

# NATIONAL RECOMMENDATIONS FOR ENHANCING THE CONDUCT OF ETHICAL HEALTH RESEARCH WITH HUMAN PARTICIPANTS IN POST-DISASTER SITUATIONS

The intricacies and time- sensitivity of conducting high- quality and clinically relevant health-related human subject research in post-disaster situations challenges traditional approaches to ensuring optimal protection that study participants are protected from exploitation and harm. This article briefly reviews the ethics and guidelines for conducting research in post-disaster periods and offers recommendations to improve human subjects research conducted in situations defined by the National Response Framework as 'disasters' and 'emergencies.' (*Ethn Dis.* 2008;18:378–383)

**Key Words:** Ethics, Human Subjects Research, Disaster, Federal Regulations, IRB

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## INTRODUCTION

In August 2005, Hurricane Katrina followed shortly thereafter by Hurricane Rita, flooded the entire city of New Orleans, displaced >2 million people from their homes to other cities, and killed >1,300 people in what has been described as the largest natural disaster in American history and the largest migration of Americans since the Civil War.<sup>1,2</sup> In addition, the magnitude of impact these hurricanes had on the health and healthcare systems for the residents of Louisiana and Mississippi was unprecedented. The burden of the disaster on the health of the affected population and the health care systems struggling to provide for them were exacerbated by the high rates of poverty and lack of health insurance in the affected population. The affected population was mostly composed of African Americans.<sup>3–5</sup> Even now, more than two years after Hurricane Katrina hit ground, studies of the affected populations, as compared to national estimates, have documented continuing negative effects of being exposed to the disaster, including higher rates of mental disorders,<sup>6</sup> respiratory disorders,<sup>7</sup> disruptions in chronic disease management,<sup>8</sup> and unmet need for health and mental health services.<sup>9</sup>

The problems encountered during the aftermath of these hurricanes contributed to a major reassessment of local, state, and national response to disasters. The *National Response Plan* was updated and work on the recently finalized *National Response Framework* was initiated.<sup>10,11</sup> The *National Response Framework* presents principles to guide all response partners in preparing for

and providing a unified national response to disasters and emergencies. The purpose of the *Framework* is to establish a comprehensive, national, all-hazards approach to domestic incident response – from the smallest incident to the largest catastrophe. However, while quite comprehensive in scope, these documents do not address the specific needs of protecting human subjects when research is proposed and conducted during post-disaster time periods. On further review of the literature and federal regulations, we could find no national policies addressing this specific issue. This paper briefly reviews existing policy statements and guidelines regarding human subject research for their applicability to post-disaster settings; explores the limitations of these statements and guidelines; and then offers recommendations for addressing some of the gaps within these national policy guidelines. Other work has addressed ways to improve the implementation of current federal regulations around human subjects research.<sup>12</sup> Although implementation of existing guidelines is an important area, our recommendations are to address the lack of specific national policy guidelines for human subjects research in post-disaster situations.

Throughout the article, we have included quotations (in italics) provided

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by our community co-author from New Orleans (HG). These quotations were collected as part of group discussions about the topic on conference calls and, while presented in her words, they capture the sentiment of the community co-authors about the challenges of conducting ethical human subject research in periods like those experienced in the aftermath of the hurricanes.

*We were like children in the wilderness. We see people dying around you. There was no water and no ice. There was confusion because people were trying to get some water. If you tried to get water, you couldn't get on the helicopter. And if you missed the helicopter, you didn't know whether you would ever get out. (HG, New Orleans resident and survivor of Hurricane Katrina)*

The fear and uncertainty of post-disaster periods cannot be overstated. In the face of the confusion and chaos associated with large-scale interruption of many societal systems, it can be difficult to determine when, and even if, health-related human subjects research is appropriate. However, if we avoid human subjects research during these times, we may never be able to improve our understanding about what health services should be prioritized and how to provide services effectively in a post-disaster situation.<sup>13,14</sup>

Guidelines proposed by the World Health Organization have suggested that research studies in post-disaster situations should prioritize three areas: etiology/prevalence of illness and risk factors for illness, assessment of operations or systems to improve care, and clinical intervention research to improve the provision of medical care.<sup>15</sup> It is clear that many potential research studies could meet the ethical requirement that research with human participants has social and/or scientific value (generalizable knowledge).<sup>16,17</sup> Indeed, certain questions can only be answered in the context of post-disaster situations:<sup>18–21</sup> What are appropriate

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mental health services for people who have suffered psychological trauma? How does one deliver these services? How does a system ensure that people with chronic illnesses such as diabetes or hypertension obtain necessary medications when health systems have been destroyed? What are the best approaches for ensuring clean food and water in post-hurricane areas?

While the need for better information to guide post-disaster response is apparent, valid concerns are expressed regarding the ethical conduct of such research in post-disaster situations.<sup>13,18–20,22,23</sup> In addition to the challenge of determining an appropriate risk-benefit ratio of research after a disaster, concern is expressed about the potential negative impact a disaster may have on people's decision making capacity and the challenge of ensuring proper informed consent in such a context.<sup>22,23</sup> In particular, concerns have been raised about the ethics of conducting research with people who may be vulnerable because they have recently been displaced, may suffer psychological and physical consequences of a disaster, and may be poor and disempowered even prior to the traumatic event.<sup>15,20,23</sup>

None of the following well-known research ethics guidelines—the Declaration of Helsinki, the Council for International Organizations of Medical

Sciences guidelines, the Belmont Report, nor U.S. Federal Regulations—addresses the unique circumstances of conducting research in post-disaster situations, and in particular the challenges of enlisting potential research subjects under these circumstances.<sup>15,20,24–27</sup>

As identified by our community co-authors, the situation in the affected Gulf States in the aftermath of these hurricanes exemplifies many unique challenges to researchers trying to conduct ethical research. In this article, we discuss three (1) informed consent, (2) confidentiality, and (3) balancing the principles of beneficence, 'do no harm,' and justice.

## INFORMED CONSENT ISSUES

*At the convention center, there were lots of news persons and out-of-state papers and a lot of people asking all sorts of questions. I wasn't sure who they were. Were they news reporters, researchers, government people? I didn't know who any of these people were. They kept asking me, "How do you feel that you had to evacuate? Do you know where you are going? Who organizes this? Is someone contacting your family?" I was so confused. I didn't understand them. I couldn't get in touch with anyone and I was so scared. I had no idea who these people were. (HG)*

While concern has been raised that the psychological sequelae of a disaster may make informed consent for participation in research a challenge, it is not clear that actual decision-making capacity is impaired.<sup>19,22</sup> Informed decision-making could be difficult if persons were unable to focus on the informed consent process because they were distracted by needing to fill their basic needs such as obtaining shelter, food and water, or if they were concerned about obtaining care for basic medical needs.<sup>20,28</sup> In the case of the hurricane-affected communities, low literacy rates

made the informed consent process even more challenging.<sup>1,2</sup>

Because many existing services were non-functional, and replacement services were slow and sparse,<sup>4,5</sup> the potential for affected individuals to confuse researchers for service providers and to mistakenly believe that participation in research might help the participant gain needed resources, became a possible form of therapeutic misconception. Therapeutic misconception generally refers to the confusion in clinical trial research between the primary goals of research (generalizable knowledge) and the primary goals of clinical care (improving the health of an individual).<sup>30</sup> Multiple studies have documented the pervasiveness of therapeutic misconceptions in clinical research.<sup>31-35</sup> One study found that a low participant education level was correlated with high levels of therapeutic misconception in gene therapy studies.<sup>33</sup> Of concern is the potential that researchers themselves could also harbor mistaken beliefs that the research itself is more beneficial to participants than it has the potential to be, and thus might not be alert to these mistaken beliefs on the part of research participants or might inadvertently foster these misconceptions.<sup>30</sup> Although mostly described in the clinical trials research literature, misconceptions about the purpose of research and activities of researchers is a potential problem for all human participant research. The international relief literature has expressed enormous concern regarding the ethical need to guard against misconceptions between research and provision of needed health-related and non-health related services in the social disruption present in camps for displaced persons and in war torn countries.<sup>13-15,20</sup> These concerns are relevant to domestic disasters as well,<sup>20,24</sup> as exemplified in the following quote:

*Someone asked me about medications. I had medications for my high blood pressure but they were running out. I*

*didn't know where I was going to get a refill. I thought these people were going to help me. I was so confused. (HG)*

Finally, trust can be a prerequisite to voluntary informed consent. Distrust of authorities was documented to be a sentiment among minority, Hurricane Katrina evacuees.<sup>35</sup> Ironically, lack of trust may impair voluntary informed consent if individuals feel pressured to consent to research out of a desire not to appear unhelpful to anyone in authority for fear that essential survival services could be taken away or not provided to them.

## CONFIDENTIALITY ISSUES

Confidentiality of the participants' identity and responses to sensitive topics may be challenging to maintain in post-disaster situations.<sup>23</sup> For example, it may be challenging to find areas where participants' confidentiality can be maintained in large shelters, on street corners, and in areas where there are no buildings. Furthermore, in some cases, research participants might actually want the researchers to share the information they provide in the context of research. For example, they may want government officials to know that they need assistance with finding a loved one or obtaining housing. Another example would be a participant may want someone to know about their hypertension and diabetes. Determining which information should be kept confidential and which information should be shared with others responsible for or able to provide direct help is an important challenge for researchers in post-disaster situations. Determining which authority could be a repository for information that ought to be shared could enhance the more immediate benefit of collecting information by researchers. It would also enhance the informed consent process to inform participants which information could

be shared, and provide participants with the opportunity to decide if they want that information shared and to opt out of sharing particular pieces of information when desired.

## BALANCING BENEFICENCE, DO NO HARM, AND JUSTICE ISSUES

*I thought when they were asking all of these questions, I thought that they would offer some hope and offer some answers – some enlightenment of hope or some water. (HG)*

Hurricanes Katrina and Rita had their most devastating effects on individuals from under-served, minority communities who have a history of exploitation in biomedical research and are frequently poorly represented in health research.<sup>35-40</sup> This reality serves to remind the research community of the need for research designed to advance knowledge of how best to help individuals and communities like those most affected by these hurricanes, and that the research meets high ethical standards. Determining the appropriate balance of risks and potential benefits of research, as well as the appropriate distribution of research burdens and benefits are difficult in every research study involving human participants. Acknowledging that research might add to burdens or risks for harm and might not provide needed benefits may be difficult when thinking about the devastation that individuals and communities experience after disaster strikes.

Ensuring that research studies conducted address questions that are pertinent to the affected individuals and communities is critical to the fulfillment of these ethical principles.<sup>16,17</sup> Both researchers and research oversight bodies (eg, institutional review boards [IRBs] and other oversight bodies) are responsible for ensuring that these

ethical principles are fulfilled.<sup>26</sup> Ideally, community voices will contribute to these determinations.<sup>16</sup> In practice, the ideal of community participation is hard to fulfill in general, and may seem impossible in the chaos and confusion post-disaster. When broad community participation is achieved in post-disaster situations, relevance of efforts to address the health concerns of minority populations appears to be enhanced.<sup>16</sup> We believe that striving to fulfill the principles of community-partnered participatory research is critical, even when the chaos that ensues after a disaster strikes makes them difficult to fulfill.<sup>16,17</sup> One possibility to ensure that the community perspective is not ignored as research studies are planned and conducted is to tap into the national network of community research partners to help identify individuals from unaffected communities who might have experience or expertise to represent the community perspective broadly speaking until members of the affected communities can become partners in this process.

On a more individual level, it is not clear whether and what type of harms might result from asking people to discuss a recent traumatic experience, particularly when there are limited opportunities for therapeutic interventions to handle adverse psychological reactions if and when they might occur.<sup>12</sup> At the very least, researchers must be aware of the mental health services available and be ready to help individuals in need to access these services. Researchers, and IRBs, should also be aware that many research studies might be targeted toward the same group of participants and care should be taken either by researchers, or by IRBs, to reduce the burden potentially associated with being asked to participate in multiple research studies. Enhanced coordination of IRBs could provide a useful service in mitigating these types of potential burdens.<sup>39</sup>

Hurricanes Katrina and Rita had their most devastating effects on underserved, African American communities. Protection not only of individuals, but also of their communities is important to consider, as information released about a community could have negative impact on it and as a result upon the individuals that are part of that community.

### NATIONAL RECOMMENDATIONS FOR ENHANCING THE ETHICAL CONDUCT OF RESEARCH IN POST-DISASTER SITUATIONS

The breakdown of government systems at all levels in the aftermath of Hurricanes Katrina and Rita is well-documented.<sup>12,41-45</sup> Policy makers have enacted legislation and developed policies aimed at improving coordination of services and disaster preparedness that incorporates local, state and federal activities with an eye toward a truly national response.<sup>11,12,41</sup> We suggest that the ethics of research in the aftermath of disasters would be enhanced by specific national policy attention aimed at guiding the coordination of human subjects research as well. Toward this end, we suggest the following concepts should be included in explicit national level guidance such as the National Response Framework to enhance the ethics of research conducted when there has been a Declaration of a State of Emergency or Disaster by the President to address the current gaps in federal regulation:<sup>11,12,47,48</sup>

1) The individuals and communities affected by declarations of a state of emergency or disaster should be considered "vulnerable subjects" for the purposes of human subjects research and enhanced strategies for protecting their interests and well-being should be designed into any proposed research. We suggest that their vulnerability is more akin to the type of vulnerability acknowl-

edged in the Common Rule that attends to "economically or educationally disadvantaged persons,"<sup>25</sup> rather than that which attends lack of decisional capacity per se.

- 2) A national steering committee to guide and oversee human subjects research should be formed by Department of Health and Human Services to oversee all research involving participants from areas declared to be in a state of emergency or disaster, and perhaps be activated when the National Response Framework is invoked. It could serve to coordinate IRB activities, and perhaps in some cases serve as a Central IRB like that used by the National Cancer Institute.<sup>48</sup> This national steering committee will function as a central IRB for all research protocols in all areas designated by the president to be in a "state of emergency" or "disaster."
- 3) The national steering committee should have experts in disaster research, health disparities, and content experts in mental health, public health and safety, lay members who are survivors of a disaster, and lay members who are residents of the affected areas.
- 4) Attention should be paid to ongoing monitoring of the safety, ethics, and scientific merit of research with human participants in federally designated disaster or emergency areas by someone in addition to the researchers. This monitoring could be done by the central IRB or a separate data and safety monitoring board. This monitoring is particularly critical because ethical review before commencing the research may have been constrained by a short time frame.
- 5) All investigators doing research related to the emergency or disaster should be required to complete a special human subjects protection module on the ethics of doing



research in these types of situations, which needs to be developed.

- 6) Language specific to the unique situation of protection of victims of disasters as well as their communities should be drafted by the central IRB for inclusion in informed consent forms of all studies conducted in disaster situations.
- 7) A percentage of federal research dollars for research related to the aftermath of disasters should be set aside for work that examines the ethics of research with participants in post-disaster situations, following the model of the Ethical, Legal, and Social Issues program of the National Human Genome Research Institute.

We believe that clear, proactive ethical guidance is needed to address gaps left by existing US federal regulations covering conduct in the aftermath of declared emergencies and disasters, regulations governing research, and widely recognized research ethics guidance. We believe that attention to conducting ethical research should be a standard part of the National Response Framework, and that particular attention be paid to the ethical challenges that arise when disasters strike underserved, and often minority populations like the survivors of Hurricane Katrina and Rita.

#### REFERENCES

1. Kaiser Commission on Medicaid and the Uninsured. Key facts: a look at the health care delivery system for low-income people in New Orleans. Available at: <http://www.kff.org>. Accessed October 20, 2007, 2007.
2. The Urban Institute. Katrina: Demographics of a Disaster. Available at: [http://www.urban.org/UploadedPDF/900835\\_katrina\\_factsheet.pdf](http://www.urban.org/UploadedPDF/900835_katrina_factsheet.pdf). Accessed June 18, 2007, 2007.
3. Rosenstein DL. Decision-making capacity and disaster research. *J Trauma Stress*. 2004;17(5):373–381.
4. Brodie M, Weltzien E, Altman D, Blendon RJ, Benson JM. Experiences of Hurricane Katrina evacuees in Houston shelters: implications for future planning. *Am J Public Health*. 2006;96(8):1402–1408.
5. Centers for Disease Control and Prevention (CDC). Assessment of health-related needs after Hurricanes Katrina and Rita – Orleans and Jefferson Parishes, New Orleans area, Louisiana, October 17–22, 2005. *MMWR*. 2006;55(2):38–41.
6. Kessler RC, Galea S, Gruber MJ, Sampson NA, Ursano RJ, Wessely S. Trends in mental illness and suicidality after Hurricane Katrina. *Mol Psychiatry*. 2008;1–11[epub ahead of print].
7. Rabito FA, Iqbal S, Kiernan MP, Holt E, Chew GL. Children’s respiratory health and mold levels in New Orleans after Katrina: A preliminary look. *J Allergy Clin Immunol*. 2008 [epub ahead of print].
8. Hurricane Katrina Community Advisory Group, Kessler RC. Hurricane Katrina’s impact on the care of survivors with chronic medical conditions. *J Gen Intern Med*. 2007;22(9):1225–1230.
9. Wang PS, Gruber MJ, Powers RE, Schoenbaum M, Speier AH, Wells KB, Kessler RC. Disruption of existing mental health treatments and failure to initiate new treatment after hurricane katrina. *Am J Psychiatry*. 2008;165(1):34–41.
10. U.S. Department of Homeland Security. Notice of Change to the National Response Plan. Available at: [http://www.dhs.gov/xlibrary/assets/NRP\\_Notice\\_of\\_Change\\_5-22-06.pdf](http://www.dhs.gov/xlibrary/assets/NRP_Notice_of_Change_5-22-06.pdf). Accessed on February 2, 2008.
11. U.S. Department of Homeland Security. National Response Framework Resource Center. Available at: <http://www.fema.gov/emergency/nrff/>. Accessed on February 2, 2008.
12. Collogan LK, Tuma FK, Fleischman AR. Research with victims of disaster: institutional review board considerations. *IRB*. 2004;26(4):9–11.
13. Sumathipala A, Siribaddana S. Research and clinical ethics after the tsunami: Sri Lanka. *Lancet*. 2005;366(9495):1418–1420.
14. The Sphere Project. Humanitarian charter and minimum standards in disaster response. Oxford, England: Oxfam Publishing; 2000.
15. World Health Organization. Consultation on applied health research in complex emergencies. Available at: [http://programs.ssrc.org/HIV/publications/SGBV\\_2005/background\\_docs/consult\\_app\\_health.pdf](http://programs.ssrc.org/HIV/publications/SGBV_2005/background_docs/consult_app_health.pdf). Accessed October 21, 2007.
16. Chen DT, Jones L, Gelberg L. Ethics of clinical research within a community-academic partnered participatory framework. *Ethn Dis*. 2006;16(S1):118–135.
17. Emmanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701–2711.
18. Collogan LK, Tuma F, Dolan-Sewell R, Borja S, Fleischman AR. Ethical issues pertaining to research in the aftermath of disaster. *J Trauma Stress*. 2004;17(5):363–372.
19. Levine C. The concept of vulnerability in disaster research. *J Trauma Stress*. 2004;17(5):395–402.
20. Hill P. Ethics and health systems research in ‘post’-conflict situations. *Dev World Bioeth*. 2004;4(2):139–153.
21. Dennis MR, Woods G, Schrodt P. Making sense of New Orleans flood trauma recovery: ethics, research design, and policy considerations for future disasters. *Analyses of Social Issues and Public Policy*. 2006;6(1):191–213.
22. Rosenstein DL. Decision-making capacity and disaster research. *J Trauma Stress*. 2004;17(5):373–381.
23. Leaning J. Ethics of research in refugee populations. *Lancet*. 2001;357(9266):1432–1433.
24. Black R. Ethical codes in humanitarian emergencies: from practice in research? *Disasters*. 2003;27(2):95–108.
25. United States Department of Health and Human Services. Protection of Human Subjects. Vol 846 CFR 46; 2005.
26. World Medical Association. Ethical principles for medical research involving human subjects. <http://www.wma.net/ef/policy/b3.htm>. Accessed October 21, 2007, 2007.
27. Council for International Organizations of Medical Sciences. International ethical guidelines for biomedical research involving human subjects. Available at: [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm). Accessed October 21, 2007.
28. Maslow AH. *Motivation and Personality*. New York: Harper and Row; 1954.
29. Appelbaum P, Roth L, Lidz C. The therapeutic misconception: informed consent in psychiatric research. *Int. J. Law Psychiatr*. 1982;5:319–329.
30. Appelbaum P, Lidz C, Grisso T. Therapeutic misconception in clinical research: frequency and risk factors. *IRB*. 2004;26:1–8.
31. Lidz C, Appelbaum P, Grisso T, Renaud M. Therapeutic misconception and the appreciation of risks in clinical trials. *Soc Sci Med*. 2004;58:1689–1697.
32. Henderson GE, Easter MM, Zimmer C, King NM, Davis AM, Rothschild BB, Churchill LR, Wilfond BD, Nelson DK. Therapeutic misconception in early phase gene transfer trials. *Soc Sci Med*. 2006;62:239–253.
33. King NM, Henderson GE, Churchill LR, Davis AM, Hull SC, Nelson DK, Parham-Vetter PC, Rothschild BB, Easter MM, Wilfond BS. Consent forms and the therapeutic misconception: the example of gene transfer research. *IRB*. 2005;27:1–8.
34. Kimmelman J, Levenstadt A. Elements of style: consent form language and the therapeutic misconception in phase 1 gene transfer trials. *Hum Gene Ther*. 2005;16:502–508.

35. Cordasco KM, Eisenman DP, Glik DC, Goldern JF, Asch SM. "The blew the levee": distrust of authorities among Hurricane Katrina evacuees. *J Health Care Poor Underserved*. 2007;18(2):277-82.
36. Farquhar S, Dobson N. Community and university participation in disaster relief recovery: An example from eastern North Carolina. *J Community Practice*. 2004;12(3-4):203-217.
37. Boscarino JA, Figley CR, Adams RE, et al. Adverse reactions associated with studying persons recently exposed to mass urban disaster. *J Nerv Men Dis*. 2004;192(8):515-524.
38. Gamble VN. Under the shadow of Tuskegee: African Americans and health care. *Am J Public Health*. 1997;87(11):1773-1778.
39. Thomas SB, Quinn SC. The Tuskegee Syphilis Study, 1932 to 1972: implications for HIV education and AIDS risk education programs in the black community. *Am J Public Health*. 1991;81(11):1498-1505.
40. Rosenbaum S. US health policy in the aftermath of Hurricane Katrina. *JAMA*. 2006;295(4):437-440.
41. Rudowitz R, Rowland D, Shartz A. Health care in New Orleans before and after Hurricane Katrina. *Health Aff (Milwood)*. 2006; 25(5):w393-406.
42. Berggren RE, Curiel TJ. After the storm - health care infrastructure in post-Katrina New Orleans. *N Engl J Med*. 2006;354(15): 1549-1552.
43. Ferdinand KC. Public health and Hurricane Katrina: lessons learned and what we can do now. *J Natl Med Assoc*. 2006;98(2): 271-274.
44. Nieburg P, Waldman RJ, Krumm DM. Hurricane Katrina. Evacuated populations - lessons from foreign refugee crises. *N Engl J Med*. 2005;353(15):1547-1549.
45. Quinn SC. Hurricane Katrina: a social and public health disaster. *Am J Public Health*. 2006;96(2):204.
46. United States Department of Homeland Security. *The Federal Response to Hurricane Katrina: Lessons Learned*. Washington, D.C.: Department of Homeland Security, 2006; 1-217.
47. Robert T. Stafford Disaster Relief and Emergency Assistance Act. Vol 42 U.S.C. § 5121-5207; 2007.
48. Christian MC, Goldberg JL, Killen J, et al. Sounding board: a central institutional review board for multi-institutional trials. *N Engl J Med*. 2002;346(18):1405-1408.

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