TABLE OF CONTENTS

Acknowledgements

01  I.  Introduction
02  II.  What is an IRB?
02  III.  Why do IRBs exist?
04  IV.  What does an IRB do?
04  V.  What value does IRB review add to the research process?
05  VI.  Why is it important to have an IRB dedicated to gender-sensitive research?
05  VII.  Who composes an IRB committee?
06  VIII.  How does an IRB work?
06  IX.  What authority does an IRB have?
06  X.  How does an IRB evaluate risk?
07  XI.  What is informed consent?
08  XII.  IRB review timeline
10  XIII.  IRB step-by-step process
15  XIV.  Common IRB terminology
16  XV.  IRB standard operating procedures (SOPs) and forms
17  XVI.  Reference material
Acknowledgements

IREX and the USAID Takamol Project are grateful to the International Center for Research on Women (ICRW) for the information provided in this document. Originally part of a series of trainings1 led by ICRW staff for researchers from Jordanian universities in 2016, these materials helped launch the first non-medical institutional review board (IRB) in Jordan. With support from the USAID Takamol Project, an IRB for gender-sensitive social behavioral research was launched at the Princess Sumaya University for Technology in Amman, Jordan in 2019.

The USAID Takamol Project particularly thanks Kathryn Reitz, Program Director of the Human Research Protection Program at ICRW, for her contributions to strengthening institutional capacity for gender-sensitive research in Jordan. We would also like to thank Dr. Nadia Sweis of the Faculty of King Talal School of Business Technology at Princess Sumaya University for Technology for her tireless efforts towards the establishment of the gender-sensitive IRB.

For additional information, please contact: communications@irex.org.

1 Training provided was in compliance with the Pre-2018 Common Rule (US Federal Regulation for the Protection of Human Subject in Research). All reference to US Federal regulation and requirements for IRB review/policy/procedures are based on the Pre-2018 Common Rule.
Since the mid-20th century, over 130 countries and international institutions have created authoritative bodies capable of approving or denying any research involving human subjects.2 Variously known as Institutional Review Boards (IRB), Independent Ethics Committees (IEC), Ethical Review Boards (ERB), or Research Ethics Boards (REB), these entities are charged with protecting the rights, safety, and welfare of human subjects, especially society’s most vulnerable populations, participating in research studies that are under their purview. Given the centuries of terrible abuses of human subjects under the guise of research, IRBs have an important role not just in academia but in the greater society as well. Grounded in principles of the Belmont Report,3 respect for persons, beneficence, and justice, IRBs add instrumental value to the research process as well as protections for the public.

While it is more common to find IRBs focused on medical research, it is widely understood that social behavioral research IRBs, including those for gender-sensitive research, are quite important for the research process. Since women constitute a significant vulnerable population in many countries and pregnant women are specifically identified as a vulnerable population in the US Federal Regulation4 (45 CFR 46 Subpart B5), any human subjects research involving women as participants should undergo ethical review and/or require IRB approval. In addition, research with all genders that explores power relations and inequities may involve psychosocial risks to research subjects that necessitate ethical review and IRB approval. The advantages of an IRB for gender issues include an increase in the quality, efficiency, and effectiveness of review and an accurate assessment of the research ethics and risks.

This document provides an overview covering the most basic information about social behavioral research IRBs and their role in the research process.6 It gives insight into how social scientists undertaking human subjects research, particularly gender-sensitive research, should pursue their endeavors. It concludes with a step-by-step process on what researchers should expect in the IRB review process and useful forms and resources for undertaking human subjects research.

---

3 The Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission, created as a result of the National Research Act of 1974, was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with those principles.
4 US Department of Health and Human Services (HHS) Policy for Protection of Human Research Subjects
5 US HHS Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
6 In accordance with the Pre-2018 US Common Rule (45 CFR 46)
II. What is an IRB?

An IRB is an administrative body whose primary responsibility is to protect the rights, safety, and welfare of human research subjects. Also known as an Independent Ethics Committee (IEC), an Ethical Review Board (ERB), or a Research Ethics Board (REB), the body ensures that human subjects research adheres to ethical standards, such as respect for persons, beneficence, and justice. In practical application, an IRB is designed to review, approve, and monitor research involving human subjects.

An institution or organization establishes an IRB committee in accordance with international guidelines and local law. For example, in the U.S. the Office for Human Research Protections of the Department of Health and Human Services governs IRBs and includes regulations that mandate additional protections for vulnerable populations.

An IRB is NOT: a scientific review committee (unless designated); a peer review committee; a committee responsible for employee/medical records; a legal counsel; a privacy board (unless designated); a risk-management or safety board; a data-safety monitoring board (unless designated); a research-funding office; or an editorial service.

III. Why do IRBs exist?

IRBs began to form following discoveries of crimes against humanity committed with the justification that they were necessary for the advancement of science and research. During World War II, Nazi doctors and scientists conducted experiments on prisoners without consent. After they were put on trial for these war crimes in 1946, ethical rules for the conduct of human experimentation, known as the Nuremberg Code, were developed. The Nuremberg Code outlines ten research ethics principles for conducting research with human subjects. The code states:

• The voluntary consent of the human subject is absolutely essential.
• The experiment should be such as to yield fruitful results.
• Anticipated results justify the performance of the experiment.
• The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
• No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur.
• The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
• Proper preparations should be made and adequate facilities provided to protect the experimental subject.
• The experiment should be conducted only by scientifically qualified persons.
• During the course of the experiment, the human subject should be at liberty to bring the experiment to an end.
• During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage.
Later, in 1964, the World Medical Association established the Declaration of Helsinki. This declaration provides a set of ethical principles for medical research involving human subjects. It confirms the idea that the well-being of the human subject should take precedence over the interests of science and society.

In the U.S., another impetus for IRBs came after revelations about a U.S. Public Health Service study titled “The Tuskegee Study” (1932-1972), which showed that researchers withheld treatment from subjects who suffered from syphilis, even though penicillin was an accepted treatment in 1943 and available for syphilis treatment in 1952, in order to track the disease’s full progression. Thus, in 1974, the National Research Act established regulatory protections for human subjects. The National Research Act also founded the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which, in 1979, wrote the Belmont Report, the cornerstone statement of ethical principles for the treatment of research subjects in the U.S.

The Belmont Report summarizes three basic ethical principles and guidelines for resolving ethical problems that surround the conduct of research with human subjects. It distinguishes medical practice (treatment) from research. While practice solely enhances the well-being of an individual patient or client, research tests a hypothesis, permits conclusions to be drawn, and develops and contributes to generalizable knowledge.7

The Belmont Report establishes three important ethical principles:8

1. Respect for persons
   - Individuals must be treated as autonomous agents.
   - Individuals with diminished autonomy are entitled to protection.
   - This requirement demands, in most cases, that:
     - Research participants be provided with adequate information about the study through the process of informed consent; and
     - Participants enter into research voluntarily.

2. Beneficence
   - Individuals must be treated in an ethical manner by:
     - Respecting their decisions;
     - Protecting them from harm; and
     - Making efforts to secure their well-being.
   - This commitment is an obligation to protect persons from harm by:
     - Maximizing anticipated benefits; and
     - Minimizing possible harms.

3. Justice
   - The benefits and burdens of research must be distributed fairly.
   - The participation of individuals must be the outcome of a fair selection process.
   - Those who bear the burden of the research must, or must be provided the opportunity to, benefit from the research.
   - This commitment mandates that an assessment of the risks and benefits of the research to the subjects and society be conducted.

The Belmont Report informed the US Federal Regulation for the Protection of Human Research Subjects, which established the responsibility of US investigators, and others receiving US Federal funding for human subjects research, to submit research activities for IRB review. If any part of an activity includes research and involves human subjects, the activity must be reviewed to ensure the protection of human subjects.

---

8 Ibid., Part B.
IV. What does an IRB do?

An IRB reviews proposed research to determine if participants in the study will be placed at physical, psychological, social, or other risks. If so, they certify that the following conditions have been met (criteria for approval of research):

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
- Selection of subjects is equitable.
- Informed consent will be sought.
- Informed consent will be documented when appropriate.
- Provisions for monitoring the data collected to ensure the safety of subjects are in place.
- Adequate provisions are in place to:
  - Protect the privacy of subjects.
  - Maintain data confidentiality.
- Additional safeguards are in place when some or all of the subjects are vulnerable to coercion or undue influence (due to gender, age, disability, class, caste, immigration status, etc.).

The IRB also ensures that participants (and their guardians) are fully aware of:

- The purpose of the research and what they will be asked to do.
- Risks related to participation and protections in place to minimize risks.
- Benefits to participants or others and benefits to society.
- Any compensation they will receive for participation.
- The voluntary nature of their participation.
- Their ability to withdraw from the study at any time without any form of penalty.

The IRB reviews approved research at intervals the Board feels are appropriate to the degree of risk involved (e.g., 3 months, or after 20 participants are enrolled) but no less frequently than annually.

Lastly, it reviews any modifications to the research plan and approved study documents prior to implementation (unless the modification is required to eliminate an immediate hazard to participants – in which case the IRB may review after the change has been implemented), such as data collection tools, consent forms, or recruitment material.

V. What value does IRB review add to the research process?

The IRB provides an independent, non-biased review of research. It ensures ethical conduct and compliance with applicable laws, regulations, policies, and best practice. It protects against placing individuals at risk of harm unnecessarily, without their consent, and without protections in place to minimize risks.

Many countries, government agencies (such as the U.S. Agency for International Development), international institutions, and private donors (such as the Bill and Melinda Gates Foundation) require IRB review for research involving human subjects which they fund. IRB review may also be required in order to publish the results of research.

In addition, when research is conducted in a foreign country, researchers must adhere to the requirements of the host country. IRB review may be required in order to obtain permission (e.g. a government-issued research permit) and/or a local ethical review from the host country (e.g. in-country IRB review, Ministry of Health review) may be required.

---

9 Criteria are in compliance with the Pre-2018 Common Rule
VI. Why is it important to have an IRB dedicated to gender-sensitive research?

Many laws, regulations, policies, and procedures were developed for clinical trials or medical research, and as a result, they do not apply, or are difficult to apply, to social behavioral research. For example, physical risks resulting from experimental procedures or routine medical tests performed specifically for the research activity, are not necessarily relevant in social science research. Risks to social behavioral research are generally psychological and related to social harms, privacy, and confidentiality.

Furthermore, for social behavioral research on gender-sensitive issues, there is a need to have an IRB comprised of those with expertise and experience specific to gender research and social science. Specifically, IRB members with knowledge of gender-related vulnerabilities are needed for the review process. Such specialization on an IRB for gender issues will increase the quality, efficiency, and effectiveness of the review because membership will be composed of individuals intimately familiar with the techniques, theories, and standards of social science, and common risks and/or cultural considerations associated with gender research.

In addition, specialized gender IRB members may be part of the professional community conducting similar research on gender issues and are thus aware of the best practices and are able to understand the ethical considerations in a given study design. A specialized gender IRB can assess not only the ethics of such research but also can determine if revisions of the research plan are required in order to adequately protect subjects and meet the IRB approval criteria. Because of their experience and expertise, they will be able to suggest changes that address the ethical concerns and maintain the scientific integrity or merit of the proposed project.

VII. Who composes an IRB committee?

Per the US regulation, an IRB committee must have at least five members with varying backgrounds in order to promote a complete and adequate review of research activities commonly conducted by the institution. The five members must include a chair, a vice chair, at least one scientist whose training is within a behavioral or biomedical research discipline, at least one non-scientist whose training, background, and occupation would help him/her view research activities from a viewpoint outside of any biomedical or behavioral scientific discipline, and one member who is from outside the institution (non-affiliate). 10 Outside consultants may also assist in the research review process, but are not considered members of the IRB.

An IRB must include members with the professional competence necessary to review specific research activities. It should include persons knowledgeable and able to ascertain the suitability of proposed research in terms of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice.

To promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, the IRB must be sufficiently qualified. Namely, it must be qualified through the experience, expertise, and diversity of its members. Best practice and international guidelines mandate diversity of IRB members in race/ethnicity, gender, cultural backgrounds and sensitivity to issues such as community attitudes. In particular, if an IRB regularly reviews research that involves a vulnerable category of subjects, it must include one or more individuals who are knowledgeable about and experienced in working with these subjects. 11

10 US Federal Regulation 45 CFR 46.107
11 For example, both diversity and experience with vulnerable populations are mandated in US regulations on IRB membership. See 45 CFR 46.107
VIII. How does an IRB work?

In order to perform its duties, per the US Regulation, an IRB must have written procedures\(^{12}\) for:

- Determining which human subjects research requires an IRB review, including criteria for risk classifications and for expedited review eligibility (see sections X and XII).
- Conducting an initial and continued review of research, including verification of the extent to which approval criteria have been met.
- Reporting its findings and actions to the investigator and the institution.
- Determining which projects require review more often than annually.
- Determining which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review.
- Ensuring prompt reporting to the IRB of proposed changes in a research activity.
- Ensuring that changes in approved research are not initiated without IRB review and approval except when necessary to eliminate apparent and immediate hazards to the subject.
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the sponsor or funder about:
  - Any unanticipated problems involving risks to subjects or others;
  - Any serious or continuing non-compliance with the requirements or determinations of the IRB;
  - Any suspension or termination of IRB approval.

IX. What authority does an IRB have?

An IRB has the authority to approve, require modifications to secure approval (conditional approval), or disapprove research involving human subjects.\(^{13}\)

In order to approve research, per the US Regulation, the IRB must verify and document that all of the criteria for IRB approval are met and the risk/benefit ratio is acceptable (see section X). If conditional approval is granted, then modifications to secure approval must be verified before final approval is issued. The IRB cannot approve research (even with modifications or conditions for approval) if it does not find that all criteria for approval have been met. Finally, the IRB must find and document additional safeguards for vulnerable populations, if applicable. If the IRB finds that there is not enough information to approve, the study may be tabled or deferred, and the researcher is offered the opportunity to revise and re-submit. In this case, the institution must provide justification for the deferral, and may provide feedback and recommended modifications for the re-submission.

X. How does an IRB evaluate risk?

IRBs must determine whether research is of minimal or more than minimal risk based on the probability that risk will occur and the magnitude or the severity of harm if it does occur. Common risks in social behavioral and gender-sensitive research are psychological, social, or economic. The IRB must consider the risk to the research population as a whole.

---

12 US regulation 45 CFR 46.103
13 45 CFR 46.109
The unit of analysis in risk assessment is the type of procedure involved, whether it be social behavioral research procedures or standard procedures. Research procedures are driven by the nature of the research (i.e. if the individual were not a participant in the research they would not be exposed to the procedure or activity) and risk must be evaluated by experts familiar with the design and/or research question. Standard procedures are activities the individual would be exposed to regardless of participation in the research. Risks related to research procedures must be evaluated by the IRB and included in the informed consent document (see section XI). Risks related to standard procedures are not under the purview of the IRB and should not be considered when the IRB assesses risks because the individual will be exposed to the risk regardless of participation in the research.

The research risk classification scale is as follows:

- Exempt (risk level is not evaluated), IRB review is not required
- Minimal risk, and qualifies for expedited IRB review
- Minimal risk, but requires convened IRB review
- Greater than minimal risk (GTMR), requires convened Board review

As part of the IRB initial review, research is classified and, if non-exempt, assigned a risk level and IRB review process. For non-exempt research, the risk level must be reassessed with each subsequent (continuing or modification) review.

**XI. What is informed consent?**

Informed consent is central to the protection of human subjects. It is both a process and a procedure. The process is the exchange of information that takes place between the prospective subject (and/or their legally authorized representation (LAR), if applicable) and the investigator and study staff, before (during recruitment), during (when the subject is enrolled), and sometimes after the study (in the case where debriefing or notification of changes to the study is required). The process includes the development of an informed consent document (ICD) that clearly explains the research, including the risks and benefits (if any), and that participation is voluntary, reviewing the ICD with the participant (or LAR) and allowing sufficient time for questions, and signing of the document by the participant or LAR. There are also times when the IRB can waive or alter the informed consent process and/or waive the requirement for signing the ICD.

Informed consent is based on the principle of respect for persons. It requires that individuals be treated as autonomous agents and that the rights and welfare of persons with diminished autonomy be appropriately protected. According to the Belmont Report, an autonomous agent is “an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.” Respect for persons requires that prospective research subjects “be given the opportunity to choose what shall or shall not happen to them” and thus necessitates adequate standards for informed consent.

---

XII. IRB review timeline

1. Initial review – new research protocol
2. Continuing review – review of approved, ongoing research (at least annually)
3. Amendment – any investigator-initiated changes to already approved and ongoing research
4. Unanticipated problems/Adverse events - timely reporting of any unanticipated problems or adverse events that occur during the research process
5. Study closure – report to IRB when research is completed

**Expedited review**

Expedited review is a review of proposed research by an IRB chair, vice chair, or designated IRB member(s). This review may only be used for minimal risk research, and/or modifications to previously approved research.

Even though the review time may be shorter, IRB members should be allowed sufficient time to review and evaluate all criteria for approval. The IRB chair or other IRB staff, depending on the written policy, may designate expedited reviews based on study design and availability of members.

The expedited reviewer acts on behalf of the IRB. The expedited reviewer must make all determinations the convened Board would make at a meeting. In addition, the expedited reviewer may exercise all the authorities of the IRB except that he/she may not disapprove research. The IRB must be informed of all expedited review actions. The convened IRB may overturn or require additional reviews of an expedited review determination.

**Convened (or full) board review**

Protocols may be referred to the convened IRB in the following instances:

- Research is minimal risk, but does qualify for expedited review (per the US regulation, in order to qualify for expedited review, the research must fall into one or more of the expedited review categories).  
- Expedited reviewer refers to the convened board due to uniqueness or complexity of the study.
- Expedited reviewers do not reach consensus in a preliminary review.
- IRB staff, chair, or members determine that the protocol is likely greater than minimal risk.

**Continuing review**

Continuing review is a periodic re-evaluation of ongoing human subjects research. Here, the IRB examines how project execution is progressing and compares actual execution to planned, approved execution. Continuing review must be performed at least annually.

This type of review is a cooperative effort between researchers and an IRB to review, identify issues, and correct problems. At the time of initial review and at each subsequent continuing review, the IRB assigns an approval period and expiration of approval date (based on the degree of risk). Continuing review must be conducted and research re-approved within the original approval period, prior to the expiration of approval established at the time of the initial or last continuing review. Extensions are prohibited. If the approval period expires, the project must be suspended (exceptions may be made in cases of threat to the safety of subjects, such as in clinical trials).

---

16 Per the Pre-2018 US Common Rule
Continuing reviews can be reviewed by the convened IRB or by expedited review. They require the same level of deliberation and consideration as the initial review. The criteria for approval are the same as for an initial review. If enrollment is expected to continue, the current informed consent document, tools, and recruitment material are reviewed and approved as part of the continuing review.

At a minimum, a continuing review study progress summary should include:

- The number of research subjects enrolled to date.
- The number of subjects that withdrew or failed to follow up with the study, and reason (if known).
- Modifications or amendments (previously approved and proposed).
- Any new risks identified.
- Adverse events, unanticipated problems involving risks to subjects, or complaints received.

Continuing review may be conducted by the expedited process if: 1) written IRB policies and procedures allow for expedited continuing review; 2) the protocol was initially approved using the expedited process and there have been no changes that impact the risk level; 3) the IRB had determined and documented at a convened meeting that the research involves no more than minimal risk, future reviews may be expedited, and no additional risks have been identified; and/or 4) the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions; and 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 (Expedited Review category 8).

**Modification to an approved study**

A modification request is required when an approved study is changed, including but not limited to changes to: study procedures; survey instruments; informed consent (procedure or document); survey pre-notification and cover letters; recruitment execution plan (e.g. the way participants will be contacted); recruitment material; or research personnel.

Modification review by the expedited process can occur if a project had originally been reviewed via the expedited process and the modification does not change the classification or risk level of the study. It can also be expedited if the changes are minor and the following conditions are met:

- The IRB determined at a meeting that the study was minimal risk and future reviews could be expedited.
- It is within the approval period previously authorized by the convened Board.
- “Minor” changes do not affect the overall risk/benefit assessment.

**Reportable events**

Researchers should report all unanticipated or adverse events to the IRB. Reportable events include protocol deviations or violations, non-compliance of research staff or participants, adverse events (anticipated and unanticipated), and unanticipated problems. Researchers must report unanticipated problems involving risks to subjects or others or serious or continued non-compliance.
Study closure
Continuing IRB review and approval is required as long as study activity continues, including intervention or interaction with subjects or data analysis. After all research-related interventions or interactions with human subjects are completed and all data collection and analysis are finished, the study can be closed. Investigators should notify the IRB when a study can be closed and provide a final report.

XIII. IRB step-by-step process

Step 1: Researcher contacts the IRB office to obtain forms for preliminary determination
Step 2: IRB office/administrator determines if the research requires review
Step 3: Researcher is notified of review requirements/research classification
Step 4: Research submits to the IRB (if required)
Step 5: IRB office/administrator conducts pre-review of submission
Step 6: IRB reviews
Step 7: Researcher is notified of the review outcome
Step 8: Additional reviews (response to conditions for approval/verification, modification review, continuing review, event review, etc.)

Step 1: Contact
First, the researcher contacts the IRB office. Then, the IRB administrator provides forms and templates to collect preliminary information on the proposed research to enable the IRB or IRB office to determine whether further action is required (see sample forms in Section XV). The forms and templates may be provided by email, by directing researchers to a website where forms can be accessed, or by providing log-in information for the IRB management system.

Step 2: Determinations
The IRB or IRB office staff reviews the submitted forms and determines if the research requires review. An IRB administrator, chair, member, or other designee may make this determination. However, a researcher cannot make this decision.

If the IRB determines that the research is not human subjects research, then no further action is required unless the researcher’s own institution mandates it. If it does not meet the definition of research involving human subjects, it is not under the purview of the IRB.

If the IRB/IRB office determines that the research is human subjects research, it can make two designations. If the research meets the criteria for exemption, IRB review is not required, and the researcher must follow institutional policy, if any, for exempt research review. If the research is non-exempt, it requires IRB review and the researcher must prepare a full submission and apply for IRB review.

Step 3: Researcher Notification
The IRB office should notify the researcher in writing, via formal letter or email of the determination and provide instruction for the next steps (if any).

Step 4: IRB Submission
For IRB review, a researcher must submit a protocol, informed consent and assent forms (if applicable), recruitment material, tools and measures, initial review application, and any other forms required by the institution, for example, researcher responsibility and conflict of interest disclosure, a C.V. or resume, and a confirmation of human subjects training (see samples in Section XV).
The research protocol should be a detailed and complete description of the planned research. It should include information on the scientific and technical aspects of the project, details on conducting the human subjects research, including the process for recruitment and informed consent, as well as the ethical considerations for the IRB review (i.e. risk/risk mitigation, research burden for participants, local context, etc.).

There are three protocol options. First, the IRB may require or encourage researchers to use a standard template. The advantage of a standard template is that it facilitates IRB review when the protocol format does not vary. The disadvantage is that since research varies, the template may not fit every type of study or the researcher may already have developed a protocol in a different format.

Second, the IRB could provide a checklist of topics or questions that must be addressed in the protocol. The advantage of this option is that the researcher is free to develop the protocol in a format tailored to the specific study. The disadvantage is that this may require more time for the IRB review, given that the IRB is not familiar with the format.

The last option, though not recommended, is that the IRB provides no guide or template for protocol development. The disadvantages (why this is not recommended) are that the researcher may not know how to write a protocol, the researcher may not include enough information for IRB review, the pre-review of the protocol will take longer, IRB review will take longer, and/or the submission may lack consistency and quality.

The next step involves developing the informed consent forms. Informed consent is the process by which potential participants learn about and understand the purpose, procedures, benefits, and potential risks related to participating in a research study. Per the US regulation, the informed consent form must address all required basic elements of informed consent17 and, when applicable, additional elements18 of informed consent. The three options the IRB may provide/require for an informed consent form are a standard (flexible) template, a checklist, or no guidance. The advantages and disadvantages of each option are the same as for the protocol.

Recruitment material must also be reviewed by the IRB. The protocol must include information on the manner in which participants will learn there is/about a study and any material used for this must be approved by the IRB. Because recruitment is study specific, the IRB will likely not require a standard template for this material. The researcher should develop the material as needed and appropriate for the study. Only the IRB-approved material can be used to conduct the study. Any changes to the material must be approved before implementation. Recruitment materials include advertisements, phone scripts, in-person scripts, email templates, posters, letters, etc.

---

17 Basic elements (45CFR46.116): (1) Statement that the study involves research, purposes, expected duration of participation, description of procedures, identification of experimental procedures; (2) Description of any foreseeable risks; (3) Description of any benefits expected; (4) Alternative procedures; (5) A statement describing confidentiality; (6) Explanation of any compensation; (7) Explanation of whom to contact for questions about the research, subjects’ rights, and in the event of a research-related injury; and (8) Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

18 Additional elements (45CFR46.116): (1) Statement that treatment or procedure may involve risks to the subject (or embryo or fetus) which are unforeseeable; (2) Circumstances under which the subject’s participation may be terminated by the investigator; (3) Any additional costs; (4) The consequences of a subject’s decision to withdraw and procedures for orderly termination; (5) A statement that significant new findings will be provided to the subject; and (6) The approximate number of subjects involved in the study.
Finally, tools and measures must be developed and reviewed by the IRB. Like recruitment material, because tools and measures will be study specific, the IRB will likely not require a standard template, however, tools must be in final or near-final form when submitted. Only IRB-approved tools can be used to conduct the study and changes must be approved before implementation. These tools and measures include data collection instruments, such as interview or focus group guides, surveys, and intervention activity details.

For the initial submission to the IRB, the researcher must submit the required material and the initial IRB review application. The IRB may require an application form or cover letter in which the researcher provides a summary of the study for the IRB and highlights any key ethical/regulatory requirements. The researcher must also provide justification for any special requests, such as a waiver of documentation of informed consent, use of incomplete disclosure or deception, and compensation.

In addition, depending on institutional requirements the IRB may also need to evaluate the researcher. If required, the principal investigator and research staff should provide an acknowledgment of responsibilities, a disclosure of any conflict of interest, their qualifications (CV or resume), and documentation of human subjects research protection training.

**Step 5: IRB Administrator tasks (pre-review)**

During this step, an IRB administrator completes a pre-review of the submission material. The extent of the review depends on the administrator’s authority, level of training (e.g. if the administrator is a certified or experienced IRB professional he/she will be able to evaluate to ensure all ethical/regulatory requirements are met, however, if he/she is an administrative professional, with little or no IRB experience he/she may only be able to review to ensure all required material has been submitted), and status (e.g. if he/she is an IRB member he/she may also be able to complete the IRB review if the study qualifies for expedited review, or if he/she is a researcher qualified to evaluate the scientific design of the study, he/she may provide feedback on that aspect of the study).

The administrator may have the authority to decide whether the activity qualifies as research, and if it is research, whether it is exempt or non-exempt. The administrator may also determine the risk level of the research, and if it is eligible for expedited review. The administrator may assign primary and expedited reviewers as well. Any decision the administrator is authorized to make should be described in the IRB’s written policies and procedures and based on the status and level of experience of the individual. Regardless of the extent of pre-review, the IRB administrator is responsible for serving as the liaison between the IRB and the researcher(s).

The pre-review may just ensure the completeness and accuracy of forms and that all necessary documents have been submitted. Alternatively, if the IRB administrator is a certified or experienced IRB professional, it may also involve screening, revising, and working with the researcher to clarify regulatory and/or technical issues with the protocol, informed consent forms, and other documents submitted for review. Pre-review depends on the administrator’s professional training and experience.

Once the pre-review is complete the IRB administrator prepares the submission for the IRB review (expedited or convened Board). The administrator may assign IRB members as reviewers, including expedited reviewers and primary reviewers for convened Board meetings, depending on institutional policy. In this case, the administrator must determine which members are available or best qualified and may need to consult with the IRB chair. The administrator prepares the submission and reviewer forms for IRB members.
Step 6: IRB Review
The submission is scheduled for review at an ad-hoc, or pre-scheduled IRB meeting, or forwarded for expedited review and assigned a deadline for review to be completed.

If the research study qualifies for expedited review, the submission is forwarded to one or more members of the IRB for review, depending on institutional policy. An IRB member completing an expedited review may make decisions on behalf of the IRB, however, may not disapprove the research. If the IRB administrator is a member of the IRB he/she may conduct expedited reviews, so long as there is not a conflict of interest (e.g. the administrator helped write/revise the research proposal). If the administrator is not a member of the IRB, the administrator must refer to an IRB member for expedited review.

If the research study requires convened Board review, the submission should be reviewed at the next scheduled meeting (provided time is allowed for the IRB to review the submission prior to the meeting), or at an ad hoc meeting. At the convened meeting, the protocol will be reviewed by all present IRB members. The review may be led by the IRB administrator, primary reviewers (if assigned), or the IRB chair depending on institutional policy. All IRB members are afforded the opportunity to comment on the protocol, focusing on the criteria for IRB approval of research. All discussions and review outcomes/determinations are documented in the IRB meeting minutes.

Step 7: Notification
The IRB administrator is responsible for notifying the researcher in writing (or via email) of the IRB’s decision. If the IRB approves the research, the activities may begin. If the IRB requires an approval stamp on the documents, the researcher will be issued stamped informed consent forms and recruitment material. If the IRB grants a conditional approval, research may not begin until the conditions for approval have been verified by the IRB or designee, depending on institutional policy. If the convened IRB disapproves the research study, formal notification will be issued to the researcher and include justification for the disapproval and information on actions the research may take to appeal the decision (if applicable).

Step 8: Additional reviews
Additional IRB reviews required include continuing research review, at least annually, modification review (investigator-initiated changes to already approved and ongoing research), and unanticipated problems and adverse events review. Once the research is complete, the researcher closes the study with a report to the IRB.

The IRB administrator is responsible for tracking the progress of studies and IRB approval expirations and must establish a tracking system to ensure compliance of the IRB and researchers. The IRB administrator may send out notifications when IRB approval of research will be expiring and follow-up with the researcher to ensure that no changes were implemented without approval (post-approval monitoring). For additional reviews, the review process (pre-review – notification of IRB decision) is repeated.

The chart on the following page presents the general protocol review cycle for research submitted to the International Center for Research on Women (ICRW)’s IRB.
ICRW Protocol Review Cycle

Create Protocol Required Documents
- See Initial Submission Checklist for IRB Submission Requirements (Intranet)
- Write Protocol
- Create Data Collection / Intervention Tools, Informed Consent Forms (ICFS), Assent Forms, Recruitment Material, etc.
- Note CITI Training Completion Requirements

Create Protocol Required Documents
- Submit to Project Manager for Technical Review
- Submit to Portfolio or Project Director for Review
- Submit Final Documents for IRB Review (IRB@ICRW.ORG)
- Expedited Review
- Approved Research May Begin!
- Modifications / Protocol Deviations / Reportable Events / Continuing Reviews
- Full Board Review
- Deferred
- Conditional Approval
- Expeditied: Allow at least 2 weeks for pre-review cycle
- Full board: Pre-review deadlines set to ensure IRB submission deadline is met
- May take longer subject to IRB member availability
- Review at next IRB meeting provided the submission deadline has been met
- Review outcome notification
- HRPP Office will issue within 2 business days of completed IRB review.

New IRB Submissions:
- Expedited: Allow at least 2 weeks for pre-review cycle
- Full board: Pre-review deadlines set to ensure IRB submission deadline is met
- May take longer subject to IRB member availability
- Review outcome notification
- IRB@ICRW.org

ICRW Protocol Review Cycle

14 institutional review board
XIV. Common IRB terminology

The following definitions come from the Pre-2018 US regulations and may differ slightly based on which international, national, or funder guidelines are followed:

- **Research**: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Minimal risk**: 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 of routine physical or psychological examinations or tests.
- **Human subject**: 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.
- **Intervention**: includes both physical procedures by which data are gathered and 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.
- **Identifiable**: the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **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.

Other Definitions/Terms:

- **Exempt human subject research**: does not require IRB review.
- **Non-exempt human subject research**: requires IRB review (full board or expedited).
- **Full board review**: review of proposed research at convened meetings at which a majority of the IRB members are present, including at least one member whose primary concerns are in non-scientific areas. In order to approve research, the majority of those members present at the meeting must approve.
- **Expedited review**: review carried out by the IRB chair or by one or more experienced IRB members designated by the chair. Reviewers may exercise all of the authorities of the IRB, but they may not disapprove the research.
- **Engaged in non-exempt human subjects research**: means obtaining data about research subjects through intervention or interaction, identifiable private information, or the informed consent of human subjects for the research.

---

19 See 45 CFR 46.102
The following are some illustrative examples and resources:

**Northwestern IRB** provides all information and forms for general and specific IRB SOPs. This website contains all the information listed below, but additional sources are provided as well.

- Written policies and procedures for IRB review and management:
  - This document from the US Department of Health and Human Services Office for Human Research Protections and the Food and Drug Administration provides a guide for drafting written policies and procedures for all IRBs.
  - In addition to providing a lot of other useful information, the University of Nebraska-Lincoln provides these policies and procedures for IRB operation.

- Determination process (method for determining which projects require IRB review):
  - This manual from the University of Texas at Austin provides IRB policies and procedures, including its method of how to determine if a project requires IRB approval. Researchers can also look at the human subjects research determination form on the Northwestern University IRB website.

- IRB submission forms for researchers – many IRB websites share their required submission forms for research. In addition to the form for submitting a research protocol for review, additional forms may be established for expedited reviews; submissions for modifications, renewals, or closures; informed consent, and conflict of interest disclosures. Recommended IRB websites for reference include Northwestern IRB website, Western Institutional Review Board (IRB) website, and the New English IRB website. The Princess Sumaya University for Technology, the IRB established through the support of USAID-Takamol, has posted the Request for IRB Review of Research Involving Human Subjects form online.

- IRBs often establish documentation specifically for board review members, including meeting templates, meeting minute templates, discussions guides for steps of the research protocol review. There are not many of these internal IRB documents available online, however Tufts University (for a health IRB) and Northwestern have posted the IRB Member Reviewer Resources and SOPs. Most IRBs also have online protocol tracking systems where researchers can check the progress of their IRB review. Since access to these protocol tracking systems requires a login, no examples can be provided.
XVI. Reference material

Please click each title to view the following reference materials:

- **Belmont Report**
- **The Common Rule (45 CFR 46)**
- **The Collaborative Institutional Training Initiative (CITI) Program** is a leading provider of research education content. Their web-based training materials serve millions of learners at academic institutions, government agencies, and commercial organizations in the U.S. and around the world.
  - The **Human Subjects Research — a Citi Program document** gives important information about human subjects research.
- **Human Subjects Assurance Training (online)**
- **IRB: Ethics and Human Research** is a journal devoted to philosophical and regulatory questions about biomedical and behavioral research with human subjects. Visit the [Hastings Center](https://www.hastingscenter.org).
- **The Association for the Accreditation of Human Research Protection Programs** promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs).
- **The U.S. Department of Health and Human Services (HHS)** provides leadership in the protection of rights, welfare, and well-being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services. OHRP helps to ensure this goal is met by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.
- Since its founding in 1974, **Public Responsibility in Medicine and Research (PRIM&R)** has pursued two core goals: creating a strong and vibrant community of ethics-minded research administration and oversight personnel, and providing educational and professional development opportunities that give communities the ongoing knowledge, support, and interaction they need to raise the bar of research administration and oversight above regulatory compliance.
- **The IRB Forum** promotes the discussion of ethical, regulatory, and policy concerns with human subjects research. The IRB Forum strives to create an atmosphere for open and respectful conversation about issues of mutual interest to the members.