Commentary: Is there a problem Consent in Escrow can solve?

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I welcome the opportunity to comment on Consent in Escrow by VanderLoos and her colleagues.1 The authors are correct in their premise that the conduct of human subject research after a natural or manmade disaster is ‘rife with... ethical, legal and policy challenges’.2 But I disagree with their conclusion that a revision to the process of informed consent used in the conduct of such research will overcome any of these challenges.

The authors’ introduction points out two of what I believe to be two of the three key barriers to the conduct of post-disaster research. First, they mention the challenge of conducting research in a setting where the basic health and social services infrastructure has been damaged or destroyed. The ethical conduct of human subject research in the wake of Hurricane Katrina for example was likely hindered by the lack of local health care providers of institutions with whom investigators could collaborate or to whom they could refer subjects in need of additional health or mental health care. Second, the authors mention the challenges researchers face when conducting time sensitive research in need of rapid review by an Institutional Review Board (IRB). In general, domestic IRBs have limited experience with or mechanisms in place to provide a quick review of research. This challenge is likely exacerbated when the disaster has struck a low resource region that has no mechanism in place for review and oversight of human subject research. Third, and not mentioned by the authors, is the lack of responsive, flexible funding mechanisms to support the conduct of time sensitive research in the wake of a natural disaster. Once a funding application is submitted, the standard review and funding cycle for a Federal grant is six to eight months.3 An investigator interested and capable of conducting research immediately after a disaster must seek alternative

1 Kiah I. Vander Loos et al., Consent in Escrow. J. LAW & BIOMED. 1, 10 (2014) DOI: 10.1093/jib/lsu031.
2 VanderLoos et al., supra note 2, at 2.
3 US National Institutes of Health, Standard Due Dates for Competing Applications, http://grants.nih.gov/grants/funding/submissionschedule.htm (accessed Apr. 20, 2015).
sources of funds, conduct the research in hopes of securing funds in the future, or enter the field many months after the acute phase of disaster and its immediate affects. While I believe that the authors and I are in agreement with the types of barriers mentioned above, I disagree that they separately or together lead one to conclude that the informed consent process ought to be the focus of our attention to encourage or facilitate the conduct of post-disaster research.

A couple of years ago I received a pilot grant to investigate the ethical issues encountered by the investigators conducting post-disaster mental and behavioral health research and the challenges encountered by IRBs responsible for the review of such research. In order to create a sample of key informants with experience in the conduct or oversight of human subject research after a disaster, I completed a systematic review of the literature to identify what types of mental and behavioral health research had been conducted and published in the wake of US-based man-made and natural disasters between 2005 and 2012. The goal of this literature review was to identify, based on the publications identified, the investigators and institutions familiar with the conduct and oversight of post-disaster research. The search terms included the types of man-made and natural disasters as well as common terms used in reference to previous disasters (eg Katrina, 9/11). Additional search terms were used to limit the output to research with human subjects related to mental and behavioral outcomes for individuals and communities affected by a disaster. A total of 557 articles were identified. Abstracts of all 557 articles were reviewed to determine which involved primary data collection from human subjects (see Fig. 1). The goal of this review was to create a sample of (1) investigators who had conducted human subject research post-disaster in the USA, and (2) as well as the institutions with which the investigators were affiliated to identify the relevant IRB leadership to conduct pilot in-depth interviews. Of the 577 abstracts identified and reviewed, 331 (59 per cent) met the criteria of research reports of primary data

Figure 1. Abstract Review Flow Chart.

4 Preparedness and Emergency Research Center (PERRC), Johns Hopkins Bloomberg School of Public Health. Ethical Challenges in the Conduct and Review of Post-Disaster Mental and Behavioral Health Research Dec. 1, 2011 to Aug. 31, 2012.

5 With technical assistance from Welch Medical Information Specialist Donna Hesson.
collection from human subjects in the wake of a manmade or natural disaster. The full manuscript of the 331 abstracts eligible for further review fell into seven categories by unique disaster or disaster type (see Table 1).

The bulk of the manuscripts report on epidemiologic investigations of mental health and behavioral status of those exposed to a specific disaster. As the vast majority of these reports were published in peer review journals, it is safe to assume that each project was reviewed and approved by an IRB and each subject provided informed consent prior to their participation. I believe that at least one conclusion from the results of this literature review is that many disaster mental and behavioral health investigators have successfully navigated the ethical, legal, and policy issues related to the conduct mental and behavioral health research in the wake of natural and man-made disasters. I will add that in my subsequent interviews, while both investigators and IRB leaders discussed the potential vulnerability of those approached to consider enrollment in research and whether special protections ought to be adopted, none of them suggested that obtaining informed consent was a particular challenge or barrier to the approval or conduct of research.

Related, I want to question the authors’ assumption that informed consent is a unique challenge in the post-disaster context because there is a ‘[r]easonable questionable ability to provide informed consent due to the stress associated with the acute situation’ and therefore requires the adoption of a novel consent procedure.6 As the authors note, attention to the potential vulnerability of those who experience or are exposed to a man-made or natural disaster has been recommended in the past;7,8,9,10

| Disaster                              | Number of abstracts | Percent of total |
|---------------------------------------|---------------------|------------------|
| World Trade Center                   | 134                 | 43%              |
| Hurricane Katrina                    | 131                 | 42%              |
| Other Hurricanes                     | 15                  | 5%               |
| Oklahoma City Federal Building*      | 9                   | 3%               |
| Virginia Tech Shooting*               | 5                   | 2%               |
| Wildfires                            | 5                   | 2%               |
| Other (each a different disaster)     | 13                  | 4%               |
| **Total**                             | **331**             | **100%**         |

*Review and oversight of research proposed to include the bombing of the Oklahoma City Federal Building and those affected by the shootings at Virginia Tech were coordinated by single committees.

6 Van der Loos et al., supra note 2, at 6.
7 Laura K. Collogan, Farris Tuma, & Alan R. Fleischman, Research with Victims of Disaster: Institutional Review Board Considerations, 26 IRB: ETHICS & HUM. RES. 4, 9 (2004).
8 Laura K. Collogan, et al., Ethical Issues Pertaining to Research in the Aftermath of Disaster, 17 J. TRAUMATIC STRESS 5, 363 (2004).
9 Carol Levine, The Concept of Vulnerability in Disaster Research, 17 J. TRAUMATIC STRESS 5, 39 (2004).
10 Donald L. Rosenstein, Decision-making Capacity and Disaster Research, 17 J. TRAUMATIC STRESS 5, 373 (2004).
one set of authors advocating that potential subjects of disaster research ought to be considered vulnerable class of subjects in need of additional protections.\textsuperscript{11} While investigators ought to be sensitive to the experience and situation of potential subjects, I disagree that they ought to be considered vulnerable—either that their competence or ability to provide voluntary consent is compromised—individually or as a group. The exception to this would be circumstances under which we decide the conduct of human subject research in the wake of a disaster would be impossible with survivors of a disaster who are gravely injured, have lost their home, livelihood and are grieving over family and friends. That is, under these circumstances at the very least, these individuals ought not to be approached to consider enrollment in research until their essential needs are met. In addition, I am unaware of any empirical research that indicates that the competence of an individual affected by a disaster is potentially compromised. It would seem unwarranted to adopt a novel approach to informed consent, as the authors propose, to address a problem for which there is no evidence. Empirical evidence has indicated that a small percentage of individuals asked to recall traumatic events in the context of post-disaster research project experience adverse reactions, none serious.\textsuperscript{12,13} While this evidence supports a requirement that appropriate referral mechanisms ought to be in place to support the small number of subjects who need follow-up, we ought not to equate risk of minor psychological harm as a proxy for lack of competence to provide informed consent.

Finally, the authors argue that ‘a model [of consent] that enables individuals to opt out of participating in a study to which they contributed under acute circumstances has not been broached’.\textsuperscript{14} I disagree. The Food and Drug Administration allows for such an option in the context of emergency research.\textsuperscript{15} These ‘Emergency Regulations’ require the investigator to provide research participants that survive the acute event that made them eligible for inclusion in research in absence of informed consent, the option to refuse to continue their participation. If the authors want to posit that the competence of some or all potential research subjects affected by a disaster is compromised, why not advocate for an extension on the regulations that already exist that allow for enrollment research in absence of informed consent? One reason may be that the research conducted in the emergency context has to meet criteria that participation may be in the best interest of a patient/subject with no or limited treatment options. There is very little evidence in the literature that any post-disaster research is designed to benefit the subject. The data collected is meant to inform best practices and adequate resource allocation when responding to future events (eg what percentage of those exposed may require access to short-term or long-term mental health interventions) and is unlikely to provide direct benefit to individual subjects. In addition, the authors note that

\begin{itemize}
\item \textsuperscript{11} Alan R. Fleischman & Emily B. Wood, Ethical Issues in Research Involving Victims of Terror, 79 J. URBAN HEALTH 3, 315 (2002).
\item \textsuperscript{12} Joseph A. Boscarino et al., Adverse Reactions Associated with Studying Persons Recently Exposed yo Mass Urban Disaster. 192 J NERVOUS & MENTAL DIS. 8, (2004).
\item \textsuperscript{13} Sandro Galea et al., Participant Reactions to Survey Research in the General Population After Terrorist Attacks, 18 J. TRAUMATIC STRESS 5, 461 (2005).
\item \textsuperscript{14} Van der Loos et al., supra note 2, at 7.
\item \textsuperscript{15} US Food and Drug Administration. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors Exception from Informed Consent Requirements for Emergency Research, \url{http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf} (accessed on Apr. 3, 2015).
\end{itemize}
consent in escrow, ‘cannot be applied to studies with an immediate health intervention or short-term goal’ (p. 9). It seems to me that this would be the best place to apply such an approach as there may be some potential direct benefit to the subject. On the other hand, the authors have failed, in my estimation to identify a clear problem that their proposal is meant to solve. I also don’t think that there is anything in the way of investigators choosing to adopt an informed consent process that meets the spirit of consent in escrow in absence of any regulatory change or mandate to do so. As the authors note, informed consent is a process and one could decide a tiered process as proposed is a respectful way to engage with subjects exposed to a disaster. Another option would be to test whether such a process improves understanding and/or subject satisfaction with the process prior to wide implementation.