



AX11-V2/SOP-03/V2

IEC form for re-review of research proposals

Project No.
Title:
Principal Investigator :

Section A-Grouping of project

Mention the section in *PSF to which IEC query was raised.	Revision / Amendment made in the Section / Subsection (Mention NA if no changes required)
	Original:
	Amendment:

Section B- Project Fact Sheet

Mention the section in *PSF to which IEC query was raised.	Revision /Amendment made in the Section/Subsection (Mention NA if no changes required)
	Original:
	Amendment:

Section C- Project Submission Overview

Mention the section in *PSF to which IEC query was raised.	Revision /Amendment made in the Section/Subsection (Mention NA if no changes required)
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	Original:
	Amendment:

Section D- Budget Sheet for the Proposed Study**

Mention the section in *PSF to which IEC query was raised.	Revision /Amendment made in the Section/Subsection (Mention NA if no changes required)
	Original:
	Amendment:

Sign & Date of Principal Investigator	
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***PSF = Project Submission Form**

****In case of revision in budget sheet, the signed detailed budget sheet has to be attached**

AX12-V2/SOP-03/V2

Instructions for Submission of Projects for Institutional Ethics Committee Approval

The latest version of IEC documents are available with the IEC Secretariat of BBCI and the same will be available on the website of BBCI.

All IEC submissions should initially be made by email to iecbbc2021@gmail.com and later on should be submitted in a single hard copy after receiving notification from the IEC Secretariat.

- ❖ Kindly refer to the checklist of documents to be submitted to IEC. All documents listed may not be applicable to your project.
- ❖ A brief description of study designs is provided along with the document checklist for your assistance.
- ❖ The checklist of documents, study design and this instruction page is for your reference and should not be submitted at the time of IEC submission of your study.
- ❖ The IEC will process all study related documentary submissions within one week of submission of documents to the IEC office.

Initial Review of Projects

Instructions for filling the IEC submission form.

1. IEC submission form has 4 sections- A, B, C and D
2. All sections should be completely filled.
3. Questions not relevant to your study should be filled as NA.
4. **Do not alter or remove the version no. and date reflecting in header of IEC submission form.**
5. Do not make any formatting changes in the IEC submission form.
6. **The title of the study should be same in all four sections of the Project Submission Form.**
7. All 4 sections should be signed and dated by the Principal Investigator.
8. The signatures of your DMG Convener (if applicable) and Head of Department should be obtained before submission of hard copy of the IEC form to IEC.

After initial review of projects

After review of project by IEC, your study may attain any one of the following statuses:

A) Approved- Your study is scientifically and ethically sound and you may initiate the study subject to terms indicated in the final approval letter.

B) Revisions with minor modifications/amendments- Implies that your study may be approved once all the queries/recommendations of IEC are addressed satisfactorily. The revisions will not be taken up for full board and would be reviewed by Member Secretary the respective lead discussant on behalf of the full board. However, in some cases may be referred for a full board review.

C) Revisions with major modifications for resubmission- The study design and/or ethical aspect of the study is not satisfactory and would require extensive revision and would be re reviewed during full board Ethics Committee Meeting.

D) Not Approved- The study is not approved in its current form. A negative decision on an application will be supported by clearly stated reasons. If the investigator wishes to appeal to the decision, he/she may do so by contacting the IEC Secretariat within 21 working days.

If your project, after initial review attains the status **B** or **C**, the following documents are to be submitted to IEC:

- 1) IEC form for re-review of projects **AX11-V2/SOP-03/V2**
- 2) Response letter, if applicable
- 3) Supporting documents such as modified protocols, CRFs, ICFs and any other documents if applicable and any other documents

You do not have to submit the IEC PROJECT SUBMISSION FORM which was submitted at the time of initial review.

The checklist of document provided to you lists out the mandatory documents to be submitted at the time of initial review. Instruction/template to develop them is provided below:

General information

- Protocol, CRF, ICF, should bear Project title, page number, **version no. & date** (not to be confused with the version no. and date present in the BBCI-IEC submission form.
- **The vernacular versions of ICF (Assamese and any other language) should be submitted in 'pdf' format.**
- The ICF template provided by IEC is a reference document to assist in developing an effective informed consent document. However, the Principal Investigator may develop a customized ICF to suit the protocol requirement while addressing all key points.
- Kindly ensure that the study rationale and procedures described in the ICF is not a mere replica of the protocol. The ICFs should be written in a simple, non-technical style keeping in mind the educational and socio-economic background of the BBCI patient population. Similarly, the child information sheet should be simple. It should be developed keeping in mind, the age group being addressed. Parent Information Sheet and consent form should be submitted in case of minors.
- In case of collaborative studies, kindly provide a draft MOU, CTA, MTA along with institutional legal advisor's comments whichever is applicable.
- Find below a brief definition of the study designs presented in the IEC Project Submission Form. In case, your study is based on a study design which is not

mentioned in Section C of the IEC form, please specify the same while filling up the IEC Submission Form.