# INSTITUTIONAL REVIEW BOARDS (IRBs): FREQUENTLY ASKED QUESTIONS

## What is an IRB?

An IRB is a committee that conducts ethical reviews of proposed data collection involving human participants and collection or use of personally identifiable information and data. IRBs ensure data are collected ethically and aim to minimize any potential harm to those involved. Harm is of a particular concern to an IRB when special or vulnerable populations such as children or people with disabilities are involved. IRBs also ensure that an appropriate process for informed consent is in place, and data about participants are kept confidential.

IRBs are established and governed by different institutions. This means an IRB's authority is limited to data collection occurring within particular jurisdictions. For example, many school districts, hospitals, universities, and state government agencies have their own IRBs. Grantees need to identify which IRB(s) would have jurisdiction over their proposed data collection activities. If a local IRB does not exist, several national IRBs are available to review and regulate research (see section below about finding an IRB). Additionally, if you are working with multiple organizations, you might have to obtain approval from each organization's IRB.

## Does it apply to me?

An IRB review is generally required when data are being collected from human participants. This can include focus groups, surveys, or collection of administrative or medical records. As a general rule, IRB review is required if at least one of the following is true:

- The data are collected through intervention or interaction with people.
- Personally identifiable information is collected from people.
- Sensitive personal questions are asked.
- Primary or secondary data will be analyzed for research reports.
- The results will be disseminated to a broader audience.

There are some instances in which data collection is exempt from IRB review. However, you must submit an IRB package for the IRB to make this determination. The requirements and process for obtaining exemption status also vary by IRB.

## What are the different types of IRB review?

The IRB will determine whether your data collection is exempt from review, qualifies for an expedited review, or requires a full review. Each IRB sets its own standard for each type of review, and the timeline for its determinations. To understand what the IRB requires for the

designation of full review, expedited review, or exemption, consult the IRB's website or speak with a representative from the IRB.

## What are the differences between IRB approval and approval from school district or school board research review boards?

Even though you might have approval from an IRB, many districts also require an application to their research review board (RRB) before collecting data from youth. To determine school district requirements, refer to the district's website. If you cannot locate the requirements, search the website for terms like "external research application," "research proposal," "research review board," "research council," "office of research and evaluation," or "program evaluations." Applications will vary, but the materials required are often similar to those requested for an IRB.

In many cases, through the process of obtaining approval from the RRB, the district will consult the school board or the school board will review the application instead of an RRB. Work with your contact from the school, the district, or both to determine whether you require additional consultation, documents or requirements, and approval from the school board.

Note that receiving district or school board approval does not mean the target schools or their staff and students are required to participate in the data collection activities. Principals often still have final say about whether their school will participate. Additionally, most IRBs will require parents to provide consent to the data collection and students to provide their assent. Having district support is very helpful in recruiting schools, but it is not a guarantee—it is only one more step in the process.

## Should I go to the school board or IRB first?

We recommend obtaining IRB approval first. School districts often want to see the IRB approval as part of their review process.

## What are the differences between IRB approval and community approval when working with American Indian and Alaska Native populations?

An IRB approval, even by a tribal IRB, is not the same as seeking approval from the tribe or community to conduct research or evaluation. In some cases, you will need more than one IRB review. If you are conducting research or evaluation activities on tribal lands, it is best to obtain community approval. Obtaining both community approval and IRB approval shows respect, helps ensure ethical research, and strengthens the relationship between the researcher and the community.

For more information on conducting research and evaluations in tribal communities, see https://els.comotion.uw.edu/express_license_technologies/rethics-research-ethics-training-for-health-in-indigenous-communities.

## How can I find an IRB to work with?

IRBs often operate within public or private nonprofit entities, such as universities, state agencies, or hospitals. A Title V State SRAE grantee that is collecting data on behalf of all program sites within the state might have an IRB through its state agency. Other direct service organizations will need to identify an IRB. Grantees might want to check with partner organizations to see if there is an existing relationship with an IRB.

If needed, grantees can also work with an external IRB. A national list of registered IRBs is available at http://ohrp.cit.nih.gov/search.

## How long does this process take?

The IRB review process varies depending on the IRB and the type of approval required. Full reviews take longer than expedited and exempt reviews. Contact your IRB to ask about the estimated time for approval. Ensuring that your application includes all relevant information can help move the approval process along quickly. Also check to see how frequently your IRB meets to review studies. Some IRBs meet once or twice a week; others meet monthly, and they often request materials be submitted within a specific time frame to be included in the next review. Explore your IRB's website or speak with someone at the IRB to determine the review schedule and confirm when you should submit the required materials.

IRBs often charge fees for their review. The fees for similar types of reviews often vary across IRBs.

## What can I expect from an IRB?

After the IRB reviews your application, it might ask questions to clarify procedures, request changes to your data collection forms, or request additional information. If no additional clarification or changes are required, it will grant approval. The IRB will send you an approval form, which you should keep for your records (see below). The timing for approval can vary based on the IRB.

The IRB typically requires approval annually. You will need to submit a request for renewed approval which often includes documenting your data collection efforts (for example, number of consents, number of withdrawals, numbers of surveys conducted, any adverse events and actions taken). The items and format required for requesting renewed approval can vary depending on the IRB; check the IRB's website for specifics or confirm with your IRB contact.

## What documents do I need to prepare for the IRB package?

The documents required for submission will vary based on the IRB and the level of review required. To determine which documents your IRB submission requires, contact the IRB or review its website for specific application instructions.

Examples of the types of documents typically required include the following:

- **Rationale and purpose of the data collection**, including a broader description of the research study design (if applicable)
- **Summary of your data collection plan** and the proposed activities, including a description of your consent and data collection procedures, and steps taken to protect confidentiality
- **Consent forms** explaining what it means to participate in the study. These forms should contain specific consent language as required by the IRB.
- **Data collection instruments** such as surveys or interview and focus group protocols
- **Any other relevant documents**, including but not limited to recruitment materials, notification materials, and study pamphlets or brochures
- **Any IRB-specific** submission forms. These are often available on an IRB's website, if applicable.

Some IRBs also require the following:

- **Resumes or CVs** of staff involved in data collection activities
- **Conflict of interest forms** disclosing potential conflicts of interest among staff
- **A data security plan** detailing how the study will protect any personally identifiable information gathered
- **Proof of training in human subjects research** for all of those involved in collecting and analyzing the data. Free training in human subjects research is available through the National Institutes of Health (see https://phrp.nihtraining.com/users/login.php). Your institution might also be a part of the Collaborative Institutional Training Initiative, which provides online training materials for a fee (see https://www.citiprogram.org/).

## What do I share with my project officer to document the final decision?

After the IRB reviews your submission, you will receive an approval letter or a notice of exemption. Share this document with your project officer. Be sure to read the approval letter and note any conditions of your approval. For example, some IRBs will require you to include information (such as approval date and version number or the contact information for the IRB) on the approved forms. It is important to follow any conditions the IRB specifies as part of your approval. The approval letter will also include the expiration date of your approval—note this date so you know when you will need to submit a request for annual renewal.

Generally, any changes to your data collection plans necessitate notifying the IRB. Your contact can work with you to determine if you require a formal modification or amendment. For example, you will need to apply for IRB amendments or modifications if you add sites or make changes to consent and data collection procedures or to the data collection instruments (including consent forms).

Do not move forward with any of the proposed changes until you receive approval from the IRB. If you have submitted changes to your consent forms or other data collection instruments, the IRB might require you to update the version number and approval date on all documents moving forward. This information will be included in the approval letter or on the approved documents.

You might also want to share a copy of the approval letter for the modifications or amendments with your project officer.