Research Compliance Guidelines
Ethics Committee
Indian Institute of Management Udaipur

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INTRODUCTION

An Ethics Committee (EC) is a committee that has been formally designated to approve, monitor, and review behavioral research involving primary data collected from human subjects. The priority of the EC is to protect human research subjects from physical or psychological harm. The EC is empowered to approve, require modifications in planned research prior to approval, or disapprove research, ensuring that research conducted on human subjects is ethical.

These research compliance guidelines are designed to provide an overview of the ethical principles, regulatory foundation and responsibilities of the EC members. IIMU's EC guidelines are basedon the principles of the Belmont Report, which can be accessed using the link (https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html). The report highlights the importance of:

1) Respect for human subjects.
2) Beneficence.
3) Justice.

The Ethical Foundations for Human Research Protection

The Belmont Report identified the following three fundamental ethical principles that must be carefully considered to ensure the ethical practice of research involving human participants:

1) Respect for human subjects

Respect for persons incorporates two key ethical convictions: (a) individuals must be treated as autonomous agents capable of making their own decisions, and (b) individuals with diminished autonomy are entitled to protection. The principle of respect, thus, implies two distinct moral requirements: the requirement to acknowledge autonomy of all and the requirement to protect those with diminished autonomy.

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2) Beneficence:

Individuals are treated in an ethical manner not only by respecting their decisions and protectingthem from harm, but also by ensuring their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" indicates acts of kindness or charity that go beyond strict obligation. In these guidelines, beneficence is regarded as an obligation involving two rules: (a) not to harm anyone, physically, mentally, or emotionally and (b) maximize possible benefits of all.

3) Justice

The selection of research subjects (hereafter, participants) must be scrutinized to determine whether somegroups are systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. When research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that research benefits must be available to all irrespective of whether some groups can afford them or not.

THE ETHICS COMMITTEE

I. EC of IIMU

IIMU's EC is primarily meant to serve faculty and Ph.D. students at IIMU involved in healthcare research with particular focus on IIMU's Center for Healthcare. It should be composed of members who may or may not be affiliated to IIMU and who are qualified to review research, especially research design through their education, experience, and expertise. It should be diverse with regards to gender and cultural background.

What activities require EC's review?

Every healthcare research project that includes collection of primary data from human participants. Projects that deal with non-healthcare social science or behavioral research shall fall under the purview of the Institutional Review Board (IRB) of IIM Udaipur.

II. EC's Roles and Responsibilities

Primary responsibilities of the EC are:

1) Conducting protocol reviews.
2) Ensuring protection of dignity, rights, safety, and well-being of the research participants.
3) Applying discipline and regulatory knowledge.
4) Ensuring that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

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5) Attending meetings.

6) Avoiding conflicts of interest within the committee.
7) Developing EC-related policies.
8) Handling allegations or reports of non-compliance and maintaining confidentiality.

III. Membership requirements of EC at IIMU

The membership of EC at IIMU follows the Indian Council of Medical Research's (ICMR) protocol and includes individuals with varying backgrounds. It is multidisciplinary and multisectoral in composition with members having medical, mainstream science, and social science backgrounds involving members from the community - at least one woman member, one legal expert and one independent member must be from any other related field such as representative of non-governmental voluntary agency or philosopher or ethicist or theologian so as to reflect different perspectives. There must be a fair representation of age, gender, and important members from the community. As per sub rule 1, 50% members must be from outside the IIMU. In conformity with the ICMR Ethical Guidelines, this composition of members is meant to ensure that participants of all research projects do not experience any potential risk because of the research designs, and community and cultural values are respected and maintained.

The Chairperson must be an eminent member of the society not affiliated to IIMU to maintain independence and objectivity of the EC. The Member Secretary (MS) must be an IIMU member and is responsible for organizing the meetings and preparing the proceedings, conducting the business of the meetings, maintaining records, and communicating with all concerned – with the help of the Centre for Healthcare officials. An official of the Centre for Healthcare is responsible for preparing the minutes of the meetings and getting it approved by the Chairman and the appropriate authority before communicating it to the researchers. The Committee must possess appropriate professional competence to review the diverse types of protocols received and execute the same free from any bias and influence.

1) The Chairperson of the committee should be non-affiliated with IIMU.
2) The Committee must consist of a basic medical scientist, a clinician, a legal expert and a community advocate with local knowledge.
3) 50% of the members should be non-affiliated to IIMU.
4) Members must have a substantive knowledge about the vulnerability of human participants inbehavioral studies.

IV. Quorum requirements for EC meeting

1) A minimum of five members should be present for the meeting.
2) The quorum must include the Chairperson, the MS, both medical, non-medical or technical or/and non-technical members.
3) At least one non-affiliated member should be part of the quorum.
4) Preferably the community advocate should be part of the quorum.
5) No decision is valid without fulfilment of the quorum.

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6) An online meeting, or members joining online in a hybrid meeting, shall be considered as being present in-person and shall count for quorum.

V. Terms of reference for EC

1. The chairperson and all the committee members of the EC will be appointed by the Director of IIMU.
2. The appointment letter issued to the EC members should specify the following:
    - Roles and responsibilities of the members in the committee.
    - Duration of appointment.
    - Conditions of appointment.
3. All members of the EC will serve for a period of three years, on renewable terms. Members willing to continue after the completion of the term are retained for another term to provide continuity of their contribution of ethical expertise.
4. Members to be appointed on the EC should be willing to fulfill the EC requirements as given:
    - Provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
    - Either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
    - Be willing to undergo training or update their skills/knowledge during their tenure as an EC member.
    - Be aware of relevant guidelines and regulations.
    - Read, understand, accept and follow the Conflict of Interest (COI) policy of the NTI-IEC and declare it, if applicable, at the appropriate time;
    - Sign a confidentiality and conflict of interest agreement/s;
    - Be willing to place her/his full name, profession and affiliation to the EC in the public domain
    - Be committed and understanding to the need for research and for imparting protection to research participants in research.
5. All members are appointed on an honorary basis.

VI. Procedure for resignation, replacement or removal of EC members:

1) A Member can tender resignation from the Committee assignment with proper reasons for doing so in writing to the Chairperson and Member Secretary.
2) A Member will be replaced in the event of death or long-term non-availability or for any other reason after following due process.

VII. Standard Operating procedures for IIMU-EC

Objective and Responsibilities: To ensure that the research proposals received for ethical clearance by the ethics committee.

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- Are sound in methodological design, have statistical/ analytical validity and are conducted according to ICMR's Ethical Guidelines Health Research Involving Human Participants.
- Do not compromise rights, safety and benefits of the patients or volunteers/ study participants.
- Include solely participants who have given voluntary and informed consent.
- It may be ensured that no research project shall be/ can be started unless Ethics Clearance /Approval is obtained and that no retrospective / post facto Ethics Clearance/ Approval can be provided to research projects which were neither submitted nor vetted by the Ethics Committee.
- To review and ensure equitable recruitment of participants in the study.

Procedures:

- Any research proposal involving human participants is place before the committee for its consideration and mandatory approval.
- A quorum is required for all meetings (05 members out of 7 make a quorum). Decision on the project is made by consensus of members present at the meeting.
- The projects/proposals are circulated up to two weeks prior to conducting Institutional Ethics Committee meeting. If the Secretary to the Ethics Committee deems it appropriate to provide additional time given the nature of the proposal, they may send the proposal accordingly with more time before the meeting.
- If a member is unable to attend a meeting his/her opinion on the project may be submitted in writing to the Chairperson of the Committee before the date of the meeting or decision. The decision of the committee is taken by majority vote.
- If Chairperson is absent he/she can nominate a person from the Ethics Committee to chair the meeting.
- In case a member is absent from the Committee meeting, if no objection / comments are obtained from that member on the previously circulated projects/proposals, they are considered to be approved by that member.
- All members have to give an undertaking declaring their conflict of interest. Regarding projects, which evoke a Conflict of Interest among members of the Ethics Committee, these members should voluntarily withdraw from the EC meeting while making a decision on that project. This may be indicated to the Chairperson prior to the review and be recorded so in the minutes of the meeting.
- A Center for Healthcare official may be appointed to write the meeting minutes. Minutes are circulated to the Chairperson and after his/her approval, the letters of approval/disapproval/advise for revision may be dispatched after the signature of Member-Secretary of the Ethics Committee, to applicants.
- After the EC meeting, the decisions of the members of the committee on the projects/proposals to be obtained on the same day of the meeting.

Documents required to be submitted by the research investigators

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The applicant of a proposal is required to **submit one copy of his / her application letter with these following documents:**

1) The research protocol with at least one researcher as a full-time faculty member of IIMU or an IIMU PhD student.
2) Application form (in the format).
3) Participant Informed Consent form and Participant Information sheet in English and the same translated in vernacular language, in a simple layman's language.
4) Any other project–specific document.
5) Declaration that no work has been started.
6) Declaration that work will be done as per the EC Guidelines.
7) Permission to use copyrighted questionnaire and proforma, if any.
8) Brief Curriculum Vitae of principal investigators (only for any PIs not affiliated to IIM Udaipur).

VIII. Standard Operating Procedures for Vulnerable population

The vulnerable population in the research studies includes children, economically and socially disadvantaged persons. Following are some examples of vulnerable populations or groups as specified in the ***ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants –2017:***

- Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), prisoners, etc.).
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.
- Children (up to 18 years).
- Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- Tribal and other marginalized communities.
- Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations.
- Afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled.
- Terminally ill or are in search of new interventions having exhausted all therapies.
- Suffering from stigmatizing or rare diseases; or
- Have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).
- Current students of any of the researchers listed on the research protocol.

The EC should ensure that all the cardinal principles of research ethics - beneficence, non-maleficence, autonomy, respect for individuals, and justice are addressed in the proposed research project; it must look into the aspects of informed consent process, assess the risks and benefits to human participants, and requirements (or not) for appropriate compensations.

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The EC should ensure that the purpose of research is to obtain knowledge relevant to the health needs of the vulnerable population and that the potential risks to participants are minimized by using procedures consistent with sound research design. T.

The EC determines the appropriateness of the informed consent process and its documentation in accordance with and to the extent required. In case of any sample from the vulnerable population, the committee ensures that consent from the appropriate authority is obtained. The committee ensures that the selection of participants is equitable, taking into account the purpose of the research and the setting in which the research shall be conducted.

The EC should determine that there are adequate provisions in the research plan, where appropriate, for monitoring the data collection to ensure the safety of the participants. It also ensures that there are adequate provisions to protect privacy of participants and to maintain the confidentiality of data, where appropriate.

IX. Policy regarding training for new and existing committee members

All new members have to complete a core educational program prior to serving on the EC (by attending three to four scheduled meetings).

The core training modules consists of:
(i) **'Ethical Guidelines for Biomedical and Health Research on Human Subjects', Indian Council of Medical Research, India, 2017**, or its revisions as and when available.
(ii) **Standard Operating Procedures of EC,** or its revisions as and when available, and
(iii)Practical preparation for and observation of three to four scheduled EC meetings.

After completion of at least three years in EC, members who have earlier been trained in research methodology workshop are appointed for guiding new members through hands-on-training in Ethics Committee. Training in guidelines will provide the basic foundation in ethics for protecting human participants in research. Continuing education information is disseminated to all the Members, and they are encouraged to attend national and international training programs on research ethics in order to maintain quality in the ethical review process and help each other be abreast with the latest developments in the area of protection of human research participants.

X. Policy to monitor or prevent the conflict of interest

The following policy will be followed by EC to monitor or prevent the conflict of interest:

- Investigators do not select the committee members.
- No individual involved in the conduct of the research project under review participates in the review process, except to provide information.
- No committee member participates in the review process of any research project in which the member has a conflicting interest, except to provide information requested by the committee.
- Members having conflict of interest disclose the conflict and withdraw themselves from participation during review of that research, except to provide information on request.

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Such members do not participate in the discussions during the review of that research and in the decision-making process.

XI. Auditing/Inspection of the Ethics Committee

The EC was formed recently and has not been audited or inspected before. Audits shall be conducted as per frequency advised by the ICMR.

XII. UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairman
Name : Dr. Kirti Iyengar

Address :

Title :

2. Name and address of the office of Ethics Committee
Indian Institute of Management Udaipur Ethics Committee
IIM Udaipur, Balicha
Udaipur- 313001, Rajasthan, India

3. **Names, address, qualifications & designation of the other members of the Ethics Committee.***

Sr. No.	Name	Qualification with specialization	Current organizaion	Telephone, Mobile, e-mail, mailing address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1.	Dr Kirti Iyengar			kirtiiyengar@gmail.com	Chairperson	Non-affiliated
2.	Prof. Dina Banerjee	PhD, Sociology	IIMU	dina.banerjee@iimu.ac.in	Member Secretary	Affiliated
3.	Dr Anand Mahawar			mahawardranand@gmail.com	Basic Medical scientist	Non-affiliated
4.	Dr Gargi Goel			gargi.goel@bhs.org.in	Clinician	Non-affiliated
5.	Mr. Rohit Jain			rj@singhania.com	Legal expert	Non-affiliated
6.	Prof Amogh Kumbargeri			amogh.kumbhargeri@iimu.ac.in	Social scientist/ philosopher/	Affiliated

					ethicist/theol ogian	
7.	Ms. Smriti Kedia			smriti.kedia@gmail.com	Community advocate	Non-affiliated

XIII. The Review Process

1) IIMU's EC believes that every research is urgent in nature. Therefore, all the applications are reviewed on an expedited basis (within two weeks of the submission of the application).

2) All EC members must review the application before the meeting.

3) If any, the committee would send the comments/concerns/ suggested changes to the applicants. The average duration of response is one week, unless the committee has further comments/concerns.

4) The review process of amended applications is the same as a new application.

XIV. What criteria must be met for research to be approved?

To approve an application, the EC should determine that all of the following requirements aresatisfied:

1) Are risks to participants minimized?

2) Is subject selection equitable?

3) Is the process for obtaining consent appropriate?

4) Is informed consent appropriately and adequately documented?

5) Is there adequate provision for monitoring the data collection to ensure safety of the subjects?

6) Are the provisions for protecting privacy appropriate and adequate?

7) Are the provisions for maintaining confidentiality appropriate and adequate?

8) Have additional safeguards for subjects vulnerable to coercion or undue influence been included?

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XV. What research is exempt from review?

1) Research project that includes ONLY the use of secondary/archival data that are publicly available are exempted from the review process. However, if the researchers are skeptical about the use of certain datasets, they are entitled to apply for an EC approval.

2) Research project that already has an EC approval from another institute does not need a separate EC approval from IIMU.

XVI. Is EC approval permanent?

No. If there is a change in a research protocol, the researchers should immediately amend the application and inform the EC to seek further approval.

XVII. How does an EC make a decision?

The guiding ethical principles of respect for human participants, beneficence, and justice must beconsidered while conducting each review. The EC must also determine that ALL the following criteria are met before approving each application.

1) Minimization of risks: Both physical and non-physical risks to human subjects should be minimized as much as possible by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to any potential risk. Whenever appropriate, studies should use procedures already being performed on the participants for diagnostic or treatment purposes.

Reasonable risk/benefit ratio: Both physical and non-physical risks to human subjects should be reasonable in relation to any anticipated benefits (the risk/benefit ratio) to participants, and the importance of the knowledge that may reasonably be expected to result. The EC should account for risks and benefits that may result from the research as distinguished fromthose that participants would receive if not participating in the research. The EC must not consider possible long-range effects of applying knowledge obtained in the research. The EC should take into consideration the level of risk and the validity of the research design indetermining the risk/benefit ratio.

2) Equitable selection of subjects: The EC should take into account the research purposes and settings, special problems involving vulnerable populations in evaluating subject selection.

3) Quality informed consent forms: These should contain all required elements in alignment with regulations and ethical standards, be complete, accurate and comprehensible and provide potential participants with an accurate and fair description of the risks or discomforts and the anticipated benefits.

4) Adequate safety monitoring and provisions for privacy and confidentiality: The EC should

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ensure that research plans make adequate provisions for data and safety-monitoring toprotect the privacy of participants and to maintain the confidentiality of individually - identifiable data.

5) Protection of vulnerable participants: The EC should ensure that adequate safeguards have been included in each study to protect the rights and welfare of members from the vulnerable population.

6) Conflict of interest: The EC should ensure that steps are adequate to evaluate, manage, reduce or eliminate potential or real conflicts of interest.

7) Investigator's backgrounds: IIMU's EC would review ONLY those applications where at least one of the researchers is a full-time IIMU faculty or an IIMU PhD student.

8) Protecting IIMU members: Except under exceptional circumstance, no research should be done on IIMU students by IIMU faculty members in such a way that the researcher(s) belonging to IIMU is/are identifiable to the research participants. This includes all experimental/survey-based research studies. The researcher(s) must contact the R&D office while keeping the EC in loop so that all communication is done through an email ID that does not disclose the name of the IIMU faculty member(s) conducting the research. R&D office would facilitate IIMU faculty member(s) in circulating the survey links to the desired participants, ensuring that the name of the IIMU faculty member(s) doesn't appear anywhere in any form of communication with the desired participants. Nonetheless, researchers who donot belong to IIMU (non-host researchers) may conduct research on IIMU students, provided they have a tie-up with one of the members of IIMU (host researchers). In such cases, all communication to IIMU students must happen via non-host researcher(s). Name(s) of the host researcher(s) must not figure in any of the communication with the IIMU students; theirname would however figure in the EC application.

In the absence a non-host researcher, when IIMU faculty members are required to collect non-survey data from IIMU students, they may use the help of their Research Assistants. In that case, the faculty member MUST use a "structured consent protocol" (as appended at theend of this document) instead of their own consent forms. Please note that the structured consent protocol must be used without changing any language, except for the subjective places indicated by alphabets XYZs.

XVIII. When do researchers start collecting data?

If the application is approved, the start date for the study shall be the date of this EC approval and the study may begin upon receipt of the letter of approval.

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THE APPLICATION

I. What is informed consent?

An informed consent is a fundamental and thoughtful process to ensure respect for human participants and to ensure that their initial and continuing participation in studies is an informedand voluntary act. No study may involve a human participant unless the participant is fully informed of the basic elements of the study and the researcher has obtained the legally effective, informed voluntary consent of the person (or the subject's legally authorized representative) PRIOR to the subject's participation.

The required elements of informed consent are:

1) A statement that the study involves research.

2) An explanation of the purpose of the research.

3) A description of the procedures to be followed.

4) The expected duration of the study.

5) A description of any foreseeable risks or discomforts.

6) A description of the benefits to the subjects or others that may result from the research.

7) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and reported.

8) An affirmation that participation in the given project is voluntary and that the subject may discontinue at anytime.

9) An explanation about what will be done with information already collected if participants decide to discontinue with participation.

10) Although discouraged, if participants are to be compensated for their time or effort, the terms of payment andconditions under which subjects will receive partial or no payment.

11) An explanation of whom to contact with questions and/or concerns about the research.

12 An explanation of whom to contact for questions about participants' rights.

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Note 1: Unless waived by the EC, appropriate documentation of theinformed consent process is required. The person who obtains consent from the participant must be the study's researcher or an individual trained and designated by the researcher to perform this function.The EC requires that the researcher submit to the EC the names of all individuals who, in addition to him/her, will be authorized to obtain informed consent from the participants in the study. All of these individuals must have adequate knowledge about the study to be able to answer questions posed by the participants.

Note 2: Informed consent must be documented, generally by use of an informed consent form. All consent forms must include a line on which the individual(s) who obtain informed consent is (are) identified by name(s), signature(s), and date(s). The informed consent document should be signed and dated by the participant (or his/her legally authorized representative) and by the person obtaining the consent. In some studies, and with some population, the identity of study subjects may need to be protected beyond normal confidentiality expectations and safeguards. In such situations, the researcher may request that the EC waive the requirement to document the consent process.

Note 3: In the case of children, the child's legal guardian must sign the consent form

Note 4: Consent forms should be written at a reading level appropriate for the population being recruited for the study and available in their native language. Should a participant be incapable of reading and understanding the consent process, the EC may approve administering the consent verbally in the subject's native language and this administering of the consent and the subsequent securing of the consent can be recorded.

II. What is a "conflict of interest?

A conflict of interest involves any situation where an EC member has significant personal or financial interest that has the potential to bias the design, conduct, reporting, or reviewing of the research.

Examples of a conflicting interest would be if the EC member is:

1) Also a researcher of the study.

2) Receiving funding from the study, as listed in the study budget.

3) In a supervisory role over the researcher of the study (such as, thesis guide)

4) A family member/relative of the researcher.

A conflict of interest is also whenever an EC member has a significant financial interest inthe research proposal. A financial interest is defined as anything of monetary value, including, but not limited to:

1) Salary or other payments for services (such as, consulting fees or honoraria)

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2) Equity interests (such as, stocks, stock options or other ownership interests, excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional control).

3) Intellectual property rights (such as, patents, copyrights and royalties from such rights).

EC members should abstain from participating in an initial or continuing EC review for a project in which the member has a conflicting interest except to provide information as requested. EC members who have conflicting interest regarding a project, which is scheduled to undergo EC review, should disclose the conflicting interest to the EC. The EC member should also remove himself or herself from the decision-making process.

III. Does the EC have a role in setting review policies?

IIMU's EC has jurisdiction over all studies conducted within the purview of the Center for Healthcare and settingreview policies.

IV. What is the EC member's role in handling alleged or reported cases of non-compliance?

Study participants, family members, research staff, colleagues, or other individuals within the community may report incidents of alleged noncompliance with EC policy and procedures may be reported to the EC Chair. Also, researchers themselves should report incidents of non-compliance to the EC as soon as they become aware of an issue.

Major violations or deviations from policy are violations that may impact subject safety, condition or status, affect the integrity of study data, pose a significant risk of harm and thereby changing the risk/benefit ratio and/or affect a subject's willingness to participate in thestudy. Examples of major violations include (but are not limited to):

1) Failure to obtain informed consent.

2) Informed consent was obtained after initiation of study procedures.

3) Informed consent was obtained by someone other than individuals authorized by the EC to obtain consent.

4) Enrollment of a participant who did not meet all inclusion/exclusion criteria.

5) A study procedure was performed without EC approval.

Additional major violations associated with biomedical research include:

1) Failure to report a serious adverse event to the EC and sponsor as soon as possible once the event has occurred.

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2) Failure to perform a required lab test.

3) Study visit conducted outside of the required timeframe.

4) Failure to follow the safety monitoring plan.

Minor violations/deviations are violations that may not impact subject safety, compromisethe integrity of study data and/or affect a subject's willingness to participate in the study. Examples of minor violations may include (but are not limited to):

1) Implementation of unapproved recruitment procedures.

2) Missing pages of executed consent form.

3) Inappropriate documentation of informed consent, including missing signatures of a participant or investigator.

4) Consent form copy not given to the person signing the form.

5) Someone other than the participant dated the consent form.

6) Use of invalid consent form, i.e., consent form without EC approval stamp, or outdated/expired consent form.

7) Failure to follow the approved study procedure that, in the opinion of the PI, does not affect participant safety or data integrity.

8) Study procedure conducted out of sequence.

Minor violations must be reported by the researcher immediately upon realization to the EC. Researchers are cautioned that the above examples listed as possibly being "minor violations/deviations" may, in some circumstances, impact on participant safety, oraffect a participant's willingness to participate in the study. If these circumstances apply, then the violations/deviations must be considered to be "major."

Major study violations must be reported by the researcher to the EC Chair person(and to the sponsor if applicable) within 10 working days of discovery with the exceptions that study violations that have resulted in the death of a participant or a life-threatening event, even if anticipated, must be reported to the EC within 24 hours of the knowledge of the event. Ifthe cause of death is not available, this should not delay the reporting of the event.

Upon receiving notification of the violations, the EC Chairperson will inform senior institutional officials (Director and/or the Dean) who will in turn conduct an investigation. The results of the inquiry should be reported to the EC who makes a final determination regarding whether noncompliance occurred and if so, what sanctions or protocol and/or informed consent

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revisions are needed.

The EC and/or IIMU's senior administration have the authority to suspend, administratively close or terminate approval of human participant research studies. Such "for cause" suspension or termination may be implemented by administrative action or action of the convened EC for reasons including:

1) The research is not being conducted in accordance with institutional policies and/or procedures for research.

2) There is serious or continuing non-compliance with EC requirements, EC determinations, sponsor or government regulations.

3) A serious incident has occurred involving injury or any other serious unanticipated problem involving risk to subjects or others.

V. What are EC members' responsibilities for maintaining confidentiality?

EC members must maintain the confidentiality of any subject data that is presented to them in the review of research protocols. In addition, EC members should maintain the confidentiality of all information collected from the researchers during the review. The EC committee also handles sensitive information regarding noncompliance issues, and members are asked not to discuss these topics in their areas, families, or any other outside settings.

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INSTRUCTION FOR PREPARING THE EC APPLICATION

I. To Facilitate Review of the Protocol.

1) Avoid the use of discipline-specific jargon. Reviewers come from a variety of academic disciplines.

2) Provide sufficient information for the reviewers to be able understand what your participants will experience from recruitment onward.

3) Use titles for the nine sections as described below.

4) Paginate the protocol and label the appendices.

II. Research description (some description prompts may not apply).

A. Research design (If applicable to your research paradigm).

1) Explain the purpose of the study, providing background information as appropriate.

2) Describe the procedures in which subjects will participate and an estimate of how longeach procedure will take.

3) Describe and attach surveys, questionnaires, and interview questions or outlines as appendices.

4) If you plan on conducting life history or other "organic" interviews, provide adescription of the type and range of questions.

5) If the study involves observation, describe the events to be observed and the setting.

6) Describe methods used to assign participants to experimental conditions, if applicable.

B. Subject selection.

1) Describe your proposed subject population(s).

2) Provide the number of participants you hope to enroll.

3) Explain how you will recruit your participants.

4) Attach copies of any recruitment materials you propose to use such as posters, flyers, electronic notices, email messages, or newspaper ads. Recruitment materials targeting IIMU members must stipulate that the participants must be eighteen years or older.

D.B.

C. Risks and benefits.

1) Describe the nature of anticipated risks, if any, to your participants. If there are risks of harmother than those that could result from an inadvertent breach of confidentiality, describe howyou will you minimize the risks. Risk associated with a breach of confidentiality should be addressed in Section 4, below.

2) Describe the benefits, if any, to participants participating in the research.

D. Confidentiality.

1) Describe identifying information you propose to collect, including data that mightindirectly identify participants.
2) Describe how you will maintain the confidentiality of your participants and of the research data.

a) Where, how, and for how long will identifying information be stored? What dataprotection strategies will be used?

b) If you will retain identifiable data, who will have access to it?

c) If audio or video recordings will be made, how long will they be kept and who will have access to them?

d) How do you plan to disseminate the results of your research?

Note: If the topic or setting of your research is such that you might become aware of possible child abuse or neglect, then you must tell your participants that you are required to report abuse or neglect and to whom you will report.

E. Compensation.

1) Describe if and how your participants will be compensated. Under what conditions will subjects receive partial or no payment?

2) Report the source of compensation (example, FDA, Seed Grant, other funds etc.).

F. Informed Consent

1) Attach an Informed Consent form of your own design for each participant, population or, if appropriate, provide a script for an oral consent process.

2) If your participants are children, there are two options:

a) In most cases, you must design a parental permission process and also describe how you will secure assent of the children.

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b) Under limited circumstances, you may be able to request a waiver of the requirement to secure parental permission and/or child assent. But for that you have to secure an alternate guardian permission.

3) If you plan to work with a vulnerable population describe how will you secure the informed consent and ensure that participants' choice to participate is voluntary?

4) If English is not the primary language of your participants, provide translations of all materials intended for the subjects. We recommend that you have the English version of the materials pre-reviewed by the EC staff before you obtain or prepare the translations.

5) If there are there cultural issues limiting free choice to participate in research describe how describe how you will address these issues.

6) If the choice of participants to become participants of a study need to be protected beyond normal and customary safeguards, request a waiver of the requirement to document the consent process.

G. Deception.

If the research involves deception, such as making false statements about the purpose ofthe research or research activities, the use of confederates, the use of priming, recording subjects' behavior without their knowledge, altering or concealing the identity of the researcher, or giving subjects false information about themselves (for example, their personality type), please provide:

1) A complete description of the deception(s), and

2) Justification for each deception. Justification should address these criteria:

a) The risk must be no more than minimal. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance ofroutine physical or psychological examinations or tests.

b) The rights and welfare of the participants will not be adversely affected. For example:

i) The study will involve subliminal priming, but the subliminal priming material will be selected from information provided by the participants.

ii) The study will involve subliminal priming, but the content of the primes would not be offensive or disturbing if known to the participants.

iii) Participants will be video recorded without their knowledge but will be given the opportunityto request that their recordings not be retained.

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iv) Participants will be reassured that the feedback they received on their performance was false.

v) The research could not practicably be carried out without the deception.

H. Debriefing.

Debriefing is required if the study involves deception, unless the debriefing process would harm the participants. The debriefing should provide a step-by-step account of the experimentalprocedure and explain how the research activities were designed to address the research hypothesis. If the study involves deception, the debriefing should acknowledge that the deceptions occurred and describe why they were necessary. Expressions of regret about the need to deceive are usually incorporated into the debriefing.

I. Appendices.

Please list the items in your appendices.

Following this project description (items A-H) provide as appendices all the materials thatyour subjects will encounter. Depending on your project, these might include recruitment texts and/or scripts, consent forms, questionnaires, standardized or adapted instruments, interview questions, debriefings, releases for the use of images, etc.

D.B.

EC MEMBER GUIDANCE FOR PROTOCOL REVIEW

This is the guide that reviewers use in conjunction with the Consent Form Checklist. Items in the checklist correspond to the criteria for protocol review outlined in the Federal Regulations for Protecting Research Subjects. It may be helpful to look over the list of items that are considered during the review of a new protocol.

A. Research design (If applicable to the research paradigm).

1) Does the investigator provide sufficient information for the reviewers to understand the theoretical bases for this study?

2) Is the study design sound?

3) Is the experience of the subjects clearly described?

4) Are all of the study materials attached, such as questionnaires and interview questions?

B. Participants selection.

1) Is the participant population described in sufficient detail?

2) Does the researcher say how many participants he/she hopes to recruit?

3) Are all recruitment materials included (such as, subject pool website posting, flyers, letters of introduction)?

4) Do the recruitment materials for adult populations state that subjects must be age 18 or older? (If research is conducted abroad the age of being an adult may be different from that in India)

5) If there are different experimental conditions, is it clear how participants will be assigned?

C. Risks & Benefits.

1) Are there any foreseeable risks to the participants?

2) Are the risks minimized?

3) Are foreseeable risks reasonable in relation to anticipated benefits?

4) If no benefits to individual participants are likely, are the benefits to society at large or to thefield of study articulated in the protocol?

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D. Confidentiality.

1) Have all direct and indirect identifiers to be collected been described?

2) If relevant, has the plan for protecting the confidentiality of the data been described, including storage (location, duration) of the data and access by others?
3) If identifiable data about illegal activities are to be collected, does the researcher intend to secure a Certificate of Confidentiality?
4) If participants are to be videotaped, photographed, or audio-taped, and the recordings will bemade publicly accessible, is a release form provided? (Does not apply in public settings.)
5) If the data are to be collected and stored via the Internet, is the confidentiality protection plan technologically sound? (This may signal the need for review by the computer security consultant).
6) Are there any limits to the confidentiality that the researcher can provide, e.g. the requirement to report suspected child abuse?

E. Compensation.

1) Is the compensation commensurate with the level of respondent effort?

2) Is the compensation offered appropriate for the study?

3) If a lottery or drawing is used as an incentive, does the protocol include the required justification?

F. Informed Consent.

Full Disclosure:

1) Are all relevant elements of consent included in the consent form or script? (Complete the consent form checklist.)

2) If any elements of consent are waived or modified, does the waiver meet all four criteria as specified in the federal regulations?

3) Is the consent process consistent with the protocol?
4) Is there sufficient information for a potential participant to make an informed decisionabout whether to participate?

5) Is the informed consent process culturally appropriate?

<u>For adequate comprehension:</u>

1) Will the participants understand the terminology used?

2) Is the reading level appropriate? If there is more than one participant population, is more thanone consent form needed?

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3) If the participants' primary language is not English, has the researcher provided the consent form in the appropriate language, in addition to the English version? Is a back translation needed?

4) If child assent is required, is it appropriate to the children's developmental stage and situation?

For voluntary participation:

1) Is the researcher in a position of authority over the research participants? If so, how can the possibility of undue influence be addressed?

2) Are there any other factors that would unduly influence the decision of participants?

3) If participants are offered the right to withdraw their data, is there a clear mechanism for doing so. What is the mechanism?

4) If the researcher's own students or employees are participants of the research, is thepotential for perceived undue influence adequately managed?

Layers:

If a layered consent form is proposed because the potential participant will be asked to make more than one decision (participate in the research and be filmed), is the purpose of the layering clear?

2) If the researcher wishes to contact the participants in the future, has it been explained how andwhy that contact will take place, and do participants have the option to decline further contact?

Questions /contacts:

1) Does the consent process allow the subjects to ask questions before making a decision to participate?

2) Is contact information provided for participants who have questions during the course of the research or after the research? Is the contact information provided in an appropriate manner,
i.e. contact information cards in the absence of written consent?
3) If the research will be conducted abroad or in a low-technology environment, would it be appropriate to identify a local contact that could answer questions about participants' rights?

Documentation of consent:

1) If the researcher has requested a waiver of documentation, can the waiver be approved in

D. B.

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accordance with the federal regulations?

2) If the participants are illiterate, and documentation of consent is required, is the procedure respectful and culturally appropriate?

3) If a third party needs to witness an oral consent process, is the witness impartial?

4) When the research takes place on-line does the protocol request a waiver of therequirement to document consent?

G. Deception.

1) If the research involves deception, is the deception justified?

2) Are the participants appropriately debriefed about the deception?

H. Debriefing.

1) If required, is the debriefing provided?

2) If the debriefing is given at a time other than immediately following participation, is this justified?

I. Concordance.

Is the protocol concordant with the funding proposal?

D.B.

Appendix

THE STRUCTURED CONSENT PROTOCOL
NAME OF THE STUDY [XYZ]

You are requested to participate in a research project conducted by Dr. XYZ of the Indian Institute of Management, Udaipur. Your participation in this study is entirely voluntary. Please read the information below before deciding whether or not to participate.

Background and purpose of the study:
XYZ

Procedures:
If you volunteer to participate in this survey, you will be asked to do the following:

1) XXXX

2) YYYY

Potential benefits:
This study will not bring you specific benefits outside of an opportunity to share your views/opinions/behaviors. Your participation, however, will be of substantive benefit for academic, research, policy, and practice purposes, for it will facilitate the understanding of XYZ.

Potential risks:
This project is not intended to provoke any physical or emotional discomfort. However, you are required to know that you will be observed by research assistants as representatives of IIMU faculty members. Thus, you may feel threatened and pressured to participate in the study.

Anonymity and confidentiality:
Any identifying information will stay with the research assistants. It will not be shared withthe faculty members. During dissemination, findings will be presented as aggregates. If individual references are made, those will be done in the form of pseudonyms or serial numbers.

Participation and withdrawal:
Participation in this study is voluntary. If you choose not to participate, that will not have any negative consequence on your academic life.

Contact information:
If you have any question or concern about this research, please contact the research assistant:

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Name of the research assistant:
Email of the research assistant:

With your participation, this could be a ground-breaking project. We thank you in advance. (optional)

Dina Banerjee.

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