(Annexure 1)

Invite Letter for IHEC Members

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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. (Forofficeuse):

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

Date

Name: ……

Telephone Number……

Email Address……...

(Annexure 2(a))

One-page CV for EC Members/Investigators

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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:

(Annexure 3)

Appointment Order

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

Dr/ Mr. / Mrs.:…….……. Date: ……

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. (Forofficeuse):

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		Legal expert		
7		NGO Representative		
8		Lay person	Non-Affiliated	

(Annexure 5)

Confidentiality agreement form for IHEC members

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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

(Annexure 6)

Conflict of Interest agreement form for IHEC members

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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

(Annexure 7)

Minutes of Meetings- IHEC-CFC&RI,

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

i. note by the Member-Secretary
ii. ion of members
iii. by Chairperson
iv. 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. *(Foroffice 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. ADMINISTRATIVEDETAILS

(a) Name of the organization:……

(b) Name of the Ethics Committee: ……

(b) Name of Principal Investigator:……

(d)Department/Division: .....(e) Date ofsubmission: dd mm yy

(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/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant isa:

i) PrincipalInvestigatorattimeofsubmission ……

ii) Co-Investigator at time ofsubmission: ……

(k)Durationofthestudy:……

[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 ANDBUDGET

(a) Total estimated budget for site: ……

At site…… In India…… Globally ……

(b)Self-funding☐ Institutionalfunding☐ Funding agency *(Specify)*☐

……

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OFRESEARCH

(a)Laysummary[3](within300words):……

……

……

……

……

……

……

……

……

……

(b) Type of study:

BasicSciences	☐	Clinical	☐	CrossSectional	☐
Retrospective	☐	Epidemiological/	☐	CaseControl	☐
Prospective	☐	PublicHealth		Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples/Data	☐		
MixedMethod	☐	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) Isthereanexternallaboratory/outsourcinginvolvedforinvestigations?[4] Yes ☐ No ☐ NA ☐

(b) Howwasthescientificqualityofthestudyassessed?

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

Reviewwithinmulti-centre research group ☐ Noreview ☐

Date of review: dd mm yy

Comments of scientific committee, if any (100 words)

.....

.....

.....

.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCHPARTICIPANTS

(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)*.....

(b) i. Will there be vulnerable persons / special groups involved? Yes ☐ No ☐ NA ☐

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

Children under18yrs	☐	Pregnant orlactatingwomen	☐
Differentlyabled(Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and sociallydisadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally ill (stigmatized or rare diseases)	☐		
Anyother*(Specify)*:	☐	.....	

iii. Provide justification for inclusion/exclusion .....

.....

.....

iv. Are there any additional safeguards to protect researchparticipants?.....

.....

.....

.....

[4] *If 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 ☐ *Providedetails*

……

……

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

If yes,Monetary ☐ Non-monetary ☐ *Providedetails*

……

……

(e) Arethereanyparticipantrecruitmentfees/incentivesforthestudyprovidedtothePI/Institution?

If yes,Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

……

……

6. BENEFITS ANDRISKS

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

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

Less thanMinimalrisk ☐ Minimalrisk ☐

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

ii. Describe the risk management strategy: ……

……

……

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

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

Pleasedescribehowthebenefitsjustifytherisks……

……

……

……

(c) Areadverseeventsexpectedinthestudy[6]? Yes ☐ No ☐ NA ☐

Arereportingproceduresandmanagementstrategiesdescribedinthestudy? Yes ☐ No ☐

If Yes, Specify ……

……

……

7. INFORMEDCONSENT

(a) Areyouseekingwaiverofconsent?Ifyes,pleasespecifyreasonsandskiptoitemno.8 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) VersionnumberanddateofParticipantInformationSheet(PIS):……

VersionnumberanddateofInformedConsentForm(ICF):……

(c) Type of consent planned for:

Signedconsent	☐	Verbal/Oralconsent	☐	Witnessedconsent	☐	Audio-Video(AV) consent	☐
ConsentfromLAR (If so, specify fromwhom)	☐	Forchildren<7yrs parental/LAR consent	☐	Verbalassentfrom minor (7-12 yrs) along with parentalconsent	☐	Writtenassentfrom minor (13-18 yrs) along with parentalconsent	☐

……

Other ☐

(specify) ……

(d) Who will obtain the informedconsent?

PI/Co-I☐ Nurse/Counselor ☐ ResearchStaff ☐ Other ☐ *(Specify)* ……

Anytoolstobeused……

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

English ☐ Locallanguage ☐ Other ☐*(Specify)*……

List the languages in which translations were done……

Iftranslationhasnotbeendone,pleasejustify……

……

(f) Providedetailsofconsentrequirementsforpreviouslystoredsamplesifusedinthestudy[7]

……

……

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

Simplelanguage ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risksanddiscomforts ☐	Needtorecontact ☐	Statement that consent is voluntary ☐
Alternatives to participation ☐	Confidentiality ☐	Commercialization/ Benefit sharing ☐
Righttowithdraw ☐	Storageofsamples ☐	Statement that study involves research ☐
Benefits ☐	Return of research results ☐	Use of photographs/ Identifying data ☐
Purposeandprocedure ☐	Payment for participation ☐	Contact information of PI and Member Secretary of EC ☐
Others(Specify) ☐		

……

8. PAYMENT/COMPENSATION

(a) Whowillbearthecostsrelatedtoparticipationandprocedures[8]?

PI ☐ Institution ☐ Sponsor ☐ Otheragencies ☐ *(specify)*

……

……

(b) Isthereaprovisionforfreetreatmentofresearchrelatedinjuries? Yes ☐ No ☐N/A ☐

Ifyes,thenwhowillprovidethetreatment?……

(c) Is there a provision for compensation of researchrelatedSAE? Ifyes,specify. Yes ☐ No ☐N/A ☐

Sponsor ☐ Institutional/Corpusfund ☐ Projectgrant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participantsduringthestudyperiod?Ifyes,specify. Yes ☐ No ☐N/A ☐

……

(e) Isthereaprovisionforancillarycareforunrelatedillnessduringthestudyperiod?Ifyes,pleasespecify.

Yes ☐ No ☐ N/A ☐

[7] *Informationonre-consentrequirementscanbefoundatNationalEthicalGuidelinesforBiomedicalandHealthResearchInvolvingHumanParticipants 2017, Page 54 in Section5.8.*

[8] *Enclose undertaking from PI confirming the same.*

9. STORAGE ANDCONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. *IfYes, 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)Whowillbemaintainingthedatapertainingtothestudy?……

(c)Wherewillthedatabeanalyzed[9]andbywhom?……

(d)Forhowlongwillthedatabestored?……

(e)Doyouproposetousestoredsamples/datainfuturestudies? Yes ☐ No ☐ Maybe ☐

Ifyes,explainhowyoumightusestoredmaterial/datainthefuture?……

……

……

……

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPRISSUES

(a) Willtheresultsofthestudybereportedanddisseminated?Ifyes,specify. Yes ☐ No ☐ NA ☐

……

……

(b) Willyouinformparticipantsabouttheresultsofthestudy? Yes☐No☐NA☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the studyhasfinished?

Ifyesdescribeinbrief(Max50words) Yes ☐ No ☐ NA☐

……

……

(d) Isthereanyplanforpostresearchbenefitsharingwithparticipants?Ifyes,*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) Doyouhaveanyadditionalinformationtoaddinsupportoftheapplication,whichisnotincludedelsewherein the form?
If yes,providedetails. Yes ☐ No☐

……

……

……

……

[9] *Forexample,adataentryroom,aprotectedcomputeretc.*

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/WeconfirmthatthisstudywillbeconductedinaccordancewiththelatestICMRNationalEthicalGuidelines forBiomedicalandHealthResearchInvolvingHumanParticipantsandotherapplicableregulationsandguide- 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 yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Guide: .....

Signature: .....

Name of HOD: ..... dd mm yy

Signature: .....

dd mm yy

[10] *These 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	□	□	□		
2	Brief CV of all Investigators	□	□	□		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	□	□	□		
4	Approval of scientific committee	□	□	□		
5	EC clearance of other centers*	□	□	□		
6	Agreement between collaborating partners*	□	□	□		
7	MTA between collaborating partners*	□	□	□		
8	Insurance policy/certificate	□	□	□		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	□	□	□		
10	Copy of contract or agreement signed with the sponsor or donor agency	□	□	□		
11	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						
12	Copy of the detailed protocol[11]	□	□	□		
13	InvestigatorsBrochure(Ifapplicablefordrug/biologicals/devicetrials)	□	□	□		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	□	□	□		
15	Assent form for minors (12-18 years) (English and Translated)	□	□	□		
16	Proforma/Questionnaire/CaseReportForms(CRF)/Interviewguides/ GuidesforFocusedGroupDiscussions(FGDs)(Englishandtranslated)	□	□	□		
17	Advertisement/material to recruit participants (fliers, posters etc)	□	□	□		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	**Required**	**Not required**	**Received**	**Applied dd/ mm/yy**	**EC Remarks**
18	CTRI	□	□	□		
19	DCGI	□	□	□		
20	HMSC	□	□	□		
21	NAC-SCRT	□	□	□		
22	ICSCR	□	□	□		
23	RCGM	□	□	□		
24	GEAC	□	□	□		
25	BARC	□	□	□		
26	Tribal Board	□	□	□		
27	Others (Specify)	□	□	□		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28		□	□	□		
29		□	□	□		

**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 Com- mittee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic ResearchCentre

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

(Annexure 9)

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

Chennai Fertility Centre and Research Institute

IHEC Ref. No. *(Foroffice 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 throughEmail
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

IHEC Ref. No. *(Foroffice use):*

For official use only Proposal No.

	es	o	A	omments
ntation provided?				
ance and validity				
Will the study lead to improvements in human health and wellbeing or increase knowledge?				
If the study is a replication of a previous study, is it justified?				
Can the intervention studied be practically implemented?				
Is there provision for dissemination of results of the research?				
Has the research protocol been approved by a competent body?				
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)				
Are the objectives stated clearly?				
Is the study design appropriate in relation to the objectives?				
Are the investigators qualifications, competence and experience appropriate to conduct the study?				
). Are the facilities at the site adequate to support the study?				
. Is the manner in which the results of research will be reported and published ethical?				
ssessment of Risks/Benefits				
Is the involvement of human participants necessary to obtain the necessary information?				
Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
Is there provision for compensation for participants who sustain injuries?				
Have adequate provisions been made or dealing with and reporting adverse effects?				
Have adequate provisions been made for safety monitoring and termination of the research project?				
espect for the dignity of the research participants				
formed consent				
Is the process for obtaining informed consent appropriate?				
Are the participants competent to give consent?				
Is the justification adequate for the intention to include individuals who cannot consent?				
Will dissent be respected?				

Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
Do you approve the incentives offered?				
Is the consent given voluntarily and not due to deception, intimidation or inducement?				
onfidentiality				
Will the researcher collect only the minimum information: samples required to fulfill the study objectives?				
Is the privacy of the research participant safeguarded?				
Are data/sample storage and disposal procedures adequate?				
ights of the participants				
Is the participant's right to unconditionally withdraw from the research at any time safeguarded?				
Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
Is there provision for the subjects to be informed of results of clinical research?				
air participant selection				
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)?				
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'?				
Does the selection of participants stigmatize any group?				
Does selection of subjects favour any group ?				
Is the research conducted on vulnerable individuals or groups?				
Is the research externally sponsored?				
Is the research a community research?				
Is the research a clinical trial?				
esponsibilities of the researcher				
Is the medical care to be provided to the research participants during and after the research adequate?				
Has the researcher obtained permission from the relevant authorities?				
Are there an\ conflicts of interest, including payments and other rewards?				
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. *(Foroffice use):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Choose reasons why expedited review from EC isrequested[12]?
   - i. Involvesnon-identifiablespecimenandhumantissuefromsourceslikebloodbanks,tissuebanksand 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. Revisedproposalpreviouslyapprovedthroughexpeditedreview,fullrevieworcontinuingreviewof approved proposal. ☐
   - v. Minordeviationfromoriginallyapprovedresearchcausingnoriskorminimalrisk. ☐
   - vi. Progress/annualreportwherethereisnoadditionalrisk,forexampleactivitylimitedtodataanalysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   - vii. FormulticentreresearchwhereadesignatedECchasapprovedtheproposal,aparticipatingECmay review participating centre specific information and modifications in the study proposal through full committeemeeting/expeditedreviewdependingontheimportanceoflocalconsentrelatedissuesinvolved specific to thecentre. ☐
   - viii. Researchduringemergenciesanddisasters(SeeSection12ofICMREthicalGuidelines,2017). ☐
   - ix. Any other (please specify) ……

     ……
2. Is waiver of consentbeingrequested? Yes ☐ No☐
3. Does the research involve vulnerablepersons[13]? Yes ☐ No☐

   IfYesgivedetails:……

   ……

   ……

Signature of PI: …… dd mm yy

Comments of EC Secretariat: ……

Signature of Member Secretary: …… dd mm yy

[2] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*

[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

IHEC Ref. No. *(Foroffice use):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

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

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

ii. Observationofpublicbehavior/informationrecordedwithoutlinkedidentifiersanddisclosure 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.Publichealthprogrammesbygovernmentagencies[15] ☐

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

……

……

……

……

Signature of PI: …… dd mm yy

Comments of EC Secretariat: ……

Signature of Member Secretary: …… dd mm yy

[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 ofstudiesthatareexemptfromreview,refertoNationalEthicalGuidelinesforBiomedical&HealthResearchInvolvingHumanParticipants2017,Page51 Table4.2.*

[15] *Suchasprogrammeevaluationwherethesolepurposeoftheexerciseisrefinementandimprovementoftheprogrammeormonitoring(whereth ereare no individualidentifiers)*

(Annexure 13)

Continuing Review / Annual report format

Chennai Fertility Centre and Research Institute

IHEC Ref. No. *(Foroffice use):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Date of ECApproval: dd mm yy Validity of approval: Proposed date dd mm yy
2. Date of Start ofstudy: dd mm yy ofCompletion: dd mm yy
   Period of Continuing Report: dd mm yy ---- to------ dd mm yy
3. Does the study involve recruitment ofparticipants? Yes ☐ No ☐

(a) Ifyes,Totalnumberexpected…… NumberScreened:…… Number Enrolled:……

Number Completed:…… Number on followup:……

(b) Enrolment status – ongoing / completed/stopped

(c) ReportofDSMB[16] Yes ☐ No ☐ NA☐

(d) Any other remark……

……

(e)Haveanyparticipantswithdrawnfromthisstudysincethelastapproval? Yes ☐ No☐ NA☐

Ifyes,totalnumberwithdrawnandreasons:……

……

……

4. Isthestudylikelytoextendbeyondthestatedperiod?[17] Yes ☐ No☐

Ifyes,pleaseprovidereasonsfortheextension.……

……

……

5. Havetherebeenanyamendmentsintheresearchprotocol/InformedConsentDocument(ICD)duringthepast approvalperiod?

IfNo,skiptoitemno.6 Yes ☐ No☐

(a) Ifyes,dateofapprovalforprotocolandICD: dd mm yy

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

Ifyes,when/how:……

……

……

[16] *In 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.*

[17] *Problemsencounteredsincethelastcontinuingreviewapplicationwithrespecttoimplementationoftheprotocolascleared by theEC*

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

Ifyes,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 sincelastreview? 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. Hastherebeenanyprotocoldeviations/violationsthatoccurredduringthisperiod?

If yes, number of deviations ……

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

……

……

10. Incaseofmulticenterictrials, have reportsofoff-siteSAEsbeensubmittedtotheEC? 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? If yesgivedetails Yes ☐ No☐

……

……

Any other comments:……

……

Signature of PI: …… dd mm yy

(Annexure 14)

Application/ Notification form for Amendments

Chennai Fertility Centre and Research Institute

IHEC Ref. No. *(Forofficeuse):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Date of ECapproval: dd mm yy

Date of start of study d d m m y y

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 anyreconsentnecessary? 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 yy

[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. *(Forofficeuse):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Date ofECapproval dd mm yy Date of start ofstudy dd mm yy

2. ParticipantID: ..... Date ofoccurrence dd mm yy

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. Isthedeviationrelatedto(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): Studyparticipant☐ Quality of data☐

9. Areanychangestothestudy/protocolrequired? Yes ☐ No☐

If yes, givedetails……

……

Signature of PI: …… dd mm yy

Version 1.0

(Annexure 16)

Serious Adverse Event Reporting format (Biomedical Health Research)

Chennai Fertility Centre and Research Institute

IHEC Ref. No. *(Forofficeuse):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Participant details :

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

2. Suspected SAE diagnosis: .....

3. DateofonsetofSAE: dd mm yy

Date ofreportingSAE: dd mm yy

Describetheevent[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 yy

6. HaveanysimilarSAEoccurredpreviouslyinthisstudy?Ifyes,pleaseprovidedetails. Yes ☐ No☐

……

……

……

……

[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)*

7. Incaseofamulti-centricstudy,haveanyoftheotherstudysitesreportedsimilarSAEs?

(Pleaselistnumberofcaseswithdetailsifavailable)

……

……

8. TickwhicheverisapplicablefortheSAE:(KindlynotethatthisreferstotheInterventionbeingevaluatedandNOT 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	☐

……

Incaseofdeath,stateprobablecauseofdeath……

C. No permanent/significant functional/cosmetic impairment ☐
Permanent/significantfunctional/cosmeticimpairment ☐
NotApplicable ☐

9. Describethemedicalmanagementprovidedforadversereaction(ifany)totheresearchparticipant.(Includeinformationonwhopaid,howmuchwaspaidandtowhom).

……

……

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

……

11. Outcome ofSAE

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

……

12. Provideanyotherrelevantinformationthatcanfacilitateassessmentofthecasesuchasmedicalhistory

……

……

……

13. ProvidedetailsaboutPI'sfinalassessmentofSAErelatednesstoresearch.

……

……

……

Signature of PI: …… dd mm yy

Version 1.0

(Annexure 17)

Premature Termination/ Suspension/Discontinuation Report Format

Chennai Fertility Centre and Research Institute

IHEC Ref. No. *(Forofficeuse):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

1. Date of ECapproval: dd mm yy Date of start of study: dd mm yy
2. Dateoflastprogressreportsubmitted toEC: dd mm yy
3. Date oftermination/suspension/discontinuation: dd mm yy
4. Tick theappropriate

PrematureTermination☐ Suspension☐ Discontinuation☐

Reason for Termination/Suspension/Discontinuation:……

……

……

……

ActiontakenpostTermination/Suspension/Discontinuation(ifany):……

……

……

……

5.Plansforpoststudyfollowup/withdrawal[21](ifany): ……

……

……

6. Details of study participants:

Totalparticipantstoberecruited:…… Screened: …… Screenfailures:……

Enrolled:…… ConsentWithdrawn:…… 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: ……..……

Participantslosttofollowup:……..……Anyother:……..…….. Numberofdropouts:…….....

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. Havetherebeenparticipantcomplaintsorfeedbackaboutthestudy? Yes □ No□
If yes, provide details:……..……
……

9. Have there been any suggestions from the SAESubCommittee? Yes □ No□
If yes, have you implementedthatsuggestion?Yes □No□
10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes □ No□
11. (e.g.,makingarrangementsformedicalcareofresearchparticipants):IfYes,providedetails
……

……

Summary of results (if any):……..……

……

……

……

……

……

Signature of PI: ……..…. dd mm yy

(Annexure 18)

Application Form for Clinical Trials

Chennai Fertility Centre and Research Institute

IHEC Ref. No. *(Forofficeuse):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Type ofclinicaltrial Regulatorytrial☐ Academictrial ☐

CTRIregistrationnumber:……NABHaccreditationnumber:.....ECregistrationnumber:.....

2. Ifregulatorytrial,providestatusofCDSCOpermissionletter

Approved and letterattached ☐ Applied, under process☐

Not applied (Statereason) ☐ ……

3. Tick all categories that apply to yourtrial

Phase–I	☐	PhaseII	☐
PhaseIII	☐	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	
Others (specify)	☐	ornewrouteofadministration	☐

……

4. Trial design of thestudy

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparisontrial	☐
Cluster	☐	Superioritytrial	☐
Matched-pair	☐	Non-inferioritytrial	☐
Others *(specify)*	☐	Equivalencetrial	☐

……

II. Ifthereisrandomization,howwilltheparticipantsbeallocatedtothecontrolandstudygroup(s)?

……

……

III. Describethemethodofallocationconcealment(blinding/masking),ifapplicable.

……

……

5. Listtheprimary/secondaryoutcomesofthetrial.

.....

.....

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as publicrelation/humanresource? Yes ☐ No☐

Ifyes,NameandContactdetails:.....

.....

.....

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

Project management	☐	Clinical and medicalmonitoring	☐
Regulatory affairs	☐	Datamanagement	☐
Statistical support	☐	Medicalwriting	☐
Site management	☐	Audits,qualitycontrol,qualityassurance	☐
Finance management	☐	Recruitment andtraining	☐
Administrative support	☐	Others*(specify)*	☐

.....

7. Pleaseprovidethefollowingdetailsabouttheinterventionbeingusedintheprotocol

I. Drug/s,device/sand/orbiologics;ifyes,provideregulatoryapprovaldetails. Yes ☐ No ☐ NA☐

.....

.....

II. Alreadyapproveddrugsoracombinationoftwoormoredrugswithnewindications/changeindosageform/ routeofadministration. Ifyes,providedetails. Yes ☐ No ☐ NA☐

.....

.....

III. Providecontactdetailsofwhopreparedand/orismanufacturingthedrug/s,device/sandbiologics.

.....

.....

IV. Providedetailsofpatentofthedrug/s,device/sandbiologics.

.....

.....

8. Describeinbriefanypreparatoryworkorsitepreparednessfortheprotocol? Yes ☐ No ☐ NA☐

If yes, provide details(100words).....

.....

.....

.....

.....

9. Isthereaninitialscreening/useofexistingdatabaseforparticipantselection? Yes □ No □ NA□

If Yes, provide details[22]……

……

……

……

10. Isthereanyanticipatedincidence,frequencyanddurationofadverseeventsrelatedtotheintervention?

Ifyes,providedetailsofarrangementsmadetoaddressthem. Yes □ No □ NA□

……

……

……

11. Does the study use aplacebo?

Ifyes,justifytheuseoftheplaceboandrisksentailedtoparticipants. Yes □ No □ NA□

……

……

……

12. Willcurrentstandardofcarebeprovidedtothecontrolarminthestudy? Yes □ No □ NA□

If no, please justify.

……

……

……

13. Arethereanyplanstowithdrawstandardtherapyduringthestudy?Ifyes,pleasejustify. Yes □ No □ NA□

……

……

……

14. Arethereanyrulestostoptheprotocolincaseofanyadverseevents?Ifyes,pleasespecify. Yes □ No □ NA□

……

……

……

……

15. DoesthestudyhaveaDataandSafetyMonitoringPlan?Ifno,pleasejustify. Yes □ No□

……

……

……

[22] In order to select participants for your protcol 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. ParticipantInformationSheet(PIS)andInformedConsentForm(ICF)

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

.....

Listthelanguagesinwhichtranslationsweredone……

Justify if translation notdone……

.....

17. Involvement/consultationofstatisticianinthestudydesign Yes □ No □ NA□

18. Isthereanyinsurancecoverageofthetrial?Ifyes,providedetails. Yes □ No□

.....

.....

.....

I. IsthePIregisteredwithMedicalCouncilofIndia(MCI)ortheStateMedicalCouncilregistration?

Pleaseprovidedetails. Yes □ No□

.....

.....

II. Is the PI trained in GCP in last 3 years? If yes, Pleaseenclosecertificate Yes□ No□

Signature of PI: …… dd mm yy

(Annexure 19)

Serious Adverse Event Reporting format (Clinical Trials)

Chennai Fertility Centre and Research Institute

IHEC Ref. No. *(Forofficeuse):*

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Participant details :

Initials and Case No./ Subject ID

……

……..

Age at the time of event

……

Gender

Male ☐

Female ☐

Weight: ..... (Kgs)

Height:..... (cms)

2. Reporttype: Initial☐ Follow-up☐ Final☐

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

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

By PI–Related ☐ Unrelated ☐

By Sponsor– Related ☐ Unrelated ☐

ByEC– Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAEdiagnosis:……

……

……

4. Date of onsetofSAE: dd mm yy

Date ofreporting: dd mm yy

5. Onsetlagtimeafteradministrationofintervention:

……

Location of SAE(Clinic/Ward/Home/Other)

……

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

I.Suspectstudydrug(includegenericname)device/intervention:……

……

II.Indication(s)forwhichsuspectstudydrugwasprescribedortested:……

……

III. Route(s)ofadministration,dailydoseandregimen,dosageformandstrength:……

……

IV. Therapystartdate: dd mm yy

Stopdate: dd mm yy

7. Was study intervention discontinued duetoevent? Yes ☐ No☐

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:

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

.....

.....

II. Relevant test/laboratory data with dates: dd mm yy

.....

.....

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? If yes, please provide details. Yes ☐ No ☐

.....

.....

12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
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 information on who paid, how much was paid and to whom).

.....

.....

14. Outcome of SAE:

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 yy

(Annexure 20)

ApplicationForm for Human Genetics Testing Research (Clinical Trials)

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Describethenatureofgenetictestingresearchbeingconducted.

(e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

……

……

……

2. Doesthestudyinvolvepretestandpost-testcounselling?Ifyes,pleasedescribe. Yes □ No □ NA□

……

……

3. Explaintheadditionalsafeguardsprovidedtomaintainconfidentialityofdatagenerated.

……

……

……

4. Ifthereisaneedtosharetheparticipants'information/investigationswithfamily/community,isitaddressedinthe informedconsent?

Yes □ No □ NA□

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

……

……

……

5. Is there involvement ofsecondaryparticipants? Yes □ No □ NA□

Ifyes,willinformedconsentbeobtained?Statereasonsifnot. Yes □ No □ NA□

……

……

6. Whatmeasuresaretakentominimize/mitigate/eliminateconflictofinterest?

……

……

……

7. Isthereaplanforfutureuseofstoredsamplesforresearch? Yes □ No□

Ifyes,hasthisbeenaddressedintheinformedconsent? Yes □ No□

SignatureofPI:…… dd mm yy

(Annexure 21)

ApplicationForm for Socio-Behavioural and Public Health Research

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……

……

……

1. Data collection method used in thestudy

Focus group	☐	Questionnaire/Survey	☐	Observation	☐
Interviews	☐	Documents andrecords	☐	Ethnographies/Oral history/Case studies	☐
Others *(Specify)*	☐				

……

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

Yes ☐ No☐

……

……

……

2. Type of informed consent used in thestudy.

Individualconsent ☐ Gate-keeperconsent ☐ Communityconsent ☐

Others ☐ *(specify)*……

3. Providedetailsofsafeguardstoensureprivacyandconfidentialityofparticipantsintheeventofdatasharing.

……

……

……

4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.: Suicideorinfanticide)

Yes ☐ No ☐ NA☐

……

……

……

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

6. Isthereauseofaninterpreter?Ifyes,describetheselectionprocess. Yes ☐ No ☐ NA☐

……

……

……

7. Describeanypreparatoryworkorsitepreparednessforthestudy Yes □ No □ NA□

.....

.....

.....

.....

.....

.....

.....

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

Invasive□ Potentiallyharmful □ Emotionallydisturbing □ Involvingdisclosure □

Describe the risk minimization strategies.

.....

.....

.....

.....

II. Justifyreasonsifindividualharmisoverridingsocietalbenefit. Yes □ No □ NA□

.....

.....

.....

III. Describe how do societal benefits outweigh individualharm.

.....

.....

.....

9. Doesthestudyuseincompletedisclosureoractivedeceptionorauthorizeddeception?Ifyes,providedetailsand rationalefordeception. Yes □ No□

.....

.....

.....

.....

10. Describethedebriefingprocessthatwillbeusedtomakeparticipantsawareoftheincompletedisclosureor deception,includingtheirrighttowithdrawanyrecordoftheirparticipation.

.....

.....

.....

.....

Signature of PI: …… dd mm yy

(Annexure 22)

Study Completion / Final Report

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

Title of study: ……

……

……

PrincipalInvestigator(Name,DesignationandAffiliation):……..

……

1. Date of ECapproval: dd mm yy
2. Date of start ofstudy: dd mm yy Date of study completion: dd mm yy
3. Provide detailsof:

a) Totalnumberofstudyparticipantsapproved bytheECforrecruitment:……

b)Totalnumberofstudyparticipantsrecruited:……

c)Totalnumberofparticipantswithdrawnfromthestudy(ifany):……..

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 positiveandnegativeresultswillbeshared)……

……

……

5. Describethemainethicalissuesencounteredinthestudy(ifany)……

……

……

……

……

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

Deviations:…….. Violation:…… Amendments:……

7.Describeinbriefplansforarchivalofrecords/recordretention:……

……

……

……

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

8. Is there a plan for poststudyfollow-up? Yes ☐ No ☐

Ifyes,describeinbrief:……

……

……

……

……

9. Doyouhaveplansforensuringthatthedatafromthestudycanbeshared/accessedeasily? Yes ☐ No ☐ If yes,

describe in brief:……

……

……

……

……

10. Isthereaplanforpoststudybenefitsharingwiththestudyparticipants? Yes ☐ No ☐

Ifyes,describeinbrief:……

……

……

……

……

11.Describeresults(summary)withConclusion[24]:……

……

……

……

……

12.NumberofSAEsthatoccurredinthestudy:……

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

14. IsmedicalmanagementorcompensationforSAEprovidedtotheparticipants? Yes ☐ No ☐ If yes,

provide details……

……

……

……

……

Signature of PI: …… dd mm yy

[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. (Forofficeuse):

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephonenumber: Emailaddress:
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. (Forofficeuse):

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 bereported to IHEC withina 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

(Annexure 25)

nfidentiality and Conflict of Interest agreement form for Independent Consultants

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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 aforementioned 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

(Annexure 26)

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

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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

(Annexure 27)

Format for communication to the Principal Investigator

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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 _____Versionno (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

(Annexure 28)

Six monthly progress Project

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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:

(Annexure 29)

Template for Participant Information Sheet (PIS) Participant Information Sheet

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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)

(ANNEXURE 29)

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. (Forofficeuse):

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

Note: Three copies should be made, for (1) Participant, (2) Researcher, (3) Institution

(Investigators are advised to prepare the translation in simple understandable Tamil on their own)

(ANNEXURE 30)

பங்கேற்பாளர் தகவல் தாளுக்கான (PIS) 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))

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

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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: _____

(ANNEXURE 30(A))

ஒப்புதல் படிவம் (18 ஆண்டுகள் வயதிற்கும் குறைவான பங்கேற்பாளர்களுக்கு)
பெற்றோர் / சட்டப்பூர்வமாக ஏற்கப்படும் பிரதிநிதி (LAR)

சென்னை ∴பெர்ட்டிலிட்டி சென்டர் மற்றும் ரிசர்ச் இன்ஸ்ட்டிடியூட்

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:.....

(Annexure 31)

Undertaking by the Principal Investigator

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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 guidelinesapplicable 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 ofthe due date.

Signature of Principal Investigator Date

(Annexure 32)

Intimation of start of the study

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

1. Project/Trial Code Number
2. Title of the drug/multicentric 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

(Annexure 33)

Investigator's Declaration

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

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.

Place:

Date: Chief Investigator

(Annexure 34)

Letter of Authorization

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (Forofficeuse):

The letter here by status that the candidate named _____ pursuing his/her _____has not officially started his/herResearch titled_____

_____

_____

_____

_____ in our Department. He / She will be starting her research activity after the ethics committee approval.

Guide HOD

Date:

***