Research Ethics for All:
Accessible Research Ethics Education for Community Research Partners

IRB Approval Information

About *Research Ethics for All*

Overview

[Research Ethics for All](#) provides community research partners with developmental disabilities accessible education in ethical issues in social and behavioral research with people. This education is focused on the roles and responsibilities of community research partners.

Research Ethics for All prepares community research partner for responsibilities related to [The Common Rule](#) (the US policy for protecting research participants). *Research Ethics for All* also helps community researchers understand their rights and responsibilities related to the Responsible Conduct of Research.

Research Ethics for All prepares community research partners for responsibilities related to:
- Finding people to be in research studies (recruitment)
- Working with people to make decisions about being in research studies (consent and assent)
- Collecting information from people and working with information that can tell us who a person is (data collection and individually identifiable data)
- Writing about research and sharing answers to research questions (authorship and dissemination)

Research Ethics for All uses ideas from the Disability Rights Movement to help us think about important ideas in research ethics. These ideas include showing respect to people by assuming they can do things and facilitating responsible their inclusion in research. These ideas from the Disability Rights Movement can identify approaches to research and inclusion of people with disabilities in research that balance rights to self-determination and safety.

Learning Outcomes

Research Ethics for All supports community research partners to learn about ethical practices and decision-making in research with people. Completion of the training provides certification in research ethics and compliance for topics relevant to community research partners engaged in social and behavioral research.

Research Ethics for All supports community research partners to achieve the following learning outcomes:

1. Define research with people, jobs of different people on a research team, and ways community research partners can make research better.

2. State why there are rules for research with people and rights of research participants (Belmont principles).

3. Describe how to use IRB-approved recruitment and consent materials, follow eligibility criteria, and work with people with and without guardians to make informed, voluntary, and ongoing decisions about being in a research study.

4. Discuss how to keep research participants safe and what to do when there is information that cannot stay confidential.

5. Explain responsibilities of community research partners, including ways to protect the rights and well-being of people who are in research and community researchers, one's own team's rules, conflicts of interest, and authorship.

Audience

Research Ethics for All is for community research partners without advanced degrees in scientific, human research-oriented disciplines who will interact with research participants and/or their individually identifiable information for research purposes. Often community research partners do not have a primary affiliation with an academic institution.

Training Development

Research Ethics for All was created by people with developmental disabilities, disability service providers, researchers, and IRB administrators and members.
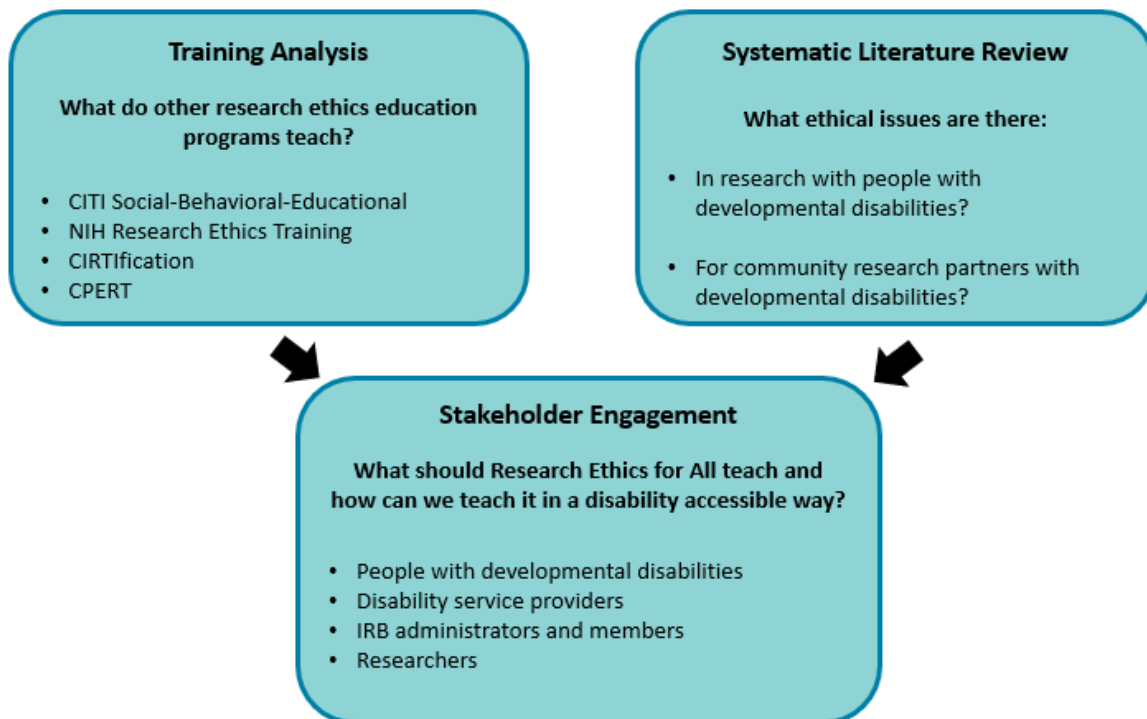
Project Team

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Development Process

We developed *Research Ethics for All* by working with people with developmental disabilities, disability service providers, researchers, and IRB administrators and members to decide together what community research partners with developmental disabilities needed to know. We reviewed other research ethics training programs, looked at ethical issues related to doing research with people with developmental disabilities, and shared our experience and expertise. We also worked together to make *Research Ethics for All* disability accessible.

Training Analysis

What do other research ethics education programs teach?

- CITI Social-Behavioral-Educational
- NIH Research Ethics Training
- CIRTIfication
- CPERT

Systematic Literature Review

What ethical issues are there:

- In research with people with developmental disabilities?

- For community research partners with developmental disabilities?

Stakeholder Engagement

What should Research Ethics for All teach and how can we teach it in a disability accessible way?

- People with developmental disabilities
- Disability service providers
- IRB administrators and members
- Researchers

Systematic Literature Review References

Funding

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IRB Approval to use *Research Ethics for All* Training

Depending on the responsibilities of community research partners, *Research Ethics for All* may help community research partners receive required certification in research ethics education.

Research Ethics for All can be used for a single IRB protocol or as an available research ethics education program for community research partners at an organization.

Engagement in Research and Researcher Training Federal Regulations and Accreditation Standards

> *Federal Regulations and Organizations*
>
> > The Common Rule (45CFR 46) regulates activities defined as human subjects research.
> >
> > The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and well-being of people involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research. OHRP is part of the Office of the Assistant Secretary for Health in the Office of the Secretary of HHS.
> >
> > The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) offers accreditation for institutions that conduct human subjects research. AAHRPP accreditation means an organization meets AAHRPP standards for protecting human subjects in research.
>
> *Engagement in Federally Regulated Research*
>
> > OHRP provides guidance to institutions on what it means to be **engaged in research**; this guidance is relied on by most institutions.
> >
> > In general, an institution is **considered engaged** in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:
> >
> > 1. data about the subjects of the research through intervention or interaction with them
> > 2. identifiable private information about the subjects of the research
> > 3. the informed consent of human subjects for the research.

Institutions are generally **not considered engaged** when they inform prospective research participants about a research participation opportunity, even if they share consent/assent forms or seek or obtain permission for investigators to contact them about research, or allow the use of their facilities for research purposes.

Principial investigators can work with their IRBs to identify which people and which organizations are engaged in human subjects research for each IRB protocol. **Not all people who are part of a research team or who help a research project may be considered engaged in human subjects research.**

Key Personnel Qualifications

The Common Rule does not regulate training of investigators and key research personnel.

Investigators and all key personnel who will be involved in the design or conduct of NIH-funded human subjects research must fulfill the protection of human subjects and responsible conduct of research education requirements. Most institutions extend this requirement to all regulated research in their Federalwide Assurance (FWA).The National Science Foundation also has educational requirements.

AAHRPP accreditation standards address expectations for researchers and research staff with regard to their education and qualifications in the following elements:

- Element I.1.E: The **organization has an education program** that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

- ELEMENT III.1.D: **Researchers determine that the resources necessary** to protect participants are present before conducting each research study.

- ELEMENT III.2.A: Researchers and research staff are **qualified by training and experience** for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.

AAHRPP standards direct institutions to understand that the protection of research participants is a shared responsibility and involves individuals being

able to understand and apply several areas of knowledge, including ethical principles, professional standards, organizational policies and procedures, and laws, regulations, codes, and guidance.

AAHRPP standards note "**the depth of knowledge and skill required depends on each individual's specific task and role**" and expect that "an organization should have a process to ensure that individuals involved with human research protection have appropriate knowledge and skills."

These standards further note that **researchers (principal investigators) are responsible for ensuring that they have the resources required, including qualified research team members,** to conduct research in a way that will protect the rights and welfare of research participants and ensure the integrity of the research. That is, researchers (principal investigators) are responsible for implementing a process for all "persons assisting with the research are adequately informed about the protocol and their research-related duties and functions."

Lastly, AAHRPP standards note that "researchers and research staff should be **qualified by training and experience for their roles and responsibilities in conducting research so that they follow the protocol and abide by the organization's policies and procedures**.

Implications for Community Research Partner Qualifications

The Common Rule does not specify educational standards or methods, though most institutions follow NIH's recommendations on education requirements for investigators and key research personnel.

AAHRP accreditation standards note that: (1) key personnel must be educated; (2) education can be tailored to the role; and (3) principal investigators bear responsibility for making sure key personnel are qualified. That is, principal investigators must have protocols to ensure research team members are adequately informed about the protocol and their research-related duties and functions and provide oversight.

***Research Ethics for All* may be an appropriate education program for community research partners who are engaged in human subjects research.**

IRB approval for a research protocol or project

You can apply for approval to use *Research Ethics for All* as a research ethics education program for community research partners working on a specific IRB

protocol or project. We encourage principal investigators to discuss using *Research Ethics for All* with their human research protections program in advance of submitting and IRB application.

The following information will help you share important information with your human research protections program and IRB.

How does the educational content in Research Ethics for All compare to basic CITI research ethics education?

> *Research Ethics for All* provides general research ethics education tailored to the roles and learning needs of community research partners with developmental disabilities. *Research Ethics for All* is not a substitute for research protocol- and role-specific training.

> [Comparison of *Research Ethics for All* to *CITI Social-Behavioral-Educational Foundations*](#)

Who Can Provide Research Ethics for All Training?

> We recommend *Research Ethics for All* be taught by experienced research project leaders (usually principal investigators or project leaders) or research ethics trainers. These individuals should have current CITI certification in social and behavioral research and experience conducting research and/or teaching about research ethics. These individuals can assess learner understanding and issue certification.

> People learning on their own can also access *Research Ethics for All.* However, people learning on their own cannot obtain certification.

How are learners certified?

> After completing the training, the person who led the training works with individual learners to check their understanding on core Learning Outcome concepts. When the person who led the training is satisfied that the learner has obtained a basic level of understanding, they can use the certificate template to issue a certificate to each learner. Project leaders can submit individual certificates in their IRB application.

Training Comparison

Content Area	*Research Ethics for All*	CITI Social-Behavioral-Educational Foundations
Introduction to Research/Defining Research with Human Subjects	• Definition and examples of scientific research with people • Differences between scientific research and non-scientific research activities • Foundational research terms (community-engaged research, data, research protocol, roles of people on research teams) • Benefits of research for research participants and society	• Regulatory definitions of research and human subjects • Differences between private and public information and behavior
History of Research Abuses, Ethics, Belmont Principles, and Federal Regulations	• History of abuses in research that led to federal regulations • Federal Regulations (The Common Rule): why they exist, research participant rights • Definition of research ethics • Belmont principles (Respect for Persons, Beneficence, Justice) • IRBs: why they exist, what they do • Definition and examples of vulnerability in research with an emphasis on people with developmental disabilities	• History of abuses in research that led to federal regulations • Federal Regulations (The Common Rule): what lead to their development, basic provisions including subparts • Belmont Report • Belmont principles (Respect for Persons, Beneficence, Justice) • IRBs: criteria for review category, authority and scope • Research with prisoners • Research with children • Research in Public Elementary and Secondary Schools • International Research • Internet-Based Research • Research Involving Workers/Employees • Vulnerable populations
Recruitment and Informed Consent	• Consent: informed, voluntary, and ongoing; essential elements of; documentation, waiver of documentation • Consent capacity, Legally Authorized Representatives (LARs), and meaningful assent	• Consent: guidelines, required and additional elements, documentation, waiver of documentation; informed, voluntary, and ongoing

Content Area	Research Ethics for All	CITI Social-Behavioral-Educational Foundations
	• Using IRB approved research materials • Eligibility criteria: what they are, why they are important • Responsible inclusion in research • Working with people who provide support and services to people with developmental disabilities	• Ways to address risks in the informed consent document and process • Vulnerable populations: safeguards for consent
Risks	• Definition and examples of different types of risks (physical, psychological, social, legal, economic) • Definition and examples of safeguards, debriefing, DSMBs • Adverse events	• Risks: identification, assessment, balancing risks and potential benefits, minimizing and managing risks • Unanticipated problems
Privacy and Confidentiality	• Privacy and confidentiality: definitions, strategies to protect privacy and confidentiality, including when research participant has a LAR • Individually identifiable information • Certificates of Confidentiality • Mandatory reporting	• Privacy and confidentiality: definitions, risks to, strategies to protect privacy and confidentiality • Certificates of Confidentiality • Privacy and reporting laws
Research Integrity	• Conflicts of interest • Rights and responsibilities related to authorship	• Conflicts of interest
Ethical Issues in Community-Engaged Research	• Keeping community researchers safe	