Institutional Review Board Tip Sheet

This tip sheet provides guidance about institutional review boards (IRBs) to Teen Pregnancy Prevention grantees conducting evaluations. It explains the purpose of an IRB and provides guidance on when to contact an IRB and whom to contact.

What is an IRB and what is its purpose?

An IRB is a committee charged with protecting the rights and welfare of human subjects in research. An IRB reviews and monitors research plans, including protocols and instruments, for risks to human participants.

The U.S. Department of Health and Human Services Office for Human Research Protections (OHRP) administers IRBs following the Code of Federal Regulations Title 45, Part 46[1], which is discussed in the HHS Grants Policy Statement (pp. I.18 and II.9-11). [2]

What constitutes human subject research?

Title 45 of the Code of Federal Regulations defines *research* as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[3] A human subject is a living individual who provides information through interactions or intervention. Data can also be obtained through data sets or private records.

This definition of *research* includes different research and data collection methodologies. Different types of evaluations can be considered research and would require IRB review, including formative, process or implementation, outcome or effectiveness, and impact evaluations. IRBs review research involving quantitative or qualitative data collection methods such as surveys, interviews, focus groups, and observations.

Can a study receive an exemption?

In some cases, particularly when data are being collected for program improvement purposes in regular education settings, an IRB may consider data collection to be exempt from a full IRB review. IRBs have differing protocols in determining whether research is exempt and in their requirements for what information would need to be submitted to obtain exempt status. In general, to obtain a formal exempt status, the research team would need to submit summary information to an IRB discussing the nature of the research effort, the data that will be collected, and protections that will be undertaken to ensure confidentiality and security of the data collected.

Exemptions do not mean the research is exempt from IRB review. Rather, it means that an IRB conducted an exemption review and determined that the research meets the federal regulations' definition of exempt research, which do not require an expedited or full review of the protocols.[4] Some types of research are not eligible for exemption under HHS policy if prisoners or children

are involved. Some IRBs also provide special considerations for research involving vulnerable populations, such as individuals that are intellectually disabled, economically disadvantaged, in foster care, or American Indian or Alaska Native. IRBs also consider the risk to the participant so research that includes sensitive, identifiable private information such as behavioral outcomes or instances of pregnancies or sexually transmitted infections may also require an expedited or full review.

While you may believe that you are exempt based on prior experience or written documentation that describes similar activities as exempt (for example, you believe your research is program evaluation or performance measures data collection), an IRB needs to make a determination about your particular case. If you are collecting data from youth, asking sensitive questions (for example, sexual intentions, attitudes and behaviors), sharing data beyond the analyses being conducted under their grant (for example, with the developer), and disseminating findings through presentations or journal articles, it is important to have an IRB review your materials and procedures to show that you have taken proper care to protect participants. Proof of IRB approval, or a letter demonstrating IRB exemption, may be required by some school districts for study implementation or by some journals for publication of study findings. Without IRB approval, research teams may face significant barriers to publishing and presenting findings to external audiences and, in some cases, my face legal consequences.

When should you contact an IRB?

IRB approval is needed before any interaction with potential research participants. Grantees should contact IRBs for review as part of the planning stage of an evaluation. For planning purposes, grantees should factor in the time it takes to develop an IRB package and to make any revisions requested by an IRB, and any costs associated with the IRB's review. If a grantee has never submitted materials to an IRB in the past, it might want to schedule a quick call with its identified IRB to discuss the process, timelines and confirm expectations.

IRBs may require periodic renewals. In addition, the grantee should notify the IRB of any significant revisions to research protocols and instruments. If research already has approval, the current IRB package should be amended or modified rather than submitting a new review.

What does an IRB review?

Grantees should confirm what their IRB will want to review as part of an IRB package. IRBs typically review an overall plan for collecting data (often called a protocol), data collection materials, all plans for obtaining and forms for documenting consent and assent, and recruitment materials. Requested materials, or the format of materials, may be specific to the selected IRB.

How long does an IRB take and how much does it cost?

An IRB review can take days to months depending on the IRB and the type of review. You should reach out to your IRB to get an estimate of the timeline for your study. Some IRBs meet only once per month and only certain months of the year, others review on demand. A review to

determine if your study is exempt will typically happen more quickly than a full review of a planned study. Some IRBs also offer expedited reviews of planned studies if you meet certain criteria.

Similarly, the cost of IRB reviews varies dramatically. The cost of an exemption review may be free or cost between roughly $500 and $1,000. A full review often costs between $1,000 and $5,000 for the initial review, with additional charges for changes and renewals.

Which IRB should be contacted?

Most universities and hospitals have an IRB. Therefore, university or hospital faculty or staff on the research team should contact the IRB with which they are affiliated. If research staff consist of independent researchers, then the grantee can contact a commercial or independent IRB.

States or local governments might require their own IRB review, especially if working with special populations. For instance, if conducting research in schools, the local school board might require review by its IRB. Tribal communities may have their own IRBs as well.

Be sure your IRB is both registered with OHRP and has a Federalwide Assurance (FWA) number, which ensures they have agreed to comply with the requirements in the HHS Protection of Human Subjects regulations. You can search this database to find an IRB or check its certification and get its FWA number.

OHRP database: https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc

Other resources for finding an IRB include the following:

- Association for the Accreditation of Human Research Protection Programs provides a list of accredited IRBs: http://www.aahrpp.org/learn/find-an-accredited-organization
- Citizens for Responsible Care and Research Inc. (CIRCARE) provides a list of commercial IRBs: http://www.circare.org/info/commercialirb.htm
- Consortium of Independent Review Boards (CIRB) provides a list of commercial IRBs: http://www.consortiumofirb.org/cirb-members/

Additional resources

- OHRP decision charts: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html
- Corporation for National Community Service tip sheet: https://www.nationalservice.gov/sites/default/files/resource/SIF_IRB_Tips_7_2014.pdf
- Sexual Risk Avoidance Education grantee tip sheet

  https://sraene.com/sites/default/files/pdfs/Frequently_asked_questions_about_working_with_IRBs.pdf

ENDNOTES

[1] Code of Federal Regulations Title 45, Part 46 (2018). Available at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML.

[2] The grants policy statement is available at https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

[3] 45 CFR §46.

[4] 45 CFR §46.104 (2018).