Guidelines for submission of project for review by IEC

(Please read the guidelines and SOP carefully before applying for the IEC approval to avoid unnecessary delay in the review process)

All proposed study/ project (**retrospective study/ prospective study or clinical drug trial**) conducted at Dr. BBCI needs to be approved separately in **DMGs/Scientific Committee** or both (if deemed necessary) followed by **Medical Ethics Committee (IEC)** of Dr. BBCI. Scientific Committee comprises of internal members from Dr. BBCI who review the scientific and technical part of the study, while Medical Ethics Committee comprises of both internal & external members will review the ethical aspects of the proposed study/ project. Post approval from scientific committee, each study/ project need to be submitted separately to the Medical Ethics Committee for review and approval.

The mandatory documents (Dossier) required for submission are mentioned below:

A) For Scientific Committee: Cover letter to Chairperson, research proposal (similar to ICMR format) & proforma (**2 copies with version no & date in footer**)

B) For Medical Ethics Committee (Refer to Checklist in project submission form available at Dr. BBCI official website):

1. Cover letter to Chairperson
2. Project Submission form – completed in all aspect
3. Study protocol
4. Participant Information Sheet & Informed Consent Form (English & Assamese mandatory) or Waiver of consent (if applicable)
5. Case Report Form (CRF) –the same CRF needs to be submitted which will be used at individual patient data enrollment
6. Questionnaire (English & Assamese mandatory) (as applicable)
7. Research Tool (as applicable)
8. CV, MRC & GCP certificates of all the investigators (with sign & date)
9. Lay summary
10. Clear copy of the Scientific approval
11. Consent from respective head of department
12. Consent from Director, BBCI (as applicable)
13. Payment receipt (if applicable)
14. Validation certificates (if applicable)
15. MoU (in cases of multi-institutional studies)

Note 1: Version no. & format of the forms should not be changed.

Note 2: Studies involving cell & gene manipulation should be submitted to **Institutional Bio Safety Committee** first.

Note 3: The approval of the documents/ dossier is subject to the submitted documents/ dossiers' only (**any subsequent changes in any document/dossier need to be informed to Medical Ethics Committee in writing as Amendment**)

Note 4: The IEC secretariat may be contacted for requirement of any form templates (project submission form, re-review form, CRA, PD/PV, SAE etc.).

- **IEC secretariat may be contacted for required forms.**
- Dr. BBCI IEC meeting is held on **the last Saturday of every month** and **the last date of study/ project submission is 14 working days prior** to the same.
- Study/ project dossier need to be **submitted initially as soft copies** to the IEC through the e-mail ID provided. After IEC secretariat reviews the softcopies, queries and clarifications may be raised in 2-3 days' time which need to be resolved within the time provided. Only post technical review confirmation, **hard copies should be submitted** to the IEC secretariat in **two sets** (One set will be acknowledged by IEC secretariat and returned to the PI for future reference).
- Cover letter should **contain the complete list of enclosures** with **version no & date** in the provided format.

Sr No	List of Documents	Version No	Date	Status

- All documents in the **IEC dossier** (protocol, CRF, ICF, lay summary) should have **version no. & date (in footer).** All documents should contain document name on first page.
- The **IEC SOP guidelines** may be referred for preparing the participant information sheet & informed consent form.
- **Lay summary** should be a 1-page document summarizing the study/ project in **layman terms** which can be easily comprehended by non-scientific members of the IEC.
- **CV, GCP& MRC** (if applicable) of all the investigators should be **signed & dated**. The validity date should be available (if applicable).
- The **final copy of study dossier (softcopy)** should contain all the documents with version no. & date and should be in **PDF format** (word format shall not be accepted). It should be mailed to the IEC e-mail ID in a **zip folder**.
- Official e-mail ID of Dr. BBCI IEC- iecbbci2021@gmail.com.

For any queries, please contact IEC administrators- murchanabk.bbci@gmail.com

- For IEC processing fees, please refer to the payment guidelines for all prospective studies & clinical trials (available in the library, Dr. BBCI).
- After submission of softcopy and hardcopies, applicants shall be notified regarding their date of presentation with **presentation guidelines** (attached herewith).
- **Decision or Approval letter** shall be shared with the applicants **within 7 working days** of the IEC meeting.
- Post IEC approval, all **serious adverse events (SAEs) / adverse events (AEs)** should be reported to DSMU, DCGI, Head of the Institute& Sponsor (if applicable) within 24 hrs of occurrence. CRA should be submitted annually or as asked by DSMU/ IEC.

Some terminologies for dossier documents are mentioned below for reference:

- **Study Protocol:** A protocol is a document that describes the background, rationale, aims, objectives, design, methodology, statistical considerations, references and organization of a clinical research study.
- **Informed Consent Form (ICF):** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial (mentioned in Participant Information Sheet) that are relevant to the subject's decision to participate.
- **Case record form (CRF)/ Proforma/ Research Tool:** A printed, optical, or electronic independent document designed to record all of the protocol required information to be reported on each trial participant.
- **Lay Summary:** This document should provide a non-scientific summary (for lay persons) of the proposal, including a statement about the importance of the question the research application will address the relevance of the research to your country or region, and the potential impact of the study results(1 page).
- **Concept Note:** This document should provide summary of study protocol (1-2 pages).

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