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Fostering IRB Collaboration for Review of International Research

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Abstract

This paper presents a review of the literature, summarizes current initiatives, and provides a heuristic for assessing the effectiveness of a range of IRB collaborative strategies that can reduce the regulatory burden of ethics review while ensuring protection of human subjects, with a particular focus on international research. Broad adoption of IRB collaborative strategies will reduce regulatory burdens posed by overlapping oversight mechanisms and has the potential to enhance human subjects protections.

Keywords

Institutional Review Board; Research Ethics Board; International research; Multinational research; Research partnership

Agencies in the United States and elsewhere have begun to emphasize the importance of streamlining ethics review in order to facilitate research (OHRP et al. 2005; FDA 2006; OHRP et al. 2006; Philippine Council for Health Research and Development 2006; College of Public Health Sciences and the Ethics Review Committee for Research Involving Human Research Subjects, Health Sciences Group, Chulalongkorn University 2010; Pittman 2006; Cave & Holm 2002; Al-Shahi 2005). In its July 2011 Advanced Notice of Proposed Rulemaking (ANPRM), the Department of Health and Human Services (DHHS) identified a streamlined approach to multisite review as both desirable and necessary to avoid duplication of effort and eliminate unnecessary delay (DHHS 2011; Emanuel and Menikoff 2011). The ANPRM calls for domestic, multi-site studies to have a single Institutional Review Board (IRB) of record; additional reviews by other participating sites, while not discouraged, would not be required for regulatory compliance. The ANPRM stipulates that

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this requirement would not apply to multinational research, largely because of the indispensable and widely accepted need for host-country input.

Not surprisingly, comments on the proposed policy suggest that many IRBs find the notion of a single IRB of record unacceptable, for many reasons (Bartlett 2012). Our purpose here is not to review and comment on the strengths and weaknesses of this proposal. In this paper, we use multinational research – which involves US researchers performing studies abroad – as a point of departure to examine mechanisms for collaborative IRB review. Such mechanisms can streamline IRB reviews for international studies, and may offer insights for an alternative approach to IRB review for purely domestic multisite research, as well. To shed light on these mechanisms, we review the relevant literature in order to identify the main problems arising in the course of IRB review of multinational research and summarize current initiatives both for purely domestic as well as international collaboration, and then we propose a heuristic that may be of use for assessing the effectiveness of a range of IRB collaborative strategies for addressing the identified problems, the goals of which are to reduce the regulatory burden of ethics review while enhancing the protection of human subjects.

Challenges that arise when protocols must satisfy the requirements and expectations of ethics review bodies in different countries have been extensively documented (Nuffield Council on Bioethics 1999; NBAC 2001; Glickman et al. 2009; Ravinetto et al. 2011). These challenges, which can delay and at times derail potentially beneficial research, can be categorized into five broad areas: 1) lack of expertise; 2) procedural challenges; 3) limited review capacities; 4) differences in review criteria; and 5) lack of trust.

Regardless of where they are located, IRBs have specific competencies (and incompetencies) based on resident expertise and research experiences. In general, US-based IRBs frequently fail to recognize differences between western norms and values and those of other countries and, as a result, do not appreciate the impact that these differences can have on how a protocol will be reviewed and how the research would be carried out in a different environment (London 2002; Macklin 2001). IRBs in developing countries may not have ready access to the scientific expertise needed to evaluate the risks and potential benefits of cutting-edge research, and may be highly dependent – expressly or implicitly -- upon US IRBs and scientific peer reviews to weigh in on such matters. In the end, protocols with study aims or consent and recruitment procedures that are insensitive to local culture or that fall outside national research agendas may be tabled or not approved by the local ethics review despite compliance with US regulatory requirements (White 1999; London 2002; Gilman and Garcia 2004; Dawson and Kass 2005; Dowdy 2006; Wahlberg et al. 2013). Complex protocols that are ethically sound but scientifically complex may require lengthy exchanges between a host-country IRB and the investigators before receiving the necessary approvals.

As shown by the increase in number of collaborative relationships (Table), US IRBs are finding ways to work together. However, consensus on procedural guidelines addressing what reviews are necessary, the order in which required reviews take place, and the process by which conflicting IRB determinations will be harmonized is generally missing in

multinational reviews. In international settings, procedural challenges attributed to differing regulatory environments, difficulties accessing investigators to respond to ethics committee queries, and the lack of open channels of communication across reviewing IRBs to support resolution of minor issues can frequently result in significant delays (Nuffield Council on Bioethics 1999; Gilman and Garcia 2004; Musil et al. 2004; Rennie 2011).

Another area of difficulty arises from the often-huge disparity between ethical review "systems" themselves. Northern governments and research institutions have invested heavily in operational resources and professional staff trained in research ethics in support of IRBs. Despite significant international efforts to increase ethics capacity in Southern countries, ethics review systems in much of the world remain understaffed and under-resourced (Kass et al. 2007). Although highly professional ethics review processes operate in a number of developing countries, South Africa being one notable example, many northern IRBs have adopted a paternalistic approach, remaining unaware of local review capacities and loathe to defer any aspect of review to their counterparts in the developing world (Gilman and Garcia 2004).

Differences in review criteria and institutional goals can also impede the review of international protocols and increase the difficulties researchers confront in securing approvals. While most US-based IRBs base their reviews primarily on the Common Rule (DHHS 2012), FDA regulations (FDA 2012) and to a certain extent the ICH Guideline for Good Clinical Practice (ICH 1999), many IRBs in other parts of the world rely on other guidance documents, particularly the Declaration of Helsinki (WMA 2008) and the CIOMS Guidelines (CIOMS 2002; Macklin 2001; Wahlberg et al. 2013). Where US reviewers focus their attention on issues relating to autonomy, beneficence and nonmaleficence, non-US reviewers may be more concerned with issues of justice, protection of the vulnerable, standards of care, and post-trial access to benefits (Hyder et al. 2004). Adding further complexity, IRB functions in some countries reside in national research and development committees charged with the dual and potentially conflicting responsibilities of ensuring human subjects protections and promoting national research priorities (Kirigia et al. 2005).

In the current international research environment in which multiple IRBs act for the most part independently, with little understanding of each other's activities, there is little room for task-sharing, reliance on each other's expertise in particular areas of review, or guidance to researchers on how to navigate the review maze. This is fertile terrain for mistrust on both sides. US IRBs assume that host-country IRBs are unable to conduct adequate reviews, and the latter are skeptical that US IRBs will be sensitive to their national concerns or place the needs of a local population above the imperatives of the US research enterprise (Klitzman 2012).

A solution to many of these challenges resides in the willingness of institutions, and by extension their IRBs, to work collaboratively. Greater IRB collaboration is supported by various international guidelines. UNESCO (2005) and the World Health Organization (WHO 2000) encourage harmonized review procedures. CIOMS goes further, recommending that either review responsibilities be allocated amongst involved IRBs, entire review responsibility be deferred to one IRB by consensus, or that single review committees

including representatives from each involved institution be created (CIOMS 2002). Inherent in all of these approaches is the potential for capacity-building. US-based IRBs can develop a better appreciation of host-country development and health priorities, cultural norms, and research settings, and host-country IRBs can directly garner knowledge regarding ethical review requirements and scientific methods and procedures (Ravinetto et al. 2011).

A number of mechanisms for multi-site ethics review have been proposed or implemented, mostly in the United States. These mechanisms appear in Table 1 as a continuum ranging from no collaboration to full shared review responsibilities. IRBs may work more closely together both for single reviews of large studies as well as for large shared research portfolios that are part of established long-term institutional partnerships. These mechanisms, which we recommend here for their ability to streamline and improve multinational research, will also contribute to more efficient and effective review in purely domestic collaborations. As shown in Table 1, purely domestic IRB collaborations are in place, and provide models on which other partnerships, domestic and multi-national, can be based.

In Figure 1, we graphically present a framework for examining how directly and effectively each class of collaborative mechanism would address the specific challenges discussed above. In order to demonstrate how this framework might be employed, we include our subjective evaluations of the extent to which each of the identified collaborative mechanisms addresses the identified barriers, given the limitation that we are not examining any particular proposal. For example, the current system of independent reviews really fails to address these challenges (and, indeed, that's why they have been identified as challenges in the literature reviewed above); we believe issues about regulatory compliance and expertise are partially addressed, in that iterative reviews by involved IRBs may provide education as a by-product, since each IRB may be exposed to requested changes made by others. On the other end of the spectrum, a joint review, involving members of 2 (or more) institutional IRBs involved in research, offers the opportunity for open discussion of standards, concerns, and values that, to our thinking, directly address all of the challenges, with the possible exception of differences in review criteria that may not be subject to negotiation.

Likewise, shared information systems for managing protocols and opening other channels for direct IRB communications can help collaborating IRBs understand how they each work, what regulations and other sets of rules and norms they apply in making decisions, in what resources and expertise they bring to bear in making decisions, and making clear how review priority and potential conflicts are resolved. These mechanisms are a move toward transparency, but because much of the learning is indirect, secondary to actual processes and decisions being made by each IRB, we consider these to only partially address those challenges. In our judgment, as we move to more active collaboration, such as with involvement of consultants with in-country or specific research expertise, or assignment to each IRB of the roles for which they are most adept, the collaboration will more directly address the shortcomings that beset the current system.

Our evaluations may serve as a starting point for others undertaking their own assessment. No one mechanism will best suit the particularities of all multi-site research. Consideration of such mechanisms by institutions seeking to collaborate and establish IRB partnerships should address their particular needs, skills, experiences and circumstances, such as the availability of computing and communication technologies, time differences, language barriers, and the like, and make their own context-specific evaluations of the merits of available alternatives.

Critically, many of these mechanisms are new, and few have been fully evaluated. There is a clear need for increased assessment of existing and conceptual collaborative review strategies, including those in current use for review of multinational research. Ongoing evaluation should also be incorporated in future partnerships. Feedback on effectiveness as well as procedural or technical limitations will help IRBs, institutions and regulators assess how well these strategies address the challenges of multinational ethics review.

A one-size-fits-all solution to streamlined ethics review of research will not work. IRB collaboration that addresses the particularities of relationships, context, and complexity will. Open communication about challenges and capacities, combined with due consideration of what may work for any given situation, is a critical first step. A collaborative approach to strengthening ethics review of international research is essential if the global research enterprise is to build the inter-institutional, inter-IRB trust necessary to increase efficiency, satisfy regulatory requirements, and meet research objectives without sacrificing human subject safety or ignoring local norms and priorities.

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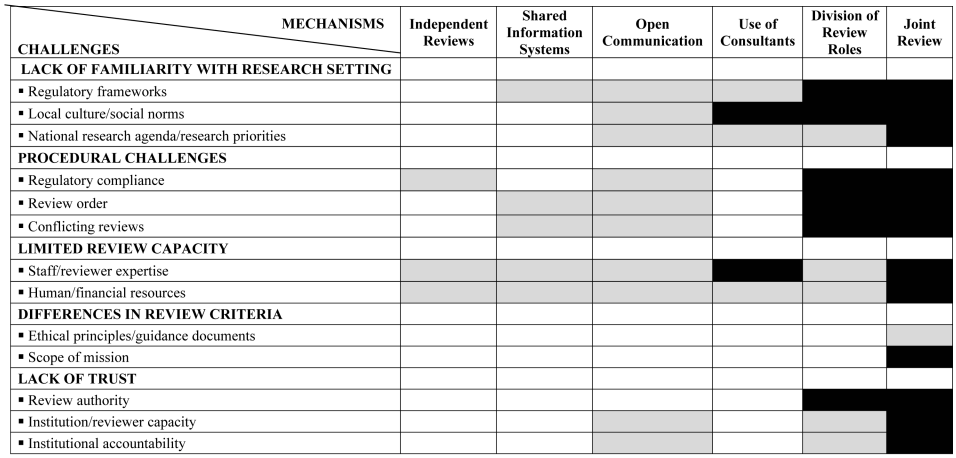

CHALLENGES \ MECHANISMS	Independent Reviews	Shared Information Systems	Open Communication	Use of Consultants	Division of Review Roles	Joint Review
LACK OF FAMILIARITY WITH RESEARCH SETTING						
▪ Regulatory frameworks						
▪ Local culture/social norms						
▪ National research agenda/research priorities						
PROCEDURAL CHALLENGES						
▪ Regulatory compliance						
▪ Review order						
▪ Conflicting reviews						
LIMITED REVIEW CAPACITY						
▪ Staff/reviewer expertise						
▪ Human/financial resources						
DIFFERENCES IN REVIEW CRITERIA						
▪ Ethical principles/guidance documents						
▪ Scope of mission						
LACK OF TRUST						
▪ Review authority						
▪ Institution/reviewer capacity						
▪ Institutional accountability						

Key: Blank = Does not address challenge; Grey = Partially addresses challenge; Black = Fully addresses challenge

Figure 1. Extent to Which Collaborative Mechanisms Address Challenges in Review of International Research

This figure displays a heuristic method for considering the extent to which the collaborative mechanisms available for IRBs to work together address the array of challenges raised in the review of international research. Every method may help IRBs improve, but we posit that certain methods more directly address the challenges, as suggested by the darker shading of the intersecting boxes.

Table 1

Continuum of IRB Collaborative Mechanisms

Mechanisms	Characteristics of Mechanism	Examples
Independent Reviews	▪ Each IRB conducts own review ▪ Investigator generally serves as the primary contact point for all IRB communications	
Shared Information Systems	▪ Standardized application forms (e.g. a single application that can be submitted to multiple IRBs) ▪ Shared access to review documents ▪ Shared electronic submission systems	▪ Research Centers in Minority Institutions Translational Research Network (RTRN) IRB Harmonization Working Group (Hammatt et al. 2011); ▪ Union College–Tbilisi State Medical University Collaboration (RePORT 2012a); ▪ IRBNet (2012). ▪ IRBShare (2012).
Open Communication	▪ Communication across IRBs (staff) ▪ Communication across IRB members ▪ Designated contacts for questions across IRBs	▪ RTRN IRB Harmonization Working Group (Hammatt et al. 2011); ▪ Mapping African Research Ethics Capacity (MARC) (Ijsselmuiden et al. 2012).
Availability of Consultants for Review	▪ Designated consultants to fill knowledge gaps (e.g. scientific, regulatory, experience with the local setting, etc).	
Division of Roles/Facilitated Review	▪ IRBs divide review tasks and inform each others' reviews ▪ Timing and order of IRB reviews is specified ▪ The review of another IRB may be used to inform subsequent reviews ▪ The primary review is done by one IRB,a preserving an opportunity for input from the local IRB before the review is finalized ▪ In the limit, IRBs may fully rely on the judgments of another (e.g., IRB of record)	▪ NCI Central IRB (Christian et al.a 2002; NIH et al. 2005); ▪ IRB Share (Davis 2011); ▪ Multicenter Academic Clinical Research Organization (MACRO) (McNeil 2007); ▪ Optional use of commercial IRBs, e.g. WIRB; ▪ Institutional authorization agreements (per protocol or for multiple protocols) (NIH et al. 2005).
Joint Review/Combined IRB	▪ Members of multiple IRBs form a joint review committee ▪ Regional IRBs are formed, comprised of members from multiple IRBs	▪ University of Minnesota Collaborative IRB (Vegoe 2012); ▪ Michigan State University Community Research IRB (McNeil 2007); ▪ Dartmouth-MUHAS Joint IRB(AITRP 2012); ▪ Indiana University-Moi University Joint IRB (RePORT 2012b); ▪ Biomedical Research Alliance of New York (BRANY 2012); ▪ Regional Ethics Committees (Wood et al. 2004).