Overview

This toolkit contains general information, frequently asked questions (FAQs), and customizable templates to support domestic research involving community groups (organizations, private practices, and independent or community clinics), in partnership with academic institutions and other organizations. This resource introduces fundamental terms and concepts, provides guidance, and outlines some of the issues that should be taken into consideration prior to partnering with another institution to conduct human research in the United States.

Importantly, the toolkit will help sites determine whether they will be engaged in research, based on federal guidance, whether they must obtain a FWA, and if yes, whether to establish an Institutional Review Board (IRB) or delegate IRB review to another institution, or to a commercial IRB.

For your assistance, we have included a glossary to help clarify key terms. This is not an all-inclusive compendium of information, and we recommend you contact a professional in this field for further guidance if/when needed.
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I. Getting Started: FWAs, IRBs, and IAAs

1. **What is a Federalwide Assurance (FWA)?**
   If your organization is engaged in human research\(^1\), then it will need a FWA. A FWA is an “assurance of compliance,” an agreement between the government and the institution that will conduct human research. Through this agreement, the institution commits to follow the laws governing human research (\textit{45 CFR 46} and the \textit{Terms of Assurance}). FWAs are issued to institutions that are engaged in non-exempt human research (\textit{e.g.}, research that is reviewed by an IRB\(^2\)), and is conducted or supported by the \textit{Department of Health and Human Services} (DHHS) – additional information about “engagement in research” is available below. A FWA is approved by the Federal \textit{Office for Human Research Protections} (OHRP). Additional information about FWAs and IRBs is available on the OHRP website.

   Note: Throughout this document “organization” is used to refer to a private practice, local clinic, or other community-based organization; “institution” is used to refer to an academic medical center or another academic institution.

2. **What is an Institutional Review Board (IRB) and who can be a member of one?**
   An IRB is a federally mandated committee responsible for protecting the safety, rights, and welfare of human research participants. As outlined in the \textit{federal regulations}, an IRB must have at least five members with varying backgrounds and professions that correspond to the type of research commonly conducted by the institution. At least one IRB member must have expertise and experience in scientific areas, and at least one in non-scientific areas; at least one member must \textit{not} be affiliated with the institution (that person cannot be employed by the institution or part of the immediate family of a person who is affiliated with the institution).

   IRB membership must be sufficiently diverse in race, gender, and cultural background, and be sensitive to such issues as community attitudes to promote confidence in its advice and counsel, and therefore, in its ability to protect the rights and welfare of human research participants. If an IRB regularly reviews research that involves a vulnerable population (\textit{e.g.}, children, prisoners, pregnant women, handicapped, or decisionally-impaired or challenged persons), one or more members who are knowledgeable about and experienced in working with the population(s) must be part of the IRB. The IRB must also be able to determine whether proposed research is acceptable in terms of “institutional commitments and regulations, applicable law, and standards of professional conduct and practice.”

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\(^1\) See glossary.

\(^2\) This may be expedited or convened IRB review; see section 2, “What is an Institutional Review Board (IRB) and who can be members of the IRB?” and \textit{45CFR46.108-111} for more information about IRBs and IRB review.
3. **What is an IRB Authorization Agreement (IAA)? What is a reliance agreement?**

An IAA is a formal written agreement between at least two institutions, where one institution or organization relies upon, or “cedes” IRB review to, another institution with an IRB. An IAA may also be called a reliance agreement. **OHRP explains** that an IAA must outline this relationship between the institutions, and include a commitment that the reviewing IRB will follow the requirements of the relying institution’s FWA.

Institutions may use a [sample IAA template](#) developed by OHRP, or institutions may choose to develop an agreement for the reliance arrangement (for a specific study, a group of studies, or a master agreement that may be used among institutions as needed). In any case, the signed agreement must be kept on file at all signatory institutions, and must be made available if requested by OHRP or any US federal department or agency conducting or supporting research to which an institution’s FWA applies.

**OHRP has outlined** the benefits of relying on a single IRB for multicenter research, and the [US Food and Drug Administration](#) has developed guidance about utilizing a centralized IRB process.
II. Information for Community Partners (e.g., community organizations, private practices, and independent or community clinics)

1. Our organization has been invited by another institution to help conduct a research study that involves human participants. What should we consider before agreeing or declining?

Deciding whether to conduct a human research study is an important decision. It is advisable to discuss the proposed research with the leadership at your organization, the overall study principal investigator (PI)\(^3\), members of the study team, and your organization’s general counsel (if you have one). Typically, organizations consider several questions when deciding whether to take part in a research project, including:

1. Do we have the appropriate and necessary experience to conduct the human research?
2. Do we have the human and financial resources to conduct the research safely and in a timely manner?
3. Do we have the necessary infrastructure, and do our staff have the time required to conduct the study?
4. Are we interested in helping to conduct the research and is our organization’s leadership supportive of our participation?

The answers to the questions above will depend on many factors, such as the nature of the study and whether the organization and/or its staff have prior experience conducting human research. Together you should review these issues and identify any outstanding information you need in order to reach an informed decision about whether to conduct the human research.

If your organization decides to commit as a participating site in a human research study, there are several steps you need to take. These steps may include applying for a FWA (if your organization does not already have one) and ensuring appropriate review of the research by partnering with an existing IRB through an IAA, hiring a commercial IRB, or even creating an IRB.

2. How do we know if what we’re being asked to do is human research?

OHRP has created decision charts to help the responsible party at your organization determine if an activity qualifies as human research, and must therefore be reviewed and approved by an IRB in accordance with federal regulations (45 CFR 46). The following decision chart may be particularly useful: “Is an Activity Research Involving Human Subjects?”

The responsible person at your organization must determine, and should document in writing, if the activity meets the criteria for human subject research, as defined by federal regulation:

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\(^3\) The PI is the investigator with overall responsibilities for the study (Read more).
“Research” is defined, in part, as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

A “human subject” is defined as a living individual about whom an investigator conducting research obtains either:
1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

An “intervention” includes both physical procedures used to gather data (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

“Interactions” includes communication or interpersonal contact between the researcher and a study participant.

“Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the study participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving humans.

3. **How do we know if our organization will be engaged in research?**
   Once you have determined that your organization will take part in the proposed human research activities, your organization must assess whether it is considered “engaged in research.” In the context of Federal research regulations, this term has a very specific meaning that has been defined by OHRP. Generally, an institution or organization is engaged in research if its employees or agents intervene or interact with living individuals for research purposes, or obtain individually identifiable private information for research purposes.

   Your organization’s leadership and the collaborating investigator(s) should carefully discuss and detail your role in the human research to determine whether you and your organization are engaged in human research. Carefully review and consider the OHRP Guidance on Engagement of Institutions in Human Subjects Research, as well as the FAQs form OHRP, and the National Institutes of Health (NIH).

4. **What do we need to do to be part of this study?**
   Once your organization decides to participate as a human research study site and determines it is engaged in research, leadership at your site needs to apply for a FWA, or ensure its FWA is current and active, and designate an Institutional Review Board (IRB) to review its research.
Other administrative aspects may also need to be addressed, including establishing and executing a contract between the sites, ensuring research training is completed and conflict of interest (COI) disclosures are made by all study team members at your institution, etc. Talk with your collaborating institution to ensure that all of the requirements are met.

5. **How do we get a FWA?**

Your organization may apply for a FWA [online]; OHRP has [detailed instructions](#) about how to file for a FWA. It is important that the person who is responsible for overseeing the human research protection program (HRPP) at your organization read this information carefully and understand the commitments your institution will make. In particular, make sure you understand the “[Terms of the Federalwide Assurance for the Protection of Human Subjects (FWA)](#).”

6. **The terms of the FWA mention that our organization must have certain written policies, is that correct?**

Yes. OHRP requires that the organization requesting a FWA have “…established written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any US federal department or agency conducting or supporting the research (or designee), and OHRP…” regarding each of the following:

1. Unanticipated problems involving risks to study participants or others;
2. Serious or continuing non-compliance with the applicable US federal regulations or the requirements or determinations of the IRB(s); and
3. Suspension or termination of IRB approval.

Or, your institution may have a policy that states that it will comply with the human research policies of the reviewing IRB. It should be noted, however, that some IRBs/institutions require a relying organization to have their own policies for the reporting requirements outlined above. Make sure to discuss this with the reviewing IRB, as it may have a policy on this issue.

7. **Who is our Signatory Official?**

The Signatory Official for the FWA is the person responsible for assuring that human research is conducted in compliance with the terms of the FWA. This person is typically the president, CEO, or vice president of a company, or the president, provost, chancellor, vice president, or dean of an academic institution.

8. **Who is our Human Protections Administrator?**

The Human Protections Administrator designated on your FWA should have comprehensive knowledge of how your organization protects human study participants, and be familiar with the organization’s commitments under the FWA. This person plays a key role in ensuring that the organization fulfills its responsibilities under the FWA, and works closely with the Signatory Official to design and carry out the roles and responsibilities of your institution’s human research protection program (HRPP).

9. **How long is a FWA valid? Does it need to be updated?**
A FWA is effective for five years and must be updated within 90 days of any changes (e.g., change to the legal name of the organization, change of the Signatory Official or the Human Protections Administrator). To maintain an active FWA it must be renewed every five years, even if changes have not occurred.

10. Does our organization need an IRB?
To apply for a FWA, an organization must designate an IRB that will review human research for the institution. This means that there must be an IRB associated with your organization. Your organization may designate an IRB by:

1. Forming its own IRB,
2. Hiring a commercial IRB, or
3. Asking another institution that has an IRB if it will serve as your institution’s IRB.

11. Which should we do first, obtain the FWA or register our IRB?
It depends. Consult the OHRP guidance for help answering this question based on your organization’s circumstances.

12. If we decide to form our own IRB, are there rules and procedures we need to follow?
Yes. In addition to complying with the Department of Health and Human Services and/or US Food and Drug Administration regulations on IRB membership requirements, federal regulation, and the terms of the FWA require an IRB to have written procedures for:

1. Conducting initial and continuing IRB review of research and reporting IRB findings to the investigator and the institution;
2. Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
3. Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

13. What if our organization decides to hire a commercial IRB? How do we do that?
There are many commercial IRBs from which to choose. The person responsible for your human research protection program (e.g., the Signatory Official or the Human Protections Administrator) can search online for commercial IRBs or may decide to ask an experienced researcher or other knowledgeable colleague for suggestions or recommendations. Commercial IRBs typically do not have a FWA, but will be registered with OHRP and therefore will have a registration number.

14. How do we go about asking another institution that has an IRB if they will serve as our IRB?
Your organization should contact the IRB leadership at the institution. This can be done by phone or in person, but it is more commonly done in writing. In this initial communication, you should include:

1. The reason for your request;
2. Whether your organization has previously conducted human research;
3. Whether the staff who will conduct the study at your organization have experience conducting human research;
4. Confirmation that your organization has the required written procedures (a copy should be included with the request); and
5. An outline of the study procedures that will be performed at your organization and who will perform them.

Some IRBs may have additional questions or specific reliance forms for you to complete. Requesting that another institution serve as your IRB is a significant undertaking for both parties. *It should not be assumed that because a request is made, the institution will automatically agree to the arrangement.* In addition, such requests may take time, especially if a prior relationship does not exist between the institutions. For example, it can take time for the institutions to negotiate the terms of an IAA or draft required policies. It is important to plan accordingly and allow sufficient time to reach an agreement.

Note: You should not designate an IRB on your organization’s FWA until the institution’s leadership has agreed to the IAA.

15. **What are our responsibilities in an IAA?**

The Signatory Official and Human Protections Administrator are responsible for ensuring that your organization meets the terms of the FWA. They share responsibility with your organization’s PI for ensuring that all of the research personnel at your organization comply with the research policies. Depending on the terms of the IAA, you may also be responsible for conducting periodic monitoring/auditing of the research at your organization. The type and frequency of the monitoring often depends on the type of research study, as well as the research experience of the staff.

While the US Food and Drug Administration has provided guidance on *Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring*, talk with the institution with which you are partnering about your responsibilities and appropriate monitoring plans. Institutional policies usually establish monitoring expectations and requirements.

16. **What does an institution consider when deciding to accept IRB oversight for another institution/organization?**

Common considerations include:

1. The type and nature of the research
2. The potential risks to study participants associated with the research study
3. The prior human research experience of the personnel
4. Whether there is a prior relationship between the institutions and/or PIs
5. Whether the research is within the institution’s mission
6. The research history of the PIs (*e.g.*, any non-compliance issues, such as not following research rules, regulations, and policies)
7. The location of the site, including ease of on-site monitoring at the ceding institution
8. The funding source for the research.

Per OHRP, institutions are responsible for ensuring that all IRBs designated under an OHRP-approved FWA “possess sufficient [knowledge of the local research context] to satisfy these requirements. This responsibility endures regardless of the IRB’s geographic location relative to the institution and the research. It is particularly critical where the research involves greater than minimal risk to study participant or vulnerable categories of subjects.” The FDA has a similar guidance pertaining to non-local IRB review.

17. **What policies will we follow?**

It’s important that you know which research policies you or your institution are expected to follow, including policies on research education and conflict of interest. Your organization may have its own research policies, or your organization might follow the policies of the institution with the IRB. Sometimes an institution will not agree to be the IRB for an organization if the organization does not have its own policies. It is important that you and your organization know and understand the policies.

If you or your organization will follow the policies of the institution on which you are relying, make sure that you receive a copy of the policies and review them carefully. It is the responsibility of your local site PI and your organization’s research leadership (i.e., the Signatory Official and Human Protections Administrator) to ensure that all of the research personnel at your site are familiar with and comply with the policies and expectations of the reviewing IRB, and to avoid issues arising from non-compliance. Establish a plan to periodically review policies, including orienting new study team members to the policies, and a plan for ensuring the study team is notified when a policy is revised or a new policy is released.

Sample IAA Templates have been created in order to help you understand the common terms. Please see the templates in Section IV.

18. **Who drafts the IAA?**

While OHRP has created an IAA template, most institutions have created a refined and tailored version. If you are partnering with another institution and your organization will give up (or “cede”) IRB oversight to another institution, consult with the reviewing IRB to determine who will draft the agreement.
III. For Researchers

Deciding whether to collaborate with a community partner on a human research project is an important decision. If you are an academic researcher who might partner with a community organization, private practice, or independent or community clinic to conduct such a study, you should consider the following:

1. Is your institution willing to let your IRB be the IRB of record for another institution or organization? As soon as you decide to partner with another site, contact your IRB office/IRB leadership. They can help guide you on the policies, process, and procedures; every institution approaches these requests differently and the process takes time.
2. Do you and your institution have the appropriate experience, funding, and support to ensure that the research is conducted safely and compliantly at the community organization(s)?
3. Does your partner site have the appropriate and necessary experience to conduct human research safely compliantly, and in a timely manner?
4. Does your partner site have the necessary infrastructure and personnel to conduct the study?
5. Is your institution’s leadership supportive of your collaboration with the organization?
6. Do you have the time to oversee the research and ensure study participant safety and data integrity at that site?
7. Does the partner organization understand what is being asked and what is expected of them?

Considerations for the Overall PI

Partnering with a community organization on a research project also carries many responsibilities for the overall study PI. As the overall PI, you and the site PI at the organization are responsible for ensuring the research is conducted in accordance with the IRB-approved protocol; you are responsible for the research staff at the community site, as if they were conducting the study in your institution.

As the primary point of contact for the community site, you are expected to help guide them through the entire research process. You need to know if your partner organization has a FWA; this information is publicly available through an OHRP database. If a community partner is relying on your institution’s IRB, you also need to understand the research policies and the terms of the IAA, as they relate to your institution and the relying institution.

A monitoring plan must be developed with the partnering institution; this plan must outline the frequency of monitoring, who will conduct the monitoring, what will be monitored, and other relevant details. Your institution probably has a research monitoring/auditing program, and tools, templates, and other resources may be available.

As the PI, you remain responsible for ensuring IRB review and approval is current, including submitting information to the IRB and FDA as required, and in a timely manner for continuing review. You are responsible for reporting serious adverse events and unanticipated problems to the IRB from all the sites engaged in the research and informing the partnering site when amendments have been made or revised documents (e.g., advertisements, informed consent forms) have been approved for use.
It is important that you have a written plan for how the sites will communicate with each other, including what information is to be communicated, how it will be communicated, to whom communications will be sent, and the timeframe for communicating the information (e.g., adverse events must be reported to the PI within five days). A plan should also be carefully documented on how and when new research team members at the institution and the participating organization will be oriented to these issues.
IV. Sample Templates and Agreements

These sample templates provide starting points for researchers at institutions as they consider entering into agreements. The specific content must be determined by the parties based on the nature of the research, and must be consistent with each institution’s policy requirements, as advised by institutional officials, research leadership, legal counsel, and others.

Disclaimer: These sample authorization agreements are provided for informational purposes only and do not constitute legal advice or opinions as to current laws, regulations, or guidelines. In addition, new laws, regulations, and guidelines are issued on a continuing basis, and institutional requirements vary. These sample documents are not a reflection of all current applicable laws, regulations, guidelines, or institutional requirements relating to authorization (reliance) agreements. While reasonable efforts have been made to ensure the accuracy and completeness of the information provided, in the ever-changing regulatory environment, institutions should consult with regulatory affairs and legal advisors regarding current applicable laws and regulations prior to executing agreements.

For Community Organizations

Community organizations with an IRB, choosing to accept or to cede IRB review

➢ Template 1, IRB Authorization Agreement (PDF) from the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP)

Community organizations without an IRB, choosing to delegate or cede IRB review of research to another institution with an IRB

➢ Template 2, IRB Authorization Agreement (PDF) for delegating the review

For Academic Research Institutions

Authorization and Reliance Agreement Sample Policies (Coming Soon)
These sample templates provide starting points for researchers at institutions as they consider entering into agreements. The specific content must be determined by the parties based on the nature of the research, and must be consistent with each institution’s policy requirements, as advised by institutional officials, research leadership, legal counsel, and others.
V. Additional Resources

Request Harvard Catalyst’s Human Subjects Training for Community Partners

This training is for community partners and/or lay individuals engaged in the conduct of human research. In addition to focusing on the ethical conduct of working with research participants, this training helps educate community partners on their roles and ethical responsibilities during the research project. Request training.

Regulations and Additional Resources

The following resources may be helpful to investigators and institutions or organizations, depending on the type of study that will be conducted. They may also help less experienced researchers or organizations form an IRB, or keep them apprised of additional human research regulations not addressed above.

Massachusetts Statutes and Codes:

- M.G.L. c. 94C §8 (Controlled Substances in Research)
- 105 C.M.R. 700.009 (Controlled Substances in Research)
- M.G.L. ch. 111L (Human Embryonic Stem Cell Research)
- 105 C.M.R. 960.000 (Human Embryonic Stem Cell Research)
- M.G.L. ch. 111, §70E (Patients Rights/Informed Consent)
- M.G.L. c.111 § 70F (Consent to HIV/AIDS Testing)
- M.G.L. c.111 § 70G (Genetic Privacy)
- M.G.L. c.112, §12F (Consent by Minors)
- M.G.L. c.112, §12J (Experimentation on Fetuses)
- M.G.L. c.201D.6; 2-1-2 to 201-4 (Health Care Proxies)
- M.G.L. c.201, §§6-6B (Guardianships)
  - Section 6. Mentally ill persons
  - Section 6A. Mentally retarded persons
  - Section 6B. Persons unable to make or communicate informed decisions
- 104 C.M.R. 31.00 (Department of Mental Health Research)
- 115 C.M.R. 10.00 (Department of Mental Retardation Research)

Establishing an IRB:

- Association for the Accreditation of Human Research Protection Programs (AAHRPP) Accreditation Procedures & Standards
- AAHRPP IRB Evaluation Checklist (MS Word): Determine whether an IRB meets accreditation standards
- AAHRPP Tip Sheet 24, Relying on an External IRB
- The Community IRB Member: Neighbor and Partner
- University of California Guide: What it Takes to be an IRB Community Member
- National Cancer Institute Central IRB Initiative
- U.S. Department of Veterans Affairs (VA) Central Institutional Review Board
- Use of Central IRBs for Multiple Center Clinical Trials
- Considerations To Support Communication Between Institutions Inside and Outside IRBs When Responsibilities Are Being Assigned for Multicenter Clinical Trial Protocols (PDF)
VI. Glossary

Commercial IRB: Commercial IRBs are for-profit boards that complete IRB reviews in exchange for fees. They are not associated with an academic institution or hospital; commercial IRBs must register with OHRP, but do not have a Federalwide Assurance (FWA).

Department of Health and Human Services (DHHS): The mission of the US Department of Health and Human Services is to enhance and protect the health and well-being of all Americans. This is fulfilled by providing effective health and human services and fostering advances in medicine, public health and social services. Both OHRP and the FDA are part of the DHHS.

Engagement/Engaged in Research: Engagement in research, as it relates to the regulations governing human research, has a specific meaning defined by the Office for Human Research protections (OHRP). Generally, an institution is considered engaged in research when the institution’s employees or agents intervene or interact with living individuals, or obtain individually identifiable private information for research purposes. The OHRP Guidance on Engagement of Institutions in Human Subjects Research is a helpful resource to determine if your institution is engaged in research. These OHRP FAQs and the National Institutes of Health FAQs may also be useful.

Federalwide Assurance (FWA): A FWA is an “assurance of compliance” that an institution will follow Federal Regulations governing human research.

Food and Drug Administration (FDA): The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and radiation emitting products.

Human subject/participant: Also called a study participant or volunteer. A living individual, about whom an investigator conducting research obtains either:

1. Data through intervention or interaction with the individual, or

2. Identifiable private information.

Human Protections Administrator (HPA): The HPA is designated on an institution’s FWA. This person should have comprehensive knowledge of all aspects of the institution’s system of protections for human subjects, as well as be familiar with the institution’s commitments under the FWA. This person plays a key role in ensuring that the institution fulfills its responsibilities under the FWA, and works closely with the Signatory Official to design and carry out the institution’s human research protection program (HRPP).

Human Research Protection Program (HRPP): “HRPP” is a general term used to refer to an integrated institution-wide program that contributes to the protection of study participants. The purpose of a HRPP is to ensure that research involving humans is conducted ethically and in compliance with applicable laws, regulations,
and policies, and promotes the safety, rights, and welfare of study participants. The term HRPP is commonly understood to include a number of offices, such as the IRB, sponsored research/grants & contracts, conflict of interest, research education, Quality Assurance (QA)/Quality Improvement (QI) and auditing, as well as scientific review committees, investigational drug services, etc.

**Institutional Review Board (IRB):** A Federally mandated committee whose responsibility is to protect safety, rights, and welfare of research participants.

**Intervention:** Interventions include physical procedures by which data are gathered, as well as manipulations.

**Interaction:** Interactions include communication or interpersonal contact between a researcher and a study participant.

**IRB Authorization Agreement (IAA):** A formal written agreement between at least two institutions, where a site relies upon or “cedes” review to one of the other institution’s IRB. Also referred to as a reliance agreement.

**Office of Human Research Protections (OHRP):** A Federal agency within the Department of Health and Human Services (DHHS) that provides leadership in the protection of the rights, welfare, and well-being of humans participating in research conducted or supported by the DHHS. OHRP helps ensure the protection of the rights, welfare, and well-being of study participants by maintaining regulatory oversight, providing clarification and guidance regarding the regulations, developing educational programs and materials, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

**Private information:** This includes information about behavior that occurs in a context in which a person can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by a person and which that person can reasonably expect will not be made public (e.g., a medical record). Additional information on this topic is available here.

**Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Signatory Official:** A high level institutional representative who is responsible for assuring that research involving human subjects is conducted in compliance with the terms of the institution’s FWA.