Ethical Issues in Research Involving Victims of Terror

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ABSTRACT *Although research after an episode of terror can provide important information to improve the health and well-being of present and future victims, there are unique ethical challenges that need to be addressed. Man-made disasters have profound effects on victims, rescue workers, and their families and on others in the community; this may impair their ability to provide voluntary and uncoerced decisions about research participation. Because such potential participants in research may be vulnerable and also subject to being overburdened with redundant research, they deserve special consideration. We propose specific recommendations to assist investigators, institutional review boards (IRBs), public health officials, and political leaders to help serve the interests of future participants in terror-related research.*

Terrorism is the intentional creation of death and destruction to instill fear and feelings of uncertainty, vulnerability, intimidation, demoralization, chaos, and helplessness among those targeted. Because of its unique characteristics and the malice that motivates its aims, there are many important reasons to study the environmental, clinical, and psychosocial impacts of terror on individuals, families, and populations. Research that focuses on the effects of terrorism can provide important information that may improve long-term survival,¹ help prepare for subsequent incidents,² assess the physical and emotional needs of a population,³ have an impact on mental health management of victims and other disaster-affected persons,⁴ and increase understanding of the human experience.⁵

After September 11, 2001, it rapidly became clear that many well-intentioned investigators wished to do studies to elucidate the impact of this disaster on the victims, their families, and other populations affected by the event. Anecdotal evidence suggests that researchers from within and outside New York initiated dozens of research studies shortly after the event. This outpouring of interest in research raised questions about whether ethical issues surrounding the design and implementation of research involving victims of terror have been addressed adequately. Specific concerns were raised in the weeks after September 11th by the city administration, particularly the Commissioner of Health, for the potential of such studies to be redundant, insensitive, and overly burdensome to an acutely vulnerable and extremely distressed population. Despite previous efforts in the field of disaster-focused research, little systematic guidance was available to answer their concerns

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and address the research ethics issues that arose specific to conducting research on victims of the September 11th tragedy.

In this article, we focus on the unique ethical challenges inherent in doing research involving victims, victims' families, and other terror-affected individuals and communities. We argue that terrorism has profound effects on its victims, and research under such circumstances requires special protections that cannot be afforded solely by the good intentions of the research community and the review of proposals by a local institutional review board (IRB). We propose specific recommendations that address some of the concerns surrounding research undertaken on terror-affected individuals and populations.

BACKGROUND

Following the September 11th tragedy, the names and addresses of the victims who were unaccounted for (both those who had worked at the World Trade Center and the fire, police, and other emergency workers who had responded to the disaster) were available from public and private sources in newspapers and on the Internet. There was no central "clearinghouse" function and no obligation for investigators to obtain permission from any public or private agency or body prior to initiating a research project. It is assumed that local IRBs reviewed and approved the human subject research that was initiated in the aftermath of the September 11th terror, but no local IRB in the Bronx, New York; Baltimore, Maryland; Boston, Massachusetts; or Berkeley, California, would have known about the research being reviewed by other IRBs. Nor would IRBs necessarily have been thoughtful about the unique circumstances of research involving victims of trauma and the need for special consideration.

The most recent man-made disaster that took place in the United States prior to the events of September 11, 2001, was the bomb explosion at the Alfred P. Murrah Federal Building in Oklahoma City, Oklahoma, on April 19, 1995. Much research was undertaken in Oklahoma, but all projects were centrally reviewed and approved through a special process put in place by the University of Oklahoma Health Sciences Center with the imprimatur of the governor.⁶ Perhaps the smaller city, the smaller number of victims, or other circumstances of the disaster made this approach possible in Oklahoma, but no such mechanism was used in New York.

Prior studies involving trauma- and disaster-affected populations have identified some of the special issues that exist as a result of the unique circumstances of terror. Specifically, the research community that deals with trauma and disaster research has noted the need to coordinate research efforts postdisaster to prevent redundancy and oversampling, the importance of sensitivity to the victims, and the potential for retraumatization that may occur as a result of participation in research.⁷⁻¹⁰ Prior studies reveal that those who have been witnesses to or victims of extreme disaster may be so emotionally upset as to be unable to provide fully informed consent or to anticipate the degree of distress that will accompany participation.^{11,12} Although disaster-focused research proposals have received approval from IRBs in the past, there is little consistency among individual boards with respect to beliefs about the potential of these studies to traumatize or upset participants, and the participants' ability to accurately predict their anticipated level of distress.¹¹

In a review of the literature from 1981 to 2001, which consisted of 177 articles that described results for 130 distinct samples composed of over 50,000 individuals who experienced 80 different disasters, several consistent outcomes were observed.¹³

Psychological problems such as posttraumatic stress or depression were identified in 74% of the samples. Nonspecific distress was identified in 39% of the samples, health problems and concerns in 25% of the samples, and in 10% of the samples, chronic problems in living and psychosocial resource losses were identified.

VULNERABILITY OF RESEARCH SUBJECTS

Federal regulations for the protection of human subjects of research define several groups for whom the ability to make voluntary and uncoerced decisions about research participation may be impaired.¹⁴ These groups are deemed “vulnerable” and include children, prisoners, pregnant women, adults who are cognitively impaired or mentally disordered, and subjects who are economically or educationally disadvantaged. When individuals from these groups are the potential subjects of research, there may be limitations on the permissible level of risk to which the subjects may be exposed without compensating benefit. In addition, investigators must create special protections to ensure the voluntary nature of the informed consent by the individual or surrogate, and IRBs must give special scrutiny to such proposals and may create procedural safeguards to protect the interests of the subjects.

There is current controversy in the field of research ethics about whether labeling a population as vulnerable may be pejorative and potentially stigmatizing. In the parlance of the social scientist, those who are vulnerable are at risk of harm; in the research ethics context, vulnerable subjects may not be at greater risk of harm from the procedures in the research project; rather, they require additional protections because their ability to provide free and informed consent is impaired. This may be due to age, capacity to make rational choices because of cognitive impairment or mental illness, or social circumstances for which voluntary and uncoerced consent may not be possible.¹⁴ It is the explicit purpose of the regulations to augment the moral virtue of the investigator with a process of oversight and review to protect the interests and welfare of research subjects.¹⁵

Whether a group of potential research subjects fits into one of the designated categories of those deemed vulnerable and entitled to special protections, any population of potential subjects who, because of individual characteristics or social circumstances, may be susceptible to increased risks or unable to provide voluntary and uncoerced consent ought to deserve special consideration and receive necessary protections. Whether recognized, terror victims and their families frequently suffer from severe psychological and emotional distress. Acute anxiety, depression, posttraumatic stress, and severe grief may have an impact on their ability to make authentic choices about research participation. These subjects may be vulnerable or even considered “doubly vulnerable” because of their potential to experience several factors that may diminish autonomy.¹⁶ Psychological impairments may be coupled with the additional stresses of permanent dislocation, social disruption, family and financial strains, environmental worry, and ecological stress, which may create a situational circumstance that may render individuals significantly vulnerable.¹⁷

It is unclear the level of closeness to the original trauma or its victims that is required to create such psychological distress as to render an otherwise competent individual subject to the need for special protection in regard to research participation. It is known that proximity to the event increases the psychological impact. Therefore, at a minimum, those who are injured, their families, those who escaped the disaster, direct observers, first responders, rescue workers, recovery personnel,

and others directly affected by the terror should be afforded additional safeguards and protections.

RESEARCH BURDEN

Institutional review boards are also responsible to ensure that subjects are not overly burdened by research as a result of redundancy of proposals or oversampling of a specific population.¹⁸ Investigators may or may not be aware that a population is being oversampled or that their work is duplicative of other active research studies. A local IRB affords insufficient protection to ensure that victims of terror and their families will not be subject to multiple research studies dealing with the same questions. Some might argue that the individual subjects of research could just refuse to participate in redundant projects. This use of the autonomous right of refusal in research may be an insufficient and insensitive way to protect distressed potential subjects from inappropriate incursions into their private lives.

PROPOSED RECOMMENDATIONS

Without the need for additional federal regulations, the research community in the United States could agree to a series of recommendations that would protect the interests of victims of terror who might become potential participants in research. The following recommendations require the collaboration of clinicians, social scientists, academic institutions, public health officials, government leaders, and research regulators to respond to this important problem.

Declaring a Serious Episode of Terror

In the event of a serious episode of terror or a natural disaster, regional public health officials in collaboration with local political leaders such as the mayor of the affected city should declare that such an event has occurred and request assistance from the director of the Office of Human Research Protections (OHRP) of the US Department of Health and Human Services. The director of OHRP should confirm the serious nature of this episode and then contact all IRBs that hold a federalwide assurance for research involving human subjects (the institutional agreement to be bound by federal regulations for all human subject research conducted under their auspices), asking them to carefully review each research proposal related to this terror and provide only provisional approval to the investigator.

Coordination and Review of Research Proposals

The state or city commissioner of health in collaboration with local university and medical school deans should create a small blue-ribbon panel consisting of senior academicians, local leaders in research ethics, and representatives of victims and their families. Local IRBs will forward provisionally approved proposals to this blue-ribbon panel for additional review and final approval. The blue-ribbon panel should encourage collaboration among investigators to decrease redundancy of research and oversampling of those affected by the event and ensure that the local IRB has taken appropriate steps to protect the interests of the subjects. Since the panel will have ultimate authority concerning which proposals are approved, it must make every effort to be fair and impartial, keeping the interests of the subjects of the research as the primary focus of concern. The blue-ribbon panel will need to

be cognizant of the urgent nature of much of the research and work diligently and expeditiously to ensure that research is not unduly delayed.

Specific Protections for Research Subjects Who Are Victims of Terror

Local IRBs should review research proposals to ensure that the following issues have been adequately addressed:

Informed Consent: Subjects of the research should be informed that others who have had such experiences with terror are often very upset and may be retraumatized by participation. They should be given the opportunity to consult with family members and others before they consent to the research study.

Privacy and Confidentiality: IRBs should be cognizant of the fact that the privacy of the subjects of research may already have been breached by the media or others who have made their names and personal identifiers public knowledge. Provisions for confidentiality of the data collected in the study should be explicit and effective, and subjects should be informed whether personal identifiers will remain linked to the data and what level of identifiers will accompany any publications.

Characteristics of the Research: All research proposals should be sensitive to the psychological fragility of the subjects and have explicit mechanisms for immediate referral of distressed subjects to mental health professionals as needed.

Training of the Research Team: The relationships among investigators, field workers, and research subjects are always important, but take on new meaning in these circumstances. Research proposals will need to reflect that the research team will be trained to interact with victims of terror in a sensitive manner and be made aware that researchers are likely to confront situations and dilemmas that may conflict with their traditional role as unbiased and objective observers.¹⁹ Proposals should also reflect that explicit mechanisms are in place for decompression of the research team and referral of research team members for mental health support as needed.

Additional Procedural Protections: IRBs may wish to require special procedural protections consistent with the specific provisions or risks of individual research proposals such as involvement of family members in the informed consent process, independent consent or research monitors, and frequent review of the progress of the research.

Informing the Victims and the Public: The blue-ribbon panel should inform the victims and the public about those research proposals that have been approved. Victims should be informed that they may or may not wish to participate in research studies, but they ought only to consider those proposals that have been officially approved.

Review of Complaints and Adverse Events: The blue-ribbon panel should remain available to respond to any complaints from investigators or research subjects and to review adverse events related to approved research proposals.

CONCLUSIONS

The ethical principles that inform the regulations to protect the interests of human subjects of research create multiple obligations for both investigators and IRBs.

Investigators must ensure that studies are designed to minimize harms and risks to the subjects, that subjects are given the opportunity to provide voluntary and uncoerced decisions about participation, and that participation is not overly burdensome to specific individuals or populations. Researchers are not only required to ensure that harm is not intentionally inflicted on participants, but also they are obligated to prevent harm, protect welfare, and promote good for the subjects of research. These duties to research subjects in general apply specifically to the unique circumstances of research involving victims of terror.

Recent events have revealed the need for guidance to investigators and IRBs responsible for the protection of human subjects of research post-terror. To assure that such research is encouraged and consistent with the highest ethical standards, there is the need for additional procedural safeguards consistent with the ethical principles that govern research and that are respectful of the victims and their families. Without the need for new regulations, the process we propose could be voluntarily invoked in the event of future disasters or events of terror to protect the welfare of potential research subjects.

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