Special Populations and the Consent Process: Disaster & Traumatic Stress Research

Roxane Cohen Silver, Ph.D.
Professor
Department of Psychology and Social Behavior
Department of Medicine
Program in Public Health
University of California, Irvine

Workshop on Proposed Revisions to the Common Rule in Relation to
The Behavioral and Social Sciences
Washington, DC
March 21, 2013

Characteristics of Traumatic Life Events

- Random
- Unpredictable
- Uncontrollable
- When a community-based event (e.g., natural disaster): shared experience among many victims

What is the Value of Early Research?

- Immediate data is necessary to identify early predictors of long-term difficulties
- Early identification of at-risk individuals enables mental health professionals to target interventions to those most vulnerable
- Educational and intervention efforts can be better informed, more sensitive and more cost-effective
- Causal paths and patterns of adjustment over time can only be investigated with longitudinal research

Why Do We Need Early Research?

- People's memories of their behaviors and feelings in the aftermath of a trauma are very poor, and are highly distorted by their feelings when you ask them to recollect their experiences
- It is a myth to assume that people can accurately reconstruct emotional experiences long after an event – indeed, one should assume that retrospective reports will be predictably biased and therefore suspect

"Delay in initiating data collection limits opportunities to obtain early information needed to understand mental health effects of disasters. If researchers cannot act quickly, important data may be lost forever."

(North & Pfefferbaum, *JAMA*, 2002, p. 634)

Challenging Ethical Issues in Trauma/Disaster Research

- Is it ethical to conduct research immediately after a tragedy – can/should we intrude on individuals during a potentially vulnerable period?
- Can individuals provide informed consent during the throes of a life crisis?
- Must participants provide written consent (especially if research seeks to obtain representative population-based samples)

Requirements for Solving Ethical Issues in Trauma/Disaster Research

- The willingness of Institutional Research Boards to trust that such research *should* be done and can be done well
- Confidence in the researcher to treat respondents fairly, sensitively, and with appropriate attention to ethical concerns

Requirements for Ensuring Ethical Sensitivity in Research

- Non-coercive subject recruitment
- Provide multiple opportunities for refusal (of initial contact, of consenting, of responding to specific questions, of ongoing data collection)
- Development of data collection instrument and methods in collaboration with trauma victims
- Well-trained interviewers

Program of Survey Research on Acute Responses to Stressful Life Events

Death of an Infant
1-2 weeks post loss
(followed for 18 mos.)

Southern CA Firestorms
36 hours post evacuation
(followed for 2 years)

Columbine High School Shootings
5 days post attack

Terrorist Attacks of September 11, 2001
9-14 days (followed for 3 years)

Minimal risk; IRB reviews: Expedited or Exempt

The Result

- >75% participation rate typical
- Usually maintain approximately 80% of sample at each wave of data collection
- “Boy, you really did your homework – your questions captured my feelings and experiences perfectly”
- “Thanks for listening – most of my friends can’t handle it”

Example: National Study of 9/11 Terrorist Attacks

- Collaboration with Knowledge Networks, Inc. (ensured that all data were de-identified; 3rd party survey research firm retains identification for longitudinal data collection; subsequent biospecimen data collection (saliva) 2 years after Wave 7)
- Waiver of written informed consent to protect identity of participants; online data collection that provides:
  - Contact information for questions/concerns
  - Reminder that participants may skip questions or terminate survey at any time without penalty (e.g., questions about trauma history)
  - Non-coercive methods (no pressure to complete any question)
- Clicking on link implies consent to participate

Example: National Study of 9/11 Terrorist Attacks

- 7 waves of data collection (10,200+ survey completions) among a nationally representative online panel
- No complaints about procedures, survey questions, etc. (despite multiple opportunities to report concerns and reminders at every contact)
- Dropout low over time (re-interviewed 79% of Wave 1 sample at Wave 7, 3 years post 9/11)

How can this research be Facilitated by the IRB?

- Willingness to approve research very quickly
- Pre-approval of a generic proposal that can be activated after a disaster
- Willingness to issue waiver of written consent

“Generic” Disaster/Trauma Protocol

- Background and rationale
- Proposed methods
- Proposed Risks/Benefits
- Research Team
- Sample questionnaire/interview questions

UC Irvine's IRB "contract"

IRB will review and approve the specific project within 24-48 hrs of submission, once provided with:

- Specific purpose / event to be studied
- Specific research methodology
- Specific sample and sample size
- Any changes to research team, methods, compensation, etc.

Proposed Hurricane Project ("At risk" Communities)

- Goal to link pre- and during-storm emotions, risk assessments, and behaviors to post-storm adjustment
- Identify participants 36-48 hours in advance of hurricane landfall
- Recruitment orally as storm approaches
- Internet-enabled tablets distributed for data collection pre-, during, post-storm (GPS ensures accurate monitoring of evacuation behavior)
- Speed essential (750 subjects to be recruited within 18 hours; requesting waiver of written consent)
- Flexibility of methods essential to protect both participants and research personnel

The Need for Post-disaster Intervention Research

"Given the devastation caused by disasters and mass violence, it is critical that intervention policy be based upon the most updated research findings.

However, to date, no evidence-based consensus has been reached supporting a clear set of recommendations for intervention during the immediate and the mid-term post mass trauma phases (i.e. ranging from the immediate hours to several months after disaster or attack)."

(Hobfoll et al., *Psychiatry*, 2007)

The Need for Post-disaster Intervention Research

"It should be clear that any interventions must be accountable and that their outcomes must be systematically evaluated in the shorter and in the longer term. *Thus, the requirement should be in place and a culture developed* to evaluate all acute post trauma interventions and their effectiveness or otherwise."

(Raphael & Dobson, 2001, p. 155)

How can IRB's facilitate Intervention Research

- Rapid review of IRB protocols
- Allow recruitment and data collection after a natural or man-made disaster
- Willingness to allow random assignment of subjects to conditions (e.g., intervention and waiting list or no-treatment control group)
- Allow flexible informed consent procedures? (i.e., How much does a potential research participant need to be told about the alternative conditions?; Waiver of written consent?)

Example: Post-earthquake in Yogyakarta, Indonesia

- IRB Review: Full Committee
- Recruitment of families via 6 elementary schools (parents consented for self and child; child must assent)
- Received waiver of written informed consent as a result of cultural norms (individuals unwilling to sign their names to documents)
  - Study explained orally
  - Research assistants available to answer questions
  - Participants reminded that they may skip questions or terminate participation at any time without penalty
  - Non-coercive methods (no pressure to complete any question)
- Remaining in the room implied consent to participate; surveys distributed

Example: Post-earthquake in Yogyakarta, Indonesia

- Completion of surveys by parents and children pre-intervention
- Biospecimen data collection (saliva) for future cortisol and genetic analysis
- Randomization (by school) of families to skills-based psychosocial intervention or waiting list control group
- Post-intervention completion of surveys by parents and children
- Intervention subsequently delivered to wait list control group