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Partnering to Harmonize IRBs for Community-Engaged Research to Reduce Health Disparities

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Abstract

Emerging advances in health disparities research include controlled trials and comparative effectiveness studies that are frequently conducted at multiple community and academic sites. Review by different institutional review boards (IRBs) presents a major impediment to the timely and effective conduct of such research. When research involves minority and underserved communities as well as multiple geographic regions, institutional requirements and interpretation of ethical standards may vary substantially. Such variations can complicate the informed consent process and research protocol, and may undermine participant respect and trial quality. In addition, multiple IRB review can lead to unnecessary delays, jeopardizing funding and capacity to perform collaborative projects. In response to these issues, the Research Centers in Minority Institutions (RCMI) Translational Research Network (RTRN) is developing a community-partnered approach to streamlining IRB review across its consortium of 18 RCMI grantee institutions that will ensure compliance while enhancing the quality of health disparities research.

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Community-academic partnerships; institutional review boards; reliance agreement; health disparities

Research with meaningful community-academic partnerships is an emerging discipline critical to improving patient outcomes. This is particularly important in minority and underserved communities, where community participation in protocol development plays a vital role in helping ensure the ethical conduct of research. Multi-institutional studies often involve redundant review by institutional review boards (IRBs), which can lead to delays in study implementation without necessarily increasing protection of human participants.¹ Review by IRBs is further complicated with collaborative studies across states and geographic regions. Centralizing the IRB process has been proposed to reduce variability, delays, and duplication of effort,^{2,3} and to allow national-level discussion of difficult ethical issues⁴ and “moral consistency,”⁵ but may not truly address local ethical and cultural issues when geographically diverse communities of study participants are targeted for research studies.

Several research networks have initiated “harmonization” projects among collaborating institutions as a way to reduce redundant IRB review. *IRB harmonization* can be defined as activities aimed at reducing regulatory and administration burdens through the implementation of various policies and procedures of integrated IRB review among institutions that frequently conduct multi-institutional studies, including community-engaged research. Current harmonization projects have been coordinated through consortia of research-intensive institutions, but have been limited to geographically proximate clusters within the consortia.⁶ To date there are no published reports of IRB harmonization for national networks dedicated to reducing health disparities in diverse underserved populations. Furthermore, to our knowledge, none of these efforts have engaged community partners in the process of harmonizing IRB review across academic institutions in many different states. To fulfill this need, the Research Centers in Minority Institutions (RCMI) Translational Research Network (RTRN) is developing a community-partnered approach to harmonization of IRB review across its network of 18 RCMI grantee institutions.

Through an award from the National Institutes of Health’s National Center for Research Resources, with co-funding from the National Center for Minority Health and Health Disparities, RTRN was formally created in 2007 as a vehicle for convening the 18 RCMI grantee institutions in a cooperative network designed to reduce health disparities. The following institutions constitute the RTRN, which spans the distance from Hawaii to Puerto Rico and crosses six time zones:

1. Charles Drew University of Medicine and Science
2. Clark Atlanta University
3. Florida Agricultural & Mechanical University
4. Howard University
5. Hunter College, City University of New York
6. City College of New York, City University of New York
7. Jackson State University
8. Morehouse School of Medicine
9. Meharry Medical College

10. Ponce School of Medicine and Health Sciences
11. Texas Southern University
12. Tuskegee University
13. Universidad Central del Caribe
14. University of Hawaii
15. University of Puerto Rico, Medical Sciences Campus
16. University of Texas at El Paso
17. University of Texas at San Antonio
18. Xavier University of Louisiana

These minority-serving academic institutions award health professional and/or science-related doctoral degrees and include eight schools of medicine, three colleges of pharmacy, six graduate programs, and one school of veterinary medicine. RTRN institutions are located primarily in urban centers in Alabama, California, Florida, Georgia, Hawaii, Louisiana, Mississippi, New York, Tennessee, Texas, the Commonwealth of Puerto Rico, and the District of Columbia. The RTRN and its Data and Technology Coordinating Center in Jackson, Mississippi, provides tools and support for joint projects with basic, clinical, and translational emphasis upon major diseases that disproportionately affect minority and underserved populations. The network also offers education and training, assistance with research design and implementation, data management, and competitive pilot funding. A working group was formed as part of the RTRN Ethics and Regulatory Subcommittee to design and implement a community-partnered approach to promoting IRB reliance as a means of reducing redundant IRB review for collaborative studies. This paper describes our methods and future goals.

Members of RTRN Ethics and Regulatory Subcommittee IRB Harmonization Working Group

An IRB Harmonization Working Group was established in December 2009 to identify strategies to address the complexity of multiple IRB review across the RTRN consortium. Consistent with RTRN's community-engaged and multidisciplinary approach to reducing health disparities, the IRB harmonization process has involved diverse stakeholders in project conceptualization and implementation. Individuals with various educational backgrounds, including community-based researchers, community faculty members, a physician, an attorney, and an IRB director, agreed to form a working group as part of the RTRN Ethics and Regulatory Subcommittee. Working group members possess expertise in IRB management, academic research, community engagement, and clinical data services and informatics through the Data and Technology Coordinating Center. In particular, those with community expertise include the Director of Community Engagement and two members of the Community Faculty tract at Charles Drew University, the Associate Director of Community Partnership and Outreach for the Jackson Heart Study, and the Executive Director and Founder of Health African American Families in Los Angeles, who has spearheaded efforts to involve community partners in the RTRN consortium since its inception and is active on local IRBs. All working group members participated in determining the project design, scope, and approach to harmonization.

Phase One

First, we have sought institutional support for IRB harmonization as our critical first step in the process. This involves face-to-face meetings with key stakeholders at the RCMI grantee

institutions. Key stakeholders include the institutional official with authority to sign agreements on behalf of the institution, the individual responsible for overseeing the IRB and/or regulatory compliance activities, and the individual responsible for administering the IRB. In our preliminary meetings with six of the 18 RCMI grantee institutions, we have found that discussion with these individuals appears likely to accelerate the pace of negotiation of the reliance agreement at each respective institution.

Second, we have focused initially upon institutions in the RTRN consortium with the capacity to conduct clinical research, namely, Charles Drew University, Meharry Medical College, Morehouse School of Medicine, Howard University, University of Hawaii, and University of Puerto Rico. Each of these institutions has obtained an RCTR (RCMI Clinical and Translational Research) award, which is modeled after the NCRR Clinical and Translational Science Award (CTSA) program, or is a CTSA partner institution. Charles Drew University, Meharry Medical College, Morehouse School of Medicine, and Howard University each participates as a partner in a CTSA program, with UCLA, Vanderbilt University, Emory University, and Georgetown University, respectively. For this reason, we have identified the individual responsible for Regulatory Knowledge and Support activities as an additional key stakeholder for those RCTR/CTSA partner institutions in the RTRN consortium.

The first phase, still in progress, involves several incremental steps. First, we obtained RTRN Steering Committee approval for use of a Memorandum of Understanding (MOU) among all 18 institutions as the appropriate tool for fostering inter-institutional IRB reliance. Second, we have been meeting with key stakeholders at each RCTR/CTSA partner institution to discuss execution and implementation of the MOU and begin to understand the cultural context and research emphasis of each institution. Key stakeholders at each institution will then assemble individuals with decision-making authority to implement the MOU and monitor IRB reliance, including IRB directors/ administrators, legal counsel, and Federalwide Assurance institutional officials. Upon approval by the appropriate individuals, the MOU, or IRB Reliance Agreement, will be signed by the institutional official. The agreement will include the following specific elements:

- type of IRB review (full reciprocity, facilitated, deferral, single study, single investigator, consortium, etc.);
- type of studies to be reviewed (full-board and expedited);
- decision tree regarding designation of reviewing/relying IRB; and
- description of reviewing/relying IRB and PI responsibilities.

In addition, Phase One will involve the following steps:

- revision of Federalwide Assurance to reflect each institution's potential reliance upon other institutions' IRB review;
- development of a Ceded Review form to enable RTRN investigators to initiate the process of ceded review electronically via the RTRN website;
- maintaining a portal on the RTRN website for IRB notification and administration;
- aligning policies and procedures to promote consistent implementation; and
- establishing a central repository for tracking IRB reliance and RTRN collaboration through the Data and Technology Coordinating Center.

Phase One is scheduled to be completed by Spring 2012, engaging all RCTR/CTSA schools in the consortium as signatories to the MOU by December 2011, and the remaining 12 institutions as signatories by March 2012.

Phase Two

Collection of data related to positive impact of harmonization—In 2009 and 2010, to spark collaboration across the consortium, the RTRN Small Grants Program funded 11 awards each year to pilot projects involving investigators from more than one RCMI grantee institution. Of the 22 projects, six required multiple IRB review. The remaining projects required only one IRB review or did not involve human subjects. Recognizing that reducing redundancy in IRB review will likely encourage greater collaboration among those who might be dissuaded by multiple IRB submissions, we expect our efforts to contribute to an increase in the number of joint projects across the network, including those funded by the Small Grants Program and external sources. By laying the foundations for simplified IRB review for multi-site projects, we hope to reduce real and perceived procedural barriers to collaboration. Working group members will track time of submission to time of approval for RTRN-affiliated studies involving more than one IRB review. We expect to demonstrate that IRB harmonization has a positive impact in terms of reduced administrative burden upon investigators and shortened time between IRB submission and approval. Moreover, we anticipate that IRB reliance will provide an incentive for collaboration across the consortium that aligns with NIH goals for translating research discoveries into improved patient care.

Development of informed consent templates—Phase Two will also involve seeking consensus among the 18 grantee institutions as to standard informed consent templates for RTRN-affiliated studies. Templates will be developed in consultation with community partners and in compliance with the U.S. Department of Health and Human Services Office of Human Research Protections policy as set forth in the Code of Federal Regulations.

Developments

Phase One

Since December 2009, working group members have convened during numerous conference calls and in-person meetings to develop an effective strategy for IRB harmonization across the RTRN consortium. Working group members have created a database with names and contact information for IRB representatives, institutional officials, community liaisons, and Research Subject Advocates at each of the 18 institutions. Our database also contains information related to IRB electronic submission capability and collaborative agreements with external entities. Informed consent templates were also gathered from each of the 18 institutions.

We have met with key stakeholders at the University of Puerto Rico Medical Sciences Campus, Ponce School of Medicine and Health Sciences, Universidad Central del Caribe, Morehouse School of Medicine, Clark Atlanta University, and Howard University, and will continue to pursue execution and subsequently monitor implementation of the MOU at these institutions. We plan to meet in person or via teleconference with key stakeholders at the remaining RCMI grantee institutions in an effort to engage all 18 as signatories to the MOU by Spring 2012.

Phase Two

We have begun planning for Phase Two. Key steps include development of a standard informed consent template with latitude for local settings and collection of data related to the positive impact of IRB harmonization. Drawing upon the templates gathered from each

of the 18 institutions, we will seek consensus amongst institutions upon a standard informed consent template for RTRN-affiliated studies. Community partners in our working group will solicit feedback from community members about the template. In addition, we will collect data for RTRN-affiliated studies pre- and post-IRB harmonization to elucidate the positive impact of IRB harmonization on reducing administrative burden for investigators conducting joint projects across the network.

Discussion

This project provides a conceptual framework for using a community-partnered approach to promote IRB harmonization across a consortium of minority-serving institutions. This framework is crucial as clinical research has increasingly moved away from small, focused studies within academic institutions to large, multi-center trials involving both private and federal sponsors.^{7,8} Moreover, a proactive approach should help to overcome any culturally-based mistrust of the researchers' intentions^{9,10} and the limited inclusion of women, children, and some ethnic groups that have historically been underrepresented in clinical research studies.¹¹

It is well documented that project reviews by multiple IRBs often lead to confusion and delay for researchers who strive to meet the different requirements of IRBs, including type of review, submission procedures, informed consent language, notification of changes, and continuing review.¹² In the context of multi-site studies across geographic boundaries that involve recruitment of participants from diverse communities, these challenges become even more complex. Federal guidelines offer little guidance in navigating the myriad of issues related to multiple IRB review. A recent national survey of IRB administrators and chairs who review mental health research suggests that "IRB chairs, arguably the most experienced and influential members of their IRBs, see a need for access to different perspectives—from scientific, research ethics, and participant communities—to help them address the ethical challenges that they face, rather than expanded guidance from OHRP [Office of Human Research Protections]."^{13[p.12]} In keeping with recommendations to convene stakeholders and establish consensus for IRB review in multi-site settings,⁹ our proposed approach will facilitate development of a common vision and practical approach to IRB harmonization that will be critical to supporting joint projects. This innovation may provide insight that could ultimately lead to revision of federal guidelines. Moreover, our approach extends its reach beyond institutional walls into communities intended to benefit from health disparities research. Although community representation is already part of IRB review in institutional settings, we seek to promote bidirectional learning that informs and strengthens such review.

We believe a community-partnered approach is innovative relative to efforts of other consortia. Indeed, community partners have been highly motivated to participate in our efforts and have played an integral role in developing this approach.

Conclusion

By promoting an IRB reliance agreement among RCMI grantee institutions, we seek to foster a well-balanced, ethically rigorous, and efficient review of multi-site collaborative studies across the RTRN consortium that streamlines research efforts while preserving local socio-cultural aspects of human study participant ethics and respect. Ultimately, this approach will provide an exemplary model to share with other consortia dedicated to improving human health through basic, clinical, translational, and community-engaged research.

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Notes

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