TRAINING IN HUMAN RESEARCH PROTECTIONS

Facilitator Manual + Curriculum Materials

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

Table of Contents

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. CIRTification was developed using a "train-the-trainer" model. These materials are designed for a facilitator who will lead a small group, not for self-study. In addition to this Facilitator Manual, CIRTification also includes a Participant Workbook.

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**

This curriculum and all associated materials were written by Emily E. Anderson, PhD, MPH, and reviewed by members of the Community Engagement and Research Core Ethics Committee of the UIC Center for Clinical and Translational Science.

The project described was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1RR029879. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

The development of CIRTification was also supported by C3, the Chicago Consortium for Community Engagement, funded by the Otho S. Sprague Memorial Institute.

Suggested Citation

Anderson EE. CIRTification: Community Involvement in Research Training. Facilitator Manual. Center for Clinical and Translational Science. University of Illinois at Chicago. 2011. Available at: **www.go.uic.edu/CIRTification**

About the Author

At the time this manual was developed, Emily E. Anderson, PhD, MPH was project director at the University of Illinois at Chicago (UIC) Center for Clinical and Translational Science (CCTS). She is currently assistant professor of bioethics and health policy at the Stritch School of Medicine at Loyola University Chicago.

Book design by Chad Spaulding | www.3979design.com

All images are used royalty-free from office.microsoft.com.

For questions or comments about the program: **cirtificationresearchtraining@gmail.com**

ACKNOWLEDGEMENTS

The author, Emily E. Anderson, PhD, MPH, would like to thank the following members of the **UIC Center for Clinical and Translational Science Community Engagement and Research Core, Ethics Subcommittee,** for providing substantive input during the development of this curriculum:

William Baldyga
Barbara Dancy
Linda Graham
Charles Hoehne
Lynn Podraza
Marilyn Willis

The author would also especially like to thank Ashley McKinney for research assistance and Jae Truesdell for research assistance and for the title of the program.

The author would also like to thank the following groups and individuals for reviewing materials:

Executive Committee of the C3 Consortium:
William Baldyga, University of Illinois at Chicago
Juana Ballesteros, Greater Humboldt Park Community of Wellness
Cynthia Barnes-Boyd, University of Illinois at Chicago
Deborah Burnett, University of Chicago
Katherine Christoffel, Northwestern University
Carol Ferrans, University of Illinois at Chicago
Cerrelda Jones
Jen Kauper-Brown, Northwestern University
Doriane Miller, University of Chicago
Bernetta Pearson, National Black Nurses Association
Ronald Rembert, Family Christian Health Center
Karriem Watson, University of Illinois at Chicago
Cassandra Welch, University of Illinois at Chicago

Members of the UIC CCTS CERC Community External Advisory Board
Special thanks to Glenda Fulton, National Sarcoidosis Society and Bernetta Pearson, National Black Nurses Association

EVALUATION AND FEEDBACK

Input from individuals and institutions who have used the CIRTification curriculum (or considered using it but did not) is extremely valuable. Please take time to complete the Evaluation and Feedback Form posted on our website at **www.go.uic.edu/CIRTification**

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 Need to Tailor Training for Community Partners

Community partners often serve on the frontlines of a research project, and have responsibilities related to recruiting participants, obtaining informed consent, and collecting data. Many have little or no prior research training or experience. Due to federal and institutional policies, many community research partners are required to complete some type of formal "human subjects protection training" (sometimes called "IRB training" or "research ethics training"). Training is usually required when individuals interact with research participants and/or handle research data.

Most currently available research ethics training programs and materials are primarily geared towards learners who have some research experience and working knowledge of research methods (e.g., graduate students and junior researchers). They do not address the unique context of community-engaged research. Thus, these programs and materials may not be well-received by community partners. A mismatch between the training needs of community partners and training programs can result in limited understanding of key concepts and rules. Community research partners may also emerge feeling uncertain about the research process.

Community partners possess considerable knowledge about the communities in which they live and work. They have creative ideas about how to approach problems. They are a rich source of information for university researchers regarding the needs, preferences, activities, strengths, and challenges of people living in their communities. Community partners have vital skills, talents, and experience from their careers and other interests. Human research protection training should provide relevant, meaningful information and skills to help community partners translate their unique knowledge and skills to research collaborations.

CIRTification: Community Involvement in Research Training

CIRTification is tailored to the unique roles of community research partners. This program was designed to substitute for (or supplement) the standard human research protection training required by many institutions. CIRTification considers community partners' limited research experience; is interactive; addresses ethical issues in plain language; uses real-world examples; and focuses on the application of new knowledge. Ideally, this training program will not only teach community research partners about the importance of protecting research participants but also enhance the overall contribution that they are able to make to their respective research teams towards the goal of becoming "co-researchers."

A sample letter that can be used to inform your Human Research Protections Program or Institutional Review Board about CIRTification can be found on page xi.

How to Use This Facilitator Manual

Facilitators

We have developed this manual for use by a variety of potential facilitators, including individuals responsible for delivering human subjects protection or responsible conduct of research (RCR) training (who may have expertise in RCR/ethics but not community-engaged research), and principal investigators of community-engaged research projects (who may have experience with community engagement but not in teaching RCR or research ethics). It is assumed that CIRTification facilitators will already be somewhat familiar with research methods and human research protections. Therefeore, background reading materials provided in the curriculum should be sufficient to support implementation of all activities and lectures. Resources providing more in-depth information are referenced throughout the manual.

Intended Audience

This curriculum and all related materials have been developed to assist in the delivery of training in human research protections to community research partners. It is expected that these individuals will have limited research training and experience. (Seasoned community research partners have likely already completed some training, although some of the CIRTification activities could be used for continuing education activities.) Community research partners may or may not also have limited formal education. They may be employees of a local community agency, school, neighborhood association, health care clinic, or other community-serving institution. They may have already agreed to work on a particular research project that involves human participants, or they/their organization may be thinking about getting involved in research but have not yet engaged with a particular investigator or project.

If community partners will be recruiting research participants, obtaining informed consent, or collecting data, then the academic institution with whom they are partnering will most likely require them to complete human subjects protection training prior to engaging in any research activities. It is our hope that your institution will allow CIRTification training – delivered by a qualified facilitator – to serve as a substitute for such training (see the next page for sample materials that can be used to promote CIRTification at your institution). These curriculum materials can also be used to train individuals from organizations who are considering engaging in research or community advisory board members.

How to Use This Facilitator Manual

Plain Language

About half of American adults read at or below at eighth grade level. We want this training to be accessible to everyone who may attend. Therefore, this manual is written in plain language to the extent possible to help facilitators explain key concepts related to research, research ethics, and the responsible conduct of research to a lay audience with limited literacy.

A Note on Terminology

Whenever possible, we use the term "research participants" rather than "subjects" as it is more respectful of the important contributions of those who give their self, time, and personal information to research. However, because the term "subjects" is still used in the federal regulations and other standard documents, it cannot be completely avoided.

Adult Learning Principles

The activities presented in this facilitator manual incorporate best practices for adult learning. Participatory activities such as brainstorming, case-based discussions, and role playing provide learners with opportunities to see, hear, discuss, and apply.

Training Research Teams

Although the primary intended audience is community research partners, we recommend delivering CIRTification to community-academic research teams. This includes academic investigators and research staff. Training research teams as a unit can demonstrate university partners' commitment to – and emphasizes the importance of – human research protections. Team training can also encourage constructive dialogue and ensure that community partners are comfortable speaking up and asking questions.

Protocol Specific Training

We strongly recommend integrating protocol-specific training with CIRTification. Focusing on individuals' designated roles will provide context for the material and assist community partners in proficiently applying the skills and information they learn to particular research tasks. Suggestions include incorporating consent forms approved for a specific study and reworking case studies to reflect the population or research setting of a specific study.

Format and Delivery of Training

We recommend delivering CIRTification in small groups of 5-8 learners, although materials could also be used with larger groups or as the basis of a one-on-one training. We suggest that, when possible, you assess the existing knowledge, strengths, needs, and expectations of your audience (referred to as "learners" throughout the rest of this curriculum) before determining which activities to include, the appropriate length of training, and assessment methods.

The materials and activities in this manual can be conducted and altered at the discretion of the facilitator. However, we do recommend at minimum following the 3-hour lesson plan below in order to ensure fidelity to the curriculum learning objectives. Depending upon your audience, your creativity, and your time limitations, CIRTification training could be longer.

Curriculum Overview

Part 1: Human Research Rules and Regulations

Part 2: Asking People to Participate in Research: The Informed Consent Process

Part 3: Being Careful with Research Information

Each Part includes:

- Session Objectives and Key Messages, highlighting primary take-away points
- Glossary and Facilitator Background Reading, providing context and additional content related to slide presentations and activities
- Lesson Plan including (varies)
  - Discussion questions and cases with discussion guides
  - Presentations with slides, notes, and participant handouts
  - Activities with handouts, worksheets, and facilitator guides

Recommended Three-Hour Lesson Plan

Part 1: Human Research Rules and Regulations (~1 hour)
Activity Introductions (~5 minutes)
Activity Brainstorming What is Research? (~10 minutes)
Handout How Does Research Happen? (optional: adds ~5 minutes)
Presentation History of Research Abuses (~10 minutes)
Activity Is it Human Research? (optional: adds ~15 minutes)
Presentation Ethical Principles, Regulations, & Institutional Review Boards (~15 minutes)
Discussion Community Engagement (optional: adds ~5 minutes)
Presentation Research with Communities (~10 minutes)

Part 2: Asking People to Participate in Research: The Informed Consent Process (~1 hour)
Activity (Discussion Case) "Just Sign Me Up!" (~10 minutes)
Presentation Informed Consent Overview (~10 minutes)
Activity/Presentation The Consent Form (optional: adds ~15 minutes)
Presentation Obtaining Informed Consent (~10 minutes)
Activity (Role Play) Informed Consent in Action (~30 minutes)

Part 3: Being Careful with Research Information (~1 hour)
Activity (Discussion Cases) "To Tell the Truth" (~15 minutes)
Presentation Being Careful with Research Information (~10 minutes)
Activity (Discussion Case) "Secrets" (~15 minutes)
Discussion How Would You Handle... (optional: adds ~10 minutes)
Presentation Privacy and Confidentiality (~15 minutes)

**It is recommended that discussions, cases, and activities be integrated to break up didactic presentations.*

Learning Objectives

All participants should be able to:

Part 1: Human Research Rules and Regulations

- Appreciate the history of research abuses
- Demonstrate familiarity with federal research regulations
- Understand the role of community partners in the research process
- Recognize the difference between research and service
- Define the three ethical principles that underlie research (the Belmont principles):
  - respect for persons,
  - beneficence, and
  - justice
- Explain the purpose of an institutional review board

Part 2: Asking People to Participate in Research: The Informed Consent Process

- Explain how the requirements of information, understanding, and voluntariness are fulfilled during the informed consent process
- List some examples of the kinds of information that should be provided to potential research participants
- Recognize the kinds of statements that should and should not be made to potential research subjects during recruitment
- Identify certain groups that may have special requirements for research participation

Part 3: Being Careful with Research Information

- Understand good practices for collecting and storing research data
- Know what to do if they observe a co-worker not following appropriate procedures
- Discuss how to maintain participants' privacy and the confidentiality of their information
- Identify some of harms that may occur to participants if privacy and confidentiality are not protected

Sample Letter to Human Research Protections Program

Dear Human Research Protections Administrator:

We request approval to substitute CIRTification: Community Involvement in Research Training for [NAME OF TRADITIONALLY-REQUIRED HUMAN RESEARCH PROTECTION PROGRAM] for our community research partners from [NAME OF PARTNER ORGANIZATION] who will be working with us on [NAME OF RESEARCH PROJECT/PROTOCOL NUMBER]. A link to the curriculum materials can be found at: www.go.uic.edu/CIRTification

CIRTification is tailored to meet the unique training needs of our community research partners. It is interactive, relevant to roles and responsibilities our community partners will have in our research project, and focused on skills-building. The curriculum considers community partners' limited experience with research, addresses research ethics and responsible conduct of research issues in plain language, and uses real-world examples. CIRTification is better suited to the unique needs of community research partners than other human research protection training programs, which are usually geared towards learners who have at least some research experience and working knowledge of research methods (e.g., graduate students and junior researchers). Ideally, CIRTification will not only teach community research partners about the importance of protecting research participants, it will also empower them to be active contributors to their respective research teams.

CIRTification was developed by Emily E. Anderson, PhD, MPH, while she was at the University of Illinois at Chicago. Dr. Anderson has doctoral training in research ethics as well as experience conducting community-engaged research and serving on institutional review boards. Experts in human research protections, training, academic faculty members who serve as principal investigators on community-engaged research projects, and community research partners both expert and novice provided input and feedback on these materials. The curriculum has been reviewed by faculty members and human research protections administrators at the University of Illinois at Chicago, the University of Chicago, Northwestern University, and Rush University and is currently offered to community research partners working with faculty at these institutions.

The training will be delivered by [NAME OF TRAINER]. [DISCUSS CREDENTIAL/EXPERIENCE OF TRAINER]. The recommended 3-hour lesson plan format will be followed, ensuring fidelity to the curriculum learning objectives.

Sincerely,

[YOUR NAME AND SIGNATURE]

PART 1

HUMAN RESEARCH RULES + REGULATIONS

Session Objectives

At the end of this session, all participants should be able to:

- Appreciate the history of research abuses
- Demonstrate familiarity with federal research regulations
- Understand the role of community partners in the research process
- Recognize the difference between research and service
- Define the three ethical principles that underlie research (the Belmont principles):
    - respect for persons,
    - beneficence, and
    - justice
- Explain the purpose of an institutional review board

Key Messages

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.

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).

Facilitator Background Reading

Introduction

In this part, participants are introduced to the fact that there are important and unique rules for human research. Everyone involved in research must know and follow these rules. While this part starts by discussing examples of abuse of research participants, examples of good research practices involving community engagement are also highlighted. Take away messages for participants should focus on the lessons learned from abuses: the importance of respect for participants, the need for formal rules for research, the importance of public trust in research, and the potential of community engagement to improve participant protections.

This part also covers ethical principles or "golden rules" for human research: respect for persons (giving people truthful information), beneficence (not doing harm), and justice (being fair).

Participants will learn about institutional review boards (IRBs) and the important role they have in the protection of research participants. They will also learn about researchers' responsibilities to communicate with IRBs.

History of Abuses in Research

There are numerous examples of research that has caused harm. Some of the most notorious examples include:

Nazi concentration camp experiments: Thousands of prisoners were used in dangerous and often purposely lethal medical experiments, during which they were

- placed in low-pressure tanks to simulate high altitude conditions and determine how long they could survive with very little oxygen
- forced to stand naked outside in freezing weather or immersed in a freezing bath
- infected with malaria to test anti-malarial drugs, many with fatal side effects
- infected with typhus after receiving an experimental anti-typhus vaccine
- deliberately wounded and then infected with mustard gas, bacteria, gangrene-producing culture, wood shavings, and glass shards in order to test new treatments
- forced to inhale mustard gas
- fed poison
- subjected to chemical or x-ray sterilization experiments

Many of these experiments involving new treatments also included "no treatment" control groups.

Twenty-three Nazi doctors and government officials were tried for these war crimes at the Nuremberg Military Tribunals in 1946 and 1947. Tribunal judges presented the Nuremberg Code, some of the first formal ethical guidelines proposed for medical researchers. The basic ideas of the Nuremberg Code are found in most codes of research ethics that have been proposed since then.

Additional References

Emanuel EJ, Crouch RA, Arras JD, Moreno JD, and Grady C. 2003. Scandals and tragedies of research with human participants. In *Ethical and regulatory aspects of clinical research,* eds. EJ Emanuel, RJ Crouch, JD Arras, JD Moreno, and C Grady. Baltimore, MD: The Johns Hopkins Press.

Levine RJ. 2004. Ethical principles for the conduct of research involving human subjects: Historical considerations: Journal of Clinical Ethics, 15(1); 13-21.

Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law, October 1946-April 1949.

Caplan AL, editor. 1992. *When medicine went mad: Bioethics and the Holocaust.* Totowa, NJ: Humana Press.

Weindling PJ. 2001. *Nazi medicine and the Nuremberg Trials: From medical war crimes to informed consent.* Basingstoke, Hampshire and New York: Palgrave Macmillan.

Willowbrook Hepatitis Studies: From 1956-1971, pediatrician Saul Krugman conducted hepatitis vaccine studies at the Willowbrook School for Mentally Retarded Children on Staten Island. At the time, many residents got hepatitis soon after moving to Willowbrook. Krugman wanted to develop a vaccine to prevent this. In a controlled experimental setting, residents of the school were fed or injected with serum, urine, or fecal matter taken from patients with either hepatitis A or B (the two forms of viral hepatitis known at the time). Then experimental vaccines were administered to the infected children.

When reports of the study first appeared in the literature, there was little criticism. Krugman and his co-investigators addressed ethical concerns, arguing that the children would be infected anyways and this was much safer. However, the potential hazards of participation had not been thoroughly explained to parents, and for a period of time, study participation was mandated for acceptance into the school.

Krugman's research did ultimately result in the development of effective vaccines for different forms of hepatitis. Many observers have been troubled by the fact that this study used particularly vulnerable children who were unable to speak for or protect themselves. People all over the world have benefited from the discovery of hepatitis vaccines, and many have argued that it would have been fairer to use adult volunteers.

The Willowbrook study was one of 22 (unnamed) studies described as unethical in Henry Beecher's classic 1966 *New England Journal of Medicine* article, "Ethics and Clinical Research." Beecher's article drew attention to the extent of abuse of research participants in the US at the time. He argued that ethically questionable behavior was widespread in mainstream science – even at prestigious institutions.

Additional References

Beecher HK. 1966. Ethics and clinical research. New England Journal of Medicine, 274; 1354-1360.

Howell JD, and Hayward RA. 2003. Writing Willowbrook, reading Willowbrook: The recounting of a medical experiment. In *Useful bodies,* eds. J. Goodman, A. McElligott, and L. Marks. Baltimore, MD: The Johns Hopkins University Press.

Lock S. 1995. Research ethics – a brief historical view to 1965. Journal of Internal Medicine, 238(6); 513-520.

Rothman SM, and Rothman D. 1984. *The Willowbrook wars.* New York: Harper & Row.

Milgram's Studies of Obedience to Authority: Stanley Milgram's social research on obedience was first published in 1963. College students were told that they were taking part in an experiment on learning behavior. They were ordered to administer increasingly severe punishments by means of a shock generator to a "student" who was in another room. Shocks were to be given whenever the student incorrectly answered a question. Participants could not see the "students"; in fact, these students were not even real. While some participants ended the experiment after the victim's protests, many continued, demonstrating the potential strength of obedient tendencies.

Milgram's experiments contributed greatly to social scientists' understanding of human psychology and obedience. However, these experiments also created anxiety in some participants. They have been criticized by other scientists as psychologically harmful to participants as well as manipulative, embarrassing, and uncomfortable. Milgram was also accused of failing to adequately "debrief" participants – that is, talk with them to explain the reason for deception and discuss any distress or discomfort they have experienced.

Additional References

Baumrind D. 1964. Some thoughts on the ethics of research: After reading Milgram's "Behavioral studies of obedience." American Psychologist, 19; 421-423.

Milgram S. 1963. Behavioral study of obedience. Journal of Abnormal and Social Psyhcology. 67(4); 371-378.

Milgram S. 1964. Issues in the study of obedience: A reply to Baumrind. American Psychologist, 19(11); 848-852.

Tearoom Trade Study: In the mid-1960s, Laud Humphreys was a graduate student at Washington University in Saint Louis, Missouri. He concealed his identity and actively observed impersonal sex between men in public restrooms – referred to locally as the "tearoom trade." The men he met had no idea that he was a researcher collecting data for his dissertation. Humphreys also recorded license plate numbers. He later visited some of the men at their homes, claiming to be conducting a general health survey. This allowed him to gather additional demographic information about these men and their families.

Humphreys' book, *Tearoom Trade: Impersonal Sex in Public Places* (1970), received commendation because the data did not support the stereotype of homosexuals as deviant but rather showed them to be average members of society. However, many sociologists criticized Humphreys' research, saying that his deceptive methods constituted an invasion of privacy.

Additional References

Babbie E. 2004. Laud Humphries and research ethics. International Journal of Sociology and Social Policy. 24 (3/4/5); 12-19.

Humphreys L. 1970. *Tearoom trade: Impersonal sex in public places* (observations). Chicago: Aldine.

Korn JH. 1997. *Illusions of reality: A history of deception in social psychology.* Albany, NY: State University of New York Press.

von Hoffman N. 1976. Sociological snoopers and journalistic moralizers. In *Tearoom trade: Impersonal sex in public places,* ed. L. Humphreys, pps. 177-190. New York: Aldine De Gruyter.

The Public Health Service (Tuskegee) Syphilis Study: This government-funded study began in October 1932. Four hundred African American men with untreated syphilis were enrolled; an additional 200 African American men without syphilis served as a control group. The stated goal was to study the natural course of untreated syphilis. However, at the time it was common knowledge among physicians that untreated syphilis produced increased disability and premature death. Study participants were promised free medical care, hot meals, and burial insurance. But they were never told that they had syphilis, nor did they receive treatment for their disease – even after penicillin, a safe, low-cost, effective treatment became widely available in 1943. Study personnel went to great lengths to keep participants from seeking treatment elsewhere. The study was initially planned to last about six months but ultimately lasted 40 years.

The Tuskegee Syphilis Study was not a secret experiment. Preliminary study results were first reported in a medical journal in 1936. Subsequently, 12 more journal articles appeared every 4 to 6 years until 1973. However, it was not until 1965 that someone from "inside" the research community wrote a letter to the Public Health Service (PHS) objecting to the study. In 1966 and then again in 1968, Peter Buxton, an epidemiologist at the Centers for Disease Control (CDC), expressed concern about the study to his colleagues. He was ignored. The study was reviewed several times – as late as 1969 – by the PHS, the Alabama State Board of Health, and the Tuskegee Institute. Continuation was always recommended. In 1972, Buxton called an Associated Press (AP) reporter, and stories about the study appeared in the *Washington Star* and the *New York Times.* The American public was outraged, and the study was stopped in March 1973. At this time, 74 participants from the experimental group were still alive. At least 28 but possibly more than 100 men in the study had died from advanced syphilitic lesions. The US government could no longer ignore the need to further examine and regulate the behavior of scientists. Congressional hearings followed.

The Tuskegee Syphilis Study played a major role in encouraging government oversight of human research, but its historic significance is much greater. Because the Tuskegee study exclusively involved African American men, it stands as a symbol of racism and the dangerous abuse of power by medical professionals. Research abuses—Tuskegee as well as other hazardous experiments conducted on slaves and other poor, vulnerable, and/or institutionalized persons—have led many African Americans and members of other minority groups to lose trust in the medical profession and the government. This mistrust has resulted into low participation rates in research and skepticism towards public health efforts to improve minority health status. The negative effects of Tuskegee on the health and well-being of US citizens continue to this day.

Additional References

Bell SE. 2000. Events in the Tuskegee Syphilis Study. In *Tuskegee's Truths,* ed. SM Reverby. Chapel Hill, NC: University of North Carolina Press.

Brandt AM. 1978. Racism and research: The case of the Tuskegee Study. Hastings Center Report, 8(6); 21-29.

Heintzelman CA. 1996. Human subjects and informed consent: The legacy of the Tuskegee Syphilis Study. Scholars 6(1); 23-30.

Jones JH. 1993. *Bad Blood: The Tuskegee Syphilis Experiment.* Free Press.

King PA. 1992. The dangers of difference. Hastings Center Report, 22(6); 35-38.

Reverby SM. *Examining Tuskegee: The Infamous Syphilis Study and Its Legacy* (The John Hope Franklin Series in African American History and Culture). The University of North Carolina Press; 2009.

A Modern Day Case of Research Harm: The Havasupai: The Havasupai are a native tribe that live in Arizona, deep in the Grand Canyon. Because they are very isolated, they have been able to maintain many of their native traditions. In the 1990s, members of the tribe approached an anthropologist from University of Arizona whom they had known for many years and told him they were concerned about rising rates of type II diabetes. The anthropologist talked to a genetics researcher, Therese Markow. Genetic causes of diabetes had been found in other native American tribes. Dr. Markow met with tribe leaders and told them that she would research the genetic causes of diabetes. As part of her research, she collected blood samples from several hundred tribe members.

In addition to diabetes research, Dr. Markow used to the blood samples to study schizophrenia. She also shared samples with researchers who studied other things, including migration patterns and inbreeding. Dr. Markow never asked or informed tribe members about the other uses of the blood samples. Given tribal traditions and taboos, some of these studies would not have ever been allowed by the tribal leaders had they been asked. Researchers did not find a genetic link to diabetes in the tribe, but they never shared this information. Additionally, some tribe members' privacy was violated when the researcher looked in their medical records without getting permission from the hospital that was on the reservation. These breaches of trust resulted in many lawsuits as well as a temporary ban on researchers visiting the reservation.

Additional References

Dalton R. 2004. When two tribes go to war. Nature, 430; 500-502.

Mello M, Wolf L. 2010. The Havasupai Indian Tribe case – Lessons for research involving stored biologic samples. New England Journal of Medicine, 363; 204-207.

Rubin P. 2004, May 27. Indian givers: The Havasupai trusted the white man to help with a diabetes epidemic. Instead, ASU tricked them into bleeding for academia, Phoenix New Times.

Wolf LE, Bouley TA, and McCulloch CE. 2010. Genetic research with stored biological materials: Ethics and practice. IRB: Ethics & Human Research, 32(2); 7.

Federal Regulations: 45 CFR 46 Subpart A, The Common Rule

Federal regulations for conducting human research were enacted in 1974. These laws were put into place after the government and the public learned of some of the research harms described above. These regulations were revised and expanded during the late 1970s and 1980s, based on the *Belmont Report* (see below).

"45 CFR 46" (CFR stands for Code of Federal Regulations) regulates human research conducted in the US (and research conducted outside the country by US investigators) that is sponsored by the US government or by institutions that receive federal funding. These regulations also apply to investigators who work at institutions that have an agreement with the federal government called a "federal wide assurance" (FWA). Institutions that receive federal funding for human research have an FWA with the federal Office of Human Research Protections (OHRP). An FWA requires all researchers employed by the institution to comply with federal regulations regardless of funding source. Additionally, all privately-funded research with human participants that results in data that will be part of an application for Food and Drug Administration (FDA) approval is subject to 45 CFR 46 as well as additional FDA regulations.

Section 46.101 (b) describes certain types of research that are exempt from the federal regulations. Section 46.102 defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." "Human subject" is defined as "a living individual about whom an investigator... conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information. *(See note on page vii regarding the use of the terms "human subject" and "research participant.")*

Section 46.103 states how to obtain a federal-wide institutional assurance (FWA). Any institution that is engaged in human research that is covered by 45 CFR 46 must provide written assurance that it will comply with the policy. They must also provide a statement of guiding principles (e.g., the ethical principles outlined in the Belmont Report), designation of one or more institutional review boards (IRBs, see below), a list of IRB members, and written procedures for IRB review and reporting.

Sections 46.111 (Criteria for IRB Approval of Research) and 46.116 (General Requirements for Informed Consent) are the most substantive. Section 46.111(a) outlines criteria that IRBs must consider when evaluating research that involves humans. These criteria are drawn from the three ethical principles outlined in the 1979 Belmont Report (discussed in more detail below): respect for persons, beneficence, and justice.

1) Researchers must make all reasonable attempts to minimize risks to participants. (Beneficence)
2) Risks to participants must be reasonable in relation to potential benefits (to participants) and the importance of potential resulting knowledge (to society). (Beneficence)
3) The selection of participants must be equitable. (Justice)
4) Informed consent must be sought from each participant (or their legally authorized representative). (Information regarding informed consent is outlined in section 45 CFR46.117 and will be discussed in detail in Part 2). (Respect for persons)
5) Informed consent must be properly documented. (Respect for persons)
6) If appropriate, adequate provisions for data monitoring must be outlined in the research plan. (Beneficence)
7) Researchers must provide adequate provisions to protect the privacy of research participants and the confidentiality of their data. (Beneficence)
8) Additional safeguards should be in place when research includes people who may be vulnerable, such as children, prisoners, pregnant women, mentally ill persons, or economically or educationally disadvantaged persons. (Respect for persons)

In June 1991, the Federal Policy for the Protection of Human Subjects (10 CFR 745, also known as the "Common Rule") was enacted. Through the Common Rule, 16 agencies that support, conduct, or otherwise regulate human research adopted 45 CFR 46 Subpart A. The FDA adopted some of the provisions (in addition to maintaining its own set of human research regulations – 21 CFR 50 and 21 CFR 56 – which overlap considerably with the Common Rule.

Additional References

Code of Federal Regulations, Title 45, Part 46 (or 45CFR46, The "Common Rule")
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Office for Human Research Protections, US Department of Health and Human Services
http://www.hhs.gov/ohrp/

Institutional Review Boards (IRBs)

As outlined in section 46.103(b), each IRB is responsible for writing its own operating procedures. These should cover the conduct of initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution. Other sections of 45 CFR 46 outline additional guidance for IRB operations.

Section 46.107 addresses IRB membership. An IRB is required to have at least five members with varying backgrounds and sufficient scientific expertise to review research. IRB members should be diverse in terms of "race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." In addition to including members with research-related expertise, an IRB's members should be able to determine the "acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standard or professional conduct and practice." This is the basis for the requirement that an IRB include at least one member "whose primary concerns are in nonscientific areas" and at least one member "who is not otherwise affiliated with the institution."

Many institutions fulfill the requirements for both a "non-scientist" and a "non-affiliated" member with one or more community representatives. These individuals are supposed to represent the type of people that would serve as research participants in studies conducted at the institution. Community representation serves several purposes. One purpose is increased transparency. Community members on the IRB learn about research activity at their local university or hospital (and theoretically share this information). Another purpose of having community members on IRBs is to represent local interests. Community IRB members can ensure that proposed research practices are in line with the goals and beliefs of the community. A third purpose of having community IRB members is that they can provide a "lay" perspective on research. For example, they can help ensure that consent forms are written in language that is understandable.

Additional References

Anderson EE. 2006. A qualitative study of non-affiliated, non-scientist institutional review board members. Accountability in Research. 13(2); 135-155.

Bankert EA, Amdur RJ. 2006. *Institutional Review Board: Management and function,* Sudbury, MA: Jones and Bartlett.

Bankert EA, Amdur RJ. 2007. *Institutional Review Board: Member handbook,* Sudbury, MA: Jones and Bartlett.

DeVries R, Forsberg CP. 2002. Who decides? A look at ethics committee membership. HEC Forum. 14(3); 252-258.

Hayes G, Hayes S, and Dykstra T. 1995. A survey of university institutional review boards: Characteristics, policies, and procedures. IRB: Ethics & Human Subjects Research. 17(3); 1-6.

Peckman S. 2001. Local institutional review boards. In *National Bioethics Advisory Commission. Ethical and Policy Issues in Research Involving Human Participants.* Appendix K. Commissioned Papers and Staff Analysis. Bethesda, MD: National Bioethics Research Commission. Available at: http://bioethics.georgetown.edu/nbac/pubs.html

Penslar RL. 1993. *Institutional Review Board Guidebook. Office for Human Research Protections.* Available at: http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

The Belmont Report: Ethical Principles for Research

The Belmont Report was published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was established after public outrage over the Tuskegee Syphilis study and other research abuses. The report outlines three ethical principles that provide the foundation for human research:

Respect for persons (giving people enough information to make a decision for themselves),
Beneficence (reducing risks), and
Justice (being fair)

This report linked ethical standards, practices, and concerns of the time with these three fundamental ethical principles and provided the basis for key revisions of the federal regulations in 1981, increasing government oversight of human research.

Respect for Persons: Researchers should respect and protect the autonomy of research participants. Autonomy is defined as a person's ability to receive and understand information, think about all the alternatives, make choices, and act on their choices without the undue influence or interference of others. Every person has the right to decide what will be done with their bodies, whether or not they will participate in research, and what information about themselves they will share with others.

Researchers show respect for participants' autonomy through the informed consent process and by providing special protections for vulnerable populations.

Vulnerable participants include those individuals with limited ability to act on their own deliberations. The federal regulations formally define three groups of vulnerable participants: prisoners; children; and pregnant women, fetuses, and neonates. Other groups, such as cognitively impaired, mentally ill, and economically disadvantaged individuals also manifest vulnerabilities that may require special protections in research.

Not all research participants may be autonomous – for example, children or adults with cognitive disabilities do not have full legal decision-making rights. Participants that have diminished autonomy deserve special protections in research. Special steps for protection should be taken when research is conducted with people who lack power. These protections might include research participant advocates, use of non-written informed consent aids (e.g., videos), and more frequent IRB review.

Beneficence: Research has the potential to produce benefits to society and to the individuals who participate. But research also can sometimes introduce the potential for harm. There are different types of harms that can result from research, including physical, social, economic/financial, psychological, and legal. (These different types of potential research harms will be discussed in more detail below.)

The saying "do no harm," part of the Hippocratic Oath, is a fundamental guiding principle for doctors and other health care providers. In the context of research, this means that researchers should not knowingly harm participants (or put participants in harm's way) regardless of the potential benefits that might come to society. Researchers should make all reasonable efforts to ensure participant well-being. Possible benefits should be maximized, and possible harms should be minimized. However, some risk is unavoidable, and there is always a potential for unknown and unforeseen risks.

In community-engaged research, one of the most common/likely risks is that participants' personal information might be leaked outside of the study. Therefore, breach of privacy and confidentiality should be emphasized to participants as potential risks. Part 3 of this curriculum focuses on privacy and confidentiality.

While all research must provide some benefit through the knowledge that it will generate, not all research provides direct benefit to participants. This is fine – as long as participants are not asked to undertake significant risk without benefit, and as long as potential benefits are not overestimated.

Justice: The benefits (good) and burdens and risks (bad) of research should be fairly distributed. Ensuring justice means that equal opportunities should be provided to all. One group or person should not be unfairly burdened more than others. In research, injustice occurs when benefit is denied without good reason or when a burden is unduly imposed. Participants should not be recruited out of convenience. The safety and welfare of some people should not be risked for the benefit of more privileged groups.

Particular attention should be paid to issues of justice in recruitment practices and materials. Special efforts should be made to ensure that individuals with cognitive impairment or poor reading skills truly understand what it is that they are saying "yes" (or "no") to. Recruitment materials such as fliers should not mislead participants into thinking that research participation is "easy money."

Unfortunately, these three principles do not always provide specific solutions in specific instances. However, considering how particular actions might affect autonomy, beneficence, and justice can guide researchers, IRB members, and others in their efforts to determine how best to protect research participants.

Additional References

The Belmont Report, http://ohsr.od.nih.gov/guidelines/belmont.html

Emanuel EJ, Wendler D, & Grady C. 2000. What Makes Clinical Research Ethical? Journal of the American Medical Association, 283(20); 2701-2711.

National Bioethics Advisory Commission. 2001. *Ethical and Policy Issues in Research Involving Human Participants,* available at: http://bioethics.georgetown.edu/nbac/pubs.html

Research Risks and Possible Protections

Research always carries a risk of potential harm that is unknown or unanticipated. Some medical procedures carry some necessary harm (e.g., surgical wounds). However, research should not be deliberately or unnecessarily harmful.

Participants may face risks in research, but the *type* and *severity* of risk depends upon the kind of research in which they are taking part. Many research studies (surveys, for example) carry no more risk than what we usually encounter in our daily lives. Such studies are referred to as "minimal risk research."

The word "risk" might immediately bring to mind the possibility of physical harm. Physical harm is a real possibility in medical research, especially when new medications or procedures are being tested for the first time. Not only is it not known if the medication will work, but not all of the potential bad side effects are known.

Some risk is acceptable. This is determined by researchers' judgment, and the IRB serves as a system of checks and balances. For example, greater risks may be acceptable for people who are participating in studies that aim to find a treatment for their life-threatening illness.

Medical research is only one type of research. Many research studies do not involve medical procedures but instead involve gathering information from participants through surveys and/or testing educational or social interventions. Different types of research carry different kinds of risk. Much research does not pose physical risks.

Table I provides examples of different types of risk that may occur to research participants. Researchers are obligated to minimize risk to participants to the extent possible. The table also lists things that can be done to protect participants from each kind of harm (possible protections).

Everyone has a different opinion of what is "risky." Some people are afraid to fly, while others pay money to jump out of airplanes. The informed consent process (discussed in more detail in Part II) provides potential participants with adequate information about risks so that they can make an informed decision about whether or not they would like to participate in the research. However, it is difficult to predict everything that might happen, so it is also important that potential research participants be told that there may be unknown risks involved.

Part III discusses how to protect privacy and confidentiality in research and some harms that may result from breaches.

Additional References

Labott SM, Johnson TP. 2004. Psychological and social risks of behavioral research. IRB: Ethics and Human Research, 26(3); 11-15.

Martin DK, Meslin EM, Kohut N. 1995. The incommensurability of research risks and benefits: Practical help for research ethics committees. IRB: Ethics and Human Research, 17(2); 8-10.

Miller FG, Joffe S. 2009. Limits to research risks. Journal of Medical Ethics, 35; 445-449.

Weijer C, Miller PB. 2007. When are research risks reasonable in relation to anticipated benefits? In Institutional Review Board Member Handbook, eds. Amdur and Bankert. Sudbury, MA: Jones and Bartlett.

TABLE I
Types of Research Risks and Possible Protections

Type of risk	Example of a study that might include this risk	Example of the type of harm that may result from study participation	Example of a possible protection
Physical	Medical study testing a new medication for Alzheimer's disease	Participants' health may be harmed permanently or temporarily if the medication has a side effect researchers don't know about	Participants should be monitored frequently and asked about any health changes that might be a result of the medication
Social	Door-to-door survey of neighborhood residents to determine prevalence of untreated sexually transmitted infections (STIs)	Participants could be stigmatized or discriminated against if someone finds out they have an STI	Names or other identifying information such as addresses should not be included on research forms that have sensitive information
Psychological	Interview study of adults asking questions about past childhood sexual abuse	Participants may become upset when talking about bad things that have happened to them in the past	All participants should be provided with information on local resources for trauma survivors Interviews could be conducted by individuals who are trained counselors
Legal	Study testing an intervention to decrease crack cocaine use among urban young adults	Simply taking part in the study could identify someone as an illegal drug user Participant could be arrested or prosecuted if information about their illegal drug use is revealed	Names or other identifying information such as addresses should not be included on research forms Any documents containing identifying information should be kept safe
Economic	Study testing an intervention to decrease alcohol abuse	Participant could lose job if employer finds out about alcoholism	(Same as above)

Community Engagement in Research

Ethical Benefits

There is a growing demand for community collaboration in determining research questions and developing studies. Arguably, community input makes research more relevant and socially responsive. Community partnerships may also improve the protection of participants. More people know about the research, and community partners can help ensure that participants are well informed.

Some examples of community engagement done right include:

Harlem Health Promotion Center
http://www.healthyharlem.org/

Prevention Research Center of Michigan
http://www.sph.umich.edu/prc/

The Framingham Heart Study
http://www.framinghamheartstudy.org/

The National Children's Study
http://www.nationalchildrensstudy.gov/Pages/default.aspx

Ethical Challenges

Community engagement can also introduce new actors and new ethical challenges into the research process. When research is conducted in a defined community – whether geographic, racial/ethnic, religious, or other – research findings can affect public perceptions of the entire community – not just those individuals who have participated. For example, a study might report that the rates of drug use among young African American males in a particular neighborhood are twice the national average. This information may promote negative stereotypes about all young African American men in the neighborhood, resulting in social harms (such as difficulty in finding employment) for everyone who lives there. When research is conducted with identifiable communities, the potential community-level risks and protections should be considered along with risk to individual participants.

Community-engaged research also raises unique privacy and confidentiality concerns. Individuals who live or work in a community may have access to personal, sensitive information about their neighbors or clients. Standard privacy and confidentiality practices may not prevent the identities of individual participants from being discoverable if participants are known to community partners. And unfortunately, familiarity may increase temptation to look at or talk about private information.

There is a lot of talk about university researchers and conflicts of interest in research. Community research partners may also have biases or competing goals that may cause them to prioritize personal, organizational, financial, or reputational interests over the interests of participants. This might lead to unjust recruitment practices or insufficient informed consent.

Community research partners may also have different ideas from academic researchers about what is fair, what is a risk, or what is a benefit. This may in part be due to the fact that they have different kinds of obligations to their community members – obligations to provide services, to advocate for change, or to cooperate with the criminal justice system. These obligations may conflict with research obligations such as privacy or beneficence.

Additional References

Anderson EE, Solomon S, Heitman E, DuBois JM, Fisher CB, Kost RG, Lawless ME, Ramsey C, Jones B, Ammerman A, and Ross LF. 2012. Research ethics education for community-engaged research: a review and research agenda. Journal of Empirical Research on Human Research Ethics, 7(2);3-19.

Community-Campus Partnerships for Health, http://www.ccph.info/

Ross LF, Loup A, Nelson RM, Botkin JR, Kost R, Smith, Jr. GR, & Gehlert S. 2010. Human Subjects Protections in Community-Engaged Research: A Research Ethics Framework. Journal of Empirical Research on Human Research Ethics, 5(1); 5-17.

Ross LF, Loup A, Nelson RM, Botkin JR, Kost R, Smith, Jr. GR, & Gehlert S. 2010. The Challenges of Collaboration for Academic and Community Partners in a Research Partnership: Points Consider. Journal of Empirical Research on Human Research Ethics, 5(1); 19-31.

Ross LF, Loup A, Nelson RM, Botkin JR, Kost R, Smith, Jr. GR, & Gehlert S. 2010. Nine Key Functions for a Human Subjects Protection Program for Community-Engaged Research: Points to Consider. Journal of Empirical Research on Human Research Ethics, 5(1); 33-47.

Community Partner Views on Research

Although community research partners who take this training may not have experience conducting research, they will undoubtedly have opinions about research based on what they read in the newspaper, see on television, or hear from friends and family. They will have knowledge of their own communities and what people who live in their communities think and say about research – and researchers. They may even have some experience as a research participant. Before delving into topics such as recruitment, informed consent, and confidentiality, it is useful and important to consider participants' current understanding of research, the views of research held by members of their communities, and their role as community partners in research. Therefore, this part includes several discussion-based activities that allow participants to share their views on research.

Lesson Plan: Part 1

ACTIVITY Introductions

ACTIVITY (Brainstorming) What is Research?

HANDOUT How Does Research Happen?

PRESENTATION History of Research Abuse

ACTIVITY Is it Human Research?

PRESENTATION Ethical Principles, Regulations, and Institutional Review Boards

DISCUSSION Community Engagement

PRESENTATION Research with Communities

Introductions

First introduce yourself as the facilitator. Say something about yourself that helps students understand why you are leading this training course. You might also tell students why you think that it is important for researchers to partner with communities. You also want to demonstrate respect for community partner roles in research. You should explain that all people who work on research projects are required to complete a training course on human research protections and that this course may fulfill that requirement.

Have students introduce themselves by stating their name and where they are from or where they work. Ask them to describe the research project they will be working on and what they will be doing — in as much or little detail as they would like, as some people may not be familiar with their projects.

If there is time, start with a simple icebreaker. You want this to be an interactive session, so it's important to get everyone comfortable with speaking right from the start.
Some ideas:

- What is something you enjoy about your neighborhood?
- What country would you most like to visit?
- Are you the oldest, middle, or youngest child?

You could also do a simple poll, asking people to respond with a show of hands.

- Has anyone ever been in a research study?
- Has anyone ever known anyone who's been in a research study?
- Who has heard the terms... human subject...research participant... institutional review board... Tuskegee Syphilis Study... data collection.... etc.

This can also help you to quickly assess the knowledge base, needs, and expectations of those in the group.

Brainstorming: What Is Research?

Overview of Discussion Questions:

What is research? (What do you think it is?)

- Why do we do research?
- What do people in your communities know and think about research?
- Why might some people or groups have a negative view of research?
- What can be done to increase trust in research/researchers?

What is research? (What do you think it is?)

Participants might discuss:

- Various types of research that do not involve humans (animal research, laboratory research)
- Finding answers to questions, finding solutions to problems
- Using the internet, reading a book, studying people bodies

You might introduce, emphasize, or ask:

- Research can help find answers to health and other social problems.
- Finding the answers to some questions/problems requires conducting research with people. For example, human participants are needed to find cures for or ways to prevent certain diseases. Any research that involves interacting with people or information about people is called "human research." Sometimes you might hear the term "human subjects research," but the term "participants" is preferable to "subjects."
- How is research that uses people different from research that doesn't use people? What about research that uses human cells? Animals?

TAKE AWAY MESSAGE

In this training, we will be talking about research that involves people. 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. Later you will learn about these guidelines.

Why do we do research?

Participants might discuss:

- Finding cures for diseases
- Fixing social problems (crime, education)
- Gaining knowledge

You might introduce, emphasize, or ask:

- Research helps find answers that can help improve our health and well-being or solve social problems related to education, crime, employment, etc. If we don't do research, we won't be able to find out what works.
- Research helps us determine what treatments or programs work best to help people with certain diseases or problems.

TAKE AWAY MESSAGE

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.

What do people in your communities know and think about research?

Participants might discuss:

- Experiences of friends or family members helped or hurt by research participation
- Positive or negative experiences they or others have had working with local universities
- Impact of research on their own lives (e.g., recent discovery of new medications)
- Historical or more recent news stories about abuse of research participants

You might introduce, emphasize, or ask:

- Research is often discussed in newspapers and magazines and on the internet, radio, and television news. Have you heard anything about research lately?

TAKE AWAY MESSAGE

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.

Why might some people or groups have a negative view of research?

Participants might discuss:

- Historical or more recent news stories about abuse of research participants
- "Helicopter research," i.e., when researchers come into a community to collect data, leave, and never share results with community members or apply those results to solve problems
- Research participation and partnership demands a lot but doesn't always give back
- Fear or mistrust of scientists

You might introduce, emphasize, or ask:

- In the presentation that will follow this discussion, the facts of Tuskegee and other research abuses will be presented.

TAKE AWAY MESSAGE

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, both purposive and due to mistrust, has contributed to health disparities in the US.

What can be done to increase trust in research/researchers?

Participants might discuss:

- The importance of rules and regulations
- Transparency

You might introduce, emphasize, or ask:

- In response to public outrage over Tuskegee, the federal government implemented rules for research, which will also be discussed today.
- Research involving people must be approved by an ethics committee called an Institutional Review Board (IRB). All universities that do research will have an IRB. Many other types of organizations have them too, including hospitals, large community health clinics, and even some large community-based organizations that do research. IRBs are based at institutions and required to report to the federal government. IRBs are responsible for making sure that research gets done the right way, safely – and in the way it is proposed in research protocols. Research cannot start until the IRB has approved it. You will hear more about IRBs in a later presentation.

TAKE AWAY MESSAGE

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.

Handout: 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)?

Presentation: History of Research Abuses

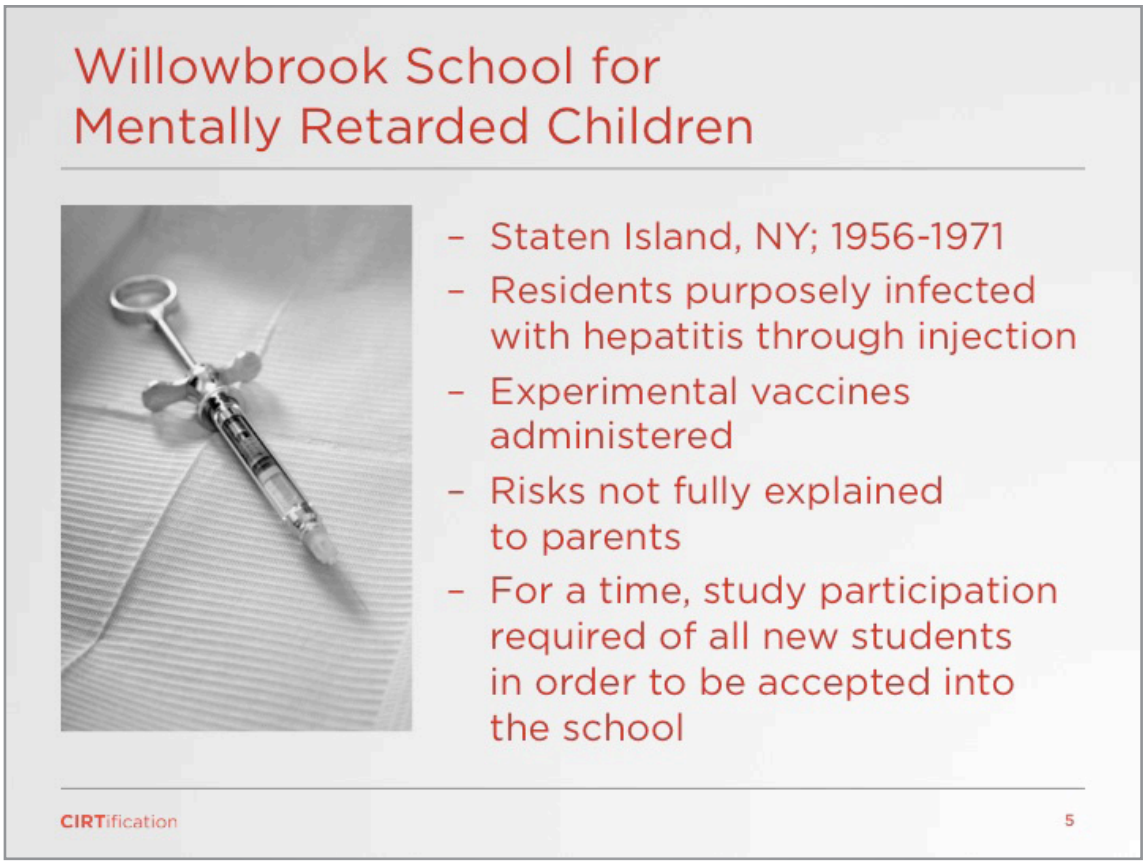
Suggestion: Select 2-4 historical examples of abuse that will most resonate with the group you are training.

- There are many examples of studies throughout history which caused harm.
- It is important to learn about these studies in order to understand the importance of treating research participants ethically and respectfully.
- These harms demonstrate why research rules and protections are necessary, and how the behavior of one researcher can affect all research.

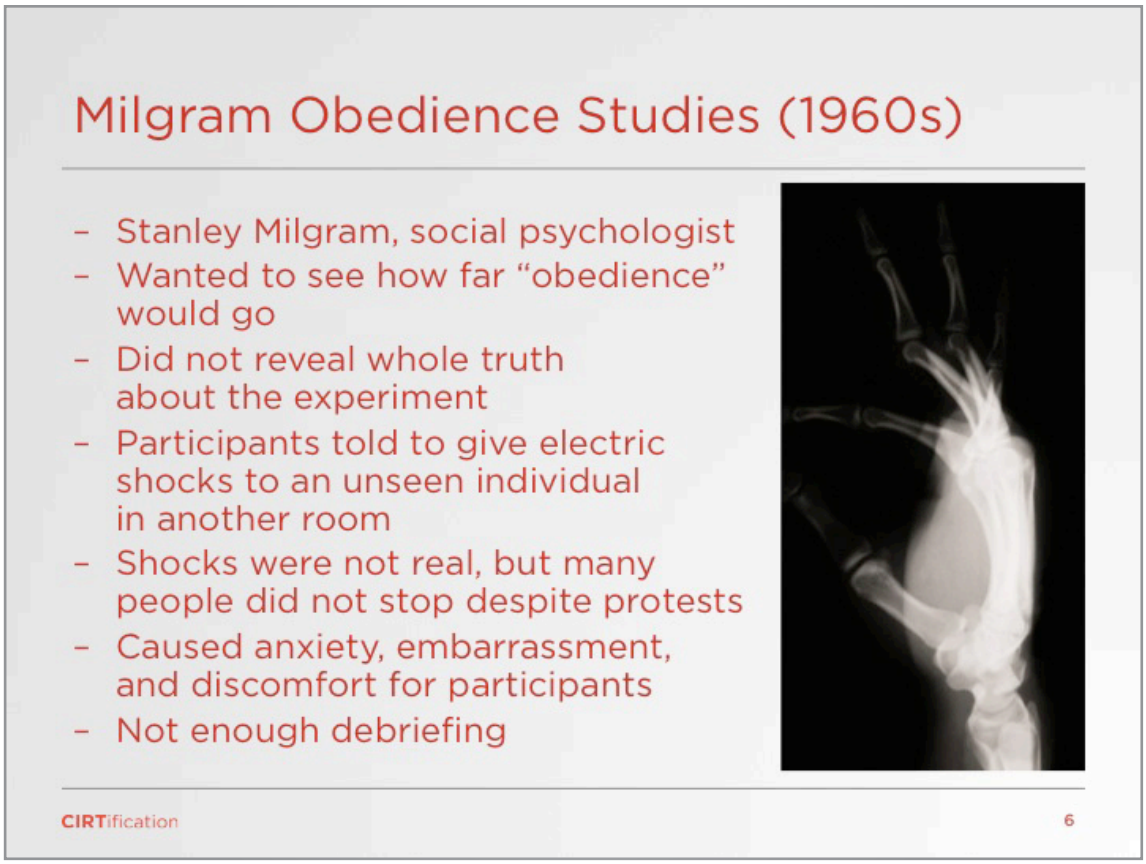
Note: We suggest you choose 2-4 historical cases that will most resonate with your audience.

- Most of these studies occurred in the U.S.
- Some are medical studies in which people were physically harmed, but a few are social science studies where participants experienced other types of harm, such as psychological harm or invasion of privacy.
- Many of these examples are from over 40 years ago, but some are more recent.

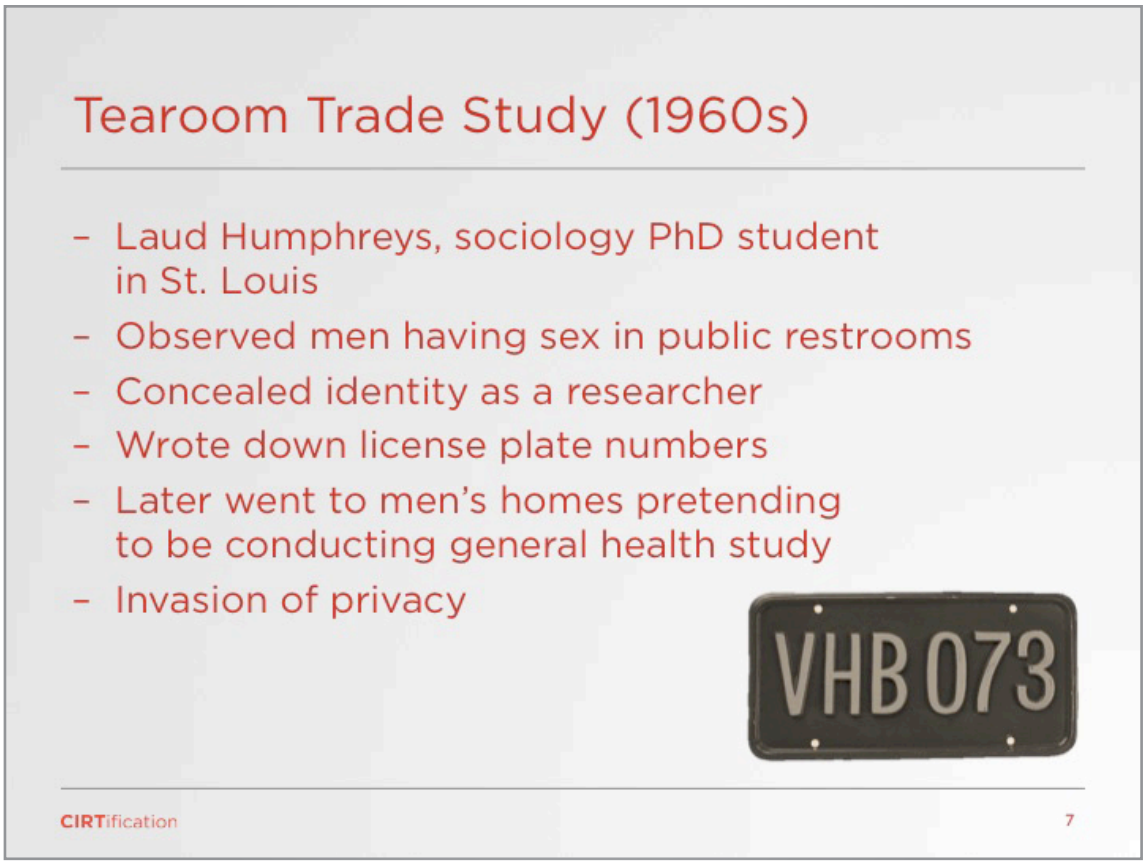
- During WWII, thousands of prisoners in Nazi concentration camps were used in dangerous and often purposely lethal medical experiments.
- For example, some prisoners were made to stand naked outside in freezing water or immersed in a freezing bath, after which doctors attempted re-warming of their bodies.
- Prisoners were also infected with malaria in order to test anti-malarial drugs, many of which had fatal side effects.
- Prisoners were deliberately wounded and their wounds were infected with various agents, including bacteria and glass shards so that experimental treatments could be tested.
- Twenty-three Nazis, including many medical doctors, were tried in 1946 and 1947 for these crimes. These trials prompted development of the Nuremberg Code, one of the first formal sets of ethical guidelines for medical researchers. The basic ideas of the Nuremberg Code are found in most codes of research ethics that have followed, including federal regulations for research in the U.S.



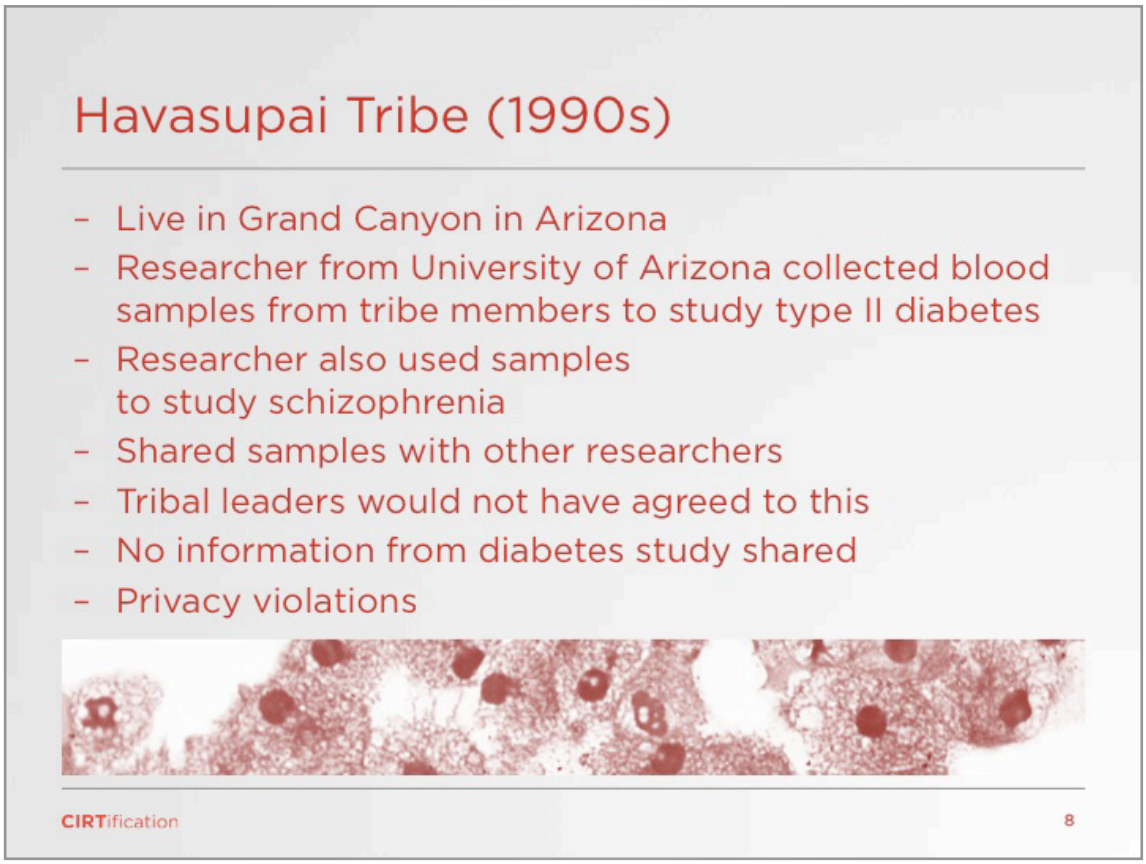
- Willowbrook was a school for mentally retarded children in Staten Island, NY.
- Residents lived there year-round. This was common for children with special needs at this time in history.
- Because of the living conditions, many (if not most) residents of Willowbrook naturally acquired hepatitis A and B.
- For a time, all parents of new students were required to enroll their children in a research study in order to gain admission. Parents were not adequately told of the risks of study participation, and many critics argue that parents were coerced into allowing their child to be a part of the study.
- This study tested experimental vaccines and involved purposely infecting children with hepatitis by feeding or injecting serum made with urine or fecal matter taken from patients at the school who were known to be infected.
- This research, conducted by Saul Krugman, did result in development of effective vaccines.
- Many observers are troubled by the fact that this study used particularly vulnerable children who were unable to speak for themselves. People all over the world — not just institutionalized children — have benefited from discovery of hepatitis vaccines, and many argue that it would have been fairer to use adult volunteers who had the ability to freely agree to participate.



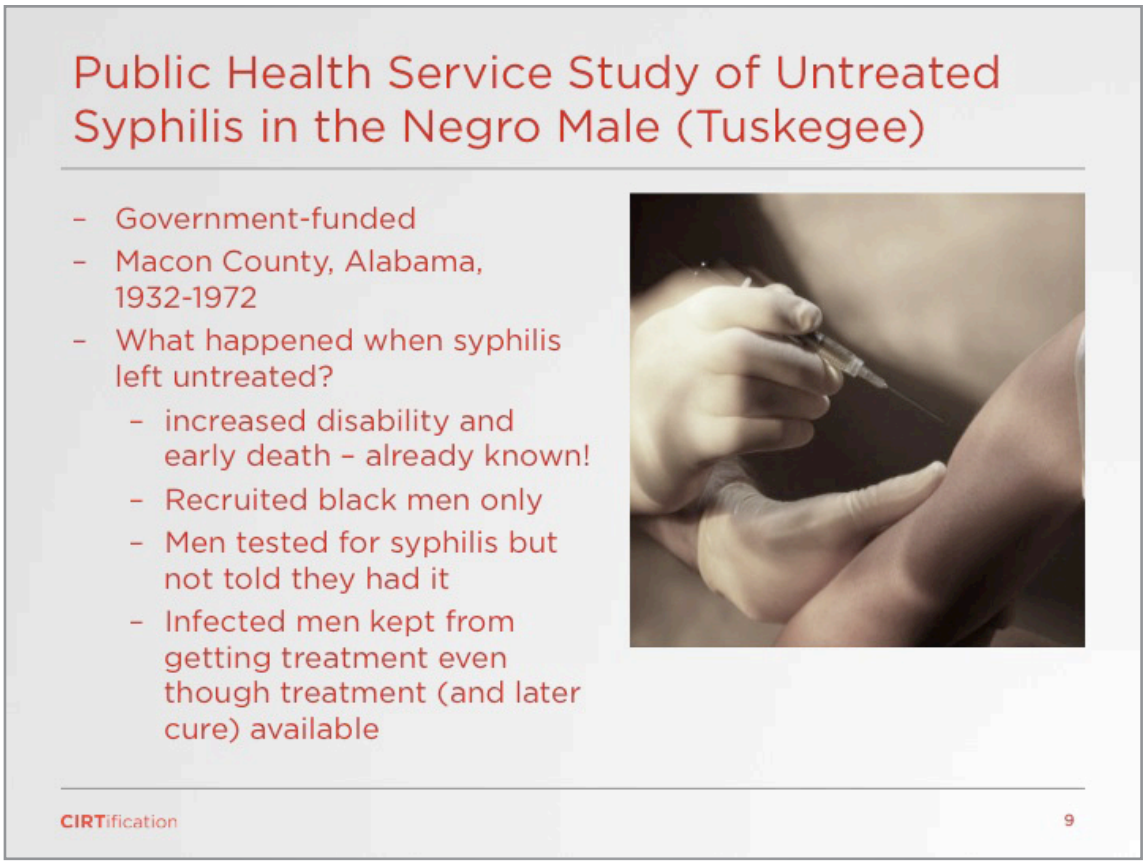
- Stanley Milgram conducted experiments to examine obedience to understand why people sometimes follow orders against their own conscience.
- Volunteers were told this was a study on learning behavior and randomly assigned to be "students" or "teachers." Teachers were ordered to give electric shocks to students who gave incorrect answers to word exercises.
- Teachers were led to believe that students were strapped into chairs with electrodes on their wrists in another room. As the intensity of the shocks supposedly increased, the teachers heard students screaming for the shocks to stop. A research assistant told teachers to continue administering shocks despite the screaming.
- Very few participants refused to stop, although some who did not stop did tell the researcher who was in the room that they were uncomfortable.
- Neither the students – nor the shocks – were real, so no one was physically harmed.
- Those participants selected to be teachers developed high levels of anxiety during the experiments. Milgram has been criticized for causing psychological harm, embarrassment, and discomfort, to participants, and these experiments have been called manipulative. It has also been said that he should have spent more time debriefing participants, that is, talking to them after the experiment to explain the purpose, answer questions, and minimize any potential distress.



- This was a study conducted by Laud Humphreys, a graduate student in sociology living in Saint Louis, Missouri, in the 1960s.
- Humphreys hid his identity and observed what was at the time called "the tearoom trade"—anonymous sex between men in public restrooms. This was a time when gay people were heavily discriminated against, and these individuals obviously wanted to keep this behavior private.
- Humphreys did not reveal that he was a researcher collecting data for his dissertation. He simply volunteered to act as a lookout.
- He wrote down car license plate numbers and went to men's homes, pretending to administer a general health survey. He collected information about their families, occupations, and social habits.
- Humphreys discpvered that many of these men were average citizens and some were even prominent community members – not "social deviants" as was commonly thought.
- Although Humphreys' research helped to break down some stereotypes about gay men, many people feel that his deceptive research methods constituted a serious invasion of privacy.



- The Havasupai live in Arizona, deep in the Grand Canyon. They are very isolated and maintain many of their native traditions.
- In the 1990s, members of the tribe approached an anthropologist from University of Arizona who they had known for many years and told him they were concerned about raising rates of type II diabetes. He introduced them to a genetics researcher.
- The genetics researcher told the tribe she was going to look for genetic causes of diabetes. She collected blood samples from several hundred tribe members.
- The genetics researcher also used to the samples to study schizophrenia, and she shared samples with researcher who studied other things, including migration patterns and inbreeding.
- The genetics researcher did not ask or inform tribe members about the other uses of the blood samples. Given tribal traditions and taboos, some of these studies would not have ever been allowed by the tribal leaders had they been asked.
- Researchers did not find a genetic link to diabetes in the tribe. They never went back to the tribe to tell them this.
- Additionally, tribe members' privacy was violated when the researcher looked in their medical records without permission to look for history of mental illness.



- Researchers wanted to study what happened if syphilis was not treated, even though doctors already knew what would happen: people get very sick and die.
- This study included many poor black men from rural Alabama, but men and women of all races and ethnicities suffer from syphilis.
- Participants were tested, but never told that they had syphilis. Even long after a safe, effective, and low cost treatment for syphilis (penicillin) was discovered, participants were actively prevented from visiting other doctors so that they would not learn about their syphilis and seek treatment.
- Researchers in this study lied to men about their real diagnosis and never told them that they were part of a research study. They implied to participants that they would be receiving state of the art care and lured men to participate with promises of payments, special medical care, and other perks.
- Researchers placed participants – and their families and sexual partners – at unnecessary risk keeping them in the study (and unaware of their syphilis) for so long, even after effective, low-cost treatments such as penicillin became widely available.
- Researchers took advantage of vulnerable men who were poorly educated and did not have much access to health care services outside of those available through the study. Such abuses would most likely not have gone undetected for so long in a wealthier, more advantaged community.

Public Outrage Over Tuskegee

- Many scientists knew about the Tuskegee syphilis study – it was NOT a secret!
- But once it was reported in Washington, DC newspaper, **the public demanded government action**
- A federal commission was formed to address protection of research participants and develop federal guidelines

CIRTification 10

- Many scientists knew about the Tuskegee syphilis study. This study was NOT a secret, and about a dozen articles about the study appeared in scientific journals while the study was going on.
- However, once news about the study appeared in a Washington, DC newspaper, and then on the front page of the New York Times, the American public immediately saw that this was wrong and demanded government action. That is essentially why stronger federal regulations for research were created.

Activity: Is It Human Research?

Introduction

There are many activities that involve people that are similar to human research. Sometimes it can be very hard to tell the difference. However, as we are learning, there are special rules for research that involves human participants. It is important to know the difference between things that are human research and those that are not.

This exercise will help us determine what kinds of activities are subject to federal guidelines for human research.

There are several definitions in the **Glossary of Key Terms** that should be reviewed with learners prior to starting this activity. These are:

Data Collection

The process of getting information in research. Data collection may include direct contact with research participants. For example, doing surveys and interviews involves interacting with participants and asking them questions to get information. Data collection can also include observation. For example, 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 records that already exist, such as medical, laboratory, or school records.

Human Research

A study that collects information from or about living people.

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 *with* subjects). However the term "human subjects" is still used in many formal research-related documents and guidelines.

INSTRUCTIONS

This activity can be structured in several different ways. You can have all students complete the worksheet on their own and then discuss answers as a group. You can also go through the questions as a group, and either discuss answers as you go or after all questions have been answered.

Think about each activity. Decide whether it fits the definition of "human research" that you have just learned. It's okay if you're not sure. Not all questions have an easy yes or no answer.

1. To find out how well a new medicine works, people in Group A get a new medicine, and people in Group B get the old medicine and their health is compared.

   Answer: **YES.** This is research testing an experimental medicine and using people.

2. A telephone survey asks Chicago residents their views on metered street parking.

   Answer: **MAYBE.** It depends who is asking and the purpose. If the parking meter company wants to know how people like the new meter system, then it is not research. If researchers want find out if the meters affect use of public transportation, then it is human research.

3. A reporter stops you on the street and asks your opinion about the new parking meters for a TV news segment.

   Answer: **NO.** This is journalism, not research.

4. Your son's school sends home a survey about family meals for parents to complete and return in a sealed envelope.

   Answer: **MAYBE.** If this is research, information should be included with the survey explaining the purpose of the research, what the information will be used for, that your participation is voluntary, and how confidentiality of your responses will be maintained. However, the school might just be asking in order to develop programs.

5. Your doctor recommends that you attend a free program at a nearby community center. He says the program is effective in helping people manage their hypertension.

   Answer: **MAYBE.** This is probably service, not research. The program has already been shown to be effective, and it is available in the community. However, there may be a research component.

6. A student collects the addresses of all the schools, parks, and liquor stores in the neighborhood and puts them on a map.

   Answer: **NO.** This is research, but it does not involve people, so it is not human research. The information the student finds might be important for people's health.

7. While browsing the Internet you see a link that says: "Are you a smoker? Click here if you would like to participate in a research study about your smoking habits."

   Answer: **YES.** It says it is a research study. However, Internet surveys are also sometimes for marketing. If a survey is being done online for research purposes, it should be clear who is doing the study and that it was approved by an IRB. If you cannot find this information, it's probably a marketing survey being done by a company.

8. You ask a neighbor to tell you about her involvement in the civil rights movement.

   Answer: **MAYBE.** If you are tape recording this discussion and taking notes, and writing a report, this might be human research. If you are just chatting, you don't need IRB approval!

9. A neurologist looks at the medical records of patients diagnosed with multiple sclerosis to see what tests were done to rule out other diagnoses.

   Answer: **MAYBE.** It depends on his purpose. If he is looking for patterns in the information and plans to share his findings with the scientific community, this is research. Even though the researcher never talks to the patients, he looks at their data, and depending on institutional requirements, he may need to get informed consent from patients. If he is just looking to improve his own practice, and these are his own patients, then it is not research and he does not need permission.

Presentation: Ethical Principles, Regulations, and Institutional Review Boards

Ethical Principles for Research

- 3 "golden rules"
  - Respect for persons
  - Beneficence (Do good, not harm)
  - Justice (Fairness)
- Federal research regulations are based on these three rules

CIRTification 2

- The ethical principle of respect for persons requires that researchers provide enough information to potential participants — and in a way that ensures clear understanding — so that they can make their own decision about whether or not they want to participate.
- Informed consent is how researchers show respect for participants.
- Later on, we will talk about informed consent – free voluntary agreement to participate in research based on adequate, truthful information provided by the researcher.
- Not everyone is capable of making their own decisions, for example, children, or adults with mental disabilities. However, research can be beneficial to these groups and therefore special protections are required – such as appointed guardians who make decisions about research participation in the best interest of the vulnerable individual.

- The ethical principle of respect for persons requires that researchers provide enough information to potential participants — and in a way that ensures clear understanding — so that they can make their own decision about whether or not they want to participate.
- Informed consent is how researchers show respect for participants.
- Later on, we will talk about informed consent – free voluntary agreement to participate in research based on adequate, truthful information provided by the researcher.
- Not everyone is capable of making their own decisions, for example, children, or adults with mental disabilities. However, research can be beneficial to these groups and therefore special protections are required – such as appointed guardians who make decisions about research participation in the best interest of the vulnerable individual.

- Research should not deliberately or unnecessarily harm people. However, there are always risks that are unknown or not thought of ahead of time. Also, some medical procedures carry some necessary harm - for example, wounds from surgery.
- The word "risk" might immediately bring to mind the possibility of physical harm. Physical harm is a possibility in medical research, especially when new medications or procedures are being tested for the first time. Not only is it not known if the medication will work, but not all of the potential bad side effects are known.
- Different research has different kinds of risk – different *types* and *severity* of risk. Many research studies (surveys, for example) carry no more risk than what we encounter in our daily lives.
- Other examples of risks in research include:
- The risk that information provided might not be kept safe and people might find out private information about others (e.g., that you are HIV+)
- The risk of becoming upset when asked questions about sensitive topics (e.g., about your health)
- The risk that information discovered from research might get into the wrong hands (e.g., someone's boss finds out they are using illegal drugs and they get fired from their job)
- Everyone has different ideas about what is "risky." Some are afraid to fly, while others pay money to jump out of airplanes. The informed consent process (discussed in more detail in Part II) provides potential participants with information about risks so that they can make a good decision.

- The benefits (good) and burdens and risks (bad) of research should be fairly distributed across all groups of citizens.
- Researchers should not exploit people who may not be able to say no because of educational, financial or other circumstances.
- Equal opportunities to participate in research should be provided to all.
- Some people/groups should not be put at risk for the benefit of others.

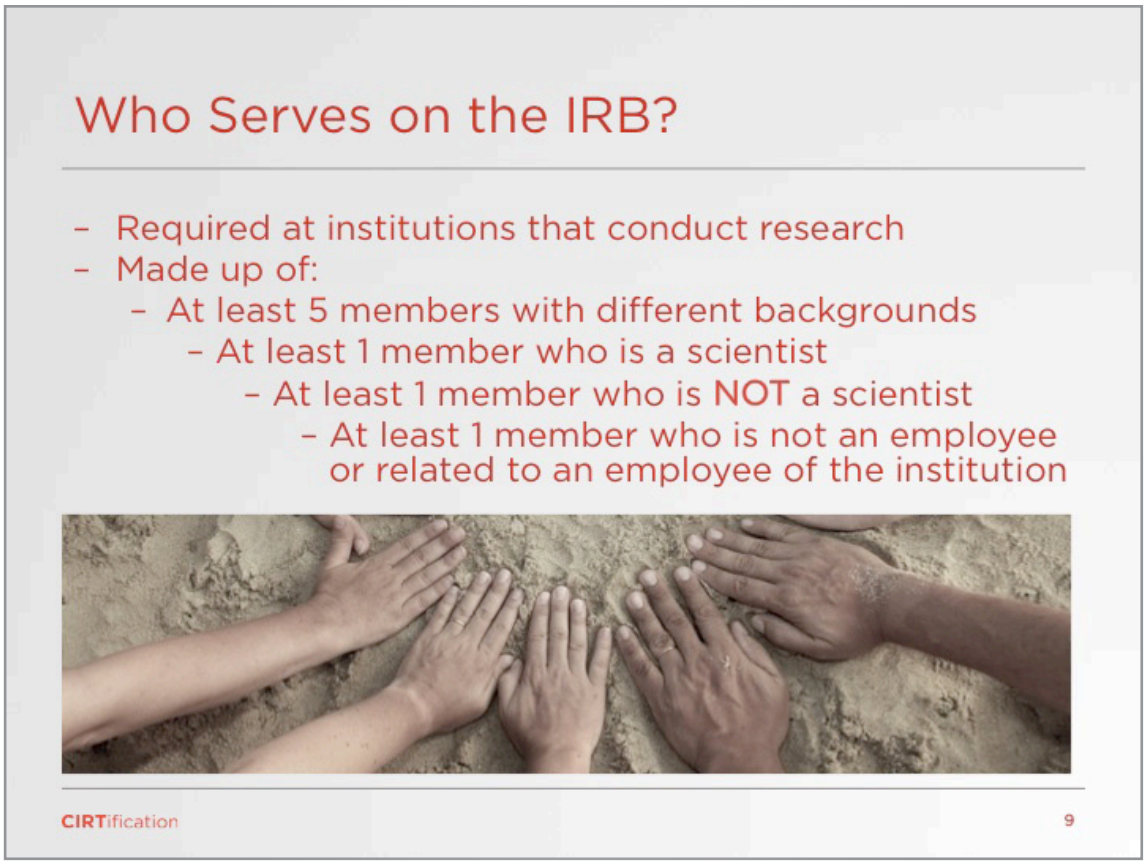
- The federal government has made laws for how research should be done. These laws are in a government document called the Code of Federal Regulations, specifically in Title 45 Part 46.
- This code spells out rules for how research participants should be informed about a study and what kinds of information they need to be told; guidelines for how research should be reviewed before it can start and who should do this review; and rules about other protections that must be in place before research starts.
- Everyone who is involved in research must follow these rules.
- This includes lead investigators as well as those anyone who has contact with participants and/or data. You may be attending this training today because it is a requirement for you to be able to work on a research study.
- Special review committees called institutional review boards or "IRBs" enforce these rules at the local level in order to protect the rights and welfare of participants.

- The main goal of IRBs is to protect human participants from harm.
- IRBs are responsible for making sure that research gets done the right way and safely.
- The IRB looks at all the procedures and forms used in a research that involves human participants.
- A research study cannot start until the IRB has reviewed and approved it.

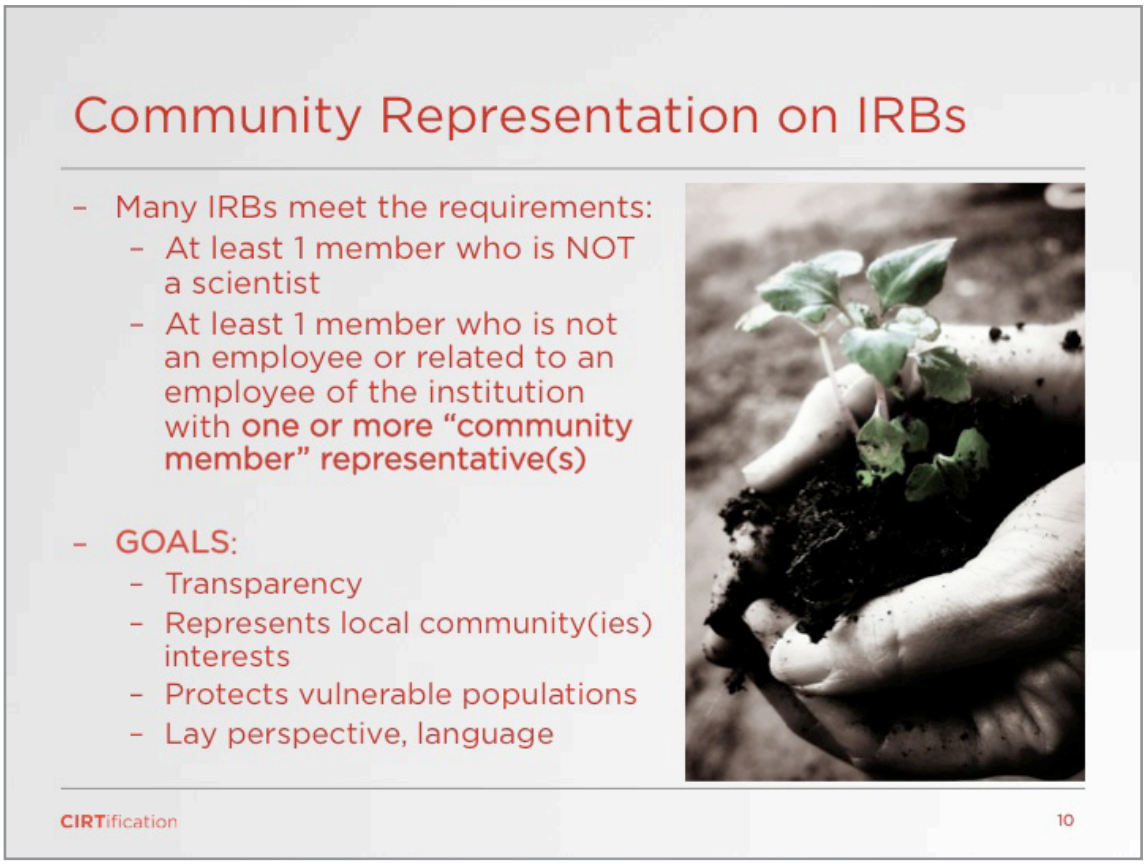
When reviewing a research study, the IRB looks at issues such as:

- What are the potential risks and benefits to participants? Can risks be minimized? And if so, how?
- How are participants recruited? Is this fair? Are some groups excluded or are some groups unfairly targeted?
- What are the informed consent procedures? Later we will talk in-depth about informed consent.
- Are adequate steps taken to keep participant information private?

- The IRB may require changes– big or small—that the researcher must make before the study can be approved. Research cannot start until IRB approval is received.
- The IRB may think that a particular study is too risky and may require many major changes.



- All universities and other institutions that have faculty members and staff that do research with humans must have an IRB.
- Many other types of organizations may also have an IRB, including hospitals, large community health clinics, and even some large community-based organizations that do a lot of research.
- IRBs are "local" and based at individual institutions. They are required to report to the federal government Office for Human Research Protections (OHRP).
- The federal regulations set rules for who should be members on an IRB. All IRBs are required to have at least five members with different backgrounds. At least one member must be a scientist, and at least one member must NOT be a scientist. Every IRB must also have at least one member who is not an employee or related to an employee of the institution.



- Many IRBs have one or more community representations. These are individuals who are both not scientists and do not work at the institution.
- These individuals are supposed to represent the type of people that would serve as research participants in studies conducted at the institution.

Community representation aims to accomplish many things, including:

- *Transparency:* If community IRB members know about what's going on at the university, they can ensure better protections for research participants.
- *Representing local community interests:* Community IRB members make sure that proposed research practices are in line with the goals and beliefs of the community.
- *Protecting vulnerable populations:* Having a community member on the IRB can help ensure that vulnerable individuals and groups are not exploited.
- Community participants can provide a "lay" perspective on research. For example, they can help ensure that consent forms are written in language that is understandable.

- Any changes that the researcher wants to make to the research must be reviewed and approved by the IRB.
- Researchers must also provide annual (or sometimes more often) updates to the IRB.
- Any problems that happen during the research must be reported to the IRB. Serious problems in human research are sometimes called "adverse "events. Some problems that should be reported might include:
  - When a staff member does not follow proper procedures
  - When a participant complains about something they are asked to do in the research
  - If a harm occurs to a participant – other than those minimal harms that were anticipated (examples of minimal harms would include experiencing minor discomfort while having blood drawn or being asked questions about their sexual history)
- If any of these things happen during rsearch the lead investigator should be informed as soon as possible.
- If rules aren't followed, appropriate forms aren't used, then researchers are "non-compliant" — that is, they are violating federal regulations. This can be very serious.

Discussion: Community Engagement

Why is it important for researchers to partner with communities to do research? What are the benefits from this partnership to researchers and to communities?

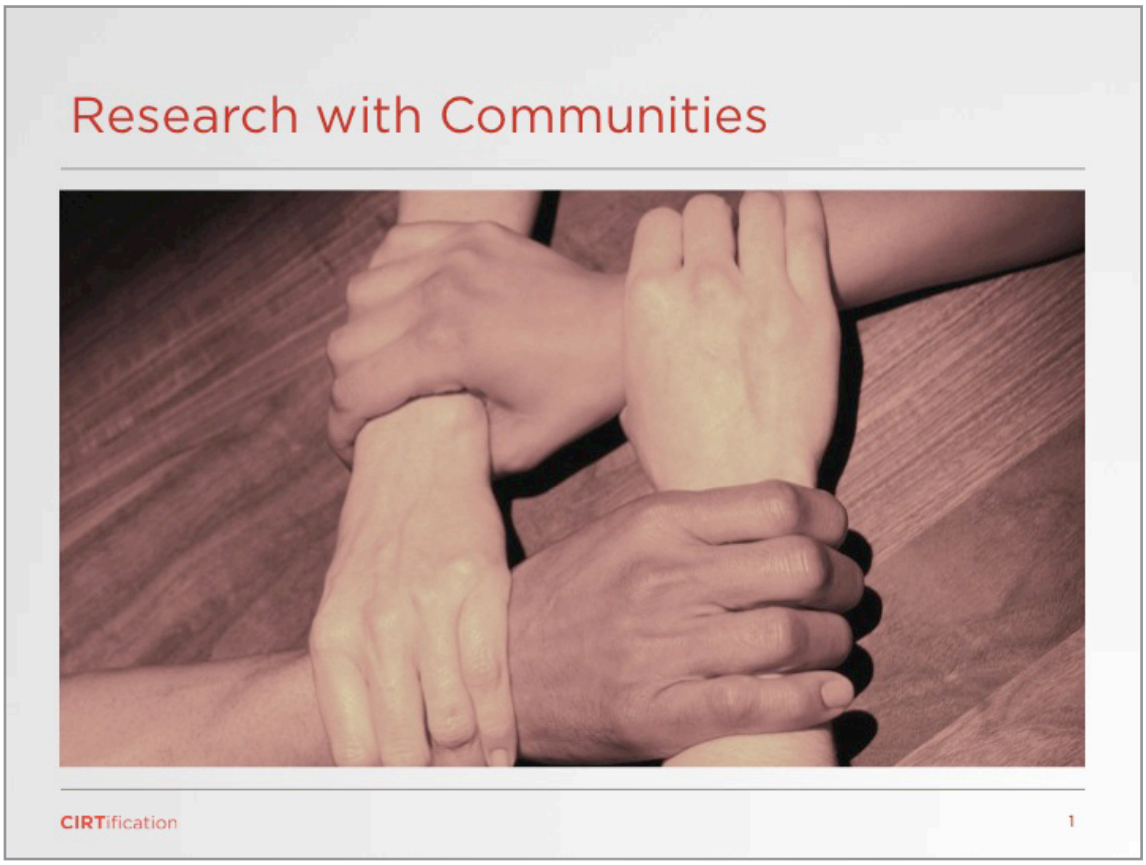
You might introduce, emphasize, or ask:

- In *community engaged research* (sometimes called community based participatory research), academic researchers work together with diverse partners including representatives from community agencies, health care service organizations such as hospital or clinics, and schools.
- Community partners can work with researchers to identify research priorities, design research projects, recruit participants, collect data, deliver interventions, analyze data, and share findings.
- This is a growing practice, stemming from the realization that *not* involving communities in research has contributed to disparities in health and education and in some cases, mistreatment of research participants.
- Many funders are requiring investigators to prove they can reach out to underserved populations and work with community partners to conduct research.
- Partnering with communities can help make sure that the research addresses issues that are important to the community.
- Community partners can make sure that individual rights are respected.
- Partnering with communities can make sure that more people know what research studies are being conducted in their community and that more people find out the results of research that is conducted in their community.
- Partnering with communities can help make sure that those who participated in the research are more likely to benefit from the research.
- Researchers might find that if they partner with the community, more people may be aware of their study and may want to participate.

TAKE AWAY MESSAGE

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.

Presentation: Research With Communities



- Community engaged research has some unique aspects that make it different from traditional research.
- Many people argue that community-engaged research is not only more relevant because of its commitment to local health issues and translating research findings into policies and programs, but also that it is more ethical.

- A community can be geographic (e.g., a neighborhood), racial/ethnic (e.g., African American community), religious (e.g., Muslim), or defined by other similarities (e.g., people with AIDS)
- Now there are even "online communities"

- Research can affect public perceptions of an *entire* community, not just the individuals who have participated. For example, a study might report that drug use among young African American males in a particular neighborhood is twice the national average. This information may promote negative stereotypes about *all* young men in the neighborhood, resulting in social harms (such as difficulty in finding employment) for everyone who lives there.
- Community-engaged research also raises unique privacy and confidentiality concerns. Through research activities, individuals who live or work in a community may have access to personal, sensitive information about their neighbors or clients. Standard privacy and confidentiality practices may not prevent the identities of individual participants from being discovered if participants are known to community partners. And unfortunately, familiarity may increase temptation to look at or talk about private information.

- Research partners may have different, competing ideas or interests (e.g., personal views, financial gain, reputation) that may take priority over the best interests of participants.
- For example, community research partners may have biases against or in favor of certain areas of a neighborhood or certain clients. These biases could lead to unfair recruitment practices.
- Academic and community partners may have different ideas about the root cause of a health problem.
- Community research partners may also different kinds of obligations to their communities — for example, obligations to provide services, to advocate for policy change, or to focus on certain social and/or health issues. These may be very different from the goals of academic researchers, who are looking to contribute to knowledge.

- Many researchers partner with communities because they think it is the right thing to do and that it will make research more useful.
- As we just discussed, research with communities can introduce new ethical challenges into the research process.
- Partnering with communities to do research can help protect participants in research from harm. This means that community partners need to know – and follow – the rules for human research protections.
- Community partners should also ask questions about things that they don't understand and raise issues with the investigators or other members of the research team if they think something about the research is not right.

PART 2

ASKING PEOPLE TO PARTICIPATE IN RESEARCH: THE INFORMED CONSENT PROCESS

Session Objectives

At the end of this session, all participants should be able to:

- Explain how the requirements of information, understanding, and voluntariness are fulfilled during the informed consent process
- List some examples of the kinds of information that should be provided to potential research participants
- Recognize the kinds of statements that should and should *not* be made to potential research subjects during recruitment
- Identify certain groups that may have special requirements for research participation

Key Messages

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, that if they do enroll they can withdraw at any time, and that 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. There are special rules for working with certain vulnerable groups such as children, pregnant women and prisoners.

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

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.

Facilitator Background Reading

Introduction

This part focuses on the processes of recruiting research participants and obtaining informed consent, two activities in which community research partners are frequently involved.

Recruitment

One of the first steps in research is recruitment, which can be defined as finding and inviting the right people to participate in a study.

The eligibility criteria (sometimes called inclusion/exclusion criteria) are defined requirements for participation in a given study. Examples of eligibility criteria might be age, sex, state of health, a defined range for a biologic measure (e.g., glucose or cholesterol levels), or zip code. From a scientific standpoint, recruiting only people that meet the eligibility criteria ensures the integrity of the study results. From an ethical perspective, the principle of justice requires that research participants be selected in a manner that is fair and equitable. This is to assure that the benefits and burdens of research are equally distributed and that some groups are not put at risk for the benefit of others. So for both scientific and ethical reasons, it is very important that all research participants meet the study eligibility criteria.

All materials used to recruit participants should present the research study honestly. Fliers and other advertisements do not have room for much detailed information. But these materials should include important details such as the purpose of the study, basic eligibility requirements, and who to call for information. If research participants will receive payment for their involvement and time, this can be stated in recruitment materials but should not be emphasized (for example, by putting dollar amount in bold, capital letters at the top of the flier). Uncertain benefits (such as improved health or well-being) should not be promised.

The IRB reviews all recruitment protocols and materials (such as fliers, print and radio ads, screening surveys, and scripts used by those individuals who will be engaged in recruiting participants). Only materials that have been approved and date-stamped by the IRB should be used to recruit and enroll prospective participants. These materials are an important part of the informed consent process, because they are the first information a person will get about a research study.

Informed Consent: A Process

Informed consent is a process of information exchange that begins when a potential research participant is first told about the research and continues until participation ends. The informed consent process includes:

- Participant recruitment materials (e.g., information sheets, flyers, newspaper or Internet ads)
- Oral information (e.g., a group presentation, a brief summary of the project, an invitation for someone to hear more about the study and find out if they are eligible)
- Written information (e.g., consent form, study brochure)
- Opportunities to ask questions and get answers
- Assessment of participant understanding (e.g., through a formal quiz or teach-back process)
- Voluntary agreement (usually in writing)
- Continuing understanding and agreement

The Code of Federal Regulations (45 CFR 46.116) outlines specific requirements for legally effective participant informed consent, based upon the ethical principle of respect for persons. Prospective participants should be given sufficient time to consider whether or not to participate in a study. Information provided should not be coercive or "unduly influential" and should be presented in the preferred language of the subject (or legal representative), at their appropriate reading level (i.e., "understandable"), and may not include any inappropriately persuasive statements such as, "Your doctor would like you to participate in this study."

The consent form is a very important part of the informed consent process. It is the key document that communicates information about study requirements, risks, potential benefits, and procedures. It should be thought of like a tool. A signed consent form does not necessarily mean that consent is truly "informed." It is important during the informed consent process that: 1) participants are provided with sufficient *information* in a clear, comprehensible format; 2) participants *understand* the information that is presented to them (this means that they should have ample opportunities for questions to be clarified and that extra time and effort are taken with individuals who do not understand whether due to illiteracy, educational level, deficiencies in English, cognitive disabilities, or illness); and 3) that individuals make the decision to participate in research freely and *voluntarily.*

Additional References

Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press, 1986.

Flory J, Wendler D, & Emanuel EJ. 2007. Informed consent for research. In *Principles of Health Care Ethics,* eds. RE Ashcroft, A Dawson, H Draper, JR McMillan. Chichester, UK, John Wiley & Sons, Ltd.

Information

During the recruitment process, potential participants are provided with information about the study. This can be done face-to-face or over the phone, and most studies have information in writing that can be shared with potential participants, such as information sheets or brochures.

In general, the consent form should tell potential participants things like:

- what being part of the research will involve (for example, how long the study will take or how many times they will be required to do something as part of the study)
- what the risks and benefits to them might be
- who will see any information they provide, and
- who they can talk to if they have problems or questions.

The consent form also lets the participant know that they don't have to participate if they don't want to and how to quit the research if they decide they don't want to participate any longer after they start.

According to the Code of Federal Regulations (45 CFR 46.116), the following specific information must be provided to each potential subject during the informed consent process:

1) A statement that the study involves research, a description of the research and its purpose, and a description of the requirements of participation, such as what tasks need to be completed, how long they will take, where they will take place, etc.

2) A description of "reasonable foreseeable" risks and discomforts

3) A description of any reasonably expected benefits to the subject or to others (e.g., future patients)

4) Alternatives to participation (e.g., in a medical research study, all other treatments that are regularly available for patients with a particular diagnosis)

5) A description of measures taken to ensure participant privacy and data confidentiality

6) Whether or not compensation or medical treatments are available if injury occurs (if the research involves more than minimal risk)

7) Information regarding who participants should contact if they have a question about their rights or in the event of a research-related problem

8) Assurance that participation is voluntary, refusal will not involve penalty or loss of benefits to which the participant is otherwise entitled (e.g. services from a health care provider or community agency), and that the participant may stop participation at any time without penalty or loss of benefits

The Code of Federal Regulations (45 CFR 46.116(b)) also outlines additional informational elements that should be included in the informed consent document when appropriate. These include:

1) A statement that research procedures may involve unforeseeable risks (e.g., in the case of experimental medical treatments)

2) Circumstances under which a participant's participation may be stopped by the investigator regardless of their consent

3) Any additional costs to the participant that may result from taking part in the research (e.g., if an experimental medication or intervention available only as part of the research is not free)

4) The consequences of a participant's decision to withdraw from the study and procedures for orderly termination of participation (e.g., if termination of participation involves discontinuation of study medication, medical monitoring may be required after termination for safety reasons)

5) A statement that any significant new findings discovered during the course of the research that may potentially affect willingness to continue will be provided to all participants

6) The approximate number of study participants

Understanding

Giving people information is not enough to ensure "informed" consent. Researchers are obligated to ensure participants understand what they have been told. Sometimes research can be complicated, and a lot of information is presented to potential participants.

Everyone has different types of intelligence as well as different vocabularies, language abilities, and reading skills. We all have different ideas and distractions that affect the way we process information.

For many people living in the US, English is not their first language. Research studies must consider if and how people who do not speak English can participate. In a small study with limited resources, it may be necessary to exclude non-English speakers. Although this is not ideal, it is more harmful to enroll someone into a study they do not understand than to exclude them. If members of the population targeted for enrollment will speak a language other than English, all study materials – including the consent form – should be translated. Study information should not be translated from English into another language "on the spot," and family members should not be used as translators. If translation or interpretive services are needed, these should be provided by a trained professional.

Additional References

Flory J, Emanuel EJ. 2004. Interventions to improve research participants' understanding in informed consent for research. Journal of the American Medical Association, 292(13); 1593-1601.

Voluntariness

A person's agreement to participate in research should be freely given. Participants should not be persuaded by implicit or explicit threats or offered extreme amounts of money for compensation. Importantly, decisions about research participation should not be influenced by anyone involved in conducting the research.

Compared to information and understanding, voluntariness is abstract and difficult to judge or measure. However, in studies where there is potential for certain individuals to be influenced by potential benefits, misunderstanding, or pressure from others, safeguards can be implemented. These safeguards include:

- Giving participants sufficient time to decide about study participation before beginning study procedures;
- Involving a third party (someone who does not have a vested interest in the research) to serve as an advocate for participants who may be susceptible to undue influence (this is common in studies with adolescents that do not require parental permission);
- Prohibiting a potential participant's personal physician from inviting them to take part in research studies;
- Having someone with whom the participant does not have an existing relationship obtain informed consent.

Additional References

Nelson RM, Merz JF. 2002. Voluntariness of consent for research: An empirical and conceptual review. Medical Care, 40(9 supplement); V69-V80.

Payment for Research Participation

It is customary – but not required –for research studies to pay participants, especially when studies take up a significant amount of participants' time or follow participants over several years. Payments are for participants' time and considered an acknowledgment of participants' contribution to the research process. While payment certainly provides an incentive for research participation, payments for participation should not be so large as to tempt participants to do something they would not otherwise do, nor should they be considered payment for undertaking risk. However, they should be fair in reflecting the important contribution that participants make to science.

Additional References

Emanuel EJ. Ending concerns about undue inducement. Journal of Law, Medicine, and Ethics, 32 (1); 100-105.

Grady C. Money for research participation: Does it jeopardize informed consent? American Journal of Bioethics, 1(2); 40-44.

Macklin R. 1981. "Due" and "undue" inducements: On paying money to research subjects. IRB: Ethics and Human Research, 3(5); 1-6.

Documenting Informed Consent: The Signature

According to 45 CFR 46.117, informed consent should be documented using a written, IRB-approved consent form. The form should be signed by the participant or the participant's legally authorized representative and dated. A copy should be provided to the participant and/or representative. In studies where multiple people are obtaining informed consent from participants, it is good practice to also document who obtained consent.

When (Written) Signed Informed Consent is NOT Required: Waivers of Documentation

In most studies, participants are asked to sign an informed consent form. However in some studies, this signature may not be required. This is generally because either:

1) The study is minimal risk and requires a brief one-time interaction (such as a survey). The research procedures can be briefly explained and the participant's completion of the survey can be taken to signify their consent.

OR

2) There is a good reason to maintain complete anonymity of participants' identities. For example, the study asks extensively about illegal behavior, and the signed consent form would be the only document linking participants' names to the study.

If a researcher thinks there is a good reason not to obtained signed informed consent, he or she can request a waiver of documentation for informed consent from the IRB. The application must include a justification that this will not increase potential risk to participants. Even when a signature is not required, participants must still be properly informed. Participants must understand what they are agreeing to and provide verbal consent. Therefore, procedures for obtaining and documenting informed consent (without participants' names and signatures) must be outlined.

When Informed Consent is NOT Required: Waivers of Informed Consent

45 CFR 46.116(c) states that an IRB may 1) approve a consent procedure that alters some or all of the informational elements of informed consent or 2) waive the requirements to obtain informed consent IF:

- The research involves no more than minimal risk to participants
- A waiver or alteration will not adversely affect participants' rights and welfare
- It would not be possible to do the research without the waiver or alteration AND
- When appropriate, participants will be provided with additional pertinent information after participation

If there is a good reason to not tell participants some information, such as the purpose of the study, an alteration (rather than a waiver) might be approvable. For example, telling participants that a study is examining discriminatory attitudes towards newly arrived immigrants might cause participants to change their responses.

Some research aims to observe "normal" human behavior or interactions, and telling people that they are being studied might alter behavior. For example, a study might aim to gather data on what activities people do when they are in the doctor's office waiting room. Also, telling people they are being studied might not be necessary if the information being collected is anonymous and not private. One example would be a study of how people use public parks for physical activity. In this example, an IRB might approve a waiver of informed consent.

Waivers of informed consent are also commonly approved for recruitment purposes. If researchers are looking for people who meet very specific eligibility criteria, they may want to look in medical, school, or other records to minimize the number of ineligible people who will be contacted about study participation and maximize use of available resources. Participant authorization is normally required to gather information from medical records, but getting authorization for recruitment might not be feasible.

Research With Special Populations

Sometimes researchers talk about "vulnerable" populations.

These include:

Prisoners: due to their incarceration they are not able to make their own decisions

People with low literacy or limited English proficiency: their limited ability to understand makes it difficult for their choice to be fully "informed"

People or are severely mentally ill or cognitively impaired: their limited ability to understand makes it difficult for their choice to be fully "informed"

Children: they are not mature, their full intelligence has not developed, and they do not have the authority to make decisions for themselves

Children cannot legally provide consent for research. A parent(s) provide(s) "permission" for a child to participate in research. When children/minors are included in research, the parent/guardian(s) must sign a parental permission document. Depending on the child's age, the child may provide "assent." Assent is a child's affirmative agreement to participate in research. If the child is 7-17 years of age, some form of assent, either written or verbal, is usually obtained. Language must be simplified to the extent that the youngest person in the group understands.

It is still possible to do research with people from these vulnerable populations, but special precautions must be taken. It is important not to exclude certain groups of people from research because the research may provide benefits for them.

Additional References

Zion D, Gilliam L, and Loff B. 2000. The Declaration of Helsinki, CIOMS, and the ethics of research on vulnerable populations. Nature Medicine, 6(6); 615-617.

Ruof MC. 2004. Vulnerability, vulnerable populations, and policy. Kennedy Institute of Ethics Journal, 14(4); 411-425.

Levine C, Faden R, Grady C, Hammerschmidt D, Eckenwiler L, Sugarman J. 2004. The limitations of "vulnerability" as a protection for human research participants. American Journal of Bioethics, 4(3); 44-49.

Kipnis K. 2001. Vulnerability in Research Subjects: A bioethical taxonomy (commissioned paper). In *Ethical and Policy Issues in Research Involving Human Participants.* National Bioethics Advisory Commission. Available at: http://bioethics.georgetown.edu/nbac/pubs.html

Vulnerability in biomedical research (Issue). 2009. Journal of Law Medicine and Ethics, 37(1); 6-11.

Lesson Plan

ACTIVITY (Discussion Case) "Just Sign Me Up!"

PRESENTATION Informed Consent Overview

REVIEW Consent Form and the Elements of Informed Consent

PRESENTATION Obtaining Informed Consent

ACTIVITY (Role Play) Informed Consent in Action

Discussion Case: "Just Sign Me Up!"

Bill works at a local community-based organization and runs several after-school programs for youth. He is well-liked by all the parents and their children. He has been asked by the head of the organization to help recruit parents to participate in a research study on parenting. Parents will be required to attend 8 one-hour sessions over the course of a few months and fill out questionnaires four times over a period of one year. They will be paid $10 cash each time they complete questionnaires. One day Bill approaches Elizabeth, a mother of one of the 12 year-olds in his computer club, and asks her if she'd be interested in participating in the study. When he hands her the 3-page consent form, Elizabeth quickly says, "I don't need to read this whole thing. If you think this study's okay, just sign me up. I'll do it!"

Can Bill sign up Elizabeth to be in the study?

- The correct answer is no, not yet. Even though Bill gave Elizabeth *some* information about the study and she agreed to participate, , she is not really informed.
- However, this does not mean that Bill cannot sign up Elizabeth to be in the study. There are a few things he can do to try to give her more information.
- It is okay to continue to try to enroll Elizabeth because she seems open to the idea of participating in the study. If she had shouted, "No, I don't have time for anything else!" at Bill, it would be somewhat disrespectful to keep pushing the issue.

TAKE AWAY MESSAGE

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.

What is the difference between saying "yes" and understanding what you say yes to?

- Withholding all the details can sometimes be just as bad as a lie
- The importance of truth, how lying decreases trust

Provide examples from everyday life:

- You signed up for a new credit card, but you did not read all the papers that came with it. Later, you were charged a monthly fee that you didn't know about.
  How would that make you feel?
- You got a text message on your phone from your phone company asking if you wanted to try a new ringtone. You said yes without finding out more information, and on the next month's bill you were charged $9.99.
  You gave your consent but do you think you were informed?

TAKE AWAY MESSAGE

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.

What reasons might Elizabeth have for saying yes before she has read the consent form?

- She might not have time to read the form
- She might feel that she has to say yes to Bill to keep receiving services for her child
- She may have left her glasses at home
- She may not be able to read
- She may not realize that she has a choice
- She really wants or needs the money being offered
- She may like Bill and trust his opinion

TAKE AWAY MESSAGE

There are a variety of reasons that people may say yes (or no) to research participation.

What should Bill do next?

Possibility: Tell Elizabeth that you are glad she is interested, but that if she wants to participate, it is really important that she understands what she is getting into. If she does not have time now she can take the form home and call you later to discuss and possibly sign up. This is a good option if it appears that she is simply in a hurry or quickly agreeing because she does not want to talk to Bill.

Possibility: Ask Elizabeth if she would prefer that the two of you have a conversation about the information on the form (see next point).

Possibility: Read the form to her, or explain all the important key points. It is possible that Elizabeth does not want to read the form because she has poor reading skills. There are many ways to tell Elizabeth about the important aspects of the study without drawing attention to this possibility and potentially embarrassing her.

TAKE AWAY MESSAGES

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.

Think about how you might feel or act differently if you were asked to participate in a research study by: a stranger; a neighbor; your doctor; the principal of your child's school; or a friend's daughter working towards a masters degree.

Discuss how people may feel like they have to participate in order to keep getting services or maintain good relationships. Maybe Elizabeth thought that her son might not get to stay in computer club if she did not agree to participate. But as we have learned, research cannot be used as a threat in this way.

TAKE AWAY MESSAGES

- 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. Everyone has different ideas about what risks they are willing to take and what personal information they are willing to share.
- People may overestimate the benefits of research participation if they know the person asking them.

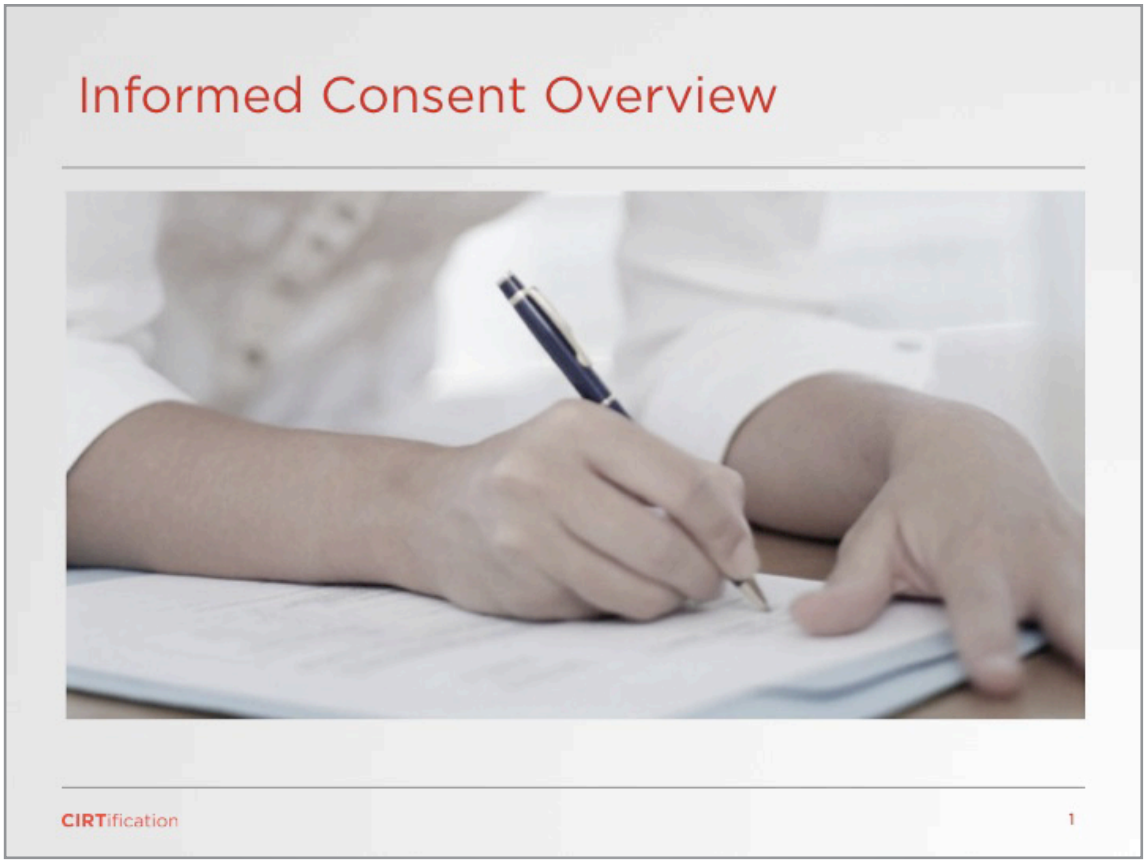
How can getting informed consent make the research experience better – for the participant and for the research team?

- Telling a potential participant that it is important for their safety and comfort that they understand what the research will involve as well as all the risks and benefits can increase trust.
- If you take the time to help participants understand the research, there is less of a chance that they will be surprised or upset by anything that happens in the research.
- When participants trust you, they will tell you the truth and take time to think about their responses.
- If you offer detailed information, participants will feel comfortable asking you a question if there is something they do not understand. Their understanding will improve the study.
- When participants respect you, they will be more likely to show up for scheduled appointments on time or call when they are not able to make it to a scheduled meeting. Your interactions with participants will be more satisfying.

TAKE AWAY MESSAGE

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.

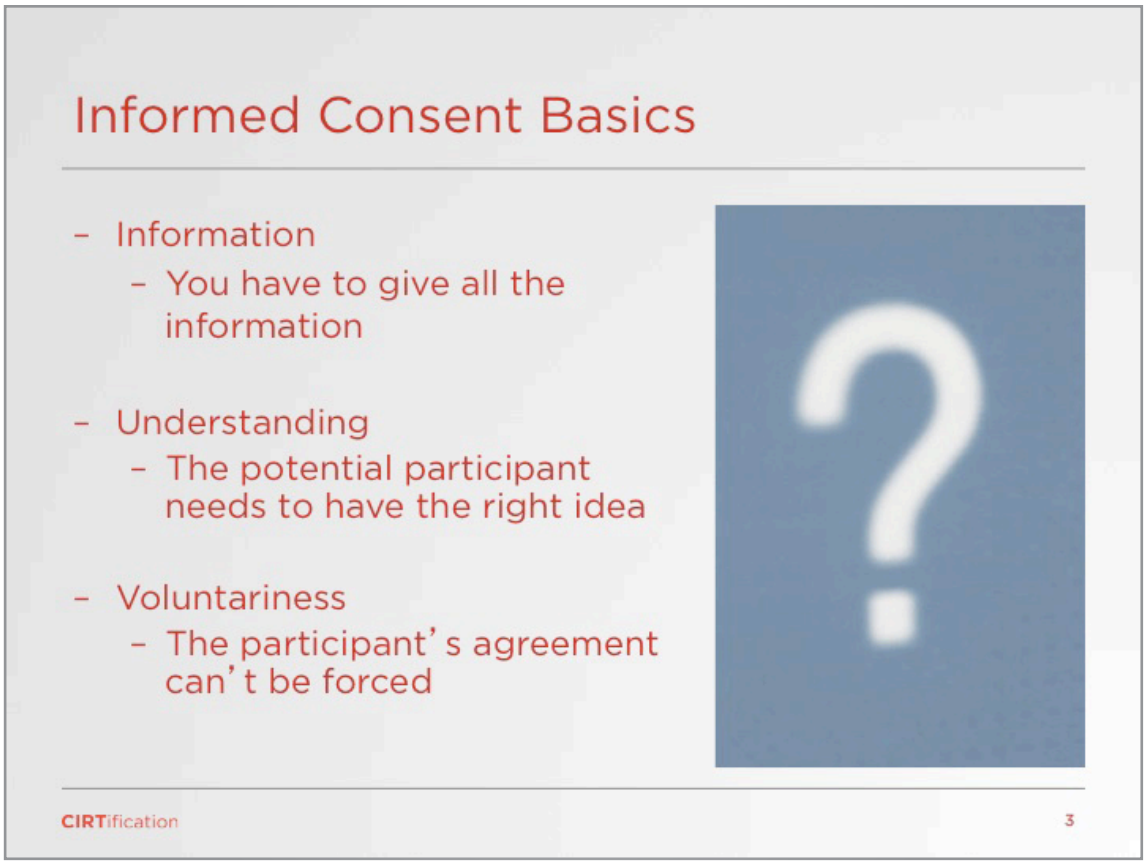
Presentation: Informed Consent Overview



- Informed consent is a process – and information exchange – that begins when a potential research participant is first informed of the research.
- Informed consent continues until participation has been completed.
- Obtaining informed consent from a participant should be a conversation– not just a means to get a signature.

  The process includes (at least):
  - Participant recruitment materials (e.g., information sheets, fliers)
  - Oral instructions (e.g., an invitation to hear more about the study; a brief summary of what's involved)
  - Written information (e.g., consent form/informed consent document)
  - Opportunities for questions and answers
  - Voluntary agreement in writing (signed consent form)

- The informed consent process starts as soon as recruitment begins.
- Recruitment materials such as flyers or information sheets should follow the same rules as consent forms.
- Participants can walk away at any time.

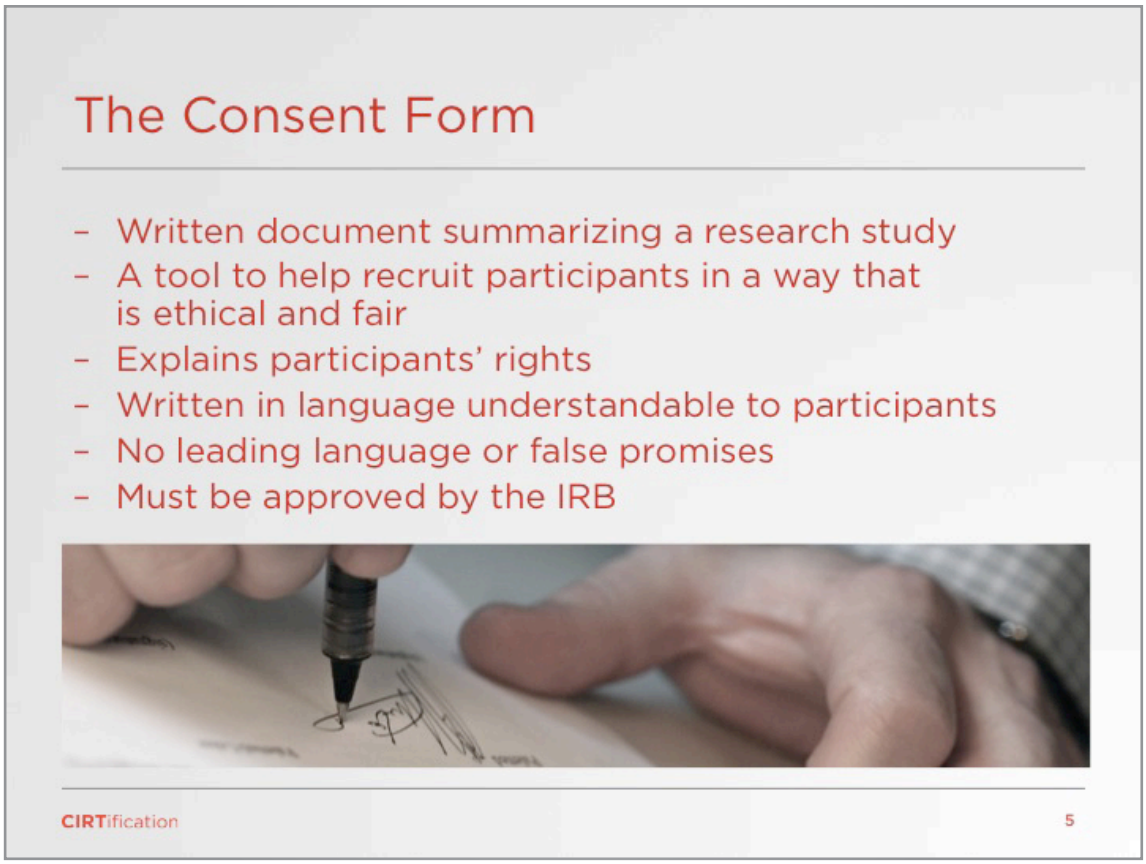


- Research participants must be given all the necessary information about participating in a study
- Participants must understand this information.
- Their decision to take part must be made freely.

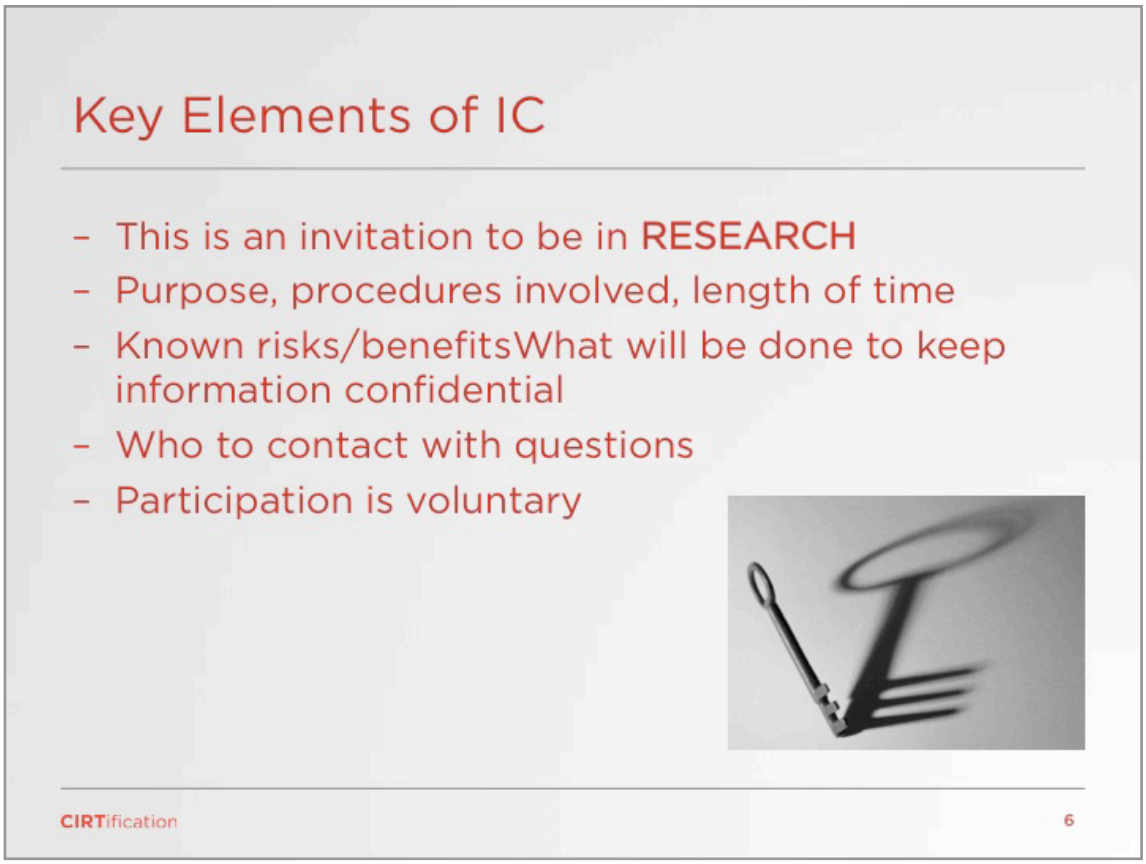
- Recruitment can be defined as finding and inviting the right people to participate in a research study.
- The eligibility criteria (also called the "inclusion/exclusion" criteria) are defined requirements that people must have in order to participate.

  Examples might be:
  - Age (over 40)
  - Sex (only women)
  - State of health (must have diabetes)
  - Defined range for a biologic measure (cholesterol over 200)
  - Area of residence (in the East side neighborhood)

- Only people who meet the eligibility criteria should be invited. Sometimes potential participants will need to be asked some questions or take some tests to see if they are eligible.
- Following the eligibility criteria and not including people who do not fit is important to make sure that the research is correct, useful, and fair.



- The consent form is the key document that explains the research to participants.
- It should be written in language that is very clear and truthful.
- The words in the consent form should not try to influence people to participate if they do not really want to.
- Studies are required to use consent forms that have been reviewed and approved by their institution's IRB.



Information that participants must be told during the IC process :

- They are being invited to participate in RESEARCH ; Purpose of the research, how long it will last, and what they will do; All the risks and benefits that the researchers know about; What will be done to keep information that participants share private; Who to contact with questions; participation is voluntary, they don't have to participate if they don't want to, that they can stop participation whenever they want to, and that if they choose not to participate there will be no negative consequences

Some other information that might be included in the consent form:

- There may be risks that the researcher does not know about yet; Why a researcher might decide to stop a person from participating; Any additional costs for participation; What to do if you want to stop being in the research; How many people are going to take part in the research; alternatives to participating (for example, if it is a medical study looking at a new type of medicine, are there other treatments that are already available); if and how participants will be taken care of if they are injured.

- Some people are not able to look out for their own interests.
- It is allowable to include people from these populations in research, but special precautions must be taken so that they are not influenced to do something that is against their own best interest.
- It is important not to exclude certain groups of people from research because the research may provide benefits for them.
- If the research you are involved in involves people who may be vulnerable to being used against their wishes, you should ask your academic partners about any special rules that might apply.

Activity/Presentation: The Consent Form

Model Consent Form

The callouts on the right side of the model consent form point out required elements of informed consent.

The model consent form is also available in PowerPoint slide format.

This activity can also be done using the actual consent form that will be used by a research project.

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.

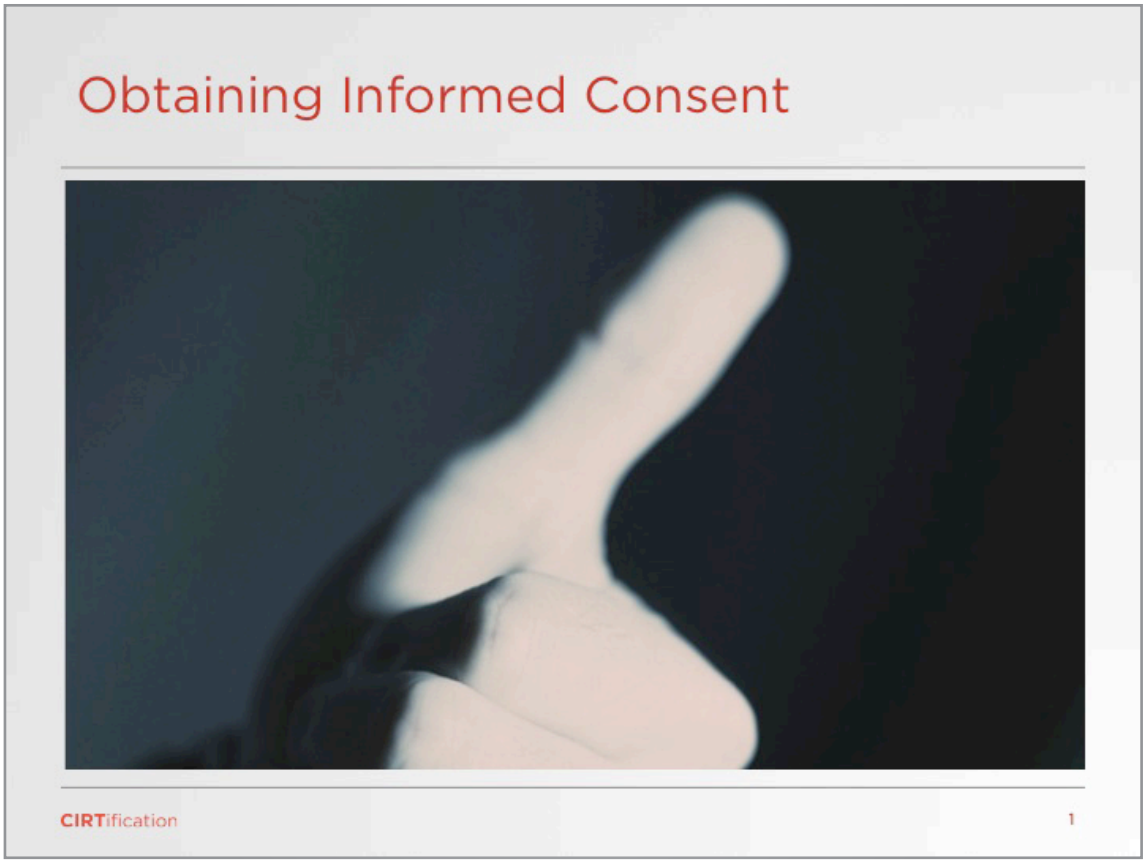
PRINTED NAME DATE

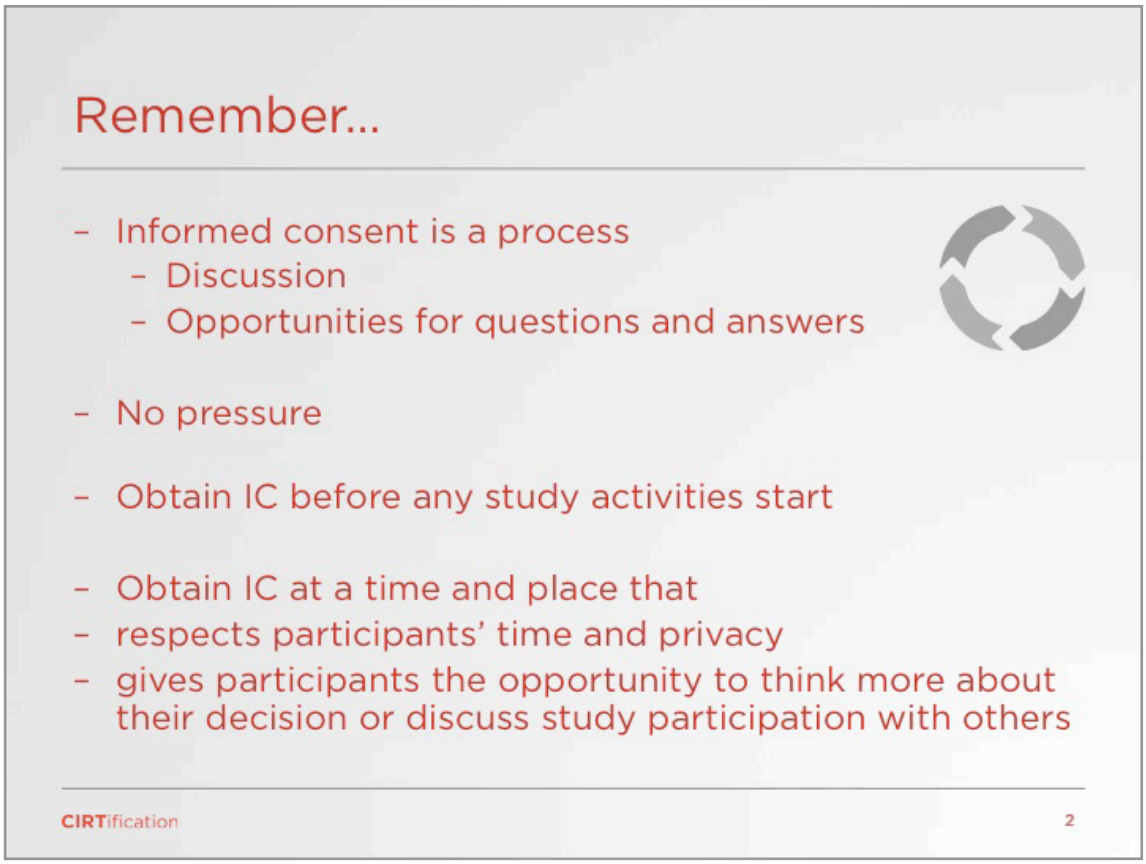
SIGNATURE OF RESEARCH PARTICIPANT

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

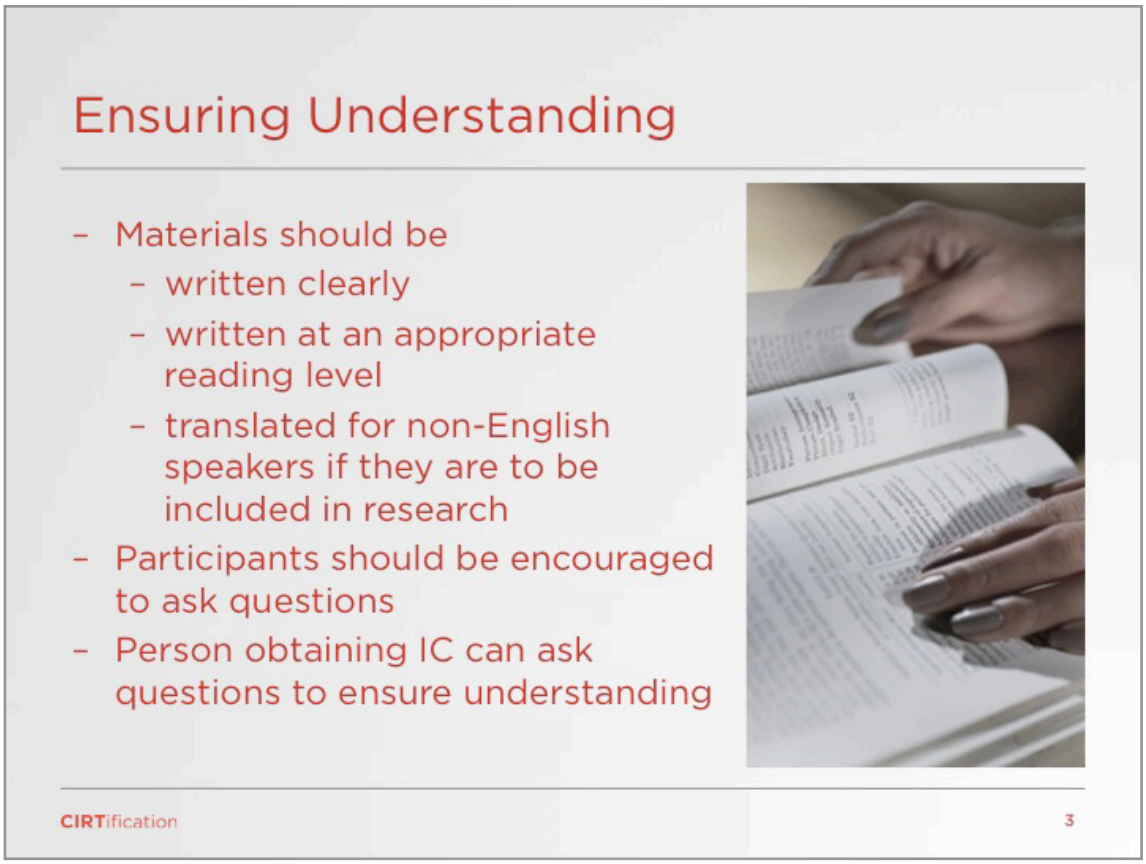
PRINTED NAME OF PERSON OBTAINING CONSENT

Presentation: Obtaining Informed Consent

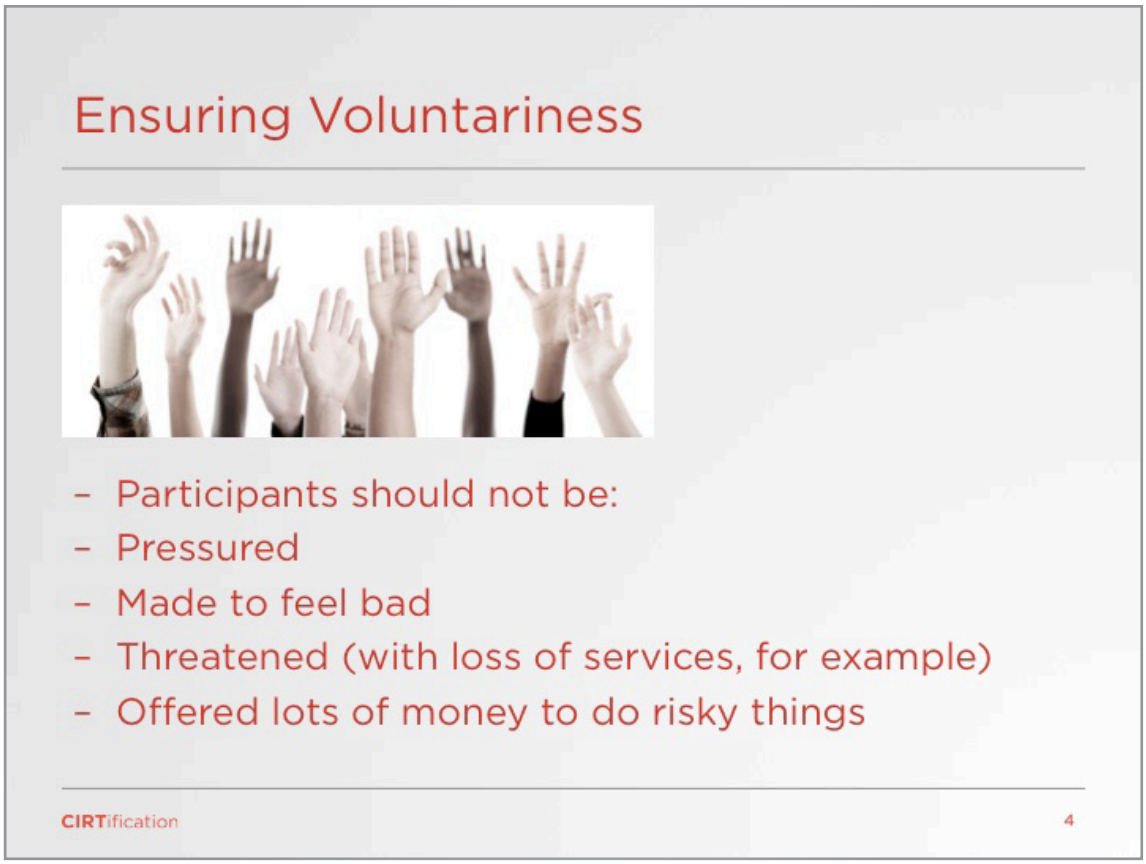




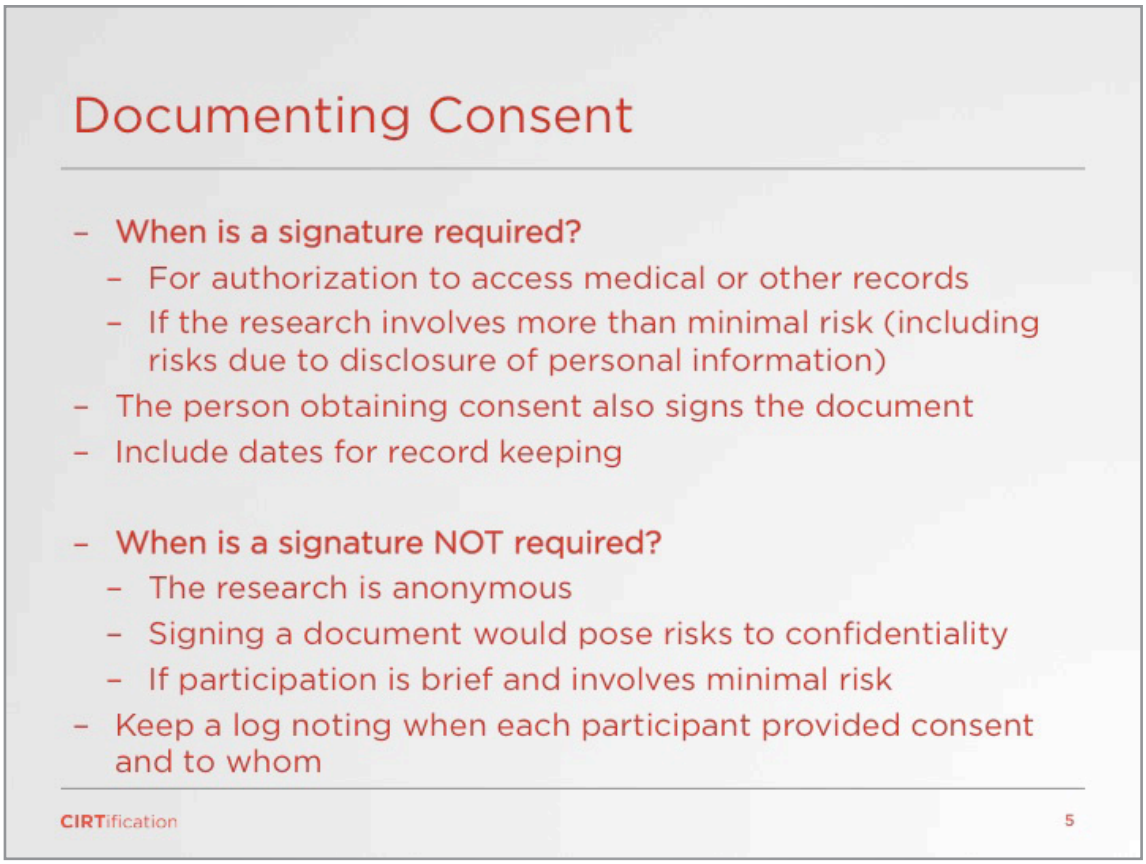
- Remember that informed consent involves more than just handing someone a consent form and asking them to sign it.
- It is very important that informed consent be obtained before a participant is asked to do anything related to the study such as fill out questionnaires.
  - The only exception to this is when you need to ask certain questions to find out if a particular person is eligible to participate.
- People should not be pressured to participate.
- Recruitment and informed consent activities should be conducted in ways that protect participant privacy. If possible, avoid public areas where others can hear conversations.



- Materials should be written clearly and at a reading level that is appropriate for the participant population.
- Materials should be translated for non-English speakers if they are to be included.
- Have participants describe the study procedures to you in their own words, especially if you think a person does not understand what they are being asked to do.
- Take time to have a discussion with participants. Let them ask questions. This is especially important if they do not or it appears that they have not taken time to read the consent form.

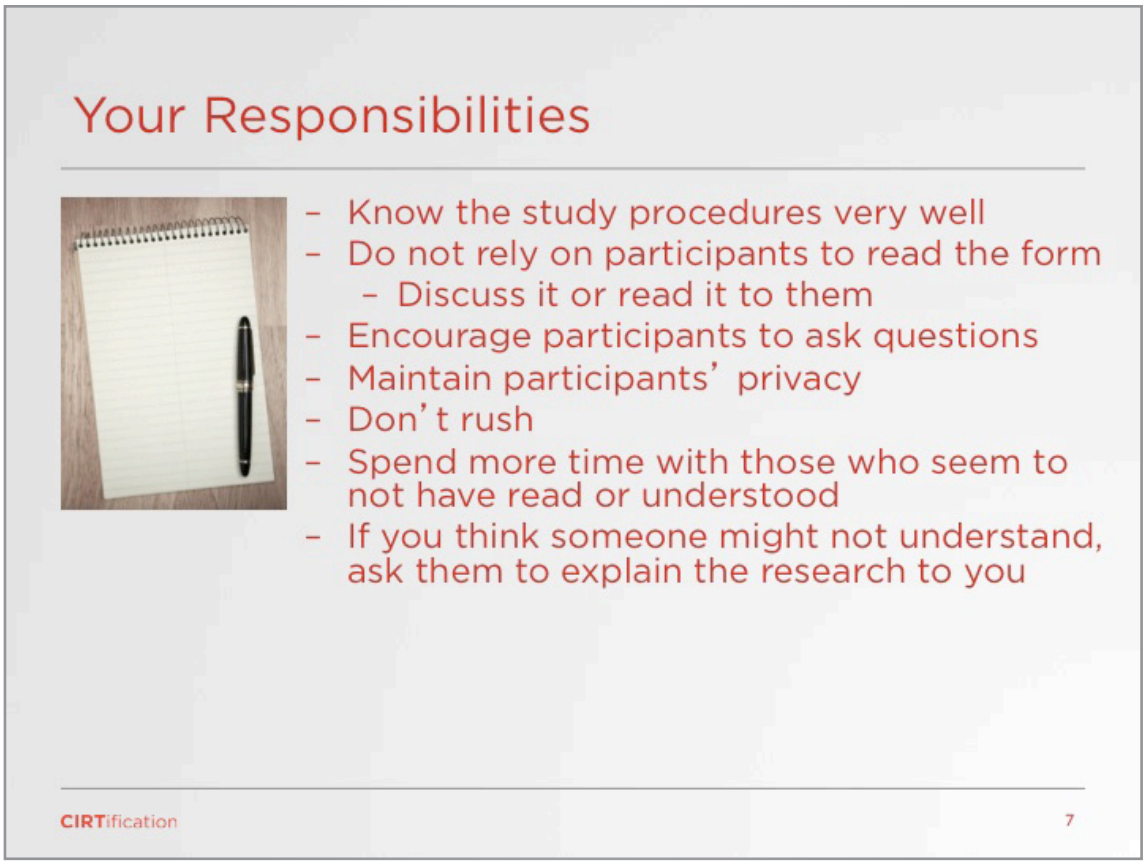


- People should not be pressured to participate.
- Participants should not be threatened, made to feel bad if they do not want to participate.
- Safeguards to promote voluntariness include:
  - Making sure that people have enough time to decide about participation before beginning in a study
  - Having someone not directly involved in the research assist and advocate for participants who might be susceptible to exploitation (for example, individuals with intellectual disabilities)
  - Not having certain influential individuals (like children's teachers or people's personal doctors) invite people to participate in research



- Not all studies require a signed consent form, but many do.
- If the study you are working on requires a signed consent form, participants should not sign until they have read everything and you have discussed any questions or concerns with them.
- If you are responsible for obtaining consent, you may also need to sign the consent form. This will depend on the particular study.
- It is very important to make sure that dates are included with any signed study-related documents.
- If signed consent is not required for the study, then a participant's agreement should be noted somehow. This will vary according to different studies.

- Getting voluntary informed consent from research participants can be challenging.
- Even when participants are well-educated and take time to read, the form is often long and contains a lot of information.
- Many Americans read only at a grade school level, and many researchers write forms using big words or scientific jargon.
- Even when researchers try simple explanations, it is not always easy to explain complicated research using plain language.
- Especially in medical studies, some people have a hard time understanding that they may not get better if the research is looking at a new, unproven medicine or treatment. People may exaggerate the benefits in their own minds even if you clearly do not.
- If the study offers money to participants, some people may do it just for the money, even if they do not really want to or if they don't understand the risks. The money offered to research participants should not be so high an amount that it makes people do something they otherwise would not agree to.



- If your role in research includes obtaining informed consent from participants, make sure you understand every aspect of the study and the consent form so that you can answer any questions.
- If something is unclear – ask for an explanation from the study investigators. Don't be embarrassed – it's your responsibility to ask questions! And if you don't understand something, chances are the participants won't either.
- If you ask questions now, this can help improve the informed consent process for the participants.

Role Plays: Informed Consent In Action

Role plays should be done in small groups of 2 or 3 depending on the size of the class. Students should spend about 20 minutes doing role plays. Then the entire group should come together to discuss.

This activity can be done using one of the model consent forms or ideally, the consent form for the study on which participants will actually be working. Role players will need to study the consent form and the notes below prior to the role plays

Individuals in each small group should take turns being the person obtaining informed consent and the participant. The observer role is optional and can be replaced by discussion. (Observer/discussion notes can also be the basis of the larger group discussion).

Role Play 1: *Understanding*
George: Responsible for obtaining informed consent.

Rita: 60-year old woman. Has diabetes and meets other inclusion criteria. Has limited reading skills and poor eyesight. Makes excuses about why she does not want to read the form. Makes incorrect statements about the research. Asks questions that show that she does not understand what is involved in research participation.

Observer/Discussion: Note different strategies that George can use to help Rita understand the study without making her feel uncomfortable.

Role Play 2: *Inclusion/Exclusion Criteria*
Martha: Responsible for obtaining informed consent

Joseph: Does not have diabetes and therefore does not meet inclusion/exclusion criteria. Still wants to participate because the research study provides $10. Lies about having diabetes in order to try to qualify. Tries to persuade Martha that she should let you sign up because you really need the money.

Observer: Note questions that Martha can ask to ensure that Joseph meets the study's inclusion/exclusion criteria. Note ways that Martha can explain to Joseph why he cannot participate. Note strategies that Martha can use to tell Joseph no without being rude.

Role Play 3: *Coercion*

Fred: Responsible for enrolling participants and obtaining informed consent. Has not successfully recruited anyone today. Begs, pleads, bribes, and uses guilt – i.e., tries everything! to get Rick to sign the consent form. Tells Rick that the research is really going to help him and going to do a lot of good for the community. Tells Rick that he will lose his job if he doesn't sign up enough people. Tells Rick that if he is concerned about privacy, he doesn't have to use his real name or answer questions honestly.

Rick: Does not want to participate because he does not have time and is also concerned about his privacy and the confidentiality of the information he will share.

Observer: Note what is wrong with the ways that Fred tries to persuade Rick to sign the consent form. Note the various things that Rick does and says to demonstrate that he is not interested. Note what might be some more appropriate ways of dealing with Rick's concerns about privacy.

Role Play 4: *Participant Questions*

Kim: Responsible for obtaining informed consent.

Janet: Is interested in the study, but also has a lot of concerns, questions, and ideas about research.

She wants to know:

- Why is this research being conducted in my neighborhood?
- Who is this research going to help? What changes can she expect in her community?
- Is she going to be used as a guinea pig? Are scientists going to experiment on her?
- How is her information going to be kept private? Her cousin signed up for a research study, and his identity was stolen 2 weeks later.
- Where is the money for this research coming from? Why isn't that money being used to provide community services?

Observer: Note the answers Kim provides in response Janet's questions. Are they accurate and persuasive? What are some other potential responses?

Group Discussion

- What did you learn?
- What tips do you have for each other about informed consent?
- What other challenges might you encounter?
- How do you know when to keep trying and when to give up when recruiting someone?
- What other questions do you think potential participants might have?

PART 3

BEING CAREFUL WITH RESEARCH INFORMATION

Session Objectives

At the end of this session, all participants should be able to:

- Understand good practices for collecting and storing research data
- Know what to do if they observe a co-worker not following appropriate procedures
- Discuss how to maintain participants' privacy and the confidentiality of their information
- Identify some of harms that may occur to participants if privacy and confidentiality are not protected

Key Messages

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.

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.

Facilitator Background Reading

Introduction

Basic issues related to protocol adherence and data integrity are presented. Privacy, confidentiality and unique issues that may arise in community-engaged research are discussed.

Good Research Practices

Individuals who collect data from research participants are responsible for ensuring that the information is accurate and protected. Otherwise, the study may not be worthwhile. If all pieces are not fully completed, scientific objectives cannot be met. 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.

Additional References

Johns Hopkins University School of Public Health. (2010). *Human Subjects Research Ethics Field Training Guide.* Available at: http://www.jhsph.edu/bin/u/p/Field%20Guide_25Feb10.pdf

Privacy and Confidentiality

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. Securing privacy and confidentiality is important to maintaining the trust of participants and the general public in research.

Perhaps the most common risk of research participation is the risk that participants' private information will be revealed outside of the research context. This risk is present in all types of research – although some information is more sensitive than others. Everyone involved in research is responsible for keeping information that participants share private. In some cases, serious harm can come from revealing other people's personal, sensitive information. Family and social relationships could be harmed. Someone could lose their job or be arrested.

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 locked office. Electronic information should be maintained on secure computer systems that restrict access, require passwords, and/or encrypt information so that it cannot be read by those who are not supposed to see it.

Additional References

Bayer R, Levine C, and Murray TH. 1984. Guidelines for confidentiality in research on AIDS. IRB: A Review of Human Subjects Research, 6(6); 1-7.

Wiles R, Crow G, Heath S, and Charles V. 2008. The management of confidentiality and anonymity in social research. International Journal of Social Research Methodology, 11(5); 417–428.

Protected Health Information and the HIPAA Privacy Rule

If research is related to health or health care, and especially if data are being collected in a health care setting, community partners will need to know about the HIPAA Privacy Rule. These federal regulations address the use of "Protected Health Information," or "PHI." PHI is any information that relates to past, present, or future health, health care, or payment for health care and that identifies the individual, directly or indirectly. If PHI is being collected in research, community partners may be required by the institutions involved in the study to take another separate training course on the HIPAA Privacy Rule.

Conducting research using patient medical records requires IRB approval and in some cases may require informed consent from individual patients.

Additional References

Annas GJ. 2002. Medical privacy and medical research – judging the new federal regulations. New England Journal of Medicine, 346; 216-220.

The HIPAA Privacy Rule, http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html

Kulynych J, Korn D. 2002. The effect of the new federal medical-privacy rule on research. New England Journal of Medicine, 346; 201-204.

Lesson Plan

ACTIVITY (Discussion Cases) "To Tell the Truth"

PRESENTATION Being Careful with Research Information

ACTIVITY (Discussion) How Would You Handle...

ACTIVITY (Discussion Case) "Secrets"

PRESENTATION Privacy and Confidentiality

Discussion Case: "To Tell the Truth"

You work for a youth advocacy agency. The agency is partnering with a local university on a research project. You and a coworker, Mike, are going door-to-door in the neighborhood to find out how many people in each house have asthma. If there is a child in the house with asthma, you then ask a parent to complete a brief survey. You go block by block, with you and Mike each working on opposite sides of the street. That way, you can move through each block quickly but still feel safe. You learned at training that it's okay to read the survey out loud and fill in answers for people, but that you should write down the answers while the person is telling them to you.

When you get back to your car, you notice that Mike is writing an awful lot on one of the surveys. You ask what he is doing, and he responds, "Oh, the person in the blue house asked me to read the questions to them, so I'm just filling in the answers." You also notice that he's marked only one of the houses on his block as still needing to be surveyed, when you were pretty sure there were at least 2 others with no answer at the door.

Would you say something to Mike?

- As a member of the project team who recognizes a problem, you have a responsibility to do something about this situation.
- You might feel more comfortable having a conversation with Mike about what he is doing rather than going to a supervisor. Other people may feel differently and may want to talk to someone other than Mike.

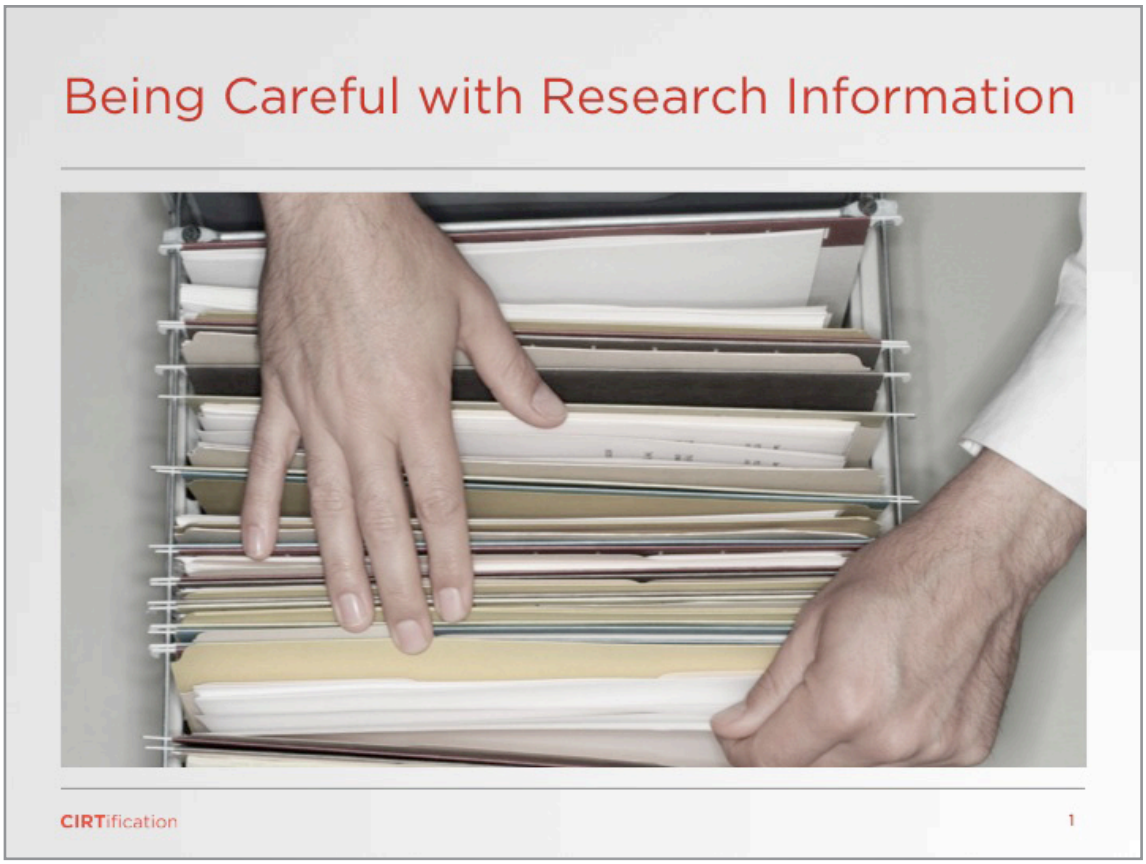
What would you say?

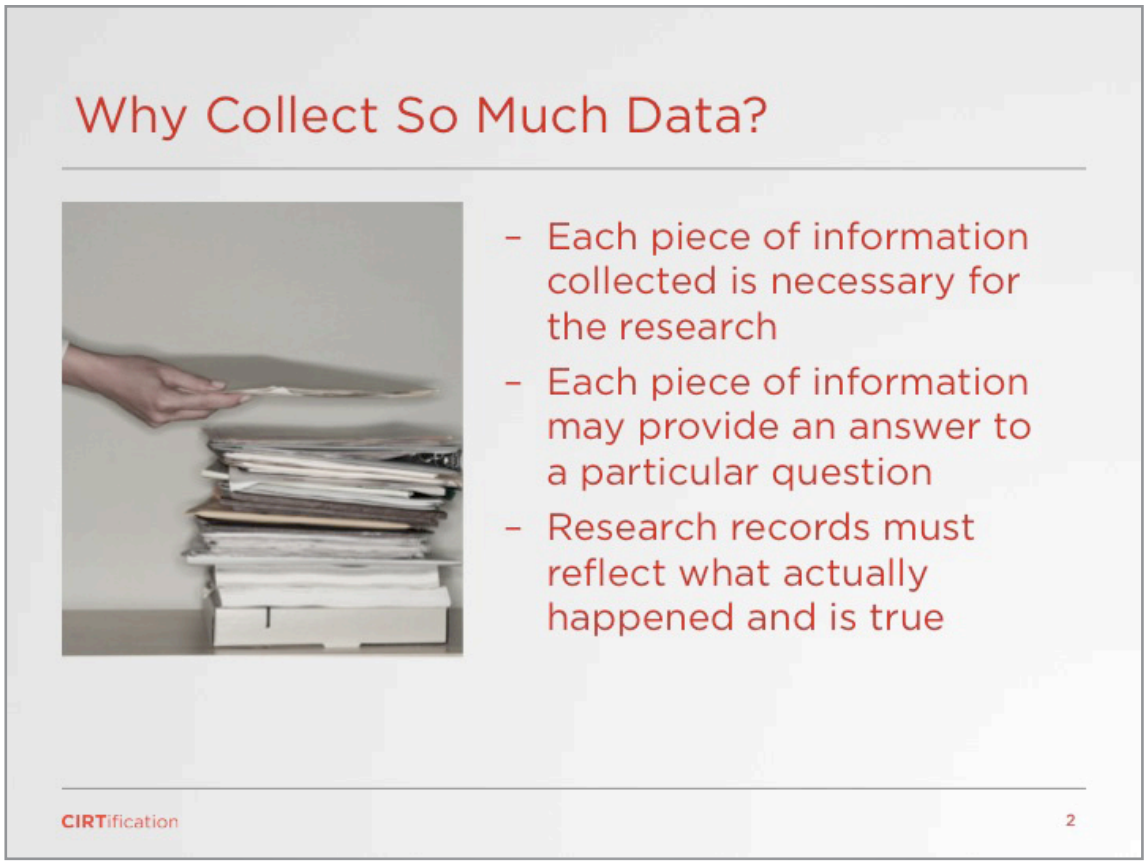
- A "nice" approach may be to simply remind Mike about the procedures you are supposed to follow. His reaction may help you decide what to do next.

Who should you tell about Mike's behavior?

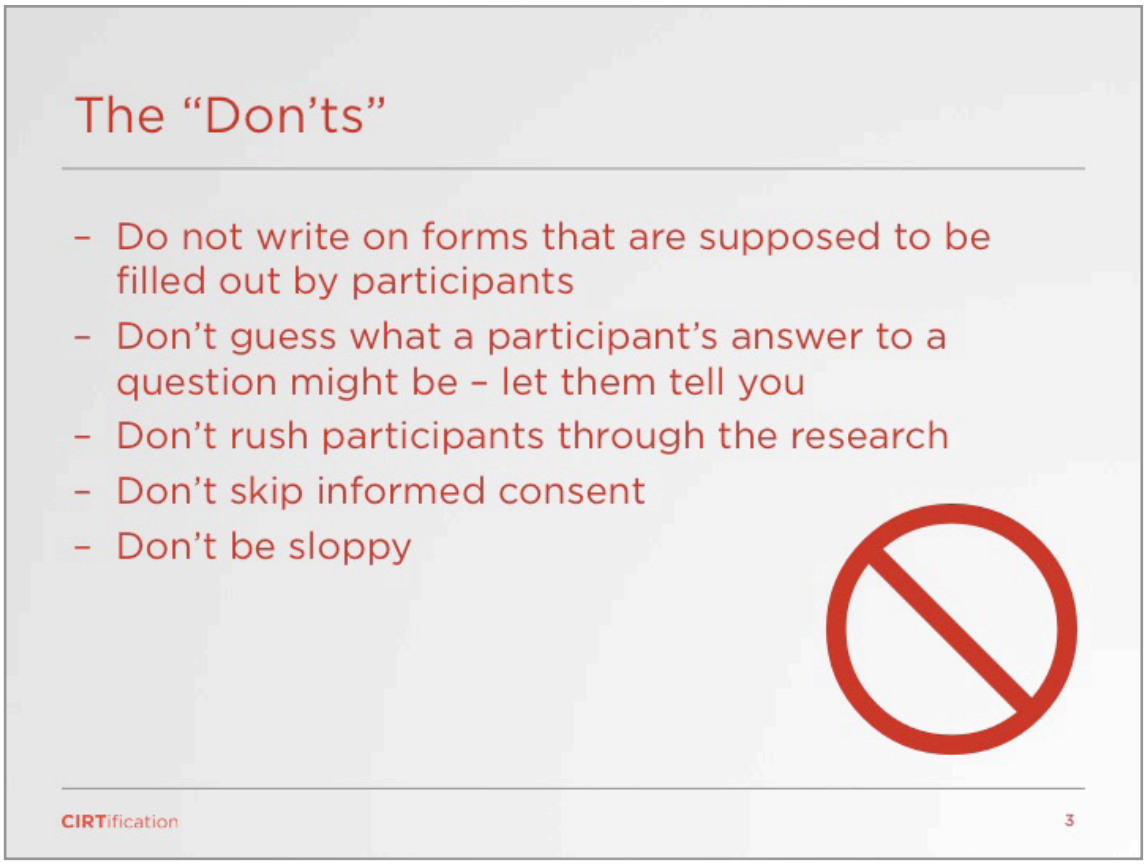
- There are many people involved in the research project who you might want to tell. The best options are your direct supervisor or the principal investigator, the researcher who is leading the project. It depends on your comfort. If you tell a supervisor, you can ask them to not tell Mike that it was you who said something. However, this may be a difficult secret to keep if you and Mike always work together and don't work with any other partners.
- It is best to tell as few people as possible, and to only tell those people who are in a position to find a solution, such as supervisors.

Presentation: Being Careful With Research Information





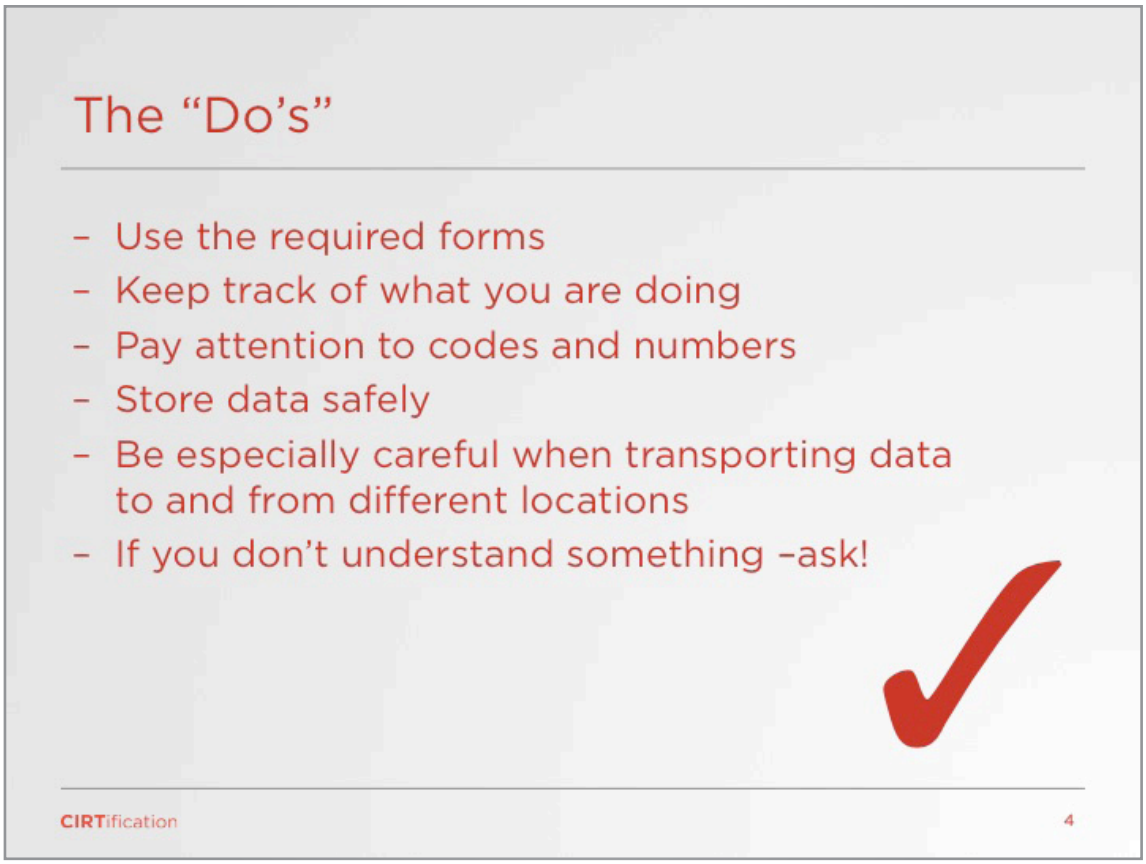
- Sometimes it seems that researchers collect a lot of information – maybe too much.
- Each piece of information collected is necessary in order to understand the problem that is being studied.
- Think of each piece of information as a "piece of the puzzle."
- Therefore it is important to collect all the research data required and take care of the research data we collect.



- Changing information about a research participant or changing information that the participant provides is never appropriate.
- Changing study information can seriously damage the credibility of the results.

Examples of other "don'ts" include:

- Filling out the answers you think people would give instead of really asking them the questions or making up answers
- Rushing through what you're supposed to say to participants instead of taking the time to make sure they understand the directions you are giving or questions you are asking
- Skipping the informed consent process
- Making notes that are sloppy and unreadable



- Use the correct forms.
- Documentation should be completed as the research occurs, not at a later time from memory.
- Sometimes codes are used on surveys and other research materials to help keep information private. That way, researchers can link surveys together over time without having to use participants' names. It is very important to give the right survey to the right person.
- All information should be filled out completely and accurately.
- Research information should be properly documented and stored.
- Survey forms, tapes, and other materials that contain participants' information should be taken to their final storage location as soon as possible. If you need to keep participants' information (data) for a few days before depositing it in its final location, it should be stored in a safe.
- Data should never be left sitting around the office, at home, or in the car.
- Computer files should have passwords, Access to these should be given to only those who really need it.
- If you are going to help participants fill out surveys and you don't understand the meaning of or responses to a question, please ask!

- No matter what kind of information is collected in a research study or how it is collected, it is extremely important to be accurate.
- The truthfulness and usefulness of the research may be harmed if the study procedures are not followed correctly.
- Information should be recorded and stored carefully to avoid error.
- The records of research activity should represent what actually occurred. Accurate documentation also allows others to more easily detect any errors that may be included in the information collected. If information is recorded inaccurately, the results of the study may not be useful.
- Any information collected about an individual should be handled with care through proper documentation and secure storage. Failure to properly handle research information may result in wasted resources, violating confidentiality, and misrepresenting the participants' answers.
- Any deviation from the research protocol by a member of the research team must be reported to the IRB. This may result in sanctions, delays, or the stopping an entire research project.

Discussion: How Would You Handle...

We don't plan to reveal confidential information. It usually happens by accident.

How would you handle the following situations?

Your boss asks if she can have research participants' names and addresses so that she can send letters to ask for donations for your organization.

Appropriate response: Tell her that you cannot give her this information – even if the research took place at the organization. In any research project, participants are promised that their names and contact information will not be shared with anyone. If there is ever an exception to be made to this rule, the consent form will specifically state who the information will be shared with and in some cases allow participants to refuse even if they still take part in the research.

Someone at work asks you for a participant's phone number because they want to ask her out on a date.

Appropriate response: Tell them that this is not allowed! See above.

You run into a study participant on the street. Your sister asks how you know the person.

Appropriate response: Even letting someone just know that a person is part of a research study may reveal private information about them, such as the fact that they have breast cancer or that they have been the victim of domestic violence. Different studies may not seem this private, but in this situation it is best simply to say "I know them from work." This should satisfy your sister's curiosity.

Discussion Case: "Secrets"

(This case has been adapted from "Ethical Protections in Community-Engaged Research," Michigan Institute for Clinical & Health Research, Stephanie Solomon and Patricia Piechowski-Whitney)

Mary is employed as a data collector for a survey to find out more information about the needs of people in her community who are HIV positive. For the next two weeks, she is supposed to sit at a table in the lobby of a community clinic that serves people who are HIV positive and also provides HIV and other STD testing and counseling services. She is supposed to ask everyone who walks by if they would be willing to take 10-15 minutes to fill out a health survey. This way, she does not ever ask people directly if they are HIV positive. Instead, HIV status is a question within the survey, and those who answer yes are directed to complete an extra set of questions. People are told not to write their names on the survey in order to keep the answers private.

While she is working, she sees her neighbor, Joe, who has also been romantically involved with her cousin Sandy for a few months. Mary asks Joe to complete a survey. He agrees, but Mary is not sure that Joe recognizes her. Mary is supposed to place each survey in a sealed envelope and not look at the answers.

Discussion

If you were Mary, would you be tempted to look at Joe's survey to find out if he is HIV positive?

- Discuss that while it is natural to be curious in the situation, the temptation to look at Joe's private survey should be resisted. Because the survey that Joe filled out is anonymous (his name has never been collected) he has been led to believe that no one will be able to link his answers with his identity. Therefore to look at Joe's answers is violating his trust in the research.

What if you don't look at Joe's survey, but you tell your cousin that you saw Joe at the clinic. Is this okay?

- Discuss with participants the obligations that people may feel that they have to protect their family members and other loved ones. This case presents a situation where the obligation of confidentiality to research participants conflicts with family concerns. However, the conclusion should be that the promise to Joe as a research participant that his answers remain anonymous and private is ABSOLUTE.

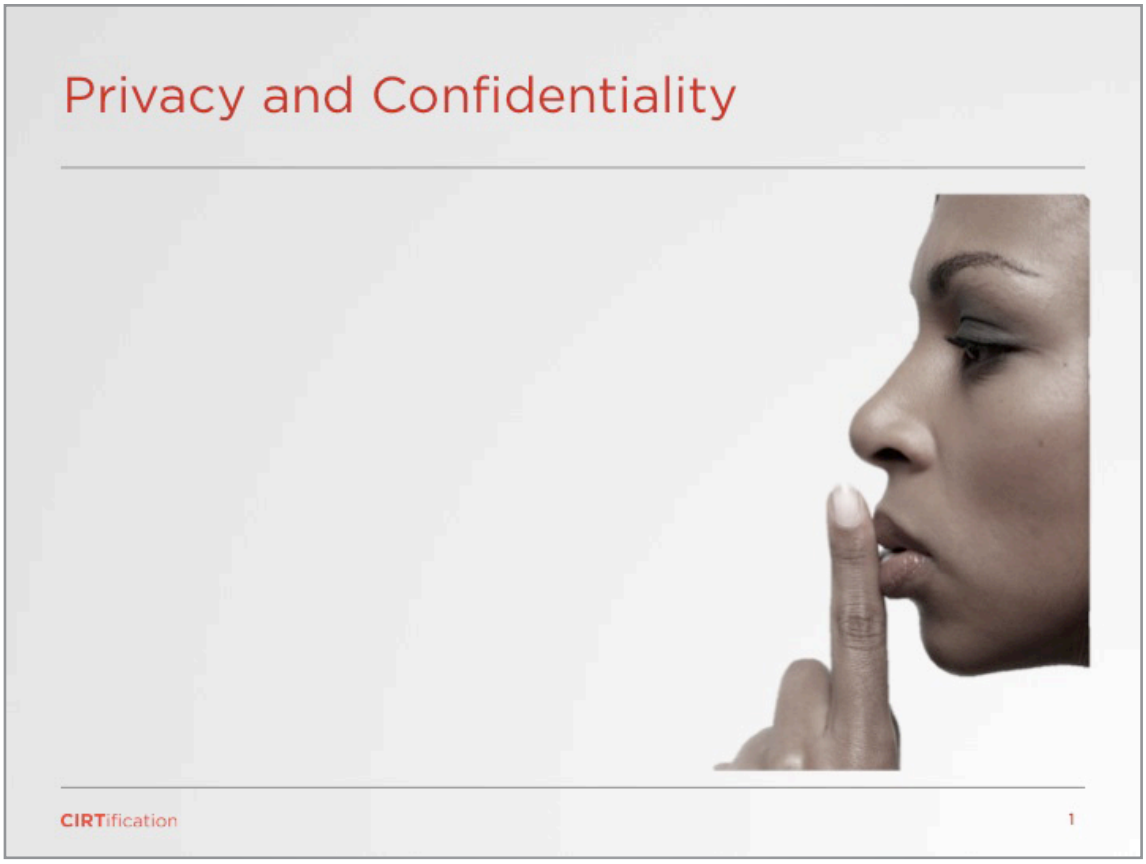
Researchers partner with local communities so that participants can interact with someone who is familiar. However, this case demonstrates how problems can occur when research places people in situations where they might learn private information about people they know. What are some of the "pluses" and "minuses" of being involved in research in one's own community?

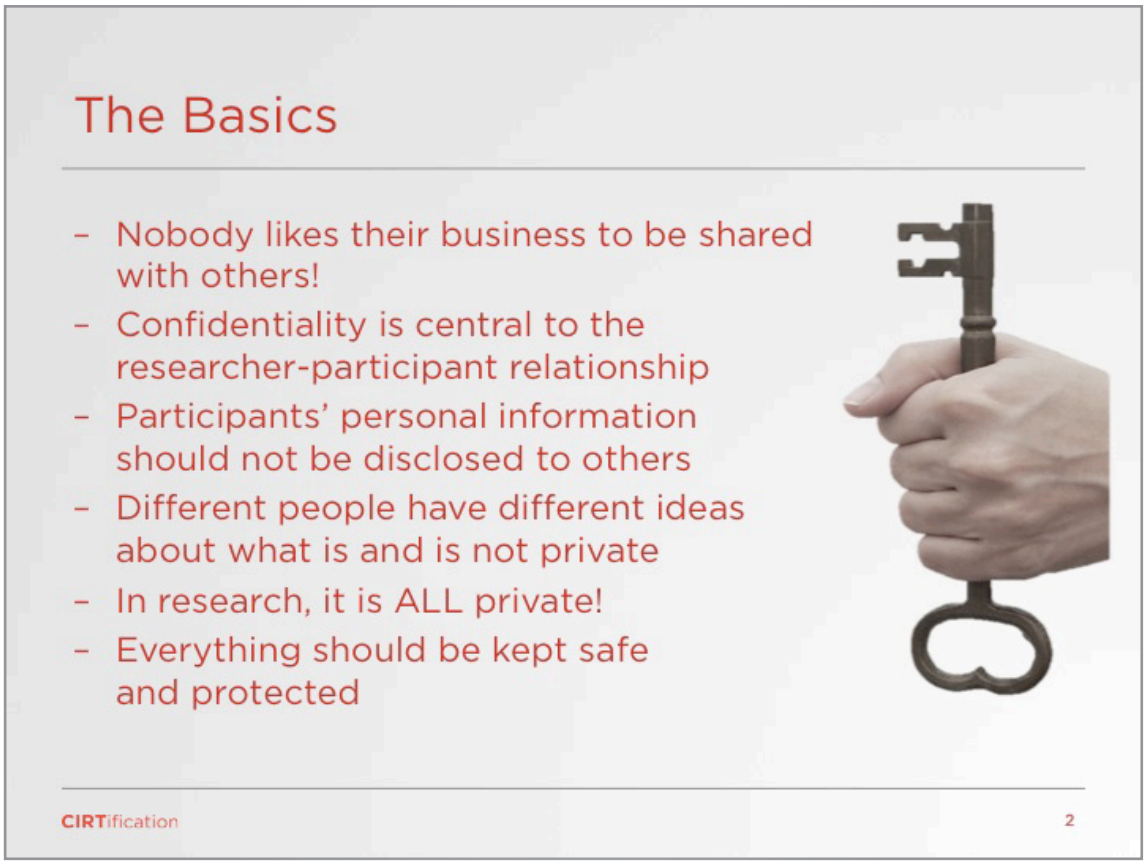
- Discuss how it can be more difficult to keep information about people private when you know them. There are more people who might be interested in knowing what you know about a neighbor. However, research information should not become neighborhood gossip.
- Participants may also bring up some of the issues discussed in the case of Bill in Part 1 of this curriculum.

How might this study have been planned better in order to avoid this problem?

- The surveys could have been on a table with no person present – but then other people walking by might be tempted to steal them from the sealed envelopes.
- The study could have hired someone who was a stranger to the community – but in any city, no matter how large, there is always a chance of running into someone you know.
- The possibility of seeing someone known to her should have been discussed at the training Mary received before she started working on this project. Ask participants to about how the projects they are going to work on might raise unique privacy issues. Ask them to share their thoughts with the group if they are comfortable.

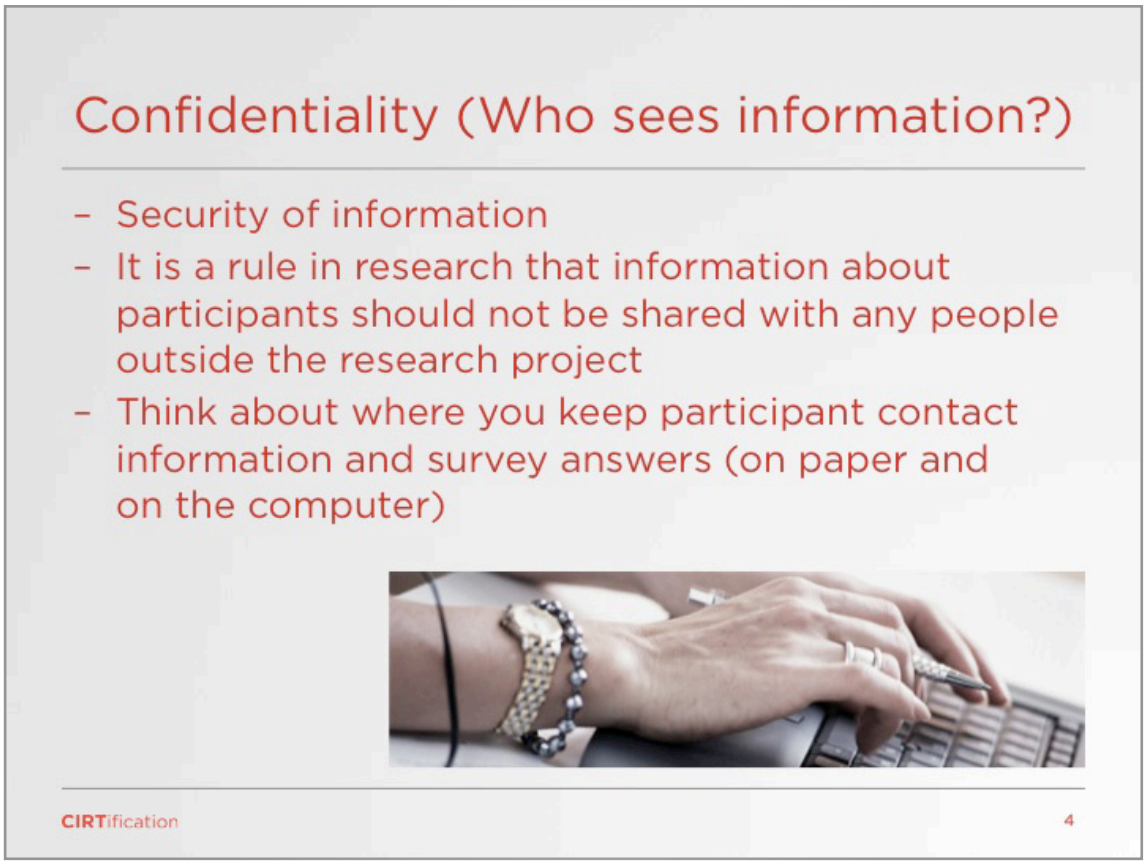
Presentation: Privacy and Confidentiality





- We all prefer that our private business stay private.
- Nobody wants their phone number given out to just anyone who asks for it.
- In research, privacy and confidentiality are necessary in order to make sure that participants trust the research and feel comfortable taking part in it.
- A participant's personal information should not be shared with anyone without that participant's permission.
- In research, everything is private.

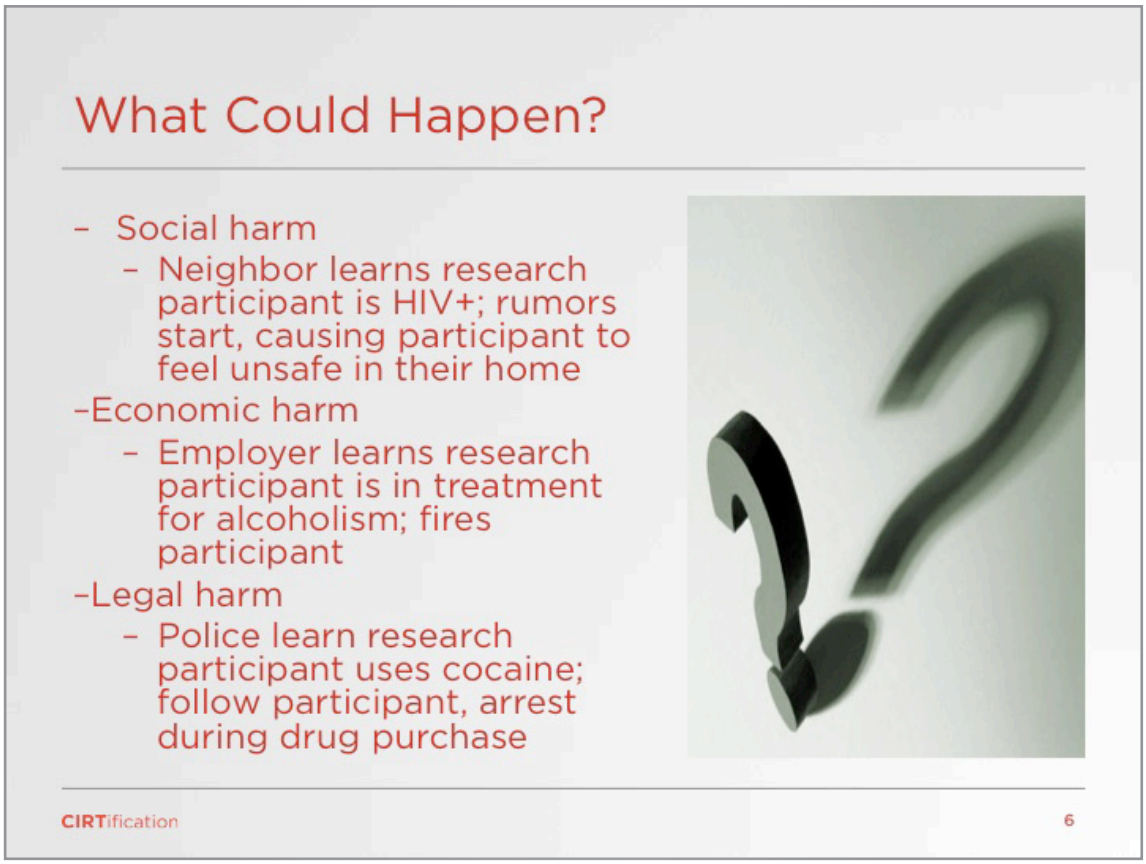
- We talk about privacy and confidentiality together, but they actually mean two slightly different things. Both are important.
- It is a rule in research that people are allowed to decide if and when they are going to talk to researchers and share information about themselves.
- Privacy is about participants being seen. Some participants might not want others to know they are in a study, so it is important to think about where research is being conducted and who might see participants.
- Privacy is also about not bothering people if they do not want to be participants in research.



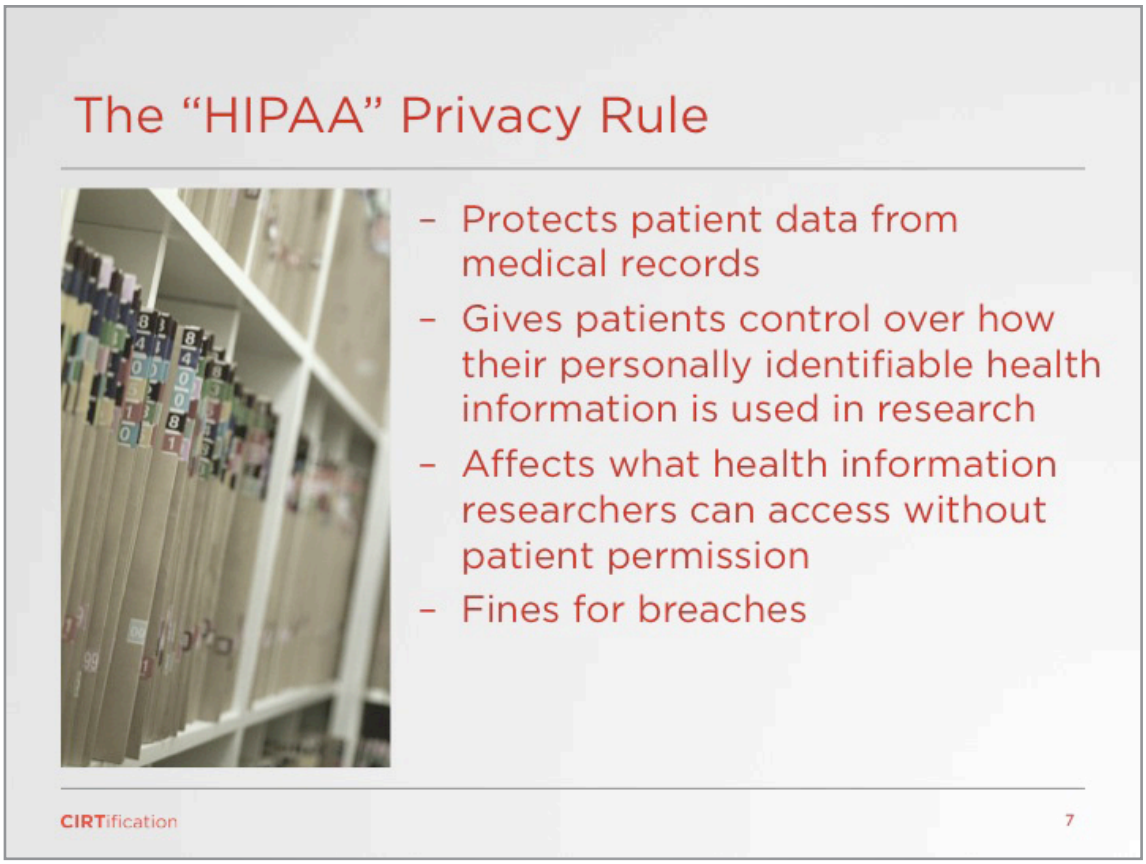
- Confidentiality is about keeping *information* private.
- It is a rule in research that information about participants that is collected for research purposes should not be shared with any people outside the research project.
- It is important to think about where you keep participant contact information and survey answers (on paper and on the computer).
- Privacy and confidentiality go hand in hand.

Every single piece of information that you collect from a research participant should be kept safe.

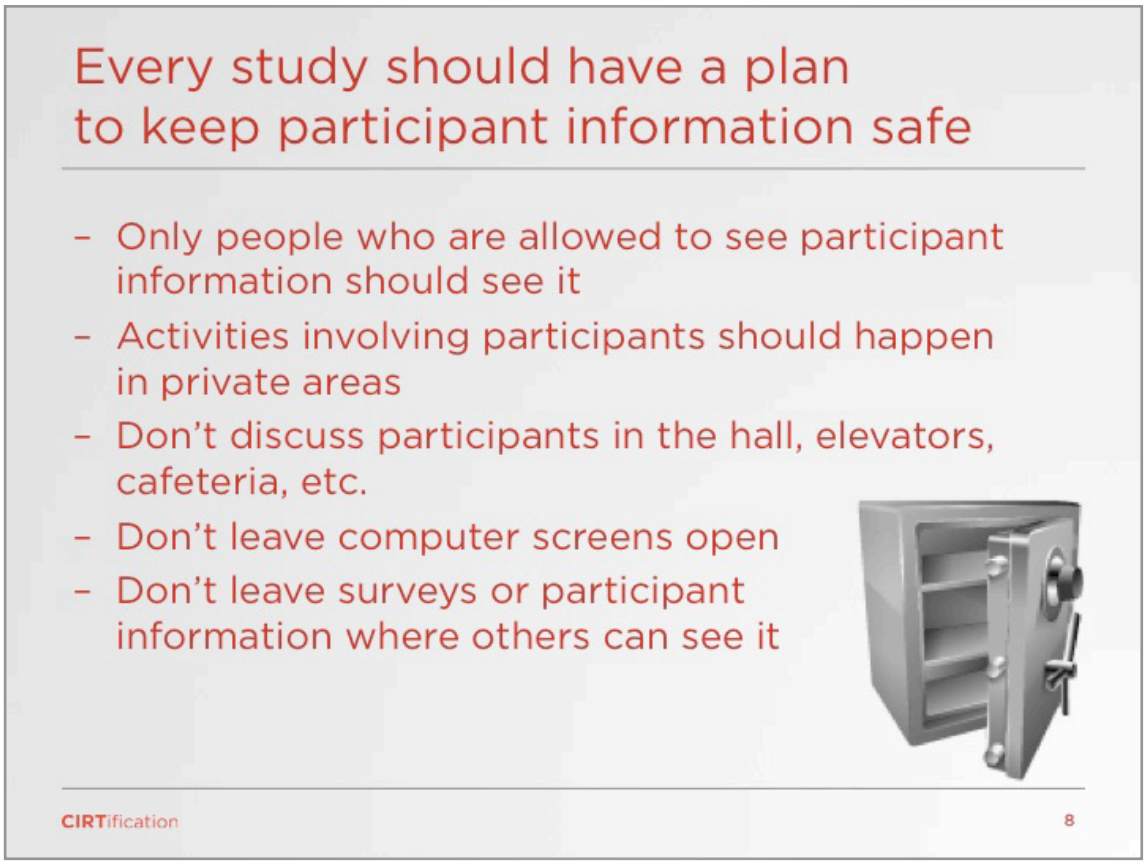
- Names and contact information
- The fact that they are in the research
- Any health conditions that would qualify them to be in the research
- Health habits
- Other sensitive information, especially if it involves illegal or stigmatized behavior



- Different types of harm that might result from a breach of confidential research information include social, economic, and legal harm.
- For example, if research materials for an HIV study are sent to participants' homes with information that identifies the person as being HIV+, a neighbor may see these materials. This may cause rumors to spread, and the research participant might end up feeling uncomfortable or even unsafe in his own home. This is an example of a social harm.
- If a research study involves a sensitive topic like alcohol abuse, and information is released outside of the context of the research, an employer may find out that a participant is being treated for alcoholism. This may cause the employer to terminate the participant's employment (even though this is not legal). This is an example of an economic harm.
- Police may learn that a research participant is using cocaine and may follow that person in order to catch them in the act of buying drugs, which may result in an arrest. This is an example of legal harm.



- You may have heard the term "HIPAA" before. It is a federal law that relates to health information and health insurance.
- The HIPAA Privacy Rule covers patient data from medical records – records that are kept by hospitals, doctors' offices, and other health care facilities.
- HIPAA restricts what patient information researchers can access and when they need particular types of permission from patients to use their information for research purposes.
- If you are working on a research study that is related to health and/or health care, especially if the research takes places in a health care environment (such as a hospital or clinic), you will need to know about the HIPAA Privacy Rule. You may even be required to take another training course on the HIPAA Privacy Rule.
- Health care facilities and individuals can be fined for privacy breaches.



- To protect participants' privacy, avoid collecting personal information in a public place. Try to find somewhere private. Realize that for some people, home may not always be a "private" location.
- Keep all research documents safe. Do not leave completed surveys in your car overnight or at your house. Do not leave completed surveys lying around in your office where others can look at them.
- The research protocol should provide guidelines for carefully storing all paper-based data (such as surveys) and lists with participants names and contact information. These should be kept in a locked file cabinet and/or office, and only a few designated individuals should have access.
- Sometimes the research team will have conversations about individual participants, especially if it is a long term study with many opportunities for contact with participants. Think about where you talk and to whom you talk about the research.
- Research information is not gossip! Don't ever share anything outside of the research team. This includes participants' names and personal information like telephone numbers as well as their answers to study surveys or questionnaires.

APPENDIX I

ASSESSMENT QUESTION BANK

Assessment Questions

1.1 The federal regulations for conducting research in the United States:

- ☐ Protect researchers from harm
- ☐ Require citizens to participate in research
- ☐ Protect research participants from harm

1.2 The local committee that is responsible for reviewing research to protect participants is called:

- ☐ An ethics review committee (ERC)
- ☐ An institutional review board (IRB)
- ☐ An office of research (OR)
- ☐ A research justice committee (RJC)

1.3 Is it okay to do research that will cause harm to participants if it could mean finding the cure for a deadly disease?

- ☐ Yes
- ☐ No

1.4 Which of the following is a requirement of research?

- ☐ Researchers should prevent harm to participants
- ☐ Participants must be chosen fairly
- ☐ Participants must know what they are agreeing to do
- ☐ All of the above

1.5 Can research start once information is submitted to the institutional review board?

- ☐ Yes
- ☐ No

2.1 You have explained a research study to someone and invited them to participate. They say no. You should:

- ☐ Tell them that you will lose your job if they don't say yes
- ☐ Remind them that they will get paid for their participation
- ☐ Accept their decision and thank them for their time
- ☐ Ask them for their phone number so you can call and talk to them later

2.2 What information should be included in an informed consent form?

- ☐ Risks and benefits of taking part
- ☐ Who will have access to information provided by participants
- ☐ How long participation in the research study will last
- ☐ All of the above

2.3 Informed consent must be obtained

- ☐ Before a participant is told anything about a study
- ☐ Before a participant starts any study activities
- ☐ After a participants completes surveys or questionnaires but before any medical tests are done
- ☐ At any time that is convenient for the participant

2.4 It is important that research participants:

- ☐ Are given enough information about a research study
- ☐ Understand the information that has been given to them
- ☐ Decide to participate without feeling threatened
- ☐ All of the above

2.5 When discussing informed consent, you should NOT:

- ☐ Have the person sign the form before reading it in case they forget
- ☐ Make sure they have enough time to decide if they want to take part
- ☐ Ask if they have any questions before they sign the form
- ☐ Tell the person all the risks of participating in the research

3.1 Is it okay to fill in answers for a research participant if you think you know what they would say?

- ☐ Yes
- ☐ No

3.2 Which of these is a good place to collect research information?

- ☐ On a street corner or other public area
- ☐ In a private room with a door that can be closed
- ☐ Have research participants fax research forms to your office
- ☐ At the participant's home with their husband or wife present

3.3 Which of these is a good place to store research information?

- ☐ On your desk at work
- ☐ At home
- ☐ In a locked file cabinet in your office
- ☐ In the trunk of your car

3.4 What information about participants can be shared with people who are not part of the research team?

- ☐ Participants' names
- ☐ Participants' contact information (telephone number, email address)
- ☐ Information about participants' health issues
- ☐ None of the above

3.5 Is it okay to tell people in your family what you know about individuals who participate in a research study?

- ☐ Yes
- ☐ No

Answer Key

1.1 The federal regulations for conducting research in the United States:

- ☐ Protect researchers from harm
- ☐ Require citizens to participate in research
- ☐ **Protect research participants from harm**

1.2 The local committee that is responsible for reviewing research to protect participants is called:

- ☐ An ethics review committee (ERC)
- ☐ **An institutional review board (IRB)**
- ☐ An office of research (OR)
- ☐ A research justice committee (RJC)

1.3 Is it okay to do research that will cause harm to participants if it could mean finding the cure for a deadly disease?

- ☐ Yes
- ☐ **No**

1.4 Which of the following is a requirement of research?

- ☐ Researchers should prevent harm to participants
- ☐ Participants must be chosen fairly
- ☐ Participants must know what they are agreeing to do
- ☐ **All of the above**

1.5 Can research start once information is submitted to the institutional review board?

- ☐ Yes
- ☐ **No**

2.1 You have explained a research study to someone and invited them to participate. They say no. You should:

- ☐ Tell them that you will lose your job if they don't say yes
- ☐ Remind them that they will get paid for their participation
- ☐ **Accept their decision and thank them for their time**
- ☐ Ask them for their phone number so you can call and talk to them later

2.2 What information should be included in an informed consent form?

- ☐ Risks and benefits of taking part
- ☐ Who will have access to information provided by participants
- ☐ How long participation in the research study will last
- ☐ **All of the above**

2.3 Informed consent must be obtained

- ☐ Before a participant is told anything about a study
- ☐ **Before a participant starts any study activities**
- ☐ After a participants completes surveys or questionnaires but before any medical tests are done
- ☐ At any time that is convenient for the participant

2.4 It is important that research participants:

- ☐ Are given enough information about a research study
- ☐ Understand the information that has been given to them
- ☐ Decide to participate without feeling threatened
- ☐ **All of the above**

2.5 When discussing informed consent, you should NOT:

- ☐ **Have the person sign the form before reading it in case they forget**
- ☐ Make sure they have enough time to decide if they want to take part
- ☐ Ask if they have any questions before they sign the form
- ☐ Tell the person all the risks of participating in the research

3.1 Is it okay to fill in answers for a research participant if you think you know what they would say?

- ☐ Yes
- ☐ **No**

3.2 Which of these is a good place to collect research information?

- ☐ On a street corner or other public area
- ☐ **In a private room with a door that can be closed**
- ☐ Have research participants fax research forms to your office
- ☐ At the participant's home with their husband or wife present

3.3 Which of these is a good place to store research information?

- ☐ On your desk at work
- ☐ At home
- ☐ **In a locked file cabinet in your office**
- ☐ In the trunk of your car

3.4 What information about participants can be shared with people who are not part of the research team?

- ☐ Participants' names
- ☐ Participants' contact information (telephone number, email address)
- ☐ Information about participants' health issues
- ☐ **None of the above**

3.5 Is it okay to tell people in your family what you know about individuals who participate in a research study?

- ☐ Yes
- ☐ **No**

APPENDIX II

CERTIFICATE OF COMPLETION

Community Involvement in Research Training

This certifies that

_____

has completed _____ hours of training in Human Research Protections.

_____ _____

SIGNATURE OF TRAINER DATE

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

THE COMPLETE CURRICULUM IS AVAILABLE AT
www.go.uic.edu/cirtification