



Addressing Implicit Bias in Human Subject Protection

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Why Address Implicit Bias in Clinical Research

Contributes to under-
representation

Inclusion in research
matters

Examples:
Psychiatric disorders

Generalizability

Justice

Implications for
including older adults

Implicit Bias: “A form of bias that occurs automatically and unintentionally, that nevertheless affects judgments, decisions, and behaviors...” [1]

Benevolent Prejudice: “A superficially positive type of prejudice ... expressed in terms of positive beliefs and emotional responses, which results in keeping the group members experiencing prejudice in inferior positions in society...” [1]

Care/Concern  Need more protection
Need more support or are less reliable

Human Subject Protections



STUDY DESIGN



REVIEW



CONDUCT OF
RESEARCH

Implicit Bias and Psychiatric Disorders

- Under-represented in clinical research
 - Medical conditions [2]
 - Psychiatric conditions [3,4]
- Biases/Assumptions
 - Benevolent Prejudice



Example 1: Research Risks



- Excessively risky [5-8]
- Depression and suicide risk [9-13]
- Response [11, 14)
 - Identify and address risks [15]
 - Mitigate and manage risks [16-19]
 - Justify risks in light of potential benefits

Example 2: Decision- making Capacity



- Unable to understand information and give valid informed consent [5,6, 20- 21]
- Response
 - Assess, don't assume [20,22-23]
 - Foster capacity using evidence-based methods [20-21]

Example 3: Anticipated Population “Challenges”



- Anticipated Poor Adherence
- Anticipated burden, e.g., require additional resources to include [18, 24]
- Response
 - Evidence of adherence [19,25]
 - Evidence-based tools to foster adherence [26]
 - Too bad!
 - Requirements for the ethical conduct of research include value and validity (generalizability)

Improving Inclusion Requires...

Identifying Barriers

What is the bias, problem, concern, or objection?

Implementing Evidence-based Informed Consent Practices to Address the Risk of Alzheimer's Dementia and Cognitive Impairment in Clinical Trials (DuBois - Washington University)

Overcoming Barriers

Based on fact?

- Can the concern be mitigated? How?

Based on bias or unjustified assumption?

- Address or correct with evidence?

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