STANDARD OPERATING PROCEDURES FOR "INSTITUTE ETHICS COMMITTEE"

INDIAN INSTITUTE OF TECHNOLOGY, KANPUR

IIT KANPUR, KALYANPUR, KANPUR - 208016 (U.P.), INDIA

Submission and Review Procedures

- Researchers should submit research proposals as soft to the Secretariat for review in the prescribed format and required documents as per EC SOPs. The EC should prepare a checklist for the required documents as given in the table.
- This list is subject to modifications, depending on the type of research, EC SOPs and institutional policies.

Table-1

Details of documents to be submitted for EC review

1. Cover letter to the Member Secretary	16. Regulatory permissions (as applicable)
2. Type of review requested	17. Relevant administrative approvals (such as HMSC approval for International trials)
3. Application form for initial review	18. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
4. The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable)	19. MoU in case of studies involving collaboration with other institutions (if applicable)
5. Case record form/questionnaire	20. Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)
6. Recruitment procedures: advertisement, notices (if applicable)	21. Documentation of clinical trial registration (preferable)
7. Patient instruction card, diary, etc. (if applicable)	22. Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
8. Investigator's brochure (as applicable for drug/biologicals/device trials)	23. Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
9. Details of funding agency/sponsor and fund allocation (if applicable)	24. Any additional document(s), as required by EC (such as other EC clearances for multicentric studies)
10. Brief curriculum vitae of all the study researchers	25. Protocol
11. A statement on COI, if any	
12. GCP training certificate (preferably within 5 years) of investigators (clinical trials)	
13. Any other research ethics/other training evidence, if applicable as per EC SOP	
14. List of ongoing research studies undertaken by the principal investigator (if applicable)	
15. Undertaking with signatures of investigators	

Table-2

Details of documents to be included in the protocol

The protocol should including the following:

1. the face page carrying the title of the proposal with signatures of the investigators;
2. brief summary/ lay summary;
3. background with rationale of why a human study is needed to answer the research question;
4. justification of inclusion/exclusion of vulnerable populations;
5. clear research objectives and end points (if applicable);
6. eligibility criteria and participant recruitment procedures;
7. detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
8. duration of the study;
9. justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;
10. procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples;
11. plan for statistical analysis of the study;
12. plan to maintain the privacy and confidentiality of the study participants;
13. for research involving more than minimal risk, an account of management of risk or injury;
14. proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
15. provision of ancillary care for unrelated illness during the duration of research;
16. an account of storage and maintenance of all data collected during the trial; and
17. plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.
18. ethical considerations and safeguards for protection of participants.

Table-3

Types of Review

Sl. No.	Types of review	
1	**Exemption from review**	Proposals with less than minimal risk where there are no linked identifiers, for example; • research conducted on data available in the public domain for systematic reviews or meta-analysis; • observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • quality control and quality assurance audits in the institution; • comparison of instructional techniques, curricula, or classroom management methods; • consumer acceptance studies related to taste and food quality; and public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
2	**Expedited review**	Proposals that pose no more than minimal risk may undergo expedited review, for example; • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • research involving clinical documentation materials that are non-identifiable

		(data, documents, records); • modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); • revised proposals previously approved through expedited review, full review or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk; • progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and • for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. • research during emergencies and disasters
3	**Full committee review**	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are; • research involving vulnerable populations, even if the risk is minimal; • research with minor increase over minimal risk • studies involving deception of participants • research proposals that have received

		exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; • amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; • major deviations and violations in the protocol; • any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; • research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need; • prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

- The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review.
- A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to

the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

- Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs.
- Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting.
- EC members should be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.
- All EC members should review all proposals. However, the EC may adopt different procedures for review of proposals in accordance with their SOPs.
- The EC may adopt a system for pre-meeting peer review by subject experts and obtain clarifications from the researchers prior to the meeting in order to save time and make the review more efficient during the full committee meeting, especially in institutions where there are no separate scientific review committees.
- The EC may have a system of appointing primary and secondary reviewers. The Member Secretary should identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise.
- The Member Secretary may identify subject experts to review the proposal as per need. These experts may be invited to the EC meeting or join via video/tele conference but will not participate in final decision making.
- The EC should meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed.
- The designated (primary and secondary) reviewers and subject experts should conduct the initial review of the study protocol and study related documents as per the pre- defined study assessment form and for factors as described in Table above.

Table-4

Ethical issues related to reviewing a protocol

1	**Social values**	• The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.
2	**Scientific design and conduct of the study**	• Valid scientific methods are essential to make the research ethically viable as poor science can expose research participants or communities to risks without any possibility of benefit. • Although ECs may obtain documentation from a prior scientific review, they should also determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. • The EC can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.
3	**Benefit-risk assessment**	• The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research. • Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole.

		• The EC should review plans for risk management, including withdrawal criteria with rescue medication or procedures. • The EC should give advice regarding minimization of risk/discomfort wherever applicable. • Adequate provisions must be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials)
4	**Selection of the study population and recruitment of research participants**	• Recruitment should be voluntary and non-coercive. Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit. • Participants should be able to opt out at any time without their routine care being affected. • No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits. • Vulnerable groups may be recruited after proper justification is provided.
5	**Payment for participation**	• Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences should be reviewed. • There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement. No undue inducement must be offered.

6	**Protection of research participants' privacy and confidentiality**	• ECs should examine the processes that are put in place to safeguard participants' privacy and confidentiality. • Research records to be filed separately than routine clinical records such as in a hospital setting.
7	**Community considerations**	• The EC should ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs. • The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized. • Plans for communication of results to the community at the end of the study should be carefully reviewed. • It is important to examine how the benefits of the research will be disseminated to the community.
8	**Qualifications of researchers and adequacy assessment of study sites**	The EC should look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.
9	**Disclosure or declaration of potential COI**	• The EC should review any declaration of COI by a researcher and suggest ways to manage these. • The EC should manage COI within the EC and members with COI should leave the room at the time of decision making in a particular study.
10	**Plans for medical management and compensation for study related injury**	• The proposed plan for tackling any medical injuries or emergencies should be reviewed. • Source and means for compensation for study related injury should be ascertained.
11	**Review of the informed consent process**	The informed consent process must be reviewed keeping in mind the following: • the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for

		vulnerable populations; • the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs; • contents of the patient/participation information sheet including the local language translations • back translations of the informed consent document in English, wherever required; • provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and • if consent waiver or verbal/oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria.

Full Committee Meeting

- All proposals that are determined to undergo full committee review must be deliberated and the decision about the proposal taken at a full committee meeting.
- ECs should conduct regular full committee meetings to deliberate proposals in accordance with a pre-decided schedule, as described in the SOPs.
- A meeting will be considered valid only if the quorum is fulfilled. This should be maintained throughout the meeting and at the time of decision making.
- If a member has declared a COI for a proposal then this should be submitted in writing to the Chairperson before beginning the meeting and should be recorded in the minutes.
- The member who has declared COI should withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon. This should be minuted and the quorum rechecked.
- A list of absentee members as well as members leaving or entering in-between the meeting should be recorded.
- Proposals should be taken up item-wise, as given in the agenda.
- No of proposals reviewed in a meeting should justify that there is ample time devoted for review of each proposal. If there are more number of proposals for consideration per meeting either meetings may be more frequent or more EC's to be constituted as per requirement of the institution.
- Time allotted for the meeting should be reasonable to allow ample discussion on each agenda item.
- The minutes of the previous meeting and list of protocols that were exempt from review or underwent expedited review should be ratified.
- The researcher may be called in to present a proposal or provide clarifications on the study protocol that has been submitted for review but should not be present at the time of decision making.
- The primary and secondary reviewers can brief the members about the study proposal and review carried out as per EC SOPs.
- The comments of an independent consultant (if applicable) could be presented by the Member Secretary or subject experts could be invited to offer their views, but they should not participate in the decision-making process. However, her/his opinion must be recorded.

- Representative(s) of the study group population can be invited during deliberations to offer their viewpoint but should not participate in the decision-making process.
- The EC may utilize electronic methods such as video/conference calls for connecting with other subject experts/independent consultants during the meeting.
- All members of the EC (including the Chairperson and the Member Secretary) present in the room have the right to vote/express their decision and should exercise this right.
- The decision must be taken either by a broad consensus or majority vote (as per SOP) and should be recorded. Any negative opinion should be recorded with reasons.