SHIV NADAR
INSTITUTION OF EMINENCE DEEMED TO BE UNIVERSITY
DELHI NCR

Guidelines for Shiv Nadar (Institution of Eminence Deemed to be University) Institutional Ethics Committee (IEC) for Human Research

1. Objective:

The objective of this guidelines is to contribute to the effective functioning of the Institutional Ethics Committee (IEC) so that a quality and consistent ethical review mechanism for research involving human is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR.

2. Role and mandate of Shiv Nadar IoE IEC

IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. The basic responsibility of IEC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner.

The IEC will look into the aspects of informed consent process, risk benefit ratio and distribution of burden. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

The mandate of the Shiv Nadar IoE-IEC will be to review all research projects involving human subjects to be conducted at the University, irrespective of the funding agency.

3. Composition of IEC

IECs should be multidisciplinary and multisectorial in composition. Independence and Competence are the two hallmarks of an IEC.

The Chairperson of the Committee should be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary who will belong to the same Institution should conduct the business of the Committee. Other members should be a mix of medical / non-medical scientific and non-scientific persons including lay public to reflect the differed viewpoints in the country.

IEC should be constituted in the following pattern:

i) A Chairperson

ii) A Member Secretary,

iii) 5-15 members from different Departments / Specialties / disciplines or areas

etc.

4. Authority under which Shiv Nadar IoE-IEC is constituted:

The Vice-Chancellor constitutes the IEC.

5. Membership requirements:

a) The duration of appointment is initially for a period of 3 years and may be extended for one more term.
b) At the end of 3 years, as the case may be, the committee shall be reconstituted, and 50% of the members shall be replaced.
c) A member can be replaced in the event of death or long-term non availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
d) A member can tender resignation from the committee with proper reasons to do so.
e) All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
f) Conflict of interest should be declared by members of the IEC

6. Quorum requirements:

The minimum of 5 members are required to compose a quorum.

7. Offices

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

8. Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC .

9. Application Procedures:

a) All proposals should be submitted in the prescribed application form, the details of which are given under Documentation.
b) All relevant documents should be enclosed with application form.

c) Required 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 of the Departments to the ethics committee.
d) The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
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. Review procedures:

a) The meeting of the IEC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.
b) Decisions will be taken by consensus after discussions, 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 minuted and Chairperson's approval will be taken.

The IEC member secretary office will screen the proposals for completeness of the application submitted. Depending on the risk category of the proposal may categorise into three types of review. An investigator may mention the category of the proposal based in the risk profile in their application but the decision of IEC will be considered final.

- **Exemption from Review**

Research with less than minimal risk presented to human participants may fall under this category. **Minimal risk could be defined as when the anticipated harm or discomfort is not greater than encountered by the participants in their routine daily activities or during the performance of routine physical or psychological examination or tests**. For Example

- Exception
    - If the study can identify human participants directly or through identifiers or through identifiers and the disclosure of information outside research could subject the participants to the risk of civil or criminal or financial liability or psychosocial harm
    - When interviews involve direct approach or access to private papers.

- **Expedited Review**

Proposal which present no more than minimal risk to research participants may be subjected to expedited review.

- **Full Review**

Research proposal presenting with more than minimal risk or those which do not qualify for exempted or expedited review. Projects involving vulnerable population and special groups shall be subjected to full review.

11. Element of review

a) Scientific design and conduct of the study.
b) Examination of predictable risks/harms.
c) Examination of potential benefits.
d) Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
e) Management of research related injuries, adverse events.
f) Compensation provisions.
g) Justification for placebo in control arm, if any.
h) Availability of products after the study, if applicable.
i) Patient information sheet and informed consent form in local language.
j) Protection of privacy and confidentiality.
k) Involvement of the community, wherever necessary.
l) Plans for data analysis and reporting
m) Adherence to all regulatory requirements and applicable guidelines
n) Competence of investigators, research and supporting staff
o) Facilities and infrastructure of study sites
p) Criteria for withdrawal of patients, suspending or terminating the study

12. Decision-making

a) Members will discuss the various issues before arriving at a consensus decision.
b) A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
c) Decisions will be made only in meetings where quorum is complete.
d) Only members can make the decision. The expert consultants will only offer their opinions.
e) Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
f) In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

g) Modified proposals may be reviewed by an expedited review through identified members.
h) Exemption and Expedited review
    a. A sub-committee of five members including the member secretary may be constituted for deciding the proposals marked for Exemption or Expedited review.
        i. The decision made by the committee shall be tabled at the next IEC meeting for ratification
i) Procedures for appeal by the researchers.
    a. In case of rejection of proposal by the IEC, the researcher may appeal the decision to the chairperson describing the reasons for appeal with new evidence and supporting information.
    b. The chairperson may convene an IEC meeting to consider the new information provide.
    c. The appeal shall be decided by two third majority.
    d. Decision made on appeal petition is considered final and binding on the researchers

13. Communicating the decision

a) Decision will be communicated by the Member Secretary in writing.
b) Suggestions for modifications, if any, should be sent by IEC.
c) Reasons for rejection should be informed to the researchers.
d) The schedule / plan of ongoing review by the IEC should be communicated to the PI.

14. Follow up procedures

a) Reports should be submitted at prescribed intervals for review.
b) Final report should be submitted at the end of study.
c) All SAEs (Serious Adverse Event) and the interventions undertaken should be intimated.
d) Protocol deviation, if any, should be informed with adequate justifications.
e) Any amendment to the protocol should be resubmitted for renewed approval.
f) Any new information related to the study should be communicated.
g) Premature termination of study should be notified with reasons along with summary of the data obtained so far.
h) Change of investigators / sites should be informed.

15. Record keeping and Archiving

a) Curriculum Vitae (CV) of all members of IEC.
b) Copy of all study protocols with enclosed documents, progress reports, and SAEs.
c) Minutes of all meetings duly signed by the Chairperson.
d) Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
e) Copy of all correspondence with members, researchers and other regulatory bodies.
f) Final report of the approved projects.
g) All documents should be archived for prescribed period.

16. 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. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s).
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
9. Curriculum vitae of all the investigators with relevant publications in last five years.
10. Any regulatory clearances 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 Events (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 arrangements for indemnity, if applicable (in study-related injuries); 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.

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

Appendix

DOCUMENT 1

Approval Letter

To
Dr

This is to certify that the project No. ----------, entitled " ----------" submitted by you, has been approved by the Institute Ethics Committee at its meeting held on---------- under the following terms and conditions.

This approval is valid for one year or the duration of the project whichever less is.

The following members of the ethics committee were present at the meeting held on (date, time, place)

_____Chairman of the Ethics Committee
_____Member secretary of the Ethics Committee

SHIV NADAR
INSTITUTION OF EMINENCE DEEMED TO BE UNIVERSITY
DELHI NCR

_____Name of each member with designation

We approve the research work submitted under current proposal to be conducted in its presented form.
The Institutional Ethics Committee to be informed about the progress of the study, any serious adverse events occurring in the course of the study, any changes in the protocol and patient information/informed consent and to provide a copy of the final report on completion.

Yours sincerely
Member Secretary,

DOCUMENT 2

Proforma to be submitted to the Institutional Ethics Committee (Human studies)

1. Title of the Project :-
2. a) Name, Designation, Address, E mail ID and mobile no. of Principal Investigator :-
   b) Name, Designation(s) & Address(s), E mail ID and mobile no. of Co-investigators :-

3. Background information & purpose of study :- (include 4 - 6 relevant references and justify the reasons for undertaking the study, in 100 – 200 words)
4. Research Hypothesis :-
5. Aim and Objectives :-
6. Materials & Methods :-
   i. Whether study involves humans, animals or both?
   ii. Type of study
   iii. a.) Inclusion criteria
   b.) Exclusion criteria
   iv. Number of groups studied
   v. Sample size in each group and method of determination of sample size
   vi. Interventions
   vii. Methodology

viii. Methods of statistical analysis to be used
ix. Relevant references Number of projects with the PI & Co investigator

7. Permission of Drug Controller of India (DGCI) (if applicable) - copy of permission to be attached.
8. Permission of any government or non-government organization – if their resources are being used: Copy of permission to be attached.
9. Ethical issues involved in the study :- (less than minimal risk / minimal risk / more than minimal risk to the study subjects) (please consult ICMR guidelines)
10. To attach consent forms parts 1 & 2 in English and local language
11. Conflict of interest for any other investigator(s) – if yes, please explain in

DOCUMENT 3

CHECKLIST FOR STUDY SUBJECT's INFORMED CONSENT DOCUMENTS

1.1 Essential Element:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all procedures and
4. Description of any reasonably foreseeable risks or discomforts to the subject
5. Description of any benefits to the subject or others reasonably expected from research. If no benefit is expected subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the subject.
7. Statement describing the extent to which confidentially of records identifying the subject will be maintained and who will have access to subject's medical records

8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Compensation and/or treatment(s)available to the subject in the event of trial-related injury
10. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury.
11. The anticipated prorated payment, if any, to the subject for participating in the trial
12. Subject's responsibilities on participation in the trial.
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled
14. Any other pertinent information

1.2 Additional elements, which may be required

a. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.

b. Additional costs to the subject that may result from participation in the study.

c. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.

d. Statement that the subject or subject's representative will be notified in a timely manner if significant new finding develop during the course of the research which may affect the subject's willingness to continue participation will be provided.

e. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

f. Approximate number of subjects enrolled in the study

SHIV NADAR
INSTITUTION OF EMINENCE DEEMED TO BE
UNIVERSITY
DELHI NCR

DOCUMENT 4

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)
2. Name and address of the area where the study will be conducted: Education, training & experience that qualify the Investigator for the study
3. Name and address of all facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will assisting the Investigator in the conduct of the investigation (s).
6. Protocol Title and study number (if any)
7. Commitments:
   (i) I have reviewed the protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
   (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, expect where necessary to eliminate an immediate hazard(s) to the trial subjects or when the changes(s) involved are only logistical or administrative in nature.
   (iii) I agree to personally conduct and/or supervise the study
   (iv) I agree to report to the sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory guidelines
   (v) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about obligations in meeting their commitments in the study.
   (vi) I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the sponsor, Ethics Committee, Licensing Authority or their authorized representative,, in accordance with regulatory provisions . I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the sponsor.
   (vii) I agree to promptly report to the Ethics Committee all changes in the

clinical trial activities and all unanticipated problems involving risk to human subjects or others.

(viii) I agree to inform all unexpected serious adverse events to the sponsor as well as the Ethics Committee within seven days of their occurrence.

(ix) I will maintain confidentially of the identification of all participating study patients and assure security and confidentially of study data.

(x) I agree to comply with all other requirement, guidelines and statutory obligations as applicable

8. Signature of Investigator with date