



VA
HEALTH
CARE

Defining
EXCELLENCE
in the 21st Century

Navigating IRBs as a Suicide Researcher

Peter M. Gutierrez, Ph.D.

VISN 19 MIRECC

American Association of Suicidology
Annual Conference, April 19, 2012



Be Prepared

- Start with all up-to-date required forms
- Ask to see colleagues' applications as examples
- Develop and consistently use standard language
- When in doubt, ask questions before you submit
- A well planned study is priceless

It's Impossible to be too Thorough

- Anticipate likely concerns and address proactively
- Draw on expertise of lab to cite tried and true procedures
- A well articulated safety plan is invaluable
 - Critical items
 - Follow-up procedures
 - Participant resources
 - DSMB/Medical Monitor

Get to Know your IRB

- Meet with chair or panel chair in advance of application review
- Volunteer to serve on the IRB
- Take advantage of your mentor's record

TYPES OF STUDIES AND ASSOCIATED RISKS

Observational

- Web surveys
- Cross sectional in-person
 - Self-report measures
 - Interviews
- Individual vs. group administration

Asking People About Suicide Will Make them Suicidal, Right?

- NO!
- Gould et al. (2005). Evaluating Iatrogenic Risk of Youth Suicide Screening Programs: A Randomized Controlled Trial. *JAMA*, 293, 1635-1643.
 - No differences in distress level or depressive feelings post-screening or 2 days later
 - No differences in report of ideation post-screening
 - High-risk students less distressed and suicidal post-screening

Quasi Experimental

- Baseline assessment
- Exposure to an intervention (e.g., school-based suicide prevention program)
- Follow-up assessment

Randomized Controlled Trial

- Active treatment group
 - Therapeutic intervention
 - Medication
 - Prevention program
- Control group
 - No treatment
 - Waitlist
 - Alternative treatment (TAU, Enhanced-TAU)
 - Sham treatment

RCT Tracking

- How frequently to assess
- What do you do with assessment data?
- Clinical vs. research obligations to participants
- Adverse events
 - Anticipated
 - Unanticipated
- Stopping rules

Non-Human Subjects

- No, I don't mean animal models
- Secondary analyses of national data sets
 - National Violent Death Reporting System
 - National Death Index
 - VA databases

SECURING YOUR DATA

Good Data Management

- Separate master ID list from participant identifiers
- Store signed consent and HIPAA forms in separate locked locations
- Don't take raw data out of the lab

Create De-Identified Data Set

- Can't contain any of the following
 - Names or initials, geographic subdivisions smaller than state, dates except for year and ages over 89, phone/fax numbers, e-mail addresses, SSNs, medical record numbers, health plan beneficiary numbers, account numbers, certificate or license numbers, vehicle identifiers and serial numbers (including license plate), device identifiers and serial numbers, URLs, IP addresses, biometric identifiers, full-face or comparable photographic images, any other unique identifier

Dealing with Challenges

- Requested revisions
- Questions of clarification
- Non-approved application
- Coming before the IRB
- Reporting adverse events
- Discovering mistakes during publication process

Is it All Worth It?

- YES!
- Now is a great time to be a suicide researcher
 - Military Suicide Research Consortium dissertation completion award
 - 2013 MSRC Pre-Conference Institute
 - www.msrc.fsu.edu

Thanks for Your Attention

Questions

Contact



peter.gutierrez@va.gov