The Importance & Value of Good Research Ethics

Community Partner Research Ethics Training and Certification

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WHAT IS RESEARCH?

- An organized way to gather information
- Attempts to provide valuable knowledge to serve societal benefit
- Has the potential to improve the care or well-being of future generations

WHAT ROLES DO WE PLAY IN RESEARCH?

- Participant
- Researcher
- Stakeholder
- Partner
- Team
  - YOU
  - Community Agency
  - University Staff
  - Service and Medical Providers
WHAT IS A RESEARCH PARTICIPANT?
• Anybody we gather research information about
• Information comes from
  • experiments
  • surveys
  • observations
  • medical record reviews
  • interviews

What REALLY happens when the research begins...
• Experience with research
• Perception of research

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
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.

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.

Identify Good Research Ethics Principles Used

**Research staff**

- Accommodated child’s and parent’s needs
- Consent process conducted thoroughly and provided clear understanding
- Provided follow up information regarding findings and project next steps
Alternative Scenario 1
An interview with child and their parents (in separate rooms) on strategies parents use to prevent substance use among Lesbian, Gay, and Bisexual Youth.

What Does Good Ethical Research Look Like?
Scenario 1:
• Participant – LGBT youth and their parents
• Research Staff – Experienced in working with LGBT youth
• 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

Identify Good Research Ethics Principles Used
Research staff ……
• Accommodated child’s and parent’s needs
• Consent process conducted thoroughly and provided clear understanding
• Provided follow up information regarding findings and project next steps
Scenario 2
In high school setting a violence prevention research project was recruiting male athletes grades 9th-12th

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

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
Alternative Scenario 2
In high school setting a social media project helping LGBT youth deal with stress. They recruited LGBT Youth from 9th - 12th grade.

What Does Good Ethical Research Look Like?
Scenario 2:
• **Participant** LGBT youth
• **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

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
Scenario 3
At the Veterans Affairs (VA) Hospital a research study was conducting a randomized trial with alcoholic liver disease patients.

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

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
Alternative Scenario 3
At the Veterans Affairs (VA) Hospital a research study was conducting a randomized trial with Human Immunodeficiency Virus (HIV)

What Does Good Ethical Research Look Like?
Scenario 3:
• Participant – HIV patients
• Research Staff – Physician expertise in care and treatment
• Outcome – Participant was connected with the study; care was provided to improve his health condition

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
Scenario 4
At a doctors office researchers were recruiting patients for a dermatology study

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

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
Alternative Scenario 4
At a doctors office researchers were recruiting patients for a HIV study

What Does BAD Research Ethics Look Like?
Scenario 4:
• Participant – Patient coming in for clinical care
• Research Staff – Recruited patient after receiving a serious diagnosis
• Outcome – Unpleasant consent process and poor research ethics

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
Reflection

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

Covering All Aspects of Good Research Ethics

• History
• Guiding Principles
• Rules
• Privacy

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!
**Historical Events have informed existing guidelines**

**NUREMBERG CODE:** “RULES FOR TREATING PARTICIPANTS”
- Set the research standards
-Outlined rules for conducting research

**DECLARATION of HELSINKI**
- Expanded standards for consent process, participant and researcher relationship and research guidelines

The Belmont Report
- CORE research ethics: Respect, Beneficence & Justice

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**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

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**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
### APPLYING GUIDELINES

<table>
<thead>
<tr>
<th>Principle</th>
<th>Applications</th>
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| Respect for Persons | • Informed consent  
• Privacy (Confidentiality and Anonymity) |
| Beneficence        | • Protecting participants from harm  
• Assessment of risks and benefits |
| Justice            | • Choosing participants                                                      |

### 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

### 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
UNDERSTANDING CONSENT

• Clearly written
• Everyday words
• Plan for participants who cannot read
• Plan for participants who are not English speakers
• Plan for participants who may have additional needs to comprehend consent language

ACTIVITY

Practicing Informed Consent Process

[10-15 minutes]

WHO CAN GIVE CONSENT?

• In Pennsylvania:
  • For minors (age 17 or younger), parent or legal guardian
  • For adults (18 or older) can consent for themselves, unless mentally unable, then “proxy” consent used

• EXAMPLES
  • Teenage mother can consent for her child but not herself
  • If IRB waives parent consent, minor can assent to participation
  • Parental consent with minor “assent”

• Discussion of Scenarios
PRIVACY

• All personal information remains confidential (private)
  • Behaviors
  • Lab tests
  • Questionnaire results
  • Age, phone numbers, etc

PROTECT FROM HARM

• Telling people about all possible risks
  • Do not enroll people that are likely to be harmed
  • For many studies, not observing privacy is the biggest harm

RISKS AND BENEFITS

• Vary greatly by research project!
  • RISKS:
    • Results from study surveys/questionnaires
    • Breach of confidentiality
    • Others?
  • BENEFITS:
    • Gain in knowledge
    • May not be immediate
    • Does not include compensation
    • Others?
COERCION & SETTING OF RESEARCH STUDY

• Perception that a potential participant MUST consent and participate in the research study

• EXAMPLES:
  • Church with religious services
  • Clinic with medical services
  • Schools with after school programs
  • Senior communities with recreation

CHOOSING PARTICIPANTS

• Fair process
• Include all who may benefit from research
• Be careful with vulnerable populations
  • Pregnant women, fetuses, neonates/newborns
  • Children
  • Prisoners
  • Mentally impaired

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
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

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/