



DEPARTMENT OF HEALTH AND HOSPITALS

Addressing Institutional Review Board Barriers to Health Research Implementation: *Louisiana's Experience*

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Overview

- Selected disaster research proposals
- Major risks of disaster research
- Lessons learned
- Recommended proposal considerations

Major risks in disaster research

- Privacy issues
- Therapeutic misconceptions
- Community vulnerability
- Disconnection of displaced populations
- Stressing the health department system
- Good for science but not the community



Hurricane Katrina Refugees in Baton Rouge: Medical, Mental Health, and Community Services Needs Assessments During Immediate and Late Post-Hurricane and Other Disaster Periods (2005-2006)

- Evaluate rapid-needs assessments conducted by the state mental health services provider
- Completion of a questionnaire and case studies of 6000 Katrina evacuees
- No prior approval of protocol
- Consent forms were recorded
- IRB approval of study prior to publication



Validating a Group Treatment Protocol for Post Traumatic Stress Disorder (2008)

- **Examine efficacy of a group treatment protocol for PTSD in a community mental health sample**
- **Existing protocol modified for Hurricane Katrina survivors in Louisiana**
- **200 subjects receiving treatment in two community health centers**
- **One individual session and 14 weekly group sessions**



Multi-Systems Theory Relative to Stress Reduction in Substance-Abusing Adults Located in a Disaster-Prone Region (2009)

- Identify the most effective therapy model in stress reduction of substance-abusing adults in disaster regions
- Clients who entered addictive disorders clinic correlated to periods of natural disaster that occur in the region
- Population unknown at the time of IRB review
- Consent at time of treatment



Lifetime Adversity, the Oil Spill, and Reproductive Outcomes (2010 – 2014)

- Compare mental and physical health outcomes in women exposed in varying degrees to the Deepwater Horizon Disaster
- 1,800 woman from two affected communities
- Signed consent to interviews, blood and saliva samples
- Six exposures
- Four outcomes
- Five confounders



Lessons Learned

- **Participants can mistake certain types of research for clinical services.**
- **Therapeutic benefits of the participants are different from the purpose of the research.**
- **Investigators are responsible for assessing the individual decisional capacity and the effects of the research on participants.**
- **Ground-level program staff must be prepared to redirect researchers to the IRB.**
- **Community views represented in IRB review.**



Lessons Learned

- **Research or support staff should be trained to identify potential participants who are distressed and in need of aid.**
- **Plan care of researchers exposed to emotionally difficult situations.**
- **Monetary incentives may seem coercive.**
- **Pre-approval of the protocol and methodology expedites deployment of the study.**
- **Provisions for confidentiality and privacy should be an explicit part of the research plan.**



Recommendations for a Favorable Review

- Does the design make it easy to collect data immediately after the disaster occurs?
- Do the researchers contribute their time in relief efforts in addition to collecting data?
- Are the researchers prepared to convince disaster relief workers that the study is beneficial to the survivors in order to gain access to participants?
- Does the protocol account for continuing research and recruitment during and after the relocation of survivors?



Recommendations for a Favorable Review

- Will researchers ask participants for contact information to be shared from agencies as part of informed consent?
- What alternative resources will the researchers provide to participants?
- Do consent forms account for diversity in age, culture, and education?
- How will the researchers determine who may give consent for minors to participate?
- Has the community given consent?



Conclusion

- **Disaster takes us out of routine.**
- **Normal activities require additional oversight.**
- **The state IRB must employ additional measures to:**
 - **Ensure proper protections for public health consumers participating in post-disaster research.**
 - **Safeguard the ability of the department to maintain the standard operating level during catastrophic events.**

