



Format for Communication to the Principal Investigator
Chennai Fertility Centre and Research Institute

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:

Member Secretary
Institutional Human Ethics Committee