TRAINING IN HUMAN RESEARCH PROTECTIONS

Participant Workbook

CIRTification was developed by Emily E. Anderson at
The University of Illinois at Chicago Center for Clinical and Translational Science.

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About CIRTification

CIRTification is a human research protection training program designed specifically for community research partners who do not have prior background or experience with research or familiarity with research ethics.

Copies of all materials are freely available for download from the University of Illinois at Chicago (UIC), Center for Clinical and Translational Science, Community Engagement and Research Core: **www.go.uic.edu/CIRTification**

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Background and Rationale for CIRTification

Defining Community Engagement

In community-engaged research, academic researchers collaborate with many different types of partners. These may include people from community agencies, health care delivery organizations, departments of public health, schools, and other kinds of organizations. Together, academic and community partners identify research priorities, design projects, recruit participants, collect data, deliver interventions, analyze data, and disseminate findings.

Community research partners are thus defined as individuals from non-academic settings who collaborate with university investigators to develop and implement research projects.

The Goals of Community-Engaged Research

Academic researchers work with community members and organizations to make sure that research and the information researchers collect is as useful and relevant as possible to the lives of real people. Community engagement also ensure that the views and voices of community members are included in important decisions about who participates, what problems are studied, and what procedures are acceptable.

The Strengths of Community-Engaged Research

Non-academic community partners have significant knowledge about the communities in which they work and their community members' strengths and challenges. They have ideas about how to approach problems, and they are a rich source of information for university researchers regarding the needs, preferences, and activities of people living in their communities. They have many skills and talents gained from training and experience related to their careers and other interests.

Community research partners bring many strengths and assets to research partnerships, but many have little to no prior research training or experience. According to the policies of many academic institutions, community partners may be required to complete approved "human subjects protection training" (this is also sometimes referred to as "IRB training"). Training is usually required when individuals interact with research participants and/or handle research data. *CIRTification* is tailored to the unique roles of community research partners and was designed to substitute for or supplement the standard "human subjects protection training" required by many institutions.

How to Use This Workbook

CIRTification will be taught by a facilitator who may be a community partner, a study investigator, or someone who teaches research ethics. This workbook provides materials for you to follow along with the facilitator. We hope these materials are a valuable a resource to you when you begin working on a research project.

PART 1

HUMAN RESEARCH RULES + REGULATIONS

Glossary of Key Terms

Beneficence (Benefit): Researchers should not knowingly harm research participants. Researchers should also try to prevent or minimize potential harms and provide benefits to participants if possible.

Community Engaged Research (CEnR): Research conducted jointly between academic institutions and community partners. These may include people from community agencies, health care delivery organizations, departments of public health, schools, and other kinds of organizations. Together, researchers and community partners identify research priorities, design projects, recruit participants, collect data, deliver interventions, analyze data, and disseminate findings.

Data Collection: The process of getting information. Data collection may include contact with research participants. Surveys and interviews involve talking with participants and asking them questions to get information. Data collection can also include observation. Research may involve watching people do something, such as grocery shopping, and writing down information about them and what they do. Data collection can also involve getting information about people from medical, laboratory, or school records.

Ethics: A set of rules (either belonging to an individual or shared by a group) for right actions.

Human Research: A study that collects information from or about living people.

Institutional Review Board (IRB): A committee that reviews research to ensure that participants will not be harmed. Any organization that conducts research with people must have an IRB or find one from another organization to review their research. IRB members include researchers with different kinds of expertise as well as people who do not work for the institution. A research project must be approved by an IRB before it can start.

Justice: It is a rule in research that researchers should be fair in choosing who they ask to take part in research. All groups of people should be included in research. The risks and benefits of research should be shared by everyone.

Minimal Risk Study: A study that does not involve any harm or discomfort than is more than what someone might face in their daily life. Studies that involve more than minimal risk must follow extra rules.

Principal Investigator (PI): The lead person who is responsible for a research project. The PI is often a scientist from a university but can also be a community partner.

Research: A planned study to better understand a question or problem.

Research Participant (Human Subject, Research Subject, Subject, Participant): A living person about whom information is collected in research. We prefer the term "participant" rather than "subject." Participant implies active engagement in the research (research with participants) rather than passive involvement (research on subjects). However the term "human subjects" is still used in many formal research-related documents and guidelines.

Research Protections: Rules that researchers should follow to make sure that research participants are not harmed. Specific protections include providing participants with adequate information and obtaining informed consent; minimizing risk; and monitoring study data. Federal guidelines for research are in the Code of Federal Regulations, 45 CFR 46.

Respect for Persons: It is a rule in research that people should decide for themselves whether or not they want to take part. If a person does not have the ability to decide for themselves due to their young age, poor health, or some other disadvantage, then the person who makes the decision for them should be looking out for their well-being.

Risk: The possibility that harm may occur.

Risk/Benefit Ratio: The balance between the risk that a research study poses and the potential benefits that it may provide. The greater the risks of research, the greater the benefit it must offer directly to participants in order to be considered ethical.

Study Sponsor (Funder): The organization that financially supports a research project through a grant or contract. Depending on the funder, the researcher may have to meet specific requirements (for example, a final report).

Introduction

Research that involves human participants comes with special responsibilities. There are specific federal guidelines for human research that aim to protect research participants from harm. Everyone involved in human research must be aware of and follow these guidelines.

Research has important social value. It can help us find answers to important questions and improve human health and well-being. Therefore it is very important that the public trust research and the work that researchers do. Having rules and regulations for research helps protect participants and therefore promotes public trust.

Your research responsibilities may include approaching individuals, informing them about a research study, and asking them to participate. It is important to keep in mind that the people you encounter may have opinions about or experiences with research that may affect how they react to you.

Some groups – for example, minorities, women, children – have been excluded from research participation and therefore have not received the benefits of research. Mistrust and fear of research also prevents many people from participating in research, particularly those from groups that have been the target of past abuses. This lack of representation has contributed to health disparities in the US.

It is important that research rules are followed so that people can trust researchers. Otherwise no one would take part in research, and new discoveries could not be made. Your behavior affects the image of other researchers, and their behavior affects your image.

Collaboration with community partners can greatly enhance research. You are here today as a first step in improving the research process. Your knowledge of research protections can also help keep participants safe from harm.

Take Away Points

1. Human research is regulated by federal guidelines.

2. These rules and regulations are necessary because research has the potential to harm participants (intentionally or unintentionally).

3. These rules and regulations were created based on three key ethical principles:
   a. *Respect for autonomy:* All people should be allowed to make their own decisions. Research participants should have enough information to decide if they want to take part in a research study.
   b. *Beneficence:* Researchers must protect participants from harm and try to provide benefits when possible.
   c. *Justice:* Certain people or groups should not be targeted, used for or excluded from research for convenience. The risks and benefits of research should be shared equally across all groups of people.

4. An institutional review board (IRB) is a committee that reviews research to make sure that the rules for research are followed at the local level. A research project must be reviewed and approved by an IRB before it can start.

5. Researchers must explain to the IRB:
   a. What risks there might be and how participants will be protected
   b. How participants will be identified and invited to take part in research
   c. What participants will be told about the study and how consent will be documented
   d. How information collected about research participants will be kept safe

6. Researcher responsibilities also include:
   a. Conducting research according to IRB policies
   b. Contacting and signing up participants using approved materials and processes
   c. Obtaining informed consent from participants prior to participation
   d. Submitting information about ongoing studies to the IRB for continuing review
   e. Reporting adverse or unanticipated events
   f. Submitting any changes (amendments) for IRB approval

7. Academic researchers work with diverse community partners to: identify research priorities, design research projects, recruit participants, collect data, deliver interventions, analyze data, and share findings.

8. Community-engagement can help protect research participants but can also introduce group-level risks, challenges to privacy/confidentiality, and conflicts or bias.

How Does Human Research Happen?

Research with human participants involves gathering information about people – sometimes directly from them, using surveys or questionnaires.

There are many different kinds of research studies:

- Some research is done in order to get a "picture" of a particular problem.

  Example: How many people in the neighborhood have diabetes?
  Where do they go for treatment?

- Some research is done in order to compare different groups.

  Example: What percentage of men living in the neighborhood have diabetes as compared with the women? Are men or women more likely to follow their doctor's recommendations?

- Some research is done to compare different groups AFTER the environment has been changed, a new policy has been put in place, or a program has been started.

  Example: How much weight on average did diabetic women lose after participating in a special 8-week program as compared to diabetic women who did not participate in the same program?

There are basic rules for conducting research with humans that apply to all studies. The specific actions and responsibilities of researchers may vary depending on:

The design of the study:
- How often will researchers interact with participants?
- Will a new (experimental) program or treatment be tested?

The research question and the topic of the study:
- Is the information being collected private or sensitive?
- Could participants be harmed if the information gets out?

The kinds of people who are going to participate:
- Are you recruiting members of groups that may be disadvantaged and need special protection or consideration (such as children or homeless adults)?

PART 2

ASKING PEOPLE TO PARTICIPATE IN RESEARCH: THE INFORMED CONSENT PROCESS

Glossary of Key Terms

Informed Consent: A person's voluntary agreement to participate in research, based upon good understanding about the purpose, tasks, risks, and potential benefits. In most studies, research participants are asked to sign a ***consent form*** to show that they understand the research and agree to take part. In other cases, participants may provide verbal agreement only. Even when participants are not required to sign a consent form, they must be told enough information about the study to help them make their decision.

Recruitment: The process of finding people to take part in research. Recruitment may involve sharing information in ways that will let individuals who are interested contact the researchers. For example, researchers may post fliers or advertise in the newspaper, providing a phone number that interested people can call. Recruitment might also involve directly inviting individuals to participate. For example, a researcher might get a list of all clinic patients with high blood pressure and send these patients a letter about the study.

Voluntariness (Voluntary): It is a rule in research that the decision to take part in a research study should be made freely. Participants should know that nothing bad will happen if they do not want to take part or if they decide later that they want to stop. Participants should not be convinced to take part in research with large amounts of money or false promises.

Introduction

In research, it is not enough for participants to agree to participate – they must know exactly what they are agreeing to. The federal regulations for research that we discussed in Part 1 outline what details are required for "informed" consent.

It is a pretty universal rule that lying is wrong. In research, this is especially true. Because of all the research abuses that we learned about in Part 1, telling participants the truth about research participation – and not just the truth, but all the important details that might affect participation – is very important.

We are bombarded daily with lots of information, and it can be overwhelming. Life is fast paced, and everyone has busy schedules. Asking people to participate in research is adding to their burden, and asking people to take extra time to read long consent forms can be uncomfortable.

Not reading "the fine print" is very common. We can all think of a time when we have signed something without really reading – a cell phone contract, a child's report cards, petitions, and forms at the doctor's office or the hospital. If you are responsible for obtaining informed consent from research participants, it is your job to make sure they understand the purpose, risks and benefits, procedures, and time commitment involved.

There are many reasons that people may say yes (or no) to research participation. Everyone has different ideas about what risks they are willing to take and what personal information they are willing to share.

It is much harder to say no to someone you know. If you trust the person asking, then it is quite easy to say yes. But research is a unique situation and participating is a personal decision. People may overestimate the benefits of research participation if they know the person asking them.

If the public believes that researchers do not follow rules, lie to participants, and treat them like "human guinea pigs," then people may not want to participate in research. This will limit the ability of researchers to recruit enough people into studies and gather good data. This will have a negative effect on the usefulness of research.

Take Away Points

1. Informed consent is a process, not just a form. Even when a signed consent form is not required, participants must still be told what it is that they are being asked to do.

2. During the informed consent process, potential participants should be told about the purpose of the research, what they will be required to do if they agree to participate, the risks or potential discomforts of participation, how the private information they provide to researchers will be kept confidential, and who they can contact with questions or concerns.

3. Research participation is voluntary. Participants should always be assured that they do not have to take part and if they do enroll they can withdraw at any time. There will be no bad consequences if they decide not to participate.

4. Participants should always have the option to stop participating, and they should be told what steps to take in order to do so in a way that is safe and allows them to decide what is done with their research information.

5. Participants should be told about and recruited to be in research using only the materials and practices developed for the study and reviewed and approved by the IRB.

6. Only those individuals who meet the study inclusion and exclusion criteria should be enrolled. Enrolling individuals who do not meet these criteria can damage the research and make the findings unusable and meaningless.

7. Efforts should be made to ensure that potential research participants understand what their involvement will require – including what they will be asked to do, how long it will take, and what will be done with their information. When participants understand their involvement, then they are able to give true, voluntary, informed consent.

8. Efforts to recruit human participants to participate in research should not pressure people or try to entice them with lies, large amounts of money, or promises of unlikely benefits.

9. Members of disadvantaged groups, such as children and the cognitively impaired, can participate in research, but special care must be taken to protect their best interests.

10. Every member of the research team should be very familiar all the elements of the consent form before they try to recruit participants.

Model Consent Form

MODEL CONSENT FORM

University of Anywhere
Research Information and Consent for Participation in Research
Community Diabetes Study

You are being asked to take part in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you make an informed decision. Please feel free to ask any questions you may have.

This study is being conducted in partnership by researchers at the University of Anywhere (UA) and the North Side Community Health Partnership (NSCHP).

Principal Investigator Name and Title: Anne Smith, Professor
Department & Institution: School of Public Health, University of Anywhere
Address & Contact Information: 101 Main Street, Anytown, Anystate, USA, (555) 123-4567
Email: annesmith@usomewhere.edu
Sponsor: National Institutes of Health

Why am I being asked?
You are being asked to participate in this research because: you are a resident of the North Side community; you are between the ages of 18-64; you have been diagnosed with Type II diabetes within the last year; and your doctor has recommended that you lose 10 or more pounds.

Why are certain individuals asked to participate? What makes someone qualify?

Your participation in this research is voluntary. Your decision whether or not to take part will not affect your current nor future relationships with the UA or the NSCHP. If you decide to take part, you are free to stop at any time without affecting these relationships.

A clear statement that research participation is voluntary and that refusing to participate will not have negative consequences.

Approximately 100 participants may be involved in this research.

How many participants are going to be in the study?

Why is this research being done?
The purpose of this research study is to find out if the "Shape Up, Slim Down" program can help people who have recently been diagnosed with Type II diabetes lose weight. "Shape Up, Slim Down" was created especially for adults who live in large cities who might not be able to find other programs such as gyms or exercise classes. This program will show you ways to exercise at home and give you tips for making healthy meals

What are the researchers trying to learn?

Are any of the procedures new or experimental?

"Shape Up, Slim Down" is considered research because we do not know yet if it will really help.

What procedures are involved?

Participation in this study will involve the following activities:

What will participants be required to do?

How long will participation last?

- First, you will come to one of our 5 community sites for a program orientation. This meeting will last about 3 hours. We will give you more information about the activities discussed below, and we will show you how to fill out the food and exercise diary.

- At this first meeting, you will fill out several surveys that ask about you, your health history, health habits (like what activities you do for exercise and what you eat), and what you know about health, exercise, and nutrition. We will weigh you and measure your body fat. We will also take a small amount of blood (about 2 tablespoons) so that we can measure your blood sugar and cholesterol. We will share this information with you.

- For the first month you are in the program, a North Side Health Expert will come to your home once a week for 2 hours (4 visits total). During the first and third sessions you will be shown some simple exercises that you can do in your home. During the second and fourth sessions, you will learn how to make meals like a little bit healthier. These sessions will be scheduled at the first meeting.

- After Month 1 is over, a North Side Health Expert will come to your home once a month for 1 hour for 5 months (Months 2-6; 5 visits total). You will talk about how you have been using what you learned during the first month. You will discuss any problems or questions that you have. You will schedule these sessions month-by-month.

- Each time the North Side Health Expert comes to your home, you will complete a short questionnaire about diet and exercise, you will be weighed, and your body fat will be measured. This all will take about 15 minutes of the total time he or she is at your home.

- You will be asked to write in a food and activity diary every day for all 6 months that you are in the program. This will take 5 minutes each day. We will show you how at the first meeting. Each time the North Side Health Expert comes to your home, he or she will also make a copy of your diary for our research. You will keep the original for yourself.

- About 2 weeks after your last session with the North Side Health Expert, you will be asked to come back to one of our community locations to complete surveys and talk to someone about how you liked the program. At this time, we will also weigh you and measure your body fat. We will take a small amount of blood (about 2 tablespoons) so that we can measure your blood sugar and cholesterol. We will share this information with you. This meeting will take about 1 hour.

- 6 months after your last session, someone will come to your home. You will complete a final survey. We will also weigh you and measure your body fat, and we will take 2 tablespoons of blood so that we can measure your blood sugar and cholesterol. We will share this information with you. This visit will take about 30 minutes.

What are the potential risks and discomforts?

You may feel uncomfortable discussing food, exercise, or your weight or being weighed. If you feel uncomfortable at any time, you can choose not to answer a particular question that we ask on a survey. You may also experience some minor discomfort when blood is drawn. You may get bored filling out all the surveys. You may not like the exercises we show you. To the best of our knowledge, the things you will be doing in this research have no more risk of harm than you would experience in everyday life.

Is the research going to involve any medical procedures such as drawing blood?

Another risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not been given permission to see this information). We take special care to protect your information.

Is the interviewer going to ask questions about sensitive issues like past sexual behavior or illness?

What harm might occur to participants if someone outside the research sees their private information?

Are there benefits to taking part in the research?

You may or may not benefit from this research. We may find out information that will help type II diabetics lose weight in the future.

Are there any individual or social benefits to taking part in the study?

What other options are there?

You have the option to not participate in this study.

If the study involves a new treatment, are participants told what other treatments exist for their illness or condition?

What about privacy and confidentiality?

The only people who will know that you are participating in research will be the North Side Health Expert who comes to your home and other members of the research team. No information about you that is provided by you during the research will be disclosed to others without your written permission except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UA Institutional Review Board monitors the research or consent process) or if required by law.

You will be assigned an identification number that will be kept separate from confidential information like your survey answers and results of your blood tests. The number will appear at the top of all your study materials. Only the North Side Health Expert and the Project Coordinator will have access to the list that links that number to you. This list along with all other study information will be kept in a locked file cabinet in a locked office at the NSCHP office. This list will be destroyed once the study ends. Electronic data files will be stored in databases that are protected by passwords. When the results of the research are published or discussed at conferences, no information will be included that would reveal your identity.

How will the confidentiality of participants' information be maintained?

What are the costs for participating in this research?

There are no costs to you for participating in this research.

Are there any additional costs that might result from participation in the research, such as costs for medical treatment billed to an insurance company?

Will I be paid for my participation in this research?

You will receive a $20 at the end of the first meeting. Each time the North Side Health Experts visits your home, you will receive $5 (9 visits x $5=$45). If you cancel a visit, you will not receive compensation. You will also receive small items throughout the course of the program to help you make changes such as cookbooks, inexpensive exercise equipment (such as stretchy bands), and other health education materials. At the end of the 6 month program, when you are asked to return to one of our community sites for questionnaires, you will receive $20. At the final in-home visit, 6 months after the program is over, you will receive $40. Overall, you may be paid up to $125 in cash if you complete all research activities.

Will the study provide incentives?

What should participants do if they want to stop taking part in the research?

Can I withdraw or be removed from the study?
You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you do not want to answer and still remain in the study.

You may change your mind and stop taking part at any time. If you want to stop, we ask that you please call us to let us know. We will also want to ask a few questions about why you are stopping. This will be very brief. It is important to help us learn about the program. Please call: Mary Jones, Project Coordinator, at (555) 555-5555.

Who should participants contact if they have general questions?

Who should I contact if I have questions?
You may ask any questions now. You may also call Mary Jones, Project Coordinator, at (555) 555-5555 at any time. During the study, you will always be able to call the North Side Health Expert who visits your home at any time. Dr. Anne Smith is the Principal Investigator of the study. You may contact Dr. Smith at (555) 123-4567 at any time.

Who should participants call if they have not been treated as described in the informed consent form, or if they have complaints or concerns, or believe they have been injured as a result of the research?

What are my rights as a research participant?
If you feel you have not been treated according to the descriptions on this form, or if you have any questions about your rights as a research participant, including questions, concerns, complaints, or to offer input, you may call the Office for Protection of Research Participants at (555)765-4321 or (800)765-4321 (toll-free).

Remember:
Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current nor future relationship with the UA or the NSCHP. If you decide to participate, you are free to withdraw at any time without affecting this relationship. **You will be given a copy of this form for your information and to keep for your records.**

Signature of participant
I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

Your signature indicates that you are providing consent to participate in the research study.

PRINTED NAME DATE

SIGNATURE OF RESEARCH PARTICIPANT

SIGNATURE OF PERSON OBTAINING CONSENT DATE (MUST BE SAME AS SUBJECT'S)

PRINTED NAME OF PERSON OBTAINING CONSENT

PART 3

BEING CAREFUL WITH RESEARCH INFORMATION

Glossary of Key Terms

Anonymous Data: Information that cannot be linked in any way to the person who gave the information.

Confidentiality (also see Privacy): It is a rule in research that information about participants that is collected for research purposes should not be shared with any people outside the research project.

Identifiable Personal Information: Information that has enough details to reveal the identity of the person (participant) who provided it.

Privacy (also see Confidentiality): It is a rule in research that people are allowed to decide if and when they are going to share information about themselves.

Introduction

If you collect data from research participants, you are responsible for making sure that the information is accurate and protected. Otherwise, the study may not be worthwhile.

The research plan ("protocol") must be carefully followed. This plan should explain how to collect, record, store, and transport data. Individuals who recruit participants and collect data should be comfortable talking to their supervisors if they have a problem, make a mistake, or see others not following directions.

Often in research, participants provide a lot of personal information. They might provide their address and phone number as well as share private or sensitive things about themselves or others. For instance, we might learn that someone is a drug user or HIV positive. People may be sensitive about how much they weigh or about health issues, such as diabetes or cancer.

It is important to keep names separate from research information – even if the information seems harmless to you. Everyone involved in research is responsible for keeping information that participants share private.

In order to protect privacy (participants' identities), surveys should not be administered in a public location where others can see and/or hear what is going on. Participants' names, telephone numbers, and other contact information should not be shared outside of the research.

In order to protect the confidentiality of research data, written information should be kept in a safe, secure location, such as a locked file cabinet in a lost office. Electronic information should be maintained on secure computer systems that restrict access, require passwords, and/or encrypt ("scramble") information so that it cannot be read by those who are not supposed to see it.

Take Away Points

1. Every piece of information that a participant provides in a research study should be kept safe.

2. All procedures for conducting research should be carefully followed.

3. There are special rules when research involves medical records.

4. If you are the member of a research team, you should always ask questions if there is something about the research or something that you are supposed to do that you do not understand.

5. You should talk to the lead investigator or another supervisor if you see someone else on the research team doing something that you think they are not supposed to be doing.