

# Responsible Conduct of Research with Individuals with Developmental Disabilities: Strategies for Ethically Strong Research and IRB Approval



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# Responsible Conduct of Research

- Scientific Integrity: The awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research
- *What does scientific integrity look like when disability justice is centered?*
  - *More equally shared and more democratic*
  - *More inclusive of people with developmental disabilities across different stages of the research*

# Democratizing Science

- People with developmental disabilities experience significant **disparities**
- **New knowledge** is needed for social and health equity
- Ethical and social dynamics contribute to people with developmental disabilities being **understudied**, at risk for **inappropriate inclusion**, and a **mismatch of priorities** in science
- Emphasis on **direct representation** in research and broader **influence over science**

# This webinar will address:

- Infusing disability justice into the responsible conduct of research with a focus on people with developmental disabilities
  - Inclusion as research participants
  - Inclusion as co-researchers
- Discussion
  - Reflecting on the ethical issues of community-based Participatory Action Research

# Historical Context of Human Experimentation

- Many examples of exploitation in the name of science
- “Participants” belonging to marginalized groups (decreased social value)
- “Participants” embedded in coercive contexts
- “Participants” with limited capacity to understand information and act upon a decision
- Convenience samples
- Deception
- Little to no prospect of personal or social benefit

# Legacies of Exploitation

- Regulation of human experimentation
- Community views on science/research

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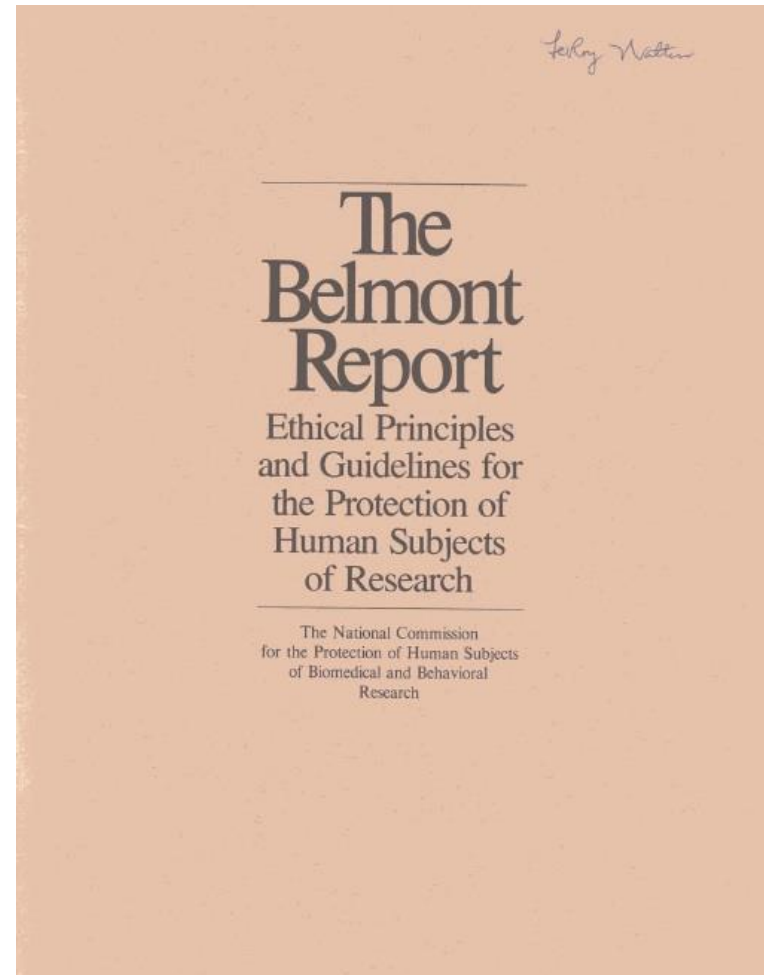


# Correcting the Problem: Regulations and Guidance

- International
  - The Nuremberg Code (1949)
  - The Declaration of Helsinki (1964)
- US
  - The Belmont Report (1979)
  - The Common Rule (1991; revised 2018)
    - Institutional Review Boards (IRB)
  - *Research Involving Individuals with Questionable Capacity to Consent: Points to Consider* (National Institutes of Health, 2009)
  - Institutional policies (“mental disorders”, “mental disabilities”, “cognitive impairment”, “questionable capacity”)

# The Belmont Report (1979)

- Ethical principles to guide human research
  - Respect for Persons
  - Beneficence
  - Justice





# Common Rule (45 CFR 46)

- Codified the Belmont Principles
- Applies to federally funded research (many institutions apply to all research)
- Special provisions for research involving:
  - Neonates, fetuses and pregnant women (Subpart B)
  - Prisoners (Subpart C)
  - Children (Subpart D)

# Institutional Review Boards (IRB)

- Scientists, non-scientists, non-institutional affiliates, and, if applicable, a prisoner representative who **independently review research** to ensure that researchers **safeguard the rights and welfare of individuals participating in research**

# IRB Review

- **Exemption:** Normal educational practices, surveys, interviews, public observations, extant data, public benefits/services, public officials
- **Expedited:** No more than minimal risk; clinical studies, some blood samples, noninvasive biological specimens, routine clinical practice, data collected for non-research purposes, recorded data, surveys, interviews, oral histories, program evaluation; minor changes to approved protocols
- **Full:** Greater than minimal risk; classified populations
- **Continuing Review:** minimally annual review for greater than minimal risk studies (primarily)

# Minimal Risk

- The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

# Including People with Developmental Disabilities as Research Respondents

- Include!
- Assume competence
- Build in flexible accommodations and supports
- Approach consent and assent as a dynamic process
  - Emphasize agency, self-determination
  - Facilitate understanding
    - Use multiple modalities for communicating information
    - Concretely illustrate and demonstrate research procedures



### Project ETHICS Survey Consent and Assent Form

If you are the legally authorized representative for a person who may take part in this study, permission from you is required and the assent (agreement) of your relative or ward is required. When the word "you" appears in this consent form, it refers to the person for whom you are the legally authorized representative.

You are invited to be in a **research study about adults with an intellectual disability being in research.**

Katherine (Katie) McDonald, PhD, at Syracuse University is in charge of this study.



You are being asked to take the survey because **you have important experiences.** We hope to have 500 people take the survey.

This form has **information about being** in this study.



It is **up to you** to decide whether you want to be in this research study.

This project is funded by a grant from the National Institute of Child Health and Human Development, a part of the National Institutes of Health (NIH).

#### What is the study for?



To learn what **you think** about topics such as:

- How important it is that different things happen when adults with an intellectual disability are in research studies.
- How safe adults with an intellectual disability are when people who do research do certain things.



We also want to learn about your experiences being in research studies and some of your personal information, like your gender and age.



We hope to learn about what different people think about these topics.

This form has been approved by Syracuse University:

# Including People with Developmental Disabilities as Respondents

- Maximize benefits
- Direct (personal)
  - Insight into self, learning
  - Treatment, interventions
  - Meet new people
  - Satisfaction with contribution to science
  - *Compensation/Incentives are NOT a benefit*
- Indirect (societal)
  - Scientific knowledge that will benefit others
  - Knowledge translation

# Risks

- Risks are varied (physical, psychological, social, legal, economic)
- Who is vulnerable and what are they vulnerable to?
  - How are risks experienced by people with developmental disabilities?
  - Consider the risks of proxy report and exclusion from research



# Protections

- Investigator training
  - Knowledge of disability justice, familiarity with people with developmental disabilities
- Supported decision-making
- Upholding confidentiality, avoiding undue influence
- *Are the protections responsive to the risks? Are the protections consistent with disability justice? Are the protections perceived as safe by people with developmental disabilities?*

# IRB Review – Tips for Success

- Do not use labels or diagnoses to automatically preclude research participation
- Consider and discuss the importance of including people with developmental disabilities in research
  - Agency, capacity, direct and indirect benefits, respect
- IRB as a floor, not a ceiling
- Interactive review – talk with IRB administrator/chair/member
- Obtain research materials and IRB applications from others
- *Involve people with developmental disabilities in designing and carrying research ...*

# To Consider: Not Everyone Speaks – Communication Recommendations

- Everybody communicates and has an opinion about his or her life – find out how
- It is possible to learn from people who communicate in alternative ways
- Always assume intelligence.
- Adopt an attitude of high expectations and the belief that everyone communicates, and a person's style of communication can be identified and understood.
- If gathering information primarily from staff, talk with the staff who knows them the best. Talk to multiple staff to validate.
- Preparation for communication

# A useful communication tool- AAC Vocabulary Aids

Available in English, Spanish, and Haitian Creole

- <http://disabilities.temple.edu/aacvocabulary/e4all.shtml>

- Example:

- <http://disabilities.temple.edu/aacvocabulary/e4all/EprepPictureAid.pdf>

**Emergency Communication 4 ALL ..... Picture Communication Aid**

FREE SPACE (for your custom message)

I can't speak but I can hear and understand you.

My technology needs to be charged.

My vital information is on the back on this page.


Please contact my family.

Ask me questions if you need to, but please wait patiently for my replies.

I will point to where I hurt. →

MY NAME IS	I, me, my	Bleed	Infect	Allergy	Disability	Help	Bathroom
WHO	You, yours	Broken	Need/Want	Blanket	Disaster	Home	Walker
WHERE	She, her, hers	Burn	Rescue	Clothes	Emergency	Hospital	Wheelchair
WHAT	He, his, him	Choke	Spell	Cold	Family	Sick	Wind
WHEN	They, them, their	Communicate	Talk	Damage	Fire	Pets	Worried
WHY	Us, ours	Evacuate	Understand	Danger	Flood	Shelter	Worst/Worse
HOW	YES	Hurt/Injure	Wait	Communication Device	Heat/Hot	Seizure	NO

0 1 2 3 4  
5 6 7 8 9  
A B C D E  
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The Picture Communication Symbols  
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# PAR Background and Methods

- People with developmental disabilities often have **little influence over research**
  - Research may **not be grounded in disability rights principles** nor address their **priorities**
- **Community-Based Participatory Research**
  - Response to issues faced by marginalized communities
  - Puts community representatives as full members of research team
  - Involves equitable exchange of power and expertise
  - Can be used with any research methodology
  - Can lead to better science, community capacitation, empowerment, improved knowledge translation
    - Can we do it? How do we do it? Are benefits achieved?



# PAR Principle #1

## **Builds on strengths and resources within the community**

- Advisory Board/Community Planning Committee members include youth with disabilities, parents and family members, community members, professionals
- Focus groups with key stakeholders
  - Alternatives to focus groups
- Feedback from stakeholders before new phase



# PAR Principle #2

**Facilitates collaborative partnerships in all phases of the research**

- PYLN
- George Washington University
- Pattan
- National Council on Disability
- GW Law Students
- Quality Trust
- Racial Empowerment Collaborative



# PAR Principle #3

## **Integrates knowledge and action for mutual benefit of all partners**

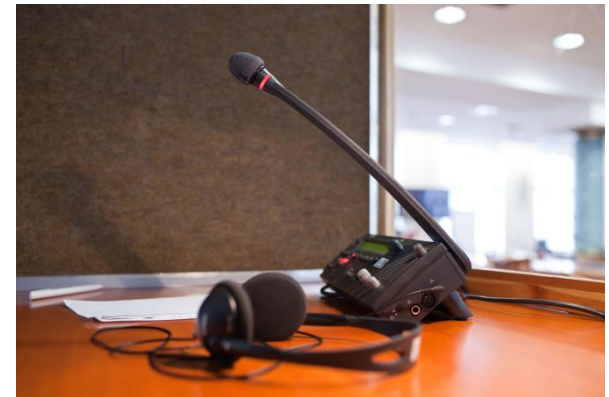
- Inclusion in all phases of research
  - Grant proposal/development of project goals
  - Research protocol development
    - Focus group procedures and questions
    - Target audiences and comfortable locations
  - Ideas about incentives
  - Marketing and dissemination
  - Data gathering
  - Data analysis
  - Project reports



# PAR Principle #4

## Promotes a co-learning and empowering process that attends to social inequalities

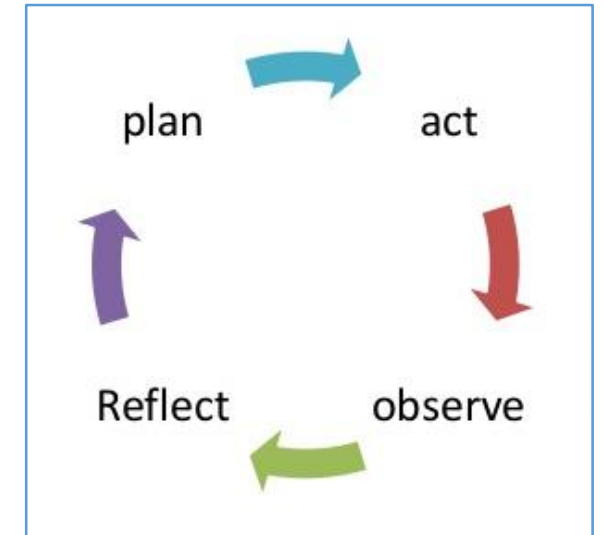
- We as researchers learn from the knowledge and theories of the community members involved
- Community members acquire further skills in how to conduct research
- Finding accessible locations, limitations to those
- We are all learning about how social inequality gets upheld through research
- Simultaneous translation of focus group to promote linguistic competency of project and highlight how other projects/institutions may not be addressing same need



# PAR Principle #5

## Involves a cyclical and iterative process

- Projects support growth and development of community (PYLN, School, Law Students)
- Maintaining grounded theory approach
- Conducting validation workshops/member checks
  - Sharing relevant data
  - Conducting interviews
- Utilizing advisory committees and community members to analyze thematic data in order to then (re)create next round of themes to explore
- Translational = working with/disseminating info to systems in real time



# PAR Principle #6

## Disseminates findings and knowledge gained to all partners

- Project reports at various types of outlets/by various stakeholders
  - DD council reports
  - State meetings
  - AUCD
  - AAIDD
  - PA Transition Conference
  - State legislative expo
  - GW Transition program coursework
  - PYLN youth leadership events



# Case Study of Responsible and Inclusive Research



# Guiding Questions for Reflection and Discussion

Working through some of the ethical issues in community-based participatory research.

# Guideline One:

Who or what are we trying to *understand*?

- Question:

Are our inclusive research efforts focused on fixing marginalized people or on fixing the **inequitable conditions and structures that marginalize people**?

## Guideline Two:

### Does our work mitigate or transform?

- Question:

Are our inclusive research efforts a **threat to the existence of injustice** or do they merely mitigate the symptoms of injustice?

## Guideline Three:

### Are we dancing around or digging in?

- Are our inclusive research efforts **contributing to the *permanent* redistribution of access and opportunity** or leaving the current distribution in place and helping marginalized people be more comfortable as *marginalized* people?



# Guideline Four: Who are the experts?

- Are our inclusive research efforts based in collaborations with marginalized people deferring to their expertise? Are we working “on” marginalized people or “**with**” marginalized people?

(adapted from Gorski, et.al, GMU)

# Thank you for participating in today's webinar!

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# References and Resources

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