

# Illuminating Theology With Psychological Science

## Introduction to Ethics in Research with Human Subjects



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# 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



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## **Vulnerabilities**

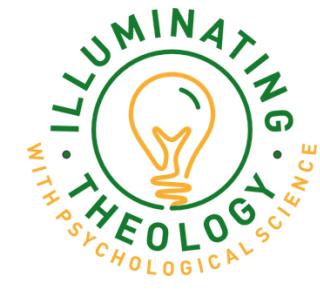
- What are the official vulnerabilities?
  - Common Rule subpart D - children



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

## 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