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 the 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 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			
	c) FSSAI	Yes	No	NA

Sr.	Title	Remarks		
	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 HUMAN participation

1. **Proposal Title**

2. **Principal Investigator Details**

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

4. **Project Personnel Details**

5. **Please provide a brief description of the research and goals of the project** [Including scientific rationale (with the results of previous animal and human studies), 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]

6. **State the role of human participants, including what will happen to the participants and what they will be told about the research.**

7. **Describe the population to be studied, inclusion and exclusion criteria, and numbers to be recruited.** [Include justification for the sample size]

8. **Describe recruitment procedures, what information will be shared with potential participants, any compensation or incentives that will be provided for participation.**

9. **Attach a copy of the recruitment flyer/ notices to be shared**

10. **Attach a copy of the informed consent form (ICF) to be shared with the participants. Please include copies of the forms with translations in regional language forms.**

11. **Describe any features that would not be disclosed to the participants and provide a justification for the same.**

12. **State the type of data to be collected as interviews, face to face interviews, questionnaires, education tests, physical measurements, physiological measurements, physiological sample collections including blood samples, etc.**

13. **Describe data collection procedures. Please attach questionnaires, interview protocols.**

14. **Describe procedures for maintaining confidentiality of participants**

15. **Please list the expected study sites.**

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

17. **Describe real and potential risks to the participants.**

18. **Please classify the risk category as one of the following based on definitions provided in the Guidelines for Institute Ethics Committee.**
(Less than minimal risk / Minimal risk / Greater than minimal risk)
[Refer ICMR guidelines (Pg 21 of document) for the risk category: https://www.indiascienceandtechnology.gov.in/sites/default/files/file-uploads/guidelineregulations/1527507675_ICMR_Ethical_Guidelines_2017.pdf]

19. **Please list potentially harmful effects that can be adequately detected, prevented, or treated.**

20. **Describe definite and potential benefits to the participants.**

21. **Describe ethical issues in the study and plans to address these.**

22. **List any regulatory clearances required / obtained and attach application and approval copies of the same.**

23. **List the sources of funding and financial requirements for the project.**

[Attach copy of relevant approvals of funding]

24. State conflicts of interest, if any.

25. A statement describing any

a) compensation for study participation (including expenses and access to medical care) to be given to research participants;

b) a description of the arrangements for indemnity, if applicable (in study-related injuries);

c) a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

26. Are the results to be published? Please note that confidentiality of the participants must be maintained while publishing.

27. Provide any other information relevant to the study

28. Start Date of the study

After IEC approval is obtained

29. End Date of the study

30. 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

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 all Serious Adverse Events and the interventions undertaken.
iii. inform the IEC of any protocol deviation with adequate justifications, prior to the deviation.
iv. submit any protocol amendment to IEC for renewed approval.
v. inform the IEC of any new information related to the study.
vi. notify the IEC of any premature termination of study along with reasons and summary of the data obtained until the termination.
vii. inform the IEC of any change of investigators / sites.
viii. submit continuing review report annually.
ix. submit a final report at the end of study to the IEC.

PI Signature:

Date:
Place:

PI Name:
Department:
Tel No:
Email: