Roadmap for the Protection of Disaster Research Participants: Findings from the World Trade Center Evacuation Study

Kristine A. Qureshi, RN, MSN, DNSc;1 Robyn R.M. Gershon, MHS, DrPH;2 Elizabeth Smiales, PhD;3 Victoria H. Raveis, PhD;4 Bridgette Murphy, MPH;5 Frederick Matzner, MD;6 Alan R. Fleischman, MD7

Abstract

Introduction: This report addresses the development, implementation, and evaluation of a protocol designed to protect participants from inadvertent emotional harm or further emotional trauma due to their participation in the World Trade Center Evacuation (WTCE) Study research project. This project was designed to identify the individual, organizational, and structural (environmental) factors associated with evacuation from the World Trade Center Towers 1 and 2 on 11 September 2001.

Methods: Following published recommended practices for protecting potentially vulnerable disaster research participants, protective strategies and quality assurance processes were implemented and evaluated, including an assessment of the impact of participation on study subjects enrolled in the qualitative phase of the WTCE Study.

Results: The implementation of a protocol designed to protect disaster study participants from further emotional trauma was feasible and effective in minimizing risk and monitoring for psychological injury associated with study participation.

Conclusions: Details about this successful strategy provide a roadmap that can be applied in other post-disaster research investigations.


Introduction

Disaster research can provide valuable information that can lead to improvements in the prevention, mitigation, response, and recovery of other significant events. This holds true for all types of disasters, including naturally occurring (e.g., weather or geological events or epidemics), inadvertent technological accidents (e.g., industrial or transportation accidents), or intentional events (e.g., terrorism or civil strife). However, a number of potential challenges to conducting well-designed, ethical disaster research are recognized. These include: (1) funding timeliness; (2) rapidity of institutional review board approval of applications; (3) time required for the preparation of research protocols, instruments, and other materials; (4) access to survivors and/or families of victims; and (5) sampling biases.1–3 Most important, however, is the challenge of conducting disaster research while maintaining a high level of protection for participants against psychological injury associated with study participation.

Keywords: disaster; ethics; human subjects; protection; roadmap; World Trade Center research

Abbreviations:
IRB = institutional review board
PANYNJ = New York and New Jersey Port Authority
PAR = participatory action research
PCL-C = Post-Traumatic Stress Syndrome Civilian Checklist
IRB = institutional review board
PANYNJ = New York and New Jersey Port Authority
PAR = participatory action research
PCL-C = Post-Traumatic Stress Syndrome Civilian Checklist
PTSD = post-traumatic stress syndrome
WTCE = World Trade Center Evacuation

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In the aftermath of the Oklahoma City bombing, the terrorist attacks on 11 September 2001, and other recent natural and intentional disasters, the level of interest in disaster-related studies has increased. At the same time, in keeping with the overall heightened sensitivity regarding the impact of participation in research studies in general, disaster researchers, institutional review boards, survivor advocacy groups, and local and national officials increasingly were becoming concerned about disaster study participation. The concern is whether disaster survivors require additional protections above and beyond the human subjects protections already in effect. Since survivors frequently have experienced adverse psychological effects related to the disaster,4–7 there is a concern that re-living these experiences through research participation may exacerbate pre-existing mental health problems and vulnerabilities.8–10 In fact, studies show that survivors with higher levels of post-traumatic stress disorder (PTSD) symptomatology were more likely to report greater levels of distress from participation in studies.10–13 Richards and Schwartz note that disaster research also could lead to exploitation of participants and/or exacerbate their anxiety levels.14 However, it also should be noted that when conducted correctly, participation in these types of studies may be beneficial for some survivors.10,11,14 For example, trauma researchers have found that discussing the traumatic experience in a safe and supportive manner can be healing.10,11,16 In general, it appears that a greater benefit is derived from a face-to-face interview than from self-administered questionnaires.10,12,13 While these studies generally have shown positive outcomes, research on the impact of participation in trauma studies is quite sparse, and even scarcer with respect to post-disaster research. There is a research gap regarding specific information on effective strategies to protect disaster study participants.

Shortly after the World Trade Center (WTC) and Pentagon attacks, and the subsequent, intentional release of anthrax during fall 2001, numerous individuals and organizations, from academic and non-academic venues, began plans to conduct various studies on these events. Research on the 11 September terrorist attacks was aimed at evacuees who actually experienced the events, their family members, first responders, and the general public. Initially, none of these research projects were coordinated, and the New York City Department of Health and Mental Hygiene (DOHMH) was concerned that the disaster victims and New York City residents potentially could be victimized further. Clearly, there was a need to assure that the multiple projects were of scientific merit, not redundant, did not over-sample an already stressed population, and were sensitive to the needs of individuals, their families, and the community at-large. With guidance provided by the multidisciplinary study group that formed shortly after the Oklahoma City bombing,17 the research and public health communities self-monitored this process. From this experience, several recommendations were published that addressed some of these issues.8 Building further on this, in 2003, the New York Academy of Medicine and the National Institute of Mental Health convened a panel of ethical issues experts that included leading ethicists, mental health professionals, disaster researchers, public health officials, institutional review board (IRB) representatives, disaster survivors, and family members of deceased disaster victims. The panel reviewed the existing data, policies, and procedures in place for protecting subjects in the context of disaster research. Subsequently, a set of specific recommendations was published to provide guidance for the protection of disaster victims.18

The panel's recommendations for disaster research addressed the following considerations: (1) decisional capacity of the study subjects; (2) the psychological state of individuals who might serve as potential participants; (3) timely referral of subjects in need of mental health consultation; (4) training of investigators and staff to recognize emotional problems in research participants; (5) the determination and assessment of the risk and benefit of participation on study subjects; (6) representation and input on the research planning and implementation from the community under study; (7) informed consent procedures that reduce the likelihood that participants would mistake research for clinical services; (8) provision of a safe, controlled environment conducive for making an informed decision about participation; (9) provisions for the confidentiality of the data and the protection of the participants' privacy; (10) training of research staff to recognize and respond appropriately to the emotional challenges the research participants could experience; (11) dissemination of the study findings to the participants; and (12) collaboration and coordination among the disaster research community to help minimize redundant research and the burden placed on participants.

These recommendations expand on the basic tenets of ethical research involving human subjects, namely: (1) respect for persons (individuals should be treated as autonomous agents, fully informed and participating with their free will, and those with diminished autonomy are entitled to special protections); (2) beneficence (the aim of the research should be to do no harm and maximize the potential benefits); and (3) justice (all segments of society should equally share the burden of the research and reap the benefits of the findings, to the extent possible).19,20

In recognition of these basic tenets and in keeping with the panel's expanded recommendations, the World Trade Center Evacuation (WTCE) Study Team developed specific protocols and procedures in order to adhere to the highest ethical standards while informing the science of high-rise building evacuation.

Methods
A roadmap, (Table 1) addressing these tenets and guidelines18,19–20 was developed for each of the four phases of the study: (1) planning the project; (2) conducting the study; (3) analyzing the data; and (4) disseminating the results.

Phase 1: Planning the Study
Strategic Planning and Risk-to-Benefit Considerations—In 2002, strategic planning for the WTCE Study occurred in order to ensure the validity of the questionnaire domains...
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<th>Basic tenets of ethical human subject research</th>
<th>Expanded guidance and recommendations for disaster research</th>
<th>Procedures included in the study design to address these tenets and expanded recommendations</th>
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| Respect for persons: Informed consent must be assured | - Decisional capacity to provide meaningful and voluntary informed consent | - Study team utilized Columbia University’s IRB Committee expertise for crafting the consent forms  
- Consent form specifically included discussion of the psychological risks for participation in the study and the fact that this was research and not clinical services  
- Pre-screening of participants during qualitative procedures to assess decisional capacity  
- Ability to opt out of study at any time and still receive honorarium |
| Beneficence: Research should do no harm and should maximize potential benefits | - Risk-benefit ratio must be considered  
- Research proposals should be scrutinized based on the level of risk. Additional safeguards can be implemented as needed.  
- Privacy and confidentiality: strict steps must be undertaken to assure privacy and confidentiality of subjects, many of whom may already have been identified by media  
- Characteristics of the research: Acknowledgement of the fragility of the subjects—Mechanisms in place to identify and refer those who exhibit mental stress related to the study procedures  
- Training of the research team: must assure that the researchers remain sensitive to the vulnerability of the subjects, as well as vulnerability of themselves. Mechanism for researcher psychological decompression essential.  
- Additional procedural protections: Where necessary, IRBs may require additional protective steps, such as familial involvement in the consent process, or external monitoring of the project  
- Review of complaints and adverse events: Availability of a panel to review: (1) complaints from investigators or subjects; or (2) adverse events  
- Collaboration among investigators and coordination of research to decrease burden and redundancy | - Experts in the field were consulted to assess risk  
- Use of Data Safety Monitoring Board to assure positive intentions of the study as well as monitor for ill effects on participants  
- Study delimitations set to exclude the most fragile, i.e., those with high levels of PTSD  
- Confidentiality agreement signed with agencies that shared data; NY NJ Port Authority, CDC, NIST  
- Research team included clinicians with expertise in trauma, psychiatry and clinical psychology  
- All of the research team members received training related to study procedure protocols, recognition of psychological stress among subjects, and their own psychological distress  
- Established a liaison and agreement with the local psychiatric emergency department to assure rapid crisis intervention in the event it was necessary for subject or researchers  
- Psychiatrist available on call to participants  
- Family members encouraged to accompany participant to test site  
- Emergency contact information for all qualitative procedures participants obtained  
- There always was at least one facilitator present who could recognize signs/symptoms of psychological distress present at each session with subjects  
- Each subject in the in-depth interviews and focus groups was assessed for PTSD at three points: pre-screening for participation eligibility, 24 hours later and 2 weeks later  
- Researchers debriefed each other after each session and periodically with a study psychiatrist |
| Justice: All segments of society should equally bear the burden and rewards from the research | - Informing the victims and the public: both the victims and the general public should be informed about research proposals that have been peer reviewed and approved  
- Representation from the affected community involved in the planning and implementation of the research | - Recruitment included blue collar and white collar workers to assure representation of WTC employees  
- Advisory Board that included community groups and other interested parties to assure that all key stakeholders were adequately represented (included: Sky Scraper Safety Committee, Survivors’ Network, NY/NJ Port Authority personnel)  
- PAR team had input into final report and recommendations  
- Preliminary and final results of study shared with: study participants, general public, practitioners, professionals in the field of high-rise safety and the emergency preparedness and disaster scientific communities so that findings could be used to benefit high-rise safety  
- Multiple agency coordination to minimize duplication |

Table 1—Roadmap based on the basic tenets of ethical research and recommendations of disaster research subject protection (CDC = Centers for Disease Control and Prevention; IRB = institutional research board; NIST = National Institute of Standards and Technology; PTSD = post-traumatic stress syndrome; WTC = World Trade Center)
Assurance of Adequate Individual Subject Protections—The study required six different consent forms, each addressing specific aspects of human subject involvement across the various study procedures. All of the consent forms were developed with guidance from the Institutional Review Board of the Office of Human Research Protection at Columbia University. The consent forms explicitly stated that the study was for research purposes and potential participants were informed that services for the provision of mental or other healthcare services would be available. A brochure listing free or low cost mental health and other support services in the New York/New Jersey metropolitan area available to participants was prepared. An additional level of protection of the confidentiality of the data obtained in the study was provided by obtaining a Certificate of Confidentiality from the National Institutes of Health. Also, since the PANYNJ building occupant database was used as one of the sources for participant recruitment, a confidentiality agreement was developed and co-signed by the Columbia University principal investigator and the PANYNJ with assistance of Columbia University's legal counsel. This agreement provided explicit assurance that the PANYNJ would remain the gatekeeper of the occupant database, further protecting the confidentiality of the participants and their employer organizations. Similar arrangements were made with the New York City DOHMH World Trade Center Registry, which was the primary resource for recruitment.

Phase 2: Conducting the Study

Decisional Capability—It was decided that all potential participants in the in-depth interviews and focus groups would be pre-screened in order to determine their decisional capability and eligibility for participation. This phase commenced in 2003. Two weeks prior to enrollment in the study, potential participants completed a 10-minute telephone interview. At this time, the disclosure statement and consent form was read to them, and an initial post-traumatic stress disorder (PTSD) symptom-screening test was conducted. Additionally, demographics, emergency contact information, mental health and prescription history, and World Trade Center employment information was collected. Probable PTSD symptoms attributed to 11 September 2001 were assessed using questions from the PTSD Civilian Checklist (PCL-C). Interviewers also noted if
individuals displayed “red flags,” (e.g., were overly upset, hostile, or confused). All of the information was reviewed by the research staff and the study psychiatrist to determine if the participant had the decisional capacity to make an informed choice about study participation, and to assess if participation was likely to result in negative psychological outcomes. Throughout this screening process, callers were told what topics would be discussed so they could determine whether they would find participating psychologically troubling.

Individuals below the exclusion score for PTSD were deemed to have met the inclusion criteria. Subjects were scheduled for one of the qualitative procedures. The lag between initial recruitment and actual participation in the study afforded the participants an opportunity to opt out of the study after further contemplation or consultation with family members.

Impact of Participation and Assurance of Available Mental Health Resources—In addition to use as an eligibility tool, the PCL-C21 also was used to assess the impact of participation on those recruited for the Phase 1 qualitative procedures of the study (e.g., in-depth interviews or focus groups). This scale has 17 items that meet the DSM-IV diagnostic criteria for PTSD, and a five-point response scale ranging from “not at all” (1) to “extremely” (5). The PCL has excellent test-retest reliability (0.96) and has been administered by self-reports and by interviewers.22,23 The assessment was administered to each participant at three points in time during their participation in the study: (1) two weeks before participation in the qualitative procedures (to establish a baseline and determine participation eligibility) (T1); (2) directly following the interview or focus group to assess the immediate impact of participation (T2); and (3) two weeks following participation in the qualitative procedures to assess the delayed impact of participation (T3).

Assessment of Psychological State of Participants—For the in-depth interview and focus group sessions, study participants who requested the presence of a family member or friend to accompany them to the Research Office were encouraged to do so. Interviewers/facilitators were instructed to ensure that all participants were capable of safely leaving the research site at the conclusion of the interview. Finally, the management team from the local psychiatric emergency department was briefed fully about the study and was prepared to receive any participant referred to them for immediate care, if necessary.

During the quantitative stage of the study, in 2004, participants involved in the questionnaire development (e.g., cognitive testing and pilot testing) as well as participants completing the questionnaire (either a paper or Web-based version) were provided with explicit disclosure regarding the questionnaire items so that potential participants could decline without reviewing the questionnaire. The PTSD assessment steps taken for the qualitative stages of the study were not utilized during quantitative data collection (either as paper based or online survey). No serious adverse events related to participation were identified during the qualitative phase of the study. Therefore, the likelihood of participant injury from completion of the survey was extremely low and did not warrant the logistical efforts that would be required to conduct pre-screening and follow-up. However, the consent forms provided contact information and information regarding the availability of the study psychiatrist and other mental health resources in the metropolitan region.

Obtaining Signed Consent—At the time of participation in the qualitative procedures, participant consent was obtained formally in person within a private, controlled setting. Every effort was made to provide a comfortable and pleasant session (refreshments were served, incentives and metro cards were provided). Individuals were informed that they could opt out of the study at any point in time, and, that if they chose to do so, they would still receive their participation stipend ($50). For the quantitative data collection, informed consent was obtained for both Web-based and paper versions.

Coordination of Efforts—Steps were put into place to alert subjects that there were other ongoing studies on the events of 9/11 that they might be interested in learning about. They also were given a chance to decline any further contact with the WTCE Study. Wherever feasible, efforts were made between researchers to limit duplicate sampling of evacuees (e.g., by limiting recruitment to specific floors).

Phase 3: Data Analysis

Involvement of Representatives of the Study Population—Soon after preliminary analyses were completed (2006), participatory action research (PAR) teams were formed with the expressed purpose of identifying strategies for improvement in emergency preparedness efforts for high-risk building evacuation. Members were chosen from the study population. Similar measures were taken to assure the decisional capability of members, and as a further protection, the study psychiatrist attended several of the sessions so that team members could get to know him and to allow the psychiatrist to observe the teams’ processes. The teams reviewed the data that were presented in formats understandable to non-scientists using “total quality management techniques,” (e.g., pareto charts, fishbone diagrams). Quality assurance processes continued throughout Phase 3 and 4 of the study.

Phase 4: Dissemination

Dissemination of Study Findings to Participants—At the conclusion of the study (2006), two conferences were organized to present the findings to both the scientific and lay communities. The scientific conference was designed for fire safety, emergency preparedness, and disaster researchers and practitioners. The lay conference was open to the general public, and WTC survivors were encouraged to attend. The study results and PAR team recommendations were presented at both conferences. The lay conference provided an opportunity to address the ethical commitment for full disclosure to those impacted by the event. At the suggestion of the PAR teams, a non-denominational healing ceremony was conducted at the community conference, followed by
the presentation of commemorative pins that were designed by members of the PAR team. Certificates of appreciation to all team members also were provided. In addition to the lay conference, efforts were made to ensure that results were disseminated widely to reach the general public. Findings were posted on the study’s Website and presented at stakeholders meetings, at the Fourth Annual Voices of September 11th Forum, and through various media outlets.

Results

Decisional Capability—Of nearly 100 inquiries regarding participation in various qualitative procedures, three participants were referred to the study psychiatrist and subsequently excluded from participation due to concerns regarding the potential participant’s decisional capability.

Participant Profiles—A total of 50 participants actually participated in either an in-depth interview or focus group, and of these, three focus group members were not reached at either the 24-hour (T1) or two-week follow-up (T2). Therefore, complete data were collected for 47 of the participants, and the analysis is reported for this group. The demographic profile of the participants was: the mean values for the ages were 44 years (SD ±10 yrs); 57% were male; 72% were Caucasian; 100% graduated from high school, and 81% graduated from college; and 55% reported being married.

Impact of Participation—The results of an ANCOVA indicated that the demographic profiles of each group (in-depth interview and focus group) did not differ, and therefore, the two groups were combined for purposes of analysis. The mean value for the PTSD screen scores (out of a possible range of 17–65) for the two week period prior to the procedure (T3) was 34.85 ±14.28; 24 hours directly following participation (T2) 33.49 ±13.94; and two weeks after participation (T1) it was 30.60 ±13.43. Paired sample t-tests were then conducted to evaluate for changes in PTSD screening scores from T1 to T2 and then from T2 to T3. There were no significant changes in PTSD screen scores between T1 and T2 (t(47) = -0.84, p = 0.41), but a statistically significant decrease in PTSD screen scores from T2 to T3 (t(47) = -2.82, p <0.01) was identified. Overall, 26% (11 participants) met the criteria of PTSD at baseline.

Psychological Assessment—Throughout the study, whenever the research team was in contact with a participant, they were sensitive to participants who exhibited signs of acute psychological stress related to the WTC event or participation in the study. As per the protocol, if needed, the individual's participation in the study was to be terminated, and a referral to the on-call psychiatrist was to be offered. Of the >1,500 participants in the study, only six participants were identified as potentially requiring referral for follow-up. Of these, only four were known to have directly made contact.

Assurance of Adequate Subject Protections—The fact that the researchers in the various studies could not provide identifying information about participants in their respective studies, created some challenges for assuring that survivors were not over-recruited. Because of the procedures that were established/agreed upon by the community of researchers studying the event, none of the researchers could provide identifying information about respondents. This inability to share information on participants across studies created some problems. In one instance, a participant declining to participate in the WTCE Study thought that this meant he was protected from being contacted by recruiters from other studies. He was not, and consequently, he was upset when his wishes were not honored. This led to the only instance of a participant contacting either the Columbia University IRB office or the WTCE Study office to complain. In terms of opting out of the study once enrolled, only one participant requested removal from the study, for unspecified reasons. With regards to the assurance processes, both the DSMB and QAB were dutiful in their periodic assessments; no serious lapses in protocol or serious adverse events were noted. Goals and objectives were met as specified in the study protocols and reported on schedule to the study’s Advisory Board.

Impact on Research Team—Weekly team debriefings continued throughout the qualitative data collection phase and were held on an as-needed basis for the remainder of the study. At one point in the study, soon after subjects began completing the study questionnaire, a sizeable number of personal objects, mementos, photographs, and the like were mailed to the study office by participants. All staff, including non-study team members, found this to be upsetting, and the study psychiatrist facilitated a group meeting so that the entire staff could discuss this development and share their feelings on this matter. The study psychiatrist also met in person or by telephone at staff members’ request. Based on these interviews, one interviewer was reassigned to other duties on the study and deferred from working directly with participants.

Discussion

The adverse mental health consequences of disasters are well-documented.4 Galea et al document that community PTSD levels rose significantly after the WTC disaster and that they persisted for certain subgroups for up to 12 months after the event.24 Those most directly affected were found to have higher rates than those more distantly affected by the disaster. By these measures, it was expected that a significant portion of survivors of the evacuation itself would have high levels of PTSD. Recent research by DiGrande indicates that this is, in fact, true; 15% of the WTC Tower survivors enrolled (#3271) in the New York City DOHMH WTC registry, probably experienced PTSD 18 months after the disaster.25 These data support other research on survivors of traumatic events, and further document the potential risk for survivors participating in research.

In this study, using the PCL-C, it was found that study participants had baseline levels in keeping with other published data, and similarly found that significant increases in PTSD symptoms did not result from participation; in fact, participation may have been beneficial to some individuals. Participation was viewed as a positive and uplifting experi-

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ence. Visible signs of improvement could be detected in subjects after participation, as if "a weight had been lifted from their shoulders". Participants felt their input would have an impact on the safety of high-rise buildings and that from their experience, something positive would result. Participants felt their "story" held important facts that could help others, and they welcomed the opportunity to share their experiences. This especially was important before the survivors had organized themselves into a more formal collective group (WTC Survivors’ Network). That group now plays an activist role in high-rise safety. The study also provided many participants with an opportunity to channel their rage, anger, disbelief, and helplessness onto a target area, namely high-rise safety, thus providing a focus for these feelings and a sense of control. The passage of time (the study began nearly 18 months after the event occurred) may have provided sufficient opportunity to process the experience; many participants reported that they would not have been able to revisit the experience in such detail at an earlier point in time. However, it should be pointed out that these findings are subject to several limitations. Namely, the fact that persons with potentially very high PTSD levels were screened out may have led to a sampling bias.

The safety processes that were implemented were effective in protecting not only the health and well-being of the study participants, but the research team members as well. As Armstrong and others have noted, the contagion of trauma can result in vicarious traumatization, and it was important that this be avoided as much as possible. No breaches of confidentiality were noted, and the single complaint was a result of strict adherence to protocol.

The experience of implementing the participant safety protocol leads to three recommendations for improvement. First, in order to conduct pre-screening and post-test follow-ups for mailed or on-line questionnaires, participation cannot be anonymous. For studies to incorporate testing for all participants, there must be some type of registration process. A registration process that safeguards the participants' identifying information is simple to program and easy to follow. In addition, a referral if it may be required. Given the findings of trauma researchers indicating that questionnaire administration probably will be beneficial in other studies. Second, when a finite pool of subjects is the target of a community of investigators, a method that allows a potential participant to opt out of all recruitment efforts related to a specific disaster is needed. This might be accomplished through a centralized gatekeeper of the master sample frame. Finally, the follow-up period for this assessment was very brief; further studies are needed on the long-term impact of disaster research participation, as well as the impact on the family members of participants.

From the disaster researcher's perspective, following this roadmap heightened their sense of responsibility in assuring that the system of data collection was sensitive to the participants' needs and concerns. By operationalizing and utilizing strategies based on the ethical roadmap study participants were protected effectively. Use of these measures also was reassuring to the research team and helped to limit the negative psychological impact that could result from working on the project. While the additional measures taken to assure the safety and well-being of participants may appear to be tedious, even onerous, this was not our experience. Using the roadmap as a guide, the implementation of recommendations was relatively simple. These steps did not add greatly to the cost of the research and added only slightly to the timeline originally set for the study.

Conclusions
Through adherence to ethical recommendations, vulnerable groups can be adequately protected during participation in post-disaster research. This roadmap may provide guidance to other disaster research studies and local IRBs in their efforts to maintain the highest ethical standards possible. As the field of disaster research continues to grow and evolve, it is incumbent upon the scientific community to proactively assure adequate protections to these potentially vulnerable study participants.

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