrics & Gynaecology)	Affiliated	F
12	Mr. K.S. Karthik Raja	Legal expert	Non-Affiliated	M
13	Mr. S.Maruthavijayan	Legal expert	Non- affiliated	M
14	Mr. R. Prabakaran	Lay person	Non-affiliated	M

List of Independent Consultants

Name	Department
Dr. K. Hari Prasad	Anaesthesiology

1. Introduction:

The Chennai Fertility Centre and Research Institute (CFC & RI), is a tertiary fertilitycenter involved in the treatment, education and research in the field of reproductive medicine and it is recognized as one of the leading fertility center in Asia.

It is dedicated to helping childless couples by providing high quality diagnosis and treatments procedures to correct various infertility issues. Its academic, research and development wing focus on interdisciplinary and multi-disciplinary high-quality innovative programs in the field of reproductive medicine to help the society to have a better understanding on various fertility issues and treat them efficiently with an advanced procedure.

The Institutional Human Ethics Committee(IHEC) is established to ensure the safety, well-being and rights of human participants in research conducted by any of the institutions under the administrative authority of the Chairman, Managing director, Chennai Fertility Centre and Research Institute, Chennai, India.

2. Objective:

The objective of this Standard Operating Procedures of the Institutional Human Ethics Committee (IHEC) of Chennai Fertility Centre and Research Institute (CFC & RI) is to maintain effective functioning of the IHEC so that to ensure quality and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human participants 2017 and New Drugs and Clinical Trial Rules 2019, Government of India.

3. Jurisdiction of the Institutional Human Ethics Committee, CFC & RI

The Institutional Human Ethics Committee (IHEC) of CFC & RIshall receive, review, approve (or otherwise) and monitor research proposals involving human study volunteers in the following Institutions

1. All branches of Chennai Fertility Centre and Research Institute,
2. Fertility Society of India(FSI),
3. Chennai Institute of Medical Sciences (CIMS)
4. Dr. Thomas Fertility Center, Puducherry.

This includes both intramural and extramural research by faculties and students. All studies including clinical trials proposed to be conducted in CFC & RI must obtain approval from the IHEC of CFC & RI. Approval given by ethics committee of another institution to carry out a study shall not be valid for carrying out the same study in CFC & RI.

4. Functions of Institutional Human Ethics Committee (IHEC)

The objective of IHEC – CFC & RI will be to safeguard the dignity, rights, safety and well-being of research participants and review the research. IHEC is responsible for scientific and ethical review of research proposals and based on the well defined standard operating procedures (SOPs) for all functions.

The IHEC should be multidisciplinary, competent and independent in its functioning with the chairperson and minimum of 50% members as non-affiliates. Each member of the IHEC has a defined role and responsibility. IHEC members should be trained in protection of human research participants, SOP and Good Clinical Practice (GCP) guidelines, and are conversant with relevant ethical guidelines and regulations.

It should provide an independent, competent and timely review of the ethics of proposed studies within the ethical norms laid down by the latest revisions of the Ethical Guidelines for Biomedical Research on Human Subjects of the Indian Council for Medical Research (ICMR) and other relevant guidelines before the commencement of a study and should regularly monitor the ongoing studies. In addition, it will ensure that all research it approves will also confine to applicable central, state and local laws and regulations.

The IHEC take care of all the cardinal principles of research ethics viz. autonomy, beneficence, non-malfeasance and justice are taken care of in planning, conduct and reporting of the proposed research. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IHECs will be to review all research projects involving human subjects to be conducted at the Institute. The conduct of IHEC meetings has discussed in detail in SOP 14.

5. Constitution of IHEC

The Institutional Human Ethics Committee will be multidisciplinary and multi-sectoral incomposition. The committee is composed of a minimum of 7 and maximum of 15 members. The IHEC should be multidisciplinary, competent and independent in its functioning with the chairperson and minimum of 50% members as non-affiliates. Each member of the IHEC has a defined role and responsibility. It includes scientific and non-scientific, clinicians and non – clinicians, clinical pharmacologist, a social scientist, lawyer, expert in ethics, scientific member, layperson needed to represent a different point of view. The committee should have adequate representation of age, gender and community to safeguard the interests and welfare of all sections of the community / society. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism. IHEC members should be trained in protectionof human research participants, SOP and Good Clinical Practice (GCP) guidelines, and are conversant with relevant national and international clinical & ethical guidelines and regulations.

The chairperson should be a non-affiliate, a well-respected person, preferably a clinician with priorexperience of having served/serving in an EC. The member secretary should be a staff member of the institution. He/She should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. The composition, affiliations and qualifications of IHEC members will be maintained as prescribed in the latest revisions of Handbook on National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR (2017) and other relevant guidelines. Quorum requirements have discussed in detail in SOP 13.

5.1. Structure of IHEC

The composition should be as follows: -

1. Chairperson (non-affiliated)
2. Member-secretary (affiliated)
3. 1-2 clinicians
4. Basic medical scientist
5. Clinical Pharmacologist
6. One legal expert or retired judge or medico-legal expert
7. One social scientist / representative of non-governmental voluntary agency
8. One philosopher / ethicist / theologian
9. Scientific Member
10. Lay person from the community

Composition and structure of IHEC - CFC & RI

S.no.	Name of the Member of IHEC	Area of Expertise	Affiliated to CFC & RI or not	Sex
1	Dr. N. Pandiyan (Chairperson)	Reproductive Medicine, Clinician (Obstetrics &Gynaecology)	Non-Affiliated	M
2	Dr. L. Krishnavignesh (Member-Secretary, IHEC)	Embryologist	Affiliated	M
3	Dr. Smisha Sridev Barathan (Clinician)	Basic medical Scientist Reproductive Medicine, Clinician (Obstetrics & Gynaecology)	Affiliated	F
4	Dr. S. Swarnalakshmi (Social Scientist)	Ethicist / NGO Representative	Non-Affiliated	F
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6	Dr. R. Satishkumar (Basic Medical Scientist)	Plant Molecular Biology, Biotechnology	Non-Affiliated	M
7	Dr. Chitra Ramanathan (Clinician)	Clinician (Obstetrics & Highrisk Pregnancies)	Affiliated	F
8	Dr. T. Puvithra (Clinician)	Reproductive Medicine, Clinician (Obstetrics & Gynaecology)	Non-Affiliated	F
9	Dr. N. Punithavathi (Clinician)	Clinician (Obstetrics & Gynaecology)	Affiliated	F
10	Dr. Malar K.T (Clinician)	Reproductive Medicine, Clinician (Obstetrics & Gynaecology)	Affiliated	F
11	O. Deepa (Scientific Member)	Embryologist	Affiliated	F
12	Mr. K.S. Karthik Raja	Legal expert	Non-Affiliated	M
13	Mr. S. Maruthavijayan	Legal expert	Non- affiliated	M
14	Mr. R. Prabakaran	Lay person	Non-affiliated	M

6. Authority under which IHEC is constituted:

The Chairman of Chennai Fertility Centre and Research Institute constitutes the IHEC and has the authority to dissolve the IHEC.

7. IHEC Membership

a. The duration of appointment will be initially for a period of 3 years.

b. The membership can be renewed for another term of 3 years. There will be no bar on the members serving for more than one term but it is desirable to have around one third of fresh members every three years.

c. At the end of 3 years, the committee is to be reconstituted, and one third of the members can be replaced by a defined procedure.

d. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

e. A member can tender resignation from the committee with proper reasons to do so.

f. All members should maintain absolute confidentiality of all discussions during the meeting.

g. Conflict of interest should be declared by members of the IHEC.

h. If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of appointment.

7.1. Resignation / Replacement procedure

a. The members who have resigned may be replaced at the discretion of the appointing authority for the same. IHEC members (includingMember- Secretary) who decide to resign must inform the Chairman, CFC& RI and Chairperson, IHEC in writing about their intention to resign by citing reasons for the same at least 30 calendar days prior to the next scheduled meeting.

b. In case of resignation of the Chairperson, he/she is required to inform the Chairman 30 calendar days prior to his/her resignation. If there is a situation which warrants an emergency resignation of a member wherehe/she could not give a 30-day notice, her/his resignation may beaccepted.

c. In case of resignation, Chairman, CFC & RI would appoint a newmember, falling in the same category of membership if it is a mandatedcategory as per New Drugs and Clinical Trial Rules 2019, Government of India. Chairman appoints Member-Secretary and Chairperson as per the procedure described in this SOP.

7.2. Termination / Disqualification procedure

A member may be relieved or terminated of his/her membership in case of:

a. Conduct unbecoming for a member of the Ethics Committee, inability to participate in the meetings on any grounds

b. If a regular member fails to attend more than 3 meetings of IHEC. The membership shall be reviewed by the IHEC and a letter of reminder will be sent to the concerned member. If deemed necessary, the IHEC may decide to terminate the membership and recommend to the Chairman, CFC & RI, by the Chairperson IHEC for necessary action

c. Relocate to another city

d. In any such situation/circumstances, Chairman, CFC & RI will serve a letter of termination to the member citing the reason.

e. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IHEC meeting and IHEC membership circular/ roster will be revised.

7.3. Members going on long leave

Long leave refers to duration of leave that is taken as three months (90 days) or above. If a situation occurs when a member is required to go on long leave for professional and personal reasons the following will befollowed.

a. If the period of leave is less than or equal to 6 months and the IHEC appointment term is valid for more than 6 months.

b. He/she can continue as the member of IHEC if he/she wants to do so. If not, the member should tend her/his resignation from IHEC prior to going on leave as per the clause described in 7.1. If the member intending to go on leave is an office bearer (see 8.1 below for definition of office bearers) the same rules will be implemented. In addition, any suitable,consenting member of the IHEC can hold the post of the office bearer untilshe/he returns.

c. If the member is going on leave for more than one year she/he should tend her resignation from the IHEC as per clause 7.1 even if the term of the member is valid. This is to ensure efficient and uninterrupted functioning of IHEC review mechanism. A suitable replacement of the member in the same/similar specialty will be inducted to IHEC. This will be applicable to all the office bearers of the IHEC too.

8. Conditions of Appointment

a. Name, age, sex, profession, and affiliation of IHEC members will be publicized through the CFC & RI website and notice boards (and that of the CFC & RI for whom CFC & RI reviews study protocols).

b. Members must accept the appointment in writing.

c. Submit a CV and training certificates in Ethics and / or GCP.

d. Disclose any Conflict of interest.

e. Members must apprise themselves of the relevant documents, codes, GCP,ICH guidelines and the ICMR code & IHEC, CFC & RI SOPs.

f. All Members (including Chairperson, Member secretary) are required to sign the confidentiality agreement and Conflict of Interest statement (Annexure 5, Annexure 6) at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IHEC in the course of its work.

g. An investigator can be a member of the IHEC; however, the investigator as-member cannot participate in the review and approval process for any project in which he or she has presence as a PI, Co-PI or Co-I or potential conflict of interest.

8.1. Appointment Procedures

The IHEC will have the following office bearers who have the expertise and professional qualifications to review what comes in:

8.2. Chairperson

The Chairperson will be appointed by the Chairman, CFC & RI from amongst the members.

8.3. Criteria for selection of Chairperson

The Chairperson is selected based on their experience as members of ethics committee. The Chairperson should preferably be a medical professional. A person in order to be considered for the post of Chairperson should have the experience of serving in an ethics committee and should not be affiliated to CFC & RI Institutions.

8.4. Member-Secretary

He / She will be appointed by the Chairman, CFC & RI in consultation with the Chairperson, IHEC and will be affiliated to the CFC & RI.

8.4.1. Terms of Reference for Member-Secretary

Ensure that members and research investigators are functioning inconformity with the IHEC's SOP.

i. Liaisoning between the Chairperson, IHEC and Chairman, CFC & RI and updating them about the developments

ii. Liaisoning between the IHEC members and Chairman, CFC & RI.

iii. Communicating with Chairperson, members and Principal Investigators (PIs)

iv. Protection of safety, rights and confidentiality of the research participants.

v. Categorization of study proposals received

vi. Assigning categorized study proposals to primary reviewers

vii. Guiding the office staff in the day-to-day functioning of the IHEC Secretariat.

viii. Overseeing documentation and archiving of study documents (Preparation, maintenance and distribution of study files).

ix. Overseeing the maintenance of a database of all proposals received, reviewed and archived

x. Convening IHEC Expedited Committee Meeting as and when required (with the help of the IHEC Secretariat staff)

xi. Convening IHEC Full Board Review Meeting regularly (with the help of the IHEC Secretariat staff)

xii. Preparation of agenda and minutes of the meetings (with the help of the IHEC Secretariat staff)

xiii. Communicating with IHEC members and PIs (with the help of IHEC Secretariat staff).

xiv. Monitor the review procedures

xv. Participate in the IHEC meeting regularly.

xvi. Maintain confidentiality of the documents and deliberations of the IHEC meetings.

xvii. Declare conflict of interest, if any.

xviii. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IHEC Secretariat

xix. To be updated on relevant laws and regulations

xx. To participate in continuing education activities in biomedical ethics and biomedical research and encourage members to do so.

xxi. Arrangement of training for personnel and IHEC members

9. Members

All members shall be appointed by the Chairman, CFC&RI in consultation with the Chairperson and Member-Secretary of IHEC.

Flow Chart

Activity		Responsibility
Appoint the SOP team	→	Chairman
List all relevant SOPs	→	Secretariat
Design a format and layout	→	Secretariat
Design a format and layout	→	Secretariat
Approval for implementation	→	IHEC Members
Implement, distribute and file all SOPs	→	Secretariat
Review and request for a revision	→	Chairperson, Chairman
Review the new/revised SOP /Investigators of NIE	→	IHEC members / Secretariat
Manage and archive superseded SOP	→	Secretariat

10. Independent Consultants

The IHEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if needed. 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. They will be required to give their specialized views but should not take part in the decision-making process which will be made by the members of the IHEC. These consultants must sign the confidentiality agreement (Annexure- 25) regarding meeting, deliberations, and related matters.

11. Secretariat

Secretariat is composed of Member-Secretary, IHEC and the administrative and supporting staff. The supporting staff consists of staff members of IHEC, CFC & RI appointed by the Chairman, CFC & RI.

11.1. The secretariat shall have the following functions:

a. Organizing an effective and efficient tracking procedure for each proposal received
b. Maintain a database of all proposals received, reviewed and archived.
c. Preparation, maintenance and distribution of study files
d. Organizing IHEC meetings regularly
e. Preparation of agenda and minutes of the meetings
f. Maintaining IHEC documentation and archive.
g. Communicating with IHEC members and PIs.
h. Arrangement of training for personnel and IHEC members.
i. Providing necessary administrative support for IHEC related activities to the Member-Secretary, IHEC.

11.2. Terms of Reference for the administrative officer/s/staff

a. Correspondence with the IHEC members and external experts
b. Correspondence with the investigators
c. Pre and post arrangements of IHEC meetings
d. Preparing agenda and minutes of the IHEC meetings
e. Answering queries of the investigators
f. Filing study related documents
g. Archiving and maintaining the study files

11.3. Duties of the attendant/s /Secretariat staff /s (as assigned by the Member-Secretary / Secretariat office in-charge)

a. Assisting the secretariat in arranging the IHEC meetings
b. Dispatching sets of study documents to IHEC members and external experts.
c. Receiving the study related documents from and dispatching the IHEC letters to the investigators.
d. Filing study related documents
e. Archiving and maintaining the study files

All staff of CFC & RI- IHEC secretariat will follow the rules and regulations as per CFC & RI norms.

12. SOP Team:

The Chairperson will constitute a SOP Committee consisting of the Member-Secretary and two-three more members of the IHEC / Independent Consultants/ Internal Investigators who have a thorough understanding of the ethical review process. The term of SOP Committee shall be as long as the member continues in the IHEC. If the term of a member of the SOP Committee as member of IHEC expires, that member shall automatically cease to be a member of the SOP Committee from that date.

13. Quorum Requirements:

Minimum of five members should be present to meet the quorum requirements. In case of clinical trials as per the ICMR- National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017, the following specialties should be represented in the meeting.

1. A minimum of five members should be present in the meeting
2. The quorum should include medical, non-medical or technical or/and non-technical members. *
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO
6. No decision is valid without fulfillment of the quorum. Without satisfying these conditions, any decision taken by the committee shall remain null and void.

   No quorum should consist entirely of members of one profession or one sex. In absence of the Chairperson, any member who is independent of the institution will chair the meeting as acting Chairperson.

(*Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.)

14. Conduct of the Meeting

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

a. The Member secretary in consultation with the chairperson may convene the IHEC meeting once in every six months or as necessary. The Member Secretary is responsible for maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.

b. 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 workload.

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

d. All the proposals will be received at least three weeks before the meeting, checked for completeness as per check list initially by the office clerk (Annexure-9), subsequently by the member secretary (through a nominated person) using the evaluation form (Annexure-10).

e. Members will be given not less than 2 weeks' time in advance to review study proposals and the relevant documents.

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

g. Signatures of the Chairperson and the Member secretary will be obtainedon the minutes of the meeting document. The minutes will be circulated to all the guides / HODs in case of student proposals.

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

i. There should be provision for allocating reasonable amount of funds for smooth functioning of the IHEC.

j. Members will be given appropriate remuneration for each sitting

15. Categories of Risk

Type of Risk	Definition / Description
Less than minimal risk	Research on anonymous or non-identified data / samples, data available in the public domain, meta-analysis etc.,
Minimal risk	Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.,
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

16. Application Procedures:

a. All proposals should be submitted in the prescribed application form.
b. All relevant documents should be enclosed with application form.
c. A soft copy of the proposal along with the application in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators must be sent to the member secretary.
d. The date of meeting will be intimated to the researcher to be present for clarification.
e. The decision will be communicated in writing. If revision is to be made, the revised document should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

16.1. Submission process:

16.1.1. Submission of Documents:

The PI can submit research proposal to the IHEC secretariat for review and approval under any of the 5 sections mentioned below within the specified time period mentioned below:

16.1.2. New proposals for Review:

Fifteen days prior to the upcoming IHEC meeting

16.1.3. Re-submission of Protocols with Corrections:

15 days from the date of receipt of IHEC decision letter

16.1.4. Protocol Amendment or any other Amendments:

Fifteen days prior to the IHEC meeting

16.2. Submission of SAE (On-Site):

For all clinical trials approved by DCGI the SAE will be submitted by the PI to Page 17 of 35 the licensing authority, the IHEC and the sponsor within 24 hours. The detailed report of SAEs, after due analysis, should be forwarded by the investigatorand sponsor to Chairman of the IHEC, Licensing Authority and the Head of theInstitution within fourteen calendar days of occurrence of the SAEs. If this SAE is death then the causality analysis will be forwarded to the expert committee of the licensing authority in addition to the above-mentioned authorities.

16.3.1. Submission of protocol deviations / violations:

Within 7 days of occurrence

16.3.2. Continuing Review of Approved Protocols:

Fifteen days prior to the scheduled review/expiry date

16.3.3. Protocol Completion / Termination:

The study completion report should be submitted by the study PI in the prescribed formats within 30 days of completion / termination.

It is the responsibility of the IHEC members to review the study completion report and notify it or request for further information, if necessary.

16.3.4. Receiving and Verifying Contents of Submitted Protocols

Secretariat will check the protocol documents as per the checklist attached to the Application Form for Initial Review(Annexure-8) to ensure that all required forms and materials are submitted (see guidelines to prepare informed consent: Annexure -30)

i. Verification includes
   a. Duly filled and signed Application Form for Initial Review(Annexure-8)
   b. Study protocol
   c. Other relevant documents

ii. Return the protocol documents to the applicants, if the documents are incomplete, clearly stating the missing items

17. Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation
2. Name of the Institute / Hospital / Field area where research will be conducted. Letter forwarded by the Head of the Institution / Head of the Department. (Should be there)
3. Protocol of the proposed research
4. List of Ethical issues in the study and plans to address these issues.
5. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.
6. Informed consent process, including patient information sheet and informed Consent form in local language(s).
7. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
8. Curriculum vitae of all the investigators with relevant publications in last five years.
9. Any regulatory clearances required.
10. Source of funding and financial requirements for the project.
11. Other financial issues including those related to insurance.
12. An agreement to report all Serious Adverse events (SAEs)
13. Statement of Conflict of interests, if any
14. An agreement to comply with all national and international guidelines
15. 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;
16. 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.
17. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
18. Any other information relevant to the study

18. Responsibilities of Sponsor/Investigator

18.1. Responsibilities of Sponsor

i. The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol, Good Clinical Practice (GCP-2012) Guidelines issued by the Central Drugs Standard Control Organization, New Drugs and Clinical Trials Rules (2019), Directorate General of Health Services guidelines, Government of India, ICMR ethical guidelines for biomedical research in human participants -2017, as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

ii. Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.

iii. In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of Serious adverse drug reactions (Annexure-17), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;

iv. Any report of serious adverse event /death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee, DCGI and chairman of the expert committee constituted by the licensing authority as defined under New Drugs and Clinical Trials Rules (2019).

v. In case of injury or death occurring to the clinical trial subject, the sponsor (whethera pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financialcompensation for the clinical trial related injury or death in the manner asprescribed in New Drugs and Clinical Trials Rules (2019).

vi. The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the LicensingAuthority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority as prescribed in New Drugs and Clinical Trials Rules (2019).

18.2. Responsibilities of the Investigator(s)

i. The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and for compliance as per the undertaking given in Appendix VII of New Drugs and Clinical Trials Rules (2019). Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the licensing authority as defined in New Drugs and Clinical Trials Rules (2019), the sponsor or his representative, whosoever had obtained permission form the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within the stipulated period of their occurrence as per New Drugs and Clinical Trials Rules (2019). The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and DCGI /Chairman of the Expert Committee constituted by the licensing authority under Appendix XII with a copy of the report to the licensing authority and the head of the institution where the trial has been conducted within the stipulated period of their occurrence as per New Drugs and Clinical Trials Rules (2019). The report of the serious adverse event/death, after due analysis shall be forwarded to the DCGI, Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within thestipulated period of their occurrence as per New Drugs and Clinical Trials Rules (2019).

ii. The investigator shall provide information to the clinical trial subject through informed consent process as provided in New Drugs and Clinical Trials Rules (2019) about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He/She shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

19. Record keeping and Archiving

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

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

c. Minutes of all meetings duly signed by the Chairperson.

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

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

f. Final report of the approved projects.

g. All the documents both hard copy and soft copy should be archived for prescribed period.

20. Follow up of research projects with respect to Serious Adverse Events:

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

ii. 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.

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

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

v. A life-threatening adverse drug event

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

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

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

ix. Important Medical Event (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.

x. Any Serious Adverse Event should be reported to the sponsor within 24hours and to the IHEC within 7 days (in the format given in New Drugs and Clinical Trials Rules (2019), Appendix XV). In case of death, it should be reported to the IHEC within 24 hours.

xi. 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 indetail in the final report of the study.

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

21. Review procedures:

a. The meeting of the IHEC should be held at regular intervals based on the need and workload with prior intimation.

b. The proposals will be sent to members at least 2 weeks in advance.

c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

d. Researchers will be invited to offer clarifications if need be.

e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

f. The decisions will be minuted and Chairperson's approval taken in writing.

22. Element of review

a. Scientific design and conduct of the study.

b. Approval of appropriate scientific review committees.

c. Examination of predictable risks / harms.

d. Examination of potential benefits.

e. Procedure for selection of subjects in methodology including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.

f. Management of research related injuries, adverse events.

g. Compensation provisions.

h. Justification for placebo in control arm, if any.

i. Availability of products after the study, if applicable.

j. Patient information sheet and informed consent form in local language.
k. Protection of privacy and confidentiality.
l. Involvement of the community, wherever necessary.
m. Plans for data analysis and reporting
n. Adherence to all regulatory requirements and applicable guidelines
o. Competence of investigators, research and supporting staff
p. Facilities and infrastructure of study sites
q. Criteria for withdrawal of patients, suspending or terminating the study.

23. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairperson to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified. To expedite review a sub-committee consisting of the member secretary, a non-scientific and a scientific member maybe constitutedto review the proposal and approved by the chairperson.

An expedited review may be conducted, only if the protocols involve minimal risk to the participants:

a. Revised proposal with minor modifications previously approved through full review by the IHEC.
b. Continuing review of approved proposals where there is no deviation from the original protocol approved by the IHEC.
c. Anonymous surveys and retrospective study of medical records.
d. Analysis of discarded pathological specimens / stored paraffin blocks without personal identifiers.
e. Proposals involving previously banked biological materials and/or tissues without any identifiers.

Research activities that involve only procedures listed in one or more of the following categories:

Clinical studies of drugs and medical devices only when –

i. Research is on already approved drugs except when,
   a. Study of drug interaction
   b. Conducting trial on vulnerable population OR
   c. Adverse Event (AE) or unexpected Adverse Drug reaction (ADR) of minor nature is reported

ii. Other documents which would be considered for expedited review are as follows but may not restrict to:
   a. Minor deviations from originally approved research during the period of approval (usually of one-year duration)
   c. Change in the name, address of sponsor
   d. Change in contact details of PI and Member- Secretary, IHEC
   e. Request for change in PI, Co-I, change in any member involved in the research.
   f. Minor amendments in the protocol, CRF (Case Report Forms)
   g. Minor corrections in budget other administrative changes in the IB (Investigator's Brochure), ICF (informed consent forms).

24. Full Board Review

All research presenting with more than minimal risk, research protocols which do not qualify for exemption or expedited review and projects that involve vulnerable population and special groups should be subjected to full board review by all the members.

25. Review of Research proposals involving vulnerable population

a. Vulnerable research participants are individuals who are socially, economically or politically disadvantaged and therefore susceptible tobeing exploited, whose willingness to volunteer in a research trial may beduly influenced by the expectation of (whether justified or not), benefits associatedwith participation, retaliatory response from higher authorityin case of refusal to participate, and whose consent may not be valid forvarious reasons. They include infants, children and adolescents, pregnantand lactating women, students and employees, mentally, challenged patients, critically ill patients, prisoners etc.

b. 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.

c. 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.

d. 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 obtainedfrom parents / guardian)

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

26. Review of Protocol Deviation/Non-Compliance / Violation / Waiver:

1. IHEC secretariat is responsible for receiving deviations -Violations/waiver reports submitted by the PI and forwarding to Member-Secretary or the site monitoring team.
2. IHEC members review and act upon the reports.
3. The PI himself / herself may forward protocol deviation / non- compliance / violation / waiver reports to IHEC within 7 days of occurrence in the prescribed format (SOP – V 1.0/ ANX 13).
4. The Secretariat can detect protocol deviation / non-compliance / violation from:
    - failure to comply with statutory requirements
    - not responding to requests from IHEC within reasonable time limit
    - not responding to communication made by IHEC
5. During site monitoring if conductof the project is not as per IHEC approved protocol study design / national / international regulations. The site monitoring team will inform the Secretariat in writing within 24 hours from the time of finding [one working day] violation. when scrutinizing annual / periodic reports / SAE reports
6. Communication received from the Investigator / trial site / sponsor /study monitor / CRO

7. Communication / complaint / information received by IHEC Secretariat from research participant who has been enrolled or any individual who has been approached for enrollment.

26.1. Categorization

Based on the risk involved the Member-Secretary will categorize the protocol violation / non-compliance / protocol deviation / waiver report/s for placing either in the expedited or full board review (SOP 04 – V 3.0). Reports on deviations involving major risk will be sent to the primary reviewer for comments.

26.2. Expedited review

Protocol violation / non-compliance / protocol deviation / waiver report/s categorized as expedited will be reviewed as per SOP Section 23.

26.3. Full Board Review

Full Board will review Protocol violation / non-compliance / protocol deviation / waiver report/sas per SOP Section 24.

26.4. Communicating the decision

i. Decision of the meeting on the proposals will be communicated by the Member Secretary/secretariat to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified ICMR format. All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.

ii. The communication letters shall be collected by the PI from IHEC office.

26.5. Filing of the Documents

Copies of the notification letter, protocol deviation / violation / non-compliance / waiver reports and the IHEC decision letter are placed in the protocol file and an additional copy of the notification letter in the “non-compliance’ file.

26.6. Post-review activities

Compliance report to be submitted by the PI within the specified time period as decided by the IHEC. The IHEC Secretariat will keep track of the reports. Reminders will be sent if no reports are received.

In case of suspension, IHEC will revoke the suspension after receipt of satisfactory compliance report from the PI.

In case a PI fails to respond to the IHEC letter, it will be discussed at the next full board meeting and a decision will be taken for specific action.

A separate file that identifies investigators who are found to be non-compliant with national / international regulations or who fail to follow protocol approval stipulations or fail to respond to the IHEC request for information/action is maintained and reviewed by the IHEC periodically.

Protocol Deviation – explanation:

If the deviation meets any of the following criteria, it is considered a protocol violation. Example list is not exhaustive.

I. The deviation has harmed or posed a significant or substantive risk of harm to the research subject.

Examples:

• A research subject received the wrong treatment or incorrect dose.

• A research subject met withdrawal criteria during the study but was not withdrawn.

• A research subject received an excluded concomitant medication.

II. The deviation compromises the scientific integrity of the data collected for the study.

Examples:

- A research subject was enrolled but does not meet the protocol's eligibility criteria.
- Failure to treat research subjects per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)
- Changing the protocol without prior IRB approval.
- Inadvertent loss of samples or data.

III. The deviation is a willful or knowing breach of human participant protection regulations, policies, or procedures on the part of the investigator(s).

Examples:

- Failure to obtain informed consent prior to initiation of study-related procedures
- Falsifying research or medical records.
- Performing tests or procedures beyond the individual's professional scope or privilege status (credentialing)

IV. The deviation involves a serious or continuing noncompliance with federal, state, local or institutional human participant protection regulations, policies, or procedures.

Examples:

- Working under an expired professional license or certification
- Failure to follow federal and/or local regulations, and intramural research or CC policies
- Repeated minor deviations.

V. The deviation is inconsistent with the NIH Human Research Protection Program's research, medical, and ethical principles.

Examples:

- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

27. Decision Making

i. Decision is arrived at by consensus, if consensus is not possible, voting is carried out.

ii. Opinions of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.

iii. Any committee member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

iv. Any subject expert - Independent Consultant who is attending the meeting will take part in discussion and offer their expert comment – but will not take part in decision making.

28. Follow up procedures

a. Reports should be submitted annually for review.

b. Final report should be submitted at the end of study.

c. All SAEs and the interventions undertaken should be intimated.

d. Protocol deviation, if any, should be informed with adequate justifications.

e. Any amendment to the protocol should be resubmitted for renewed approval.

f. Any new information related to the study should be communicated.

g. Premature termination of study should be notified with reasons along with Summary of the data obtained so far.

h. Change of investigators / sites should be informed.

29. Updating IHEC Members

All relevant new guidelines should be brought to the attention of the members.

i. All IHEC members must be conversant with the ICMR guidelines for research involving human participants, New Drugs and Clinical Trials Rules (2009), the Declaration of Helsinki and ICH-GCP guidelines (1964).

ii. IHEC members will also be provided with a copy of the Standard Operating Procedure.

iii. IHEC members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.

iv. A record will be maintained of the training obtained by IHEC members and updated annually.

v. IHEC members will receive introductory training in ethical aspects of biomedical researches and functioning of IHEC and will be exposed to ongoing opportunities for enhancing their capacity for ethical review. All training programs will be organized by the IHEC.

30. Policy to monitor or prevent the conflict of interest along with standard operating procedures:

i. It has been recognized that the potential for conflict of interest will always exist but has faith in the IHEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

ii. When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the HEC review or approval except to provide informationrequested by the Committee.

31. Annual report of the IHEC

Annual activity report (including details of study proposals received) should be prepared and submitted to the Chairman, CFC & RI and other relevant authorities.

32. Self-assessment

For continuous improvement of quality assurance of its services, the IHEC will undergo self-assessment once in 2 years or as and when required.

33. List of Annexures

1. Invite Letter for IHEC Members-Annexure-1
2. Membership Consent Letter-Annexure-2
3. One-page CV for EC Members/Investigators-Annexure-2 (a)
4. Appointment order-Annexure-3
5. List of members of IHEC-CFC&RI - Annexure-4
6. Confidentiality agreement form for IHEC Members-Annexure-5
7. Conflict of Interest agreement form for IHEC Members-Annexure-6
8. Minutes of Meeting-Annexure-7
9. Application Form for Initial Review-Annexure-8
10. Initial check list to verify completeness of documents submitted Form-Annexure-9
11. Evaluationform for Verification of proposals submitted to IHEC-CFC&RI-Annexure-10
12. Application Form for Expedited Review-Annexure-11
13. Application Form for Exemption from Review-Annexure-12
14. Continuing Review / Annual report format-Annexure-13
15. Application/Notification form for Amendments- Annexure-14
16. Protocol Violation/ Deviation Reporting form (Reporting by case) - Annexure-15
17. Serious Adverse Event Reporting format (Biomedical Health Research)-Annexure-16
18. Premature Termination/ Suspension/ Discontinuation Report Format-Annexure-17
19. Application for Clinical Trials-Annexure-18
20. Serious Adverse Event Reporting format (Clinical Trials)-Annexure-19
21. Application Form for Human Genetics Testing Research (Clinical Trials) -Annexure-20
22. Application Form for Socio-Behavioural and Public Health Research- Annexure-21
23. Study Completion / Final Report-Annexure-22
24. Format for Curriculum Vitae for Investigators-Annexure-23
25. Certificate of Approval-Annexure-24
26. Confidentiality and Conflict of Interest Agreement Form for Independent Consultants-Annexure-25
27. Confidentiality Agreement Form for Observer Attendees to IHEC, CFC & RI Meetings-Annexure-26
28. Format for Communication to the Principal Investigator-Annexure-27
29. Six monthly progress Project-Annexure-28
30. Template for Participant Information Sheet (PIS) Participant Information Sheet-Annexure-29
31. Participant Informed Consent Form (PICF)-Annexure-30
32. Consent form (for participants less than 18 years of age) Parent/ Legally accepted representative (LAR)-Annexure-30 (a)
33. Undertaking by the Principal Investigator-Annexure-31
34. Intimation of start of the study-Annexure-32
35. Investigator's Declaration-Annexure-33
36. Letter of Authorization-Annexure-34

34. Bibliography / References:

1. Institutional Human Ethics Committee. Standard Operating Procedures, ICMR-National Institute of Epidemiology, Chennai. [Version 02.1, 10th November 2017]
2. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research. [Cited October 2017]
3. ICMR. Ethical Guidelines for Biomedical research on Human Participants. New Delhi: Indian Council of Medical Research; 2006. [cited 2012 July 24].
4. CDSCO. Good Clinical Practice for Clinical Research in India. Central Drugs Standard Control Organization. [cited 2012 Jul 24].
5. World Medical Association. Declaration of Helsinki. [cited 2012 July 24].
6. Draft Guidelines on Reporting Serious Adverse Events, Central Drugs Standard Control Organization, New Delhi. [cited 11-05-2011]
7. Tata Memorial Centre. Standard Operating Procedures. Human Ethics Committee, Tata Memorial Centre, Mumbai. [cited 2012 July 24]
8. PSG Institute of Medical Sciences & Research Standard Operating Procedures. Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research, Coimbatore. [cited 2017 December 15].
9. Chettinad academy of research and education. Standard operating procedures. Institutional Human Ethics Committee, Chettinad Academy of Research and Education, Kelambakkam. [cited 2017 October 27].
10. Indira Gandhi Institute of Medical Sciences. Standard Operating Procedures. Human Ethics Committee, Patna. [cited 2013 December 12].
11. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,Oviedo [cited 1997].
12. Indian Institute of Science. Standard Operating Procedures. Human Ethics Committee, Bangalore. [cited 2010 August 01].
13. Operational Guidelines for Ethics Committees That Review Biomedical Research. World Health Organization, Geneva. [cited 2000].
14. Standard operating procedure for Institutional Ethical Committee. Mandya Institute of Medical Sciences, Mandya. [Version: 1.0 / dated: 12.08.2015].
15. SOP on General Functioning of Institutional Human Ethics Committee. Sri Balaji Vidyapeeth Deemed University, Pondicherry. [revised version 01-November 2017]
16. WHO. Handbook for Good Clinical Research Practice. [cited 2012 Jul 24].

CFC

CHENNAI FERTILITY CENTER

Annexures

Invite Letter for IHEC Members

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Date:_____

Lr.No.CFC&RI/IHEC/_____ /_____

From

The Chairman
CFC & RI
Chennai-600029

To

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

Dear Sir / Madam

On behalf of Chennai Fertility Centre and Research Institute, I invite you to join our Institutional Human Ethics Committee (IHEC), in this regard I request your concurrence for appointment as a member in the same. Membership tenure will be for 3 years. Kindly send your consent in the enclosed format and provide the necessary information requested.

Yours sincerely
Signature:
Name:

(Annexure 2)

Membership Consent Letter

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

From

To

The Chairman,
Chennai Fertility Centre& Research Institute
Chennai-600029

Sub: Consent to be a member of Institutional Ethics Committee (Human Studies)- Reg

Ref: Your Letter No: **Dated:**

Dear Sir/ Madam,

In response to your letter stated above, I give my consent to become a member of IHEC of CFC&RI, Chennai. I shall regularly participate in the IHEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

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 here with enclose my latest CV with date and signature.

Thanking you,

Yours sincerely
Signature:
Name:

Name: _____ **Telephone Number:**_____

Email Address: _____

(Annexure 2(a))

One-page CV for EC Members/Investigators

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Last Name	First Name	Middle Name
Date of Birth (dd/mm/yy):		Sex:
Professional Mailing Address (Include Institution name)		Permanent Address:
Telephone (Office):		Mobile Number:
Telephone (Residence):		Email:

Academic Qualifications (Most recent qualification first)		
Degree/Certificate	Year	Institution, Country

Current and previous positions (most recent position first)		
Month and Year	Title	Institution/Company, Country

Brief summary of relevant research experience:

Training records*: GCP ☐ Research Ethics ☐ Any others ☐

Kindly attach the certificates of the same.

Signature:	Date:
	Place:

Appointment Order

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Date:_____

Dr/ Mr. / Mrs.:_____

I am pleased to appoint you as..... of the Institutional Human Ethics Committee (IHEC) (Human Studies) at Chennai Fertility Centre&Research Institute, Chennai w.e.f..... for a term of.....year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.

2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.

3. You consent to sign confidentiality agreement between you & the IHEC regarding meeting deliberations, applications, information on research participants, & related matters. The renewal of your appointment will be by consensus & 1-month notice will be necessary prior to resignation of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IHEC, CFC & RI, Chennai.

You will be paid a sum of Rs.1000/- per sitting as Honorarium for your services rendered & as per the guidelines given in Terms of Reference-IHEC, CFC & RI.

We sincerely hope your association with IHEC, CFC & RI, Chennai will be fruitful to the Institute & the Community we serve.

Signature of Appointee

(Annexure 4)

List of members of IHEC-CFC&RI

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

The Institutional Human Ethics Committee is constituted as per CFC & RI guidelines with the following members The tenure of the members will be three years from _____

S.No.	Name of the Member of IHEC	Area of Expertise	Affiliated to CFC & RI or not	Sex
1	Chairperson		Non-Affiliated	
2	Member-Secretary		Affiliated	
3		Clinician		
4		Basic Medical scientist		
5		Pharmacologist		
6		Scientific member		
7		Legal expert		
8		NGO Representative		
9		Lay person	Non-Affiliated	

Confidentiality agreement form for IHEC members

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

In recognition of the fact, that I, Dr./Mr./Ms..... herein referred to as the "Undersigned", has been appointed as a member of the Institutional Human Ethics Committee (IHEC), would be asked to assess research studies involving Human Study Participants in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the IHEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IHEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IHEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of Human Study Participants;

The undersigned, as a member of the IHEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IHEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IHEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that my performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality / Non-Disclosure Agreement

In the course of my activities as a member of the IHEC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr./Mr./Ms./Master ..... have read and I accept the aforementioned terms and conditions as explained in this agreement.

Signature

Date

Chairperson, IHEC

Date

2 / 2

(Annexure 6)

Conflict of Interest agreement form for IHEC members

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

In recognition of the fact, that I, Dr./Mr./Ms. ..... herein referred to as the "Undersigned", has been appointed as a member of the Institutional Human Ethics Committee (IHEC), would be asked to assess research studies involving Human Study Participants in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the IHEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IHEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IHEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of Human Study Participants;

The undersigned, as a member of the IHEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

It has been recognized that the potential for conflict of interest will always exist but has faith in the IHEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of Human Study Participants.

In accordance of the policy of the IHEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IHEC.

Signature :_____ Date : _____

The Undersigned will immediately disclose to the Chairperson of the IHEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IHEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IHEC member(s) in question. The committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IHEC review or approval except to provide information requested by the Committee. Examples of conflict of interest cases may be any of the following

A member is involved in a potentially competing research program.

Access to funding or intellectual information may provide an unfair competitive advantage.

A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

In the course of my activities as a member of the IHEC, whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting. I, Dr./Mr./Ms. ..... have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Signature

Date

Chairperson, IHEC CFC & RI

Date

IHEC Ref. No. (For office use):_____

i. Welcome note by the Member-Secretary
ii. Introduction of members
iii. Remarks by Chairperson
iv. Quorum requirement to be ensured
v. Confidentiality agreement to be signed by non-IHEC members, if present
vi. Appointment of new / resignation by IHEC members, if any
vii. Declaration of Conflict of Interest, if any, by the members

Items for discussion

1. Ratification of minutes of the meeting held on _____
2. Ratification of amendment to IHEC SOP Version _____, if any
3. Ratification of proposals reviewed in the expedited review meeting(s) held on _____ (Annexure I)
4. Ratification of proposals exempted from review (Annexure II)
5. Review of Serious Adverse Events (SAEs)
6. Projects for initial review:

Project No.

Date Received	Principal Investigator	Co-investigators	Primary Reviewers
Title:			

7. Proposals for Continuing review:

Project No.

Date Received	Co-Investigators	Primary Reviewers	Co-Investigators
Title:			

8. Deviations/Violations

Project No.	Principal Investigator	Patient ID	No of Deviations (D) / Violations (V) / Waivers (W)	Date of occurrence	Date of Deviations/ Violence/ Waivers submitted.
Title:					

9. Amendments:

Date Received	Principal Investigator	Co-investigators	Primary Reviewers
Title:			
Discussion on:			

10. SAEs:

Proposal No.	Principal Investigator	No of SAEs		Letter Date	Comments by the IC (SAEs)
		On site	Off site		

11. Study Closures:
Project No.

Date Received	Principal Investigator
Title:	
PI's letter dated:	

12. Notifications:
a. Payment of Participants
Project No.

Date Received	Principal Investigator
Proposal:	
Payment list of travel allowance given to patients – PI's letter dated:	

13. Any other matter will be discussed with the permission of the Chair.

Member Secretary
Institutional Human Ethics Committee

(Annexure 8)

Application Form for Initial Review

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

General Instructions: a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A – BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of the organization :_____

(b) Name of the Ethics Committee :_____

(c) Name of Principal Investigator :_____

(d)Department/Division :_____ (e) Date of submission :____ /_____ /_____

(f) Type of review requested[1]:

Exemption fromreview ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study :_____

_____

_____

Acronym/Shorttitle,(Ifany) :_____

(h) Protocol number (Ifany) :_____ Version number :_____

(i) Details ofInvestigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator			
Co-investigator			
Student/Fellow/Guide			

(j) Number of studies where applicant isa:

i) PrincipalInvestigatorattimeofsubmission ii) Co-Investigator at time ofsubmission:

_____

(k)Duration of the study

1. Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review.
2. Include telephone/mobile, fax numbers and email id

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site : _____

At site _____ In India _____ Globally _____

(b)Self-funding ☐ Institutional funding ☐ Funding agency (Specify) ☐

_____

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a)Lay summary[3] (within 300 words): : _____

_____

_____

_____

_____

_____

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological	☐	Case Control	☐
Prospective	☐	PublicHealth	☐	Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples/Data	☐		
Mixed Method	☐	Any others(Specify)	☐		

_____

4. METHODOLOGY

Sample size/ number of participants(as applicable) : _____

At site _____ In India _____ Globally _____

Control group _____ Study group _____

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation

_____

_____

_____

_____

_____

_____

[3]Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.

(a) Is there an external laboratory / outsourcing involved for investigations?[4] Yes ☐ No ☐ NA ☐

(b) How was the scientific quality of the study assessed?

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre ☐ No review ☐

Research group

Date of review:

Comments of scientific committee, if any (100 words)

_____

_____

_____

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

a) Type of participants in thestudy:

Healthyvolunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ (Specify) _____

Who will do the recruitment? _____

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radioads/ Social media/ Institutionwebsite ☐ Patients / Family/ Friends visiting hospitals ☐ Telephone ☐

Others ☐ (Specify) _____

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally ill (stigmatized or rare diseases) ☐

Anyother(Specify): ☐

iii. Provide justification for inclusion/exclusion

iii. Provide justification for inclusion/exclusion

_____

iv. Are there any additional safeguards to protect research participants?

_____

_____

4If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU

(c) Is there any reimbursement totheparticipants? Yes ☐ No ☐

If yes,Monetary ☐ Non-monetary ☐ Provide details

(d) Are there any incentives totheparticipants? Yes ☐ No ☐

If yes,Monetary ☐ Non-monetary ☐ Provide details

(e) Are there any participant recruitment fees/incentives for the study provided to the PI/Institution? Yes ☐ No ☐

If yes,Monetary ☐ Non-monetary ☐ Provide details

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical / social / psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5]:

Less than Minimal risk ☐ Minimalrisk ☐

Minor increase over minimal risk or lowrisk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy:

(b) What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks

(c) Are adverse events expected in the study[6]? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify

7. INFORMEDCONSENT

(a) Are you seeking waiver of consent? If yes, please specify reason sand skip to item no Yes ☐ No ☐

[5]For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1

[6]The term adverse events in this regard encompass both serious and non-seriousadverseevents

(b) Version number and date of Participant Information Sheet (PIS)_____

Version number and date of Informed Consent Form (ICF):_____

(c) Type of consent planned for:

Signed consent ☐ Verbal / Oral consent ☐ Witnessed consent ☐ Audio-Video(AV) consent ☐

Consent from LAR (If so, specify fromwhom) ☐ For children<7yrs parental/LAR consent ☐ Verbal assent from inor (7-12 yrs) along with parental consent ☐ Written assent from minor (13-18 yrs) along with parental consent ☐

Other (specify)_____

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ (Specify)_____

Any tool stobe used_____

(e) Participant Information Sheet (PIS) and Informed Consent Form(ICF)

English ☐ Local language ☐ Other ☐ (Specify)_____

List the languages in which translations were done_____

If translation has not been done, please justify_____

_____

(f) Provide details of consent requirements for previously stored samples if used in the study[7]

_____

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form(ICF)

Simple language ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐
Alternatives to participation Right to withdraw ☐	Confidentiality ☐	Commercialization/ Benefit sharing ☐
	Storage of samples ☐	Statement that study involves research ☐
Benefits ☐	Return of research results ☐	Use of photographs/ Identifying data ☐
Purpose and procedure ☐	Payment for participation ☐	Contact information of PI and Member Secretary of EC ☐
Others (Specify) ☐		

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures [8]?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ (specify)

_____

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ NA ☐

If yes, then who will provide the treatment?_____

(c) Is there a provision for compensation of research related SAE?

Sponsor Institutional/Corpus fund Project grant Insurance

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ NA ☐

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ NA ☐

[7]Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section5.8. | [8]Enclose undertaking from PI confirming the same.

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. If Yes, specify Yes ☐ No ☐ NA ☐

Anonymous/ Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded?

(e.g. data stored in a cabinet, password protected computer etc.) _____

_____

(b) Who will be maintaining the data pertaining to the study? _____

(c)Where will the data be analyzed[9] and by whom? _____

(d) For how long will the data be stored? _____

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material data in the future? _____

_____

_____

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

_____

_____

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the studyhasfinished? Yes ☐ No ☐ NA ☐

If yes describe in brief (Max 50 words) _____

_____

_____

(d) Is there any plan for postre search benefits haring with participants? If yes, specify Yes ☐ No ☐ NA ☐

_____

_____

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐ NA ☐

_____

_____

(f)Do you have any additional information to add in support of the application, which is not included else where in the form? If yes,provide details. Yes ☐ No ☐ NA ☐

_____

_____

_____

_____

9 For example, a data entry room,a protected computer etc.

SECTION E: DECLARATION AND CHECKLIST[10]

11. DECLARATION (Please tick as applicable)

	I/We certify that the information provided in this application is complete and correct.
	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
	I/We confirm that this study will be conducted inaccordance with the latest ICMR National Ethical Guidelines forBiomedicaland Health Research Involving Human Participants and other applicable regulations and guide- lines.
	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
	I/Wewillcomplywithallpoliciesandguidelinesoftheinstituteandaffiliated/collaboratinginstitutionswhere this study will beconducted.
	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
	I/We declare that the expenditure in case of injury related to the study will be taken care of.
	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
	I/We have the following conflict of interest (PI/Co-I): 1..... ..... 2..... .....
	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: _____

Signature: _____ dd mm yyyy

Name of Co-PI: _____

Signature: _____ dd mm yyyy

Name of Guide: _____

Signature: _____ dd mm yyyy

Name of HOD: _____

Signature: _____ dd mm yyyy

10These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements
Acknowledgement for Receipt of Application (Copy to be provided to PI)

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter					
	Brief CV of all Investigators					
	Good Clinical Practice (GCP) training of investigators in last 3 years					
	Approval of scientific committee					
	EC clearance of other centers*					
	Agreement between collaborating partners*					
	MTA between collaborating partners*					
	Insurance policy/certificate					
	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification					
	Copy of contract or agreement signed with the sponsor or donor agency					
	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authoritiesforproposedstudy (whetherinsamelocationorelsewhere) and modification(s) toprotocol					
PROPOSAL RELATED						
	Copy of the detailed protocol11					
	InvestigatorsBrochure(Ifapplicablefordrug/biologicals/ devicetrials)					
	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)					
	Assent form for minors (12-18 years) (English and Translated)					
	Proforma/Questionnaire/CaseReportForms(CRF)/ Interviewguides/ GuidesforFocusedGroupDiscussions(FGDs) (Englishandtranslated)					
	Advertisement/material to recruit participants (fliers, posters etc)					

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
	CTRI					
	DCGI					
	HMSC					
	NAC-SCRT					
	ICSCR					
	RCGM					
	GEAC					
	BARC					
	Tribal Board					
	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks

*For multicentre research

MTA-Materialtransferagreement;CTRI-ClinicalTrialRegistry-India;DCGI-DrugControllerGeneralofIndia;HMSC-HealthMinistry'sScreeningCommittee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic ResearchCentre

11Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

Initial Check list to verify completeness of documents submitted Form-IHEC-CFC&RI

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

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 Email
2. Proforma and consent forms (English) matching with those given in IHEC, CFC & RI website
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 XIX and XIX (a) in both English language and the local language (Tamil)
6. Complete address and phone number of the investigator/guide provided in the appropriateplace in consent form Annexure XIX
7. Appropriate Consent form Annexure XIX (a) enclosed for adults and children (less than 18 years)

(Annexure 10)

Evaluationform for Verification of proposals submitted to IHEC-CFC&RI

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

	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?				
6. Have adequate provisions been made or 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?				

	Yes	No	NA	Comments
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 any time 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 ?				
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 an\ 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

(Annexure 11)

Application Form for Expedited Review

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Choose reasons why expedited review from EC isrequested12?

i. Involvesnon-identifiablespecimenandhumantissuefromsourceslikebloodbanks,tissuebank sand left-over clinical samples. ☐

ii. Involvesclinicaldocumentationmaterialsthatarenon-identifiable(data,documents,records). ☐

iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐

iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐

v. Min ordeviation from originally approved researchcausing no risk or minimal risk. ☐

vi. Progress/annualreportwherethereisnoadditionalrisk,forexampleactivitylimitedtodataanalysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐

vii. For multi centre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committeemeeting/expedited review depending on the importance of local consent related issues involved specific to thecentre. ☐

viii. Researchduringemergenciesanddisasters(SeeSection12ofICMREthicalGuidelines,2017). ☐

ix. Any other (please specify)_____

_____

2. Is waiver of consentbeingrequested? Yes ☐ No ☐

3. Does the research involve vulnerablepersons13? Yes ☐ No ☐

If Yes give details: _____

_____

Signature of PI: _____ dd mm yyyy

Comments of EC Secretariat: _____

Signature of Member Secretary: _____ dd mm yyyy

[13]For details, refer to application for initial review, Section-C, 5(b)

* In case this is first submission, leave it blank

(Annexure 12)

Application Form for Exemption from Review

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Choose reasons why exemption from ethics review is requested[14]?

i. Research on data in the public domain/ systematic reviews ormeta-analyses ☐

ii. Observation of public behavior/information recorded without linked identifier sand disclosure would not harm the interests of the observed person ☐

iii. Quality control and quality assurance audits in the institution ☐

iv. Comparison among instructional techniques, curricula, or classroom management methods ☐

v. Consumer acceptance studies related to taste and food quality ☐

vi.Publichealthprogrammesbygovernmentagencies15 ☐

vii. Any other (please specify in 100 words): _____

_____

_____

_____

_____

Signature of PI: _____ dd mm yyyy

Comments of EC Secretariat: _____

Signature of Member Secretary: _____ dd mm yyyy

[14]Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.

[15]Such as program me evaluation where the sole purpose of the exerciseis refinement and improvement of the programme or monitoring (wherethereare no individualidentifiers)

(Annexure 13)

Continuing Review / Annual report format

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Date of ECApproval: dd mm yyyy Validity of approval: dd mm yyyy

2. Date of Start of study: dd mm yyyy Proposed date of Completion: dd mm yyyy

Period of Continuing Report: dd mm yyyy ---- to ------ dd mm yyyy

3. Does the study involve recruitment of participants?

(a) If yes,Total number expected _____ Number Screened: _____ Number Enrolled: _____

Number Completed _____ Number on followup _____

(b) Enrolment status – ongoing / completed/stopped

(c) Report of DSMB[16] Yes ☐ No ☐ NA ☐

(d) Any other remark _____

_____

(e)Have any participants with drawn from this study since the last approval? Yes ☐ No ☐ NA ☐

If yes, total number with drawn and reasons: _____

_____

_____

4. Is the study likely to extend beyond the stated period?[17] Yes ☐ No ☐

If yes, please provide reasons for the extension _____

_____

_____

5. Have there been any amendments in there search protocol/Informed Consent Document (ICD) during the past approval period? Yes ☐ No ☐

If No, skip to item no.6

(a) If yes,date of approval for protocol and ICD: dd mm yyyy

(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No ☐

If yes, when / how:_____

_____

16In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.
17Problemsencounteredsincethelastcontinuingreviewapplicationwithrespecttoimplementationoftheprotocolaslearedby theEC

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6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐

fyes,discussindetail: _____

_____

_____

7. Have any ethical concerns occurred duringthisperiod? Yes ☐ No ☐

If yes, give details: _____

_____

_____

8. (a) Have any adverse events been noted since thelast review? Yes ☐ No ☐

Describe in brief: _____

_____

_____

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number ofSAE's _____ Type of SAE's: _____

_____

_____

(c) Is the SAE related tothe study? Yes ☐ No ☐

Have you reported the SAE to EC? If no,statereasons Yes ☐ No ☐

_____

_____

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations _____

Have you reported the deviations to EC? If no,statereasons Yes ☐ No ☐

_____

_____

10. Incase of multi centerictrials, have reportsofoff-siteSAEs been submitted to the EC? Yes ☐ No ☐ NA ☐

11. Is there any change in investigators/co-investigators? Yes ☐ No ☐

If yes, give details _____

12. Are there any publications or presentations during this period? Yes ☐ No ☐
If yes give details

_____

_____

Any other comments:

_____

Signature of PI: _____ dd mm yyyy

(Annexure 14)

Application/ Notification form for Amendments

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Date of ECapproval: dd mm yyyy Date of start of study dd mm yyyy

2. Details ofamendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD 18

3. Impact onbenefit-riskanalysis Yes ☐ No ☐

If yes, describe in brief:_____

_____

4. Is any reconsent necessary? Yes ☐ No ☐

Ifyes,havenecessarychangesbeenmadeintheinformedconsent? Yes ☐ No ☐

5. Type of review requested foramendment:

Expedited review (No alteration in risktoparticipants)

FullreviewbyEC(Thereisanincreasedalterationintherisktoparticipants)

6. VersionnumberofamendedProtocol/Investigator'sbrochure/ICD: _____

Signature of PI: _____ dd mm yyyy

[18]Location implies page number in the ICD/protocol where the amendment is proposed.

(Annexure 15)

Protocol Violation/ Deviation Reporting form (Reporting by case)

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Date of ECapproval: dd mm yyyy Date of start of study dd mm yyyy

2. ParticipantID: _____ Date of occurrence dd mm yyyy

3. Total number of deviations /violations reported till date in the study: _____

4. Deviation/Violation identified by: Principal Investigator/studyteam ☐ Sponsor/Monitor ☐

SAESubCommittee/EC ☐

5. Is the deviation related to (Ticktheappropriatebox):

Consenting	☐	Sourcedocumentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participantnon-compliance	☐
Investigational Product	☐	Others(specify)	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation: _____

_____

_____

_____

7. Corrective action taken by PI/Co-I:

_____

_____

_____

8. Impact on (if any): Study participant ☐ Quality of data ☐

9. Areanychangestothestudy/protocolrequired?

If yes, givedetails_____

_____

_____

Signature of PI: _____ dd mm yyyy

(Annexure 16)

Serious Adverse Event Reporting format (Biomedical Health Research)

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Participant details :

Initials and ID	Age at the time of event	Gender	Weight: ..... (Kgs)
_____	_____	Male ☐ Female ☐	Height: .....(cms)
_____	_____		

2. Suspected SAE diagnosis :

3. Date of onset of SAE: dd mm yyyy

Date of reporting SAE: dd mm yyyy

Describe the event [19]:

_____

_____

_____

_____

_____

4. Details of suspected intervention causing SAE [20]

_____

_____

_____

_____

_____

_____

5. Report type:Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initialreport dd mm yyyy

6. Have any similar SAE occurred previously in this study? If yes,please provide details

_____

_____

_____

_____

_____

_____

[19]Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious

[20]Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)

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7. Incase of a multi-centric study,have any of the other study sites reported similar SAEs?
(Please list number of cases with details if available)

8. Tick which ever is applicable for the SAE:(Kindly note that this refers to the Intervention being evaluated and NOT diseaseprocess)

A. Expectedevent ☐ Unexpected event ☐

B. Hospitalization ☐ Increased Hospital Stay ☐ Death ☐ Congenital anomaly/ birth defect ☐

Persistent or significant disability/ incapacity ☐ Event requiring intervention (surgical or medical) to prevent SAE ☐ Event which poses threat to life ☐ Others ☐

Incase of death, state probable cause of death

C. No permanent/significant functional/cosmetic impairment ☐
Permanent/significant functional/cosmetic impairment ☐
Not Applicable ☐

9. Describe the medical management provided for adversere action (if any) to the research participant. (Include informationon who paid, how much was paid and to whom).

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom)

11. Outcome ofSAE

Fatal ☐ Recovered ☐
Continuing ☐ Unknown ☐
Recovering ☐ Other(specify) ☐

12. Provide any other relevant information thatcan facilitate assessment of the case such as medical history

13. Provide details about PI's final assessment of SAE relatedness to research.

Signature of PI: dd mm yyyy

(Annexure 17)

Premature Termination/ Suspension/Discontinuation Report Format

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Date of ECapproval: dd mm yyyy Date of start of study dd mm yyyy
2. Date of last progress report submitted to EC: dd mm yyyy
3. Date of termination/suspension/discontinuation: dd mm yyyy
4. Tick the appropriate

Premature Termination ☐ Suspension ☐ Discontinuation ☐

Reason for Termination/Suspension/Discontinuation _____

_____

_____

_____

Action taken post Termination/Suspension/Discontinuation (if any): _____

_____

_____

_____

5.Plans for post study followup/withdrawal 21 (ifany): _____

_____

_____

_____

6. Details of study participants:

Total participants to be recruited:_____ Screened:_____ Screen failures: _____

Enrolled: _____ Consent Withdrawn: _____ Reason (Givedetails): _____

_____

_____

Withdrawn byPI:_____ Reason (Give details): _____

21 Describe post-termination/suspension/discontinuation follow up plans if any. Also describe any withdrawal plans for the study.

Active on treatment: _____ Completed treatment: _____ Participants on follow-up: _____

Participants lost to follow up: _____ Any other: _____ Number of drop outs: _____

Reasons for each drop-out: _____

7. Total number of SAEs reported till date in the study

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes ☐ No ☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐

If yes, provide details: _____

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No ☐

If yes, have you implemented that suggestion? Yes ☐ No ☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No ☐

11. (e.g.,making arrangements for medical care of research participants):If Yes, provide details Yes ☐ No ☐

Summary of results (if any) _____

Signature of PI: _____ dd mm yyyy

(Annexure 18)

Application Form for Clinical Trials

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Type ofclinicaltrial Regulatory trial ☐ Academictrial ☐

CTRI registration number:_____ NABH accreditation number:_____ EC registration number:_____

2. If regulatory trial, provide status of CDSCO permission letter

Approved and letter attached ☐ Applied, under process ☐

Not applied (State reason) ☐ _____

3. Tick all categories that apply to your trial

Phase–I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational Newdrug	☐
Medical devices	☐	New innovativeprocedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalencestudies	☐
Non-drug intervention	☐	Repurposing an existingintervention	☐
Indian system of medicine (AYUSH)	☐	Stemcells	☐
Phytopharmaceutical drug	☐	Approved drug for any newindication or new route of administration	☐
Others (specify)	☐		☐

_____

4. Trial design of the study

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Others (specify)	☐	Equivalence trial	☐

_____

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

_____

_____

III. Describe the method of allocation concealment (blinding/masking), if applicable.

_____

_____

5. List the primary/secondary outcomes of the trial.

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation / human resource?

If yes, Name and Contact details:

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others (specify)	☐

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device / sand / or biologics; if yes, provide regulatory approval details. Yes ☐ No ☐ NA ☐

II. Already approved drugs or acombination of two or more drugs with new indications / change in dosage form/ route of administration. Yes ☐ No ☐ NA ☐

If yes, provide details.

III.Provide contact details of who prepared and / or is manufacturing the drug/s, device / sand biologics.

IV. Provide details of patent of the drug/s, device / sand biologics.

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, provide details (100words)

9. Is there an initial screening/use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details 22 _____

10. Is there any anticipated incidence, frequency and duration of Adverse events related to the intervention? Yes ☐ No ☐ NA ☐

If yes, provide details of arrangements made to address them. _____

11. Does the study use a placebo? Yes ☐ No ☐ NA ☐

If yes, justify the use of the placebo and risks entailed to participants. _____

12. Will current standard of care be provided to the control armin the study? Yes ☐ No ☐ NA ☐

If no, please justify. _____

13. Are there any plans to withdraw standard therapy during the study? Yes ☐ No ☐ NA ☐

If yes, please justify. _____

14. Are there any rules to stop the protocolin case of any adverse events ? Yes ☐ No ☐ NA ☐

If yes, please specify. _____

15. Does the study have a Data and Safety Monitoring Plan ? Yes ☐ No ☐

If no, please justify _____

22 In order to select participants for your protocol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same

16. Participant Information Sheet(PIS) and Informed Consent Form(ICF)

English ☐ Local language ☐

Other (Specify) ☐ (certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

List the languages in which translations were done

Justify if translation not done _____

17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Is there any insurance coverage of the trial ? Yes ☐ No ☐

If yes, provide details. _____

I. Is the PI registered with Medical Council of India(MCI) or the State Medical Council registration? Yes ☐ No ☐

Please provide details. _____

II. Is the PI trained in GCP in last 3 years? Yes ☐ No ☐

If yes, Please enclose certificate _____

Signature of PI: _____ dd mm yyyy

(Annexure 19)

Serious Adverse Event Reporting format (Clinical Trials)

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Participant details :

Initials and Case No./ Subject ID	Age at the time of event	Gender	
_____	_____	Male ☐	Weight: ..... (Kgs)
_____	_____	Female ☐	Height: ..... (cms)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yyyy

What was the assessment of relatedness to the trial in the initial report?

By PI–Related ☐	By Sponsor – Related ☐	ByEC – Related ☐
Unrelated ☐	Unrelated ☐	Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis: _____

_____

_____

4. Date of onset of SAE: dd mm yyyy Date of reporting: dd mm yyyy

5. On set lag time after administration of intervention: _____ Location of SAE(Clinic/Ward/Home/Other) _____

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name)device/intervention: _____

_____

II. Indication(s) for which suspect study drug was prescribed or tested: _____

_____

III. Route(s) of administration, daily dose and regimen, dosage form and strength: _____

_____

IV. Therapy start date :_____

_____

7. Was study intervention discontinued due to event? Yes ☐ No ☐

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8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

If yes, provide details about the reduced dose _____

9. Did the reaction reappear after reintroducing the study drug/procedure ? Yes ☐ No ☐ NA ☐

If yes, provide details about the dose _____

10. Concomitant drugs history and lab investigations: dd mm yyyy

I. Concomitant drug (s) and date of administration:

_____

II. Relevant test/laboratory data with dates:

_____

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

_____

11. Have any similar SAE occurred previously in this study ? Yes ☐ No ☐

If yes, please provide details. _____

_____

12. Seriousness of the SAE:

Death	☐	Congenitial anamoly	☐
Life threatening	☐	Required intervention to prevent	☐
Hospitalization-initial or prolonged	☐	permanent impairment/damage	☐
Disability	☐	Others (specify)	☐

_____

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include in formation on who paid, how much was paid and to whom).

_____

14. Outcome ofSAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other (specify)	☐

_____

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

_____

_____

17. Has this information been communicated to sponsor/ CRO/ regulatory agencies? Yes ☐ No ☐

Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol ? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants
(Include information on who pays, how much, and to whom)

_____

Signature of PI: _____ dd mm yyyy

(Annexure 20)

Application Form for Human Genetics Testing Research (Clinical Trials)

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

Principal Investigator (Name, Designation and Affiliation):_____

1. Describe the nature of genetic testing research being conducted.
(e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

2. Does the study involve pre-test and post-test counseling? If yes, please describe. Yes ☐ No ☐ NA ☐

3. Explain the additional safe guards provided to maintain confidentiality of data generated.

4. If there is a need to share the participants' information/ investigations with family/community, is it addressed in the informed consent? Yes ☐ No ☐ NA ☐

   If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐

   If yes, will informed consent be obtained ? State reasons if not. Yes ☐ No ☐ NA ☐

6. What measures are taken to minimize/mitigate/eliminate conflict of interest?

7. Is there a plan for future use of stored samples for research? Yes ☐ No ☐

   If yes, has this been addressed in the informed consent? Yes ☐ No ☐

Signature of PI: _____ dd mm yyyy

(Annexure 21)

ApplicationForm for Socio-Behavioural and Public Health Research

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

Principal Investigator (Name, Designation and Affiliation):_____

1. Data collection method used in the study

Focus group ☐	Questionnaire / Survey ☐	Observation ☐
Interviews ☐	Documents and records ☐	Ethnographies/Oral history/Case studies ☐

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies.

2. Type of informed consent used in the study

Individual consent Gate-keeper consent Community consent

Others (specify) _____

3. Provide details of safe guards to ensure privacy and confidentiality of participants in the event of data sharing.

4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and Participant recruitment ? Yes ☐ No ☐

6. Is there a use of an interpreter ? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

II. Justify reasons if individual harm is over riding societal benefit.

III. Describe how do societal benefits out weigh individual harm.

9. Does the study use incomplete disclosure or active deception or authorized deception?

If yes, provide details and Rationale for deception.

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Signature of PI: dd mm yyyy

(Annexure 22)

Study Completion / Final Report

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

Title of study:_____

_____

_____

Principal Investigator (Name, Designation and Affiliation):_____

_____

_____

1. Date of ECapproval: dd mm yyyy

2. Date of start of study: dd mm yyyy Date of study completion: dd mm yyyy

3. Provide details of:

a) Total number of study participants approved by the EC for recruitment:_____

b)Total number of study participants recruited:_____

c) Total number of participants with drawn from the study (if any):_____

Provide the reasons for withdrawal of participants [23]:_____

_____

_____

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)

_____

_____

5. Describe the main ethical issues encountered in the study (if any)

_____

_____

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

Deviations:_____ Violation:_____ Amendments:_____

7. Describe in brief plans for archival of records/record retention:_____

_____

_____

_____

_____

[23] Explanation for the withdrawal of participants whether by self or by the PI

8. Is there a plan for post study follow-up? Yes ☐ No ☐

If yes, describe in brief: _____

9. Do you have plans for ensuring that the data from the study can be shared / accessed easily? Yes ☐ No ☐ If yes,

If yes, describe in brief: _____

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No ☐

If yes, describe in brief: _____

11. Describe results (summary) with Conclusion [24]: _____

12. Number of SAEs that occurred in the study: _____

13. Have all SAEs been intimated to the EC? Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants ?

If yes, provide details _____

Signature of PI: _____ dd mm yyyy

[24] For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.

(Annexure 23)

Format for Curriculum Vitae for Investigators

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Name:	
Present affiliation (Job title, department, and organisation):	
Address (Full work address):	
Telephone number:	Email address:
Qualifications:	
Professional registration (Name of body, registration number and date of registration):	
Previous and other affiliations (Include previous affiliations in the last 5 years and other current affiliations):	
Projects undertaken in the last 5 years:	

Relevant research training/experience in the area[25]:	
Relevant publications (Give references to all relevant publications in the last five years):	
Signature	Date:

25 Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training

(Annexure 24)

Certificate of Approval

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

Project no: **Date:**

The IHEC of Chennai Fertility Centre and Research Institute has considered and approved the above project at the meeting held on_____, under the following terms and conditions:

- This approval is valid for three years or duration of the project whichever is less.
- Any serious adverse event occurring during the course of the study should be reported to IHEC within a period of 24 hours.
- A yearly progress report of the project has to be submitted to the IHEC for review.
- Any change in the study procedure / site /investigator should be informed to them IHEC.

Chairman

Member secretary

Confidentiality and Conflict of Interest agreement form for Independent Consultants

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

I, Dr./Mr./Ms. ..... (Name and Designation) as a non-member of IHEC understand that the copy (ies) given to me by the IHEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IHEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IHEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Agreement on Conflict of Interest

In the course of my activities as an Independent Consultant of the IHEC, whenever I have a conflict of interest, I shall immediately inform the committee about it and / or shall refrain from giving my expert comments on the project on this ground.

I, Dr./Mr./Ms. ..... have read and I accept the a fore mentioned terms and conditions as explained in this Agreement.

Signature

Date

Chairperson of IHEC

Date

I, Dr./Mr./Ms. ..... (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IHEC and me.

Signature of the recipient Date

Confidentiality Agreement Form for Observer Attendees to IHEC, CFC&RI Meetings

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

I, Dr./ Mr. / Ms. _____, understand that I am allowed to attend the IHEC meeting scheduled on _____ at _____ am / pm as an observer.

I understand that I should not take part in the discussions or decision-making process during the meeting.

The meeting will be conducted in the IHEC Meeting room, CFC & RI.

In the course of the meeting of the IHEC some confidential information may be disclosed or discussed.

Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

Signature of the Observer Date

Chairperson of IHEC Date

I..... (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IHEC and me.

Signature

Date

Format for communication to the Principal Investigator

Chennai Fertility Centre and Research Institute

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

To,

Prof./Dr. _____

_____

_____

_____

_____

Dear Prof./Dr. _____

Dated:

The Institutional Human Ethics Committee in its meeting held on _____, has reviewed and discussed your application to conduct the clinical trial/project entitled

_____

_____

_____

_____

_____

_____

_____ Sponsored by _____ Code.no._____

The following documents were reviewed:

a. Trial Protocol (including protocol amendments)/project, dated _____Version no (s)._____

b. Investigator's Brochure, dated _____, Version no. _____

c. Patient Information Sheet and Informed Consent Form (including updates if any) in Hindi, English and/or vernacular language.

d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.

e. Current CV of investigator from outside CFC & RI.

f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.

g. Investigator's Agreement with the Sponsor.

h. Investigator's undertaking.

i. Ethics Committee Proforma.

j. DCGI approval letter/submission letter.

k. Case Report Form

l. Any other/additional documents

Decision of Committee: Institutional Human Ethics Committee Member Secretary

CHENNAI FERTILITY CENTER

IHEC Ref. No. (For office use):_____

IHEC Reference No: _____

Study title:

_____

_____

_____

_____

Name of the Principal Investigator;

_____

Designation / Department:

_____

Duration of Study:

_____

Date of Starting of the Study:

_____

Period of Six-monthly progress report: from _____ to _____

Progress report as per objectives (attach separate sheet):

Side Effect if any:
Amendments if any:
Discontinuation reasons:
Progress:

Signature of Principal Investigator
Date:

Template for Participant Information Sheet (PIS) Participant Information Sheet

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

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 lay man's language, in a narrative form, directed to Participant / Legally Authorized Representative (LAP), covering all the points given on the website, which can be understood by them:

Title of the study

Name of the research institution

1. Purpose of the study
2. Study Procedures
3. Risk of participation
4. Benefits of participation
5. Confidentiality
6. Compensation
7. Participant's rights:
8. Contacts
9. Amount of blood sample in quantity, in Tea spoon full, to be taken should be mentioned
10. Costs and source of investigations, disposables, implants and drugs/ contrast media must be mentioned.
11. In case of drug trials:
    a. The chemical name of the drug
    b. Initial Bio Equivalent study of the drug / references should be provided
12. Self-certification should be given that translation to vernacular is accurate.

(For queries related to the study: PI, name, contact details incl. phone number)

(For queries related to the rights as a study participant, please write to: The Chairperson, CFC&RI, IHEC, Chennai Fertility Centre& Research Institute, Aminjikarai, Chennai – 600029, Ph: 044-45588822)

பங்கேற்பாளர் தகவல் தாளுக்கான (PIS) மாதிரி

பங்கேற்பாளர் தகவல் தாள்

சென்னை .:பெர்ட்டிலிட்டி சென்டர் மற்றும் ரிசர்ச் இன்ஸ்ட்டிடியூட்

IHEC பார்வை எண். (அலுவலக பயன்பாட்டுக்கு) _____

இச்செயல்திட்டத்தோடு நோயாளிக்கு அல்லது ஆய்வு பங்கேற்பாளருக்கு அல்லது வயது முதிர்ச்சியடையாத இளவயது நபராக இருப்பின் அவனது / அவளது பெற்றோர் / காப்பாளருக்கு வழங்கப்படுகின்ற பங்கேற்பாளருக்கான தகவல்தாள் தரப்பட வேண்டும். பங்கேற்பாளர் தகவல்தாளை உருவாக்கும்போது சாமான்ய மனிதர்கள் பயன்படுத்துகின்ற எளிய நடையில் ஆங்கிலம் மற்றும் தமிழில், ஒரு விவரணை வடிவத்தில் கீழ்வரும் தகவலை ஆய்வாளர் ஆய்வு பங்கேற்பாளருக்கு வழங்கவேண்டும். அவர்களால் புரிந்துகொள்ளக்கூடியவாறு, வலைதளத்தில் தரப்பட்டிருக்கும் அனைத்து அம்சங்களையும் உள்ளடக்கியவாறு ஆய்வுத்தாளானது, பங்கேற்பாளர் / சட்டப்பூர்வமாக அங்கீகாரமளிக்கப்பட்ட பிரதிநிதிக்கு வழங்கப்படுவதாக இருக்கவேண்டும்:

ஆய்வின் தலைப்பு

ஆராய்ச்சி நிறுவனத்தின் / அமைப்பின் பெயர்

1. ஆய்வின் நோக்கம்
2. ஆய்வு நடைமுறைகள்
3. பங்கேற்பில் வாய்ப்புள்ள இடர்கள்
4. பங்கேற்பினால் ஏற்படும் ஆதாயப்பலன்கள்
5. இரகசியம் பேணல்
6. இழப்பீடு
7. பங்கேற்பாளரின் உரிமைகள்:
8. தொடர்பு விவரங்கள்
9. எடுக்கப்படும் இரத்த மாதிரியின் அளவானது (ஒரு முழு தேக்கரண்டி) குறிப்பிடப்பட வேண்டும்.
10. பரிசோதனைகளின் செலவுகள் மற்றும் ஆதாரம், டிஸ்போஸபிள், பொருத்தப்படும் சாதனங்கள் மற்றும் மருந்துகள் / ஊடுகதிர் புகாத்திரவம் ஆகியவை குறிப்பிடப்பட வேண்டும்.
11. மருந்துப்பொருளுக்கான ஆய்வாக இருக்குமானால்:
    a. மருந்துப்பொருளின் வேதியியல் பெயர்
    b. ஆரம்ப, மருந்துப்பொருளின் உயிரி சமநிலை ஆய்வு / சான்றாதாரங்கள் வழங்கப்பட வேண்டும்.
12. உள்ளூர் மொழியில் வழங்கப்படும் மொழியாக்கம் துல்லியமானது என்பதற்கான சுய-சான்றாக்கம் தரப்பட வேண்டும்.

(ஆய்வுக்கு தொடர்புடைய விசாரணைகளுக்கு: முதன்மை ஆய்வாளரின் (PI) பெயர், தொலைபேசி எண்ணுடன் தொடர்பு விவரங்கள்)

(ஒரு ஆய்வு பங்கேற்பாளராக உரிமைகள் தொடர்பான விசாரணைகளுக்கு: தலைவர், CFC&RI, IHEC, சென்னை .:பெர்ட்டிலிட்டி சென்டர் & ரிசர்ச் இன்ஸ்டிடியூட், அமைந்தகரை, சென்னை - 600029, தொலைபேசி: 044-45588822)

(Annexure 30)

Participant Informed Consent Form (PICF)

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

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 anytime, without giving any reason, without my medical career 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 CFC&RI. 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:

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; if the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

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

_____ Date:

(Signature of the principal Investigator) Place:

1. Witness-1 2. Witness -2

_____ _____

Signature Signature

Name & Address Name & Address

(ANNEXURE 30)

பங்கேற்பாளர் தகவல் தாளுக்கான (ஜீரு) மாதிரி

சென்னை :.பெர்ட்டிலிட்டி சென்டர் மற்றும் ரிசர்ச் இன்ஸ்ட்டிடியூட்

IHEC பார்வை எண். (அலுவலக பயன்பாட்டுக்கு) _____

IHEC வரைவுத்திட்ட வரிசை எண்: வ.எண்.

ஆய்வுத்திட்டத்தின் தலைப்பு:.....

.....

முதன்மை ஆய்வாளரின் பெயர்: மொபைல் எண்:

.....தேதியிடப்பட்டு, எனக்கு வழங்கப்பட்ட தகவல்தாளின் வாசகங்கள், நான் புரிந்து கொள்ளக்கூடிய மொழியில் என்னால் கவனமாக வாசிக்கப்பட்டிருக்கின்றன/எனக்கு விவரமாக விளக்கிக் கூறப்பட்டிருக்கின்றன மற்றும் அதன் உள்ளடக்கத்தை நான் முழுமையாக புரிந்துகொண்டிருக்கிறேன். இது குறித்து கேள்விகள் கேட்க எனக்கு வாய்ப்புகள் இருந்தன என்பதை நான் உறுதிசெய்கிறேன். இந்த ஆய்வின் தன்மை மற்றும் நோக்கம், அதில் சாத்தியமுள்ள இடர்கள்/ஆதாயப்பலன்கள் மற்றும் எதிர்பார்க்கப்படும் ஆய்வுகாலம் மற்றும் ஆய்வோடு தொடர்புடைய பிற விவரங்கள் எனக்கு விரிவாக விளக்கிக் கூறப்பட்டுள்ளன. இதில் எனது பங்கேற்பு தன்னார்வ அடிப்படையிலானது என்பதையும், எந்த காரணத்தையும் தராமல் எனது மருத்துவ வாழ்க்கைப்பணி தொடர்பான சட்ட உரிமை எதுவும் பாதிக்கப்படாமலேயே, எந்த நேரத்திலும் இதிலிருந்து விலகிக்கொள்ள எனக்கு சுதந்திரம் உண்டு என்பதையும் நான் புரிந்து கொண்டுள்ளேன்.

இந்த ஆய்வில் எனது பங்கேற்பிலிருந்து சேகரிக்கப்பட்ட தகவல் மற்றும் எனது மருத்துவக் குறிப்புகளின் பகுதிகள் CFC&RI-I சேர்ந்த பொறுப்புள்ள நபர்களால் பார்வையிடப்படலாம் என்பதை நான் புரிந்துகொண்டுள்ளேன். எனது பதிவேடுகள/ஆவணங்களை பார்வையிடுவதற்கான அணுகுவசதியை கொண்டிருக்க இந்த நபர்களுக்கு நான் மகன்/மகள்/.....

வாழ்க்கைத்துணை:.....

முழு அஞ்சல் முகவரி:

[பங்கேற்பாளரால் தேர்ந்தெடுக்கப்பட்ட எழுத்தறிவுள்ள சாட்சி, தகவலறிந்து வழங்கப்படும் ஒப்புதல் படிவத்தில் கையொப்பமிடவேண்டும். இந்த சாட்சி நபருக்கும் ஆய்வு குழுவிற்குமிடையே எந்த உறவுமுறையும் இருக்கக்கூடாது. பங்கேற்பாளர், அவரது / அவளது பங்கேற்பு விவரங்களை வெளிப்படுத்த விரும்பவில்லையென்றால், பங்கேற்பாளரின் விருப்பங்களை மதிக்கவேண்டும் என்ற நோக்கத்திற்காக, சாட்சி கையொப்ப செய்முறையிலிருந்து அவர் / அவளுக்கு விலக்களிக்கலாம். (இது எழுத்தறிவுள்ள பங்கேற்பாளருக்கு மட்டுமே பொருந்தும்) ஆய்வில் பங்கேற்க உத்தேசித்துள்ள நபரிடமிருந்து கையொப்பத்தைப் பெறுவதன் மூலம் ஆய்வு பணியாளரால் இது ஆவணப்படுத்தப்பட வேண்டும்]

மேற்கண்ட ஒப்புதலானது எனது முன்னிலையில் பெறப்பட்டிருக்கிறது என்று சான்றளிக்கிறேன்.

தேதி:

.....

(முதன்மை ஆய்வாளரின் கையொப்பம்) இடம்:

1சாட்சி-1 2.சாட்சி -2

....

கையொப்பம் கையொப்பம்

பெயர் மற்றும் முகவரி பெயர் மற்றும் முகவரி

குறிப்பு: கீழ்வரும் மூன்று நபர்களுக்கு இதன் நகல்கள் வழங்கப்பட வேண்டும் (1) பங்கேற்பாளர் (2) ஆய்வாளர் (3) ஆய்வு நிறுவனம்

(புரிந்துகொள்ளக்கூடிய எளிய தமிழில் மொழிபெயர்ப்பை அவர்களாகவே சொந்தமாக தயார்செய்யுமாறு ஆய்வாளர்கள் அறிவுறுத்தப்படுகின்றனர்)

(Annexure 30(a))

Consent form (for participants less than 18 years of age)
Parent / Legally accepted representative(LAR)

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

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 participants7 to 18 years of age)

Signature of parent/ LAR _____ Date: _____

Signature of the Witness _____ Date: _____

Signature of the investigator _____ Date: _____

IHEC பார்வை எண். (அலுவலக பயன்பாட்டுக்கு) _____

பங்கேற்பாளர் பெயர்: முகவரி:

பெற்றோரின் / சட்டப்பூர்வ அங்கீகாரம்
பெற்ற பிரதிநிதியின் பெயர்:
ஆய்வு செயல்திட்டத்தின் தலைப்பு:

.....

.....

.....

ஆய்வின் விவரங்கள் எழுத்துப்பூர்வமாக எனக்குத் தரப்பட்டிருக்கின்றன மற்றும் எனது சொந்த மொழியில் எனக்கு விளக்கிக் கூறப்பட்டிருக்கிறது. மேற்கண்ட ஆய்வு விவரங்களை நான் புரிந்து கொண்டிருப்பதையும், கேள்விகள் கேட்க எனக்கு வாய்ப்பு இருந்ததையும் நான் உறுதிசெய்கிறேன். இந்த ஆய்வில் எனது குழந்தையின் பங்கேற்பு தன்னார்வ அடிப்படையிலானது மற்றும் மருத்துவமனையில் வழக்கமாக வழங்கப்படும் மருத்துவ கவனிப்பு சேவை பாதிக்கப்படாமல் எந்த நேரத்திலும், எந்த காரணத்தையும் குறிப்பிடாமல் எனது குழந்தையை ஆய்விலிருந்து விலக்கிக்கொள்ள எனக்கு சுதந்திரம் உண்டு என்பதையும் நான் புரிந்துகொண்டுள்ளேன். இந்த ஆய்விலிருந்து எழக்கூடிய முடிவுகள் அல்லது எந்தவொரு தரவின் பயன்பாட்டை, அறிவியல் சார்ந்த நோக்கங்களுக்காக மட்டுமே அத்தகைய பயன்பாடு இருக்குமானால், கட்டுப்படுத்தாமல் இருக்கவும் நான் சம்மதிக்கிறேன். ஆய்வு குறித்த விவரங்களை தருகின்ற ஒரு தகவல்தாள் எனக்கு வழங்கப்பட்டிருக்கிறது. மேற்குறிப்பிடப்பட்ட ஆய்வில் எனது குழந்தையின் பங்கேற்பிற்கு நான் முழுமையாக சம்மதிக்கிறேன்.

குழந்தையின் ஒப்புதல் பெறப்பட்டது (7 முதல் 18 ஆண்டுகள் வயது வரையிலான பங்கேற்பாளர்களுக்கு)

பெற்றோரின் / சட்டப்பூர்வ அங்கீகாரம் தேதி:.....

பெற்ற பிரதிநிதியின் கையொப்பம்:.....

சாட்சியின் கையொப்பம்:..... தேதி:.....

ஆய்வாளரின் கையொப்பம்:..... தேதி:.....

Undertaking by the Principal Investigator

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

1. NAME AND CODE NUMBER OF THE PROJECT

2. NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR

3. OTHER MEMBERS OF THE RESEARCH TEAM

4. NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE

5. NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE PI.

    1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
    2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IHEC at the earliest.
    3. I confirm that the CO PI and other members of the study team have been informed about their obligations and are qualified to meet them
    4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
    5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IHEC, Regulatory authorities, Sponsors ortheir authorized representatives.
    6. I will inform the IHEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
    7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
    8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
    9. I will inform IHEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IHEC within 4 weeks of the due date.

Signature of Principal Investigator Date

Intimation of start of the study

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

1. Project /Trial Code Number
2. Title of the drug/multi centric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IHEC
7. Date of start

(Signature of Principal Investigator)

Date

Investigator's Declaration

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

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 and 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 and confidentiality of the subject/s will be maintained.

Letter of Authorization

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

The letter here by status 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:

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