**Did you know?** New Federal Mandate for Clinical Trial Billing to take effect January 1, 2014

Effective January 1, 2014, the Centers for Medicare & Medicaid Services (CMS) will require inclusion of the 8-digit National Clinical Trial Number (NCT) on claims associated with clinical trial participation. Clinical trial related claims submitted to Medicare for dates of services on or after January 1, 2014 will be returned to the provider if the 8-digit clinical trial number is not present.

The 8-digit NCT number is assigned to each trial registered in ClinicalTrials.gov. As mandated by federal law, applicable clinical trials must be registered with ClinicalTrials.gov by the responsible party. The responsible party being the sponsor of the clinical trial or the responsible principal investigator (PI) of such clinical trial.

According to FDAAA 801 requirements, an “applicable clinical trial” is defined as:

1. Trials of Drugs and Biologics: controlled clinical investigations, other than Phase 1 investigations, of a product of subject to FDA regulation.

2. Trials of Devices: Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post market surveillance.

If you have any questions, please contact the Office of Compliance & Quality at (573) 882-8957.
Conduct and Oversight of Research after a Natural/Man-Made Disaster

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Problem Statement
I have a standing interest in the ethical quality of institutional review board (IRB) review. I had the opportunity to conduct a pilot project regarding the conduct, review, and oversight of human subject research on mental/behavioral outcomes related to manmade and natural disasters. While there is a growing literature on the incidence and prevalence of mental and behavioral health outcomes in the wake of a natural or man-made disaster (Kelen and Sauer 2008; Smith et al 2009), there will unfortunately be additional opportunities to advance our understanding about the effect of disasters on individuals and communities (Pfefferbaum et al 2010). In addition, there are gaps in the current evidence base that ought to guide future research efforts to expand and deepen our understanding of post disaster effects (Collogan et al 2004; Pfefferbaum and North 2008). 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 (Fleishman and Wood 2002; Black 2003; Jacobsen and Landau 2003; Levine 2004; Rosenstien 2004; Pfefferbaum and North 2008). It is important for institutions and individuals considering or actively engaged in such research to be ready to review and approve the conduct of systematic data collection under these circumstances. My specific aim was to describe and consider the ethical challenges encountered by principal investigators and IRBs conducting and reviewing post disaster mental and behavioral health research. The overall goal of the project is to iteratively combine empirical and normative methods to identify key issues IRBs/PIs ought to consider in preparing for and reviewing proposals for the conduct of mental and behavioral health research among adults and children affected by a natural or manmade disaster. The ultimate goal of this effort is to determine whether these findings can contribute to considerations regarding the quality of the ethical review human subject research.

Description of the Research
Methods: With the help of a professional librarian, a systematic review of the literature was conducted to identify research reports published between 2005 and 2012 was conducted to identify a sample of IRB and PIs able to be key informants. Of the 557 research reports identified, 331 were identified as reports on research conducted in the US and involved the recruitment and direct engagement with human subjects. The majority of the publications reported on research conducted after the terrorist attacks on the World Trade Center (43%) or Hurricane Katrina (42%). The resulting list of institutions and investigators was sampled according to the volume of research they had conducted. In-depth interviews were then conducted with eligible and willing subjects. 8 informants affiliated with 25 of the eligible IRBs were interviewed and 9 informants among the 22 eligible investigators were sampled. All interviews were conducted over the phone, audio recorded and transcribed. Analysis of the data focused on the identification of themes and patterns among the themes identified.

Preliminary Findings: According to the IRB informant, IRBs adopt a range of models for the conduct of their review of post disaster research. Primary concerns among IRBs in their approach to the review of post disaster research include: the quality of research proposed; level of harm to which subjects may be exposed; burden on subjects, avoiding confusion between research and service and the safety of research staff. PIs report that IRBs are concerned with quality of research and the level of harm to which subjects are exposed. PIs report a range of procedural and substantive challenges in the conduct of post disaster research including: identifying funding sources, access to populations and securing appropriate referral options for subjects.

Limitations: The primary limitation of this research is that it is pilot in nature. While informational redundancy occurred among core themes some unique themes may have been confirmed with additional data collection. Next steps: The next step for this project (the results of which will be presented) will be to consider whether any of the findings, in combination with additional normative analysis ought to be considered as clear recommendations for IRBs and PIs to consider when reviewing or conducting post disaster research.

As Presented by PRIM&R at the 2013 Boston Advancing Research Conference, November 7-9, 2013 in Boston MA