Standard Operating Procedures

Institutional Ethics Committee

Lady Irwin College

Version: 4

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Constituted under the Authority of The Director, Lady Irwin College

ADMINISTRATIVE OFFICE:
Institutional Ethics Committee
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1. MANDATE

The Institutional Ethics Committee (IEC) will screen all research projects, MSc and PhD research proposals of the Institute for granting ethical clearance. Lady Irwin College will ensure that a technical evaluation has been completed before the proposal is put up to the IEC ethical review. The IEC will review every research proposal on human participants before the research is initiated. The Committee will 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 ICMR Guidelines have been followed while developing the Standard Operating Procedures for IEC of Lady Irwin College. Till now Lady Irwin College has not carried out any clinical trial of drugs.The IEC will not consider or grant approval to clinical trials of drugs and formulations.

2. OPERATING PROCEDURES

2.1 Membership requirements of the Ethics Committee

The IEC will be multidisciplinary and multi – sectoral in composition. The number of persons in the ethics committee will be 10-12 members. The IEC will appoint from among its members a Chairman who will be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary will be from the same Institution and will conduct the business of the Committee. Other members will be experts drawn from diverse backgrounds: natural sciences, medical sciences, social sciences, home science and law. Further the Committee will also include lay persons to represent general society.

The composition will be as follows:-

i) Chairperson
ii) One person from basic medical science area
iii) One clinician from an Institute
iv) One legal expert or retired judge
v) One social scientist
vi) One representative of non-governmental voluntary agency
vii) One philosopher/ ethicist/ theologian
viii) One lay person from the community
ix) Five Institutional members one each from five different streams of Home Science; Member Secretary will be selected from the Institutional members

If required, subject experts will be invited to offer their views.

2.2 Terms and Conditions of Each Office

Chairperson

The Chairperson will be elected by simple vote among the IEC members. He/She will have a term of 3 years but may be re-elected for another term of 3 years. The Chairperson will be responsible for the following:

i) Chairing the proceedings of every IEC meeting

ii) Consolidating the views of the experts/other IEC members

iii) Approving the minutes

Member Secretary

The Member Secretary shall be appointed from among the Institutional members of the IEC by consensus and will be responsible for the following:

i) Ensuring the regularity of the meetings

ii) Collecting consent form and confidentiality agreement from members on joining the Committee and conflict of interest declaration before every meeting

iii) Scrutinizing and classifying proposals based on risk before putting them up for review

iv) Setting the agenda for the meeting

v) Circulating the agenda to all the members

vi) Writing and circulating the minutes of each meeting

vii) Collecting undertaking from investigators for incorporating recommendations of IEC

viii) Notification of decisions to concerned parties

IEC Members

The members appointed to the IEC will be required

i) To study the research proposals put up for ethical clearance
ii) Give their views and suggestions to the investigators during the meeting
iii) They are required to attend all the meetings. In case of inability to attend a meeting the IEC member will submit their comments/ suggestions in writing to the Member Secretary before the meeting date.

Institutional Members

The Staff Council of Lady Irwin College will appoint the Institutional members to the IEC. The Convenor of the staff council committee will be the Member Secretary of the IEC. The members will have a term of 3 years each. A rotation system for membership would be adopted that allows for continuity, the development and maintenance of expertise within the EC, and the regular input of fresh ideas and approaches. Conflict of interest would be avoided when making appointments, but where unavoidable there should be transparency with regard to such interests. Members would be required to declare conflict of interest before each meeting and the same would be recorded in the minutes.

Non-Institutional Members

The non-institutional members would be selected according to the composition suggested by ICMR from experts in the respective fields living in Delhi or the NCR. The other criteria for the selection of the members would be awareness about the type of research carried out by the Institution. Persons trained in bioethics or persons conversant with ethical guidelines and laws of the country will be preferred for selection as Members. Names could be sought from sitting members and outgoing members. Each member would have a term of 3 years which can be renewed. The term of appointment of members could be extended for another term and not more than 30% of members would be changed on regular basis. New members will be nominated if meetings have been continuously missed by a member due to unforeseen circumstances. For this the criteria for number of missed meetings is all the meetings held in one year.

Conflict of interest would be avoided when making appointments, but where unavoidable there should be transparency with regard to such interests. Members would be required to declare conflict of interest before each meeting.

The appointment letters to the IEC members will be issued by the Director, Lady Irwin College, under whose authority the IEC has been formulated. In addition to the IEC officers, the IEC will have support staff for carrying out its responsibilities.

Support Staff

The Director, Lady Irwin College, under whose authority the IEC has been formulated, will designate the support staff from the College who would be required to:

i) Maintain the files of all the proposals submitted to the IEC

ii) Assist the Member Secretary in circulating the agenda, letters of notification and other correspondence

iii) Code and manage the data base pertaining to all research studies

A dedicated computer will be kept for maintaining the data base and all information pertaining to the IEC. The Member Secretary would have access to this computer.

2.3 Terms of Reference of the Committee

The selected members should be:

i) Willing to publicize his/her full name, profession, and affiliation

ii) Willing to sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters; in addition, all

iii) EC administrative staff will sign a similar confidentiality Agreement

Honorarium/ Consultancy to the non Institutional members/ invited experts will be Rs 3500 per meeting attended and may be revised periodically. All reimbursement for work and expenses, if any, within or related to the IEC will be recorded and made available upon request.

Frequency of meetings- Meetings will be held at least four times a year.

Payment of processing fee to the IEC for review- at present fee charged for processing will be: Ph.D/Project Rs. 5000; M.Sc: Rs. 2000; B.Sc Rs. 1500.

The SOPs will be updated periodically based on the changing requirements.

2.4 Conditions of Appointment and Quorum Required

Terms of appointment

i) **Duration of an appointment**
Three years

ii) **Policy for the renewal of an appointment**
a) Willingness of the member
b) Member has attended most meetings and contributed significantly
c) Members trained in bioethics or conversant with ethical guidelines and laws of the country

iii) **Disqualification procedure**
Member not attended consecutively all meetings in one year

iv) **Resignation procedure**
Members not able to attend and participate in deliberations due to any reason personal or professional shall submit in writing their resignation from the Committee

v) **Replacement procedure**
The Committee can decide to replace a member who has not been attending meetings regularly (missed all meetings in a year)

Quorum required

A minimum of five persons (more than 50% of members) is required to form the quorum without which a decision regarding the research proposal would not be taken. The Chairperson's presence is mandatory for the meeting. In case the member secretary is unavailable, she can nominate another Institutional member of the IEC to record the minutes of the meeting.

The quorum would not be considered complete unless at least one other non-institutional member of the IEC is present besides the Chairperson. The quorum would not consist entirely of members of one profession or one gender; a quorum would include at least one member whose primary area of expertise is in social sciences.

2.5 Procedure for Resignation/Replacement/Removal of Members

Any member is free to resign without assigning any reason. Replacement of that member will be against the category of membership based on qualifications. The Chairperson should forward at least 2-3 nominations received from sitting IEC members to the Director, Lady

Irwin College. Taking the consent of proposed members, an issue of appointment letter will be done by the Director.

2.6 Policy for Training New and Existing Members

i) The members will receive an orientation to the IEC when they join

ii) The IEC members will be encouraged to keep abreast of all national and international developments in ethics so that they become aware of their role and responsibilities.

iii) Any change in the regulatory requirements will be brought to their attention and they shall be made aware of local, social and cultural norms

iv) Will be encouraged to participate in any ongoing opportunities for enhancing their capacity for ethical review.

2.7 Process for Review of Research Proposals

The IEC will review every research proposal on human participants before the research is initiated. The Committee will evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice.

All PhD and research project proposals would come to the Full IEC Committee after Technical Review Board has cleared the proposal. The Technical Review Board comprising of two technical experts and one institutional IEC member should scrutinise the technical aspects such as hypothesis, objectives, study design, sample size computation and proposed methodology as well as ethical considerations for conducting the research study and suggest appropriate modifications in the proposal.

To review the MSc dissertation proposals, the Technical Review Board in each Department would be strengthened by co-opting one non-institutional IEC member from the same subject area, in addition to one institutional member and two technical persons. The Board would classify studies into exempt, expedited and full review category. It would also summarise the proposals for presentation to the Main IEC. The proposals would additionally be circulated to two other non-Institutional members (one technical and one other social scientist/layperson/ legal person/basic sciences person as the case may be) for comments and recommendations. The summary of the proposals and recommendation of the two IEC members then would be presented in the main IEC for comments. In case of disagreement between the two IEC

members on whether the proposal could be considered under Exempt or expedited category, it would be sent for expedited review; if there is a disagreement between the members whether the proposal can go through expedited review or come the full committee, it will come to the full committee for review. 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. An investigator cannot decide that her/his protocol falls in the exempted category.

All proposals will be scrutinised to decide under which of the following three categories it will be considered:

2.7.1. Exemption from review

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

i) Studies which do not involve animals or human subjects

ii) Secondary or subgroup analysis of data already collected during other surveys/studies.

2.7.2. Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review.

1. Minor deviations from the research proposal originally approved by IEC 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 and is limited to data analysis.

3. Research studies on non-vulnerable groups

4. Collection of data through non-invasive procedures routinely employed in clinical practice.

5. Research involving use of clinical materials (data, documents, records, or specimens) that were collected solely for non-research (clinical) purposes.

6. Studies which have already undergone full review by IEC and were asked to make certain modifications and resubmit proposals

2.7.3. Full Review

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

i) Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture.

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

iii) Research on individual or group characteristics or behavior including 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.

2.8 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:

i) The title with signature of Principal Investigator (PI) and Co-investigators as attestation for conducting the study.

ii) Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.

iii) Recent curriculum vitae of the Investigators indicating qualification and experience.

iv) Participant recruitment procedures and brochures, if any.

v) Inclusion and exclusion criteria for entry of participants.

vi) 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, if any.

vii) Plan to withdraw or withhold standard therapies in the course of research.

viii) Plan for statistical analysis of the study.

ix) Procedure for seeking and obtaining informed consent with sample of respondent information sheet and informed consent forms in English and local languages (Format in Appendix).

x) Safety of proposed intervention including results of relevant laboratory and human research where applicable.

xi) For research involving more than minimal risk, an account of management of such risk.

xii) An account of storage and maintenance of all data collected during the trial.

xiii) Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.

xiv) Details of Funding agency/ Sponsors and fund allocation.

xv) For international collaborative study details about foreign collaborators and documents for review of appropriate Committees under other agencies/authority

xvi) An undertaking from supervisor of research project stating that comments made by the Technical Review Committee have been adhered to.

xvii) A statement on conflict-of-interest (COI), if any.

2.9 Decision Making Process

The IEC will meet periodically at least four times a year to review new proposals, evaluate annual progress of ongoing ones, and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate. The following points will be considered while doing so:

i) The decision will 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 will communicate the decision in writing to the PI.

ii) If a member has conflict-of-interest (COI) involving a project then s/he should submit declare this before the review meeting starts, and it should also be recorded in the minutes by the member secretary,

iii) 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

iv) A negative decision should always be supported by clearly defined reason

v) In case of premature termination of study, notification should include the reasons for termination along with the summary of results obtained till date.

vi) 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) any new information that may influence the conduct of the study.

vii) If necessary, the applicant/investigator may be invited to present the protocol or offer clarifications in the meeting.

viii) 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.

ix) Meetings will be minuted which should be approved and signed by the Chairperson and Member Secretary of the committee.

2.10 Review Process

The method of review for MSc dissertations would be conducted first by the Technical Review Board with the co-opted non-institutional IEC member. The Chairperson, Member Secretary and at least 2 other non-Institutional IEC members (one technical and the other non-technical) would be a part of the Sub Committee which will review the exempt, expedited and full review category of M.Sc dissertation proposals. All PhD and research project proposals would come to the Full IEC Committee after being reviewed by Technical Review Board which will consist of two technical experts and one institutional ethics committee member. The ethical review and decision making would be done in formal meetings. The committee should meet at regular intervals and should not keep a decision pending for more than 3 - 6 months.

Periodic Review
The progress of ongoing research will be reviewed at regular intervals at least once a year. The principal investigator(s) will submit a summary of the research progress every year with the undertaking that the study has not changed course and is conforming to suggestions of the IEC.

Continuing Review
The IEC will continue reviewing approved projects for continuation, new information, follow-up and later after completion if need be.

Interim Review
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 are:

i) Change in sample size/ composition

ii) Change in tools used for data collection

However, decisions taken will be brought to the notice of the main committee.

2.11 Monitoring

Once IEC gives a certificate of approval it is the duty of the IEC to monitor the approved studies, periodic status reports will be asked for at intervals of one year in prescribed format.

2.12 Record Keeping

All documentation and communication of an IEC will be dated, filed and preserved according to written procedures by the Support Staff. Strict confidentiality will be maintained during access and retrieval procedures. The following records would 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) Standing operating procedures 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.

All records will 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.

2.13 Informed Consent Process

All the research involving human participants should be conducted in accordance with the four basic ethical principles, namely autonomy (respect for person /participant) beneficence, non-maleficence (do no harm) and justice. The guidelines laid down are directed at application of these basic principles to research involving human participants. The Principal Investigator is the person responsible for not only undertaking research but also for observance of the rights, health and welfare of the participants recruited for the study. S/he should have qualification and competence in biomedical research methodology for proper conduct of the study and should be aware of and comply with the scientific, legal and ethical requirements of the study protocol.

2.13.1. Informed Consent of Participants: For all research involving human participants, the investigator must obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the **Study Information Sheet and Consent Form**. The former should have following components as may be applicable:

i) Nature and purpose of study

ii) Duration of participation with number of participants

iii) Procedures to be followed

iv) Investigations, if any, to be performed

v) Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk

vi) Benefits to participant, community or medical profession as may be applicable

vii) Policy on compensation

viii) Steps taken for ensuring confidentiality

ix) No loss of benefits on withdrawal

x) Benefit sharing in the event of commercialization

xi) Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research

xii) Contact details of Chairman of the IEC for appeal against violation of rights

xiii) Participation is voluntary and participant is free to withdraw at any time without assigning reason

xiv) Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results

A copy of the information sheet should be given to the participant for her/ his record. The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and s/he could withdraw without loss of routine care benefits.

Assurance is given that confidentiality would be maintained and all the investigations/ interventions would be carried out only after consent is obtained. When the written consent as signature or thumb impression is not possible due to sensitive nature of the project or the participant is unable to write, then verbal consent can be taken after ensuring its documentation by an unrelated witness. In some cases, ombudsman, a third party, can ensure total accountability for the process of obtaining the consent. Audio-visual methods could be adopted with prior consent and adequate precaution to ensure confidentiality, but approval of

EC is required for such procedures. If the volunteer can give only thumb impression then another thumb impression by the relative or legal custodian cannot be accepted and an unrelated witness to the project should then sign.

Fresh or re-consent is taken in following conditions:

i) Availabilty of new information which would necessitate deviation or modification of protocol.

ii) When long term follow-up or study extension is planned later.

Waiver of consent

Voluntary informed consent is always a requirement for every research proposal. However, this can be waived if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact. If such studies have protections in place for both privacy and confidentiality, and do not violate the rights of the participants then IECs may waive off the requirement for informed consent in following instances:

i) When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective, eg., study on disease burden of HIV/AIDS.

ii) Research on publicly available information, documents, records, works, performances,

iii) Reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.

2.13.2. Obligations of investigators regarding informed consent: The investigator has the duty to -

i) Communicate to prospective participants all the information necessary for informed consent. Any restriction on participant's right to ask any questions related to the study will undermine the validity of informed consent;

ii) Exclude the possibility of unjustified deception, undue influence and intimidation. Although deception is not permissible, if sometimes such information would jeopardize the validity of research it can be withheld till the completion of the project;

iii) Seek consent only after the prospective participant is adequately informed. The investigator should not give any unjustifiable assurances to prospective participant, which may influence the her/his decision to participate;

iv) Obtain from each prospective participant a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial, and in case the participant is not competent to do so, a legal guardian or other duly authorised representative;

v) Take verbal consent when the participant refuses to sign or give thumb impression or cannot do so. This can then be documented through audio or video means;

vi) Record audio consent when telephonic interviews are being conducted;

vii) Take surrogate consent from the authorized relative or legal custodian or the institutional head in the case of abandoned institutionalized individuals or wards under judicial custody;

viii) Renew or take fresh informed consent of each participant under circumstances described earlier;

ix) The investigator must assure prospective participants that their decision to participate or not will not affect the patient - clinician relationship or any other benefits to which they are entitled.

2.13.3. Essential information for prospective research participants: Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language she or he is able to understand which should not only be scientifically accurate but should also be sensitive/ adaptive to their social and cultural context:

i) The aims and methods of the research;

ii) The expected duration of the participation;

iii) The benefits that might reasonably be expected as an outcome of research to the participant or community or to others;

iv) Any foreseeable risk or discomfort to the participant resulting from participation in the study;

v) Right to prevent use of her/ his biological sample. At any time during the conduct of the research;

vi) The extent to which confidentiality of records could be maintained ie., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality;

vii) Responsibility of investigators;

viii) Freedom of individual / family to participate and to withdraw from research any time without penalty or loss of benefits which the participant would otherwise be entitled to;

ix) The identity of the research teams and contact persons with address and phone numbers;

x) Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same;

xi) Risk of discovery of biologically sensitive information and provision to safeguard confidentiality;

xii) Publication, if any, including photographs and pedigree charts.

The quality of the consent of certain social and marginalized groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

2.14 Compensation for Participation

Participants may be reimbursed for expenses incurred, in connection with their participation in research if funding is available. They may also receive free medical services/counselling. When this is reasonable then it cannot be termed as benefit. However, payments should not be so large as to make prospective participants consent readily to enroll in research against their better judgment, which would then be treated as undue inducement. All payments, reimbursement and medical services to be provided to research participants should be approved by the IEC.

Care should be taken:

i) When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;

ii) When a participant is withdrawn from research for medical reasons related to the study the participant should get the benefit for full participation;

iii) When a participant withdraws for any other reasons s/he should be paid an amount proportionate to the amount of participation.

2.15 Conflict of Interest

A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (COI). Academic institutions conducting research in alliance with industries/ commercial companies require a strong review to probe possible conflicts of interest between scientific responsibilities of researchers and business interests eg **(**ownership or part-ownership of a company developing a new product). In cases where the review board / committee determines that a conflict of interest may damage the scientific integrity of a project or cause harm to research participants, the board/ committee should advise accordingly. Significant financial interest means anything of monetary value that would reasonably appear to be a significant consequence of such research including salary or other payments for services like consulting fees or honorarium per participant; equity interests in stocks, stock options or other ownership interests; and intellectual property rights from patents, copyrights and royalties from such rights. The investigators should declare such conflicts of interest in the application submitted to IEC for review. Institutions and IECs need self-regulatory processes to monitor, prevent and resolve such conflicts of interest. Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research. Those who have also to be informed of the secondary interest in financial terms should include the institution, IEC, audience when presenting papers and should be mentioned when publishing in popular media or scientific journals.

Undue inducement through compensation for individual participants, families and populations should be prohibited. The IEC would examine this on a case-by-case basis, as some of these elements may be justifiable for collecting vital data for national use or necessary to find if some interventions may significantly have direct impact on policies.

Safeguarding confidentiality - The investigator must safeguard the confidentiality of research data, which might lead to the identification of the individual participants. Data of individual participants can be disclosed under the following circumstances:

i) Only in a court of law under the orders of the presiding judge or

ii) If there is risk to public health it takes precedence over personal right to privacy and may have to be communicated to health authority.

Therefore, the limitations in maintaining the confidentiality of data should be anticipated and assessed and communicated to appropriate individuals or authorities as the case may be.

2.16 International Collaboration / Assistance In Bio-Medical /Health Research

Special Concerns

i) Given the magnitude and severity of the health problems in different countries, capacity building to address ethical issues that arise out of collaborative research must be promoted on a priority basis. Strategies should be implemented so that various countries and communities can practise meaningful self-determination in health development and can ensure the scientific and ethical conduct of research.

ii) The collaborating investigators, institutions and countries can function as equal partners with sponsors even when in a vulnerable position by building appropriate safeguards. Community representatives should be involved early enough while designing the protocol and in a sustained manner during the development, implementation, monitoring and dissemination of results of research.

iii) Careful consideration should be given to protect the dignity, safety and welfare of the participants when the social contexts of the proposed research can create foreseeable conditions for exploitation of the participants or increase their vulnerability to harm. The steps to be taken to overcome these should be described and approval taken from IEC.

iv) Every adult participant in the research should voluntarily give informed consent and child her/his assent as may be applicable.

v) As different kinds of research (epidemiological studies, product development, behavioural and social science oriented research etc.) have their own particular scientific requirements and specific ethical challenges, the choice of study populations for each type of study should be justified in advance in scientific and ethical terms regardless of the place from where the study population is selected.

vi) The research protocol should outline the benefits that persons / communities / countries participating in such research should experience as a result of their participation. Care should be taken so that these are not presented in a way that unduly influences freedom of choice in participation. The burden and the benefit should be equally borne by the collaborating countries.

vii) Guidelines, rules, regulations and cultural sensitivities of all countries participating in collaborative research projects should be respected, especially by researchers in the host country and the sponsor country. These could be with reference to intellectual property rights, exchange of biological materials (human, animal, plant or microbial), data transfer, security issues, and issues of socially or politically sensitive nature. In this context, it is essential for researchers to follow the GOI notification on "Exchange of Human Biological Material for Biomedical Research" issued on 19.11.97 and obtain appropriate regulatory clearances as prevalent in the country for international collaboration and EC approval from all trial sites before the initiation of research.

2.17 Researcher's Relations with the Media and Publication Practices

Researchers have a responsibility to make sure that the public is accurately informed about results without raising false hopes or expectations. It should also not unnecessarily scare the people. Researchers should take care to avoid talking with journalists or reporters about preliminary findings as seemingly promising research that subsequently cannot be validated or could lead to misconceptions if reported prematurely. Or, the results of research may be reported in such a way that it would seem that the human application is round the corner, only to be told later by the researchers that considerable time has to pass before these findings can be translated into tools for human use. In such circumstances, retractions most often do not appear in the media. Therefore, it is important to avoid premature reports and publicity stunts. The best safeguard against inaccurate reporting is for the researcher to talk to media on condition that the reporter submit a full written, rather than oral version, of what will be reported, so that it enables the researcher to make necessary corrections, if needed, prior to publication.

Investigator's publication plans should not threaten the privacy or confidentiality of participants. Maintenance of confidentiality while publishing data should be taken care of. In case there is need for publication / presentation of photographs/ slides / videos of participant (s), prior consent to do so should be obtained. Identification features should be appropriately camouflaged. The same safeguard should be observed for video coverage.

With regard to authorship, the International Committee of Medical Journal Editors (ICJME) has laid down criteria based on credit and accountability. Only those who make substantial contribution to the article and take responsibility for the published matter can be co-authors.

Plagiarism or falsification of data and authorship are important ethical issues in publications. The term 'misconduct in research' means fabrication, falsification, plagiarism, selective omission of data and claiming that some data are missing, ignoring outliers without declaring it, publication of post-hoc analysis without declaring it, gift authorship, not citing others' work, not disclosing conflict of interest, redundant publication, and failure to adequately review existing research.

3. STANDARD OPERATING PROCEDURES FOR VULNERABLE POPULATION

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialised areas of research which require additional safe guards / protection and specific considerations for the IEC. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialisation of research and international collaboration.

Selection of Special Groups as Research Participants: Pregnant, Lactating Women, Children and Vulnerable Groups

Home Science research endeavours to improve delivery systems, monitor and use the knowledge of science to give impetus to National Programs. Women and children in all stages of the life cycle are covered by various National Programs. The Institutional Ethics Committee will endeavour to achieve good research practices in eliciting data from these vulnerable groups. Research mandate at Lady Irwin College includes both qualitative and quantitative research to study compliance to National Programs like food/nutrient supplementation, AIDS control, safe motherhood, inclusive education; study health and nutritional status, health and nutrition care seeking behaviour; issues of people with disabilities and operational research to improve access to and utilisation of services. The Institution has engaged in this type of effort and data collection for the past eight decades and has the expertise in developing Information Education Communication material for educating the masses and monitoring Government initiatives.

Research for the betterment of vulnerable groups is the need of the hour, however utmost care will be taken while screening research proposals pertaining to them. No clinical trials will be conducted on these groups.

APPENDICES

A - Template of Study Information Sheet and Consent Form

B- Consent Form and Confidentiality Agreement

C- Checklist for Submission of Research Proposal for Ethical Clearance

D- Format for Annual Compliance Report

E- Details of IEC Members

F- Details of Support Staff

Appendix A: Template of Study Information Sheet and Consent Form

Study Information Sheet

(Name the group of individuals for whom this information sheet is written. In case your study is carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important tp provide group specific consent forms –ie you identify which group a particular consent is for although the study information sheet may be the same.)

This study information sheet is for ..... participating in the research titled- .....

Principal Investigator:
Supervisor:
Organization: Lady Irwin College, University of Delhi

Introduction
You are invited to participate in a research study conducted by----------. This study is funded by----------. Your participation in this study is voluntary. You should read the information below, and ask questions about anything you do not understand before deciding whether to participate or not. Please take as much time as you need to read the consent form. You are free to ask me any queries or if you do not understand anything. If you decide to participate, you will be asked to sign this form.

(For studies involving children…..Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.)

Purpose
In the present study, we wish to study ----------*(explain in simple lay terms)*

Type of Research Intervention
Briefly state the type of intervention if any that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves taking a blood sample, anthropometric measurements or simply being asked questions.

Participant selection
State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

Voluntary Participation
Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

e.g. Your participation in the study is voluntary. You can choose to say No and not participate in the study. You may choose to withdraw at any time during the study.

Study Procedures
If you agree to participate, you will be asked to *fill up a questionnaire/ be a part of focus group discussion/ undergo Body Measurements or blood tests (as the case may be).*
Brief description of what is expected of the subject.

The procedures will be carried out at your home or at a place as per your convenience.

Duration
Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant. Mention the time the participant will need to spend in each interaction.

Benefits
Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

e.g. Your participation would help us/community in ----------.

Reimbursements
State clearly what you will provide the participants with as a result of their participation. eg expenses incurred as a result of participation in the research. These may include, for example, travel costs and money for wages lost due to visits to the study locale.
Or for eg.....You will not be provided with any payments to take part in the study. However your -------test results will be provided to you. Also, you can ask for free counselling (*optional*) during the course of the study.

Confidentiality
The information shared by you will be kept confidential. Your personal data and identity would not be revealed at any stage. *You should also inform the participant if research findings will be published in scientific journals and presented in conferences but the identity of the participants will not be disclosed* .

Risks and Discomforts
If you feel uncomfortable talking about any topic or sharing any personal information, you will not be forced to answer any question that you do not wish to. The study does not involve any risk to your health or to your life....*only in case the intervention is related to their health / disease risk*

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw.
Tailor this section to ensure that it fits for the group for whom you are seeking consent.

Who to Contact

If you have questions, concerns or complaints as a research participant, you may contact any of the following:..
give contact details of principal investigator and supervisor - phone and email id.

Consent form (*for adult participants and parents of child participants*)

I … … … … … … … … …., a resident of…… have read the information in the study information sheet / have had the study information sheet read out to me. I am over 18 years of age and, exercising my free power of choice, hereby willingly give my consent to participate in the study/ for my child to participate in the study. I certify that:

(1) I have fully understood the information provided about the study.
(2) My rights and responsibilities have been explained to me by the investigator.
(3) I have been informed that there are no known risks associated with this study and explained the possible benefits.
(4) I am aware of the fact that I/my child can opt out of the study at any time without having to give any reason and this will not affect my access to ...(*eg. facilities in school/health and nutrition services/....).*
(5) I hereby give permission to the investigators to release the information obtained from me/ my child as result of participation in this study to the sponsors, regulatory authorities, and Government agencies.
(6) My/ my child's identity will be kept confidential when the data are published or presented in scientific meetings.
(7) I have been provided information about individuals whom I can contact to seek clarifications during the study period. I have also been provided a copy of the study information sheet and the consent document.

(*If illiterate:**A literate witness must sign as witness to the thumb print consent by the person giving consent (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should have their thumb-print taken and this should be backed up by two witnesses who are not part of the study team .)*

_____ _____
Name of the participant *Date*

_____
Signature /Thumb impression of the participant (if thumb impression then take signature of the witness and their address

Address- _____

_____

*Contact No-*_____ *Email id-* _____

Note: When the subject is a child parental consent for the child's participation in the study will be taken first - form will be referred to as Parental Consent. After parental consent, the assent is to be obtained from the child if the child is 7 years of age or beyond.. The child study information form can be separate, and then it should be in a language that the child can understand. If the child gives her/his assent the signature of the child is to be taken in the child assent form given below

Child's Assent Form

I have read this information (or had the information read to me). I know that my parents have agreed to my participation in the study. I have had my questions answered and know that I can ask questions later if I have any further queries.

I have understood the information provided to me regarding the study and I agree to take part in the study.

_____ _____

Name of the Participant *Date*

_____

Signature of the Participant

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

State the procedures that the participant has to undergo like participating in discussion/ filling a questionnaire/ having body measurements taken, etc.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of study information sheet has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____ Day/month/year

Appendix B: Consent Form and Confidentiality Agreement

CONSENT FORM AND CONFIDENTIALITY AGREEMENT

Institutional Ethics Committee

Lady Irwin College

University of Delhi

I, _____ consent to be a member of the Institutional Ethics Committee of Lady Irwin College, University of Delhi. I understand all the Confidentiality and Conflict of Interest Norms of the Committee regarding meeting deliberations, applications, information on research participants, and related matters. I promise to abide by them.

Residential Address:

Telephone/mobile no.

Appendix C- Checklist for Submission of Research Proposal for Ethical Clearance

Document	Yes/No/ N.A.	Page No.
i) The title with signature of Principal Investigator (PI) and Co-investigators as attestation for conducting the study.		
ii) Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.		
iii) Recent curriculum vitae of the Investigators indicating qualification and experience for the kind of work to be undertaken if required.		
iv) Participant recruitment procedures and brochures, if any.		
v) Inclusion and exclusion criteria for entry of participants.		
vi) 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, if any.		
vii) Plan for statistical analysis of the study.		
viii) Procedure for seeking and obtaining informed consent with sample of respondent information sheet and informed consent forms in English and local languages (Format available with IEC secretariat).		
ix) Safety of proposed intervention, including results of relevant laboratory, animal and human research where		
x) For research involving more than minimal risk, an account of management of such risk or injury.		
xi) Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.		
xii) A statement on probable ethical issues and steps taken to tackle the same		
xiii) Details of Funding agency/ Sponsors and fund allocation.		

xiv) For international collaborative study details about foreign collaborators and documents for review by appropriate Committees under other agencies/authority		
xv) For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.		
xvi) An undertaking from supervisor of research project stating that comments made by the Technical Review Committee have been adhered to.		
xvii) A statement on conflict-of-interest (COI), if any.		

Appendix D – Format for Annual Compliance Report

Annual Compliance Report

Title of Study:

Principal Investigator:

Supervisor(s):

Date of IEC clearance:

Summary of work done in the past one year in not more than 500 words

Undertaking

This is to certify that I have not deviated from the study protocol approved by the Institutional Ethics Committee of Lady Irwin College in its meeting held on _____.

The study is progressing satisfactorily and there are no adverse events in the study population to report.

Signatures

Principal Investigator Supervisor(s)

Date:

Appendix E – Details of IEC Members

S . No	Name	Speciality	Quali-fication	Organizational Title	Mailing Address	Contact details
1	Dr Peeyush Jain	Chairperson	MBBS, MD (Medicine)	Head, Dept of Preventive Cardiology, Fortis Escorts Heart Institute, Okhla Road, New Delhi-25	79, SRM Apts, Plot 106, IP Extension, Delhi 110092	9818701043 dpn2005@gmail.com
2	Dr. Sona Khan	Legal Expert	PhD (Islamic Law), PhD (Asian Juris Prudence B.A., LLB	The Khan Law Firm, A-2, Oberoi Aptt., Shyamnath Marg, Delhi-110054	A-2, Oberoi Aptt., Shyamnath Marg, Delhi-110054	9868209352 thekhanlawfirm@gmail.com
3	Dr. Amita Joseph	Legal Expert	PhD, LLB, PGDM in Human Rights Law	Business & Community Foundation (BCF) Sri Aurobindo Society Campus. Shaheed Jeet Singh Marg, New Mehrauli Road, Adhchini, Delhi -110017.	Y 57, First floor, Hauz Khas, New Delhi 110016	9811299989 amita.joseph@gmail.com
4	Dr Hrudananda Mallick	Medical Science (Neurophysiology)	MD, PhD	Professor, Dept Of Physiology, AIIMS	406, Hawa Singh Block, Asiad Village, New Delhi 110049	9810755486 drhmallick@yahoo.com
6	Dr Vijay Tankha	Philosopher	PhD	Associate Professor, Dept of Philosophy, St Stephens, University of Delhi	B1 Staff Quarters, St Stephens College, Delhi University North Campus, Delhi	9971654666 vtankha@gmail.com

S . No	Name	Speciality	Quali-fication	Organizational Title	Mailing Address	Contact details
7	Ms Bindu Dogra	Layperson	B.Sc, B.Ed	N.A.	C 114, The Summit, Sector 54, DLF City V, Gurgaon-122011, Haryana	9958584187 Bindu.dogra@me.com
9	Prof Simmi Bhagat	Member Secretary and Institutional member (Fabric and Apparel Science	PhD	Professor, Dept of Fabric and Apparel Science, Lady Irwin College, University of Delhi	G 72, Park Place, DLF Phase V, Sector 54, Golf Course Road, Gurgaon 122009 Haryana	9818694864 simmi.bhagat@lic.du.ac.in
10	Dr Punya Pillai	Institutional member (Human Development & Childhood Studies)	PhD	Associate Professor, Dept of Human Development & Childhood Studies, Lady Irwin College, University of Delhi	E 43, second floor, Saket New Delhi 110017	9818438298 punya.pillai@lic.du.ac.in
11	Prof Puja Gupta	Institutional member (Resource Management & Design Application)	PhD	Professor, Dept of Resource Management & Design Application, Lady Irwin College, University of Delhi	# 34, Sector 15, Vasundhara, Ghaziabad, 201012	9711881316 puja.gupta@lic.du.ac.in
12	Prof Rupa Upadhyay	Institutional member (Development Communication & Extension)	PhD	Professor, Dept of Development Communication & Extension, Lady Irwin College, University of Delhi	Lady Irwin College	9818023629 rupa.upadhyay@lic.du.ac.in

S . No	Name	Speciality	Quali-fication	Organizational Title	Mailing Address	Contact details
13	Prof Seema Sekhri	Institutional member (Fabric & Apparel Science)	PhD	Professor, Dept of Fabric & Apparel Science, Lady Irwin College, University of Delhi	2, Willingdon Cottage, Lady Irwin College New Delhi 110001	9868375777 seema.sekhri@lic.du.ac.in
14	Prof Manisha Sabarwal	Institutional member (Food & Nutrition)	PhD	Professor, Dept of Food and Nutrition, Lady Irwin College, University of Delhi	Lady Irwin College	9810895026 manisha.sabarwal@lic.du.ac.in
15	Prof Renu Malaviya	Institutional member, Education	PhD	Professor, Dept of Education, Lady Irwin College, University of Delhi	1, Willingdon Cottage, Lady Irwin College, Sikandra Road, New Delhi-110001	9811103480 malaviyadelhi@gmail.com

Appendix F – Details of Support Staff

S.No.	Name	Qualification	Organizational Title
1	Mr Ashok Kohli	Graduate	Director's PA
2	Mr Rajesh Kumar	12th Pass	Peon
3	Mr Naveen Singh	10th Pass	Driver
4	Ms Bhawna Singh	Graduate	Typist

Mailing Address:

Director's Office,
Lady Irwin College,
Sikandra Road,
New Delhi – 110001

Telefax: 011 23711222