CHENNAI FERTILITY CENTRE

(Annexure 10)

Evaluation form for Verification of Proposals submitted to IHEC-CFC & RI

Chennai Fertility Centre and Research Institute

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 well being 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 with hold 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?				
8. 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?				

	Yes	No	NA	Comments
5. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
6. Do you approve the incentives offered?				
7. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
CONFIDENTIALITY				
1. Will the researcher collect only the minimum information: samples required to fulfill the study objectives?				
2. Is the privacy of the research participant safeguarded?				
3. Are data / sample storage and disposal procedures adequate?				
RIGHTS OF THE PARTICIPANTS				
1. Is the participant's right to unconditionally withdraw from the research at 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 any conflicts of interest, including payments and other rewards?				
4. Are there any other ethical / legal social financial issues in the study?				

Additional Comments:

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

Name of Reviewer:
Signature
Date