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Research and Publication Ethics Committee (RPEC)-Standard Operating Procedures (SOP)

Introduction

The promotion of research culture among faculty members and students has been a significant activity undertaken by IIMBG over the past many years. IIMBG envisages a responsive role with a vision to promote intellectual contributions through academic research in all functional areas. In its endeavour to promote academic research and publication, IIMBG encourages faculty members to undertake externally funded major and minor research projects that can have an impact on society, business, and other stakeholders. IIMBG also provides seed money to the faculty members to undertake Minor/Major Research Projects (MRPs).

IIMBG is committed to perform an ethical review of research studies by protecting the rights and welfare of human subjects as well as supporting IIMBG's research mission. The institute has a comprehensive review process to ensure that all research involving human elements addresses relevant ethical considerations and is subject to appropriate review.

Hence all research having human element considerations are referred to the Research and Publication Ethics Committee (RPEC), which has been constituted by the institute. The RPEC reviews all research involving human subjects before recruitment and data collection, which is conducted by IIMBG faculty, students, and staff. **The proposals are reviewed in three cycles every year, i.e., in February, June, and October, or as and when required.** RPEC is also known as the Institutional Ethics Committee (IEC), Institutional Review Board (IRB), Ethics Review Board (ERB), and Research Ethics Board (REB) in many countries and situations.

Research and Publication Ethics Committee (RPEC)

The aim of ethical review is to review and approve ethical aspects of research involving human subjects. They are a valuable part of the research process and not merely a means of accessing data. However, the ethical review also helps to protect the researcher. By obtaining ethical approval the researcher is demonstrating he/she has adhered to the accepted ethical standards of a genuine research study which could increase recruitment potential. The committee will advise on matters of ethical research conduct, especially where the research involves human subjects and offers guidelines aimed at streamlining the research processes to ensure ethical and legal adherence.

It is generally accepted that funders, such as research councils, will not provide financial support for research that does not have ethical approval. Many publications will now no longer accept for publication results of research that was not ethically approved. As such, researchers may need to present evidence of ethical approval in order to publish their results to the wider research community.

There are a number of ethical standards that have been accepted, which all researchers and ethical committees are expected to comply with. This policy document has taken guidelines from the US Department of Health and Human Services (DHHS) (https://www.hhs.gov/) and its 45 CFR 46 (CFR - Code for Federal regulations). This has been the norm for most of the operating RPECs, even for institutions based in India. Indian Council of Medical Research (ICMR) also has some guidelines for ethics committees, which are primarily

focused on biomedical research in India, with a short section on social and behavioural sciences research for health (pp. 104-111) [https://icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf]. These guidelines have also been noted for this policy document. The DHHS has more comprehensive details to guide research across disciplines and is not just limited to biomedical or health research with humans, and therefore it has been the primary guiding force for this policy document. The main components are listed below:

- All participants must be fully informed of the study and what is being asked of them, including the potential risks/benefits and exclusion criteria, in order to make a fully informed decision about whether or not to participate in the research. This must be an active step on behalf of the participant and not due to any inducement, coercion or perceived pressure to participate. This is required of all participants in a research study,
- Research involving human participants must have a benefit to society, and the risks involved to participants must be balanced against the potential benefit to the overall community.
- All participants have the right for their participation to remain confidential in that only the researcher will be aware of who has participated.

Ethical codes and documents which have guided researchers in conducting research ethically over the years include the following:

- The Nuremberg Code (1948): https://history.nih.gov/research/downloads/nuremberg.pdf
- The Belmont Report (1974): https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
- Declaration of Helsinki (last revised in 2000): https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- 45 CFR 46 (2018): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Purpose of the RPEC

The primary purpose of the RPEC is to protect the rights and welfare of the human subjects. Investigators who are planning to do research involving human subjects may approach the RPEC to obtain review and approval before beginning their research. RPEC will also guide researchers in their research activity involving human subjects.

1. The Committee's primary responsibility will be the protection of the safety, rights and confidentiality of the research subjects.

2. The Committee will keep all information submitted to them confidential, especially proprietary information.

Types of research that require ethical approval

Precisely, all human subject research conducted by students, faculty members, and staff at IIMBG must receive approval by the RPEC at IIMBG before the commencement of research. If your research meets the definitions of both "RESEARCH" and "HUMAN SUBJECTS", you must complete the RPEC process before starting research. The following types of research are considered to involve more than minimal risk and require ethical approval:

- R**esearch involving potentially vulnerable groups**, for example, children and young people, those with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship.

- **Research involving those who lack capacity**. All research involving those who lack capacity or who, during the research project, come to lack capacity,

- R**esearch involving sensitive topics** – for example, participants' sexual behaviour, their experience of violence, their abuse or exploitation, their mental health

- R**esearch involving groups where permission of a GATEKEEPER is normally required** for initial access to members. This includes research involving GATEKEEPERS such as adult professionals (e.g. those working with children or the elderly) or research in which access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent or husband of the participant) or a community leader.

Definitions

a. Research

"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

b. Human Subjects

Human Subject means "a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information."

c. Human Subject Research

Human Subject Research is any research or investigation that involves human subjects.

d. Intervention

"It includes manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes

by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

e. Gatekeeper

A gatekeeper is defined as a person based at the case study sites who could act as an intermediary between a researcher and potential participants with the authority to deny or grant permission for access to potential research participants.

f. Institution

It is defined in 45 CFR 46.102(b) as any public or private entity or agency.
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

Types of research that do not require ethical approval

The following types of research do not require ethical approval unless an external funding body or other external body specifically requires approval. Activities that may not be considered as research include case report, program evaluation, oral history, quality assurance and public health surveillance.

The following link has a full description of the excluded categories of activities: htstps://www.ecfr.gov/cgi-bin/text-idx?SID=300df04ebff09c7b23735d902a3f645a&mc=true&tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl

If the activity does not involve "research" and "human subjects", RPEC review is not required. For guidance to determine this aspect, one can follow the decision charts in the following link.

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

Precisely, following types of research do not require RPEC approval

- Studies of public behaviour that are purely observational (non-invasive and non-interactive), unless the recorded observations identify individuals (names, photographs) which could place them at risk of harm, stigma or prosecution.
- Research involving the use of non-sensitive, completely anonymous educational tests, surveys and interview procedures when the participants are not defined as "vulnerable" and participation will not induce undue psychological stress or anxiety.
- Research involving the use of educational tests, surveys and interview procedures on human participants in the public arena (e.g. elected or appointed public officials

Functions of RPEC

The RPEC has the authority to review, approve, reject, or require changes in the research conducted with human participants. The RPEC will ensure the protection of the human subjects involved in research at IIMBG. RPEC's functions will include the following:

1. It determines what constitutes human subject research.
2. It reviews, approves, or requires modifications in the research study, or rejects the research study before the start of the research.
3. It ensures that the human subjects are provided information via the informed consent according to the appropriate laws and regulations (45 CFR 46.116) before their participation in the research. Their participation will be voluntary and free from coercion. The research study must be designed and implemented to minimize harm to the human subjects, and they should be informed of the potential risks and benefits.
4. It will notify the investigator in writing about the decision to approve or reject the proposed research activity. If it is rejected, a written notification of the decision will be provided to the investigator.
5. It can suspend the approval of research if it is not being done in accordance with the RPEC's requirements. For any suspension, the committee will provide a written statement of the reason for a suspension to the principal investigator and other concerned departments

RPEC Composition and Responsibilities

The RPEC is constituted of medical, legal and subject experts of different backgrounds. The committee will consist of members who collectively have the qualifications and experience to review the ethical aspects of a proposed research project. A list of committee members, their qualifications and their affiliations will be maintained in the committee's records.

The RPEC members should be particularly aware of special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, cognitively or mentally impaired persons, or economically or educationally disadvantaged persons.

1. Regular Members

a. The regular members of the RPEC will include individuals (within and outside the Institution) as follows:

1 A majority of members from the Social Science profession with experience and expertise in Management studies and its functional areas
2 Medical professional Regulatory background
3 Professionally Qualified management experts
4 Legal Expert

2. Chairperson

a) The Chairperson would be the Director/Dean of the institution.
b) The Chairperson will be responsible for conducting all committee meetings and will lead all discussions and deliberations pertinent to the review of the ethical aspects of the research proposals.
c) In case of anticipated absence, the Member secretary will have all the powers of the Chairperson for that meeting.

3. Member Secretary

a) The Member Secretary will be the Chairperson - Research & Publications Committee from the institution.

b) In consultation with the Chairperson, the Member Secretary will be responsible for the following functions:

1) Receiving all research proposals.

2) Forwarding all materials for review by the committee members.

3) Preparation and dissemination of agenda for all committee meetings (7 days prior to the meeting date).

4) Inviting special attendees to the scheduled meetings, if needed.

5) Preparation and circulation of minutes (within 7 days of the meeting).

6) Notification of review outcome to Principal Investigator of research proposals.

7) Retention and safekeeping of all records and documentation.

8) Performance of other duties assigned by the Chairperson.

4. Tenure of Membership

The tenure of committee members will be a continuous period of five (5) years.

The functions of the Research and Publications Ethics Committee (RPEC) include

- Identifying and weighing up the risks and potential benefits of research;
- Evaluating the process and materials (printed documents and other tools) that will be used for seeking participants' informed consent;
- Assessing the recruitment process and any incentives that will be given to participants;
- Evaluating risks to participants' confidentiality (and the related risk of discrimination) and the adequacy of confidentiality protections;
- Examining any other issues that may affect the ethical acceptability of the research.

Conflicts of Interest

The RPEC and leadership are required to disclose any conflict of interest. Conflict of Interest may include the following:

• Being a research investigator (or having an immediate family member including the spouse, and dependents)

• Having a significant financial interest (or having an immediate family member with such an interest) in the sponsorship of the research

• Having any other conflict that might be perceived to prevent a fair and unbiased review of the research

Any RPEC member with a conflict of interest will not be assigned to review the specific research study where the conflict is evident.

Meetings of the RPEC

a) The RPEC will hold meetings at least once in the three cycles – in February, June and October every year or as and when required.

b) All regular members will receive notification of meeting schedules at least one week in advance.

c) Meetings will be held as scheduled, provided there is a quorum. A quorum will be defined as one-half of the current regular members of the committee.

d) Hierarchy

1) There will be one Chairperson and one Member Secretary.

2) The Chairperson will be the head of the committee.

3) The Member Secretary will be the guardian of all documents and funds in the committee's possession.

4) All other members will be regular committee members with equal ranking.

e) Minutes

1 The proceedings of all meetings will be recorded in English and in the form of minutes.

2 The Member Secretary will be responsible for the coordination, recording and circulation of the meeting minutes.

3 If any member(s) of the committee is/are participating in the research project under discussion, they will opt out of all deliberations on the project.

4 Conflict of interest needs to be avoided or should be declared and discussed among the members of the RPEC.

f) Review Outcome:

The Committee will document its view on the following:

- Approval
- Request for modification or information
- Disapproval
- Termination/suspension of the research proposal/ongoing study

g) Notification of Review Outcome

The outcome of the Committee's review will be recorded in writing within a week of the date of the review and conveyed to the Principal Investigator (PI)

h) Review of Amendments to the Approved Research Proposal

All amendments to the approved research proposal shall be submitted to the committee immediately for its review.

Application procedure

Download the RPEC application forms from the IIMBG Website and complete the forms The application with the relevant number of copies is to be forwarded to the Member Secretary, RPEC.

a. The RPEC Committee will require the submission of one original and one soft copy of each of the documents listed below for every research proposal.

d. The documents required for submission are the following:

1) RPEC Application form
2) Research proposal
3) Cover letter (Annexure 1)
4) Resume of the Investigators (Annexure 2)
5) Undertaking by the Principal investigator to follow ethical guidelines (Annexure 3)
6) Undertaking by the Principal investigator that study hasn't started yet (Annexure 4)

7) Project risk assessment form (Annexure 5, should be submitted only if the risk involved is minimal or more than minimal)
8) Tool translation undertaking (Annexure 6, should be submitted only if the local/regional language was used to collect data and then translated to English or vice-versa)

Reports Required of Principal Investigator

The Principal Investigator/ shall submit the following reports to the RPEC:

1. Annual Progress Reports

The first report shall be submitted within thirty (30) days of completion of the year following the date of the first approval. Subsequent reports will be submitted at one-year intervals following the first report.

2. In addition, the investigator should also promptly report the following to the RPEC:

a. Deviations from, or changes of, the protocol to eliminate immediate hazards to the respondents.

b. Changes increasing the risk to subjects and/or significantly affecting the conduct of the study.

c. New information that may affect adversely the safety of the subjects or the conduct of the study.

Records Retention

The RPEC will retain the following records for a period of at least Five (5) years after the completion or termination of a study:

1) Standard operating procedures (SOPs) in effect at the time of review
2) Membership list at the time of review
3) Occupation/affiliations of the members at the time of review
4) All documents pertinent to the research proposal
5) Minutes of meetings and,
6) All correspondence with the Principal Investigator

Classroom and Research done by E-Cell, Finance Lab (related to behavioral finance), Samatvam etc which involves HUMAN subjects.

Any research conducted in the classroom on IIMBG campus across all programs as a part of the classroom activity will also need to be reviewed by the RPEC before the start of the class activity. The participation of students will not be linked to their grades in any way.

Any research carried out in the IIMBG E-Cell, Finance Lab (related to behavioral finance), Samatvam etc. will need to be reviewed by the RPEC before the commencement of the research project. Students from all programs on the IIMBG campus can be recruited for the lab-based research studies after obtaining approval from the RPEC.

Types of Review

Depending on the risk involved, there are three levels of review.

1. Exempt or excused review
2. Expedited review
3. Full committee review

If the risk is greater than minimal, the research study requires full committee review, while minimal risk studies may be eligible for expedited review or exempt certification.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45.CFR.46.102(j)) (Common Rule).

RPEC will decide if the research qualifies for exempt, expedited, or full review. The RPEC members may do the review. Sometimes, ad-hoc reviewers may also be invited.

1. Exempt review

The investigator cannot certify his/her own study as exempt. The investigator has to submit the ethics application to the RPEC, which will certify that the study qualifies for exemption. Exempt research involves minimal risk and includes one of the following categories.

Category 1 (Educational Exemptions - [45 CFR 46.104(d)(1)]): Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn the required educational content and does not adversely impact the assessment of educators who provide instruction.

Category 2 (Surveys, Interviews, Educational Tests, And Observation of Public Behavior [45 CFR 46.104(d)(2)]) Research that only includes: interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

Category 3 (Benign Behavioural Intervention [45 CFR 46.104(d)(3)(i)]): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and collection of the information.

Category 4 (Secondary Research With Identifiable Private Information/Biospecimens [45 CFR 46.104(d)(4)]). Secondary research for which consent is not required. Secondary research uses of identifiable private, if at least one of the following criteria is met:

(i) Identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

This new exemption permits data collection via an interaction (e.g., survey, interview, audio/visual recording) from **adult subjects with the prospective agreement**. The following cannot be exempt:

• Research with children

• Deception, unless prior agreement is obtained

• Physiological data collection methods (e.g., EEG; wearable devices; blood pressure monitors)

• Linking to additional personally identifiable information (PII)

2. Expedited Review

Expedited review studies typically are reviewed by a small number of RPEC reviewers. Expedited review is appropriate for studies that according to 45 CFR 46.110 and 21 CFR 56.110:

• Involve no greater than minimal risk AND

• Fit into one (or more) of the following nine specific expedited review categories (the categories in bold may be more relevant for IIMB-related research).

Category 1: Approved drug or device being used for its approved indication

Category 2: Blood sampling (limited amounts) from a finger stick, heel stick, ear stick, or venipuncture

Category 3: Noninvasive specimen collection for research

Category 4: Noninvasive, routine clinical procedures, such as MRI or EKG (no sedation, general anesthesia, x-rays or microwaves)

Category 5: Use of data or specimens collected for non-research (medical treatment, diagnosis) or research purposes (e.g., data, records, specimens)

Category 6: Collection of data from voice, video, digital, or image recordings

Category 7: Low-risk behavioral research including, but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, focus group, or human factors evaluation.

Category 8: Continuing review of inactive research or studies that were approved earlier and are essentially complete

Category 9: Continuing review of other minimal-risk research studies

Source: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

3. Full Committee Review

These studies are reviewed by the RPEC committee at a convened meeting. It must be used for the initial review of all studies that are not eligible for expedited review or exemption, and research involving vulnerable populations, including prisoners, cognitively impaired, elderly, pregnant women and neonates.

Full committee review is required for:

• Greater than minimal risk studies OR

• Studies that are minimal risk, but do not fit in an expedited review category.

• Examples of studies requiring full committee review: Intentional deception, sensitive/vulnerable population (children and minors), procedures that are likely to be personally intrusive, stressful, or traumatic (stress can be physical, psychological, social, financial, or legal).

Few other points

- If one of your collaborators has an RPEC/ IEC, IRB, ERB/ REB/similar institutional body approval, you may not apply for RPEC approval again.
- Collaborators and co-authors who are not affiliated with IIMBG, as well as the faculty advisors of graduate student researchers, are not required to complete or submit proof of ethics training. However, the RPEC recommends that all researchers involved in human subjects' research complete ethics training.
- Case studies may not require RPEC approval.
- Avoid or minimize anything that will cause physical or emotional harm to participants. Make participants aware of any potential harm prior to their participation. Try to remain neutral and unbiased. Don't let your personal preconceptions or opinions interfere with the data collection process.
- Term paper/ summer projects or any other study conducted by the students as a part of their course or to fulfil the course requirement shall be exempted from taking RPEC clearance. If students are collecting data for their research work which will be submitted to any journal or any agency or publisher to publish their research outcomes

under the supervision of faculty members where faculty members may or may not be an author are supposed to take RPEC clearance.

Other Matters related to RPEC

- All published/submitted research articles should maintain around 18% of the overall similarity index. From a single source, the similarity should not be more than 2% (150 words), which is presently accepted standard by most of the journals indexed in ABDC and ABS. This limit can be modified from time to time, and it can be a bit relaxed for review-based or theoretical studies.
- Any conflict/ unethical practice or such cases can be brought to the notice of the RPEC, and the Director of the IIMBG will take an appropriate decision based on the severity of the unethical issue in consultation with the RPEC.

RPEC Process

The RPEC process includes the following steps:

1. The investigator (researcher) should contact the RPEC at rpec@iimbg.ac.in if he/she is not sure if their research needs RPEC review. If the RPEC confirms the need for RPEC review, the investigator can proceed with the following steps.
2. The investigator must fill out the ethics application (downloadable from IIMBG Website) and provide all the required information in the application, along with the consent form, recruitment documents (emails, snowballing letter, information letter) and research study stimuli and submit it to rpec@iimbg.ac.in. The guidelines for filling out the forms are also available on IIMBG Website.
3. The investigator will receive an email of acknowledgement from the RPEC.
4. The ethics application and related documents will be screened initially by an RPEC member within one week of submission. If any information is missing or inaccurately stated according to the guidelines of the ethics application, the investigator will be sent an email to modify their ethics application and resubmit it.
5. After the initial screening has been approved by the RPEC member and an acknowledgement email sent to the investigator, it will be forwarded to the RPEC Member Secretary.

6. The RPEC Member Secretary will send the application to RPECs to review it.
7. Overall, it may take 2 to 5 weeks for the first review of the ethics application from its date of submission, depending on the level of review (exempt, expedited or full). Exempt reviews will take less time compared to expedited and full reviews.
8. In case of conflict or mixed opinions/ recommendations from the RPEC members about any RPEC application, the Decision of the Chairperson REPC would be final.
9. The investigator cannot start their research study until he/she has been informed of the approval of their application in writing.
10. If there is any change proposed in the research study (including the change in investigators, study design, participation criteria, funding, and questionnaires), the investigator must submit the amendment form (downloadable from IIMBG Website) to the RPEC at rpec@iimbg.ac.in before the change is put into practice.
11. Each ethics application will be approved for a specific time of period. Exempt reviews do not need to provide a follow-up but other levels (expedited and full review) should submit a research status form (downloadable from IIMBG Website) at the end of the period allotted by the RPEC for their data collection.
12. Continuing Review is a periodic review of research activities necessary to evaluate the progress of the study and to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to participants or others, and whether any new information regarding the risks and benefits should be disclosed to participants. The RPEC conducts the continuing review at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46.109(e) and 21 CFR 56.109(f)). Although the RPEC usually adheres to the scheduled date for a protocol's continuing review, depending upon the risk, the RPEC can determine that a protocol must have a continuing review at any time. Continuing review guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html#section-a
13. The research policy is subject to review after every five years or as and when required.

RPEC Review Process

Initial Contact & Submission

•The investigator should contact the RPEC at rpec@iimbg.ac.in if he/she is not sure if their research needs RPEC approval. If the RPEC confirms the need for RPEC approval, the investigator can proceed with the following steps.

•The investigator must fill out the ethics application with the consent form selecting one of the levels of review (exempt/expedited/full) and submit it to rpec@iimbg.ac.in with the related documents.

•The investigator will receive an email of acknowledgement from the RPEC.

Screening

•The ethics application will be screened initially by a Research and Publication Committee member within three days of submission. If any information is missing or inaccurately stated, the investigator will be sent an email to modify their RPEC application and resubmit it.

•After the initial screening has been approved by the Research and Publication Committee member and acknowledgment email sent to the investigator, it will be forwarded to the RPEC.

Review

•The ethics application will be reviewed by the RPEC.

•Overall, it may take 1 to 5 weeks for the first review of the ethics application from its date of submission, depending on the level of review (exempt, expedited or full). Exempt reviews will take less time compared to expedited and full reviews.

Investigator 's Responsibilities

•The investigator cannot start their research study until he/she has been informed of the approval of their application in writing by the RPEC.

•If there is any change proposed in the research study, the investigator must submit the amendment form to the RPEC at rpec@iimbg.ac.in BEFORE the change is put into practice.

Approval & Follow-Up

•Each ethics application will be approved for a specific time of period. Exempt reviews do not need to provide a follow-up, but other levels (expedited and full review) should submit a research status form at the end of the period allotted by the RPEC for their data collection.

•Continuing Review is a periodic review of research activities necessary to evaluate the progress of the study and to determine whether the risk-benefit ratio has changed.

•The RPEC may conduct the continuing review at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46.109(e) and 21 CFR 56.109(f)). The RPEC can determine whether a protocol must have a continuing review at any time.