East-West University
Institutional Research Board (IRB) Handbook

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Why Institutional Review Boards are Necessary

An Institutional Review Board (IRB) is a type of committee that reviews the methods proposed for research to ensure that they are ethical. The purpose of an IRB is to safeguard ethical conduct of research concerning both national and international norms, regulations or codes. It must be empowered to assure appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. The IRB should formally approve, monitor, and review biomedical and behavioral research involving humans. The IRB may often conduct some risk-benefit analysis to determine if research should be completed.

An effective IRB protects human subjects from physical or psychological harm by reviewing research protocols and related materials. The protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices (or, if that is not possible, informed permission given by a suitable proxy), and seeks to maximize the safety of subjects.

IRBs are most commonly used for studies in the fields of health and the social sciences, including anthropology, sociology, and psychology. Such studies may be clinical trials of new drugs or devices, studies of personal or social behavior, opinions or attitudes, or studies of how health care is delivered and might be improved.

A Little History

"Ethical Principles and Guidelines for the Protection of Human Subjects of Research," better known as **The Belmont Report**, was created by the former United States Department of Health, Education, and Welfare—now known as Health and Human Services (HHS)—and is an important historical document in the field of medical

ethics. The report was created on April 18, 1979 and gets its name from the Belmont Conference Center, formerly a part of the Smithsonian Institution and located in Elkridge, Maryland, where the document was drafted.

The Belmont Report explains the unifying ethical principles that form the basis for the National Commission's topic-specific reports and the regulations that incorporate its recommendations. The three fundamental ethical principles for all human subject are

1. **respect for persons:** protecting the autonomy of all people and treating them with courtesy and respect;
2. **beneficence:** maximizing good outcomes for humanity and research subject, while minimizing or avoiding risks or harm; and
3. **justice:** ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly.

Federal IRB Requirements

IRBs are responsible for critical oversight functions for research conducted on human subjects that are "scientific", "ethical", and "regulatory". The National Research Act of 1974 and the Belmont Report identified outlined the primary ethical principles in human subjects review to include "respect for persons", "beneficence", and "justice" (see https://www.hhs.gov/ohrp/ for more info). This led to the "Common Rule" on IRBs, outlined in 45 CFR 46, defining the rules and responsibilities for institutional review of all research that receives support, directly or indirectly, from HHS. Over time, most agencies have signed on to the Common Rule:

- Agency for International Development (22 CFR part 225)
- Consumer Product Safety Commission (16 CFR part 1028)
- Department of Agriculture (7 CFR part 1c)
- Department of Commerce (15 CFR part 27)
- Department of Defense (32 CFR part 219)
- Department of Education (34 CFR part 97 subpart A)
- Department of Energy (10 CFR part 745)
- Department of Health and Human Services (45 CFR part 46 subpart A)
- Department of Housing and Urban Development (24 CFR part 60)
- Department of Justice (28 CFR part 46)
- Department of Veterans Affairs (38 CFR part 16)
- Department of Transportation (49 CFR part 11)
- Environmental Protection Agency (40 CFR part 26)
- National Aeronautics and Space Administration (14 CFR part 1230)
- National Science Foundation (45 CFR part 690)
- In addition, the Central Intelligence Agency must comply with all subparts of 45 CFR part 46 under Executive Order 12333.

Essentially, to ever be eligible for any type of government research grant, educational institutions need to comply with the regulations, and register their compliance with HHS' Office for Human Research Protections. Specific legal review of additional agency-specific regulations (as cited above) may be necessary for any particular grant. Additional requirements apply to IRBs that oversee clinical trials of drugs involved in new drug applications, or to studies that are supported by the United States Department of Defense. The IRB is subject to the FDA's IRB regulations when studies of FDA-regulated products are reviewed and approved. However, compliance with the main part of 45 CFR 46 is a prerequisite to all.

An IRB may only approve research for which the risks to subjects are balanced by potential benefits to society, and for which the selection of subjects presents a fair or just distribution of risks and benefits to eligible participants. A bona fide process for obtaining informed consent from participants is also generally needed. However, this requirement may be waived in certain circumstances – for example, when the risk of harm to participants is clearly minimal.

In addition to registering its IRB with the OHRP, an institution is also required to obtain and maintain a Federal-wide Assurance or FWA, before undertaking federally funded human research. This is an agreement in which the institution commits to abiding by the regulations governing human research. A secondary supplement to the FWA is required when institutions are undertaking research supported by the U.S. Department of Defense. This DoD

Addendum includes further compliance requirements for studies using military personnel, or when the human research involves populations in conflict zones, foreign prisoners, etc.

Naming and Composition

Although "IRB" is a generic term used in the United States by the FDA and HHS, each institution that establishes such a board may use whatever name it chooses. Many simply capitalize the term "Institutional Review Board."

The regulations set out the board's membership and composition requirements, with provisions for diversity in experience, expertise, and institutional affiliation. For example, the minimum number of members is five, at least one scientist, and at least one non-scientist. The guidance strongly suggests that the IRB contain both men and women, but there is no regulatory requirement for gender balance in the IRB's membership. The full requirements are set out in 21 CFR 56.107.

Originally, IRBs were simply committees at academic institutions and medical facilities to monitor research studies involving human participants, primarily to minimize or avoid ethical problems. Today, some of these reviews are conducted by for-profit organizations known as 'independent' or 'commercial' IRBs. The responsibilities of these IRBs are identical to those based at academic or medical institutions, and they are governed by the same U.S. federal regulations.

Convened and Expedited Reviews

Unless a research proposal is determined to be exempt, the IRB undertakes its work either in a convened meeting (a "full" review) or by using an expedited review procedure. When a full review is required, a majority of the IRB members must be present at the meeting, at least one of whom has primary concern for the nonscientific aspects of the research. The research can be approved if a majority of those present are in favor.

An expedited review may be carried out if the research involves no more than minimal risk to subjects, or where minor changes are being made to previously approved research. The regulations provide a list of research categories that may be reviewed in this manner. An expedited review is carried out by the IRB chair, or by their designee(s) from the board membership. Research activity cannot be disapproved by expedited review.

When You must apply for IRB Review

All research connected with members of the East-West University community must be reviewed and approved by the East-West University Institutional Review Board (IRB}. The East-West University IRB defines "research" as a systematic investigation—including research development, testing and evaluation—involving a living individual about whom you obtain:

1. data through intervention or interaction, INCLUDING surveys and interviews, and/or
2. identifiable private information in a form associable with that individual.

If you are a member of the East-West University community and intend to conduct research that involves human participants, either on campus or elsewhere, you must have your research plans reviewed and approved by the IRB prior to the initiation of your project. Researchers who are not affiliated with Smith who intend to conduct research involving members of the East-West University as participants are also required to secure East-West University IRB approval prior to beginning their research.

If you wish to conduct a **research study at** East-West University **that has been approved by another institution (primary IRB)**, you must also receive approval from the East-West University IRB. The review performed by the primary IRB must meet the human subject protection requirements of the East-West University IRB. Approval by the primary IRB does not guarantee approval by the East-West University IRB.

All student research, including research conducted in connection with coursework (if not exempt under new Classroom Research Policy), requires the supervision and signature of a Faculty Adviser prior to submission. The Faculty Adviser's signature on the Research Proposal confirms that they have supervised the composition of the proposal and they approve of the research proposal as submitted. With their signature, faculty acknowledge that they are supervising the project and are responsible for its overall conduct as represented in the proposal to the IRB.

When you can avoid IRB Review

East-West University policy does **not** require you to submit an application to the IRB if your research activities fall into categories (1) or (2) below. This means that examinations you give students in courses you teach, assessments of what students are learning in your classes, and similar activities do not have to be submitted to or approved by the IRB. However, you should keep copies of instruments you use for such purposes (e.g., copies of the tests you give your students) as part of your course records, and in case any questions arise about why you judged them exempt from IRB review.

The IRB law (45 CFR 46) describes these "Statutory Exemptions" from review as follows:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

> (i) research on regular and special education instructional strategies, or
>
> (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

> (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
>
> (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Which IRB Review Application box should you choose

You must check one of the following boxes when you complete an application for IRB review:

☐ **EXEMPT f**rom Review	☐ **EXPEDITED** Review	☐ **FULL** Review	☐ **UNSURE**

Here is what each means.

Exempt from Review.

If it meets the conditions below, you can propose that your project be judged "Exempt from Review" (by checking that box on the application form). However, the IRB must approve the exemption before you can conduct the research. Typically, projects determined to be exempt are examined quickly, and you should hear back from the IRB in a few days at most.

Note that East-West University policy does **not** require you to submit an application to the IRB if your research falls into categories (1) or (2). However, you should keep copies of instruments you use for such research (e.g., copies of the tests, quizzes, or surveys you give your students) as part of your course records: See "When You can skip IRB Review" above.

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy (i.e., Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects).

> (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
>
> > (i) research on regular and special education instructional strategies, or
> >
> > (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
>
> (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
>
> > (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under section (2), above, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Federal regulations limit the categories of research that qualify for exemption. "Data obtained in person, or that are coded and linked to name, record number, social security number or other identifiers do not qualify for exempt review status."

Expedited Review

Expedited Review may be appropriate when research activities present no more than minimal risk to human subjects. **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. Expedited Review:

- **may not be used** where identification of the subjects and / or their responses would place them at risk of criminal, or civil liability or be damaging to subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- **may not be used** for classified research involving humans
- **must** use an informed consent

If your research meets the definition of minimal risk and involves only procedures listed in one or more of the categories below, it may be reviewed by expedited procedures.

1. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as for medical treatment or diagnosis).

2. Collection of data from voice, video, digital, or image recording made for research

3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

4. Continuing review of research previously approved by the convened IRB as follows:

- Where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects; **or**
- Where no subjects have been enrolled and no additional risks have been identified; **or**
- Where the remaining research activities are limited to data analysis

5. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the IRB has determined and documented at a convened meeting that the research involves greater than minimal risk and no additional risks have been identified.

6. Clinical studies of drugs and medical devices that do not require investigational new drug or investigational exemption application

7. Collection of blood samples by finger stick, heel stick, or venipuncture

8. Collection of biological specimens for research purposes by noninvasive means (e.g. hair and nail clippings, etc. to name a few)

9. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves (e.g., body weight, electrocardiograph, ultrasound, moderate exercise when appropriate).

Full Review

If your project cannot meet the requirements for an expedited or exempt review then you must complete the standard, full IRB documentation.

What the IRB may decide

When East-West University's Institutional Review Board receives an application, the review process will continue dependent on the type of review that is necessary. The Review Board will meet each month as needed. At those meetings, the reviewers will discuss the applications and take one of the following actions:

A. Approve without Revisions: The IRB may approve the project as submitted without any changes noted for a maximum period of 12 months.

B. Approve with Revisions: The IRB may approve a project contingent upon modifications to be completed by the principal investigator. When the IRB Chair receives the changes, he/she will compare the modifications received with the actions requested. If the modifications comply, the Chair will approve the project for a maximum period of 12 months.

C. Disapprove Pending Resubmission: If the IRB deems that the proposal and/or informed consent as submitted require major revisions, the IRB will require the Researcher to resubmit the application and attachments with all the changes required.

D. Disapprove: The IRB may disapprove a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. The IRB will notify the principal investigator and the faculty supervisor (if the Principal Investigator is a student). Notification will include all the reasons and rationale behind the disapproval. Upon disapproval, the principal investigator has the option of: revising and resubmitting the project, reducing the risks to the subjects.

East-West University's current IRB Application form

Here is a copy of the IRB Application used at East-West University. You can download MSWord version (in .docx format) from the East-West University website IRB page (http://www.eastwest.edu/IRB/).

East West University

IRB Application for Review of Research Involving Human Subjects

Application #

Leave this box blank; the IRB will assign a number to your application.

Be sure to attach any questionnaires and consent forms and other supplemental information to ensure your application gets processed in a timely manner.

This application is for (check one):

Project Title: _____

Project Start Date: _____ End Date (application is good for one year): _____

Principal investigator (student's name if this is student-led research):

Name: _____ Program: _____

Mailing Address: _____

_____

Telephone: _____ Email address: _____

This project is being sponsored and funded by (if applicable): _____

If student research, faculty member supervising the research: _____

Type of Review Requested:

☐ **EXEMPT f**rom Review	☐ **EXPEDITED** Review	☐ **FULL** Review	☐ **UNSURE**

If you checked **EXEMPT**, do not begin the project until the IRB confirms your requested status. If you checked **EXPEDITED**, **FULL**, or **UNSURE**, do not begin the project until you get written IRB approval.

DIRECTIONS

In considering applications, the IRB committee will want to see the following issues addressed in brief (e.g., 1-2 page) statements included in or attached to this Application. The Committee's general concern is the safety and well-being (both physical and psychological) of human subjects in research. Failure to answer all questions can result in the proposal being returned to you for further information. Please allow at least two weeks for review. A member of the Review Committee will contact you with a decision in writing. **Do not collect data prior to this time.** The application number you will be given must appear on all documents such as survey forms, reports, and summaries related to this research project. Please type/computer print your responses; the boxes will expand to fit your responses.

1. What is the purpose of the study? Please provide a brief description of the hypothesis and issues under consideration?

2. What pool of subjects or subject group(s) will you work with, and how will you recruit them?

3. If the study will take place at a site other than East-West University, how will you obtain permission from the site? (Attach copy of written permission from the site where the research is to be conducted, if applicable.)

4. What information will you offer subjects about your study before they participate? (E.g., how will you describe the study to subjects? what incentives will you offer them?) Except in special circumstances (which you must describe and justify), potential subjects should be given enough information about the project to make an informed decision about whether to participate. Subjects should not be coerced or pressured, and should be told that they are free to withdraw from participation at any time.

5. Does the study involve children, minors, or members of a population classified as vulnerable (prisoners, mentally disabled individuals, etc.) for whom parental/guardian consent is required as well as assent of the subject? (Note: Research involving children normally requires written permission from parents or guardians, in addition to written permission from a school principal or other institutional director, if applicable.) Describe how you will seek this permission, attaching copies of your written Informed Consent forms to this application.

6. How will you plan to protect the privacy and/or anonymity of your subjects, and the anonymity of the data after the study? Please specify how you will destroy the data. If you do not intend to destroy the data, how will it be stored and protected?

7. Does the study involve deception? If so, explain why deception is necessary and how you will address any potentially harmful consequences.

8. What are your experimental procedures? Are there any potentially harmful effects that might occur in your study? If so, what are they, and how will you guard against them or seek to minimize them?

9. If appropriate, how will you debrief your subjects after their work is completed?

10. List here any attached copies of any survey, questionnaire and/or consent form(s) you plan to use. (NOTE: If the data-gathering instrument is changed, a revised version must be submitted to the IRB.)

Send the completed application, together with any attachments (e.g., survey forms, Informed Consent forms) as enclosures with an email to Dr. Karishma Mukherji (karishma@eastwest.edu0, the Chair of East-West University's Institutional Research Board (IRB).

Obtaining Informed Consent from your project's participants

Many research projects involving human subjects require the researcher to obtain written informed consent from the participants, and to preserve the evidence that such consent was obtained by the principal investigator. You can download a template useful for creating an Informed Consent agreement {in an MSWord version.docx file) from the East-West University website IRB page (http://www.eastwest.edu/IRB/).

Investigators should seek consent under circumstances that provide the prospective participants sufficient opportunity to consider whether to participate, and that minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is understandable and clear to potential participants. The consent process may not include exculpatory statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence (in compliance with Protection of Human Subjects Federal Regulations 45 CFR 46, 2009).

Basic Elements of Informed Consent

As you develop your consent form or procedure, please include the following information.

- State that the study involves research.
- Explain the purposes of the research and the expected duration of the participants' participation.
- Describe the procedures that directly involve human participants, and identify any procedures that are experimental.
- Describe any foreseeable risks or discomforts to participants.
- Describe any benefits to participants or to others that may reasonably be expected from the research.
- Disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.
- Describe the extent to which confidentiality of records identifying participants will be maintained, where the records will be stored, how long they will be stored, and who will have access to the records.
- For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs. If compensation or treatments are available, they should be described. The procedures for obtaining additional compensation/treatment information should be stated.
- Identify who participants can contact for answers to pertinent questions about the research, and participants' rights including the faculty supervisor (for student=led research), the IRB chair, and a resource in case of discomfort (e.g., SGA).
- State that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.
- If you intend to audio- or videotape an interview, include a separate signature lines for consent to the audiotaping or videotaping in addition to the signature line for general consent to participating in the project.