IRB Step-by-Step Process

Step 1: Researcher contacts the IRB office

Step 2: IRB determines if the research requires review

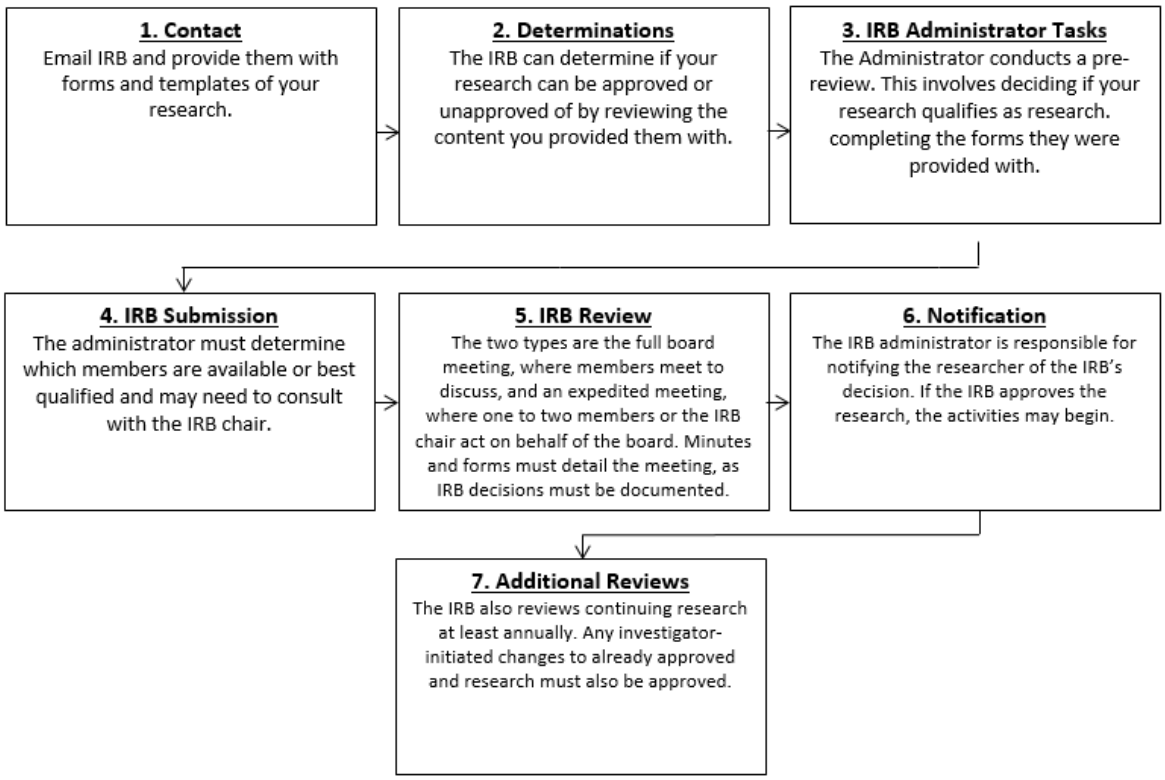
Step 3: IRB administrator review (pre-review)

Step 4: Submission to the IRB

Step 5: IRB review

Step 6: Researcher notification

Step 7: Additional reviews



Step 1: Contact

To start the process the researcher must contact the IRB office, then the IRB office must provide them with forms and templates 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

From this point the IRB can determine if the research requires a review as the researcher cannot make this decision independently. Now the IRB can make one of two designations. If

the research is exempt, IRB review is not required, and the researcher must follow institutional policy. If the research is non-exempt, it requires IRB review and the researcher must prepare a submission and apply for IRB review.

For IRB review, a researcher must submit protocol, informed consent and assent forms, recruitment material, tools and measures, initial review application, researcher responsibility and conflict of interest disclosure, a C.V. or resume, and a confirmation of human subjects' training. This protocol should be detailed and a complete description of the planned research. It should include information on the scientific and technical aspects of the project as well as the ethical considerations for the IRB review.

There are three protocol options. First, the researcher could 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.

The researcher could provide a checklist of topics or questions that must be addressed in the protocol. Although researchers can then format the protocol as needed for the specific project, a new format requires more time for review.

The last option, though not necessarily the one recommended, is that the researcher can submit no guide or template. The advantage is that it facilitates IRB review when the protocol format does not vary. The disadvantages 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, or the submission may lack consistency and quality.

The next step involves informed consent forms. The three options 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 sent to the IRB. It must include the manner in which participants will learn there is a study, for instance. Although there is no standard template for this submission, IRB approved material can be used to conduct the study and all changes must be approved before implementation. Examples of recruitment materials include advertisements, phone scripts, email templates, and posters.

Finally, tools and measures must be sent to the IRB. Although there is no standard template, the submission must be in final or near final form. 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.

The IRB process then transitions into an initial review. Here, the researcher provides a summary of the study for the IRB. The researcher provides justification for the request, such as a waiver of documentation of informed consent, use of incomplete disclosure or deception, and compensation.

Lastly, the IRB evaluates the researcher. The principal investigator and the research staff should provide an acknowledgment of responsibilities, a disclosure of any conflict of interest, their qualifications, and documentation of human subjects research protection training.

Step 3: IRB Administrator Tasks

During this step, an IRB administrator completes a pre-review. The extent of the review depends on the administrator's authority, level of training, and status for example, whether he/she is an IRB member.

The administrator has the authority to decide whether this 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 is eligible for expedited review. The administrator may assign primary and expedited reviewers as well. Any decision the administrator makes should be described in the IRB policies and procedures.

The pre-review may just ensure the completeness of forms and that all necessary documents have been submitted. It may also involve screening and revising the protocol, consent, or other documents. Pre-review depends on the administrator's professional training and experience.

An IRB member may make decisions on behalf of the IRB (expedited review). If the administrator is not a member, the administrator must refer to IRB members or consult with the IRB chair.

Regardless of the extent of pre-review, the IRB administrator is responsible for managing the IRB review process and serve as the liaison between the IRB and the researcher(s).

Step 4: IRB Submission

This step involves more tasks for the IRB administrator. The administrator assigns IRB members as reviewers, including expedited reviewers and primary reviewers for full board meetings. The administrator must determine which members are available or best qualified and may need to consult with the IRB chair. The administrator should ensure that policies and procedures describe the process and should prepare reviewer forms.

Once the type of review has been determined, the administrator must assign the protocol for review at a pre-scheduled meeting or forward the research to IRB members for expedited review and assign a deadline for review.

Step 5: IRB Review

The two types are the full board meeting, where members meet to discuss, and an expedited meeting, where one to two members or the IRB chair act on behalf of the board. Minutes and forms must detail the meeting, as IRB decisions must be documented.

Step 6: Notification

The IRB administrator is responsible for notifying the researcher of the IRB's decision. If the IRB approves the research, the activities may begin. If the IRB grants a conditional approval, research may not begin until conditions have been verified. If the IRB stamps the

documents, the researcher may issue stamped consent forms. Finally, the administrator may issue a notification letter and approved documents.

Step 7: Additional Reviews

The IRB also reviews continuing research at least annually. Any investigator-initiated changes to already approved and research must also be approved. Finally, unanticipated problems and adverse events must be reported. Once the research is complete, the researcher closes the study with a report to the IRB.

The IRB administrator is responsible for tracking and must establish a tracking system to ensure compliance of the IRB and researchers. The IRB administrator must also send out notifications of expiration of approval and follow-up with the researcher to ensure no changes were implemented without approval (post approval monitoring). The review process is repeated.

The chart below presents the general protocol review cycle for research submitted to the International Center for Research on Women (ICRW) IRB.