Institutional Review Board (IRB) Guidance for Harm Reduction Programs

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Purpose

The purpose of this document is to help harm reduction programs understand:

- what an Institutional Review Board (IRB) is,
- what IRBs do, and
- when to submit a data collection plan to an IRB.

We provide an overview of IRBs, explain what it means to collect data from human subjects, discuss the benefits of using an IRB, offer ways to access an IRB, and tell you what to expect when submitting for IRB review. This document can be found online at: sharpta.uw.edu

Please note: This guidance applies to organizations in the US. Different international regulations apply in other settings.

What is an Institutional Review Board (IRB)?

An IRB reviews proposals for research with human subjects according to federal regulations.[1] If you have worked with academic research before, you may have heard of the Common Rule. **The Common Rule[2] is the section of federal regulations that governs the use of human subjects in federally funded research**.

The IRB language of "human subjects" and "not human subjects" is odd, but **human subjects research refers to data collected from or about human persons** versus data that are not from or about humans (e.g., animal research, research about organizations or programs). Human subjects research involves a living individual where someone: 1) obtains information or biospecimens from the individual, and uses, studies, or analyzes the information or biospecimens; or, 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.[3]

Are You Conducting Human Subjects Research?

"Human subject" means any person from whom or about whom data are collected or compiled. Non-human subjects data include non-identifiable program or organizational data that are not specific to individual persons. The table below shows what might be considered human subjects versus non-human subjects data, but this is not exhaustive. When in doubt, consult with IRB staff before collecting data, if possible.

[1] University of Washington Office of Research. "Institutional Review Board (IRB)." Accessed July 2, 2024. https://www.washington.edu/research/glossary/institutional-review-board-irb/.

[2] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

[3] National Archives. "Code of Federal Regulations 45 Part 46-Protection of Human Subjects, AKA 'The Common Rule' (2018 Revision)." Accessed July 27, 2024. https://www.ecfr.gov/on/2018-07-19/title-45/part-46.

Human Subjects Data	Non-Human Subjects Data
Demographics	Inventory data (e.g., count of syringes, pipes)
Housing status	Total participant visits
Experiences with overdose or reversing an overdose	Types of services or supplies a program provides
Experiences with law enforcement	Hours per week program operates
Experiences with healthcare providers and other referrals	Program activities
In general: experiences, beliefs, attitudes of participants and staff	In general: program information *not* at the participant-level

When do You Need to Use an IRB?

Deciding when you need to use an IRB can be complicated. We understand that many harm reduction programs do not currently use IRBs and some organizations may not have access to an IRB. If you have access to an IRB, it is a good idea to use them as a resource before starting data collection. You may contact the IRB directly, discuss your work, and see if you need to submit your data collection or research protocol.[4] The federal **Office of Human Research Protections (OHRP)** has decision charts available here[5] to help determine if your research must be submitted to an IRB, but they may be confusing or may not feel applicable to your program. Below, we describe situations when you likely want to use an IRB.

You want to share findings outside of your organization

Your harm reduction program may want to share what you've learned from gathering and analyzing data to entities outside of your organization. **If this information is directly collected from participants or staff and is going to be shared outside of your organization, it is likely considered human subjects research.** Here are a few examples of sharing human subjects research outside of your organization: presenting findings about participant overdose experience and demographics at a city council meeting; presenting findings about experiences with housing on social media; or, submitting a manuscript for publication in a peer-reviewed journal.

[4] The University of Rhode Island Division of Research and Economic Development. "Does My Research Need IRB Review?" Accessed July 2, 2024. https://web.uri.edu/research-admin/office-of-research-integrity/human-subjects-protections/does-my-research-need-irb-review/.

University of Washington Office of Research Office of Research. "Is Your Project Considered Research?" Accessed July 2, 2024. https://www.washington.edu/research/hsd/do-i-need-irb-review/is-your-project-considered-research/.

[5] https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

In general, if your program may want to share data it collected outside of your organization (i.e., to anyone other than staff and board members) and the data collected are from human subjects, it is good practice to have your data collection protocol reviewed in advance by an IRB.

You have federal funding

Your organization likely needs to have a data collection plan reviewed by an IRB if the data collection itself or if the program the data would be used to evaluate are federally funded (e.g., by SAMHSA, CDC, HRSA, NIDA). OHRP mandates IRB review for any projects receiving federal funding that entail collection of human subjects data.[6] This can include projects explicitly designed as research projects but may also include projects not designed specifically as research but that will involve collection of human subjects data for program monitoring and evaluation. If a program that receives federal funding for a project is found to have not obtained IRB review before collecting human subjects data related to or required as part of the funded activities, they may risk being ineligible to receive future federal funding. If you receive direct federal funding, other requirements (e.g., Federal Paperwork Reduction Act[7]) may apply, which your funding agency should tell you about.

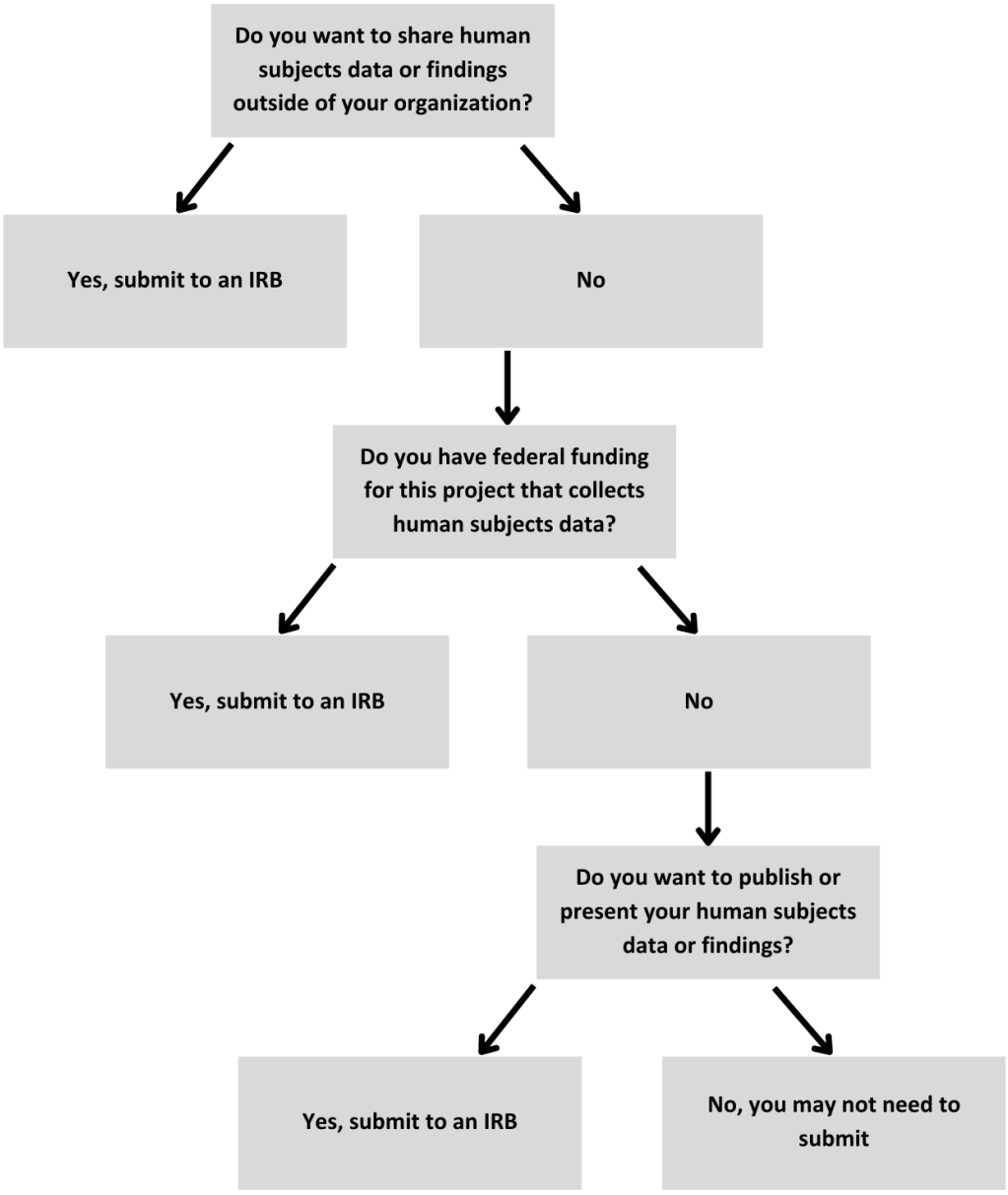
You want to publish your findings

Journals usually will not accept a manuscript for publication if there was not an IRB review; this is also true of many conferences.

[6] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

[7] Digital.gov. "A Guide to the Paperwork Reduction Act: Do I Need Clearance?" Accessed July 8, 2024. https://pra.digital.gov/do-i-need-clearance/

Flowchart of when to submit to an IRB



What Does an IRB Do?

An IRB applies The Common Rule to your data collection or research plan (called a **protocol**) to determine if your plan needs **further review**, is **exempt from further review** (called **exempt**), or is **not human subjects research**. If your proposal is determined exempt or not human subjects research, this means the IRB does not need more information about your research plans or findings, unless something changes that increases risks for participants (e.g., who is being recruited, what incentive is being offered).

An IRB uses the following to determine the status of your research protocol:
Type(s) of data being collected
Method(s) used to collect data
Level of risk for research participants, including risks of trauma and risks to privacy, confidentiality, reputation, and legal rights
Vulnerability of participants based on federal definition of vulnerable populations
The extent that collected data will be identifiable

Only an IRB can determine if your research is exempt; not the **investigator (person collecting the data)**, program, organization, or funder (even federal funders).

Benefits of Using an IRB

Generally, individuals and organizations use IRBs to help:

- ensure their data collection is ethical,
- protect participant privacy, rights, and welfare,
- protect staff, volunteers, and organizations (e.g., offer another protection against overturning program data to law enforcement), and
- ensure programs may share what they find from their data collection publicly.

Preparing an IRB research protocol is an opportunity to ask yourselves these questions:
WHO – is being asked? Who is being compensated? Who is asking? Who will have access to the data?
WHAT – is being asked and what objectives it serves?
WHEN – will you collect data?
WHERE – will you collect data?
HOW – will you collect data? How long will it take participants? How might power dynamics affect data collection? How will it be stored? How will you use it?
WHY – do you want these data?

An especially vital part of an IRB protocol is examining how power dynamics may affect data collection and how to address power dynamics so participants do not feel coerced to take part in research. An important part of addressing power dynamics is through the **consent** process. As an IRB training states,

> [obtaining] consent should begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding the research, what is expected of them, and the potential risks of harm and benefits.[8]

You should get participants' consent for all data collection, as explained in the SHaRP guidance on informal qualitative data.[9] As in all aspects of life, consent to include someone in research should be explicit, active, and ongoing.

While IRB review is necessary to ensure data collection or a research plan meets an institutions' ethical standards, it is also helpful as an organization to develop your own ethical standards. This is especially important given the potential for harm when collecting data from or about people who use drugs. Even in cases where your organization's data collection may not meet federal requirements for IRB review, going through IRB and establishing internal ethics standards for your organization's approach to data can best protect your participants.

How Can I Access an IRB?

Funders require most of the data that harm reduction programs collect. If funders require programs to disseminate their data outside of their organization or are federal and require data collection, they should give programs access to IRBs, either directly or through funding. There are three kinds of IRBs in the US:

- **academic/institutional**,
- **commercial**, and
- **community**.

Academic/institutional

Academic or institutional IRBs are based at academic institutions, medical centers, research hospitals, and departments of health. Some of these will only review research protocols for studies that will take place on-site or be led by their employees or learners (e.g., students, medical residents); others will review projects to take place in the surrounding community. If you do not have an affiliation with an institution that has an IRB, you still have options. You may consider collaborating with a researcher who has access to an IRB. Keep in mind that, depending on the university or hospital, members of an academic IRB may have little or no experience with harm reduction and people who use drugs. It may be necessary to provide enough background in the research plan you submit for the person reviewing it to understand why you want to do

[8] Hicks, Lorna. "Informed Consent - SBE: University of North Carolina at Chapel Hill Group 2 Social and Behavioral Research Module." CITI, 2019. Accessed July 8, 2024.

[9] Healy, Elise, Bayla Ostrach, and Arianna Means. "Leveraging Informal Qualitative Data Collection and Use at Syringe Services Programs." UW-SHaRP, 2023. Accessed July 8, 2024. https://www.sharpta.uw.edu/syringe-servicesprogram-monitoring-and-evaluation-resources/leveraging-informal-qualitative-data-collection-and-use-at-syringe-services-programs/.

things the way you do and explain why it makes sense for the setting and context. Having a collaborator based at the institution who understands harm reduction can help with this process.

Benefits: If your organization has a relationship with the institution or a trusted collaborator at the institution, submitting protocols to an institutional IRB should be free and can, over time, increase that IRB's understanding of ethical issues affecting people who use drugs.

Cost: If your organization has a relationship with the institution or a collaborator at the institution, submitting protocols should be free. Some institutional IRBs review community proposals for a fee, which may be on a sliding-scale.

Commercial

Commercial IRBs are independent, pay-for-service IRBs that provide regulatory and ethical review. Commercial IRBs may have little or no experience with harm reduction. Before contracting with a commercial IRB, we recommend asking them about their experiences working with community-based organizations, community driven research, and people who use drugs.

Benefits: Commercial IRBs typically review protocols from any client who can pay, and they provide documentation of the resulting determination.

Cost: Commercial IRBs may be expensive, so we recommend getting details on their processes and costs so you can budget time, money, and other resources appropriately (a cursory review of commercial IRB costs found initial project review costs ranging from $700-$1,690).

Community

Community IRBs are formed by and for specific communities that want to have more say in the review of research protocols designed to collect data about them. Community IRBs are often in place to support the integrity of research from academic and other research institutions for conducting community-driven and people-centered research where research participants are treated not simply as subjects, but as partners with valuable knowledge.[10]

Benefits: If available in your area, community IRBs may be less expensive than commercial IRBs and likely have more experience and expertise with community driven research.

Cost: IRBs do charge a fee, but this is often on a sliding-scale and some have a discount or scholarship-type fund for community organizations.

Deciding which type of IRB to use may depend on which you have access to, as much as which is best-suited for your purposes.

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[10]Beloved Community. "Meet the IRB Housed at a Black Womxn Led Nonprofit." Accessed July 2, 2024. https://www.wearebeloved.org/blog/inside-the-beloved-community-irb.
SSG Research & Evaluation Team. "Community IRB." Accessed July 2, 2024. https:/www.ssgresearch.org/community_irb.

What if I Cannot Access an IRB?

If your organization cannot access an IRB, it is still good practice to prepare a step-by-step plan for your data collection. You may think ahead about the same elements that go into an IRB protocol, including those listed in the Benefits of Using an IRB section. These topics are covered in the SHaRP guidance on informal qualitative data[11]. As presented in the SHaRP guidance on ethical data collection[12], it is also good practice to minimize data collection and to ensure data is kept private and secure. One way to protect participants is to not collect any identifying information, including for a unique identifier code (see SHaRP guidance on unique identifiers[13]).

Considerations when Working with an IRB

Timelines

Once you have determined you need IRB review, you need to allow time for the review process. Review times vary dramatically across IRBs and according to the research or data collection methods. Individual IRBs can give you information on their average review times.

Training

IRBs typically require everyone who will recruit research participants and/or collect data (also called investigators and study team members) to complete an online research ethics training. Most often this is a **CITI course**, **an online training that covers the conduct of ethical research**. Once you have completed CITI training, it is good for several years. Some IRBs may have a specific research ethics training for community members who will be involved in community-based research, which may feel more accessible for many folks.

Research Collaboration

If you have opportunities to partner with a researcher(s) based at an institution with an IRB, some important questions to ask include:

- Are they willing to learn about your participants and your setting?
- What are they offering to do for and with you, instead of just asking for something?
- Do they have resources they can share (e.g., write your organization into a grant)?
- Do they ask what you want to learn about, or are they only interested in their questions?
- Who will own and be able to access the collected data?

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[11] Healy, Elise, Bayla Ostrach, and Arianna Means. "Leveraging Informal Qualitative Data Collection and Use at Syringe Services Programs." UW-SHaRP, 2023. Accessed July 8, 2024. https://www.sharpta.uw.edu/syringe-servicesprogram-monitoring-and-evaluation-resources/leveraging-informal-qualitative-data-collection-and-use-at-syringe-services-programs/.

[12] Buer, Lesly-Marie with the SHaRP team. "Good Practices and Ethical Data Collection at Harm Reduction Programs: A Brief Summary." UW-SHaRP, 2023. Accessed July 18, 2024. https://www.sharpta.uw.edu/syringe-services-program-monitoring-and-evaluation-resources/good-practices-and-ethical-data-collection-at-harm-reduction-programs-a-brief-summary/.

[13] Deutsch, Sarah with the SHaRP team. "Using Unique Identifiers Within Syringe Service Programs." UW-SHaRP, 2023. Accessed July 18, 2024. https://www.sharpta.uw.edu/syringe-services-program-monitoring-and-evaluation-resources/using-unique-identifiers-within-syringe-services-programs/.

For more examples of how other harm reductionists have developed guidelines for working with researchers, see information from Boilevin et al. 2019,[14] Simon et al. 2021,[15] the Drug Policy Alliance,[16] and the NAOMI Patients Association.[17]

Preparing a Research Protocol

Even if you are not collaborating with a researcher outside your organization, it is useful to work with someone who has submitted to an IRB before because the processes can be confusing. IRBs require you to submit specific forms and these vary by IRB. They generally require the same information (listed below) and people who have submitted to IRBs often have standard language for these forms. A typical study protocol will include the following sections.

Section	Contents
Study team	Outlines who will recruit participants and collect data, this often needs to include a record of those individuals' research ethics course completion (CITI or something similar)
Methods	Explains who, what, when, where, and how you will recruit participants or collect data; some IRBs want sample recruitment language, drafts of any surveys, questionnaires, or interview guides, and data analysis plans
Consent	Details how, when, and where you will obtain consent, some IRBs want sample consent language
Data storage	Outlines how you will keep data secure, private, and confidential; plans for de-identification; and explains who will have access to data
Risks and benefits	Details what risks are possible for participants in relation to the research, how you will minimize risks, and what benefits you anticipate from the research, to both participants and to society as a whole
Incentives	Explains how you will compensate participants for their time and incentivize them to participate

[14] Boilevin, Louise, Jules Chapman, Lindsay Deane, Caroline Doerksen, Greg Fresz, DJ Joe, Nicolas Leech-Crier, et al. Research 101: A Manifesto for Ethical Research in the Downtown Eastside. Vancouver, 2019. https://open.library.ubc.ca/cIRcle/collections/ubccommunityandpartnerspublicati/52387/items/1.0377565.

[15] Simon, Caty, Sarah Brothers, Knina Strichartz, Abby Coulter, Nick Voyles, Anna Herdlein, and Louise Vincent. "We Are the Researched, the Researchers, and the Discounted: The Experiences of Drug User Activists as Researchers." The International Journal on Drug Policy 98 (2021): 103364. https://doi.org/10.1016/j.drugpo.2021.103364.

[16] Drug Policy Alliance. Recommendations for Community Driven Drug Policy Research. New York: Drug Policy Alliance, 2022. https://drugpolicy.org/wp-content/uploads/2023/05/Recommendations_for_Community_Driven_Research.pdf.

[17] Boyd, Susan and NAOMI Patients Association. "Yet They Failed to Do so: Recommendations Based on the Experiences of NAOMI Research Survivors and a Call for Action." Harm Reduction Journal 10, no. 1 (April 18, 2013): 6. https://doi.org/10.1186/1477-7517-10-6.

Vulnerable Populations

IRB trainings cover the federal regulations governing categories of participants considered **"vulnerable"** or in need of additional protections that under federal regulations include: pregnant people, newborns, children, incarcerated people, and "individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons."[4] This means research that specifically targets these groups for recruitment undergoes a more strenuous level of review. However, if the research plan is to recruit an overall population based on other criteria that would happen to include pregnant people and recently incarcerated people (or those on parole or probation), that is usually considered different than specifically recruiting a vulnerable population and is unlikely to require special steps.

Stigmatized Groups and Community Consultation

There can be specific harms related to research with stigmatized and criminalized groups, such as people who use drugs. One recommended way to avoid or minimize group harms, especially for historically dehumanized groups is to engage in community consultation. This includes directly involving people and organizations that represent the community about or with whom you hope to do research. In the case of a harm reduction program, this could mean taking a draft of your research plan to the participant advisory board or to participants for feedback, or better yet, soliciting input from the participant advisory board or participants, who are compensated for their time, in developing your research plan from the beginning.

Conflict of Interest

In a research context, **conflict of interest** occurs when **financial or non-financial considerations may compromise a researcher's data**. Potential researcher bias may affect decisions about who is asked to provide data, who is chosen to collect data, how consent is gathered, and how data are collected, analyzed, and interpreted.[18] For example, if someone's salary is funded by a particular grant, it might be a conflict of interest for them to collect and/or analyze data for the evaluation of that grant. Likewise, if a staff person is the only person who does SSP mobile deliveries, it could be a conflict of interest for SSP mobile delivery participants to be recruited for a research study if participants think they must participate in order to continue receiving supplies or services.

Considering Power Dynamics

Power dynamics can affect research plans and an IRB will take these into consideration when reviewing a protocol. Such dynamics can influence the potential vulnerability of and risks to research participants. For example, many IRBs consider the power dynamics between:

- employees and their employers,
- patients and their medical providers, and
- participants and their caseworkers.

[18] Moore, Julie, and Cristy McGoff. "Conflicts of Interest in Human Subjects Research: University of North Carolina at Chapel Hill Group 2 Sociobehavioral Research Module." CITI, 2019. Accessed July 8, 2024.

In the context of harm reduction programs, it is important to consider what power the people who will recruit, collect, analyze, and interpret data have (or may be perceived to have) over participants who provide data. For example, harm reduction program staff asking participants if they want to complete a survey before they receive services could make participants feel like they must complete the survey to get supplies.

HIPAA and Privacy Protections

The **Health Insurance Portability and Accountability Act (HIPAA)** rules and the Common Rule overlap in some areas. However, HIPAA rules only apply to what are called "covered entities" and their "business associates**."** Many harm reduction programs may not qualify as a HIPAA-covered entity unless your program is part of a larger healthcare organization that electronically transmits certain client information.[19] HHS has an online decision tool you can use to help determine if you are a covered entity. Remember, it is good practice to preserve participants' privacy and confidentiality with all information gathered for program and research purposes.

[19] US Department of Health and Human Services. "HIPPA Covered Entities." 2015. Accessed July 8, 2024. https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html.