



A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF CRISIS RESEARCH

CRITICAL INCIDENT STRESS DEBRIEFING (CISD) AND INCIDENCE OF PTSD IN FIREFIGHTERS

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OVERVIEW

The social, behavioral, and educational research (SBER) case studies provide education and guidance on how to identify and mitigate risks associated with SBER. These studies may be used by both IRB administrators and investigators when reviewing and designing research studies that involved SBER components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) regulatory, cultural, and ethical issues, and 3) a risk/benefit analysis and risk management options. This format was created to allow for flexibility in applying the case studies.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining risk mitigation options, the case studies can be used in a variety of ways, which include: 1) as an education tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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CASE STUDY

SCENARIO/FACT PATTERN:

A researcher is given a grant by the Department of Defense (DoD) to identify risk factors related to developing and coping with post-traumatic stress disorder (PTSD) in firefighters following critical incidents (CI). The research will also assess the relationship between PTSD and a widely used, group-based management approach to CI stress debriefing (CISD). CISD allows a group that is having difficulty coping or functioning after a CI to share their experiences, learn coping strategies, and identify those who may benefit from further assistance.

The researcher proposes a controlled study to (1) assess whether or not CISD is helpful or harmful in CI-related stress management among firefighters, (2) assess the effects of CISD on short and long-term psychological well-being, and (3) identify who may benefit from more intensive support and intervention.

The research will consist of phone and internet-based screenings and data gathered from firefighters before and after a CI. The researchers have defined characteristics of a qualifying CI, and selected Chicago, San Francisco, Denver, Dallas, and Boston as research sites. Six fire departments will be followed in each city (three with CISD programs, and three without). To identify when a qualifying CI has occurred, researchers will monitor the FEMA website and subscribe to text warning system for the selected cities.

The PI will contact fire department chiefs as well as each city's fire superintendent for permission to recruit. Flyers posted in fire departments, bulk email, and a letter sent by US mail will be used to aid recruitment.

The informed consent process will be conducted by phone prior to asking any research questions. Consent forms will be mailed or emailed in advance. Specially trained research assistants or behavioral health clinicians will summarize the consent form section by section and ask for verbal consent. The process will include a clear disclosure of the type of questions that will be asked.

The research will exclude people who have a high risk for serious and persistent mental illness such as those with diagnosed psychosis, bipolar disorder, major depressive disorder, etc., or those who indicate intent to harm themselves or others.

Participants will be screened by phone. The phone screening will use standard psychological scales to screen for depression, psychosis, mental capacity, acute stress disorder, and PTSD. The screening will also capture subjects' gender and age, and will include questions about prior experiences with CIs, their estimation of how well they coped with prior CIs, and whether or not they received additional assistance (medication, cognitive behavioral therapy, or group support). A follow-up Internet-based questionnaire will be used as well as an online system that repeats some of the psychological scales used at enrollment, and provides a venue for journaling. Following a qualifying CI (a large-scale incident), the researchers will repeat the scales at 90 days, 120 days, and one year.

The PI will also receive anonymous health insurance claim data on medications and behavioral health interventions such as cognitive behavioral therapy or counseling. These data will be grouped by fire department, age, and gender.

There may be no direct benefits to participants. This study will collect data that may be beneficial in determining the effect of CISD on the incidence of PTSD in firefighters following a CI, and may aid in the development of new programs to assist firefighters and other emergency responders.

CRITICAL INCIDENT STRESS DEBRIEFING (CISD) AND INCIDENCE OF PTSD IN FIREFIGHTERS- DISCUSSION

DISCUSSION

Questions/Comments for the researcher:

- Does the capacity for consent change over time? Following a CI? How will you assess this?
- Can the study design, or other procedures, help assure that mental status does not affect a subject's cognitive capacity to consent?
- Is there a risk that participation could affect the participant's quality of life, employability, or standing in the community?
- How can study design lower risk to subjects?
- Will a participant's lack of response to follow-up constitute full withdrawal from the study?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

- **Timeliness:** The specifics of the crisis are unknown. Once an event has met the CI criteria, the PI will need to submit a protocol amendment and the IRB(s) must be able to make a timely review.
- **IRB Review:** It is impossible to foresee a CI and therefore to know which institutions might have researchers involved in the research; there may be multiple institutions (multiple IRBs) on short timetables for review and/or multiple jurisdictions involved in CIs. How will IRB reviews be determined and made prospectively?
- **Meaningful Consent/Capacity for Consent:** Participant consent must be considered throughout the research as capacity to consent may change over time. Is informed consent possible in a disaster zone or following a critical incident? Could changing mental status affect legally authorized consent in such a way that a surrogate legally authorized representation might need to consent?
- **Safety and Monitoring:** Additional protections may be required for this type of behavioral research in a community setting.
- **Level of Risk:** Multiple IRBs must identify benchmarks and use appropriate and equivalent standards for risk assessment and mitigation.
- **Cultural Context, Feasibility, and Ethics:** Stigma may be associated with study participation. Could stigma affect a firefighter's future performance in the team?
- **Applicable Regulations:** This is a complex study occurring in different states; thus, applicable regulations must be determined.

Questions for the IRB:

- Are disaster-affected populations necessarily "vulnerable populations?"
- How do you assess the level of risk in this type of mental health research?
- What standards or benchmarks are there for making risk assessments?
- What are the procedural risks of this study?
- Are there specific study design components that can harm participants?
- If findings indicate large-scale mental illness in first responders how might this affect departments and public confidence in first responders?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

- The questions regarding activities of daily life, feelings, and emotions pose minimal risk. While the psychological scale includes sensitive questions, the privacy protections are adequate to reduce the risks to minimal. All screening tools are validated psychological scales used in routine psychological exams.
- Since the CISD would be performed as usual and as per normal procedures, the CISD risks will not be factored into the risk assessment.
- Since the population of interest is actively working first responders, this suggests a level of cognitive capacity and functionality; the risk of including persons with a diminished capacity is low.

Note: DoD regulations stipulate active service persons cannot be involved in research that is greater than minimal risk without a prospect of direct benefit.

Mitigation/Management of Risks:

- IRBs and PI should consult local fire department chiefs and a local FEMA representative when developing the project and/or reviewing/assessing risk.
- Consider working with known and respected associations (unions, professional organizations, etc.) to support outreach and recruitment; this may minimize stigma or perceived stigma associated with participation.
- Train community consultants (firefighters and FEMA administrators) using community-engaged research training materials (such as those designed by Harvard Catalyst (**see website**)).
- Work with academic centers with public health or behavioral health research programs in the selected cities.
- Choose sites with existing IRB review agreements (i.e., a central IRB, reliance agreement, etc.).
- An action plan and follow-up plan should be in place if a participant (or prospective participant) indicates intent to harm self or others during initial or ongoing screening(s). I.e., the site PI will be paged, will call the (prospective) participant to triage the situation, and then refer or call 911. The screener should disclose this action plan prior to screening.
- A study monitor may be initially assigned to perform spot observation of the enrollment process.
- De-identified data collected from health and behavioral health claims should be scrubbed of identifiers and reported only at the fire department level.
- The online component must use a secure site, where data is encrypted and coded (at a level equal to that required by HIPAA) to prevent electronic privacy breaches.
- Consider using existing data; leaders in the area may already be collecting the same data you are interested in collecting.
- Make plans to attend to the psychological needs of research staff. Choosing staff with experience in first response will help, but do not assume they are immune to experiencing psychological issues related to this work. The PI, or other psychiatrist on staff, should debrief research staff and have an ongoing plan for attending to their occupational health needs.
- Institutions might consider implementing an IRB application process for crisis/disaster research, i.e., allow for a general standing application and fast track review of specific amendments.

Alternate Details:

- The investigators receive additional funding from the National Institute of Mental Health (NIMH) to recruit a portion of their subjects into a substudy to explore correlations between PTSD and healthy relationships. Subjects are asked to recruit their significant others into the substudy which will involve couples interviews and one-on-one sessions with a counselor/interviewer.
- The DoD asks the researchers to include in their sample a specific elite military unit, which was involved in a gruesome attack overseas in which several colleagues were lost as well as civilian life.

Other Events:

- Research staff member who has experience investigating “hero syndrome,” in which persons seeking recognition create a situation which they can resolve, approaches the PI when they think that they have identified such an individual after analyzing statements made while completing the journaling activities.
- Researcher staff detects what looks to be prescription medication abuse when reviewing the records of a firefighter who has concurrent and redundant prescriptions to painkillers from three different prescribers. What about the risk of the researcher identifying the firefighter with the prescription medication abuse problem?

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Rosenstein DL. Decision-making capacity and disaster research. *J Trauma Stress*. 2004 Oct;17(5):373-81. PMID: 15633916.

ADDITIONAL RESOURCES

Resources for Cognitive Capacity Assessment:

UCLA Office of Human Research Protection Program. "Decision Making Cognitive Capacity Assessment Tool." PDF file. 22 August 2012.

http://ora.research.ucla.edu/OHRPP/Documents/Consent/Decision_Assessment_Tool.pdf.

UCLA Office of Human Research Protection Program. "Guidance and Procedure: Research Involving Persons with Cognitive Impairments." PDF File. 24 May 2013.

http://ora.research.ucla.edu/OHRPP/Documents/Policy/9/Cognitive_Impairments.pdf.

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International Critical Incident Stress Foundation, Inc. (ICISF Inc.)

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