INDUSTRIAL RESEARCH AND CONSULTANCY CENTER
Office of the Dean R&D, IIT Bombay

Proposal Title: _____

IEC Checklist for Review & Approval

Note: Reg. the documents/information submitted, faculty members are required to strike out the options that DON'T apply from the Remarks column.

Sr.	Title	Remarks		
1.	Proposal for Studies INVOLVING human participants	Yes	No	NA
	a) Aims & objective of the study	Yes	No	NA
	b) Rationale/need of the study	Yes	No	NA
	c) Inclusion/exclusion criteria	Yes	No	NA
	d) Methodology	Yes	No	NA
	e) Flow chart of the study	Yes	No	NA
	f) Data on previous studies	Yes	No	NA
	g) Sample size and justification for the same	Yes	No	NA
	h) Start date of study: After approval of IEC	Yes	No	NA
	i) End date of study	Yes	No	NA
	j) IEC contact details added in the proposal	Yes	No	NA
2.	Proposal for studies involving the usage of biological fluids/samples/data	Yes	No	NA

Sr.	Title	Remarks		
	a) Aims & objective of the study	Yes	No	NA
	b) Inclusion/exclusion criteria	Yes	No	NA
	c) Methodology for obtaining samples	Yes	No	NA
	d) Plan for coding and decoding of samples	Yes	No	NA
	e) Flow chart of the study	Yes	No	NA
	f) Plan for sample storage for future use	Yes	No	NA
	g) Start date of study: After approval of IEC	Yes	No	NA
	h) End date of study	Yes	No	NA
	i) IBSC contact details added in proposal	Yes	No	NA
3.	Signed Undertaking by PI	Yes	No	NA
4.	Informed Consent Form (ICF)	Yes	No	NA
	a) ICF in English	Yes	No	NA
	b) IEC Contact details in the ICF	Yes	No	NA
	c) ICF in vernacular language(s)	Yes	No	NA
	d) Back translation of ICF	Yes	No	NA
	e) Assent Form in English when study participants are minors (12 to less than 18 yrs)	Yes	No	NA
	f) Assent form in vernacular language(s)	Yes	No	NA

Sr.	Title	Remarks		
	g) Questionnaire in English	Yes	No	NA
	h) Questionnaire in vernacular language(s)	Yes	No	NA
5.	Recruitment procedures: advertisement, notices notices and flyer copy *mandatory*	Yes	No	NA
6.	Funding related	–	–	–
	a) Details of funding agency/sponsor and fund allocation	Yes	No	NA
	b) Letter from the funding agency	Yes	No	NA
7.	Curriculum vitae of all the study researchers	Yes	No	NA
	a) Principal Investigator [PI]	Yes	No	NA
	b) Co-PI	Yes	No	NA
	c) Researcher personnel	Yes	No	NA
8.	GCP training certificate of the Study Investigators (within the last 3 years) for clinical studies	Yes	No	NA
9.	Conflict of Interest (CoI), if any	Yes	No	NA
10.	Vaccination certificate for blood related studies	Yes	No	NA
11.	Regulatory permissions	–	–	–
	a) Biosafety (IBSC)	Yes	No	NA
	b) Stem Cell Research			

Sr.	Title	Remarks		
	c) FSSAI	Yes	No	NA
	d) Any others, please mention: _____	Yes	No	NA
12.	Relevant administrative approvals (HMSC, CTRI, etc.)	Yes	No	NA
13.	Draft MoU for studies involving collaboration with other institutions (Mandatory if Applicable)	Yes	No	NA
14.	MTA for studies involving sample transfer	Yes	No	NA
15.	Insurance policy for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (Note: It is preferable to have the entire policy and not only the insurance certificate)	Yes	No	NA
16.	Additional documents required by IEC	–	–	–
	a) IEC clearances from other centres for Multicentric studies	Yes	No	NA
	b) IEC clearances from local IEC if the study site is not within the geographical limits	Yes	No	NA
	c) Letter of consent from external personnel contributing to the study	Yes	No	NA
17.	For **Revised version** of Proposals	–	–	–
	a) Changes highlighted in proposal and ICF	Yes	No	NA
	b) Response to PR comments / IEC recommendations	Yes	No	NA

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IEC Proposal Submission Format for Studies involving usage of Biological fluids/Samples/Data

1. **Proposal Title**

2. **Principal Investigator Details**

3. **co-PI (if any)**

4. **Project Personnel Details**

5. **Start Date of the study**
   After IEC approval is obtained

6. **End Date of the study**

7. **Please check the sample(s) to be used in the study.**

	Blood
	Tissues (specify)
	Spinal fluid
	Urine
	Secretions (Saliva, Tears)
	Hair
	Others (specify)

8. **Mention sample size and provide justification for the same.**

9. **Please provide a brief description of the research and the goals of the project.**
   (Including scientific rationale, results of previous studies, hypothesis, aims & objectives, methodology, study design along with statistical basis for the structure of the investigation, flow chart of the study and risk stratification)

10. **State the purpose of the biological samples.**

11. **Please note that the biological samples received from institutes outside IITB should also be accompanied with relevant ethical clearance documents.**

12. **Provide a description of how the samples will be obtained.**

13. **Describe the plan for coding and decoding the samples.**

14. **State if the samples be put stored for further use and the period for which it will be stored. Please note that this period cannot be beyond the end date of the study.**

15. **If yes, describe the plan for storing the samples for future use.**
    Please note that the consent form should include information about storing samples for future use.

16. **Will the samples be shared with individuals outside of this proposal or sent to individuals outside IITB.**

17. **If yes, include the plan on sharing or sending outside IITB.**
    Please note that the consent form should have information on sending the samples out.

18. **Draft MoU / LoA from the expected study site (if applicable)**

19. **List the sources of funding and financial requirements for the project.**
    [Attach copy of relevant approvals of funding]

20. **Please state if this proposal has been submitted to the IBSC. (Yes/No)**
    Kindly note that all studies that involve biological samples must be sent to the Institutional BioSafety Committee (IBSC) for review. IBSC contact: Safety Officer, email: safetyofficer@ircc.iitb.ac.in, IITB

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Undertaking by the PI

I have read the Ethical Guidelines for Biomedical Research on Human Participants, 2017 issued by ICMR and the Guidelines for Institute Ethics Committee, IIT Bombay.

The proposal being submitted is complete in all respects as given in the Guidelines for Institute Ethics Committee, IIT Bombay.

I agree to comply with all guidelines for ethical research.

On IEC approval and initiation of the study, I will

i. personally monitor the study.
ii. inform the IEC of any protocol deviation with adequate justifications, prior to the deviation.
iii. submit any amended protocol to IEC for renewed approval.
iv. inform the IEC of any new information related to the study.
v. notify the IEC of any premature termination of study with reasons, along with summary of the data obtained until the termination.
vi. inform IEC of any change of investigators / sites.
vii. submit continuing review report annually.
viii. submit a final report at the end of study.

PI Signature:

Date:
Place:

PI Name:
Department:
Tel No:
Email: