

Illuminating Theology With Psychological Science

Introduction to Ethics in Research with Human Subjects





Ethical Principles in Human Subjects Research

- Beneficence
 - Protect participants from harm
 - Weigh risks against benefits
- Justice
 - Who is benefitting from the research?
 - Who is bearing the costs of the research?
- Respect for persons' rights and dignity
 - Informed consent
 - Vulnerable populations
- Acting with integrity and responsibility
 - Do not make up data!



Practical Considerations in Research

- Institutional Review Board (IRB) approval
- Ethics training
 - CITI Program
- Informed consent process



Working with Vulnerable Populations

What do we mean by “vulnerable”?

- Main elements of the Common Rule
 - Requirements for assuring compliance by research institutions
 - Requirements for researchers' obtaining and documenting informed consent
 - Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.
- The Common Rule includes additional **protections for certain vulnerable research subjects**:
 - Subpart B provides additional protections for pregnant women, neonates, fetuses
 - Subpart C contains additional protections for prisoners
 - Subpart D does the same for children.



Working with Vulnerable Populations

What *else* do we mean by “vulnerable”?

- Other “vulnerable” populations
 - What makes them vulnerable?
 - Categories vs. context
- Goal is always to minimize risk
 - Does this population need to be included?
 - Are our safeguards adequate?
 - What questions are appropriate?
 - Providing additional resources / waivers



Case Study: Building an App for Character Development in Muslim American Adolescents

Testing the Efficacy of the CharacterMe Smartphone App to Build Patience and Self-control

- Expand the app that previously developed to testing with Muslim-American youth.
- Maintain the moral vs. spiritual vs. instrumental framing of exercises in the app.
 - Tailor the framing of spiritual to Islam specifically.
- Study Design
 - Pre-test, 2 weeks app use, Post-test, 3 month follow up, 6 month follow up
 - Analyze the surveys as well as app use
 - Includes experience sample of emotions as well as engagement with various self-control (avoid certain words) or patience task around solving interpersonal conflicts (practicing perspective taking, reappraisal, emotional awareness – selfie)
 - Outcomes – patience, self-control, generosity, mental illness symptoms, adolescent risk behaviors (drug use, sexual behaviors, delinquency)
 - Get parent and peer reports of character strengths as well



Case Study: Building an App for Character Development in Muslim American Adolescents

Vulnerabilities

- What are the official vulnerabilities?
 - Common Rule subpart D - children



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Vulnerabilities

- What are other potential vulnerabilities and risks?
 - Religious and ethnic minority
 - Data security/confidentiality risks
 - Courts can subpoena data (NIH certificate of confidentiality)
 - Department of Homeland Security may also try to get it/surveillance
 - Even when “deidentified” demographics/ip addresses make identifiable
 - Findings could exacerbate stereotypes of Muslims
 - Sensitive information from self and informant reports on adolescents
 - Some information relates to illegal behaviors (drugs) or highly stigmatized behaviors (sex). Parents may want the information and pressure youth to disclose. (and again could be disclosed in court).
 - Youth may be self-conscious of others rating them on domains.
 - Disclosure of risk
 - abuse or religious trauma in reappraisals
 - extremely high levels of anxiety/depression – don’t include suicide risk
 - uploading of pornographic photos of minors



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Steps to Minimize and Mitigate Risks

- Don't collect sensitive info unless is the core (e.g., eliminate risk behavior measure)
- Don't give informants all measures
- Security/confidentiality
 - NIH certificate of confidentiality
 - Don't record/collect certain information (e.g., don't record IP addresses, don't save photos unless going to use)
- Response plan in place for descriptions of abuse or psychiatric distress