**INSTITUTIONAL ETHICS REVIEW BOARD**
**JAWAHARLAL NEHRU UNIVERSITY**

**Minutes of the Institutional Ethics Review Board Meeting to discuss SOP held on 29th November 2014 at 2:30 p.m. in 108, Committee Room of the IERB at Old Language Lab Complex, Jawaharlal Nehru University.**

The following members were present:

1. Professor S.C. Malik - Member
2. Professor Madhuri Behari - Member
3. Professor Ramesh Juyal - "
4. Professor Ravinder Gargesh - "
5. Dr. Tripti Khanna - "
6. Advocate Rukhsana Choudhury - "
7. Advocate Omika Dubey - "
8. Dr. Suhas Shetogovekar - "
9. Dr. Rajib Dasgupta - "
10. Professor Ritu Priya - "
11. Dr. Sunita Readdy - "
12. Dr. Abha Yadav - "
13. Prof. Sabaree Mitra - "
14. Professor Vaishna Narang, Member Secretary, IERB Chaired the meeting.

The SOP January 2010 with modifications in August 2012 was presented. The following points were raised by the members in the general discussion:

1. Ethical clearance must be taken before the commencement of the study. The completed or continuing studies which were not reviewed by the IERB prior to comment do not fall within the purview of IERB.
2. 'Subject' word in the entire text to be substituted by the word 'participant' or 'patient' in case of clinical studies
3. 'Vulnerability' to be defined. In the preamble itself some groups are mentioned but others like institutionalised persons (prisoners, patients, inmates of old age homes etc.) may be included
4. 'Stored samples /cell lines' must be mentioned in the SOP as well as in the detailed protocol format.
5. SOP must emphasise that tools /procedures approved by the IERB, if changed in the course of the study must be reported to the IERB.

6. SOP may clearly mention that any adverse effects of the study, during the course of the study must be reported back to IERB immediately, within a week, not later then 24 hrs in of death, as per GOI norms.
7. Considering the involved/expanses/wages lost in a specific study appropriate remuneration/recompensation may be fixed in advance.
8. In case of adverse effect reported, appropriate wages lost compensations for losses to be fixed based on the kind of injury/damage/loss/occurring during the course of the study.
9. A general template provided for PIS-ICF may be followed by a few examples for studies based on samples/data samples of different kinds
   (a) Biological samples
   (b) Behavioural samples
   (c) Socio-cultural- psychological data samples
   (d) Links may be provided to ethical guidelines &ICF format for Clinical trials
10. For students proposals special considerations are required, especially for MA/ M Tech/ M.Sc and M.Phil level proposals. Such proposals must be reviewed in an expedited/manner in a fast track channel/ in a time bound procedure.
11. Since IERB is the signing authority for ethical clearance, it was suggested that the contact details number of the Member Secretary IERB may be mentioned on the ICF, a copy of which remains with the participant too, so that in case of any adverse effects of the study the participant can contact the Member Secretary, IERB directly.
12. A suitable mechanism may be evolved which helps CASR of the school & the IERB to work in tandem.
13. For M.A/M.Phil coordination between IERB & the CASR of the schools/special centres one of the members of IERB may be co-opted/or appointed as a member of CASR who could advise on the students' research proposals which may require ethical clearance by IERB or which may be exempted from IERB review.

## PREAMBLE

The specific point wise revisions/modifications suggested are the following:

The Institutional Ethics Review Board since its inception in September 2008 has been actively involved in the review of the proposals received from the faculty and students if and when the project involves human subjects. It is recommended that the following principles should apply to all research carried out in the University as per national and international norms and guidelines.

- Informed consent and respect for confidentiality
- Enhanced ethical consideration in respect of those who may be vulnerable, which includes tribal populations from back ward regions, illiterates, small children and people with cognitive deficits / patients/ institutionalized persons/ homes for the aged/ who may not be able to comprehend the purpose of study and yet may be obliged to participate

- Consideration of risks, maximized benefit, minimized harm:, Research should balance the anticipated benefits against potential harms to the biosphere including human or animal subjects, and the environment.

This Standard Operating Procedures (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Jawaharlal Nehru University. This SOP document is also meant to guide the researcher on how to apply for ethical clearance, what all documents to submit and the points that s/he must observe while dealing with human participants and / or materials.

**STANDARD OPERATING PROCEDURES**
*for Institutional Ethics Review Board for Research on* Human participants
Jawaharlal Nehru University

## 1. OBJECTIVES

The IERB is responsible for reviewing research involving human participants at this institution, to ensure that subjects' safety, rights, and welfare are protected in conformity with applicable regulations and guidelines issued by the ICMR, UNESCO, WHO, Indian state and local laws and regulations where such laws or regulations provide protection for human subjects that exceed the protection afforded under national law. A number of studies pursued in JNU include biological sample (blood / tissue/ stored sample) collected from diseased and normal subjects for research purposes; and non-invasive studies on speech and language deficit in cases of neurological damage, aphasia studies, dyslexia and developmental disorders of language etc. Non invasive studies also include socio-psychological, socio-cultural studies involving human participants. All such studies on biological samples, stored samples, behavioural data samples and socio-cultural-psychological data samples involving human participants need ethical clearance by IERB. All such studies require IERB clearance before the commencement of the study.

This Standard Operating Procedures (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Jawaharlal Nehru University. The Board is entrusted not only with the initial review of the proposed research protocols prior to the initiation of the project; in case of adverse effects reported by the PI /participants, the Board is also mandated to review and fix compensations/reimbursement. All adverse effects/ injury /damage/ loss /death must be reported immediately to the IERB, death to be reported within 24 hours, as per GOI/CDSCO norms.

In case of modifications in research tools & procedures during the course of the study, reported by the PI/ participants, the Board is also mandated to review and accept/reject the modifications proposed as the case may be.

## 2. ROLE AND RESPONSIBILITIES OF THE REVIEW BOARD

The basic responsibility of IERB is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IERB shall provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee.

The mandate of the committee will be to review all research projects involving human subjects/materials to be conducted in different Centers and Schools at the University. The Board will review all research proposals involving human subjects, submitted by faculty members and research students (through their respective Supervisors). Each investigator shall be responsible, for proving the benefit of placing human subjects at risk, and assure the review committee about appropriate Informed Consent Process and Subject Confidentiality. All studies need to be approved before the study procedures begin. provide details of primary data/secondary data/stored samples/cell lines/ Buying data to the review committee in her/his presentation; also assure the review committee about appropriate IC process &subject confidentiality before the commencement of the study. No completed studies, or those already being pursued will be reviewed by the Board.

## 3. OPERATING PROCEDURES

### 3.1 CONSTITUTION OF IERB.

As per ICMR, guidelines, the IERB should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an Institutional Ethics Review Board/Committee. The members should be a mix of medical/ non-medical professionals, legal experts, experts from sciences and social sciences and humanities, philosophers and activists, internal and external, also including lay persons from NGO's to represent the civil society. (See appendix B for relevant sections of ICMR guidelines) A panel of names in each one of the categories specified below, approved by the EC, will serve as the Institutional Ethics Review Board- JNU.

Constitution of IERB -

1. Chairperson (External)
2. Scientist from Medical Practice (External)
3. Scientist from Basic Sciences (External)
4. Scientist from Basic Sciences (JNU)
5. Social Scientist / Philosopher / Social Activist (External)
6. Social Scientist / Philosopher / Activist (JNU)
7. Member of another IERB (ICMR / AIIMS / any other)
8. Legal Advisor (External)
9. Legal Advisor (Internal)
10. Lay Persons (NGOs representatives of Civil Society/lay persons).
11. Member Secretary (JNU)

As per revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials should have in the quorum at least one representative from the following groups:

1. One basic medical scientist (preferably one pharmacologist).
2. One clinician
3. One legal expert or retired judge
4. One social scientist/ representative of non-governmental organization / philosopher / ethicist / theologian or a similar person
5. One lay person from the community

**As foot note/ end note*
*Link for Drug trials-norms &guidelines to be provided*
*Link for genetic studies on human samples may be provided*
*Link for Radiological investigations-norms &guidelines to be provided*

**3.2. COMPOSITION OF A REVIEW COMMITTEE.**

The number of persons in an ethics committee should be 8 to 12, drawn from the panel of names approved by the EC, as specified above. The Chairperson, IERB will approve the names of the members of a review committee, at least one from each category, depending on the nature of the research proposal to be reviewed. (Appendix A for the current Panel of Experts in the IERB-JNU).

**3.2.1. APPOINTMENT, RESIGNATION AND RECONSTITUTION**

For appointment to the committee, a candidate should have had at least 10 years of work experience at positions of significant responsibility. Professional integrity and commitment to human welfare would be important criteria for inclusion as members.

After the initial constitution, subsequent appointment to the committee shall be guided by the quorum requirements and activity of the members involved. As per ICMR guidelines, the appointee will be informed of the rights and duties of the committee, and that the external members will receive honorarium for every consultative meeting held on the campus.

All Committee members shall sign a confidentiality agreement at the time of appointment, the terms of which shall be binding on them even after the term expires. Co-opted members are also expected to sign confidentiality agreement. All members, except the Chairperson and Member Secretary, shall serve a maximum of a three-year term on the committee, after which a fresh panel of three names in the same category will be submitted to the EC, JNU so that one out of the three may be appointed in place of the retiring person. For the sake of continuity, the Chairperson and the Member- Secretary will have a term of five years. Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.

Members may voluntarily resign from the Committee at a month's notice citing appropriate

reasons, and incase of internal members, their membership would be considered withdrawn, if they resign from the University. A member who has direct involvement or self affirmed conflict of interest with a proposal being considered, shall not form a part of the quorum. If a member is found to have a conflict of interest with the results of decision and fails to declare the same, or is found to have drawn direct benefit arising out of the results of the research, or has involved self-interest with the sponsor(s) or investigators, his/her membership shall be terminated with provision of appropriate legal proceedings.

In case a member breaches the confidentiality, his/her membership shall be terminated and the institution may initiate appropriate legal proceedings.

### 3.2.2. HONORARIUM

External members of the IERB, and experts invited (if any) shall receive appropriate compensation for the time and effort expended for the purpose.

### 3.3. PROCEDURE FOR SUBMISSION AND REVIEW

The IERB will meet at least once in two to three months /twice every semester or more if required, to review all the applications, including proposals for MA, M.Sc, M.Tech, M.Phil, Ph.D; also including research proposals submitted by the faculty involving human subjects materials for any kind of data. All proposals shall be reviewed as per the applicable guidelines given in Appendix C. (see Research and Protocol Organization Guidelines in Appendix C.) Exact meeting date shall be notified at least 15 days in advance so that all members can make themselves available for the purpose. The Chairperson / Member - Secretary shall be the convener with responsibility of laying out the agenda for the meeting. All material relevant to the agenda shall be made available to IERB at least 2 weeks in advance. Before they are circulated to the external members the Member Secretary of the committee together with one or two internal members, will screen the proposals, to see if it needs (i) exemption from review, or (ii) expedited review or (iii) full review, see appendix B, for relevant excerpts from ICMR guidelines (pp 26to 28).

* *Inputs from schools &centres, from CASR at this stage will be important*
All protocols should be submitted in the format prescribed in *Appendix C*. The proposals shall be addressed and submitted to the office of the **Member Secretary, IERB, Room no. 103, Old Language Lab Complex, Jawaharlal Nehru University, New Delhi-110067**. Eight copies each of the documents should be submitted (see 3.5 for list of documents). An application should be submitted at least three weeks prior to the next review meeting. A unique submission number shall be assigned to proposals submitted for review.

### 3.3.1. <u>To Review MA/ M.Sc/ M.Tech/ M.Phil proposals:</u>

The constitution of the committee to review students' proposals will be as under:
1. Chairperson or his nominee
2. Two external members
3. At least one legal expert member
4. Two or three internal members
5. Member - Secretary

Further the committee will review MA/ MSc./ M. Tech./ M. Phil proposals in a time bound manner, meeting at least twice every semester. This committee will take full responsibility of

all the decisions. Ph. D proposals will be reviewed in the main committee along with the faculty research proposals.

### 3.3.2. Recommendation of the Committee:

After discussion, the committee may make one of the following recommendations:

- Approval - indicating that the proposal is approved as submitted;
- Approval after clarifications - indicating that the proposal is approved if the clarification(s) requested are provided to the satisfaction of designated committee members;
- Approval after amendment(s) - indicating that the proposal is approved subject to the incorporation of the specified amendment(s) verified by designated committee members;
- Deferment - indicating that the proposal is not approved as submitted but it can be reassessed after revision to address the specified reason(s) for deferment;
- Disapproval - indicating that the proposal is not approved for the reasons specified.

Format for the Ethical clearance certificate will be as given in the Appendix C (section 2 pages-18,19)

### 3.4. DOCUMENTS FOR SUBMISSION OF THE PROPOSAL:

1. Protocol of the proposed research in the prescribed format which includes:

1.1 Rationale / Background information

1.2. A description of the ethical considerations involved in the research

1.3. Case report forms, diary cards, and other questionnaires intended for research participants

1.4. Summary of safety, pharmacological, pharmaceutical, and toxicological data available on the study product, wherever applicable

1.5. Statement of agreement to comply with ethical principles

1.6. Statement of conflict of interest

1.7. Name and address of the Sponsor/Funding agency

1.8. Insurance Statement (Wherever required)

2. Investigator's Brochure Including Report of Prior Investigations

3. Investigator(s)'s curriculum vitae

4. Informed Consent

5. In case of students' proposals, synopsis of the MPhil/Ph.D research as approved by the Centre/ School.

**3.4.1.** Regarding no.-4 above, a template is given in the annexure- C. (C, 2. pages 18 to 22) which may be modified depending on the nature of participation expected from the study participants.

## 3.5. DOCUMENTATION AND RECORDS

The proceedings of all meetings shall be documented and shall be kept in confidence. The release of the detailed documentation to non-committee members can only be made in case of exceptional circumstances, which shall be verified either by court orders or by affirmative opinions by the Chairperson and the member secretary. Minutes of the meeting shall be circulated by member secretary for verification by the Chairperson and members present during the discussion. After verification, the member secretary shall communicate final decisions regarding protocols to the investigator(s). All documentation sample for different kinds of studies and must be retained for at least five years after the completion of the/study The following records should be maintained by the IERB office:

I. The Constitution and composition of the IERB

II. Signed and dated copies of the latest, signed copies of curriculum vitae of all IERB members

with records of training if any

III. Standard Operating Procedures of the IERB and modifications approved form time to time.

IV. National and International guidelines

V. Copies of protocols submitted for review

VI. All correspondence with the members of the Board, and investigators regarding

application, decision and follow up;

VII. Notice and agenda of all IERB meetings;

VIII. Minutes of all IERB meetings with signatures of the Member Secretary and the Chairperson.

IX. Copies of decisions communicated to the applicants;

X. Record of all notifications issued for premature termination of a study with a summary of

the reasons;

XI. Final report of the study including microfilms, CDs and Video recordings/samples for different kinds of studies. PI may be asked to report completion of the study.

## 3.6. NOTIFICATION OF AMENDMENTS

Any revision to an approved research protocol or written consent form if proposed, must be brought to the attention of the board for approval. Amendments to approved protocols and other study related documents should not be initiated until the board approval has been obtained.

All deviations from the study protocol should be documented in the original records along with the reasons for doing so. In case of any adverse event the same along with the remedial measures taken must be reported by the investigator(s) immediately to the Chairperson and the Member Secretary besides making a note of it in the study documentation.

### 3.7 ANNUAL REVIEW AND FINAL REPORTING

The Committee should be updated regarding the progress of the study on an annual basis. The Committee must be notified of the trials completed or terminated (wherever applicable). A copy of the final report should be submitted as soon as it's available. Statement of PI regarding conclusion/ completion/ termination/ abandonment of the study must be submitted as soon as the study is terminated

### 3.8. RECONSTITUTION OF COMMITTEE

The Committee shall be considered non-functional and reconstitution considered in the following instances:

- No meeting is convened for a continuous period of 6 months
- Meeting attendance is below 5 independent members for four consecutive meetings

### 3.9 AMENDING THIS DOCUMENT

Any amendments to this document shall be approved under the same procedure as for other proposals under the preview of IERB.

### 4. Appendices

Appendix A: List of Members of IERB
Appendix B: Relevant sections of the ICMR guidelines
Appendix C: Research Protocol Organization guidelines
Appendix D: COPE of Good Publication practice guidelines
Institutional Ethics Review Board for Research involving Human Participants

**APPENDIX A**

**The panel of names in each category as approved by the Executive Council, JNU.**

**1. Chairperson (External)**
Prof. Shiv K. Sarin,
Director, Institute of Liver & Biliary Sciences,
Vasant Kunj, New Delhi 110070

**2. Scientist from Medical Practice (External)**

i. Prof. Madhuri Behari, Department of Neurology, AIIMS, New Delhi -110029
ii. Prof. Mahesh Arora, Professor of Anesthesia, AIIMS, New Delhi-110029
iii. Prof. S.C. Malik, Former Prof of Psychiatry, LHMC, New Delhi-110001
iv. Prof. Vivekanand Jha, Dept of Nephrology, PGIMER, Chandigarh
v. Dr. P. K. Gulati, Radiologist, Gulati Imaging Institute, Hauz Khaz, ND-16

**3. Basic Sciences / Researchers (External)**

i. Prof. Vijay Kumar, ICGEB, New Delhi
ii. Prof. Anil Tyagi, University of Delhi, South Campus, New Delhi-110021
iii. Dr. Girish Sahni, Director, IMTECH, Chandigarh
iv. Prof Narayan Srinivasan, CBCS, University of Allahabad, Allahabad.
v. Prof. Ramesh Juyal, National Institute of Immunology, New Delhi-67

**4. Basic Sciences / Researchers (JNU)**

I. Prof. Rajiv Bhat, SBT
ii. Prof. B. N. Mallick, SLS
iii. Prof. Akhilesh Pandey, SPS
iv. Prof. Suman Kumar Dhar, SCMM, JNU
v. Prof Sudha Bhattacharya, SES

**5. Social Scientist /Philosopher Social / Activist (External)**

i. Dr. D. Raghunandan, Delhi Science Forum D-158 Lower Ground Floor, Saket, New Delhi - 110017
ii. Prof. B. R Sharma, Former Professor of Philosophy, University of Delhi
iii. Prof. Kusum Chopra, Former Professor, CSRD, East of Kailash, Aptmnts, ND
iv. Prof. Arvind Agrawal, Dean, Humanities, Central University, H.P. Dharmshala.
v. Prof Ravinder Gargesh, Professor of Linguistics, University of Delhi, Delhi-110007

**6. Social Scientist /Philosopher Social / Activist (JNU)**

i. Prof. Ajay Dubey, CAS, SIS
ii. Prof. Manoj Pant, CITD, SIS
iii. Prof Sabaree Mitra, CSEAS, SLL&CS, JNU
iv. Prof. Geetha Nambissan, ZHCES, SSS
v. Dr. Ayesha Kidwai, CL, SLL & CS.

**7. Advisor from another IERB (ICMR/ AIIMS/any other)**

i. Dr. Tripti Khanna, Deputy Director, ICMR, Ansari Nagar, New Delhi-110029
ii. Dr. Sunil Mittal, Member, Ethics Review Committee, COSMOS Hospital, New Delhi
iii. Dr. Raj Kamal Bhatnagar, ICGEB, New Delhi- 110067
v. Dr. Rakesh Yadav, Dept of Cardiology, AIIMS, Member, Ethics Committee, Escorts and Prof Vaishna
Narang, Member Secretary, IERB-JNU and Convenor of the conference,
v. Prof. Renu Saxena, Member-Secretary, AIIMS ethics review committee

**8. Legal Advisor (external**
I. Advocate Shashank Shekhar, B-1001, Riviera, ELDECO- Green Meadows, Pi-I, Greater Noida- 201310 Uttar Pradesh
ii. Advocate (Mrs.) Omika Dubey, 120, DP, JNU Campus, New Delhi-110067
iii. Advocate, Rukhsana Chaudhary, 1080/1, 3rd floor, Mehrauli New Delhi 110030
iv. Advocate Bulbul Das, 23 Anupam Apartments, B 13 Vasundhara Enclave Delhi-110096

**9. Legal Advisor (JNU)**
i. Ms. Abha Yadav, Legal Cell, JNU
ii. Prof. Amita Singh, CSLG, JNU

**10. Lay persons:**
i. Mrs. Sunita Dhar

Director, JAGORI (NGO for women)

ii. Mrs. Poonam Natarajan.

National Trust (GOI trust for differently abled children)

iii. Shibani Chaudhry, Executive Director

SRUTI (Society for Rural, Urban and Tribal Initiatives)

iv. Mr Subhash Mittal, Secretary,

SRRF (Socio Research and Reform Foundation)

v. Ms. Vibhuti Sharma *Honorary Chief Operating Officer, The Liver Care*

*Foundation* S-337 Panchsheel Park, New Delhi, 110017 also Transplant

Coordinator at ILBS, Vasant Kunj, New Delhi 110070

**11. Member Secretary (JNU)**
Prof. Vaishna Narang, CL/SLL&CS/JNU

**APPENDIX B**

**Review Procedures (3.4 pp. 21)**

**Excerpts from ICMR Guidelines (page 12-15)**

The IERB's member-secretary or 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 review** (see below for explanation). **Minimal risk** would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life. An investigator cannot decide that her/his protocol falls in the exempted category without approval from the IERB. All proposals will be scrutinized to decide under which of the following three categories it will be considered:

**1. Exemption from review**

Proposals which present less than minimal risk fall under this category as may be seen in following situations:
**i.** Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**ii. Exceptions:** When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civilor criminal or financial liability or psychosocial harm.
**iii.** When interviews involve direct approach or access to private papers.
**a. Expedited Review**

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IERB or designated member of the Committee of the IERB may do expedited review only if the protocols involve-

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).

2. Revised proposal previously approved through full review by the IERB or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

3. Research activities that involve only procedures listed in one or more of the following categories:
a. Clinical studies of drugs and medical devices only when –
i. research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non- research (clinical) purposes.

5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IERB may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and **the same participants should not be included** in the clinical trial that may Institutional Ethics Review Board for Research involving Human Participants Institutional Ethics Review Board for Research involving Human Participants be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation when proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND)/ devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients –

I. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

iii. Only if the local IERB reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and *a priori* agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

**c. Review**

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.
While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

1. Collection of blood samples by finger prick, heel prick, ear prick, or vein puncture, from adults and children, where the age, weight, and health of the participants, the collection

procedure, the amount of blood to be collected, and the frequency with which it will be collected is strictly as per WHO norms.

2. prospective collection of biological specimens for research purposes by noninvasive means, for instance:

d. Skin appendages like hair and nail clippings in a non-disfiguring manner;

e. Dental procedures – deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;

f. Excreta and external secretions (including sweat);

g. Unanimated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;

h. placenta removed at delivery;

i. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

j. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

k. sputum collected after saline mist nebulization and bronchial lavages.

l. Collection of data through noninvasive procedures routinely employed in clinical practice.

Where medical devices are employed, they must be cleared/ approved for marketing, for instance:

m. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; weighing or testing sensory acuity;

n. magnetic resonance imaging;

o. electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,

p. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

q. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

r. Collection of data from voice, video, digital, or image recordings made for research purposes.

s. Research on individual or group characteristics or behavior not limited to research on

perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**Appendix C:**

## Research Protocol Organization guidelines

**1. Protocol**

Following are the section headings and brief guidelines on the protocol contents. Though the arrangement below is not binding, conformance to these will enable speedy review

1. Title of Project

2. Principal Investigator

3. Co-Investigator and other investigative team member list with identified delegation of responsibility

4. Rationale & background information: The Rationale specifies the reasons for conducting the research in light of current knowledge. It should include a well documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. It is equivalent to the introduction in a research paper and it puts the proposal in context. It should answer the question of why and what: why the research needs to be done and what will be its relevance.

5. Objectives: Specific objectives are statements of the research question(s). Objectives should be simple, specific and stated in advance. After statement of the primary objective, secondary objectives may be mentioned.

6. Study Design: The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame.

7. Participant Selection Criteria: Patients who can take part in the study (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration of the study with follow up periods.

8. Methodology: It should include detailed information on the procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. along with a tabular form study schedule of procedures, for both Qualitative and quantitative-studies

9. Evaluation of Safety: The adverse event & serious adverse event criteria and the process to record and report to the IRB and any applicable regulatory agency.

10. Research Questionnaire: The protocol should provide research questionnaire containing all parameters understudy and also provide information on how the data will be collected including data handling and coding for computer analysis, monitoring and verification.

11. Statistical Analysis: The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used, in quantitative study. For Qualitative studies as in psychology& cognitive science, the tools and instruments may be clearly explained

12. Informed Consent Forms: A description of the informed consent process is required accompanied by copies of informed consent forms, both in English and the local language in which they are going to be administered as per ICMR/WHO requirement. (DCGI/CDSCO requirement for Drug trials)

13. Budget: The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item as applicable.

14. Other support for the Project: This section should provide information about the funding received or anticipated for this project from other funding organizations.

15. Collaboration with other scientists or research institutions, if any. A copy of ethical clearance obtained from the other institution already, must be submiteed.

16. References: Brief description of the most relevant studies published, a minimum of 11 on the subject also be listed.

17. Publication policy: Publication policy should be clearly discussed regarding the authorships who will take the lead in publication and who will be acknowledged in publications. Guidelines for the publication prescribed in Appendix D.

18. Statement of agreement to comply with ethical principles.

19. Signature of PI and Supervisor or Research, Scholar, Co investigators, Chairperson/Dean of the Centre/School.

**2. Format for ethical clearance certificate (page 32)**

**3. Format for PIS-ICF (page 33-35 )**

Institutional Ethics Review Board for Research involving Human Participants

**INSTITUTIONAL ETHICS REVIEW BOARD**
**Jawaharlal Nehru University**
**New Delhi-110067**

Name of the Ethics Committee: IERB-JNU IERB Ref. No.....

Title of the Project Proposal:

Principal Investigator: Sponsor:

Fax:

Collaborators' Name, Address, Tel. No. Fax &Email:

**FOR OFFICIAL USE**

**The proposal was reviewed in a meeting held on (dt-) at (time). The following members were present.**

1. Chairperson
2. Member
3.
4.
5.
6.
7.
8. Member Secretary

The committee resolved to

[ ] Approve - indicating that the proposal is approved as submitted;

[ ] Approve- after clarifications - indicating that the proposal is approved if the clarifications requested
are provided to the satisfaction of designated committee members;

[ ] Approve after amendment/s - indicating that the proposal is approved subject to the incorporation of
the specified amendments verified by designated committee members;

[ ] Defer - indicating that the proposal is not approved as submitted but it can be re-assessed after revision to address the specified reason/s for deferment;

[ ] Disapprove - indicating that the proposal is not approved for the reasons specified*.

Comments:

Date of Approval:

Member Secretary,
IERB, Ethics Committee

(To be filled in by PI and presented at the time of Review (Periodic, Continuing, and Interim)

**Consent Form ( in English and in local language of the region)**

Part I- PIS, Part II-ICF

Title of the Project:

Investigators:

Collaborators:

Potential Funding Agency:

**PART -I Participant Information Sheet (PIS)**

भाग-1

A brief description of the study objectives in simple language.....

.....

**Section- A. The following have been explained to me,**

**1. Purpose of the Study [ ]** Explained in Detail
परियोजना का उदेश्य

.....
.....

**2. Study Procedures [ ]**
शोध सापन .....
.....

**3. Risk of the Study [ ]**
शोथ के जोखिम

.....
.....

**4. Benefits from the Study [ ]**
शोथ के लाभ

**5. Complications [ ]** .....
जटिलंताए .....

**6. Compensations [ ]** .....
क्षतिपूति

.....

**7. Confidentiality [ ]**
**गोपनीयता**

**8. Rights of Participant [ ]** .....
शोथ के अधिकार

.....

**9. Alternatives to Participation in the Study [ ]**

**शोध में भागीदारी के विक्लप**

**10.Any Other…..... [ ]**
अन्य कोई सूचना

**Name of the Subject/Participant/**शोधभागीदारी का नाम:

**Signature of Patient/Guardian/**माता/ पिता/ सरक्षक का नाम:

**Relationship to Subject/**शोधभागीदारी से सम्बन्ध

**Date/ दिनांक**
**Investigator's Statement:**

I, the undersigned have explained to the parent/guardian in a language she/he understands the procedures to be followed in the study and risks and benefits.

Signature of the Investigator/ शोधर्कता /शोधार्थी का हस्ताक्षर: **Date/ दिनाकं**

Name of the Investigator/ शोधर्कता /शोधार्थी का नाम:

Signature of the Witness/ गवाह के हस्ताक्षर : **Date/ दिनाकं**

Name of the Witness./ गवाह का नाम:

**PART-II Informed consent Form (ICF)**

The advantages and disadvantages of the research in which I am expected to participate, for which I have to donate blood/ sputum/.hair sample/any other sample has been explained to me.

I willingly, under no pressure from the researcher agree to take part in this research, and agree to participate in all investigations which will help acquire knowledge for the benefit of the mankind,

And agree to donate my and my children's 5 ml blood/specify sample...)
My consent is explicitly not for disclosing any personal information. For disclosing any such personal information obtained from the investigations conducted on my samples, further consent should be obtained.

I have been informed that JNU and the researchers (PI ..... and her/his colleagues) will take my
prior consent before they draw benefits from research based on my samples.

Signatures

| | | |
|---|---|---|
| ..... | ..... | ..... |
| Subject/patient | Witness | Principle Investigator. |

## सहमति पत्र

मुझे शोधकर्ता द़ारा जिस उद़ेश्य के लिये मुझे शोधकर्य में भाग लेना ह्रै रक्तदान और उक्तदान करना ह़ै उसके फायदे व नुकसान बता दिये गये हैं।

मैं बिना किसी दबाव के अपनी इच्छानुसार

(1)इस शोधकर्ाय में भाग लेने के लिये सहमत हूं इस शोधकर्ाय के लिये सभी प़कार के परिक्षण़ जो मानव जाति के कल्याण के लिये ज्ञान प़दान करते हैं के लिए सहमत हुं।

(2) इस शोधकर्ाय के लिये अपना या अपने बच्चों का **5** मि. ली. रक्तदान कर रहा हूं।

मेरी सहमति प़तयक्ष रूप से़ किसी भी व्यक्तिगत जानकारी के ख़ुलासे के लिये नहीं है। मेरे नमूनों से प़ाप्त व्यतिगत जानकारी के ख़ुलासे के लिये मेरी अगली अनुमति अनिर्वय है।

मुझे यह जानकारी दे दी गई है कि जे. एन. यू और इसके शोधकर्ता (PI.....एवं इनके सहयोगी किसी भी फायदे के कर्ाय से पहले जे मेरे रक्त या उतक नमूनों की जानकारी पर आधारित ह़ै मेरी अनुमति लेगें।

| | | |
|---|---|---|
| प़तिभागी/मरीज के हस्ताक्षर | गवाह के हस्ताक्षर | प़धान अन्वेषक |

# Sample II

## Community Responses to Nutritional Rehabilitation in Madhya Pradesh and Jharkhand

**INFORMED CONSENT OF RESPONDENTS IN IN-DEPTH INTERVIEWS AND FGD**

Introduction: My name is_____, I am working for Centre of Social Medicine & Community Heralth, JNU, New Delhi.. We are interviewing people here _____(name of the city/ region/ site) in order to understand your responses to the issues and the problems that you face on account of severely undernourished children and your perceptions on availability and accessibility of services at the nutritional rehabilitation centre. We are also trying to understand the reasons for the delay in reaching the facilities. (Describe the purpose of the study). These issues are being studied in another state as well.

(Name of the other state_____

**CONFIDENTIALITY AND CONSENT**

The government has started nutritional rehabilitation centres in your state to take care of malnourished children. In this context, it is important to understand the perceptions of mothers, community leaders and the providers about the availability and access to these services. The goal of this study is to understand the social dimensions, perceptions and likely determinants that facilitate and act as barriers to home-based and institutional care of severe undernutrition.

It is with this main purpose that we wish to talk to you. Your honest answers to the questions will help us understand all the involved issues better. We would highly appreciate your co-operation to provide the information on the issues by your honest and frank responses to all the questions. Your identity and information provided by you shall be completely confidential and the information so gathered from different people shall be used only for research purposes. After analysing the information we are gathering from you, we shall destroy the schedules. However, if you feel strongly not to answer one or some of the question, you feel free not to answer such questions. During the interview/FGD process, if you feel not to go ahead with the interview, you can withdraw from the interview at any time you want. You can ask any question/clarify any doubt pertaining to the issues under study, its purpose or any other related matter. The interview/FGD will take about half an hour-one hour to ask the questions. If you are willing to participate, we can begin with the interview/FGD by your consent.

**DECLARATION BY THE PARTICIPANT**

I have read/ I have been communicated the purpose and other details of the ICMR study **"Community Responses to Nutritional Rehabilitation in Madhya Pradesh and Jharkhand"** and about my voluntary participation in the study. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have also been given the right not to answer any question or withdraw from the study if I so desire.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBED.

Name and Signature of Participant ___ Date _____

**DECLARATION BY THE INVESTIGATOR**

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consent to participate.

_____ _____

Name and Signature of the Investigator Date of the Interview

- Status of the interview:

| | |
|---|---|
| Completed Successfully | 1 |
| Respondent became uncomfortable and stopped answering | 2 |
| Some interruption due to which interview stopped | 3 |
| Did not agree to complete interview | 4 |