University of Delhi
Institute Human Ethics Committee (DU-IHEC)

IHEC has been constituted by University of Delhi and registered with CDESCO. The committee can review the proposals submitted as per the following guidelines.

Application procedure:

a. All proposals should be submitted in the prescribed application form, the details of which are given under documentation; along with a PDF copy by e-mail (immunoacbrihec@gmail.com) to the member-Secretary, IHEC (Prof.Anju Katyal ,MS DU-IHEC).
b. All the relevant documents should be enclosed with the application form.
c. Three copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/Collaborators should be forwarded by the Head the Department/Institution of the ethical committee.
d. The date of the meeting will be intimated to the researcher, to be present, if necessary to offer any clarification. A PowerPoint presentation should be kept handy.
e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

10. Documentation

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation.
2. Name of the institute /Hospital/Field area where research will be conducted.
3. Approval of the Head of the Department /Institution.
4. Protocol of the proposed research.
5. Ethical issues in the study and plans to address these issues.
6. Ethical approval of the project forwarded by the hospital's human ethics committee from where the samples have been procured.
7. Proposal should be submitted with all relevant enclosure proformae, case report forms, questionnaires, follow-up cards etc.
8. Informed consent process, including patient information sheet and informed consent form in local language(s).
9. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/countries, if available. NA
10. Curriculum vitae of all the investigators with relevant publication in last five years.
11. Any regulatory clearance required.
11. Source of funding and financial requirements for the project.
12. Other financial issues including those related to insurance.
13. An agreement to report only Serious Adverse Event (SAE) to IEC.
14. Statement of conflicts of interest, if any.
15. Agreement to comply with the relevant national and applicable international guidelines.

16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangement for indemnity, if applicable (in study related injuries); a description of the arrangement for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decisions or modified protocols) 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 the account. The reasons for negative decisions should be provided.
17. Plans for publication of results, positive or negative, while maintaining the privacy and confidentiality of the study participants.
18. Any other information relevant to the study.

11. Review procedures:

a. The meeting of the IEC will be held twice a year or additional meetings may be held depending on the number of projects received. The proposals will be sent to members at least 10 days in advance by email.
b. Decisions will be taken by consensus after discussions in the meeting, and whenever needed voting will be done.
c. Researchers will be invited to offer clarifications, if need be.
d. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
e. The decisions will be recorded in minutes and chairperson's approval taken in writing.

12. Element of review

1. Scientific design and conduct of the study.
2. Approval of appropriate scientific review committees.
3. Examination of predictable risks/harms.
4. Examination of potential benefits.
5. Procedure of selection of subjects in methodology including inclusion/exclusion, withdrawal criteria and other issues like advertisement details.
6. Management of research related injuries, adverse events.
7. Compensation provisions.
8. Justification for placebo in control arm, if any.
9. Availability of products after the study, if applicable.
10. Patient information sheets and informed consent form in local language.
11. Protection of privacy and confidentiality.
12. Involvement of the community, wherever necessary.
13. Plans for data analysis and reporting.
14. Adherence to all regularity requirements and applicable guidelines.
15. Competence of investigators, research and supporting staff.
16. Facilities and infrastructure of study sites.
17. Criteria for withdrawal of patients, suspending or terminating the study.

13. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the

application, amendments, and other consideration that will be eligible for expedited review will be specified at the time of the consideration of the original proposal.