Role for CTSA's in Leveraging a Distributed Research Infrastructure to Engage Diverse Stakeholders in Emergent Research Policy Development

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Abstract

This paper is a case study of our regional Clinical Translational Science Award's (CTSA) development of a coordinated response to the advanced notice of proposed rulemaking on *Human Subjects Research Protections* during the fall of 2011. Our CTSA was well positioned to quickly activate and coordinate a response to this important and time sensitive issue because we had established infrastructure and resources both within our CTSA and through our partnering institutions, existing relationships with key individuals in the institutions, and credibility as a trusted source of information. Three town hall meetings were organized and a Website was created to collect online comments. Ultimately, comments were collected, prioritized, and organized into a single, coordinated response. This case study demonstrates the value of a distributed research infrastructure and the role CTSA's like our Institute of Translational Health Sciences can play to engage the regional research community about important developments in the research landscape and to respond to requests for feedback to policy makers. Clin Trans Sci 2013; Volume 6: 57–59

Keywords: research policy, Clinical Trial Science Award, stakeholder engagement

Background

The Department of Health and Human Services released the advanced notice of proposed rulemaking (ANPRM): "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" on July 26, 2011, initially with a public comment deadline of September 26, 2011. These proposed rules would involve substantial changes to the regulations governing the processes and criteria for review of research involving human participants and could have profound implications for researchers, institutions, research participants, and society.¹ Thus, consideration of changes to regulations that have been in place for more than 20 years was critical and required input from investigators, IRB members and staff, and institutional leadership. In a very short time frame our regional Clinical Translational Science Award's (CTSA) program ensured researchers and institutional officials in our partner institutions were aware of the ANPRM, communicated our intent to coordinate a response, discussed the proposed changes, collected comments and prepared the response. Our CTSA, the Institute of Translational Health Science (ITHS), has three primary institutional partners, University of Washington (UW), Seattle Children's Hospital (SCH), and Fred Hutchinson Cancer Research Center (FHCRC) as well as affiliated institutions in Seattle and throughout Washington, Wyoming, Alaska, Montana, and Idaho. Our objective in this paper is to illustrate the opportunity for CTSA's to serve as a convening function and highlight the challenges that can arise when mobilizing established resources to respond to important and time sensitive community engagements.

The programs within the ITHS worked collaboratively to engage our community. The ITHS Regulatory Support and Bioethics (RSB) core had existing relationships with the institutional review boards and institutional officials at the partner institutions—UW, SCH, FHCRC. Established mechanisms for advertising and Webcasting educational events were available from the ITHS Education Core, and the ITHS

Regional Collaborations Program. Our community affiliate, the Northwest Association for Biomedical Research (NWABR) had established communication channels with IRB members, institutional officials, and researchers across our region.

Approach

On July 28, 2011, RSB core leaders appreciated the implications of the proposed changes for research practices and health care while attending a Webinar on the ANPRM sponsored by Public Responsibility in Medicine and Research (PRIM&R). The RSB core director presented the proposed rule changes and timeline for comment at the next ITHS leadership meeting on August 12, 2011. The importance of informing and soliciting opinions from the ITHS research community was discussed and a proposal to conduct three "town hall" style meetings, while simultaneously collecting comments online, was developed. Subsequently, members of the administrative, education and RSB cores, along with NWABR, met to plan and implement the town hall sessions. Initial communications with the institutional review boards and other key stakeholders determined that these groups were considering independent responses but welcomed the ITHS's effort to collaboratively engage with the broader research community.

With the support of the ITHS education core information technology personnel, a Web page was built to provide information on the ANPRM, including links to relevant documents, and enable the user to submit their own comments.

Notices about the three "town hall meetings" were sent to ITHS members and partner institutions using established ITHS communication mechanisms and the NWABR e-mail list to reach the research compliance community across our region.

In order to have sufficient time for substantive discussion, selected ANPRM topics of particular importance to our constituents were presented at each session. Of the 7 key sections (II–VIII) and 74 questions identified in the ANPRM under amendment consideration by the Department of Health and Human Services (DHHS), the "town hall" Webinar series

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DOI: 10.1111/j.1752-8062.2012.00444.x

Figure 1. ITHS coordinated ANPRM response process: four elements of the stakeholder engagement process were identified as nodes through which comments were solicited, collected, and compiled to generate a coordinated response to the ANPRM—conveners, stakeholders, engagement options and response collectors. Conveners recognized the significance of the DHHS call for public comment on the ANPRM and quickly mobilized to identify stakeholders and generate a bidirectional communication process. Stakeholders synthesized information in the ANPRM via participation in various ITHS engagement options. Participation in the town hall sessions engendered the majority of the comments. No comments were received via the eComment board and only a handful of comments were sent to the RSB core via e-mail. Institutional or individual responses directly to DHHS were not tracked. The Response Collectors in turn organized and compiled stakeholder comments in a collective response submitted to DHHS.

focused on topics within 4 of these (Sections II–V). Subsequent stakeholder responses addressed 25 of the 74 questions posed and were incorporated in the coordinated response. Institutional leaders with specific expertise in the selected topics were invited to co-moderate the sessions along with RSB personnel. The first session was held at the UW on August 29, 2011 and focused on the impact of the proposed changes to research with biospecimens. The session was led by Wylie Burke, M.D., Ph.D., Professor and Chair, Department of Bioethics and Humanities at the UW. The second session focused on proposed changes to informed consent processes and IRB review of minimal risk and exempt research. The session was held at SCH on September 2, 2011 and was led by Douglas S. Diekema, M.D., M.P.H., Professor, Division of Bioethics, Department of Pediatrics and Chair of the Institutional Review Board at SCH. The third session, held at the FHCRC on September 9, 2011, focused on the proposed data security standards and multicenter single IRB review. This session was led by Ann Melvin, M.D., M.P.H., Associate Professor, Pediatric Infectious Disease, S.C.H., Suzanne McCoy, M.P.A., Assistant Director of the Medicine Privacy & Identity Theft Program at the UW, John Soltys, Informatics Security Analyst at the UW School of Medicine, and Karen Hansen, Director of Institutional Review Office at the FHCRC. The UW, SCH, and FHCRC provided venues and logistical support for the sessions (see Figure 1 for a flow diagram of the engagement and response process).

Stakeholder Participation

A total of 284 individuals, representing 45 universities, research institutes and companies from Washington, Wyoming, Alaska, Montana, Idaho, California, Tennessee, and British Columbia, Canada, participated via Webinar (204 participants) or in-person (80 participants). At each session, people were given information on how to submit comments to the RSB core to inform the ITHS response, to their primary institution (if applicable) and directly to the US Department of Health & Human Services. There were also several Web-based comment forums established by both the ITHS and our partner institutions. Our online CTSA comment board received no submissions. Many participants did however raise their opinions in person at the town hall meetings and a handful followed up with additional comments to the RSB core by direct email. The RSB core leaders compiled the comments from the online and in-person attendees of the town hall sessions along with the written comments into a response to the ANPRM. The draft response was presented to the ITHS leadership for comment and then submitted to DHHS. The final response was then disseminated by e-mail to all town hall attendees, key institutional collaborators (particularly those intending to submit their own response or one on behalf of their institution), institutional review board members and staff across our region, and specific individuals who requested a copy. Additionally, the response was posted to the ITHS home page. The full text of the ITHS response

can be accessed at <https://www.iths.org/sites/www.iths.org/files/eventmedia/ITHSresponsetoANPRM.pdf>.

Role of CTSA

This sequence of activities was novel for our CTSA but we now appreciate how the CTSA was well positioned to bring together diverse organizations to address an emergent policy issue. First, the CTSA had well established mechanisms and relationships which could be called upon to respond efficiently. These included an education core with well-developed Webcasting abilities, experience with regional partnership program's prior efforts in reaching broad communities, the RSB core's relationship with the institutional IRBs, and rapid access to the ITHS leadership group through their regular meeting schedule. Second, while there was acknowledged interest about the implications of the ANPRM by both researchers and institutional programs, the CTSA was uniquely positioned to engage with both groups and bring them together, thus developing a truly coordinated response where input from the research community was used to inform the institutional responses and vice versa.

Implications

As described above, the strength of the CTSA network is in accessing large numbers of experts in all aspects of translational science. One of the primary lessons we learned from this experience was that an institute as large and regionally expansive as our CTSA can quickly amass a group of experts, collect, and compile insights and concerns from a broad stakeholder base, and then synthesize the critical elements into recommendations to inform and advance an emerging and focused policy issue. Our CTSA was able to provide assistance quickly and

efficiently for investigators, research compliance personnel, and institutional leaders to assess the impact of the changes at their own institution, enabling more informed and comprehensive individual responses. The approach also facilitated institutional officials to engage each other, and with investigators as part of this process.

The challenge in most cases is where and how to disseminate findings from a policy engagement process such as this. The usual route of publishing in peer reviewed literature can be slow and not reach the desired policy-making audience, though it can eventually when part of the extant literature. When policy issues are under active debate, such as the ANPRM in this case, it is vital to have input reach policy makers quickly. In this case, the policy makers themselves created a venue via a solicitation of input to a Website. We synthesized the deliberations in a succinct executive summary that highlighted key considerations. This rapid response approach to emergent policy issues through our CTSA can be readily accessed and deployed to ensure that the voices of our stakeholders are conveyed to the policy makers.

Acknowledgments

The project described was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1 RR025014. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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