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Using the IRB Harmonization and Reliance Document Can Reduce Review and Regulatory Delays for the Benefit of All

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In “IRB and Research Regulatory Delays Within the Military Health Care Setting: Do They Really Matter? And If So, Why and for Whom?,” Freed and colleagues (Freed et al. 2016) proposed four areas of improvement in attempts to resolve the structural and attitudinal challenges in military health research. The improvements proposed include (1) standardization of the institutional review board (IRB) processes and forms across the Department of Defense (DoD), (2) priorities for federally funded studies, (3) transparency of processes and collection of metrics, and (4) order and necessity of science reviews. The structural and systemic challenges described are not unique to DoD; they are long-standing in the research enterprise. For instance, although Lind (1992) wrote about the evolution of the IRB as an ethics committee, Edgar and Rothman (1995) called attention to problems with the use of IRBs, and to challenges to the ethics of human experimentation that can be expected in the future. In 1998, Moreno (1998) and the Department of Health and Human Services called for a reform of IRBs. Wolf et al. (2002) explored the challenges of IRB review and human subject protections in practice-based research. For multicenter clinical trials, medical innovations often call for interdependence of partnering institutions and university–industry connections (Gelijns and Their 2002). Nevertheless, the ethically challenging multicenter protocols often required multiple IRB reviews that were inconsistent in outcomes, and, at times, confusing, as different IRBs can reach different conclusions. Corbie-Smith and colleagues (1999) highlighted the importance of involving appropriate stakeholders to bring perspectives from scientific, research ethics, and participant communities to bear on IRB attempts to address the ethical challenges that they face. Furthermore, Menikoff (2010) noted that no evidence exists showing that multiple reviews of a single study make it safer, better, or more ethical. The point by Freed and colleagues (2016) that multiple reviews provide “the appearance of added benefit and the diffusion of responsibility were adverse events to occur” is well taken. Nevertheless, Christian and colleagues (2002) proposed a central IRB for multi-institutional trials, and Silberman and Khan (2011), who explored the IRB-imposed burdens on research, called for regulatory reform. Sirotin and colleagues (2010), however, showed how IRB chairs found resources that could address problems rather than settling for expanded guidance from the Office of Human Research Protections.

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To make arguments for reform, Freed and colleagues (2016) used two compelling cases. The observations conveyed in these instances “hit close to home” in that I currently serve as the chair of the Ethics and Regulatory Sub-committee of the Research Centers for Minority Institutions (RCMI) Translational Research Network (RTRN), a partnership of 18 institutions engaged in a cooperative network to reduce health disparities. I substantiate the authors’ proposal to resolve the quagmire they describe and share our experience that demonstrates how using IRB harmonization and reliance, when appropriately implemented, can reduce the IRB review burdens and the regulatory delays that slow scientific growth and lifesaving initiatives. I submit that their proposal for improvement can work, but only if the stakeholders are willing to work together to understand their policies on protection of human subjects and are flexible in changing policies and procedures that neither are useful in protecting those who volunteer for research nor serve, in a timely fashion, the needs of service members (Lo and Barnes 2011).

I agree with Freed and colleagues (2016) that such problems demand systemic and structural responses. They are correct in recommending that there be standardization of the IRB processes and forms across the DoD. There is concern that collaborative research involving minorities and underserved populations in multiple geographic regions often requires multiple IRB reviews, which stalls timely and effective conduct of such research. This led RTRN in 2009 to create and streamline the IRB review process to ensure compliance and enhance the quality of health disparities research by engaging community partners. Since institutional requirements and interpretation of ethical standards vary and make navigation cumbersome, the IRB harmonization initiative was directed at making the informed consent process and research protocol less complicated (Hammatt et al. 2011). If the uniformed services and the National Capital Region can develop and use an IRB Reliance Agreement Form, the administrative burden of submitting and reviewing forms that “contain similar information but are in different format” can be reduced (Freed et al. 2016). Still, all stakeholders must be involved in the design, development, and implementation of such a form.

To identify strategies addressing the complexity of multiple reviews across the RTRN consortium, the RTRN Ethics and Regulatory Subcommittee formed an IRB Harmonization Working Group in 2009. It was necessary to involve diverse stakeholders in the process, from conceptualization of the harmonization to its implementation. Thus, this group included community-based researchers, community faculty members, a physician, an attorney, and the IRB director. The Working Group members had expertise in IRB management, academic research, community engagement, clinical data services, and informatics. It was appropriate to seek and obtain institutional support from stakeholders at RCMI grantee institutions. The Working Group had meetings with institutional officials who had authority to review and sign agreements on behalf of the institution, those responsible for overseeing IRB activities, and other IRB administrators. Such meetings accelerated the pace of negotiations for the reliance agreement at each institution. As a strategy to promote interinstitutional IRB reliance, the RTRN Steering Committee approved use of a memorandum of understanding (MOU) among the 18 institutions. Meetings with individuals having decision-making authority within each institution were convened to understand the cultural context and discuss implementation of the MOU, how to monitor the IRB Reliance

Agreement after it is signed by the institutional official, and how to revise the Federal Wide Assurance to reflect each institution's potential reliance upon IRB reviews by other institutions. The elements of the agreement have been reported elsewhere (Hammatt et al. 2011). In sum, if properly applied to the military treatment context, these processes can engage the servicemen and -women, just as the diverse RTRN community was engaged, to identify what is important, mark the federally funded studies that are time sensitive, and prioritize them for action by the IRBs.

Freed and colleagues (2016) identified the need for transparency of the processes and the collection of metrics that can aid in understanding of the processes and in balancing the cost of doing research with the cost of reviewing research. I agree. Between 2009 and 2010, the RTRN Working Group on IRB Harmonization tested the foundation for a simplified IRB among its Small Grants Program grantee executing multisite projects. By 2014, a standard operating procedure and a reliance document form had been designed and were to be vetted by all parties concerned. An attempt at developing a standard informed consent that was examined by community partners for the RTRN consortium had been made, and plans were in place for data collection on RTRN-affiliated studies pre and post IRB harmonization to understand the impact of IRB harmonization on reducing administrative burden for investigators conducting joint project across the network (Hammatt et al. 2011). Education across the network was also relevant. In 2014, several IRB Café seminars were conducted for research investigators to showcase the resources available at each institution and to develop trust in the capacity of each IRB. By 2015, the Ethics and Regulatory Subcommittee of the RTRN had completed and ratified with RTRN senior administration the necessary documents that can assist investigators in multi-institutional collaborative work to reduce the IRB review burdens and the regulatory delays. This model, which streamlines research efforts and preserves local sociocultural aspects of human study participant ethics and respect, can be used by the military and others dedicated to improving human health through basic, clinical, translational, and community-engaged research (Hammatt et al. 2011).

Clearly, the systemic and structural challenges that the authors of this article have highlighted are serious enough to warrant attention, consideration, and resolution (Williams, Gaten, and Hagerty 2012). The authors assert that their "experience suggests that the actual IRB committees are not the main problem. Instead, the main problems are the bureaucracies flanking these committees" (Freed et al. 2016, 36). Perhaps the "bureaucracies" need to hear from those who would benefit from improvements to the system. Social justice demands that concerned people consider these observations and think "outside the box" to implement collaborative models sensitive to community beneficence for all research stakeholders. I conclude that in this venture there is no substitute for conversations that engage the IRB workforce and those who have regulatory and signatory authority as partners within the military. They must be encouraged to embrace the goals of science reviews within a reasonable time and to promote an effective and efficient system that enables service members to benefit from the care they need in order to fulfill their mission of protecting our country. For this task, the RTRN consortium has a template of experiences that can be usefully applied, as indicated in this commentary.

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