National Institute of Environmental Health Sciences
Your Environment. Your Health.

IRB and Ethics of Disaster Research

Joan Packenham, Ph.D.

Director, Office of Research Compliance

Clinical Research Branch, Division of Intramural Research

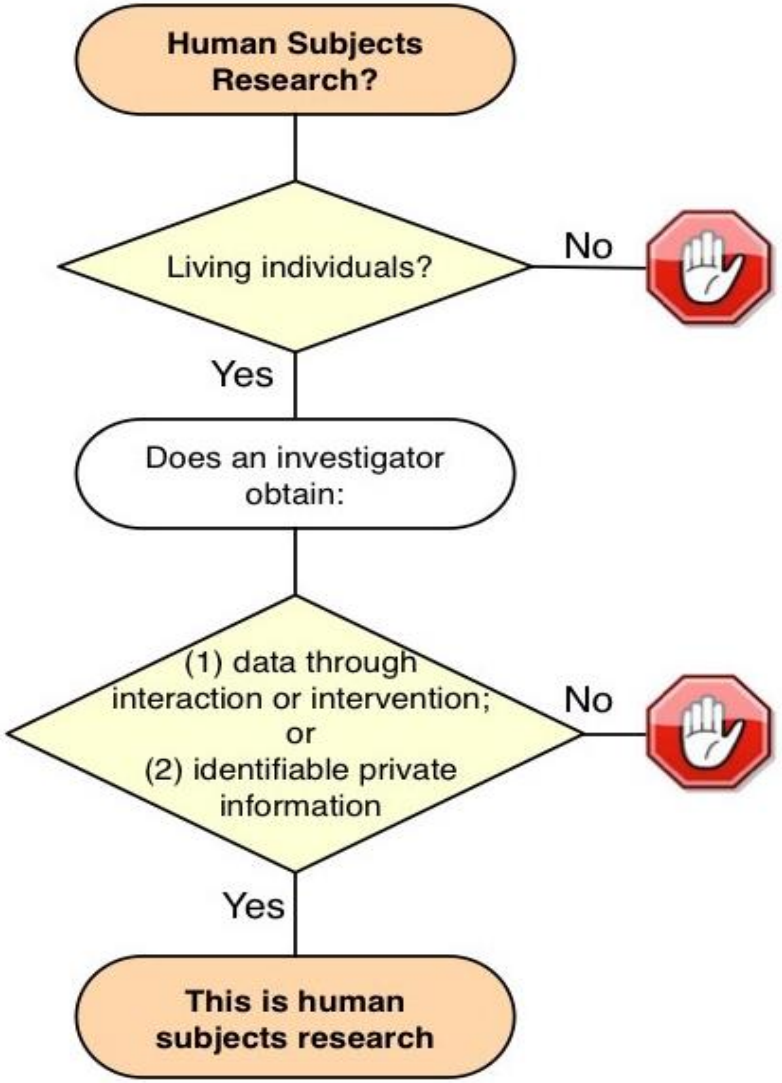
National Institute of Environmental Health Sciences

Human Subject means a living individual about whom an investigator conducting research obtains:

I. Data through intervention or interaction with an individual

II. Identifiable private information

Research is a systematic investigation designed to develop or contribute to generalizable knowledge.



Disasters and Ethics

Disasters demand the best science....FAST!

Need for time critical research

"Timely research is critical and needed after disasters to enhance the capabilities of preparedness and response thereby preventing injury, illness, disability, death and supporting recovery." - Lurie, Manolio, Patterson, Collins, Frieden. NEJM Mar 2013

- Is it safe and/or did our efforts help?
  - Physical and mental health impacts (acute and chronic)
  - Safety and efficacy of medical treatments
  - Risks of exposures and contamination
  - Efficacy of decontamination/clean-up
- Discovery of risk factors for recovery and resiliency including vulnerable populations
  - Pregnancy, children, lactating mothers
  - Elderly and those with pre-existing conditions
  - Communities with higher exposures

Disaster Research Conundrum

*"Disaster is often defined by **chaos**, and by the disruption or destruction of local social systems and organization….*

*…yet, both research and human subjects protection are often defined by an imposed framework of **order** based on social observation and interaction."*

(from David Abramson's slideset, "The Ethics of Disaster Research: IRB issues from a researcher's perspective" presented at Columbia University's IRB Annual Education Conference on April 24, 2007)

Independent Review – Institutional Review Board

- IRBs can play a key role as **gatekeepers** to the disaster research enterprise
- IRBs have the responsibility of **protecting** impacted populations from research-related harms

IRB Challenges in Disaster Research

- Lack of best practices/guidance
- **Not** business as usual
- Special considerations are needed in IRB review of disaster protocols
- Need collaboration between the IRB and investigators
- Interference in disaster response and provision of disaster aid
- Need for situational awareness to provide context
- participant and community vulnerability
- Realizing participant burden and/or research fatigue
- Lack of defined safety and training of the research team

What makes disaster research unique is the circumstances in which otherwise conventional methods are employed. Put differently, it is the context of research not the methods that makes disaster research unique." (R Stallings, 2002)

Special Considerations & Best Practices for IRB Review of Disaster Research Working Group

Purpose:

- Have an open and transparent dialogue of human research protection issues in the context of disaster research
- Identify recommendations that would be instrumental in preparing and guiding IRBs to efficiently review protocols related to public health emergencies and disasters

Outcome:

- Development of recommendations for IRBs who review public health emergency/disaster protocols

Working Group Recommendations

Categories of Recommendations:

- **IRB preparedness** for reviewing disaster related research
- **Participant vulnerability,** informed consent and research risks and benefits
- **Contextual understanding** of disaster specific factors, pre- and post-disaster local community and environment
- **IRB responsibilities** and review processes in relation to disaster research
- **Timely dissemination** of research results back to key stakeholders and participants

Brief Communication

A Section 508-conformant HTML version of this article is available at https://doi.org/10.1289/EHP2378.

Conducting Science in Disasters: Recommendations from the NIEHS Working Group for Special IRB Considerations in the Review of Disaster Related Research

Joan P. Packenham,[1] Richard T. Rosselli,[2] Steve K. Ramsey,[2] Holly A. Taylor,[3,4] Alice Fothergill,[5] Julia Shtasman,[6,7] and *Aubrey Miller[8]*

[1]Clinical Research Branch, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), Research Triangle Park, North Carolina, USA
[2]Social & Scientific Systems, Inc., Durham, North Carolina, USA
[3]Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA
[4]Johns Hopkins Berman Institute of Bioethics, Baltimore, Maryland, USA
[5]Department of Sociology, University of Vermont, Burlington, Vermont, USA
[6]Office of Research Regulatory Affairs, Children's National Medical Center, Silver Spring, Maryland, USA
[7]Department of Pediatrics, George Washington University, School of Medicine and Health Sciences, Washington, DC, USA
[8]Office of the Director, NIEHS, NIH, DHHS, Research Triangle Park, North Carolina, USA

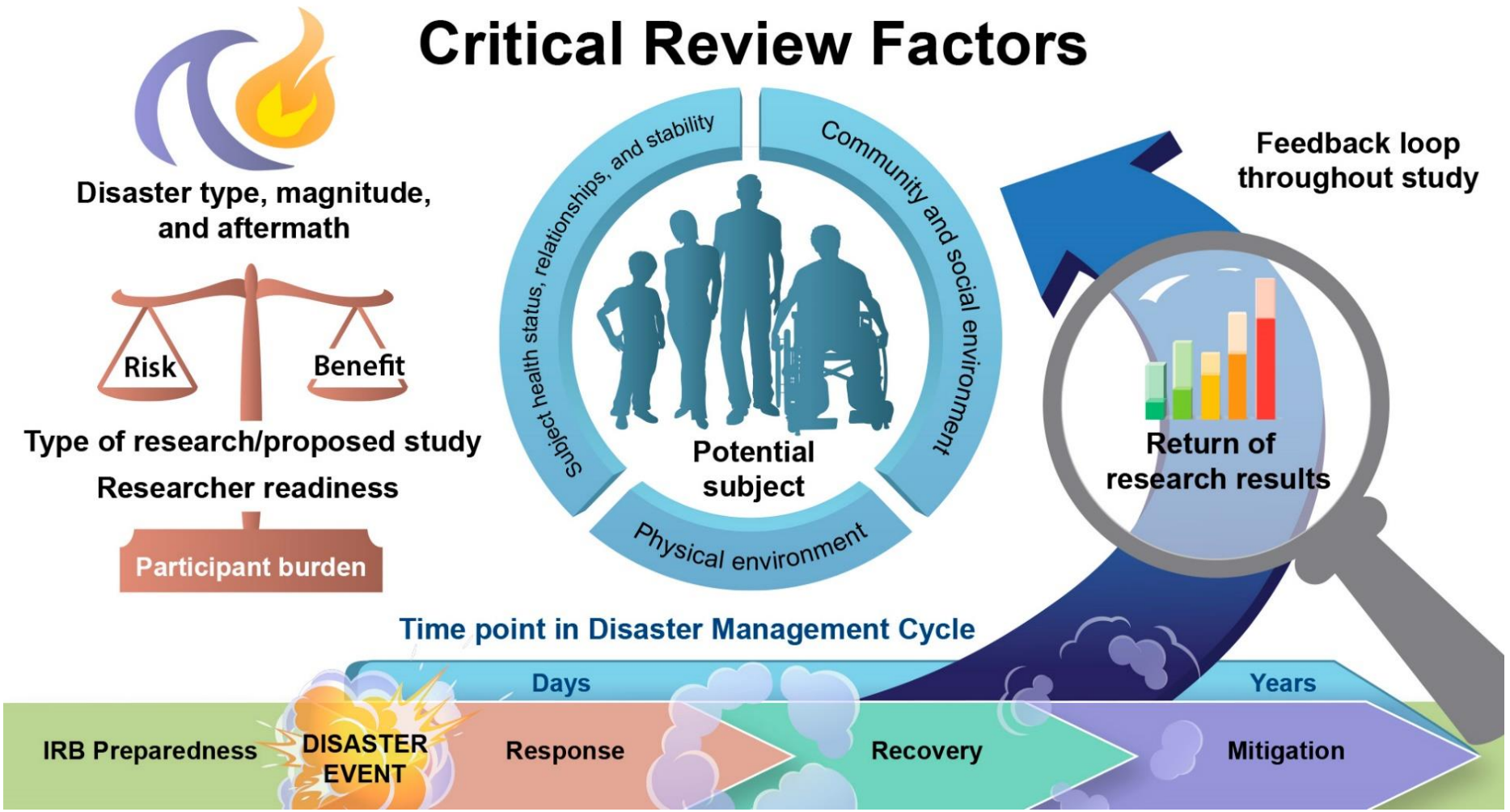
SUMMARY: Research involving human subjects after public health emergencies and disasters may pose ethical challenges. These challenges may include concerns about the vulnerability of prospective disaster research participants, increased research burden among disaster survivors approached by multiple research teams, and potentially reduced standards in the ethical review of research by institutional review boards (IRBs) due to the rush to enter the disaster field. The NIEHS Best Practices Working Group for Special IRB Considerations in the Review of Disaster Related Research was formed to identify and address ethical and regulatory challenges associated with the review of disaster research. The working group consists of a diverse collection of disaster research stakeholders across a broad spectrum of disciplines. The working group convened in July 2016 to identify recommendations that are instrumental in preparing IRBs to review protocols related to public health emergencies and disasters. The meeting included formative didactic presentations and facilitated breakout discussions using disaster related case studies. Major thematic elements from these discussions were collected and documented into 15 working group recommendations, summarized in this article, that address topics such as IRB disaster preparedness activities, informed consent, vulnerable populations, confidentiality, participant burden, disaster research response integration and training, IRB roles/responsibilities, community engagement, and dissemination of disaster research results. https://doi.org/10.1289/EHP2378

https://doi.org/10.1289/EHP2378

Establishing a DR2- National Institutional Review Board (IRB) Preparedness Program

- Developing and implementing **"IRB Best Practices and Ethical Considerations"**
- Developing the **"Disaster Research Critical Review Factors Model"**
- Developing, testing, and implementing **tools and resources**
- **Training IRBs and Investigators** in the use of the tools and preparedness strategies
- **Outreach and Engagement** to key stakeholders
- **Regulatory and ethical consultation** with investigators

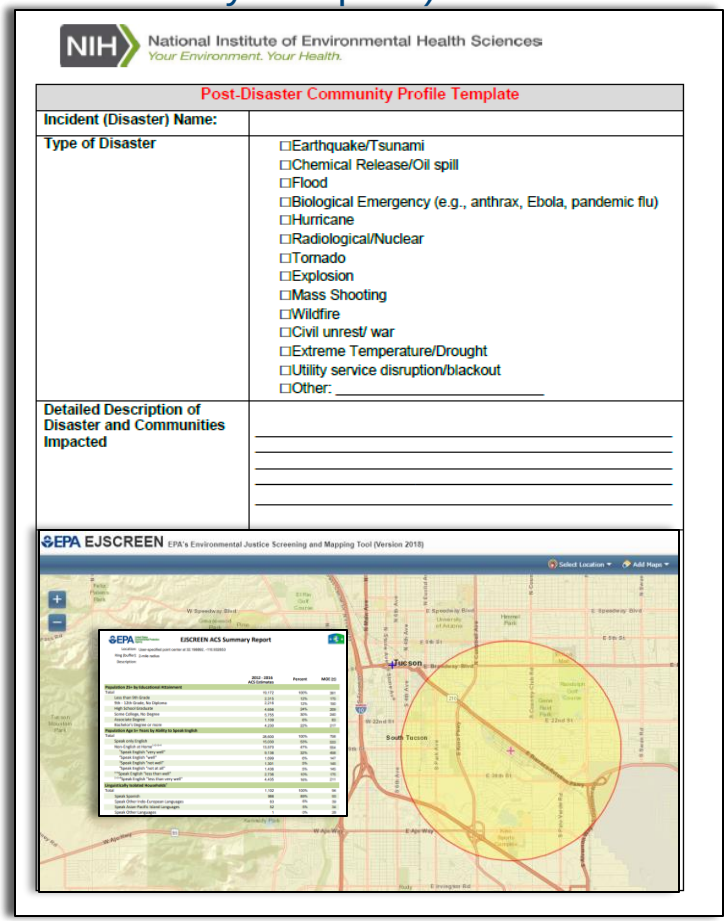
Disaster Research Review Considerations Continuum



Upcoming Manuscript: Current Environmental Health Reports: Packenham, et al
Institutional Review Board Preparedness for Disaster Research: A Practical Approach (Spring 2021)

IRB Tools for Review of Disaster Research Protocols

- PD-REACT (Post-Disaster Researcher Engagement Assessment and Community Template)



National Institute of Environmental Health Sciences
Your Environment. Your Health.

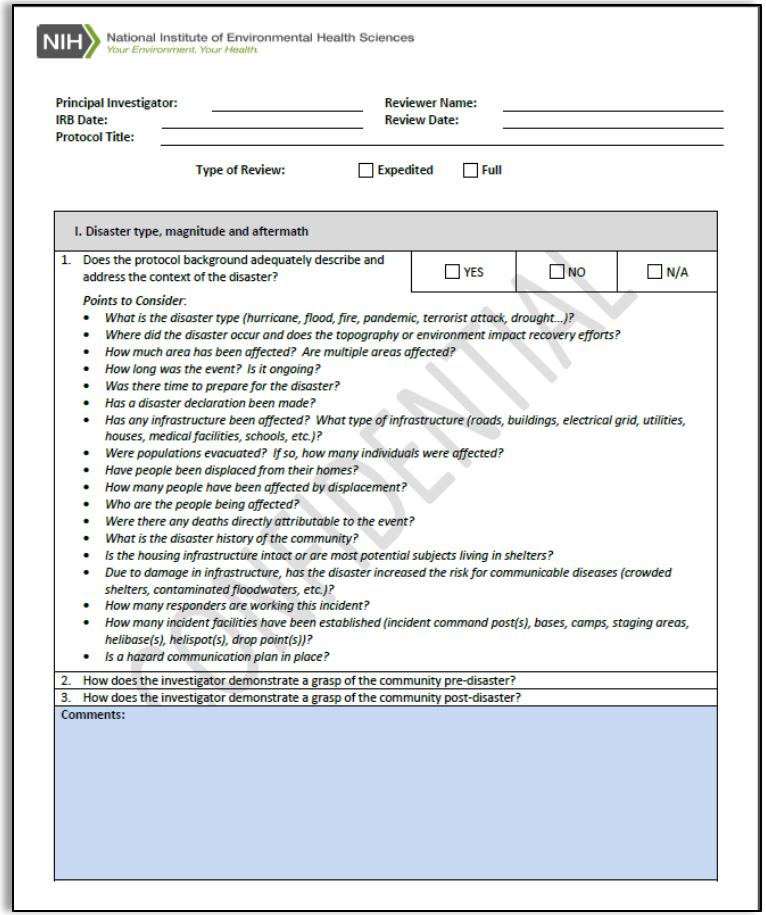
Post-Disaster Community Profile Template

Incident (Disaster) Name:	
Type of Disaster	☐Earthquake/Tsunami ☐Chemical Release/Oil spill ☐Flood ☐Biological Emergency (e.g., anthrax, Ebola, pandemic flu) ☐Hurricane ☐Radiological/Nuclear ☐Tornado ☐Explosion ☐Mass Shooting ☐Wildfire ☐Civil unrest/ war ☐Extreme Temperature/Drought ☐Utility service disruption/blackout ☐Other: _____
Detailed Description of Disaster and Communities Impacted	_____ _____ _____ _____ _____

EPA EJSCREEN EPA's Environmental Justice Screening and Mapping Tool (Version 2018)

EJSCREEN ACS Summary Report

- NIEHS Disaster Research Review Checklist



National Institute of Environmental Health Sciences
Your Environment. Your Health.

Principal Investigator: _____ **Reviewer Name:** _____
IRB Date: _____ **Review Date:** _____
Protocol Title: _____

Type of Review: ☐ Expedited ☐ Full

I. Disaster type, magnitude and aftermath			
1. Does the protocol background adequately describe and address the context of the disaster?	☐ YES	☐ NO	☐ N/A

Points to Consider:

- *What is the disaster type (hurricane, flood, fire, pandemic, terrorist attack, drought…)?*
- *Where did the disaster occur and does the topography or environment impact recovery efforts?*
- *How much area has been affected? Are multiple areas affected?*
- *How long was the event? Is it ongoing?*
- *Was there time to prepare for the disaster?*
- *Has a disaster declaration been made?*
- *Has any infrastructure been affected? What type of infrastructure (roads, buildings, electrical grid, utilities, houses, medical facilities, schools, etc.)?*
- *Were populations evacuated? If so, how many individuals were affected?*
- *Have people been displaced from their homes?*
- *How many people have been affected by displacement?*
- *Who are the people being affected?*
- *Were there any deaths directly attributable to the event?*
- *What is the disaster history of the community?*
- *Is the housing infrastructure intact or are most potential subjects living in shelters?*
- *Due to damage in infrastructure, has the disaster increased the risk for communicable diseases (crowded shelters, contaminated floodwaters, etc.)?*
- *How many responders are working this incident?*
- *How many incident facilities have been established (incident command post(s), bases, camps, staging areas, helibase(s), helispot(s), drop point(s))?*
- *Is a hazard communication plan in place?*

2. How does the investigator demonstrate a grasp of the community pre-disaster?
3. How does the investigator demonstrate a grasp of the community post-disaster?

Comments:

National Training Curriculum

"Our **REGULATIONS** provide a **FRAMEWORK** and contain the **MINIMAL REQUIREMENTS** to protect human subjects involved in research .

HUMANITY demands one to **GO ABOVE and BEYOND** the minimum to **ENSURE** adequate **PROTECTIONS** for human subjects and communities in the wake of disasters."

NIEHS Office of Human Research Compliance

NIH National Institutes of Health

Preparing for Disaster Research

IRB Preparedness and Regulatory Guidance

Who We Are

The NIH Disaster Research Response (DR2) Program is the national framework for research on the medical and public health aspects of disasters and public health emergencies.

The program is a collaborative effort between NIH's National Institute of Environmental Health Sciences (NIEHS) and the National Library of Medicine (NLM).

History

For more than 30 years, NIEHS has participated in national response and research efforts. The DR2 Program was formed to improve access to data collection tools, reduce administrative and regulatory barriers, and create a national network for disaster research coordination.

Resources provided by the DR2 Program empower disaster and public health researchers to carry out timely data collection during, and in the immediate aftermath of, disasters.

What We Do

Needs Assessment

Our goal is to increase IRB preparedness to review disaster-related protocols. Our team will help assess your organization's disaster research needs to improve IRB preparedness and processes for reviewing disaster-related research. This includes enhancing knowledge of best practices for disaster researchers to protect the rights and welfare of study participants.

Training

Using our disaster-related tools and resources, we will train your IRB, regulatory staff, and PIs to incorporate disaster-related review criteria in the assessment of disaster research protocols.

Timely research is critical following disasters. Is your IRB prepared?

For institutional review boards and disaster researchers, we provide:

- **Disaster expertise**
- **Curriculum-based training**
- **Regulatory guidance**

For more information about NIEHS, visit https://dr2.nlm.nih.gov.

For more information, contact:
DR2-IRBPREP@mail.nih.gov
https://dr2.nlm.nih.gov

March 2021

National Institute of Environmental Health Sciences
National Library of Medicine
National Institutes of Health
U.S. Department of Health and Human Services

♻ Printed on recycled paper

Is your IRB PREPARED?

For institutional review boards and disaster researchers, we provide:

- Disaster expertise
- Curriculum-based training
- Regulatory guidance

Contact Us:

- email: DR2-IRBPREP@mail.nih.gov

Thank You!

DR2-IRBPREP@mail.nih.gov