Working With Institutional Review Boards (IRB)

An Institutional Review Board (IRB) is a committee that performs ethical reviews of proposed research. IRBs have been formally designated to approve and monitor human subject research under standards and regulations set by the Food and Drug Administration and the Office of Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS).

CNCS requires that all SIF evaluations and their instruments and protocols be reviewed by an IRB.[1]

Which IRB to Consult

Any studies where university staff or faculty is involved will need approval from that university's IRB.

Programs may have an internal IRB, or an ongoing relationship with an established external IRB, which evaluation team leaders should contact.

Independent (e.g. self-employed) evaluators and programs navigating the IRB process for the first time will likely need to find an external review board, but may not know which IRB is appropriate for CNCS requirements and thus who to contact. Even for those not affiliated, local university IRBs should have staff persons available to answer questions about how to get started with applying for IRB approval, including where to apply, and how.[2]

In addition, the Association for the Accreditation of Human Research Protection Programs offers a list of IRBs that they have accredited (a voluntary process), which may serve as a resource or starting point in your search.[3]

When to Consult the IRB

In most situations, IRB approval will be required before any interaction with study participants or respondents can begin. You will need to consult with the IRB in the planning stage of an evaluation, and periodically, until data analysis has ended. The IRB will need to approve how informed consent[4] is provided, how data are collected, as well as how data will be analyzed, stored/protected, and destroyed.

[1] IRBs are governed by Code of Federal Regulations Title 45 Part 46 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).
[2] CNCS grantees could also consult their program officer or Office of Research and Evaluation.
[3] AAHRPP http://www.aahrpp.org/learn/find-an-accredited-organization
[4] Informed consent procedures may also include gaining assent from participants. For clarity, the term informed consent used here is intended to include consent and assent from study participants.

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Prior to the Study's Implementation

The IRB will have its own application form but will ask for all of the information required by OHRP, including a copy of the study's protocols and all proposed data collection instruments. ***Know the IRB's deadlines for submission and begin the application process early.*** It is recommended that you consult with the IRB prior to beginning the application, to help with completing the appropriate forms.

Researchers and IRBs must determine whether an activity is research that must be reviewed by an IRB (or if it is exempt from further review); whether the review may be performed by expedited procedures or a full board review; and whether informed consent or its documentation is required, or can be waived. There will also be other considerations, such as how an evaluator will store and protect any confidential or personally identifiable data.

As the Study Progresses

Periodic Renewal

IRB approval has a finite time period, typically one year. For studies with high degrees of risk, the IRB may request more frequent renewal. Be sure to prepare an application for IRB re-approval in advance of the expiration date of the initial approval. The study may be forced to discontinue its activities if there is a lapse in IRB approval.

You will need to keep active IRB approval until data analysis has been completed.

Changes or Amendments

Any significant changes or amendments to the approved instruments and protocol must be reviewed and approved by the IRB. This action provides an opportunity to reassess harm-to-benefit ratio to the subjects and to determine if re-consent or subject notification is required. If changes are not communicated to and approved by the IRB, the study will not be considered to have IRB approval to engage in human subject research.

Examples of Changes or Amendments

- There is a change in the data collection method.
- New data collection activities are proposed.
- There is a change in the size or demographic composition of the sample being investigated, including those who drop out.
- There is a change in key personnel.

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Serious and Unanticipated Events

The research team must notify the IRB of all serious and unanticipated events that cause harm or risk of harm to participants. This will give the IRB an opportunity to re-evaluate the risks associated with the study and suggest changes to avoid further unanticipated events, and/or modify the informed consent to apprise potential participants of the increased risk.

IRB Checklist

Prepare:

- ❑ Research IRB options and determine how much time will be needed for approval.
- ❑ Weigh time and costs involved in different IRB options (e.g. partnering with a university or contracting a commercial IRB).
- ❑ Know the deadlines. IRBs may only meet periodically to review applications and this could affect the study's timeline.
- ❑ Determine if program stakeholders also have a separate required review process and plan accordingly.
- ❑ Have key staff complete human subjects training.
- ❑ Identify the IRB and complete contract/paperwork.

Submit the application:

- ❑ Begin the application early. Understand what the IRB requires and prepare protocols, instruments, consent forms, and other documentation.
- ❑ Complete the application.
- ❑ Build in time for answering clarification questions the IRB may pose.

After IRB approval:

- ❑ Ensure the research team understands what has been approved and the parameters.
- ❑ Renew periodically, according to IRB instructions, until data analysis is completed.
- ❑ Notify the IRB of any changes or amendments to approved protocol or instruments.
- ❑ Notify the IRB of any serious or unanticipated events.

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Tips for Working with an IRB

If you have not worked with an IRB before, consider partnering with a university that does similar research, or contracting with a commercial IRB.

It is advantageous to have key project staff complete training on the rules, ethics and practices required to conduct research with human subjects prior to applying for IRB review (see training resources below).

If you are working with different stakeholder groups (e.g., school districts), be aware that they may have their own internal review processes. Even if you have IRB approval, your partners may require that you also go through their process.

It is the Principal Investigator's (PI) role to ensure that the research team (including the evaluator) knows what exactly has been approved by the IRB. It is the team's role to notify the PI of any changes to the study protocol.

Key Terms

Human Subjects

Research involves human subjects if the project obtains private information *from* or *about* living human beings through interventions or interactions, or by accessing datasets or private records.

Informed Consent

Informed consent is a dimension of human subjects protection that requires researchers to make sure that potential study participants (including control or comparison group members) are fully informed of the potential risks or benefits, if any, and conditions of study participation. The informed consent process involves:

1. Providing potential research subjects enough information to make an informed decision about whether to participate;
2. Creating an understanding of what information will be collected; and
3. Affirming that participation is voluntary.

The procedures should be designed to communicate with the subject population in language that they can understand.

If children (or anyone deemed incapable of giving consent) are research subjects, assent may be required. Children are asked if they agree (assent) to be in a study and are asked to sign an assent form. These forms are usually a simpler version of the consent form that parents sign. Assent forms would also be reviewed by the IRB.

Research

OHRP defines research as "a systematic investigation, including research development, pilot studies, testing and evaluation, designed to develop or contribute to generalizable (or transferable) 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."[5]

Resources

Information on IRBs

The **Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)** website includes a list of accredited IRB organizations in good standing (http://www.aahrpp.org/learn/find-an-accredited-organization).

The **Office of Human Research Protections (OHRP)** (http://www.hhs.gov/ohrp/) provides charts and decision trees to help researchers and IRBs determine whether an activity is research that must be reviewed by an IRB, whether the review may be performed by expedited procedures, and whether informed consent or its documentation may be waived (http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html).

The **Food and Drug Administration (FDA**) (http://www.fda.gov/) is an HHS agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices. For more information, see the FDA's IRB Information Sheet (http://www.fda.gov/regulatoryinformation/guidances/ucm126420.htm)

Training Resources

The **Collaborative Institutional Training Initiative (CITI) Program** (https://www.citiprogram.org/) provides online training in human subject research for persons affiliated with a member institution. CITI training is used by many universities, research organizations, and government agencies conducting biomedical, social, behavioral, and educational research.

The **Office of Research Integrity** offers scenario-based video trainings on the importance of protecting research subjects and following protocol (http://ori.hhs.gov/TheResearchClinic)

[5] 45 CRF 46.102: Protection of Human Subjects, U.S. Department of Health and Human Services: http://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-45-crf-46102-protection-human-subjects