INDUSTRIAL RESEARCH AND CONSULTANCY CENTRE

Office of the Dean R&D, IIT Bombay

Format for submission of Continuing Review Report

1) **IEC Project No.:**

2) **Project Title:**

3) **Principal Investigator:**

4) **Department:**

5) **Date of IEC approval:**

6) **Duration of the Study:**

7) **Version of Proposal and ICF used in the study**:

8) **Summary of participants in the study:**

   a. No. of participants approved by IEC …….
   b. No. of recruited participants …….
   c. No. of ongoing participant …….
   d. No. of Completed participants …….
   e. No. of participants who refused to consent …….

9) **Have any participants been withdrawn from this study?**

 No

 Yes (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)

10) Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IEC's evaluation of the risk/benefit analysis of participants involved in this proposal?

- ☐ No
- ☐ Yes (attach separate sheet if needed)

11) Have any unexpected complications or Serious Adverse Events (SAEs) been noted since last review?

- ☐ No
- ☐ Yes (attach separate sheet if needed)
- ☐ No. of patients who had SAEs-
- ☐ Whether reports of SAEs at have been submitted to the IEC-
- ☐ Whether reports of SAEs at other sites have been submitted to the IEC-
- ☐ Types of adverse events with nos. of participants
- ☐ Number of unexpected AE _____

Impaired participants

- ☐ None
- ☐ Physically
- ☐ Cognitively
- ☐ Both

12) Have there been any amendments in proposal/ Informed Consent Document since the last review?

- ☐ No
- ☐ Yes

13) Were these proposal/ Informed Consent Document (ICD) amendments approved by IEC?

- ☐ No
- ☐ Yes

If no, mention the amendments not approved

13) Which proposal amendment/ ICD amendment is the site following at this date?

14) Have any participating investigators been added or withdrawn since last review?

- No
- Yes (Identify all changes in the attached narrative)

15) Is report of interim data analysis available?

- No
- Yes (submit as an attachment)

16) Is report of the data safety and monitoring board available?

- No
- Yes (submit as an attachment)

17) Have any investigators developed equity or consultative relationship with a source related to this proposal which might be considered a conflict of interest?

- No
- Yes (Append a statement of disclosure)

18) Any other comments:

Signature of the Principal Investigator with Date:

Name of PI: