

MODULE 2: RESEARCH ETHICS: HISTORY AND APPLICATION



Veterans Health
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Durham VA Health Care System



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Welcome: Facilitators should welcome participants to the Module 2 training.

ICEBREAKER ACTIVITY

Icebreaker Activity:

1. **Color Codes:** have a variety of colored squares of paper or colored candy (like Starburst) and ask each person to choose one. Ask them to share their name and answer questions according to colors (ex. green=most memorable trip). Also, ask each person to share something they learned from module 1 and/or a question they have after module 1. Record any questions on poster paper and try to incorporate these into the discussion today, or note that we will address these in future sessions.

<p style="text-align: center;">Objectives</p> <ul style="list-style-type: none">• Explain the role of the Institutional Review Board (IRB)• Outline principles that guide research ethics• Describe historical case studies that demonstrate ethical blunders• Discuss ethical considerations in modern research	<p>Provide overview of the schedule and topics that will be covered in the presentation today, as well as topics that will be covered in additional presentations.</p> <p>Provide framing for the training. Sample language: <i>At our last training, we talking about what research is and why we do it. We also talked about the role of this group. Today, we are building on what we learned last time, with a focus on research ethics, or how we make sure that research is done in a way that respects the rights of participants and is done in a responsible manner.</i></p>
<p style="text-align: center;">QUICK REVIEW...ROLE OF THE IRB</p> <hr/>	

Who are the players?

- Researchers
 - Principal investigator
 - Co-investigators
 - Special consultants
- Research staff
 - Project managers
 - Interventionists (e.g., nurses, dietitians)
- Participants/patients
- Review boards
 - Grant – reviews and scores grants based on importance and quality
 - IRB – decides whether research adequately protects research subjects
 - Other oversight agencies (e.g., FDA)
 - Funders (e.g., VHA, NIH, Non-profit foundations)
 - Others?

Talking Points:

- In module 1, we talked about the many different people involved in research.
- You may recall us mentioning the IRB. Does anyone remember what that stands for?
- IRB stands for Institutional Review Board. This is the group that decides whether a research plan adequately protects research participants.

Institutional Review Boards (IRBs)

- IRBs exist to protect research participants.
- Researchers must submit a “Protocol” to the IRB that describes the plan for data collection, data storage, and how privacy and confidentiality will be protected.
- The IRB reviews protocols to make sure that the proposed research is safe and ethical.

Talking points:

- IRBs exist to protect people participating in research.
- Researchers must submit a “Protocol” to the IRB that describes their plan for data collection, data storage, and how privacy and confidentiality will be protected.
- The IRB reviews these research proposals to make sure that the proposed research is safe and ethical

Institutional Review Boards (IRBs)

- IRBs are always made up of both scientists and community members.
- Certain types of projects do not require IRB review.

Talking points:




- IRBs are composed of both scientists and community members
- Quality Improvement projects and some evaluation projects do not require IRB oversight. They are not considered “research” because their purpose is to improve a specific program, not to add to the general body of knowledge.

(Content adapted from David Edelman, MD “IRB & IC”)

Content adapted from David Edelman, MD “IRB & IC”

PRINCIPLES THAT GUIDE RESEARCH ETHICS

The Belmont Report

-  1 Respect for Persons
-  2 Beneficence
-  3 Justice

Talking Points:

- The main document that guides research ethics today is called the Belmont Report
- The Belmont Report established three major principles to help us conduct ethical research. These are:
 - 1) Respect for persons
 - 2) Beneficence- this means that benefits outweigh harm
 - 3) Justice
- We are going to talk about each of these guidelines and how they are applied in research.



The Belmont Report: Respect For Persons

What it means	How it's applied
<ul style="list-style-type: none"> • Research subjects should not be forced to participate • Those who cannot make decisions should be protected 	<ul style="list-style-type: none"> • Informed consent process • Privacy and confidentiality assurances

Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC"

Talking points:

- The first guideline is *Respect for Persons*.
- By this, we mean that each person who agrees to participate in research does so voluntarily. They should also be given all the information about the research so that they know what they are agreeing to.
- Respect for persons also means that those people who cannot make their own decisions, like children, should have special protections.
- The ways that we apply this principle in research are we obtain informed consent, and we protect privacy and confidentiality

(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC")

Informed Consent

- Informed Consent = Getting permission from research participants
- Consent is a process...



Content courtesy of Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org

Talking points:

- Getting permission from research participants is as process to make sure they understand what they are consenting (or agreeing) to participate in.
- Consent is a process:
 - Researcher tells participant all important information
 - Participant has chance to ask questions
 - Researcher answers questions
 - Participant signs a consent form agreeing to participate or provides verbal consent

(Content courtesy of Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org)

What would you want to know before agreeing to participate in a research study?

Discuss: Ask individuals what they would like to know before participating in a research study. If helpful, provide a scenario: *Researchers want to study whether drinking green tea helps people lose weight. What would you like to know if you were participating?*

Informed Consent Document

After reading the Informed Consent, research participants must understand:

- ✓ They will be participating in research
- ✓ The basic activities that will be involved in participation
- ✓ Their participation is voluntary
- ✓ Any risks and benefits of their participation
- ✓ They can withdraw at any time



Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC"

Talking points:

- An informed consent document provides information to participants about the study.
- Participants review this form and have a chance to ask questions
- Then, if they agree to participate, participants sign the form (Note: in some cases, verbal consent is used, such as during phone interviews)
- Through participating in the informed consent process, subjects should understand:
 - They are participating in research
 - The basic activities that will be involved in participation
 - That their participation is voluntary
 - Any risks and benefits of their participation
 - That they can withdraw at any time

Informed Consent Document

- Should be clearly written using everyday words
- There should be a plan for working with participants who cannot read



Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC"

Talking points:

- It is important to make sure that all potential participants understand what is on the form. It should be written clearly, and there needs to be a plan for working with people who can't read.
- **Ask:** *Why do you think we are telling you about this?*
 - It is important to know about Informed Consent because VetREP members may be asked to review these documents, or to provide feedback about what Veterans would want to know prior to participating

(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC")

Resource note: Provide a sample ICF in the participants' packet of materials. Refer to this example so participants can review this later if interested.

Activity: Informed Consent Form Review

- Does this consent form have all the elements it should?
- Are all the elements clear?
- Is anything confusing?
- What else would you want to know?

Participants should know:

- ✓ They are participating in research
- ✓ The basic activities that will be involved in participation
- ✓ That their participation is voluntary
- ✓ Any risks and benefits of their participation, and what protections are in place
- ✓ That they can withdraw at any time

Optional Activity: Informed Consent form review: Have participants review an informed consent form (or excerpt from form) and identify some of the key elements discussed in the presentation. Elements to identify include:

- a) They are participating in research
- b) The basic activities that will be involved in participation
- c) That their participation is voluntary
- d) Any risks and benefits of their participation, and what protections are in place
- e) That they can withdraw at any time

Discussion questions:

- *Researchers may ask for your feedback on their consent forms. Does this one have all the elements it should?*
- *Are all the elements clear?*
- *Is anything confusing?*
- *What else might you want to know about the study if you were considering being a research participant?*

Privacy

All personal information about research participants must remain confidential (private), including:

- ✓ Names
- ✓ SSNs
- ✓ Birthdates
- ✓ Phone numbers
- ✓ Any health information where the participant could be identified




**Your Information.
Your Rights.
Our Responsibilities.**

The law that governs this is called the Health Insurance Portability & Accountability Act (HIPAA).

Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004). www.citiprogram.org

Talking points:

- Privacy is an important component of the “respect for persons” principle.
- All personal information about research participants must remain confidential (private), including:
 - Names
 - SSNs
 - Birthdates
 - Phone numbers
 - Any health information where the participant could be identified.
 - We can talk about test results and behaviors as long as we make the discussion anonymous—we cannot include any information that could identify the participant
 - Note: the type of information listed here is not all-encompassing (other types of information are also considered identifying)
- The law that governs this is called the Health Insurance Portability & Accountability Act (HIPAA)
- Usually, research participants sign a HIPAA form that authorizes the researchers to use and share specific personal information for specific purposes. Again,

	<p>researchers may ask VetREP to review a HIPAA form to make sure it is clear and understandable.</p> <p>(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org)</p>				
<div style="text-align: center;">  <h3 style="color: red;">The Belmont Report: Beneficence</h3> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #0056b3; color: white;"> <th style="padding: 5px;">What it means</th> <th style="padding: 5px;">How it's applied</th> </tr> </thead> <tbody> <tr style="background-color: #d9e1f2;"> <td style="padding: 5px; vertical-align: top;"> <ul style="list-style-type: none"> Benefits of research should outweigh harms Researchers should maximize potential benefits to participants and minimize potential harms </td> <td style="padding: 5px; vertical-align: top;"> <ul style="list-style-type: none"> All possible risks and benefits of research are assessed Participants are made aware of risks and benefits </td> </tr> </tbody> </table> <p style="font-size: small; margin-top: 10px;">Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC"</p>	What it means	How it's applied	<ul style="list-style-type: none"> Benefits of research should outweigh harms Researchers should maximize potential benefits to participants and minimize potential harms 	<ul style="list-style-type: none"> All possible risks and benefits of research are assessed Participants are made aware of risks and benefits 	<p>Talking points:</p> <ul style="list-style-type: none"> The second principle of the Belmont Report is Beneficence. Beneficence means that when conducting research, the potential benefits to participants and/or society should be greater than potential harms to the participants or to society. It is important that researchers try to protect participants from harm and make sure that the potential benefits outweigh the risks. The way we apply this principle in research is assessing possible risks and benefits of research before we do research, and making sure participants are aware of potential risks and benefits so that they can make an informed decision about participating <p>(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC")</p>
What it means	How it's applied				
<ul style="list-style-type: none"> Benefits of research should outweigh harms Researchers should maximize potential benefits to participants and minimize potential harms 	<ul style="list-style-type: none"> All possible risks and benefits of research are assessed Participants are made aware of risks and benefits 				
<h3 style="color: red; text-align: center;">Protecting Participants from Harm</h3> <ul style="list-style-type: none"> Assessing all possible risks, including breaches of privacy/confidentiality Telling research participants about all possible risks Not intentionally harming participants Not enrolling participants who are more likely to be harmed <p style="font-size: small; margin-top: 10px;">Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org</p>	<p>Talking points: Ways we try to protect participants from harm include:</p> <ul style="list-style-type: none"> Assessing all possible risks, including breaches of privacy/confidentiality Telling research participants about all possible risks Not intentionally harming participants Not enrolling participants who are more likely to be harmed <p>(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org)</p>				

Benefits Outweigh Risks

What are benefits and risks of weighing yourself on a scale?



Discuss: *What are risks and benefits of weighing yourself on a scale?* (Ex. Risks- falling off, being upset about your weight; benefits- knowing if you are at a healthy weight)

Talking points:

- Every activity involves risk
- Researchers must have reason to believe that potential benefits of the study are greater than the potential risks.

Considering Individual Benefit vs. Societal Benefit



vs.



Sometimes, the only benefit to the participant may be knowing that she or he is contributing to knowledge that may help others.

Talking points:

- In research, we often distinguish between individual benefits and societal benefits
- The biggest benefits to research are often societal benefits- having more evidence about how to help the larger population
- Sometimes, the only benefit to an individual participant is knowing that she or he is contributing to knowledge that may help others
- As mentioned previously, researchers must have reason to believe that potential societal benefits of the study are greater than the potential risks to participants and society.



The Belmont Report: Justice

What it means	How it's applied
<ul style="list-style-type: none"> The burdens and benefits of research should be distributed fairly 	<ul style="list-style-type: none"> Diversity considered when selecting participants Exclusion of those who are more likely to be harmed

Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC"

Talking points:

- The third principle of the Belmont Report is *Justice*.
- Justice means:
 - The burdens and benefits of research should be fairly shared among the wider population
 - We try to make sure we are including those who could benefit from the results of the research and not take advantage of some people to benefit others
 - We also don't want to prevent people from participating who may benefit from the results of the research.
- The ways we apply justice to research is by:
 - Considering diversity when recruiting and selecting participants
 - Excluding people who are more likely to be harmed by the research

(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD "IRB & IC")

Who should be included and excluded

Included


- Anyone who may benefit from results of research
- Diverse research participants


Excluded

- Those who are more likely to be harmed by research
- Exclusion or protections for vulnerable populations:
 - Children
 - Prisoners
 - People with reduced mental capacity

Talking points:

- It is important that anyone who may benefit from the results of the research has the opportunity to participate
- We should exclude people we think are more likely to be harmed by the research
- We may also exclude or build in extra protections for vulnerable populations. Vulnerable populations include:
 - Children
 - Prisoners
 - People with reduced mental capacity (people with mental illness or cognitive disabilities, people who are incapacitated for another reason (like in a coma))
 - Ask:** *why are these populations considered vulnerable?* (Ex. They might not be able to make their own decisions as well- might not have power to make decisions (prisoners) or might have a hard time weighing risks and benefits)

<h2 style="text-align: center;">Underrepresented Groups</h2> <p>Historically, women and people of color have not been included in biomedical research as much as white men. According to the FDA:</p> <ul style="list-style-type: none"> • African-Americans represent 12% of the U.S. population but only 5% of clinical trial participants. • Hispanics make up 16% of the population of the U.S. but only 1% of clinical trial participants. • Heart disease is the #1 killer of women in the U.S., but only 33% of cardiovascular trial participants are female.  <p>http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM334959.pdf</p>	<p>Talking Point:</p> <ul style="list-style-type: none"> ○ Historically, women and people of color have not been included in biomedical research as much as white men. ○ Studies have found: <ul style="list-style-type: none"> ○ African-Americans represent 12% of the U.S. population but only 5% of clinical trial participants.¹ ○ Hispanics make up 16% of the population of the U.S. but only 1% of clinical trial participants.¹ ○ Heart disease is the #1 killer of women in the U.S., but only 33% of cardiovascular trial participants are female.² <p>Ask: <i>Do any of these statistics surprise you? Why or why not?</i></p> <p>Sources:</p> <ol style="list-style-type: none"> 1. http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM334959.pdf 2. http://www.brighamandwomens.org/Departments_and_Services/womenshealth/ConnorsCenter/Policy/ConnorsReportFINAL.pdf
<p>Why is it important to have diverse participants in research studies?</p> <p>What might prevent some people from participating in research?</p> <p>How can researchers make it easier or more appealing for people to participate?</p>	<p>Discuss: <i>In large or small groups, discuss the following questions:</i></p> <ul style="list-style-type: none"> • <i>Why is it important to have diverse participants in research studies?</i> • <i>What might prevent some people from participating in research?</i> • <i>How can researchers make it easier or more appealing for people to participate?</i> <p>Talking points:</p> <ul style="list-style-type: none"> ○ Everyone who could benefit from the results of the research should have equal chance to participate. ○ Risk/benefit distribution- we don't want one community to take on all the risk while another community benefits ○ Things that work well for one group of people might not work well for others <ul style="list-style-type: none"> ○ Ex. Men and women may respond to drugs differently ○ Ex. People of different cultural backgrounds might have different thoughts and preferences related to an intervention, which could affect how they adhere to or respond to it ○ Part of the reason we're asking VetREP members to consider this is that we

	<p>want them to help us understand research participants, what barriers they might face to participating, and how to best engage them</p> <p><i>Note to facilitator: this slide may be a natural segue way into discussion of the historical case studies, since people are likely to bring up ethical blunders as a reason people don't participate</i></p>
<p>HISTORICAL CASE STUDIES</p>	<p>Talking Points:</p> <ul style="list-style-type: none">• Now, we are going to transition into some historical case studies. Each of these is an example of unethical research conducted in the past.• These cases of unethical research from history led to the protections that are in place for research participants today.• For each example, please think about how the research violated the three ethical principles outlined in the Belmont report
<p>Ice Bath Experiments at Dachau</p>  <p><small>Content courtesy of Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org</small></p>	<p>Doctors at the concentration camp would place the people in ice baths and take several measurements as the person was dying. There was no regard for the human life. Many patients end up injured, disabled or even dead. You can imagine how bad it would be to be placed in an ice bath and not allowed to get out.</p> <p>The Nazis seemed to be doing these experiments because they thought it would advance science. They weren't doing it just to torture people. However, their lack of respect for certain populations contributed to their willingness to do this.</p> <p>Ask: how does this break the three principles of the Belmont Report?</p> <p>(Content courtesy of Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org)</p>

Ice Bath Experiments at Dachau



- ✘ **Respect for persons:** Participants didn't have a choice about participating
- ✘ **Benefits outweigh harms:** Participants were deliberately placed in painful, life threatening conditions
- ✘ **Justice:** Participants were singled out because they were Jewish or enemies of the Nazis

Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org

Respect for persons: Participants didn't have a choice about participating
Benefits outweigh harms: Participants were deliberately placed in painful, life threatening conditions
Justice: Participants were singled out because they were Jewish or enemies of the Nazis

(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org)

Willowbrook State School Staten Island, 1956-1963



Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org



On Staten Island in New York, there was a state school for children who were institutionalized. These were kids who had medical problems or would otherwise have no home. Many had conditions like cerebral palsy or cognitive disabilities.


Kids were only allowed into the school if their parents agreed to allow experimentation. While they may have been informed, restricting admission like this is called coercion. Many of these parents saw no other option. There wasn't another school for their kids and they couldn't care for them at home.

Kids in the Willowbrook school were purposefully infected with Hepatitis A to see what would happen. This type of experiment, while not likely to cause serious long term effects, causes significant discomfort. Hepatitis A makes people feel bad with nausea, fever and body aches. Of course, there is always a chance that the infection will be more severe.

Again, these researchers thought they were doing something to help society. By understanding the Hepatitis A infection, we would be better able to stop its spread and come up with treatment.

Ask: how does this break the three principles of the Belmont Report?

	<p>(Content courtesy of Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org)</p>
<p>Willowbrook State School Staten Island, 1956-1963</p>  <ul style="list-style-type: none">* Respect for persons: Participants were coerced into participating* Benefits outweigh harms: Participants were deliberately given a disease* Justice: Participants were exploited because of their mental status <p><small>Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org</small></p>	<p>Respect for persons: Participants were coerced into participating Benefits outweigh harms: Participants were deliberately given a disease Justice: Participants were exploited because of their mental status</p>
<p>Tuskegee Syphilis Study Macon County, Alabama 1932-1972</p>  <p><small>Content courtesy of Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org</small></p>	<p>In 1972, the news broke out of the untreated syphilis study in Alabama. Have any of you heard about the syphilis study in Alabama?</p> <ul style="list-style-type: none">• The main goal of the study was to seek out African-American males in the second stage of syphilis, and then to sporadically perform exams on these men to determine the effects that syphilis had on their bodies• 1932, “word spread throughout Macon County that ‘government doctors’ were to provide free exams to start a new health program”• The test subjects were told that they were receiving medical treatment for “bad blood,” but in reality, they never received <u>penicillin</u>, which was the most effective treatment for syphilis.• 408 men were told they had “bad blood,” and they were offered free medical care and treatments. A second group of 200 men were enrolled in a ‘control’ group.• Their names were put onto lists given to local hospitals, and they were told <u>not to treat</u> the patients. Instead, the participants had to schedule appointments with the government doctors, and while they were told they were receiving penicillin, in actuality they were just receiving aspirin or other ineffective means

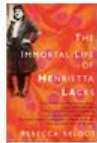
	<p>of treatment.</p> <ul style="list-style-type: none">• In those that died, autopsies were performed by white doctors without permission from the deceased.• After 40 years of this race-based experiment, the story broke nationwide.• For the first time the test subjects realized that they had been involved in this experiment and that they had not received treatment.• A group of survivors led by Charlie Pollard began to gather information to put together a law suit against the doctors who performed the medical experiment and the federal government who had financially supported the project.• In 1973, the lawsuit ended in victory for the participants and they were collectively awarded \$10 million to split between the living syphilitics and families of the deceased. <p>Ask: how does this break the three principles of the Belmont Report?</p> <p>(Content courtesy of Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org)</p>
<p>Tuskegee Syphilis Study Macon County, Alabama 1932-1972</p>  <ul style="list-style-type: none">* Respect for persons: Participants did not know they were participating in research* Benefits outweigh harms: Participants were deliberately given a disease, were not given the treatment they expected to receive, and were not informed of risks* Justice: Participants were exploited because of their race <p><small>Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org</small></p>	<p>Respect for persons: Participants did not know they were participating in research Benefits outweigh harms: Participants were deliberately given a disease, were not given the treatment they expected to receive, and were not informed of risks Justice: Participants were exploited because of their race</p>

ETHICAL ISSUES TODAY

Ethical Issues in Modern Research

We've improved a lot, but researchers still face ethical issues such as:

- Burden/cost of participating in research (co-pays, travel, time, etc.)
- What to do about unexpected findings, especially in genomic research
- What true informed consent looks like when participants have differing levels of literacy and health literacy
- Participant/family compensation for innovations developed by studying banked specimens (e.g., blood, tumor tissue)
- How to ensure participant confidentiality in the digital age
- How to prevent researcher bias when selecting participants



Talking Points:

- We've improved a lot, but researchers still face ethical issues. Some of the ethical issues we discuss today include:
 - Burden/cost of participating in research (co-pays, travel, time, etc.). How can we reduce the burden on research participants, without providing so much compensation that it is coercive?
 - What to do about unexpected findings, especially in genomic research. If we find that someone has a gene that puts them at higher risk for a disease, do we tell them? What if they can't afford medical care, or there is not a good treatment for the disease?
 - What true informed consent looks like when participants have differing levels of literacy and health literacy. How do we make sure that participants truly understand the risks and benefits?
 - Participant/family compensation for innovations developed by studying banked specimens (e.g., blood, tumor tissue). What if we develop a new drug from a finding? Should participants receive compensation for this? The book on this slide- *The Immortal Life of Henrietta Lacks*-discusses this ethical issue. Scientists used her cells without her knowledge to develop lots of health innovations. Henrietta and her family, who couldn't afford health insurance, didn't receive any

	<p>compensation from these developments. (https://www.amazon.com/Immortal-Life-Henrietta-Lacks/dp/1400052181)</p> <ul style="list-style-type: none">○ How to ensure participant confidentiality in the digital age. How can we make sure that digital information is secure? Can we use search engines or social media for research? How can this be done ethically?○ How to prevent researcher bias when selecting participants. How do we make sure that participants are selected in a fair way?
<p style="text-align: center;">Activity: “Mock” Modern Case Studies</p> <hr style="border: 5px solid #0056b3;"/>	<p>Activity options:</p> <ol style="list-style-type: none">1. Case studies: Split participants into small groups. In their small groups, ask participants to review each case study to identify potential ethical issues and what suggestions they have to remedy it. After small groups have a chance to discuss each case study, go over the examples as a large group. <p>Case studies:</p> <ol style="list-style-type: none">1. A researcher is interested in learning more about the types of food that people eat during the workday. They decide to monitor what employees are eating by observing them at lunch. They don't want the employees to know they are being observed, because they think it might make them self-conscious. As such, they don't let them know this happening.2. A researcher wants to test a new treatment for depression. They know many incarcerated people are depressed. As such, they hope to conduct the study at a nearby prison.3. A researcher is doing a study to see if counseling can help people lose weight. The study will require participants to attend multiple sessions, and the researcher knows transportation is important. Because of this, they only invite people who look like they can afford a car.

Acknowledgements

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