Community PARTners

Partnering to Assist Research and Translation

One strategy to encourage community participation in research is to invite community partners to learn about the ethics of clinical research. Many research ethics trainings are 'one size fits all.' We recognize that each study is unique and community members should inform the research process to ensure local relevance. The Community-Partnered Research Ethics Training and Certification (CPRET) was designed to help Principal Investigators to tailor research ethics training for a specific study and to encourage dialogue with community members who will participate on the research team. This training is particularly relevant for investigators engaged in clinical and translational research involving community stakeholders. Investigators have the opportunity to create and discuss scenarios that may arise in the course of the study while ensuring that core research ethics principles – i.e., autonomy, beneficence, and justice – are defined and reviewed.

The Community-Partnered Research Ethics Training and Certification (CPRET) materials provide a detailed description of how to design, implement and evaluate this study-specific community-academic partnered research ethics training and certification. Prior to any implementation, the Institution and/or Investigator should submit the packet materials, training agenda documents and forms to their home institution's Institutional Review Board (IRB) for review. Each IRB may have different requirements for community member participation on a research team. Investigators should work closely with their institution's IRB to tailor these materials to be in line with their IRB's regulations.

Investigators are encouraged to familiarize themselves with the packet of materials. Appendix 3 in particular provides guidance to investigators on the use of this research ethics training program.

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Version 1.0

Community Partner Research Ethics Training (CPRET) & Certification

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Community PARTners
Partnering to Assist Research and Translation

1. Pledge Statement

NAME: _____ **DATE:** _____

University of Pittsburgh Institutional Review Board (IRB) Pledge Statement

The University of Pittsburgh has provided this **Community Partner Research Ethics Training** for you as an organizational or community research partner to receive your **Community Partner Research Ethics Certification.**

It is designed to meet institutional policies and federal mandates for ethical practice of research and the protection of human subjects. The University of Pittsburgh IRB uses this **Community Partner Research Ethics Training** to ensure you are knowledgeable and properly trained to be involved in human subjects' research at the community level.

Please understand that:

(1) Research Misconduct reflects poorly on your integrity and professionalism.
(2) Any implications of Research Misconduct are answerable to an institutional investigation and if confirmed, can lead to institutional actions such as disciplinary action, follow up by your sponsor and/or funding agency and/or termination of your employment or involvement in a research project.

* The University of Pittsburgh will use the **Community Partner Research Ethics Training** to track who has completed and received **Community Partner Research Ethics Certification** and may contact you in the future.

Please select one of the following Agreement Statements below:

o NO, I DO NOT understand the above statement. Or, I am not the person listed at the top of this page completing this required research ethics training.

o YES, I have read and understand the above statement. I am the person listed at the top of this page and I am the person completing this required research ethics training.

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2. Training Eligibility

"Who Should Complete This Community Partner Research Ethics Training?"

- *Questions for eligibility criteria to ensure appropriate Community Partners are utilizing this training and are not using this training as a substitute for IRB required training*

Series of questions that will allow person to continue to the training:

☐ Are you collaborating with a Lead Researcher/Principal Investigator to complete research in the community?

☐ Are you a member of a Community Organization or Agency?

If, Yes what is the name of the Community Organization or Agency

_____

☐ Are you consenting people in the community to participate in human subjects research?

☐ Are you observing and recording information about human subjects?

☐ Do you collect private information about human subjects?

☐ Are you using, studying or analyzing identifiable private information or specimens provided by another institution or investigator?

☐ Are you using data collected from human subjects for research purposes?

If you said YES to any of these questions you can move on to complete the Community Partner Research Ethics Training

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The Importance & Value of Good Research Ethics

Community Partner Research Ethics Training and Certification

University of Pittsburgh

Michael Yonas, Elizabeth Miller, Maria Catrina D. Jaime and Shannon Valenti

Community PARTners
Partnering to Assist Research and Translation

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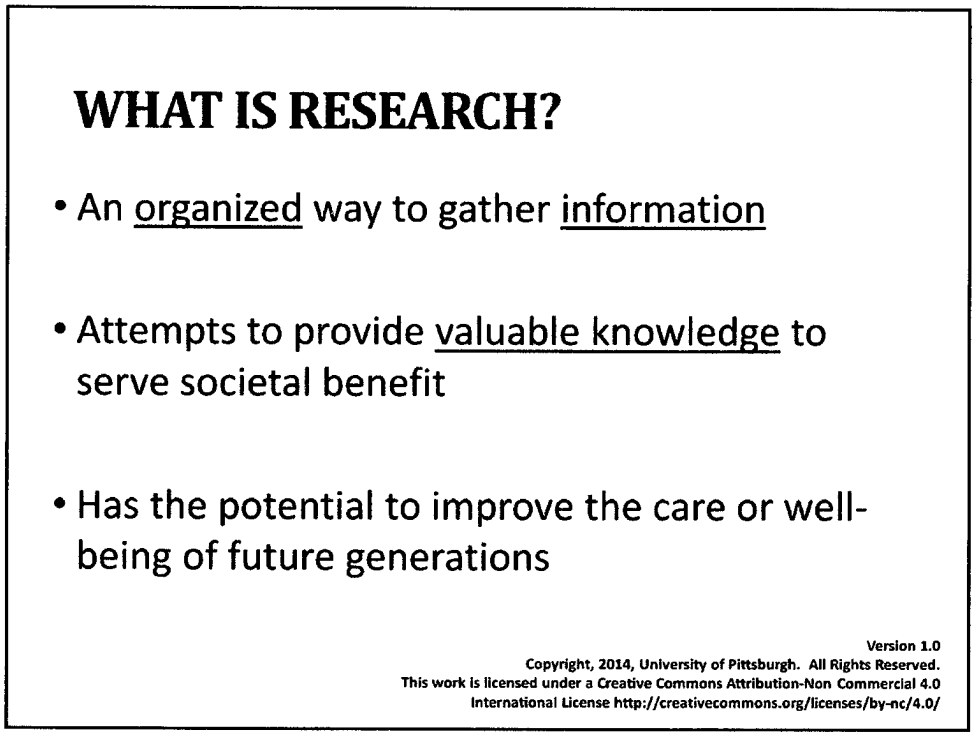
Developed by: Michael Yonas, Elizabeth Miller, Maria Catrina Jaime and Shannon Valenti



TOPIC SENTENCE: So, what comes to mind when you think of research?

NARRATIVE:
By organized, I mean that there is a structure and a plan for doing the project.
Information is anything we observe or measure about a person.
Valuable Knowledge this can be related to increase information and awareness and better practices
Improve Future "**I say society and future generations because** research is meant to help other people who were not involved in the project. If the research isn't going to help anyone after it is done, it shouldn't be done.

***For example, [ADD EXAMPLE THAT REFLECTS THE ELEMENTS OF THE PROJECT TO DISCUSS AS A GROUP]"

DISCUSSION NOTES:

TOPIC SENTENCE: There are various people involved in research and each person has various roles

NARRATIVE:
Participant – the person taking part in the research
Researcher – the person conducting the research and seeing how this research works and what can be learned
Stakeholder – can be any group or person invested, interested or potentially gaining information or benefit from the research being done
Partner – can be group or person involved in the research. For instance recruiting participants at their agency or providing services related to the research activities

***For our team, for example SPECIFY ROLES THAT REFLECTS THE ELEMENTS OF THE PROJECT AND RESEARCH TEAM
Team
- YOU
- Community Agency
- University Staff
- Service and Medical Providers

DISCUSSION NOTES:

TOPIC SENTENCE: What is a research participant? ***ALLOW PEOPLE TO ANSWER AND BEGIN THE DISCUSSION

NARRATIVE:
Basically, it is anyone we gather information about. Anyone whom we observe or make measurement on.

Information can come from a study like XXXX Project. We have specific plans to make measurements about how White- **Caucasian** and **Black** -African American women with breast cancer feel, their opinions, and their behaviors about cancer care.

For example project....another way to collect information is to review medical records. For instance, we have a plan to record information from the a Registry about women with breast cancer.

We can also get information from observation. Anytime we record something from watching, video taping, or taking photos of people, we are collecting information about them.

Examples:
Experiment – the effects of cancer treatment and the difference between, gender, race and age.
Observation – gathering a group of male athletes and asking them questions about a violence prevention program conducted by their coach
Medical Records – how frequently do women between the ages of 16-24 receive annual exams

DISCUSSION NOTES:

What REALLY happens when the research begins...

- Experience with research
- Perception of research

TOPIC SENTENCE: What really happened when the research begins? Can you please share your research experiences and perceptions? Have they been good or bad?

NARRATIVE:
***DISCUSS with the group THEIR experiences with research, and/or their perceptions and pre conceived ideas of the process, outcomes, experimentation. (NOTE: THIS IS DONE RATHER THAN STARTING OFF WITH A NEGATIVE HISTORICAL REFLECTION OF RESEARCH).

PI should come with positive and negative experiences to share with the group, particularly some related in context/content to the project at hand.

***PREPARE some examples from your OWN experiences to share

DISCUSSION NOTES:

First & Foremost

Good research ethics start with:

- Respect for all persons
- Consideration of beneficial outcomes
- Increased knowledge and information
- An attempt to improve health and well being of person(s) in society

TOPIC SENTENCE: These are the key things we first need to know and understand about good research ethics

NARRATIVE:
Respectful Behaviors includes:
- Listening to the participants needs and concerns
- Providing clear and understandable information
- Allowing the person to make an informed decision

Persons includes:
- Participant – person(s) participating in the study
- Research staff – people conducting the study
- Society – people who can be affected by research outcomes and results

***DISCUSS the increased knowledge/information and benefits SPECIFIC to your PROJECT. Prepare general examples.

DISCUSSION NOTES:

Scenario 1

In an urban community-based after-school program information was shared with parents about their child's participation in a childhood asthma project

READ NARRATIVE OF SCENARIO 1:
My child is participating in an urban community-based after-school program and information was shared about participation in a childhood asthma project to learn about perceptions of influences in the community that impact children's asthma. The study staff made multiple community presentations about the study to local parents and others from organizations to share background and answer any questions regarding the research project, background and research in general. The study times and locations identified were guided by feedback from the me and other participants/families in order to make participation as easy as possible. The formal consent process was well done, clearly explained and answered any questions we had and we were reminded that study participation was voluntary throughout the project. I continue to receive information about the project and had such a good experience with the first part I have now become involved as an advisory board member. The PI and staff working on the project work with children on a regular basis and our study visits are very comfortable, they are patient and collaborative at every phase...and are able to communicate with me by phone, email and text message regarding details of the project.

What Does Good Ethical Research Look Like?

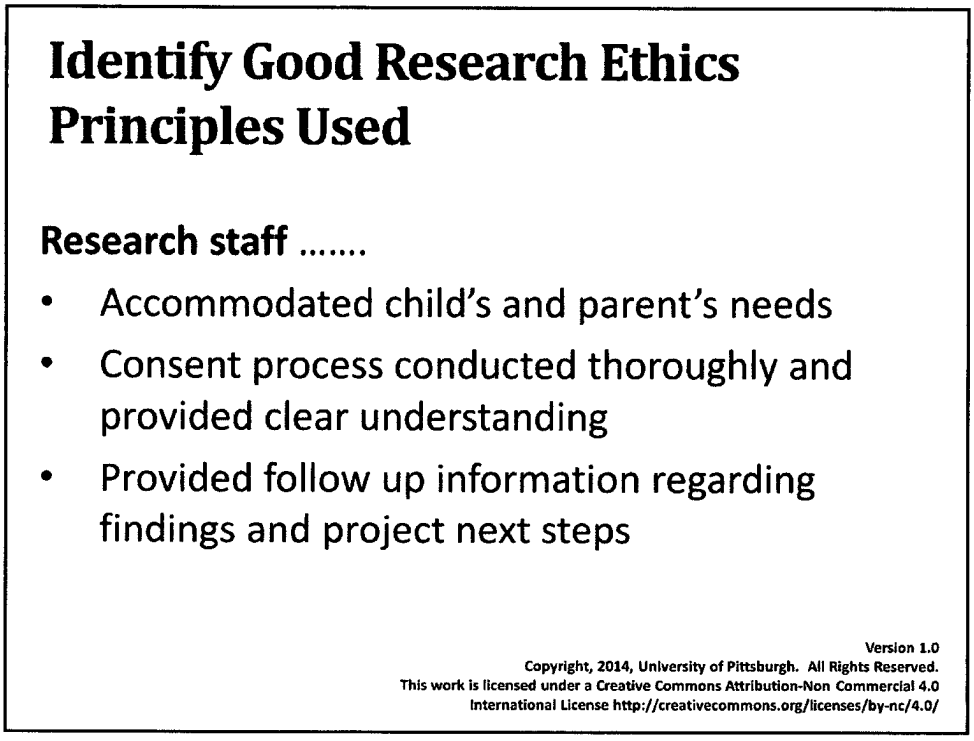
Scenario 1:

- **Participant** – Children with Asthma
- **Research Staff** – Experienced in working with children with asthma
- **Outcome** – Parents and participating child are highly involved and compliant with the research due to staff practice of good treatment and ethics during the study

TOPIC SENTENCE: What does good research ethics look like? Lets review this scenario I just read.....

NARRATIVE:
***DISCUSS the outlined bullet points in the slide, IDENTIFY the people involved and how the POSITIVE outcome came about in this scenario

DISCUSSION NOTES:



TOPIC SENTENCE: Lets identify the good research ethics used in this scenario

NARRATIVE:
***ALLOW GROUP TO IDENTIFY the SPECIFIC things from outlined bullet points in the slide

Accommodated child's and parent's needs
- They were CONSIDERATE of the participants/families feedback regarding study times and locations
- They were willing to make it EASIER for participants/families schedules, NOT just the project schedule

Consents were conducted thorough and clear
- They took the TIME to EXPLAIN and ANSWER questions
- They reminded participants that study participation was VOLUNTARY
- They were experienced working with children and made them COMFORTABLE

Provided follow up information
- They kept participant INFORMED throughout the project
- They ALWAYS made themselves available via phone, email and text message

RESULT: The participant had good compliance with project and their experience was so positive it led to participant becoming involved as an advisory board member for the project

Scenario 2

In high school setting a violence prevention research project was recruiting male athletes grades 9^{th}-12^{th}

READ NARRATIVE OF SCENARIO 2:
During a violence prevention research project with high school male athletes, parent consent forms were distributed to minors to take home for parents to review and sign in order for each athlete to participate in anonymous survey. Parent consent form contained an introductory letter and contact information for the lead researcher (also called the PI). A parent called having questions about the study and general concerns regarding her son's behavior problem. The PI continued follow up and addressed parent's follow up questions about the study and discussed the parents' concerns about son's behavior problems. Parent had positive reaction in regards to the PIs follow up, especially her willingness to talk about parents' concerns about son's behavior problems. Within the following week the athlete returned with signed parent consent form and before his participation research staff also reviewed with him his assent form before participating in the survey.

What Does Good Ethical Research Look Like?

Scenario 2:

- **Participant** – High School Male Athlete
- **Research Staff** – Worked in community based research projects
- **Outcome** – Staff addressed parent's concerns and developed an open, honest and comfortable relationship with parent and participant

TOPIC SENTENCE: What does good research ethics look like? Lets review this scenario I just read.....

NARRATIVE:
***DISCUSS the outlined bullet points in the slide, IDENTIFY the people involved and how the POSITIVE outcome came about in this scenario

DISCUSSION NOTES:

Identify Good Research Ethics Principles Used

Research staff .....

- Consent process was conducted properly with participant and parent
- Promptly followed up with parent's concerns
- Provided support regarding non-study related concerns

TOPIC SENTENCE: Lets identify the good research ethics used in this scenario

NARRATIVE:
***ALLOW GROUP TO IDENTIFY the SPECIFIC things from outlined bullet points in the slide

Consents were conducted properly with BOTH minor and parent
- Minor – Properly given his OWN ASSENT to participate or not in the study, NOT SOLELY based on the parent's permission
- Parent – Given parent consent along with additional informational letter to better understand the study

Promptly followed up with parent's concerns & Provided support regarding additional concerns not related to the study
- PI followed up followed up and ANSWERED the parent's CONCERNS about her son, NOT just about the study

RESULT: Parent had positive interaction due to the PIs follow up, which led to the athlete returning a properly signed parent consent form and the athlete was also properly consented by research staff for his willingness to participate in the survey.

Scenario 3

At the Veterans Affairs (VA) Hospital a research study was conducting a randomized trial with alcoholic liver disease patients

READ NARRATIVE OF SCENARIO 3:
At the VA hospital, a research study was being conducted which involved randomizing alcoholic liver disease patients and recruitment of comparison groups including healthy and active drinkers. IRB approved recruitment of active drinkers with stipulation that research staff could not actively recruit at bar or drinking establishments when potential participants were under the influence. Research staff established relationships with bartenders and asked permission to post flyers regarding the study. As interested participants called and followed up, one participant came as an active drinker and after his screening detected liver disease. Physician followed up and consulted with participant. After options were presented, patient decided to participate in the study. The patient was supported by the study to maintain his sobriety and complete physician visits regularly. After the study completed, patient established care with study physician at her clinic and continued follow up care. The client expressed his gratitude saying that if he had never participated in the study, he would have never known he had liver disease and his health condition would have ended his life. He attributed his new found health and well-being to the physician and the research study.

NOTE – Explain **randomized** - When a study to compare 2 or more ways of doing things, it is best to put people into groups randomly. It is the best way to see if one way of doing things is better than the other. When randomly placing people into groups, its good to explain that we do not know which group will do better, hence why the study is being conducted. This is important not to tell people they may get a "good" treatment or a "bad" treatment. We don't really know which treatment is better. For randomization to be fair, it should be decided by chance, like flipping a coin.

What Does Good Ethical Research Look Like?

Scenario 3:

- **Participant** – Alcoholic Liver Disease Patients
- **Research Staff** – Physician expertise in care and treatment
- **Outcome** – Participant was connected with the study; care was provided to improve his health condition

TOPIC SENTENCE: What does good research ethics look like? Lets review this scenario I just read.....

NARRATIVE:
***DISCUSS the outlined bullet points in the slide, IDENTIFY the people involved and how the POSITIVE outcome came about in this scenario

DISCUSSION NOTES:

Identify Good Research Ethics Principles Used

Research staff .....

- Consulted treatment options regarding patient's health condition
- Provided expertise after study completion
- Improved the care and well-being of participant

TOPIC SENTENCE: Lets identify the good research ethics used in this scenario

NARRATIVE:
***ALLOW GROUP TO IDENTIFY the SPECIFIC things from outlined bullet points in the slide

Proper follow up treatment regarding patient's conditions
• Physician – Properly provided her expertise and followed up to help patient deal with his health condition

Provided expertise after study completion
• PI continued follow up after the study to establish continued care for the patient

Improved the care and well-being of participant
• Study helped detect patient's health condition which led to improved health outcomes.

Results: Patient health condition was identified through the study screening and follow up support was provided to help treat his liver disease. Even when the study ended the patient established continued follow up care with the study physician. Overall, the study needs were met but more importantly patient health and well-being was improved.

Scenario 4

At a doctors office researchers were recruiting patients for a dermatology study

READ NARRATIVE OF "BAD" SCENARIO :
At the doctor's office, while lying face down and having a clinical procedure done to my back, a staff member asked if she could take a picture of my back. Being that I was there for a clinical procedure, I was under the impression it was for clinical purposes. I agreed. She got the camera and then said "oh, I guess I should have you sign this first". I'm face down, so I prop myself up as much as I could, read the document, and it was for a research study where they were taking images for research purposes and sharing them among different research sites. Definitely not a consent process, and definitely uncomfortable. I did end up participating in the study because the research was interesting and the de-identified images were being used as comparisons for people with the same problem as mine, but I was very unhappy with the consenting process.

What Does BAD Research Ethics Look Like?

Scenario 4:

- **Participant** – Patient coming in for clinical procedure
- **Research Staff** – Recruited patient before a clinical procedure
- **Outcome** – Unpleasant consent process and poor research ethics

TOPIC SENTENCE: What does BAD research ethics look like? Lets review this scenario I just read.....

NARRATIVE:
***DISCUSS the outlined bullet points in the slide, IDENTIFY the people involved and how the NEGATIVE outcome came about in this scenario

DISCUSSION NOTES:

Identify Negative/bad characteristics of Research Ethics

Research staff .....

- Approached participant during an uncomfortable situation
- Did NOT provide proper or respectful consent process
- Made participant unhappy and uncomfortable

TOPIC SENTENCE: Lets identify the good research ethics used in this scenario

NARRATIVE:
***ALLOW GROUP TO IDENTIFY the SPECIFIC things from outlined bullet points in the slide

Approached participant during an uncomfortable situation
• Patient was prepared for clinical procedure and was caught off guard, especially being partially undressed and laying face down on table.

Did NOT provide proper or respectful consent process
• Patient was not in approachable position to talk to nor was it a good way to explain the consent

Made participant unhappy and uncomfortable
• Poor consent process left the participant disappointed and disrespected. This type of harm and risk should be avoided, should not occur

OVERALL – Poor research ethics
- Disrespectful of the patient's privacy during her clinical visit
- Patient was not properly informed about the research study
- Patient was rushed and pressured to participate and sign the consent form
- Overall experience was not respectful or comfortable for the patient

Reflection

- Can you think of 1 or 2 good or bad examples of research ethics?

TOPIC SENTENCE: Can you think of 1-2 good or bad examples of research ethics.....

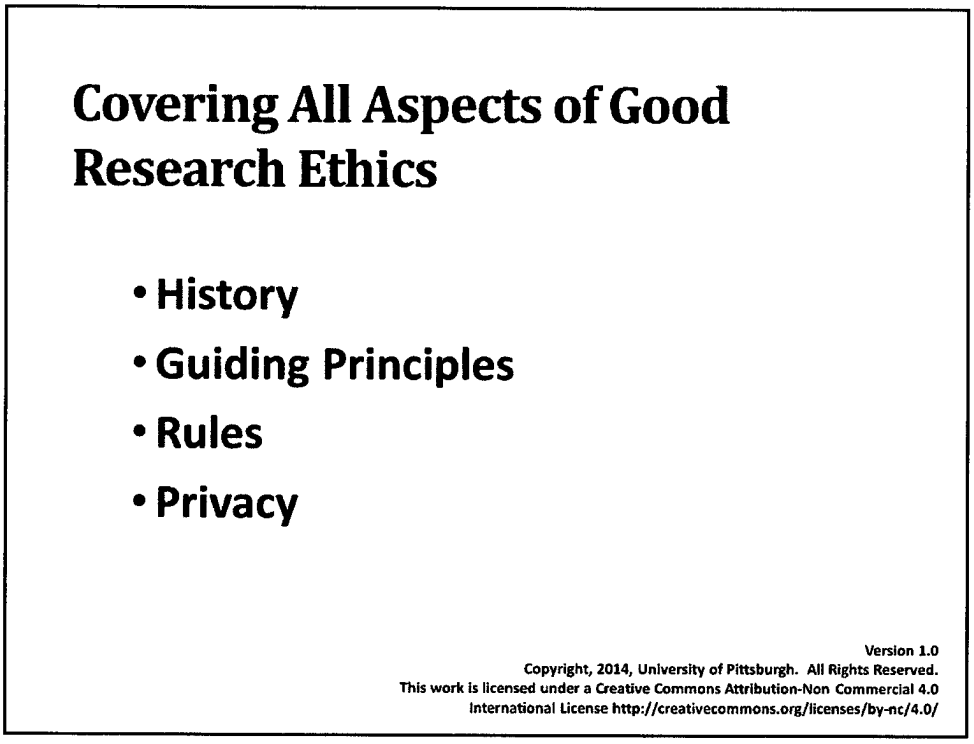
***This is the time/space to DISCUSS WITH THE GROUP THEIR experiences with research, and particularly aspects of research ethics...given what was just covered.

NARRATIVE:
(NOTE: THIS IS DONE RATHER THAN STARTING OFF WITH A NEGATIVE HISTORICAL REFLECTION OF RESEARCH).

PI should come with positive and negative experiences to share with the group, particularly some related in context/content to the project at hand.

This is a time of open reflection, no right or wrong...in a brainstorming type of fashion. Also a time to clarify for the group, answer questions about WHAT research ethics are, if needed.

DISCUSSION NOTES:



TOPIC SENTENCE: We are going to cover the history, guiding principles, rules and privacy involved in good research ethics

NARRATIVE:
For this session, we will discuss this issue of protecting people who participate in research.

To start this, we will talk about some of the history of research projects done with people and why we need to be very careful about protecting participants.

Because of bad things that happened throughout history, guiding principles were developed to help us protect participants!!!!

From the guiding principles, we have established ground rules.

The last topic we will talk about is privacy. Privacy for participants is one way to offer protection, particularly in the type of research you will be involved in.

DISCUSSION NOTES:

HISTORY

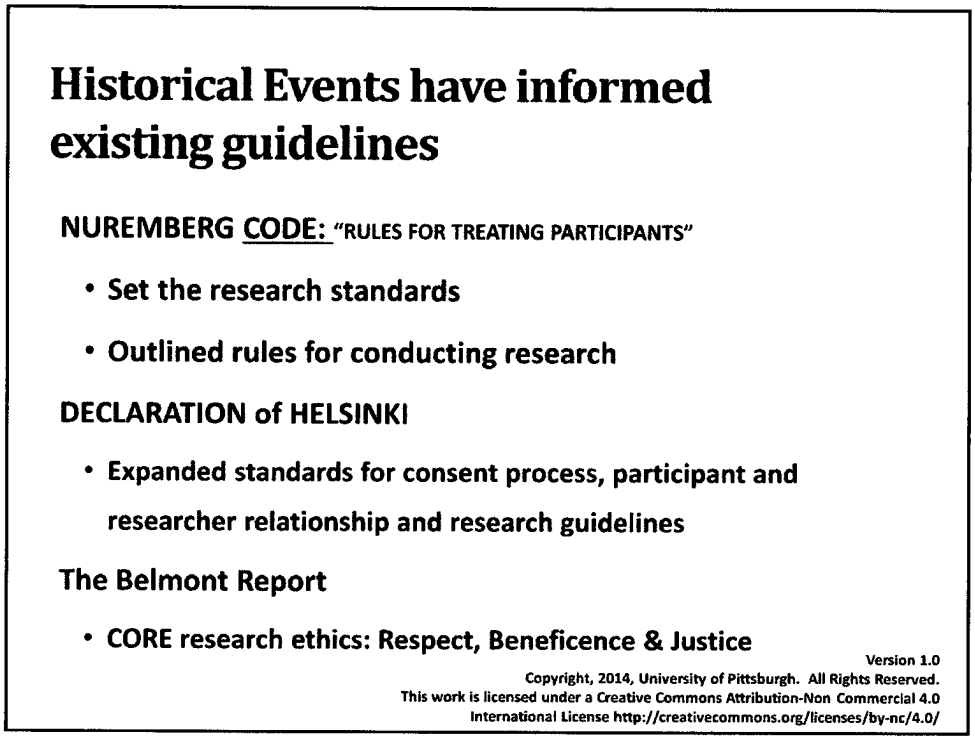
- What has happened in the past?
  - History --> guidelines --> rules
- Helps us understand the guidelines
- We don't want to make the same mistakes again!

TOPIC SENTENCE: Lets review the history.....

NARRATIVE:
I'm going to spend a fair amount of time going over problems that happened in the past. These events led to rules that now protect research participants. The cases I will tell you about are the worst case examples and are very uncommon. Most research doesn't harm the participant at all.

These mistakes from the past have led to the rules and regulations needed to help ensure we do not make these same mistakes again.

DISCUSSION NOTES:



TOPIC SENTENCE: Listed are a few key historical events that led to the development of these existing guidelines.....

NARRATIVE: Because of the events in Nazi Germany and the facts that came out of the trials lead to the development of basic rules for how we treat participants in research. The patient must volunteer to participate. The research must help society. We should be able to use the result to help others. Research should be based on previous knowledge. This is a bit more tricky. This basically means that we should have good reason to believe that it will work. The research should not cause mental and physical suffering and avoid risk of injury and death. The research should not make things dangerous for participants.

Nuremberg Code:
Voluntary agreement of the participant is required
Research must have potential to help society
Research should be based on previous knowledge
Should not cause mental and physical suffering, and avoid risk of injury and death
Amount of risk must not be more than the importance of the problem
Qualified researchers
Participant must be free to stop at any time
Researcher must be prepared to stop if there is risk of injury, disability or death

Declaration of Helsinki:
Consent should be in writing
Research should build on previous work
Research must follow written plan
Review by an independent committee
Caution if participant is in dependent relationship with researcher
Participants must receive best proven care

BELMONT REPORT
Respect - Voluntary consent & Protect those who cannot make decisions
Beneficence - Maximize benefits & minimize risk of harm
Justice - The burdens and benefits of research should be distributed fairly

DISCUSSION NOTES:

Who is the Institutional Review Board (IRB)?

- Institutional Review Board (IRB) is in charge of protecting the rights and welfare of people involved in research.
- Consists of review committees, IRB coordinators, technical support and administrative personnel
- Website of University of Pittsburgh IRB http://www.irb.pitt.edu/default.aspx

TOPIC SENTENCE: Who is the IRB....

NARRATIVE:
***REVIEW the outlined bullet points in the slide and use an EXAMPLE from the case scenarios of how the IRB would look at the different scenarios, who would review, so forth...

IRB helps set up to structure and support for GOOD ethical research.

Listed below are the things IRB helps with and provides information about:
Regulatory Questions (Including FederalWide Assurance Issues)
General Questions Regarding IRB Office Operations
Administration
IRB Vice Chairs
Exempt/Expedited Studies
Full Board Studies
Adverse Events
Education (New coordinator orientations, new board member orientations, pre-screens...)
Technical Support

DISCUSSION NOTES:

What the IRB can do?

- Provide support and guidelines on how to conduct ethical research
- Review and approve research studies
- Review study modifications, renewals, unanticipated problems, and adverse events
- Protect human subjects involved in ongoing IRB-approved research

TOPIC SENTENCE: What does the IRB do.....

NARRATIVE:
***REVIEW the outlined bullet points in the slide and AGAIN use an EXAMPLE from the case scenarios of how the IRB would look at the different scenarios, who would review, so forth...

Important to show that IRB helps set up to structure and support for GOOD ethical research.

DISCUSSION NOTES:

APPLYING GUIDELINES

Principle	Applications
Respect for Persons	•Informed consent •Privacy (Confidentiality and Anonymity)
Beneficence	•Protecting participants from harm •Assessment of risks and benefits
Justice	•Choosing participants

TOPIC SENTENCE: How it all comes together, this is how we apply these guidelines……

NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT BACK ON THE SCENARIOS AND MAKE CONNECTIONS WITH THE GUIDELINES

For the respect for persons, we try to make sure that participants give us informed consent. Have any of you given consent for research before? For anything else? What did you think about the information you were given? Did you feel like you were informed? Was there anything about the process that you did not like?

Another way we respect people is by guaranteeing their privacy. I'm going to talk a bit more about that in a few slides.

For beneficence, we try to protect participants from harm and make sure that the benefits outweigh the risks.

For justice, we try to make sure we are including those who could benefit and not take advantage of some people to benefit others. We also don't want to prevent people from participating who may benefit.

DISCUSSION NOTES:

INFORMED CONSENT

"GETTING PERMISSION FROM RESEARCH PARTICIPANTS"

- Consent is a PROCESS...
  - Researcher describes research study
  - Participant has chance to ask questions and time to make a decision about whether to participate
  - Researcher answers questions
  - Participant signs a consent form agreeing to participate

TOPIC SENTENCE: Consequently, getting permission from research participants is a process to make sure they understand what is "consent."

NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT BACK ON THE SCENARIOS TO CONNECT WITH INFORMED CONSENT

***GIVE EXAMPLE(s) from specific research study

***PROVIDE the group members a training with an example of YOUR INFORMED CONSENT FORM...

DISCUSSION NOTES:

INFORMED CONSENT

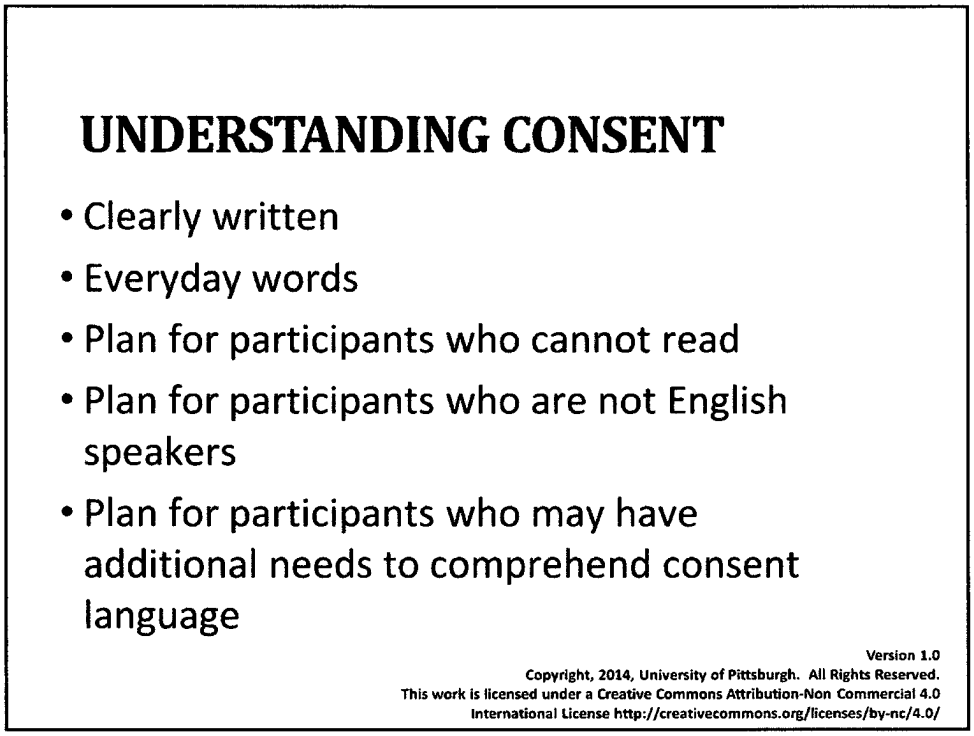
"GETTING PERMISSION FROM RESEARCH PARTICIPANTS" CONTINUED

- Consent is a PROCESS...
- Highlights:
  - The fact that this is RESEARCH
  - Description of study, duration, nature of tasks, and source of participants
  - Risks and/or benefits
  - Compensation or state if there are no payments for participation
  - How confidentiality will be maintained
  - That participation is voluntary
  - Participant can withdraw at any time
  - Contact person for research

TOPIC SENTENCE: Consequently, getting permission from research participants is a process to make sure they understand what is "consent."

NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT BACK ON THE SCENARIOS TO CONNECT WITH INFORMED CONSENT AND FURTHER DISCUSSION OF THESE DETAILS OUTLINED

DISCUSSION NOTES:



TOPIC SENTENCE: These are components that help ensure that the consent process is complete and understood by the participants

NARRATIVE:
***REVIEW the outlined bullet points in the slide and DISCUSS IMPORTANCE UNDERSTANDING "CONSENT"

DISCUSSION NOTES:

ACTIVITY

Practicing Informed Consent Process

[10-15 minutes]

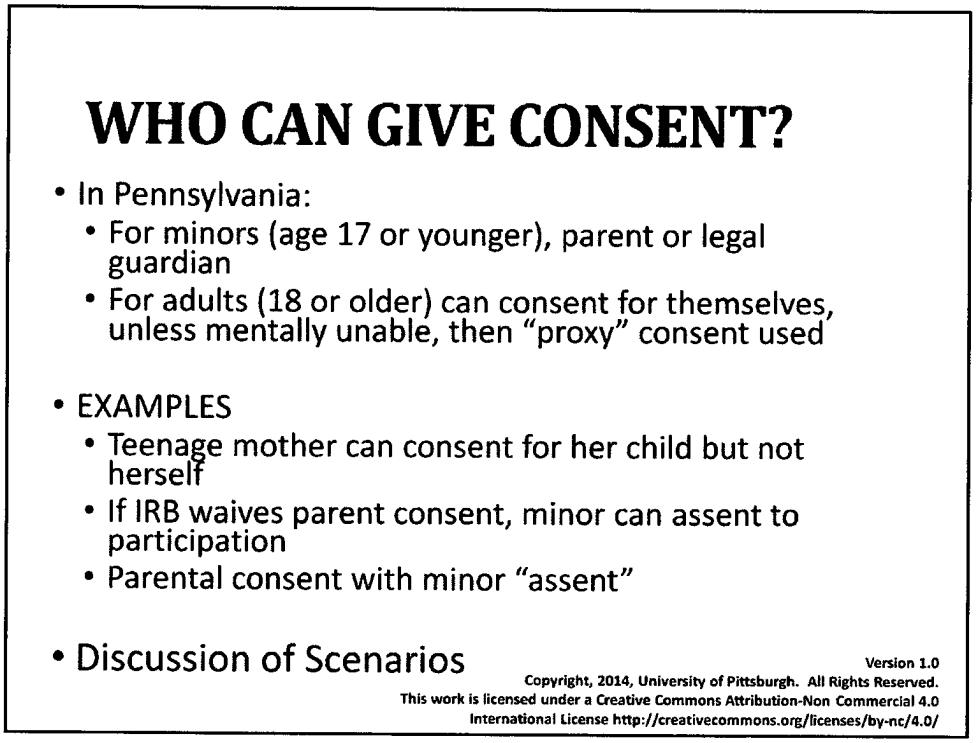
TOPIC SENTENCE: We are going to practice informed consent process and do some role playing to help us better understand this process.

NARRATIVE:
****Investigator provide copies of their Informed Consent Forms associated with their study or another study to practice. Switching roles as participant and community-researcher.

THIS IS A GREAT ACTIVITY AND PROCESS TO PRACTICE, and also strengthen new relationships..
Participant roles should vary, for example:
(1) a compliant participant,
(2) an uncertain participant,
(3) a participant that does not and decides NOT to participate.

PI will assign these respective participant role so that the community-researcher DOES NOT know.

DISCUSSION NOTES:



TOPIC SENTENCE: Who can give consent?

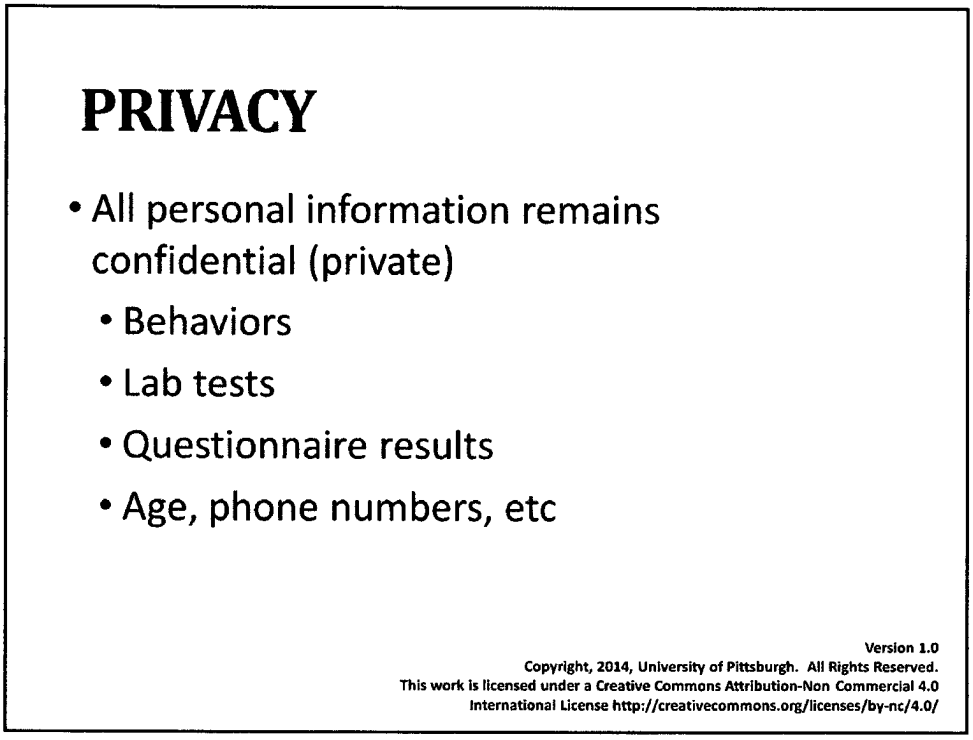
NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT applying the knowledge....How could this happen in YOUR project?

*If appropriate, can review sampling procedures and implications... such as: Snowball Sampling (MY – i.e., having community participants assist with identifying appropriate participants in a study that meet the inclusion criteria...but NOT excluding others)

Fliers, outreach and community informational sessions, developing research partnerships in which the community partners are equally invested and inspired to conduct the

Also review, types of research varies:
Clinical
Social and Behavioral
Bench/Basic science (lab science and animal research)

DISCUSSION NOTES:



TOPIC SENTENCE: It is critical we maintain all participants privacy.

NARRATIVE:
Privacy has become a big deal in medicine and research. Several years ago, a new law went into effect called **Health Insurance Portability and Accountability Act** (HIPAA). As part of this law, the requirement about privacy became very stringent. Essentially, all personal information must remain private. Personal information includes behaviors that are observed in research, lab test, questionnaire results and, of course, age, phone number, address, etc.

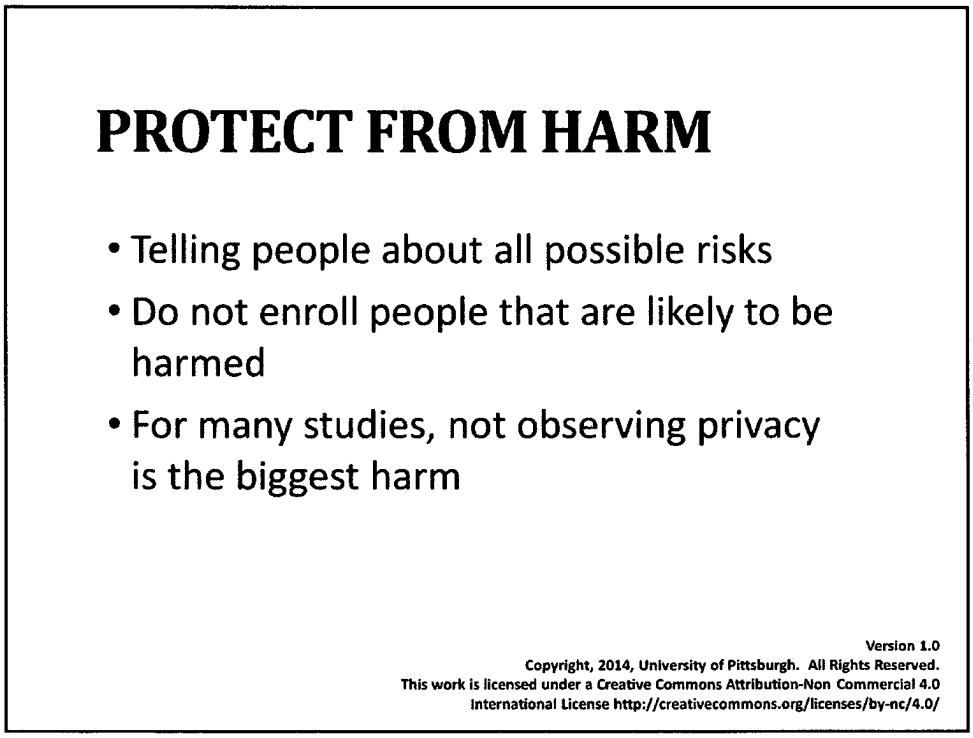
***REFLECT BACK ON THE SCENARIOS: For example, in scenario three (clinical procedure scenario), the patient's privacy, space and comfort example could be extended to include a HIPAA-type violation...or the examples below are fine. [PERHAPS ADDITIONAL Clinical research examples...MORE TO COME..]

***GENERATION OF NEW CASE EXAMPLES: SUCH AS...
For example, say Mrs. Smith's doctor knows she went to the women's hospital to do an interview for the [XXXX] project. Her doctor, who works at the women's hospital, goes to the XXX Project Coordinator and asks for the results. What do you think the XXXXX Project Coordinator should do?

Lucille is an interviewer for the XXXXX project. At the mall health fair, she saw a booth, advertising a free 3-month subscription to a women's health magazine. Lucille thought that the women she is interviewing for XXXXX would enjoy reading about the latest issues in women's health, and so she added their names and phone numbers to the list of names so the magazine could contact them for their addresses.
Do you think Lucille did the right thing?
What else could Lucille have done?

Can you think of any negative things that could happen because Lucille gave out XXXXX participants' names and phone numbers? (participant gets mad because she now gets lots of telemarketer calls)

DISCUSSION NOTES:



TOPIC SENTENCE: We must protect all participants from harm.

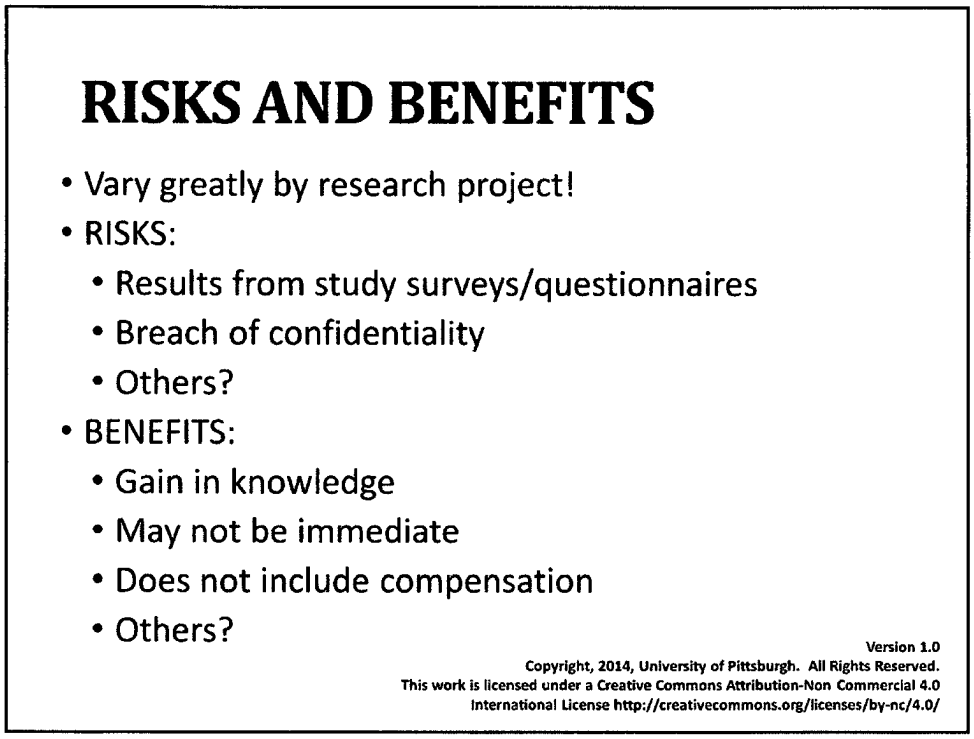
NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT applying the knowledge....How could this happen in YOUR project?

This is how we try to protect from harm. We tell people about all the risks—that way they also check for harms.

We try not to enroll people who may be harmed.

For some research, the biggest harm can be a violation of privacy. How could not observing privacy be harmful to participants?

DISCUSSION NOTES:



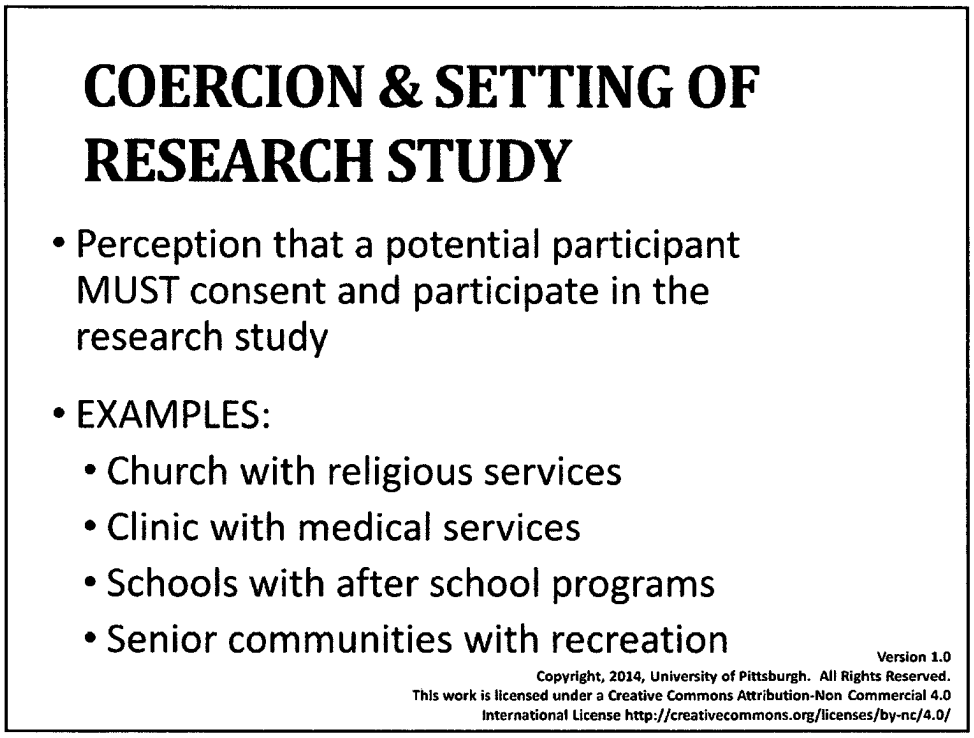
TOPIC SENTENCE: Need to know the risk and benefits involved.

NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT applying the knowledge....How could this happen in YOUR project?

(1) Present examples of Risk and Benefits

(2) Make sure to include conversation points on definitions for:
Minimal Risk
Primary vs Secondary Data
Subject/Participant Recruitment
Identifiable Personal Information (IPI)
Deception Studies

DISCUSSION NOTES:



TOPIC SENTENCE: What is coercion and the setting of the research study

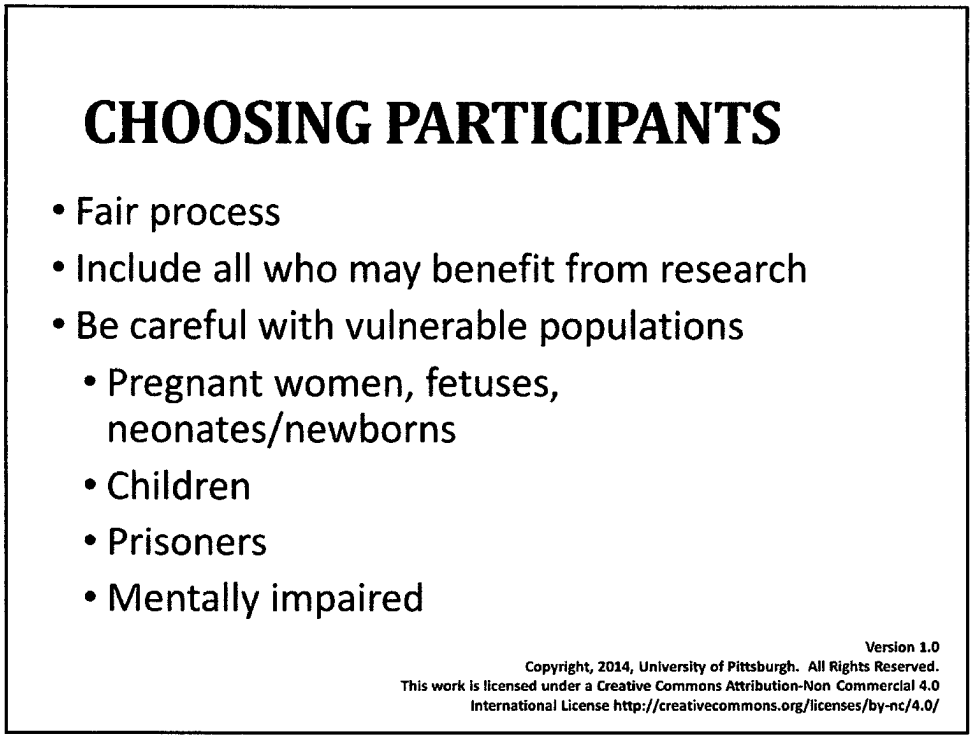
NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT applying the knowledge....How could this happen in YOUR project?

Participants may feel obligated to participate because the services or benefits may change if they do not take part in the study.

For example with a parishioner may not be welcomed to mass if they do not participate in church's survey. Similar to the patient at a doctors office, if he/she does not participate in their doctors study, they will not receive the same services at the clinic.

*OTHER related EXAMPLES: Food, money, medication, resources...etc.

DISCUSSION NOTES:



TOPIC SENTENCE: We must protect all participants from harm.

NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT applying the knowledge....How could this happen in YOUR project?

*If appropriate, can review sampling procedures and implications... such as: Snowball Sampling (MY – i.e., having community participants assist with identifying appropriate participants in a study that meet the inclusion criteria...but NOT excluding others)

Fliers, outreach and community informational sessions, developing research partnerships in which the community partners are equally invested and inspired to conduct the

Also review, types of research varies:
Clinical
Social and Behavioral
Bench/Basic science (lab science and animal research)

DISCUSSION NOTES:

Ethical Conduct of Research

- Informed consent process
- Training to protect participants (what you are doing now)
- Training to protect privacy
- All research on people must have IRB approval

TOPIC SENTENCE: Overview of all the various components related to our review and discussion of ethical research and how it is conducted.

NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT on the IMPORTANCE of this for YOUR project.

DISCUSSION NOTES:

SUMMARY

- Research involving people
  - Attempts to improve programs or treatments
  - Only done with permission of participants
  - Rules to make it as safe as possible
  - Must be approved by an IRB

TOPIC SENTENCE: This is a review summary of the key components of research and what is involved.

NARRATIVE:
***REVIEW the outlined bullet points in the slide and REFLECT on how this will be conducted in YOUR project.

DISCUSSION NOTES:

ACKNOWLEDGEMENTS

- Special thank you to our partners
  - Center for Health Equity - Community Research Advisory Board (CRAB)
  - University of Pittsburgh IRB
  - Daniel K. Nelson
    Director, Office of Human Research Ethics (UNC-Chapel Hill)
    Associate Professor of Social Medicine and Pediatrics
  - Eugenia Eng, DrPH Professor
    Department of Health Behavior and Health Education, Gillings School of Public Health, University of North Carolina at Chapel Hill

Resources

- US Dept. of Health and Human Services, Office for Human Research Protections (OHRP)
- http://www.hhs.gov/ohrp/humansubjects/index.html

- Collaborative Institutional Training Initiative (CITI)
- https://www.citiprogram.org/default.asp

- University of Pittsburgh Institutional Review Board
- http://www.irb.pitt.edu/

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Guidelines for Tailoring Template Scenario Slides

Scenario Review Checklist

As you (PI) begin to review and modify the PowerPoint slides and the notes section to your study specific scenarios, it is critical to include the Belmont principles:

Principle	Applications
Respect for Persons	• Informed consent • Privacy (Confidentiality and Anonymity)
Beneficence	• Protecting participants from harm • Assessment of risks and benefits
Justice	• Choosing participants

Remember, the scenarios you create should highlight both positive and negative participant experiences. It may be helpful to list additional examples or experiences in the notes section in the event that trainees have questions.

As you review your tailored scenarios, please ask yourself the following questions:

Respect for persons:

- ☐ Did a scenario cover informed consent?
- ☐ Did the participant give informed consent before any procedures were performed?
- ☐ Did they have a chance to ask questions?
- ☐ Did person performing consent answer all questions?
- ☐ Did the participant have the opportunity to make their own decision about participating?
- ☐ Were aspects of privacy included in your scenario?
- ☐ Were confidentiality and anonymity addressed?
- ☐ Was it reinforced that participation is voluntary?

Beneficence:

- ☐ Did a scenario cover protecting participants from harm?
- ☐ Did a scenario highlight the risks and benefits of participating in the research study?
- ☐ Were these risks and benefits well-defined to the participant?
- ☐ Was it explained what course of action would be taken if a risk was reported?

Justice

- ☐ Did a scenario cover including the correct target population and those who could benefit from the research study?
- ☐ Did a scenario show there was equal opportunity for potential participants to be involved in the study?

4. Confidentiality Agreement

COMMUNITY PARTNER RESEARCH ETHICS TRAINING AND CERTIFICATION
CONFIDENTIALITY AGREEMENT

UNIVERSITY OF PITTSBURGH

Title of Research Project: _____

Principal Investigator: _____

As a community partner member of this research team I, _____, understand that I may have access to confidential information about study participants. By signing this statement, I am indicating my understanding of my responsibilities to maintain confidentiality and agree to the following:

By selecting each of these STATEMENTS you are indicating that you have READ and AGREE to comply as instructed below:

- o I understand that names and any other identifying information about study participants are completely confidential.

- o I agree not to share, publish, or otherwise make known to unauthorized persons or to the public any information obtained in the course of this research project that could identify the persons who participated in the study.

- o I understand that all information about study participants obtained or accessed by me in the course of my work is confidential. I agree not to share or otherwise make known to unauthorized persons any of this information, unless specifically authorized to do so by approved protocol or by a supervisor acting in response to applicable law or court order, or public health or clinical need.

- o I understand that I am not to read information about study participants, or any other confidential documents, nor ask questions of study participants for my own personal information but only to the extent and for the purpose of performing my assigned duties on this research project.

- o I understand that a breach of confidentiality may be grounds for disciplinary action, and may include termination of employment.

- o I agree to notify my supervisor immediately should I become aware of an actual breach of confidentiality or a situation which could potentially result in a breach, whether this be on my part or on the part of another person.

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5a. Feedback & Evaluation Script

Community Partner Research Ethics Training and Certification Program Assessment Script

"Thank you for participating in this Community Partner Research Ethics Training and Certification program. We would like you to please consider completing this survey which should take no longer than 5-10 minutes to complete. This survey is considered research and we are asking everyone who participates in the Community Partner Research Ethics Training and Certification program to complete this survey to provide us with valuable feedback on the usefulness of the program and to help identify opportunities and areas for improvement regarding content as well as the format. Your participation is voluntary and you do not have to answer any questions you don't want to. [Pause] Do you have any questions?"

"In addition, we would like the opportunity to contact you as faculty and community participants in the future for your feedback and participation in this Community Partner Research Ethics Training and Certification program. With your permission and when feasible, we may ask to audio tape any related discussion in order to carefully document your ideas, feedback and potential influence of this training and certification program upon the research."

"You will not receive any payment for completing this survey and all responses will remain confidential and will be kept under lock and key. Do you have any questions? [or If you have questions, you can ask your trainer or representative from the Community PARTners]"

"This survey is being conducted by the Community PARTners, a part of the University of Pittsburgh's Clinical and Translational Science Institute. If you have any questions, please do not hesitate to contact us at PARTners@hs.pitt.edu"

Thank you.

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5b. Feedback & Evaluation Form

Your Feedback

Please fill out the following evaluation to help us better understand the usefulness and effectiveness of the Community Partner Research Ethics Training and Certification. Thank you!

Name: _____

Phone Number: _____ Email: _____

		Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
1.	The information presented in this training was valuable for me to learn					
2.	The information presented on research ethics was important for me to learn					
3.	The information and role playing presented on the consent process was useful for me to learn					
4.	The concepts presented in this training were clear and easy to understand					
5.	The information presented in this training was well organized					
6.	I gained new understanding of research ethics after completing this training					
7.	I will apply the knowledge/skills I acquired from this training when I am involved in or conducting research					
8.	I think the information from the training was appropriate for my involvement in research					
9.	I think the length of the training was appropriate for the information presented					
10.	I would recommend this training to be offered to others					

What information did you find most IMPORTANT after completing this training?

What NEW information did you LEARN after completing this training?

What information did you ALREADY know prior to this training?

What information, if any was MISSING from this training?

How could this training be IMPROVED?

Additional COMMENTS:

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5c. Feedback & Evaluation Form

Instructor Feedback

Please fill out the following evaluation to help us better understand the usefulness and effectiveness of the Community Partner Research Ethics Training and Certification. Thank you!

Name: _____

Phone Number: _____ Email: _____

		Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
1.	The information I presented in this training was valuable for my community partner and me to learn					
2.	The information I presented on research ethics was important for my community partner and me to learn					
3.	The information I presented in this training were clear and easy to explain to my community partner					
4.	The training I presented was easily adaptable to my study specific needs					
5.	The training I presented allowed me build a stronger partnership with my community partner					
6.	The training I presented allowed me to have better conversations and discussions about research ethics with my community partner					
7.	The training I presented will help maintain ethical practice with participants and research team members involved in the my study					
8.	I think the training I provided was appropriate for community involved research study					
9.	I think the training, involving the guidance of the CTSI Community PARTners CORE members, was appropriate for my success in delivering the training					
10.	I would recommend other investigators to deliver this training to their community partners					

What did you find most VALUABLE after delivering this training?

What NEW information did you LEARN after delivering this training?

How could preparing for the delivery of this training be IMPROVED?

How could delivery of this training be IMPROVED?

Additional COMMENTS:

6. Community Individual Investigator Agreement

NOTE – This is a sample of the official documentation from our University of Pittsburgh, Institutional Review Board, which is processed and signed by the IRB administrators to complete IRB approval of all participants' who have completed the Community Partners Research Ethics Training.

Community Individual Investigator Agreement
Community Partner Research Ethics Certification

Name of Institution with the Federalwide Assurance (FWA): University of Pittsburgh
Applicable FWA #: 00006790

Individual Community Investigator's Name: _____

Project Principal Investigator Name and IRB Protocol Number: _____

Specify Research Covered by this Agreement:
_____

---

(1) The above-named Community Individual Investigator has participated and completed the University of Pittsburgh Community Research Ethics training. In accordance with this training, the Community Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Community Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Community Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Community Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Community Investigator will complete the "Community Partner Research Ethics Training and Certification" developed by the Community PARTners (Community Engagement CORE) of the University of Pittsburgh Clinical and Translational Science Institute (CTSI) and approved by the University of Pittsburgh IRB prior to initiating research covered under this Agreement.

(6) The Community Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Community Investigator will report immediately to the listed Principal Investigator any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Community Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

(9) The Community Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(10) This Agreement DOES NOT preclude the Investigator from taking part in research not covered by this Agreement.

(11) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Community Investigator Signature: _____ Date _____

Name: _____ Degree(s): _____
(*Last*) (*First*) *(Middle Initial)*
Address: _____ phone #: _____

_____
(*City*) (*State/Province*) (*Zip/Country*)

Principal Investigator Signature: _____ Date _____

Name: _____ Degree(s): _____
(*Last*) (*First*) *(Middle Initial)*
Address: _____ phone #: _____

_____
(*City*) (*State/Province*) (*Zip/Country*)

FWA Institutional Official (or Designee):
Signature: _____ Date _____
Name: Randy P. Juhl, PhD.
Institutional Title: Vice Chancellor for Research Conduct and Compliance
Address: University of Pittsburgh, 132 Cathedral of Learning
4200 Fifth Avenue, Pittsburgh, PA 15260 Phone Number: 412-624-9111

7. Glossary

List of Acronyms & Definitions for Community Partner Research Ethics Training & Certification

Acronym	Description
CDC	Center for Disease Control and Prevention
CFR	Code of Federal Regulations
Co-I	Co-Investigator
CRAB	Community Research Advisory Board
CTSI	Clinical and Translational Science Institute
DHHS	U.S. Department of Health and Human Services
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IRB	Institutional Review Board, the review committee for research applications
NIH	National Institutes of Health
OR or OoR	Office of Research, University of Pittsburgh
PI	Principal Investigator also known as the Lead Researcher
UPMC	University of Pittsburgh Medical Center
WHO	World Health Organization

[Investigator & Community Partner ADD ACRONYMS specific to the research study]

7. Glossary

Contact information:
Institutional Review Board (IRB)
Main Phone: (412) 383-1480
Main Fax: (412) 383-1508
Mailing Address:
3500 Fifth Ave.
Hieber Building, Suite 106
Pittsburgh, PA 15213

University of Pittsburgh, Office of Research (OR)
Main Phone: (412) 624-7400
Main Fax: (412) 624-7409
Mailing Address:
University Club
123 University Place
Pittsburgh, PA 15213

Community PARTners (Community Engagement CORE of the CTSI)
Email: partners@hs.pitt.edu

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Community Partner Research Ethics Training (CPRET)

Certificate of Completion

Awarded to:

_____

For successfully completing
Community Partner Research Ethics Training

_____ _____

Principal Investigator/Project Coordinator verifying Completion **Date of Completion**

_____

Study Title and Protocol Number

Version 1.0

Appendix 1

COMMUNITY PARTNER RESEARCH ETHICS TRAINING AND CERTIFICATION DESCRIPTION

1. Pledge Statement
   • Purpose – To provide assurance that the person completing the training is indeed who they say they are and so the correct person gets certified for completing the module

2. Training Eligibility
   • Purpose – To ensure community partners are utilizing the training appropriately and not using this as a substitute for University requirements for the CITI research ethics training.

3. PowerPoint Training Presentation
   • Purpose – The educational content of the training is comprised of the following:
   - Introduction to Research & the Purpose of Research
   - Case Scenarios Connecting the History & Development of Research Ethic Principles
   - IRB & Federal regulations for Research and Protection of Human Subjects
   - Definitions and Rules of Research Conduct
   - How to Apply Various Aspects of Research Ethics and Conduct when Working with Human Subjects (i.e., Individuals Participating in a Research Study)

   • The presenter must adapt the case scenarios and slide topics as needed to relate specifically to the research study at hand. This general PowerPoint allows flexibility to become an interactive group session with questions and discussions about the topics and role plays with the case scenarios.

4. Confidentiality Agreement
   • Purpose – To have the trainee confirm that they have read, understand and agree to maintain confidentiality when it comes to research and human subjects.

   • The presenter reinforces the meaning of Confidentiality and its importance to research. Together as a group the agreement can be reviewed and signed.

5. Feedback & Evaluation
   • Purpose – To receive feedback from the participants about the training and its use for enhancing their understanding of research ethics.

   • The presenter provides feedback form for the participants to complete and fill out and submit to the Community PARTners.

Appendix 1

6. Community Individual Investigator Agreement
   • Purpose – Use as an example of the official documentation from our University of Pittsburgh, Institutional Review Board, which is processed and signed by the IRB administrators to complete IRB approval of all participants' who have completed the Community Partners Research Ethics Training.

   • The presenter can use this example if they are interested in further pursing institutional approval of using this training with community partners.

7. Glossary
   • Purpose – To provide a general list of terms used regarding research and human subjects. This is a list that can and should be updated to reflect the structure, language and culture of each specific research initiative.

   • The presenter can adapt the terms and definitions specific to the research study being discussed.

8. Certificate of Completion
   • Purpose – To provide personalized certificate of completion to each trainee who completes the training and allows acknowledgement to their organization or agency that they have completed this research ethics training.

   • The presenter can customize certification form as needed.

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Appendix 2

GUIDANCE FOR COMMUNITY PARTNERS
HOW TO COMPLETE COMMUNITY PARTNER RESEARCH ETHICS TRAINING & CERTIFICATION

Dear Community Partner,

Before completing this training, it is IMPORTANT that you have talked with the lead researcher/principal investigator (PI) of the research study you will be involved in.

As a community partner involved in research, it is IMPORTANT to complete research ethics training. The following is the training being used at the University of Pittsburgh and has been approved as our community partner research ethics training to receive **Community Partner Research Ethics Certification**.

By completing this training ensures that you have a good understanding of the following research topics:

- Introduction to Research & the Purpose of Research
- History of Research & the Development of Research Ethics Principles
- IRB & Federal regulations for Research and Protection of Human Subjects
- Definitions and Rules of Research Conduct
- How to Apply Various Aspects of Research Ethics and Conduct when Working with Human Subjects
- A clear Understanding of Your Role and Expectations Associated with the Research Being conducted

Remember, never hesitate to ASK QUESTIONS, SHARE ANY CONCERNS and ACKNOWLDGE your role as a community research partner and expert.

It is IMPORTANT to keep in mind that this training protects the people participating in research (human subjects) and protects you in your involvement in research. Your knowledge and understanding of research is essential to the protection of participants and the success of the research study.

We HIGHLY encourage you throughout this training and after receiving your certification to always communicate and ask your lead researcher and other research staff questions you may have. It is critical to understand how the details of the research study you are involved in apply to the research topics covered in this community partner research ethics training.

Once you receive your **Community Partner Research Ethics Certification** it is best to keep a hard copy for your records and your lead researcher will also keep a copy for his/her records.

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Appendix 3

GUIDANCE FOR INVESTIGATORS

HOW TO CONDUCT COMMUNITY PARTNER RESEARCH ETHICS TRAINING

Dear Investigator,

As a growing number of researchers are participating in community-based and community-partnered studies, the Community PARTners (Community Engagement CORE) of the Clinical & Translational Science Institute (CTSI) in collaboration with the Institutional Review Board (IRB) has developed a community partner research ethics training to make sure community partners know how to conduct research that is ethical and safe.

It is important to ask yourself the following questions to better understand whether or not your community partner is ACTIVELY INVOLVED in your research study and needs to complete this training.

***** This Community Partner Research Ethics Training and Certification is intended for community partners. We encourage you, Co-Investigators and any other research personnel in your research study to take the training. However, **it is NOT to be a substitute for the standard required IRB research training.**

Will your Community Partner be ACTIVELY INVOLVED in your research study?

- Will your community partner be recruiting and/or consenting human subjects to participate in your research?
- Will your community partner be observing and recording information about human subjects?
- Will your community partner be collecting private information about human subjects?
- Will your community partner be using, studying or analyzing identifiable private information or specimens provided by another institution, yourself or data collected from human subjects for research purposes?

If you answered **YES** to any of these questions above, your community partner is ACTIVELY INVOLVED in research. Therefore, it is IMPORTANT to have your community partner complete the following University of Pittsburgh IRB community partner research ethics training to receive **Community Partners Research Ethics Certification**.

Receiving this IRB-approved certification ensures that your community partner has the basic understanding of the following research topics:

- Introduction to Research & the Purpose of Research
- History of Research & the Development of Research Ethic Principles
- IRB & Federal regulations for Research and Protection of Human Subjects
- Definitions and Rules of Research Conduct
- How to Apply Various Aspects of Research Ethics and Conduct when Working with Human Subjects

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Appendix 3

Before instructing your community partner to complete this community partner research ethics training, it is necessary for you to explain the importance of this training and certification process as an opportunity to protect both themselves and the human subjects participating in the research study. Listed below is the table of contents for the training and indicates where you can include study specific content to tailor YOUR Community Partners Research Ethics Training and Certification materials.

- Pledge Statement
  - A statement completed by the person completing the training to ensure he/she is completing the training and not someone else

- "Who should complete this training?"
  - Series of eligibility questions to ensure appropriate community partners are utilizing the training

- PowerPoint Training presentation – ***Include content specific to your research study***
  - Provides the educational content for the training

- Confidentiality Agreement
  - An agreement to maintain confidentiality when it comes to research and human subjects

- Feedback & Evaluation
  - Receive feedback from the participants about the training and its use for enhancing their understanding of research ethics.

- Community Individual Investigator Agreement
  - A sample of the official documentation from our University of Pittsburgh, Institutional Review Board, which is processed and signed by the IRB administrators to complete IRB approval of all participants' who have completed the Community Partners Research Ethics Training.

- Glossary – ***Include acronyms and terms specific to your research study***
  - List of general terms used regarding the research and human subjects

- Certification of Completion
  - Provide personalized certificate of completion to each trainee who completes the training you conducted

  - Once your community partner receives Community Partners Research Ethics Certification, it is GOOD that you and your community partner keep a hard copy of the certification with your research documents. This documentation can be filed and stored with your study protocols.

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Appendix 3

Research Study Datasheet

Please provide us feedback about the nature of the research study you are involved in. Thank you!

Name of Principal Investigator or Lead Researcher:

Department:

Email:

Contact:

Name of Research Study:

Brief Description of the Research Study

Describe Your Role in the Research Study

Additional Comments/Feedback:

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