MODULE 2:
RESEARCH ETHICS: HISTORY AND APPLICATION

Veterans Health Administration

Durham VA Health Care System

VA HEALTH CARE | HONORING SERVICE EMPOWERING HEALTH

ICEBREAKER ACTIVITY

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Objectives

- 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

QUICK REVIEW…ROLE OF THE IRB

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?

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.

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Institutional Review Boards (IRBs)

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

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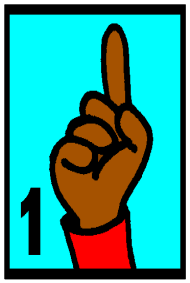
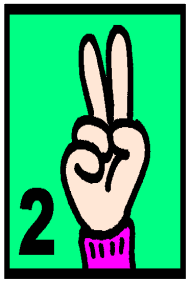
PRINCIPLES THAT GUIDE RESEARCH ETHICS

The Belmont Report

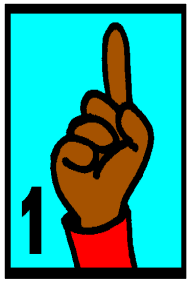


Respect for Persons



Beneficence

Justice



The Belmont Report: Respect For Persons

What it means	How it's applied
• Research subjects should not be forced to participate • Those who cannot make decisions should be protected	• 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"

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

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

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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

Department of Veterans Affairs	Research Informed Consent Form	
	Version Date: (to be updated by PI w each version)	Page 9 of 9
	IRB Template: 20160321	VA Form 10-1086
Participant Name:		Date:
Study Title:		
Principal Investigator:		VAMC: Durham

AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Participant's Signature/Legally Authorized Representative*	**Date**
Signature of Person Obtaining Consent	**Date**

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 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"

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

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

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

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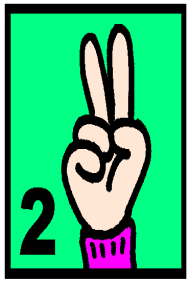

The Belmont Report: Beneficence

What it means	How it's applied
• Benefits of research should outweigh harms • Researchers should maximize potential benefits to participants and minimize potential harms	• All possible risks and benefits of research are assessed • Participants are made aware of risks and benefits

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"

Protecting Participants from Harm

- 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

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

Benefits Outweigh Risks

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

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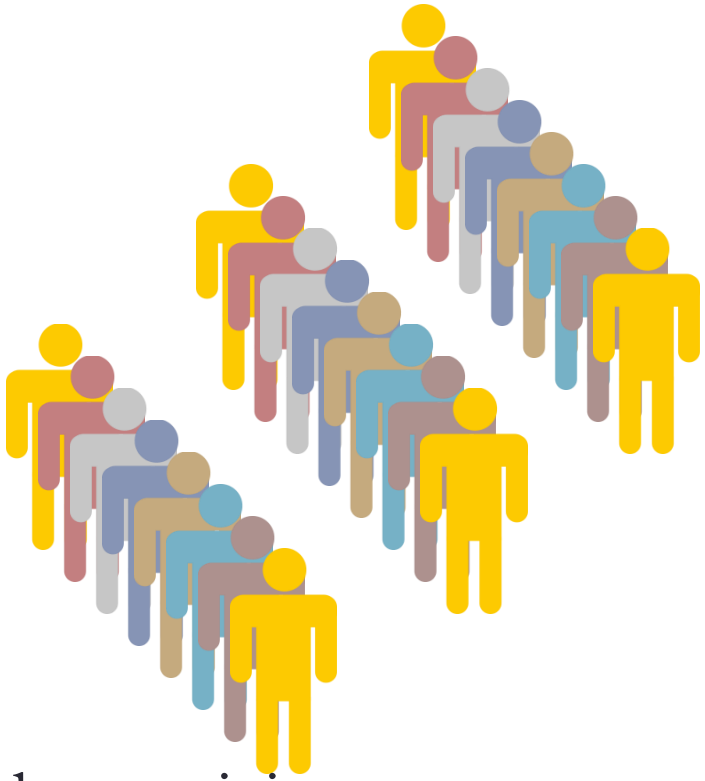
Considering Individual Benefit vs. Societal Benefit

vs.



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

The Belmont Report: Justice

What it means	How it's applied
• The burdens and benefits of research should be distributed fairly	• 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"

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

Underrepresented Groups

Historically, women and people of color have not been included in biomedical research as much as white men.

Studies have found:

- 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]

1. http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM334959.pdf
2. http://www.brighamandwomens.org/Departments_and_Services/womenshealth/ConnorsCenter/Policy/ConnorsReportFINAL.pdf

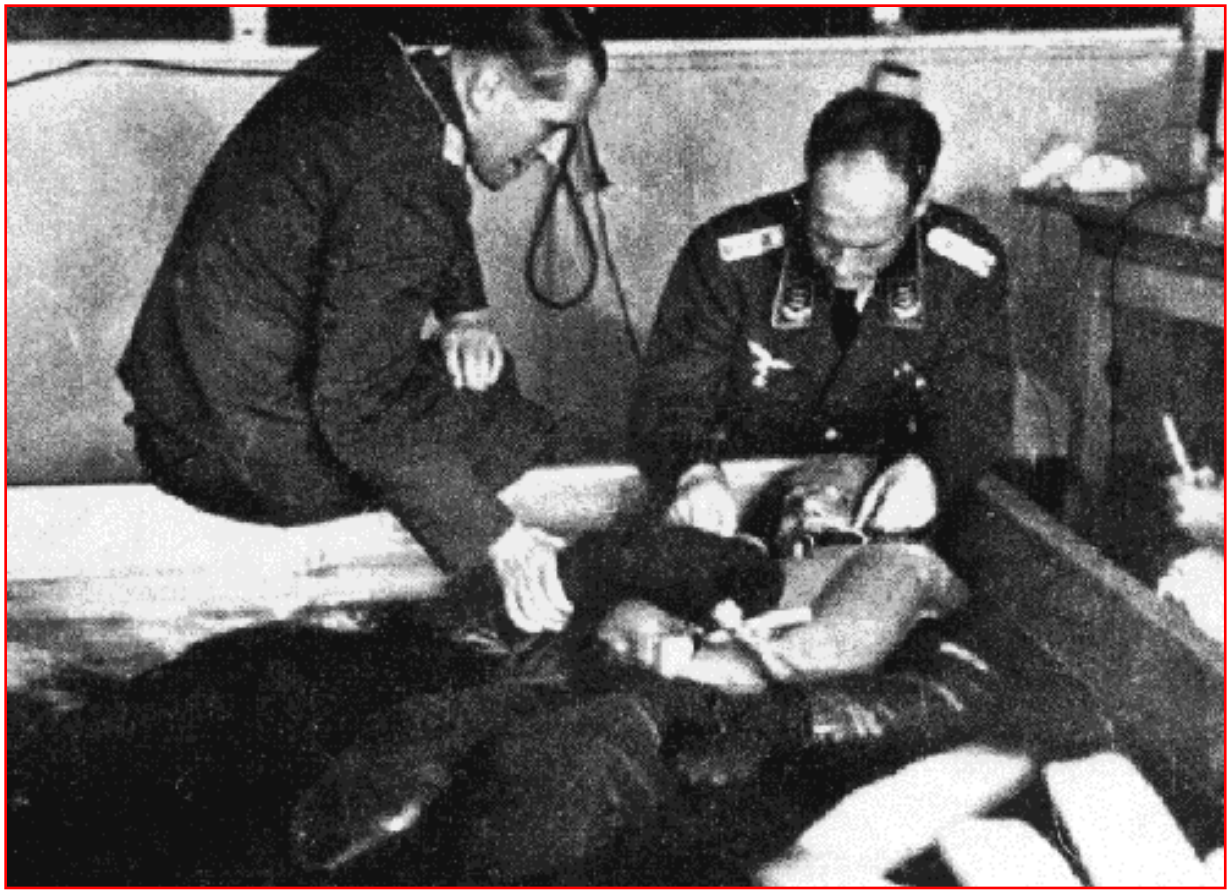
Why is it important to have diverse participants in research studies?

What might prevent some people from participating in research?

How can researchers make it easier or more appealing for people to participate?

HISTORICAL CASE STUDIES

Ice Bath Experiments at Dachau



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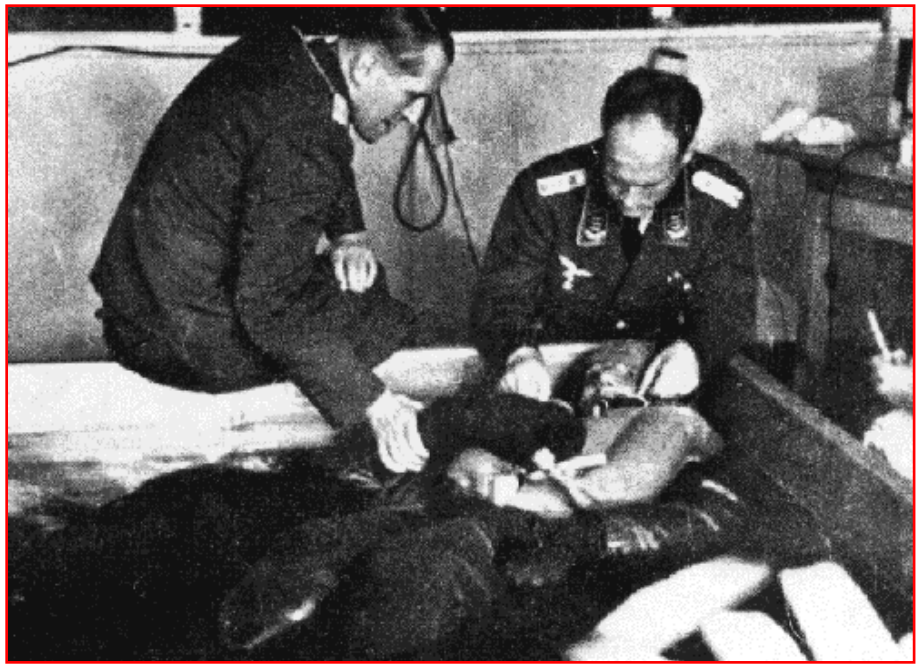
Ice Bath Experiments at Dachau



- **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

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

Willowbrook State School
Staten Island, 1956-1963

- **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

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

Tuskegee Syphilis Study
Macon County, Alabama
1932-1972

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

Tuskegee Syphilis Study
Macon County, Alabama
1932-1972

- **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 received, and were not informed of risks
- **Justice:** Participants were exploited because of their race

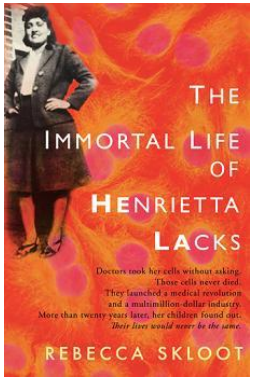
Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org

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



Activity: "Mock" Modern Case Studies

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Acknowledgements

- **Authors:** Sara Andrews, MPH, RD and MaryBeth Grewe, MPH
- **Thanks to:** Dr. David Edelman (Durham VAMC) and the UNC Center for Health Promotion and Disease Prevention for use of content from their research training modules
- **Special thanks to:** Veteran Research Engagement Panel (VetREP) Seed Group Members Elijah Sacra and Rebekah Layton and the Durham VA Medical Center VetREP Planning Committee members for providing editorial input

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