Institutional Ethics Committee, SCTIMST

Frequently asked questions:

How could I decide whether my project requires Institutional Ethics Committee (IEC) approval?

If your study satisfies *any* of the following points then it does come under research and requires IEC approval.

- If your study participants are randomized to different group
- If your protocol does demand changing treatment/patient care from accepted standards for any patient involved
- If your findings are going to be generalized.
- If you are going to take data from more than *two* subjects for your study (taking data from three or more subjects is considered as research for generalizing the finding).

Can I publish "Case report" without IEC approval?

Case report based on a single patient does not come under the purview of research. Since it is an unexpected observation under normal clinical practice, you need not take IEC approval to publish the result. However as a basic requirement of clinical ethics, you should make sure that the consent from the subject is obtained to publish the data and confidentiality of the subject is well protected. See the detail guideline published by *British Medical Journal* on consent process for case reports: http://journals.bmj.com/site/authors/author-toolkit.xhtml. For your reference, a model consent form for Case Studies is available in the Institute intranet web site (IEC section).

Do I need to take IEC approval to collect retrospective data from clinical records as part of my research?

Yes. Any research on human subjects using their clinical records or left over tissue samples, require IEC approval, even if you are planning a retrospective study. If you are taking data from three or more subjects, it's considered as research and comes under the purview of IEC.

I am planning to do an interview-based study without any clinical interventions to the study subjects. Do I need IEC approval for the study?

Yes. IEC has to review and approve the study protocol including the consenting process and the questionnaire before you can initiate the study.

I'm planning to do a study to compare two different standards of clinical practices, which are commonly followed at various centers. Do I need IEC approval for such a study?

Yes. Any systematic analysis of data which will result in generalizing the finding require IEC approval.

Do student projects, which involve collecting data from patients or healthy volunteers, require IEC approval?

Yes. There is no exemption for student projects. Based on the type of the student proposal IEC secretariat may decide whether subcommittee's review is sufficient for the study. This is mainly to avoid any delay because the student proposals are often part of their dissertation work, which require to be completed in a specific time frame.

However if the study has major ethical issues, the proposal will be referred to full committee for its review.

I am planning a basic research using umbilical cords to isolate stem cells. Do I need IEC approval?

Yes. Stem cell studies using human samples have to go through the Institutional Committee for Stem Cell Research and Therapy (IC-SCRT) before submission to IEC for final approval.

When initiating a clinical research with a foreign or national institution do I need to obtain the IEC approval from that collaborating institution also?

Yes. If the collaborating institution does not have an ethics committee, you have to state that in the IEC application form and in the covering letter.

I am planning an international collaborative study. The study involves sending human biological samples abroad. How do I proceed with that?

Endorsement from Health Ministry Screening Committee is mandatory to send human biological samples abroad. This process may experience some administrative delays, so you have to plan the study well in advance. To initiate the process you need the IEC approval. Once the IEC approves the study you can approach the Director of the Institute to recommend transfer of human biological samples to the collaborating center abroad. With these two documents (both IEC and Director's approvals) you should approach the Health Ministry Screening Committee for final endorsement. Please see the directive of Health Ministry on this regard (F.No.L.19015/53/97-IH(Pt.) GOVERNMENT OF INDIA) http://icmr.nic.in/min.htm

I have received TAC approval for my study. Pending IEC approval, can I initiate the study?

No, you should not initiate a study without IEC approval. TAC is an internal committee of the institute to help the IEC to review the scientific aspects of a study proposal. IEC, however, may reexamine the TAC recommendations and review the technical aspects also. Initiating a clinical study without IEC approval is a serious violation under the law.

Do I have to submit to the IEC yearly progress report of an approved study?

Yes. IEC monitors the progress of the study as well as takes note the adverse events associated with the study before approving its continuation for long-term.

As per the new rules, the CSDSCO officials can audit the trial sites (including surprise visits). Do I have to inform such inspection details to the IEC?

Yes. No outsiders/officials will be permitted to visit or inspect the study site without the prior permission of IEC/Director. PI should report to the IEC/Director of any such visits. Though it is incumbent upon the Ethics Committee to allow the Inspectors or other authorized officials of the CDSCO "to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors of officials in relation to the conduct of clinical trials," it is the responsibility of the PI to report about the proposed inspection to the Director's office as well as to the Secretary of the IEC before access is allowed.

Do I have to inform any change in Investigators of a study to the IEC?

Yes. Any change in study team (PI, Co-PI or Guide) need to be intimated to the IEC. If you are planning to go for a long leave and the study will be supervised by the Co-PI, then that information need to be intimated to the IEC.

My study requires healthy volunteers. How do I get IEC approval for that?

You need to submit the recruitment protocol for healthy volunteers to the IEC. Main point to note is: Do not recruit patient's relatives or the staff of the Institute who works under you, because they are highly vulnerable and may not able to say "No" to you.

You need to submit advertisement details for healthy volunteers to the IEC for its review and approval. Make sure you are giving brief information of the study and contact details in the advertisement. Final advertisement should mention about the IEC approval status of the study.

TAC has rejected one of my studies. Can I appeal to IEC to consider my proposal?

Yes. IEC will review your rebuttals and make appropriate decision.

If any adverse event occurs to one of the study subjects in our center, within how many hours/ days should I report that to the IEC?

You should report any adverse event at the earliest and in any event, within 24 hours of the occurrence to the Member Secretary, IEC by email or in writing. According to the new rules, you have to report the same to the CDSCO also within 24 hours. Please check the rules of CDSCO on compensation issues to the study participants in case of an adverse event (http://www.cdsco.nic.in/). Apart from the above, Investigator has to submit all the adverse events reports from other centers where the study has been conducted. There is a adverse event reporting format in the Institute web site. Kindly fill that up while submitting the adverse event reports.

Is insurance coverage to patients essential in a drug trial? Will the indemnity insurance suffice the requirement?

Insurance coverage to study participants is essential in a drug trial. Indemnity insurance is mainly to protect the investigator, the Institution and the sponsor. It does not directly cover the study subject if a study related adverse event occurs to him/her. The study subject needs to file a complaint against the investigator or the Institution for the trial related injury to get considered for compensation as per Indemnity insurance rules. Insurance coverage to the subjects towards any unforeseen disability due to participating in a drug trial is more appropriate and essential. You need to discuss this with the sponsor and insist on getting proper insurance coverage to all the study participants in addition to the indemnity insurance.

Is it possible to get a consent form waiver for a study?

You need to request to IEC showing the reasons on which you would like to get a informed consent waiver. Based on the type of the study, IEC may consider the request.

If I am planning to initiate a genetic study, do I have to take any additional precautions in the consenting process?

Before initiating genetic studies please go through the guidelines of ICMR (http://icmr.nic.in/ethical_guidelines.pdf) and NIH (http://www.genome.gov/27026588). Most important thing to keep in mind is that the biological samples belong to the person and you cannot use it for research without his/her consent. For genetic studies, you may have to take repeated consent for each new study you may conduct with the same sample. There are no short cuts for this other than obtaining new consent at each step. Please also note that any biological sample which go out of the country need both IEC and Health Ministry Screening Committee approval.

I have received the approval for conducting a study from IEC. But due to various reasons, I could not initiate the study in time. Do I need to inform the IEC about such deviations?

IEC approves a study protocol, assuming that you will be initiating and completing the study on the dates you have mentioned in the IEC application form. If there is a delay in initiating the study that should be promptly communicated to the IEC secretariat. If the delay is more than one year from the date of approval, you may need to take a fresh approval. Please discuss such deviations with the IEC secretariat.

While submitting a proposal to the IEC, what are the points I should keep in mind?

a) The process of reviewing and deciding on each proposal after going through hundreds of pages is a huge responsibility for the IEC members. It is therefore essential that you flag each attached documents, assign page number and index them. Make sure that your covering letter highlights the study aim and lists the documents attached.

b) Make sure you are filling up the IEC form answering to all the points. You should know that the IEC members do not have the technical knowledge on the topic you are working on. So make sure that language you use is simple and easily comprehensible. Try to avoid filling the form by 'cut and paste' from the proposal, which is often highly technical in nature.

c) Draft your consent form carefully. There are model consent forms in the intranet site of the Institute, which you can use as a guideline. Consent forms should be written in a very simple language, which could be understandable even by a primary school dropout. Substance of the English and Malayalam versions should be the same though literal interpretation is not expected. Also make sure to include telephone number of IEC Member Secretary in the consent form as a "study independent contact person" so that study participant can contact for any clarifications.

d) Please read the SOP of the IEC (available in the intranet site of the Institute) for more details on functioning of the Ethics Committee.