ADULTS WITH INTELLECTUAL AND/OR DEVELOPMENTAL DISABILITIES (IDD) AND RESEARCH

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DISCLAIMER

The content of this presentation is from the PRIM&R Conference that I have attended in Seattle, WA (November 17-20, 2024). A written permission from the presenters has been sought for purposes of sharing this training session to the committee during education/training portion of the IRB Meeting.

BACKGROUND INFORMATION

- In 2020, there are about 8.38 million people in the U.S. had an intellectual and/or developmental disability (IDD). Of these 20% of children and 44% of adults were known to their state developmental disabilities agency
- Inclusive engagement of IDD is important as team members and/or as research participants to improve health and well-being outcomes
- People with IDD experience increased risk of morbidity and early mortality, disparities in healthcare access and quality, and are systematically excluded from research
  - ➢74.6% NIH funded directly and/or indirectly excluded adults with IDD

WHAT IS COMMUNITY-ENGAGED RESEARCH?

…"the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people"…

Source: Centers for Disease Control and Prevention [CDC], 1997, p 9, as cited by Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry (2011). Principles of Community Engagement, 2nd Edition. NIH Publication No. 11-7782. Washington, DC, http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf, (p. 3)

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)

- An independent, nonprofit research funding organization that seeks to empower patients and others with actionable information about their health and healthcare choices.

- The leading funder of patient-centered comparative clinical effectiveness research in the United States.

A Holistic Approach – National Priorities for Health

Engagement

Patient-Centered CER

Infrastructure

Dissemination & Implementation

EXCLUSION FROM PARTICIPATION IN CLINICAL RESEARCH

People with IDD are routinely excluded from participation in clinical research

The research community, including investigators, sponsors and institutional review boards (IRBs), incline towards exclusion to minimize risk for both participants and investigators

This approach emerged in response to a long history of exploitation and abuse of vulnerable populations

Such protectionism can deprive people with disabilities of access to research (including important benefits), contribute to denial of individual autonomy, compromise the generalizability of research, and is a form of discrimination

EXCLUSION FROM PARTICIPATION AS COMMUNITY RESEARCHERS

People with IDD are routinely excluded from participation as community research partners

Barriers to participation may be based on implicit or explicit bias and/or a misunderstanding and unfamiliarity with the cognitive capacity of people with IDD

A failure to provide necessary accommodations, such as modified and accessible human subjects research training, further limits participation

Such exclusion, even if in the name of protectionism, inappropriately deprives people with IDD the opportunity to contribute to research, compromises the integrity of the research, violates disability rights principles ("Nothing about us without us") and laws, and is a form of discrimination

WHAT SHOULD HRPPS/IRBS DO INSTEAD?

People with IDD	• Have the right to equal access and opportunity to consider participation in clinical research as a research participant or as a community researcher
People with IDD	• Have the right to receive reasonable accommodation, such as supported decision-making to assist them with making decisions about and during research participation
IRB	• Should require written justification for disability-related exclusionary criteria and should develop policies and standards for their review
HRPPs/IRBs	• Should require provision of necessary accommodations for research participants and community researchers (e.g., accessible human subjects research training and supported decision-making arrangements)

7 RECOMMENDATIONS TO INCREASE RESEARCH ACCESSIBILITY FOR PEOPLE WITH IDD

Increase the Knowledge Gap

Build Community Partnership

Use Plain Language

Practice Accessible Dissemination

Establish Research Capacity to Consent

Offer Universal Support & Adaptations

Simplify Consent & Assent Process

PATIENT/COMMUNITY ENGAGEMENT EXAMPLES

- Count me In
- PXE International
- Cancer Moonshot

RESOURCES TO EDUCATE RESEARCHERS & THE COMMUNITY PARTNERS WITH IDD

- READI (Research Engagement and Advocacy for Diverse Individuals)
- RE4ALL (Research Ethics for All)
- Just Research - (short video)

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HELPFUL LINKS

- Eligibility Criteria in NIH-funded Clinical Trials: Can Adults with Intellectual Disability get in?
- Guide to Disability Rights Laws
- People with IDD in the United States
- Patient-Centered Outcomes Research Institute (PCORI)
- RE4ALL (Research for All)
- Cancer Moonshot
- Supported-Decision Making in GA - idecidega.org
- National Resource Center for Supported Decision-Making - supporteddecisionmaking.org