

Protecting Research Participants: Training for Community Research Assistants

PROJECT SPECIFIC INFORMATION

IRB Protocol Title:

IRB Protocol #: _____

Approved: _____

Principal Investigator

Name: _____

Phone: _____

Email: _____

Address:

Other Contact Person

Name: _____

Phone: _____

Email: _____

Address:

Franklin University

Institutional Review Board

201 South Grant Avenue

Columbus, Ohio 43215

Phone: 614-947-6037

Email: irb@franklin.edu

Dear Research Assistant,

Thank you for becoming a member of a Franklin University Research Team! We hope this research project will be a great experience, not only for you, but for your community. As a member of both the community and the research team, you have a very special role to play in this project. It is your job to help the community understand the research and to help the researchers understand your community.

Franklin University requires training for all members of the research team working with research participants or their information. There are two parts to this training. The first part is training in the specific things you have to do as part of your job. The second part is training in "Human Subject Protections". This training discusses the rights of everyone who participates in research and the responsibilities of the research team to protect the participants' rights and make sure those rights are not violated. The series of questions and answers in this booklet will give you a brief introduction to the US laws that define the rights of research participants and why they were developed. It also covers some of the procedures that Franklin University has put in place to make sure our research projects follow those laws.

If you would like to learn more about any of the topics covered in this booklet, please contact us and we will be happy to give you more information or answer any questions you may have.

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Do research participants really need protection?

Most research has had a very positive impact on the lives and health of people living today. Unfortunately, some research projects have harmed the people being studied. One example is the research done by Nazi scientists on Jewish prisoners to study the effects of long-term exposure to cold. In this case, concentration camp prisoners had no choice and the study procedures were a form of torture (people were exposed to cold temperatures until they died). The Nazis were not the only ones to do horrible things in the name of research. The US Public Health Service did a study of syphilis in African American men in Tuskegee, Alabama, from 1932 to 1972. These men were not told that they were being studied. The scientists said they were getting free treatment for “bad blood” when they were actually studying the effects of the untreated disease over time. Treatment was not given to these men even after a cure for syphilis was discovered in the 1940s. People were so upset about the Tuskegee Syphilis Study that the US government developed the first laws to protect humans in research. There are also examples of research done in American Indian and Alaska Native communities that harmed participants or their communities. The Barrow Alcohol Study and the research done with the Havasupi tribe in Arizona are two examples.

Franklin University wants our researchers to do the best research possible, but it must also be good for the people and communities involved. Franklin wants to be a good neighbor to the people and communities we work with. That means being open and honest about our research projects. It also means that we want our researchers to share what they are learning with the people and communities that are kind enough to help them.

Are there laws and regulations that require the protection of research participants?

Many international groups and government agencies have guidelines on how to do human subjects research ethically, but the most important ones for the United States are the Belmont Report and the Common Rule. The Belmont Report is a summary of the findings of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This report sets the basic ethical principles that apply to all research with human participants. These principles are beneficence, justice, and respect for persons.

The principle of beneficence requires that researchers respect a person’s wishes and protect them from harm. Two general rules summarize this principle: 1) do not harm, and 2) do as much good as you can while reducing the chance of harming anyone.

The principle of justice is another way of saying that the research must be fair. This applies to many areas of research. For example, participants must be picked fairly, so no group is chosen or excluded; such groups might be women, minorities, people in jail, people with a disability, or any other group. Another example is that everyone in the research must have the same access to any good that comes out of the research. This might be a better treatment that was developed from the research.

The principle of respect for persons has two main parts: 1) each person should be allowed to make their own decisions, and 2) people who are not fully able to make their own decisions (children, for example) must be given extra protection. The first part means that each person has to be given enough information about the research, especially about the risks and benefits, so they can choose whether or

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not to participate. Respect for persons also means not pressuring someone into participating. Many people now include respect for community, culture, and tradition as part of respect for persons.

The Department of Health and Human Services (DHHS) used the Belmont Report as the basis for the first and current US laws protecting research participants (Title 45 of the US Code of Federal Regulations Part 46 Subparts A-D). In 1991, fourteen other US agencies and departments agreed to use Subpart A of the DHHS regulations. Those regulations are now known as the Common Rule. All research done at Franklin University or by Franklin researchers must follow the Common Rule.

What is an Institutional Review Board (IRB) and who is on it?

One of the things required by the Common Rule is that all human subjects research be reviewed and approved by an Institutional Review Board (IRB). The IRB must have members that are scientists, members that are not scientists, and a least one member who has no ties to Franklin University. The IRB must have both men and women and be ethnically diverse.

As of 2020, there are nine members of the Franklin University Institutional Review Board. The IRB Office provides support for the IRB by scheduling meetings and handling all of the paperwork. This office also helps research participants who have concerns about a research project. Another job of the IRB Office is to provide educational training to Franklin faculty and staff about how to do research with human participants ethically.

What does the Franklin Institutional Review Board (IRB) do?

The main job of the IRB is to protect the rights and welfare of research participants. The IRB needs to be convinced that the research will be useful and that it has the potential to do some good and provide useful information. Although it is not a requirement, the IRB also tries to make sure that researchers are not wasting the time of the people who have agreed to participate. Most of the IRB's review focuses on how the researchers will be interacting with participants. This is to make sure that each person knows that it is his/her choice whether or not to participate. The IRB tries to make sure that people are given enough details about the research, including its risks and benefits, to make that decision.

The IRB requires researchers to explain how they plan to protect the information they collect, where it will be stored, and what will be done with it at the end of the research. Because IRB review focuses on protecting the rights of research participants, it is very different from reviews done by Medical Ethics Review Boards and Peer/Scientific Review Boards that focus on the research question, procedures, and analysis.

What is the difference between privacy, confidentiality, and anonymity?

Here are some definitions that may help explain how these three terms differ from each other.

- Privacy means that each person has the right to determine what they want to share with others and when and where that will take place.
- Confidentiality means that when information is given to someone they trust (a researcher, for example), it is understood

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that it will not be shared with others without their permission.

- Anonymity means that no one will be able to link the information a person provides to that person.

In most types of research, researchers can promise confidentiality but not anonymity. An example of anonymous research information is when the participant fills out a survey and mails it back without having to put their name or anything else that could identify them on the form. Some examples of identifying information are social security number, address, or date of birth.

What does “informed consent” mean?

Informed consent means that people are given enough information about the research to make their own choice about whether or not to participate. Whenever a researcher asks for someone’s informed consent, they need to provide the following information:

- An explanation of the purpose of the research.
- A description of the research procedures involved and what participants will be expected to do. It should also clearly state what the researchers will do.
- A clear description of the possible risks to the research participant, if there are any. This may be the chance of being hurt physically, feeling uncomfortable, or becoming upset or embarrassed.
- The realistic possible benefits of the research to the individual and to society.
- How long the participant is expected to be involved in the research and how much time it will take. The participants should also be told what will be done with their information or samples at the end of the study.

- The researcher must tell participants if they will receive any payment for being in the research.
- Participants must be given the name and contact information for the person who can answer any questions they might have about the research.
- A statement that being part of the research is voluntary (your choice). Researchers may not include anyone in a study without that person’s permission. They are also not allowed to pressure people into being part of the study. They must let participants know that there is no penalty for not being in the research. It must also be clear to participants that they can stop at any time and have their information removed from the research. Participants will not be asked to pay for or return any gift or payment they received for being in the research if they decide to quit the study.
- The researchers must also explain how they will protect participants’ personal information and that participants have the right to confidentiality (their personal information will not be shared with anyone unless they give written permission).

Getting and giving informed consent should be a process. Participants have the right to ask questions and have them answered at any point in the research. Researchers must also give participants new information (for example, about risks or benefits) as it becomes available. The researchers must also ask participants for their consent for any additional tests or procedures added after the initial consent. Again, participants must be given the opportunity to say no to any new procedures. There are two types of permission that may be needed.

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- 1 Consent – This is when an adult (18 years old or older) agrees to be in a study. In the US, a parent or guardian is required to give consent for a child to be involved in research.
- 2 Assent – In addition to the parent’s consent, researchers must give children ages 7 to 17 information about the study using simple terms that they can understand. The child can then give assent to be in the study or they can refuse (even if their parent gave consent). In most cases, researchers must get consent and assent in writing.

When research is done in certain communities, researchers may have to ask for permission from the local government, village council, or other group representing the community. Even when the community has given permission for the research, each individual is allowed to make his/her own decision about whether or not to participate.

In some types of research, mail out surveys for example, the information provided by the researcher may be very brief or not very detailed. With this type of research, it is up to the individual to decide whether or not they have been given enough information to make an informed decision. If the researcher does not provide enough information, the participant can choose not to complete the survey.

What are the responsibilities of the Principal Investigator?

The person in charge of the whole research project is called the Principal Investigator. This is usually the person who had the idea to do the research in the first place, wrote a proposal to do the research, and possibly received a grant. This person is responsible for making sure the research is done correctly and that good

scientific methods and ethical practices are followed. The Principal Investigator is the person responsible for getting approval from the IRB and the Community before starting the research. This person must also get permission from the IRB before they make any changes to an approved research project.

Another responsibility of the Principal Investigator is to make sure that everyone working on the project is trained on how to do their job. This includes making sure that everyone knows what information must be protected and how to protect it. The Principal Investigator is ultimately responsible for making sure that all participants have given informed consent and that the research team fulfills all of its obligations to each research participant.

What are the responsibilities of research personnel who enroll and work with research participants?

People who are involved in recruiting research participants, obtaining informed consent, and collecting personal information have a lot of responsibility. Both the Principal Investigator and the research participants have put their trust in you, and you have responsibilities to both.

Your responsibilities to the Principal Investigator are to always follow the approved IRB Protocol, keep good records, and follow any other specific instructions related to the research project. The Principal Investigator and other members of the research team are relying on you to ask questions when something is unclear and to immediately report any problems or concerns related to the research.

Your responsibility to the research participants is to be open and honest about the research and to answer any questions they might have

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about the research procedures. This is a very important part of the informed consent process. If you do not know the answer to a question, tell the participant that you will find out or have someone else get back to them. Remember to be patient with each participant because even though you may have done a procedure many times, they have not. You are also responsible for respecting each participant's privacy and protecting the confidentiality of their information by not discussing it with anyone outside the research team. This means you cannot discuss one participant's information with another participant even if they are a family member.

What should I do if I have a problem or concern about the research or research personnel?

Whenever possible, you should talk to the Principal Investigator about any problems or concerns so he/she can answer your questions and take care of the problem. If you are not comfortable talking to the Principal Investigator or if you think he/she did not handle the situation properly, please contact the IRB Office so we can help. Our phone number in the United States is (+1) 614-947-6037 and our email is irb@franklin.edu. If it would be hard for you to contact the IRB Office, there may be a local contact on the participant consent for the research and you can also contact that person.

What should I do if a participant has concerns about the research or research personnel?

Encourage them to contact the Principal Investigator, the IRB Office, and/or the other local contact on their consent and tell us the concerns. Many concerns can be dealt with in a simple conversation or with minor changes. Please remind the person that they can always change their mind about being in the research project. If they would like to quit the research

project, they can contact either the researcher or other people listed on their informed consent form or the IRB Office.

Why was I given a copy of the IRB Protocol?

Everyone working on the research project should have an up-to-date copy of the research protocol so they know what they can or cannot do. If you have not been given a copy of the research protocol, you should ask the Principal Investigator for one. The protocol describes all allowable procedures, the approved consent process, and includes copies of the consent forms and other materials for the participants. One of the conditions of IRB approval of the protocol is that all personnel agree to follow the same set of procedures. No research project is ever perfect, but only the Principal Investigator can ask the IRB for changes to the approved procedures, consent process, or documents. No changes may be made until the IRB has reviewed the request and approved it.

QUIZ

Instructions: Choose the best answer for each of the following questions.

1. Which of the following is NOT one of the ethical principles described in the Belmont Report?
 - A. Respect for Persons
 - B. Beneficence
 - C. Anonymity
 - D. Justice
2. The IRB requires that all research information be anonymous. Hint: Remember, we are not just talking about the research project you will be working on!
 - A. True
 - B. False

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3. Which U.S. government agency developed the first regulations (laws) to protect the rights of research participants?
 - A. Department of Education
 - B. National Science Foundation
 - C. Department of Health & Human Services
 - D. Justice Department
 - E. National Commission on Human Rights
4. Which Franklin University office should you contact if you have a concern or complaint about a research project involving human research participants that you think was not handled properly by the Principal Investigator?
 - A. Registrar
 - B. Doctoral Studies
 - C. President's Office
 - D. The Principal Investigator's Academic Department
 - E. IRB Office
5. Who is responsible for protecting the rights of research participants?
 - A. Research Staff/Personnel
 - B. Principal Investigator
 - C. Institutional Review Board
 - D. All of the above
6. Children (7 to 17 years old) must assent to being involved in research.
 - A. True
 - B. False
7. Which of the following does NOT have to be a part of the information given to someone when they are asked to be part of a research project?
 - A. Instructions on how to withdraw from (quit) the study.
 - B. The names of everyone who will have access to their information.
 - C. A description of the study.
 - D. How the researchers will protect the personal information of participants.
 - E. A description of the potential risks to the participant from being in the study.
8. The main job of the Institutional Review Board (IRB) is to:
 - A. protect Franklin University from bad publicity
 - B. protect the Principal Investigator from lawsuits
 - C. make sure that researchers do what they received money to do
 - D. train people in how to do research
 - E. protect the rights of Research Participants
9. Which principle described in the Belmont Report requires that all research participants have the same access to any good that comes out of the research?
 - A. Respect for Persons
 - B. Responsibility to do good science
 - C. Beneficence
 - D. Justice
 - E. Anonymity
10. What is the responsibility of a member of the research team (like you)?
 - A. Be open and honest with research participants
 - B. Ignore participant's questions if you do not know the answer
 - C. Respect each participant's privacy and protect the confidentiality of their information
 - D. Report problems and concerns
 - E. Answers A, C and D

Thank You!