

# Ethics, Oversight and Conduct of Post-Disaster Research

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- “It’s completely different from anything you’ve ever done and it’s exactly the same as anything you’ve ever done.” (103)

# Plan

- Background
- Literature Review
- Preliminary Findings:
  - Institutional Review Boards (IRBs)
  - Principal Investigators (PIs)

# Background

- Growing literature on the incidence and prevalence of mental and behavioral health outcomes in the wake of a natural or man-made disaster

# Background

- Given the priority of meeting the immediate medical and mental health needs of survivors of and witnesses to disaster, when and how to conduct mental and behavioral health research with these populations is logistically and ethically challenging

# Pilot Project

- Specific Aim
  - Describe and consider the ethical challenges encountered by Institutional Review Boards (IRBs) and investigators reviewing and conducting post disaster mental and behavioral health research

**Funded by:** Preparedness and Emergency Research Center, Johns Hopkins Bloomberg School of Public Health

# Pilot Project

- Data Collection
  - Literature review
    - Sampling frame
  - In-depth interviews

# Literature Review

- Reviewed literature published between 2005-2012 relevant to the human subject research conducted in the US related to mental health, behavioral interventions after a manmade/natural disaster
- Search Terms
  - Domestic: US and Cities (e.g. Oklahoma City; New York City)
  - Disaster: types (e.g. hurricane, bombing); names (e.g. WTC; Katrina)
  - Mental health, behavioral interventions



# Literature Review

Results	Type of Article/Content	Number
Not eligible for inclusion	Conducted outside US, Literature review, Commentary	101
Not human subject research	Description of project/ program	87
Includes human subjects but not eligible	Chart review, Secondary data analysis	58
Eligible for inclusion	Prospective data collection, interaction with human subject	311
<b>Total</b>		<b>557</b>

# Literature Review

Disaster	Number (%)
World Trade Center	134 (43)
Katrina	131 (42)
Other Hurricanes	15 (5)
Oklahoma City	9 (3)
Virginia Tech	5 (2)
Wildfires	5 (2)
Other	13 (4)
<b>Total</b>	<b>311</b>

# Sampling Frame

- IRBs
  - Any IRB that had reviewed more than 3 protocols across disasters
    - 25 Institutions/Interviewed 8
- PIs
  - More than 2 publications from at least two different projects
    - 22 Eligible/Interviewed 9; 1 submitted responses

# Preliminary Findings: IRBs

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- Type of Review Conducted
- Concerns
- Challenges

# Preliminary Findings: Review

- Prior to IRB Review
  - Committee created to review prior to IRB review
  - Sub-committee of IRB, followed by Full Committee Review
- IRB Review
  - Full committee review for all Proposals
    - Mainstreamed once they gained experience
  - Mainstreamed/Routine Review
  - Prioritized

# Preliminary Findings: IRB Concerns

- Quality of Research Proposed
- Level of Harm to Which Subjects May Be Exposed
- Burden on Subjects
- Avoiding Confusion Between Research and Service
- Safety of Research Staff

# Preliminary Findings: Concerns

- Quality of Research Proposed
  - Inexperienced researchers attracted by funding opportunities
    - “Another thing to tell you is when you get the outpouring of funds from [Federal agencies] and various other places after a disaster, it brings people in who are not experienced with that kind of work. And so, what we found is there were more ways the research needed to be fixed. And the people just didn’t know the rules. For example, I remember a study where they wanted to interview children in one of these centers for the refugees and **then** go ask their parents if it was okay.” (1-05)



# Preliminary Findings: Challenges

- Speed Required
- Multiple Stakeholders
- Lack of Coordination among Institutions/IRBs
- Turf Battles with Affiliated Institutions
- Multi-site Research
- Value of Certificates of Confidentiality

# Preliminary Findings: Challenges

- Multiple Stakeholders
  - Employers/unions – when workplace involved
  - Law enforcement/legal system – when crime scene
  - Funders wanting access to raw data v. aggregate data

# Preliminary Findings: PIs

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- IRB Concerns
- Challenges
  - Procedural
  - Substantive
  - Unique

# Preliminary Findings: IRB Concerns

- Quality of Research Proposed
- Level of Harm to Which Subjects May Be Exposed
  - Appropriate Referrals in Place
  - Confidentiality Protections

All reported positive experience with IRBs (with exception of navigating multiple IRBs)

# Challenges: Procedural

- Funding
- Additional layers of review
- Lack of communication among Federal sponsors
- Access to populations

# Challenges: Substantive

- Availability of Appropriate Services
- Potential Vulnerability of Subjects

# Challenges: Unique

- Community-wide impact
- Local staff at local agencies overwhelmed
- Running into other study teams/agency staff in the field



# Challenges: Unique

- Community-wide impact
  - Population
    - Includes study team (v. coming from outside)
  - Infrastructure
    - Retention and follow-up of displaced subjects

# Challenges: Unique

- Local staff at local agencies overwhelmed
  - Managing their own personal/professional priorities post event
  - Hard to train them to adopt new interventions when managing multiple priorities
    - “...even if they had no personal loss, they complained about even just the daily hassles of the fact that the Target was – it’s only open until seven now, instead of nine; and the traffic was bad because the trees – trees still down and lights out; and those daily hassles were enormously wearing on them and their ability to be fully functioning.” (203)

# Challenges: Unique

- Running into other study teams/agency staff in the field
  - Confusion among subjects
    - “A lot of times they were medial service providers, social services providers. Occasionally they were research teams. It was definitely a problem for us in that our research team would be misidentified by he respondents, and then if – I tended to think we were operating at a very professional level. And so when some other study would promise something and not deliver, and then they would look at us and think we were a part of that.” (208)

# Summary

- Starting point to understanding perspectives on conduct of post disaster research
- Better prepared for next disaster