STANDARD OPERATING PROCEDURE

(Human Studies)

INSTITUTIONAL ETHICS COMMITTEE (IEC)

SIKKIM UNIVERSITY

GANGTOK– 737 102

SIKKIM (INDIA)

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INTRODUCTION

Institutional Ethics Committee (IEC), also referred to as, Institutional Review Board (IRB), Ethics Review Board (ERB) and Research Ethics Board (REB) in many countries and situations, serves as an independent representative and competent body to review, evaluate and decide on the scientific and ethical merits of research proposals. The primary purpose of this committee is to protect the rights, safety and wellbeing of human subjects who participate in a research project. The Ethics Committees are entrusted with the initial review of the proposed research protocols prior to initiation of the projects and also have a continuing responsibility of regular monitoring of the approved research proposals till the same are completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the international guidelines for biomedical research. The need for evaluation of research proposals has been emphasized under the Statement of General Principles at item no. 5 (http://icmr.nic.in/human_ethics.htm#Guidelines) pertaining to precaution and risk- minimization.

BASIC RESPONSIBILITIES

The basic responsibility of an Institutional Ethics Committee (IEC) is to ensure a competent review of all ethical aspects of the research proposals received by it in an objective manner. IECs should 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. In institutions where this is lacking, the IEC may take up the dual responsibility of review of both, the scientific content and ethical aspects of the proposal. It is advisable to have separate Committees for each, taking care that the scientific review precedes the scrutiny for ethical issues. The scientific evaluation should ensure technical appropriateness of the proposed study. The IECs should specify in writing the authority under which the Committee is established.

Small institutions could form alliance with other IECs or approach registered IEC. Large institutions/Universities with large number of proposals can have more than one suitably constituted IECs for different research areas for which large number of research proposals are submitted. However, the institutional policy should be same for all these IECs to safeguard the research participant's rights.

The main IEC may review proposals submitted by post-graduate or PhD students or if necessary, an expert committee may be separately constituted for the purpose, which will review proposals in the same manner as described above. The responsibilities of an IEC can be defined as follows:

- To protect the dignity, rights and wellbeing of the potential research participants.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To assist in the development and the education of a research community responsive to local health care requirements.

COMPOSITION

The IECs should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC. The number of persons in an ethics committee should be kept fairly small (7 - 12 members). It is generally accepted that a minimum of five

persons is required to form the quorum without which a decision regarding the research should not be taken. The members should be a mix of medical/ non-medical, scientific and non-scientific persons including lay persons to represent the differed points of view.

The composition may be as follows: -

1. Chairperson (Outside the institution)
2. One - two persons from basic medical science area
3. One - two clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist /theologian
7. One lay person from the community
8. Member Secretary (From the institution)

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.

The Ethics Committee (EC) can have as its members, individuals from other institutions or communities with adequate representation of age and gender to safeguard the interests and welfare of all sections of the community/society. If required, subject experts could be invited to offer their views, for instance, a pediatrician for pediatric conditions, a cardiologist for cardiac disorders etc. Similarly, based on the requirement of research area, for example HIV, genetic disorders *etc.* it is desirable to include a member from specific patient groups in the Committee. Members should be aware of local, social and cultural norms. Only those Ethics Committee members who are independent of the sponsor and clinical trial should vote/provide opinion in matters related to the study.

TERMS OF REFERENCE

The Terms of References should include Terms of Appointment with reference to the duration of the term, the policy for removal, replacement, resignation procedure, frequency of meetings, and payment of processing fee to the IEC for review, honorarium / consultancy to the members/ invited experts *etc.* and these should be specified in the SOP which should be made available to each member. Every IEC should have its own written SOPs according to which the Committee should function.

The SOPs should be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. It would be preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances. For this the criteria for number of missed meetings may be defined in the SOP.

TRAINING

The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body (ies), so that they become aware of their role and responsibilities. For drug trial review, it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism.

REGULATION

Once the legislation of guidelines occurs which is currently under active consideration by the Ministry of Health, Government of India, a Biomedical Research Authority will be set up under the proposed Bill on Biomedical Research on Human Participants (Promotion and Regulation) which would require that all IECs register with this Authority. It will also evaluate and monitor functioning of the IECs, and develop mechanisms for enforcing accountability and transparency by the institutions.

REVIEW PROCEDURE

The IEC should review any research proposal it receives from different departments on human participants before the research is initiated. It should ensure that a scientific evaluation has been completed before ethical review is taken up. The Committee should evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and the justice issues.

The IEC'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 IEC. 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.

Exceptions:

i. 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 civil or criminal or financial liability or psychosocial harm.

ii. When interviews involve direct approach or access to private papers.

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 IEC or designated member of the Committee or Subcommittee of the IEC 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 IEC 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 IEC 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 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 the Drug Controller General of India (DCGI);
   iii. Only if the local IEC 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;

a. 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:

6. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
7. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
8. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
9. Protection must be ensured so that only minimal additional risk is imposed.
10. 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.
11. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
12. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property right issues.

FULL 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:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8-week period and frequency of collection is not more than 2 times per week;

ii. from other 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 has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8-week period and not more than 2 times per week;

iii. from neonates depending on the haemo-dynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

iv. prospective collection of biological specimens for research purposes by noninvasive means. For instance:

1. skin appendages like hair and nail clippings in a non-disfiguring manner;

2. dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
3. excreta and external secretions (including sweat);
4. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
5. placenta removed at delivery;
6. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
7. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
8. sputum collected after saline mist nebulization and bronchial lavages.

b. 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-

i. 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;
ii. weighing or testing sensory acuity;
iii. magnetic resonance imaging;
iv. electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,
v. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

e. 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.

SUBMISSION OF APPLICATION

The researcher should submit an application in a prescribed format along with the study protocol as prescribed in SOP of IEC concerned. The protocol should include the following: -

1. The title with signature of Principal Investigator (PI) and Co-investigators as attestation for conducting the study.
2. Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.
3. Recent curriculum vitae of the Investigators indicating qualification and experience.
4. Participant recruitment procedures and brochures, if any.
5. Inclusion and exclusion criteria for entry of participants.
6. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.),

intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any.

7. Plan to withdraw or withhold standard therapies in the course of research.
8. Plan for statistical analysis of the study.
9. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and local languages.
10. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory, animal and human research.
11. For research involving more than minimal risk, an account of management of such risk or injury.
12. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period.
13. An account of storage and maintenance of all data collected during the trial.
14. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
15. A statement on probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
16. All other relevant documents related to the study protocol like investigator's brochure for trial on drugs/devices /vaccines /herbal remedies and statement of relevant regulatory clearances.
17. Agreement to comply with national and international Good Clinical Practices (GCP) protocols for clinical trials.
18. Details of Funding agency/ Sponsors and fund allocation. (Format for Sikkim University provided)
19. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee (HMSC) or appropriate Committees under other agencies/authority like Drug Controller General of India (DCGI)
20. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
21. A statement on conflict-of-interest (COI), if any.

DECISION MAKING PROCESS

The IEC should be able to provide complete and adequate review of the research proposals submitted to them. It should meet periodically at frequent intervals to review new proposals, evaluate annual progress of ongoing ones, review serious adverse event (SAE) reports and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate. The following points should be considered while doing so:

1. The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The Member Secretary should communicate the decision in writing to the Principal Investigator (PI).
2. If a member has conflict-of-interest (COI) involving a research proposal then s/he should submit this in writing to the chairperson before the review meeting, and it should also be recorded in the minutes.
3. If one of the members has her/his own proposal for review or has any COI then s/he should withdraw from the IEC while the project is being discussed.
4. A negative decision should always be supported by clearly defined reason.
5. An IEC may decide to reverse its positive decision on a study if it receives information that may

adversely affect the risk/ benefit ratio.

6. The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
7. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.
8. The following circumstances require the matter to be brought to the attention of IEC:
   a. any amendment to the protocol from the originally approved protocol with proper justification;
   b. serious and unexpected adverse events and remedial steps taken to tackle them;
   c. any new information that may influence the conduct of the study.
9. If necessary, the applicant/investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or interest groups can be invited during deliberations to offer their viewpoint.
10. Subject experts may be invited to offer their views, but should not take part in the decision-making process. However, her / his opinion must be recorded.
11. Meetings are to be minuted which should be approved and signed by the Chairperson/ alternate Chairperson/ designated member of the committee.

REVIEW PROCESS

The method of review should be stated in the SOP whether the review should be done by all reviewers or by primary reviewer(s) in which case a brief summary of the project with informed consent and patient information sheet, advertisements or brochures, if any, should be circulated to all the other members.

The ethical review should be done in formal meetings and IEC should not take decisions through circulation of proposals. The committee should meet at regular intervals and should not keep a decision pending for more than 3 - 6 months, which may be defined in the SOP.

PERIODIC REVIEW

The ongoing research may be reviewed at regular intervals of six months to one year as may be specified in the SOP of the ethics committee.

CONTINUING REVIEW

The IEC has the responsibility to continue reviewing approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion if need be.

INTERIM REVIEW

Each IEC should decide the special circumstances and the mechanism when an interim review can be resorted to by a sub-committee instead of waiting for the scheduled time of the meeting like re-examination of a proposal already examined by the IEC or any other matter which should be brought to the attention of the IEC. However, decisions taken should be brought to the notice of the main committee.

MONITORING

Once IEC gives a certificate of approval, it is the duty of the IEC to monitor the approved studies, therefore an oversight mechanism should be in place. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights. Additionally, periodic status reports must be asked for an appropriate interval based on the safety concerns and this should be specified in the SOP of the IEC. Serious Adverse Event (SAE) reports from the site as well as other sites are reviewed by IEC and appropriate action taken when required. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB

may also be sought.

RECORD KEEPING

All documentation and communication of an IEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures. The following records should be maintained for the following:

i. the Constitution and composition of the IEC;
ii. signed and dated copies of the latest the curriculum vitae of all IEC members with records of training, if any;
iii. Standard Operating Procedures (SOP) of the IEC;
iv. National and International guidelines;
v. copies of protocols submitted for review;
vi. all correspondence with IEC members and investigators regarding application, decision and follow up;
vii. agenda of all IEC meetings;
viii. minutes of all IEC meetings with signature of the Chairperson;
ix. copies of decisions communicated to the applicants;
x. record of all notification 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.

It is recommended that all records must be safely maintained after the completion/termination of the study for a period of 3 years if it is not possible to maintain the same for more than that due to resource crunch and lack of infrastructure.

NB: ***This document has been adapted from ICMR Ethical Guidelines for Biomedical research on Human Participants (2006), Institutional Ethics Review Board draft proposal of Jawaharlal Nehru University, and Standard Operating Procedures of all India Institute of Medical Sciences, New Delhi Institute Ethics Committee.***

STANDARD OPERATING PROCEDURE
OF
INSTITUTIONAL ETHICS COMMITTEE, SIKKIM UNIVERSITY

This Standard Operating Procedures (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Sikkim 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. Since the Institutional Ethics Committee (IEC) is authorized for ethical clearance of the research proposal, there will be no substitute IEC at any level in the university. 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.

1. Informed consent and respect for confidentiality.
2. Enhanced ethical consideration in respect of those who may be vulnerable, which includes tribal populations from backward 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.
3. 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.

STANDARD OPERATING PROCEDURES (SOPs)
For Institutional Ethics Committee on Human participants Sikkim University

1. OBJECTIVES

The IEC 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 an d regulations where such laws or regulations provide protection for human subjects that exceed the protection afforded under national law.

All the studies carried out in Sikkim University including collection of biological samples (blood / tissue/ stored sample), behavioural data samples and socio-cultural-psychological data samples involving human participants need ethical clearance by Institutional Ethics Committee (IEC). Clinical trial of new drugs developed from: natural/ synthetic sources including new drug formulations are carried out on human subjects after ascertaining their safety and efficacy through pre-clinical trial. New formulations developed from already approved drugs are subjected to clinical trial involving human volunteers.

Pathological investigation & biochemical parameter observation of healthy human participants as well as patients suffering from a particular disease, bioavailability & bioequivalence studies of drugs/ drug formulations and patient counseling also need ethical clearance by Institutional Ethics

Committee (IEC). All such studies require IEC 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 Sikkim University. The Committee 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 Principal Investigator (PI) /participants, the Committee is also mandated to review and fix compensations/reimbursement. All adverse effects/ injury /damage/ loss /death must be reported immediately to the IEC, death to be reported within 24 hours, as per Government of India (GOI)/ Central Drugs Standard Control Organization (CDSCO) norms.

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

2. ROLE AND RESPONSIBILITIES OF THE REVIEW COMMITTE

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. IEC 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 Departments, affiliated colleges/ research institutes under Sikkim University. The Committee will review all research proposals involving human subjects, submitted by faculty members and research students/Research Fellow/Postdoctoral Fellow (through their respective Supervisors/Mentors). 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

CONSTITUTION OF IEC-

As per ICMR guidelines, the IEC should be multidisciplinary and multi-sectorial 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 NGOs 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 Academic Council, will serve as the Institutional Ethics Committee- Sikkim University.

Constitution of Institutional Ethics Committee (IEC)

1. Chairperson (External)
2. Scientist from Medical Practice (External)
3. Scientist from Basic Sciences (External)
4. Social Scientist / Philosopher / Activist (Sikkim University)
5. Legal Advisor (External)
6. Lay Persons (NGOs representatives of Civil Society/laypersons)
7. Member Secretary (Sikkim University)

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

COMPOSITION OF A REVIEW COMMITTEE

The number of persons in an ethics committee should be 7 to 12, drawn from the panel of names approved by the Academic Council, as specified above. The Chairperson, IEC 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 IEC- Sikkim University).

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 shall serve a maximum of a three-year term on the committee, after which names of a fresh panel will be submitted to the Academic Council, Sikkim University. 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 in case 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.

HONORARIUM

External members of the IEC, and experts invited (if any) shall receive honorarium/seating fee as per rules of the University.

PROCEDURE FOR SUBMISSION AND REVIEW

The IEC will ordinarily **meet once in two to three months or more if required**, to review all the applications, including proposals for MA, M.Sc., M. Pharm, MTech, 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 ordinarily 7 days in advance so that all members can make themselves available for the purpose. However, in case of pressing need, this can be convened with a short notice. 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 IEC in advance. Before they are circulated to the external members, the Member Secretary of the committee together with one internal member, 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.

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, Institutional Ethics Committee, Sikkim University, 6th Mile, PO: Tadong, Gangtok – 737 102**. Seven copies each of the documents should be submitted (see 3.5 for list of documents). An application should be submitted at least two weeks prior to the next review meeting. A unique submission number shall be assigned to proposals submitted for review.

To Review MA/ M.Sc./ M.Pharm. / M.Tech / PhD Proposals:

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. One internal member
5. Member -Secretary

Further, the committee will review MA/ MSc. / M.Pharm. / M. Tech. / PhD proposals in a time bound manner. 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.

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.

Authority under which IEC is Constituted:

The Institutional Ethics Committee (IEC) will be constituted by the Vice Chancellor for a period of three years. However, the Committee will continue until the formation of a subsequent Committee.

Membership Requirements:

a. The duration of appointment is initially for a period of 3 years
b. At the end of 3 years, as the case may be, the committee is reconstituted.
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.

Quorum Requirements:

The minimum of 5 members are required to compose a quorum. All decisions should be ordinarily taken in meetings after going through proposals.

Offices

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or 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.

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.

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 forms. Required number of 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 of the Departments / Institution to the Institutional Ethics Committee.
c. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
d. 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.

DOCUMENTS FOR SUBMISSION OF THE PROPOSAL:

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

- Rationale / Background information
- A description of the ethical considerations involved in the research
- Case report forms, diary cards, and other questionnaires intended for research participants
- Summary of safety, pharmacological, pharmaceutical, and toxicological data available on the study product, wherever applicable
- Statement of agreement to comply with ethical principles
- Statement of conflict of interest
- Name and address of the Sponsor/Funding agency
- Insurance Statement (Wherever required)
- Investigator's Brochure Including Report of Prior Investigations
- Investigator(s)’s curriculum vitae
- Informed Consent

In case of students’ proposals, synopsis of the Ph.D. research as approved by the Department/College/Centre.
Regarding Informed Consent, a template is given in the Appendix-E which may be modified depending on the nature of participation expected from the study participants.

DOCUMENTATION AND RECORDS

Investigator's Brochure Including Report of Prior Investigations

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 ordinarily for five years after the completion of the/study

The following records should be maintained by the IEC office:

I. The Constitution and composition of the IEC
II. Signed and dated copies of the curriculum vitae of all IEC members with records of training, if any
III. Standard Operating Procedures of the IEC and modifications approved from 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 IEC meetings;
VIII. Minutes of all IEC 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.

NOTIFICATION OF AMENDMENTS

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

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 is available. Statement of PI regarding conclusion/ completion/ termination/ abandonment of the study must be submitted as soon as the study is terminated.

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

AMENDING THIS DOCUMENT

Any amendments to this document shall be approved under the same procedure as for other

proposals under the preview of IEC.

Appendices

Appendix A: Member List of Ethics Committee
Appendix B: Relevant sections of the ICMR guidelines
Appendix C: Research Protocol- Organization Guidelines
Appendix D: Institutional Ethics Committee, Sikkim University
Appendix E: Informed consent Form (ICF)
Appendix F: Declaration by the Participant
Appendix G: Informed Assent Form (IAF)
Appendix H: Assent Agreement Form

MEMBER LIST OF ETHICS COMMITTEE **APPENDIX A**

The panel of names in each category as approved by the EC, Sikkim University (one member from each category).

Sl No.	*Name*	*Designation & Address*	*Position in IEC*
1.	Prof. Muralidhar V. Pai	**Dean,** Sikkim Manipal Institute of Medical Sciences	Chairperson
2.	Dr. B.B. Rai	**Executive Director,** Voluntary Health Association of Sikkim, Gangtok	Member
3.	Prof. Mingma Lhamu Sherpa	**Head,** Department of Microbiology, Sikkim Manipal Institute of Medical Sciences	Member
4.	Dr. Shrijana Gurung	**Head,** Department of Virology, STNM Hospital, Gangtok	Member
5.	Shri Jagat Bandhu Pradhan	**Senior Advocate,** High Court of Sikkim	Member
6.	Prof. Yodida Bhutia	**Professor,** Dept. of Education, Sikkim University	Member
7.	Prof. Satyananda Panda	**Professor,** Dept. of Psychology, Sikkim University	Member-Secretary

***Duration:** The Committee is constituted ordinarily for three years.

****The purview of Institutional Ethics Committee (IEC) of SIKKIM University will generally cover research projects/proposals that involve human subjects, such as Anthropology/Biotechnology/ Botany/ Chemistry/ Zoology and/or Allied Sciences.

RELEVENT SECTIONS OF ICMR GUIDELINES (page 12-15) APPENDIX B

The IEC'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 IEC. 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 civil or 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 IEC or designated member of the Committee of the IEC 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 IEC 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 IEC 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 IEC 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;

a. 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.

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

b. 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:

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

d. 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;

e. Excreta and external secretions (including sweat);

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

g. Placenta removed at delivery;

h. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

j. Sputum collected after saline mist nebulization and bronchial lavages.

k. 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:

l. 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;

m. Magnetic resonance imaging;

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

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

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

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

r. 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

A. 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 submitted.

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.*

B. Format for ethical clearance certificate

C. Format for Participant Information Sheet (PIS)- Informed Consent Form (ICF)

Institutional Ethics Committee for Research involving Human Participants

APPENDIX-D

INSTITUTIONAL ETHICS COMMITTEE
Sikkim University, 6th Mile,
PO- Tadong, Gangtok, Sikkim- 737 102

Name of the Ethics Committee: IEC-Sikkim University
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 (date) at (time). The following members were present.

1. Chairperson
2. Member
3. Member
4. Member
5. Member
6. Member
7. 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,
IEC, 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)

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
   .....
   .....
2. **Study Procedures [ ]**
   .....
   .....
3. **Risk of the Study [ ]**
   .....
   .....
4. **Benefits from the Study [ ]**
   .....
5. **Complications [ ] .....**
   .....
6. **Compensations [ ] .....**
   .....
7. **Confidentiality [ ]**
8. **Rights of Participant [ ] .....**
   .....
9. **Alternatives to Participation in the Study [ ]**
10. **Any Other ..... [ ]**

Name of the Subject/Participant:

Signature of Patient/Guardian:

Relationship to Subject:

Date:

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/ Date:

Name of the Investigator:

Signature of the Witness:

Date:

Name of the Witness:

PART-II: INFORMED CONSENT FORM (ICF) **APPENDIX-E**

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 I 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 Sikkim University 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	Principal Investigator

(Informed Consent Statement in Hindi / Local Language)

SAMPLE

"Community Responses to Nutritional Rehabilitation in Sikkim"

INFORMED CONSENT OF RESPONDENTS IN IN-DEPTH INTERVIEWS AND FGD

Introduction: My name is_____, I am working for Department of ..... , Sikkim University, Gangtok. 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 analyzing 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/Focus Group Discussion (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 **APPENDIX-F**

I have read/ I have been communicated the purpose and other details of the ICMR study **"Community Responses to Nutritional Rehabilitation in Sikkim"** 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:

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

APPENDIX G

INFORMED ASSENT FORM (IAF)
(for Children from 12 Years to 18 Years)

Title of Project:_____

Principal Investigator:

Name, Designation, Contact details _____

Co- Investigator(s): Name, Designation, Contact details _____

Collaborators: Name, Designation, Contact details_____

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Assent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the study about and how it might help?
2. What do you have to do if you take part in the study?
3. What discomfort there might be and what will be done to minimize it?
4. Who will answer the child's questions during the study? (Please make a mention that the child can tell the research staff and parents if something disturbs him/ her, etc.)
5. Whether an option to say "no" exists?
6. Whom do you call if you have questions or problems?

a. Research related

b. Regarding rights as a Participant

Please contact the researchers listed below to:

Obtain more information about the study

Ask a question about the study procedures or treatments

Dr. …….

Scientist.....

Department.....

Dr.....

Scientist.....

Department.....

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office.

Dr. ……..

Member Secretary

The Institutional Ethics Committee comprises of a group of people like doctors, researchers, and community people (non-scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records

APPENDIX H

ASSENT AGREEMENT FORM

(for Children from 12 Years to 18 Years)

Signature of Person Conducting Assent Discussion

Date _____

Name of Person Conducting Assent Discussion (print)

Assent Statement

I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them. I agree to take part in the research.

Name of child _____Signature of child: _____Date: _____

OR

I do not wish to take part in the research and I have not signed the assent below. _____ (initialed by child/minor)

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely. [in case of illiterate child]

Name of witness (not a parent)_____and Thumb print of participant

Signature of Witness _____Date _____

Name of Investigator _____

Signature of Investigator _____

Date: _____

(Copies of the Child information sheet and duly filled and signed ICFs of child and parent shall be handed over to the participant or his/her attendant)

(Assent Statement in Hindi / Local Language)

Reference:

1. IEC guidelines ICMR