Consent in escrow: opting to opt in

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ABSTRACT

In this paper, we reply to Taylor’s (2015) peer commentary on consent-in-escrow. Specifically, we clarify the utility of this novel approach, the way in which it minimizes risks to participants, and how it differs from existing opt-out methods. We further explore its potential use in fields beyond disaster research.

KEYWORDS: Disaster research, informed consent, refugee research, research ethics, vulnerable populations

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A disaster setting is a highly charged environment that, while profoundly affecting its victims, also provides opportunities for important research into mental and physiologic changes. Past findings from disaster research have led to improved strategies for managing post-traumatic stress disorder (PTSD), for example, and bolstered community responses to the management of both acute and long-term support needed for disaster victims, who often suffer from anxiety, depression, or PTSD.1,2 In Van der Loos et al. (2015), we proposed a two-tier model for consent that prioritizes the victim in the trauma-research setting. Consent in escrow builds on existing consent models; however, it requires that data collected in real time be held in escrow until the acute post-disaster window has closed and participants are recontacted for explicit release of their contributions.3 This affords a new, alternative approach to the protection of participants in research, alongside other prevailing methods.

We thank Taylor (2015) for her insightful response and commentary on consent in escrow. She raises important challenges for the proposed model, and we take the opportunity here to clarify the operationalization and rationale for proposing this novel approach.

**UTILITY**

Taylor (2015) questions the utility of a model in addressing an issue for which there is no evidence.4 While research may be limited in assessing the capacity of disaster victims to consent, and while Taylor explains that ‘none of them [investigators and IRB leaders] suggested that obtaining informed consent was a particular challenge or barrier to the approval or conduct of research’,5 we are not prioritizing the facilitation of study approval. Rather, the model offers a participant-centered approach to consent that aims to provide the highest level of protection for disaster victims who are especially vulnerable and at an increased risk of exploitation as research participants.6

**RISKS OF RECOLLECTION**

Taylor (2015) discusses evidence from studies suggesting that recollection of traumatic events can produce adverse reactions—likely minor—in research participants.7,8 We ask, why not minimize even this risk by providing participants a secondary opportunity to specifically allow or decline their original contributions to be part of a study? Despite the evidence showing that a limited percentage of subjects express negative feelings about completing surveys in the post-disaster setting,9 there is room for improvement,

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1 Bonnie L. Green & Jacob D. Lindy, *Post-Traumatic Stress Disorder in Victims of Disasters*, 17 PSYCHIATR. CLIN. NORTH AM. 303 (1994).
2 Bonnie L. Green, *Identifying Survivors at Risk: Trauma and Stressors Across Events*, in INTERNATIONAL HANDBOOK OF TRAUMATIC STRESS SYNDROMES (John P. Wilson & Beverley Raphael eds., 1993), at 135–44.
3 Kiah I. Van der Loos et al., *Consent in escrow*, 2 J. L & BIOSCI. 69–78 (2014).
4 Holly A. Taylor, *Commentary: Is There a Problem Consent in Escrow Can Solve?*, J. L & BIOSCI. 4 (2015).
5 Id. at 3.
6 John E. Jesus & Glen E. Michael, *Ethical Considerations of Research in Disaster-Stricken Populations*, 24 PREHOSP. & DISASTER MED. 109, 114 (2009).
7 Joseph A. Boscario et al., *Adverse Reactions Associated with Studying Persons Recently Exposed to Mass Urban Disaster*, 192 J. NERV. & MENT. DIS. 515 (2004).
8 Sandro Galea et al., *Participant Reactions to Survey Research in the General Population After Terrorist Attacks*, 18 J. TRAUMA STRESS 461, 465 (2005).
9 Boscario supra note 7.
especially as surveys are only one form of data collection. Informed consent signals an ongoing relationship between researchers and participants that is intended to be, and ought to be, renegotiated over time. Consent in escrow provides and emphasizes that responsibility and precisely offers the opportunity to fully respect the autonomy of research participants.

OPT OUT FROM STUDY CONTINUATION
Taylor (2015) highlights an existing model with the Food and Drug Administration that 'require[s] 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'. We would like to clarify that consent in escrow is different: research participants are empowered to choose whether their contributions are included in a research study after the post-disaster window has closed, rather than committing data collected immediately following a disaster to research, with the option to withdraw at a later timepoint. This is a critical feature of the model and to the participant-centered, opt-in approach offered. However, as with other traditional models, consent in escrow still allows participants to opt out from study continuation even after Tier II consent is obtained.

BEYOND THE DISASTER SETTING
Consent in escrow is already attracting attention for applicability beyond the field of disaster research. Its relevance extends to new clinical settings such as biobanking that currently uses registries for recontact, but adds to it by requiring secondary contact from the outset. It has also been discussed in the context of on-the-field concussion research during sporting events where data taken during an incident can have profound implications about an athlete’s return to play. Finally, this approach may well be an excellent model for research with refugees, whose initial participation in research is particularly sensitive with the major challenges of ‘obtaining genuinely informed consent […] and second, taking fully into account and responding to refugee participants’ capacities for autonomy’. The consent in escrow model also outlines procedures for cases in which the participant is deceased at time of Tier II contact.

We are not proposing that consent in escrow is a substitute for all consent procedures post-disaster, nor does the model dictate any particular method for gathering consent. Rather, consent in escrow complements existing models and can be adapted and operationalized in many different ways. We welcome opportunities for continued refinement and dialog on different strategies for the informed consent relationship in the multicomplex changing environment of research in the health sciences.

10 CANADIAN INSTITUTES OF HEALTH RESEARCH, NATURAL SCIENCES AND ENGINEERING RESEARCH COUNCIL OF CANADA, AND SOCIAL SCIENCES AND HUMANITIES RESEARCH COUNCIL OF CANADA, TRI-COUNCIL POLICY STATEMENT: ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS 31 (2014).
11 Taylor, supra note 4, at 4.
12 RICHARD E. GLIKLICH, NANCY A. DREYER & MICHELLE B. LEAVY, REGISTRIES FOR EVALUATING PATIENT OUTCOMES: A USER’S GUIDE (2014).
13 Catriona Mackenzie et al., Beyond ‘Do No Harm’: The Challenge of Constructing Ethical Relationships in Refugee Research, 20 J. REFUGEE STUD. 299 (2007).
14 Van der Loos, supra note 3, at 76.