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Institutional Review Boards (IRBs)

For Federally Funded Child Welfare Research and Evaluation

What is an IRB?

Importance of an IRB

Institutional Review Boards (IRBs) are a cornerstone of ethical research[1] that ensure the rights and welfare of individuals and communities participating in research are safeguarded. Historically, the need for IRBs was underscored by egregious research abuses, such as the Tuskegee Syphilis Study (Center for Disease Control, 2023), where treatment was withheld from Black men, and the Stanford Prison Experiment (Stanford University Library, n.d.), which led to psychological trauma for participants. These dark chapters in research history led to the establishment of IRBs, guided by the principles of respect for persons, beneficence, and justice outlined in the 1979 Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

In This Brief

IRBs function as guardians of ethical research by providing clear standards and regulations to ensure the rights and well-being of research participants are protected (Office for Human Research Protections, 2021a). Primary IRB responsibilities are to minimize risk or harm to individuals and communities participating in research and to ensure they are informed about the activities and purpose of the project, including any short- or long-term consequences of participation.

[1] In this brief, the term "research" encompasses both research and evaluation projects.

Definition of Human Subjects Research

A human subject is a living individual about whom a researcher (whether a professional or student) is conducting research (NIH Grants and Funding, 2020)—

- Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Purpose and Function

IRBs are committees set up by organizations and institutions to review, approve, and regulate research conducted by the organization's members, on its premises, or under its sponsorship. The primary responsibility of an IRB is to minimize the risks faced by human research participants. The most recent version of federal regulations governing the protection of human research subjects (45 Code of Federal Regulations 46, also called the Common Rule), which also describes the purpose and role of IRBs, was published in 2018 (Protection of Human Subjects, 45 C.F.R. §46.101, 2018). These regulations cover all human subjects research that is subject to regulation by any federal department or agency. Although some states and local governments have additional protections and regulations for this research, this brief focuses primarily on IRBs involving federally funded or sponsored research, particularly those implemented by organizations that receive funding through the discretionary grant program operated by the Children's Bureau (CB) within the U.S. Department of Health and Human Services (HHS), Administration for Children and Families (ACF).[2]

As described in exhibit 1, IRBs have varying levels of review depending on the nature of the research proposed and the criteria the research meets. If an IRB determines research poses more than a minimal risk, it may ask for revisions to the project's design. In some cases, the IRB may decline to approve research if it is deemed harmful to participants or unethical (Office for Human Research Protections, 2009). See the Additional Resources section for HHS presentations on exemption categories and decision charts to aid in determining whether an activity must be reviewed by an IRB.

[2] Although developed primarily for CB discretionary grant recipients, the information presented in this brief may apply and be useful to other health and human services organizations implementing research and evaluation projects.

Exhibit 1. Levels of IRB Review

Type	Definition
Exemption (Office for Human Research Protections, 2020)	• The research meets the definition of human subjects research, but also meets the criteria for one or more of the eight exempt categories (Office for Human Research Protections, 2021b). • None of the eight categories are applicable to persons who are incarcerated, and some exemptions may not be applicable to children. • An exemption determination should be made by the IRB rather than by the researcher or funding agency.
Limited Review (U.S. Department of Health and Human Services, 2022).	• Conducted by one IRB member to determine if the conditions of the exemption are fully met or if the research must go through a full board/standard review. • Applies specifically to the exemption categories of educational tests, surveys, interviews, or observation of public behavior and benign behavioral interventions. • A one-time review unless the research protocol changes, then a rereview is likely required.
Expedited Review (Lehigh University Office of the Provost, n.d.)	• Conducted for research which presents no more than minimal risk to human subjects but does not meet the criteria for exemption. • Conducted by a subset of IRB members.
Full Committee Review (Office for Human Research Protections, 2020)	• Conducted for research which is not exempt and does not meet criteria for an expedited review. • A full committee reviews the research and can (1) approve the research, (2) approve the research pending modifications that are verified by the committee, or (3) not approve the research.

Who Serves on an IRB?

An IRB consists of at least five members from diverse racial, gender, cultural, and professional backgrounds (Office for Human Research Protections, 2020). Diverse membership promotes a more complete and balanced review of proposed research studies. Membership must include at least one person who is a scientist (Office for Human Research Protections, 2020); one who is not a scientist; and one who is not affiliated with the IRB institution, such as a community member.

Definition of Scientist

The U.S. Department of Health and Human Services defines a scientist, in the context of serving on an IRB, as—

An individual whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline.

If the members do not have expertise in an area that is the subject of the research being reviewed, they can invite individuals with the expertise to assist in the review; these experts cannot be IRB members and cannot vote (Office for Human Research Protections, 2020). IRB members cannot review applications that present a conflict of interest; for example, members cannot participate if they have a financial, professional, or other personal stake in the proposed research (Protection of Human Subjects, 45 C.F.R. §46.101, 2018). More information on membership requirements can be found in the Additional Resources section.

Types of IRBs

There are different types of IRB including academic, independent, and tribal. Exhibit 2 presents each type and how they differ from one another.

Exhibit 2. Types of IRBs

Type	Description
Academic institution*	Oversees research taking place at, or under the auspices of, the academic institution including universities, colleges, and hospitals that are affiliated with a medical school.
Tribal	Oversees research on and within tribal territories and communities and ensures research aligns with the cultural norms and practices of the community. Described in further detail in the section below.
Independent organization*	Oversees research taking place at organizations without an IRB of their own and is not affiliated with an organization or academic institution that conducts or sponsors research. See the Additional Resources section for examples.
Private organization*	Oversees research conducted within the organization.
Government agency*	Oversees research taking place at, or under the auspices of federal, state, or local government agencies. Examples include the National Institutes of Health and the National Cancer Institute.
Hospital/healthcare organization*	Based at hospitals or healthcare organizations that are not affiliated with major medical schools or government agencies and that provide direct care to patients. Examples include clinics and doctor's offices.

Note: *Information from the U.S. Government Accountability Office report *Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness* https://www.gao.gov/products/gao-23-104721

As shown in the exhibit above, IRBs exist across different sectors, each tailored to meet the specific needs and standards of their respective jurisdictions. Most discretionary grant recipients will use one or more academic, private, independent, or tribal IRBs. While all protect the rights and welfare of human subjects participating in research, IRBs outside of tribal communities do not generally have

expertise in the cultural contexts of indigenous communities. Some discretionary grant clusters are made up exclusively of tribes; others have a mix of tribes, state agencies, and other organizations; and more recently, there is a cluster focused on state-tribal partnerships (Children's Bureau, 2023). Being aware of the perspectives and contexts of research conducted in indigenous communities ensures that grant recipients conduct research in a respectful and culturally sensitive way.

Perspectives and Protocols of IRBs in Indigenous Communities

Conducting research activities on and within tribal territories and communities transcends standard federal and academic guidelines. In these communities, tribal IRBs uphold sovereignty and cultural integrity by operating within the framework of tribal self-determination and respecting traditional knowledge and values (Around Him et al., 2019). Tribal IRBs prioritize cultural sensitivity, community involvement, and informed consent processes that are culturally relevant, promote data ownership, and are controlled by tribal communities. Various tribal or indigenous groups have distinct IRBs that reflect their unique cultural values, governance structures, and approaches to research oversight. Exhibit 3 below illustrates the diverse approaches and key differences in IRBs across various tribal or indigenous groups, highlighting their unique protocols, jurisdictional considerations, and oversight mechanisms.

Exhibit 3. Framework for Understanding IRB Oversight in Tribal and Indigenous Communities

Tribal nation	Tribal college	Tribally based or focused organization/department	Indian Health Services (IHS)
Tribal nations authorize research oversight for their territories, emphasizing sovereignty and self-determination in regulating research activities within their boundaries.	Tribal colleges focus on providing research oversight for educational institutions serving Indigenous communities, ensuring culturally relevant and respectful research practices.	Tribally based or focused organizations or departments oversee research within specific community contexts, tailoring protocols to align with the unique needs and values of the populations they serve.	The IHS oversees research conducted in healthcare facilities within designated regions, emphasizing ethical review and monitoring of research involving Indigenous populations.

Source: Adapted from table 1 (Around Him et al., 2019)

Does My Project Need IRB Approval?

Federal regulations require federally funded or sponsored research involving human subjects to undergo IRB review. As mentioned above, while a project may be deemed exempt from formal review, an IRB should make this determination rather than the researcher. To assess whether your research requires IRB review, you must consult the guidelines on protecting human research subjects from the following sources: (1) your funding agency; (2) the agency, organization, or institution implementing the project; and (3) if using an external researcher or evaluator, from that individual's affiliated institution (see exhibit 1). Research may also have to go through more than one IRB, including the evaluator's IRB and those of all partners when doing community work, especially when protected populations are involved in the research (see exhibit 1).

Step 1. Consult Your Funding Agency's Guidelines

Your funding agency will often provide guidance on whether your research needs IRB review and approval. For projects funded by CB or ACF, it is increasingly common for Notices of Funding Opportunity (NOFOs) to include specific information about IRB approval; some even require applicants to describe plans for obtaining approval in their grant proposals. For example, a 2021 CB NOFO (Children's Bureau, 2024) referenced HHS Protection of Human Subjects regulations and stated that applicants were required to have a plan for addressing the protection of human subjects and to obtain IRB approval if the research was deemed to be not exempt from review, as determined by an IRB.

If your project is receiving funding from multiple sources, you will need to satisfy the IRB requirements of each funding source. For example, if your project is receiving funding from both state and federal agencies, it will need to meet the requirements of both.

Step 2. Consult Your Own Agency's Guidelines

In addition to satisfying the requirements of your funding agency, you must also consider the requirements of your own organization. In cases where the funding agency does not require IRB approval, your agency (i.e., the agency that is fiscally responsible for the grant) may still require approval. For example, a university usually requires proposed research to undergo IRB review even if the funding agency does not require it. Some IRBs will require all research to apply for review, regardless of whether the investigator believes the research is exempt. The safest approach is for the investigator and the sponsoring agency to require the IRB to decide whether the research needs or is exempt from review.

The primary intent of the IRB process is to ensure potential research subjects give their informed consent to participate in research, i.e., they understand what data is being collected about them and

how the data will be used and can make a conscious decision whether to participate. Thus, even if your agency is not receiving federal funding for research or does not require IRB review, best practice—from an ethical standpoint—is to submit an IRB application to protect the welfare, rights, and privacy of human subjects.

Step 3. Consult the Guidelines of Your Evaluator's Institution.

If your project employs an institutionally affiliated external research team with its own IRB, the team may need to obtain approval from that IRB as well. For example, if you have contracted with the social work department of a local university to conduct research, the university will require a university IRB review; this review would be in addition to a review by the IRB governing research implemented or funded by your agency. Although your project will most often need approval from one IRB, you must still ensure it meets the human subjects research protection requirements of all parties, including the funding agency, the implementing agency, and the evaluator's institution.

Who is Responsible for Obtaining Approval?

All human subjects research—regardless of the funder—needs to undergo IRB review. In the context of CB and ACF grants, the organization receiving the federal funding is responsible for ensuring approval is obtained. All parties share responsibility for ensuring adequate review for all human subjects research. If the grant recipient is subcontracting with an external evaluator, the responsibility still lies with the grant recipient to collaborate with the evaluator to ensure their federally funded research study has been submitted, reviewed, and approved.

As a component of project planning, a grant recipient should include in its project workplan and budget the estimated time and cost of an IRB review. The time and cost may vary depending on the level of review (e.g., initial, continuing, exempt, expedited review) and type of IRB (see exhibit 2); even an exempt or expedited review may take 2 or more weeks. Your research partners can help estimate the time and financial costs associated with applying to a specific IRB. The one being considered typically lists the cost for each type of review on its website. Examples of some private and independent IRBs are provided below in the Additional Resources section. Your research partners can also help you determine which type of IRB (e.g., university-based, private, tribal) is most appropriate for your research.

Considerations

Keep in mind the considerations listed below when selecting an IRB and preparing an application; the examples are informed by the experiences of CB/ACF grant recipients.

- **The IRB's experience with human services research methods** (Onakomaiya et al., 2023). Some IRBs have more experience and expertise with medical and other clinical research (e.g., clinical trials of new drugs) and are not always as knowledgeable about approaches commonly used in human services research, such as qualitative and participatory research methods. IRB members who are not as familiar with human services research may ask more questions and review an IRB application with a more critical eye, which can lead to requests for changes to a research plan and delays in approval. For example, in community-engaged research when collecting primary data in collaboration with partnering service organizations, an IRB may require community partners to participate in human subjects research protections training. If your organization has the flexibility to choose an IRB, see the section above on consulting the agency and evaluator guidelines and consider looking for and engaging an IRB whose members have experience and expertise in human services research. To find an IRB with expertise in community-engaged data collection or other participatory or qualitative research methods, talking to peers, including other discretionary grant recipients, and technical assistance providers may be helpful. If you must go through an IRB that is typically focused on clinical studies, you may have to educate the IRB members on your methodology. Project teams, as standard practice, should educate community partners in human subjects research protections and research ethics before beginning a new project. One resource is the University of Illinois Chicago's human subjects training called CIRTification, which is tailored to the unique roles of community research partners (see Additional Resources below).
- **The IRB's focus is on methodological or technical issues** (Murphy, 2017; Sanders & Ballengee-Morris, 2008). Applicants may have the experience of an IRB focusing on methodological or technical issues (e.g., validity and reliability of data collection instruments, data collection protocols) rather than on their primary mission of ensuring the proposed project protects human subjects and meets other standards of research ethics. You can help avoid these digressions, and their associated delays, by ensuring your application includes minimally adequate details about your research methodology, analytical methods, and data collection procedures. The research proposal should focus on procedures and the specific ways in which the research team will minimize risk of harm through them.
- **Meeting IRB standards is not the same as having a rigorous research design**. While IRB review may ensure research protects human subjects and adheres to standards of ethical research, it does not guarantee the project will be methodologically rigorous and produce high-

quality, accurate results. For example, an IRB may confirm that a script for conducting a telephone survey includes appropriate language to ensure survey respondents are giving their informed consent to participate in research, but this does not guarantee the validity and reliability of the survey instrument itself or of the data collected using it. In addition to ensuring their work is conducted ethically, your team members are responsible for meeting high standards of methodological rigor.

- **IRB review does not address all considerations of research ethics** (Secretary's Advisory Committee on Human Research Protections, 2021; Gelinas et al., 2023). While the IRB provides a regulatory framework to ensure compliance with specific regulations, policies, and commonly accepted ethical standards, it does not address all social, racial, sexual, and cultural biases that are institutionalized in society. A thorough and comprehensive ethics review should consider the moral dimensions of the research beyond legal and regulatory requirements. For example, an approved project may not have considered whether the distribution of the burdens and benefits of the research is just, and whether certain populations are excluded from the benefits of the research. A thorough ethics review, separate from the IRB, is especially important when collecting data from people in underserved or vulnerable communities that have been exploited for research purposes and excluded from decision-making processes around the goals and use of research.

Key Points

In summary, IRB review is an important element of any research, and it is imperative to take several steps to determine whether your project requires IRB review and to adequately prepare if it does.

To determine if your research requires an IRB review—

- Consult your funding agency guidelines
- Consult your own agency guidelines
- Consult the guidelines of your evaluator's institution
- Plan for the time and cost of an IRB review
- Select an IRB in consultation with your agency and evaluator
- Select and prepare the package with the type of IRB in mind

Additional Resources

Federal Regulations
The 2018 Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46) is available on the following website: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46.
U.S. Department of Health and Human Services
Office for Human Research Protections information on 45 CFR 46 is available at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.
The Who, What, Why, and Where of IRB Meetings and Membership is available at: https://www.youtube.com/watch?v=XLZih45V_og.
How Do I Review Thee? Let Me Count the Ways: The Types and Manners of IRB Review is available on this website: https://youtu.be/2iXVexPsJs8?si=xQuH8sYOw1eVmr4-.
The ABCs of 104: Understanding Exemption Categories is available at: https://youtu.be/Iqu3eBAg7kE?si=rY0AkksbhvPLAEiv.
Decision charts to aid in determining whether an activity is research involving human subjects that must be reviewed by an IRB are on this website: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html.
Engaging in Research with American Indian and Alaskan Native Communities
The University of New Mexico (UNM) Center for Rural and Community Behavioral Health and Albuquerque Area Southwest Tribal Epidemiology Center created a resource on engaging in research with Native American communities available at: https://hsc.unm.edu/vision2020/common/docs/guiding_principles_research_native_communities2012.pdf
The UNM Office of the Institutional Review Board created a resource on research with Native American communities. This can be found at: https://irb.unm.edu/library/documents/guidance/research-with-american-indian-communities.pdf.
Tips for Writing IRB Applications
Guidance from the Texas Department of State Health Services is available at: https://www.dshs.texas.gov/office-practice-learning/institutional-review-board-irb/irb-application-writing-guidance.
Tips from the Harvard T.H. Chan School of Public Health are available at: https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/tips-and-tricks-for-a-successful-irb-submission-and-review-process/

Examples of Independent IRBs[3]
WCG https://www.wcgclinical.com/irb-resources/
Pearl IRB https://www.pearlirb.com/irb-services/
Advarra https://www.advarra.com/review-services/institutional-review-board/
The Institute for Evaluation and Research, LLC https://www.tierinstitute.com/
Human Research Protections Trainings
CIRTification is a training program in human research protections offered by the Center for Clinical and Translational Science at the University of Illinois Chicago that is tailored to the unique roles of community research partners. More information is available at: https://ccts.uic.edu/resources/cirtification/.
CITI Program Human Subjects Research training is available at: https://about.citiprogram.org/series/human-subjects-research-hsr/.

[3] The authors of this brief do not endorse or recommend any specific IRB; this is a list of examples and there are many more available.

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