

NIEHS OHRC Best Practices Working Group for the Development of Special Considerations for IRB Review of Disaster and Emergency Related Public Health Research

Meeting Purpose:

The National Institute of Environmental Health Sciences (NIEHS) Office of Human Research Compliance is initiating a series of Best Practices Working Group meetings to develop recommendations for IRB review of protocols in response to disaster-related and public health emergency research. To date, there is no special guidance to assist IRBs in the review of disaster-related research. Research conducted during a disaster situation or public health emergency situation should not be treated as clinical research as usual. Additional ethical and moral considerations need to be addressed by the IRB for a comprehensive, ethical review that takes into account considerations under these circumstances to help protect and respect the welfare of the research participant and the community in which they live. Special considerations need to focus on the entire life cycle of the study.

The Best Practices Working Group will consist of an interdisciplinary group of individuals bringing expertise from various fields within the context of public health emergency and disaster response research with emphasis on human research protections. The group will include: federal and state government officials, academicians, regulatory officials, compliance experts, community representatives and workers of disasters such as, “First Responders.”

Initial Topic for Best Practices Working Group: **Vulnerability / Vulnerable Populations**

Context: During a public health emergency/disaster, whether natural or man-made, every individual currently residing, working or visiting the affected area at the time of the disaster becomes susceptible to the exposures that result from the disaster. Due to the broad catastrophic nature of disasters and public health emergencies all individuals from the affected community may be considered vulnerable.

This potential vulnerability raises concern and questions as to whether affected individuals are truly able to make an informed/voluntary and uncoerced decision as to whether or not they should participate as subjects in public health research.

Purpose: This initial working group will focus on the topic of subject vulnerability and define additional safeguards for this category of vulnerable populations as it relates to disaster and emergency related public health research.

Specific aims:

1. Define vulnerable populations and special considerations for vulnerability and vulnerable populations in the context of disaster and emergency related research;
2. Define additional duties of the IRB as it relates to reviewing research involving disaster populations and communities;
3. Define what types of research should be permitted at different time periods after disaster;

4. Define the special considerations for minimal risk research;
5. Define the special considerations for greater than minimal risk research;
6. Determine the appropriate composition of IRB membership before review of this type of research after disasters and public health emergencies (Ad Hoc, Consultants, etc.)
7. Outline special considerations for rapid review of IRB protocols: Those studies in which PIs want to very quickly (hours to days) get into the field after a disaster and/or public health emergency;
8. Identify participant burden for vulnerable populations after a disaster or public health emergency.

Outcome: Development of a white paper from the ideas discussed and vetted by the working group that will give guidance to IRBs who review public health disaster and public health emergency related protocols.