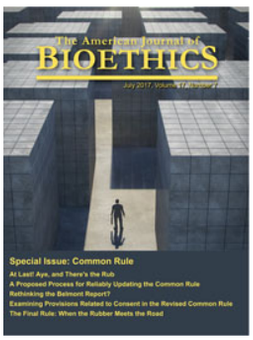

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The sIRB System: A Single Beacon of Progress in the Revised Common Rule?

Vasiliki Rahimzadeh, Edward S. Dove & Bartha Maria Knoppers

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The sIRB System: A Single Beacon of Progress in the Revised Common Rule?

Vasiliki Rahimzadeh, McGill University
Edward S. Dove, University of Edinburgh School of Law
Bartha Maria Knoppers, McGill University

While modifications to informed consent rules (e.g., recognition of broad consent and permitting secondary research on nonidentifiable biospecimens without additional informed consent) are key reforms of the Common Rule, perhaps the most significant modification from an organizational ethics and governance perspective is the mandated transition (with a few caveats aside) towards a single institutional review board (sIRB) system. Yet it is the least emphasized point in the target articles. We argue that this reform should be highlighted and applauded, as the move toward an sIRB system is an example of a historically contingent reform to science governance not unlike that which drafters of the original Common Rule accomplished.

The transition toward an sIRB system is a landmark move in the history of research ethics as an example of regulatory reformation evolving in parallel with advances in the science it seeks to govern. In their article, Berkman and colleagues (2017) convincingly argue that getting regulatory change right for an existing regulation can be more pressing than devising a new regulation given that institutional practices and policies rely on existing rules. The sIRB system, we believe, is in fact a mixture of both types of regulatory change: It represents a much-needed modification to a long-standing governance structure of research ethics review. It also represents a modification that carries with it a good deal of uncertainty in its innovation. Without a doubt, the existing IRB system is faulty (Schneider 2015; Klitzman 2015). We cannot as yet, however, point to any rigorous evidence that an sIRB system "will be significantly, not marginally better than the status quo"(Berkman et al. 2017, 11) at protecting human participants through robust, quality ethics review (though admittedly we believe it will be, especially in multisite data-intensive science). To use a research ethics analogy, we are in state of policy equipoise regarding the superiority of the proposed sIRB over the existing system as several

Address correspondence to Vasiliki Rahimzadeh, McGill University, Centre of Genomics and Policy, 740 Ave Dr. Penfield, Montreal, Quebec, H3A 0G1, Canada. E-mail: vasiliki.ra@mail.mcgill.ca

performance measures would need to be demonstrated. These include the ability of the sIRB to better protect research participants in a new era of collaborative, data-intensive research with distinct methodological approaches, to assess the social value or relevance of such research, and to assure the scientific design is both sound and respects local and/or national legislation. The regulatory shifts outlined in the Common Rule in many ways reflect a policy experiment that can be supported precisely because it is worth finding an improved alternative to what we, and others, consider a suboptimal status quo.

The revised Common Rule addresses a long-standing demand from stakeholders to reduce the procedural inefficiencies, redundancies, and delays that have become synonymous with research ethics review mechanisms under the extant system (Al-Shahi Salman et al. 2014); there is even some evidence to suggest that such mechanisms may be costing patient lives (Whitney and Schneider 2011). Despite the internationalization and data intensification of research, the same ethics review approach as applied to single-site biomedical studies often applies to multisite data-only studies. Because the jurisdiction of an IRB is limited to a single hospital, university, or clinic, multisite research projects have been subjected to multiple duplicative ethics reviews. Consequently, these redundant reviews have been known to unduly delay research and exhaust financial resources that should have been devoted to enhancing scientific knowledge on human health.

The sIRB system moves us some distance away from the problems just outlined. It may come as no surprise, however, that the language in the revised Common Rule is less prescriptive of how institutions are expected to operationalize the sIRB system and of the process for developing the interinstitutional policy architectures needed to support it. While certainly not a fatal regulatory flaw, this is nonetheless an omission that will require tremendous work down the line. The substantive and procedural complexities in working toward an sIRB system could require an additional 10 years without a common platform of procedural elements and practical guidance.

The absence of such a common platform motivated us, along with our international colleagues, to conceptualize three sIRB policy models (Table 1)—delegated, federated, and reciprocal (Dove et al. 2016)—and to draft an accompanying Ethics Review Recognition Policy for guiding their procedural implementation (Global Alliance for Genomics and Health 2017). We posit that a successful sIRB model that facilitates, rather than complicates, (inter) national collaboration in research embodies the following key elements: robust protection of research participants; preservation of the IRB's gatekeeping role for the duration of the study life cycle; integrity in the procedures and processes among all collaborating IRBs; and trust in the ethics review standards for processing, collecting, storing, sharing, and accessing research data (Dove et al. 2016).

The Ethics Review Recognition (ERR) Policy is chiefly aimed at facilitating ethics review for collaborative, multijurisdictional research involving health-related data. Its objectives are to foster mutual recognition of ethics review pursuant to an sIRB system, and to improve the consistency thereof by adopting equivalent procedural approaches. We propose that subscription to basic equivalent requirements among participating institutions in the sIRB system can inspire confidence in the quality of external ethics review. These equivalent requirements are particularly useful for United States-based researchers and collaborators within international consortia, insofar as they outline common procedural mechanisms that competent ethics review should entail. In this regard, they are meant to complement existing human rights instruments, conventions, and guidelines posed by extrajurisdictional ethics reviews.

Basic procedural elements of a sIRB system may include, but are not limited to, the following:

- Development of standardized interinstitutional policy tools (e.g., reciprocity agreements, reliance agreements, insurance policy riders, cost sharing, ad hoc REC member nomination) to manage the legal, organizational, and practical relationships between participating IRBs.
- Adequate human and material resourcing for IRBs.
- Relevant professional competence and expertise among IRB members, including for studies that involve vulnerable populations.
- Proportionate scrutiny of the review in accordance with the actual (rather than perceived) benefits and risks of the study.
- Harmonization of required forms to minimize administrative burdens.
- Transparency in making IRB operations, procedures, and decisions, if possible, publicly accessible.
- Ongoing research oversight for nonexempt research through annual IRB reporting and timely publication of study findings.

Reaching beyond merely enhancing the responsibility and credibility of the research enterprise, ethics reviews undertaken in light of the ERR Policy also facilitate the sharing of research data. Indeed, the sheer volume of data needed to make sound associations between, for example, the human genome and etiologies of disease substantiates a scientific imperative to share. The ethical permissibility of the research—justifying the informational risks that most, if not all such research poses with the benefits anticipated therefrom—rests on achieving these scientific endpoints. Data sharing has thus increasingly become a vehicle for fulfilling dual ethical and scientific imperatives in biomedical research. As a result, data sharing is already a condition of receiving research funds from some federal agencies (National Institutes of Health 2015). It is curious then that provisions on data sharing, including how IRBs can both manage and facilitate it (Thorogood and Knoppers 2017), were omitted in the revised Common Rule. We argue data sharing best fits under the ambit of transparency and preservation of scientific integrity, which many target articles rightly highlight as a missed opportunity for the Common Rule to pointedly address in its revision.

Table 1. Three models for building ethics review mutual recognition for data-intensive international research.

RECIPROCITY

An institution, funder, or regulator/government in one jurisdiction accepts the completed ethics review from another jurisdiction and vice versa through collaborative recognition of equivalent processes and/or standards

Advantages	Disadvantages	Example projects
• Helps build agreement on research participant protections while respecting local context • Flexibility with review standards Potentially time saving once a decision on equivalence is reached, if applied to a whole class of projects	• Some research ethics committee (REC) system inefficiencies remain (e.g., inconsistent or incompatible opinions) • Challenge in defining whose protections are "best" Time-consuming at the initial implementation stage	• Human Heredity and Health in Africa (H3Africa): shared ethics consultation meetings to build trust and REC alignment • International Cancer Genome Consortium (ICGC): development of ethics review policies • Personalized Risk Stratification for Prevention and Early Detection of Breast Cancer (PERSPECTIVE): customized tools and agreements approved by each institution

DELEGATION

Before review, an institution, funder, or regulator/government delegates ethics review responsibilities to one or several existing designated RECs through agreement

Advantages	Disadvantages	Example projects
• Reduces the potential for inconsistency • Researchers can channel energy and resources into one or a few RECs • Increased possibility for specific areas of ethics expertise in the designated REC(s)	• Challenge in determining how a REC is chosen • Challenge in determining how post approval activities will be handled • All-or-nothing outcome of review; no room for alternative reviews	• ICGC: agreements signed between ministries of health

FEDERATION

Institutions, funders, or regulators/governments create a central REC with representation from multiple jurisdictions

Advantages	Disadvantages	Example projects
• Reduces costs and duplication of efforts Reduces inconsistency in REC review • Drives improved standards across sites by encouraging a "herd instinct"	• Challenge in developing REC structure and process • Challenge in balancing cultural representation, power differences, or local priorities • Challenge in getting several jurisdictions to agree on policy and standards	• Indiana University–Moi University (IU- Moi): proposed REC with members of each institution • Maternal Infant Child Youth Research Network (MICRYN): federated pediatric REC across Canada

Note. Used with permission from *Science*.

We put forward the ERR Policy (and soon, more detailed "Practical Guidance" on implementation) to fill a gap in the meso-level governance strategies useful for operationalizing the sIRB system at the interinstitutional level—a system that so many researchers, institutions, patient groups, and IRB members advocated in their insightful comments over the past several years. A transition from policy theory to policy action that the Common Rule pledges for the sIRB system is a beacon of progress in the United States. It is likewise an important policy experiment for international regulatory bodies that have recently enacted similar reforms (Rahimzadeh and Knoppers 2016), or that plan to do so in the future. In addition, the proposed change opens the door for future public policy research and the development of metrics and quality indicators for IRB performance, and enables empirical evaluation of review processes pre and post sIRB codification.

The regulatory move toward an sIRB system is certainly a relief from the procedural throes that have, according to many, fallen short of improving participant protections. This is especially true for research participation in the data-intensive sciences like genetics and genomics. The only marked disappointment is that such a system was not implemented sooner.

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ORCID

Vasiliki Rahimzadeh http://orcid.org/0000-0003-3537-7601

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Common Rule Revised: Opportunities Lost

Liza Dawson, National Institutes of Health

The Common Rule was revised and released in 2017 after several years of regulatory machinations. There was a consensus that the Common Rule, while embodying key ethical principles that are critical to the oversight of human research, had become outdated, as the research landscape had changed dramatically over its 25-year tenure, and that revisions were overdue (Emanuel and Menikoff 2011). However, there was no agreement on the precise nature of changes needed, and notice and public comments processes yielded a variety of views. The discussions over the proposed revisions did not help address the true weaknesses in the rule that required significant change. Three

Address correspondence to Liza Dawson, PhD, Division of AIDS, NIAID/NIH/DHHS, 5601 Fisher's Lane Room 9G59, Bethesda, MD 20892, USA. E-mail: dawsonl@niaid.nih.gov