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Our Two Cents: Research Ethics Consultation at Johns Hopkins Bloomberg School of Public Health

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Abstract

As the faculty responsible for the Research Ethics Consulting Service (RECS) at Johns Hopkins Bloomberg School of Public Health (JHSPH), we would like to briefly describe our service and to address two of the ongoing questions inherent to performing research ethics consulting posited by Cho et al. (2008): conflicts of interest and core competencies.

BACKGROUND

The RECS at JHSPH started in March 2005. As background, The Johns Hopkins University received funds as part of an Office for Human Research Protections/United States Department of Health and Human Services (OHRP/DHHS) initiative to build institutional review board (IRB) capacity at academic medical centers nationwide. (OHRP/DHHS 2002) As members of the JHSPH faculty with core appointments in our Berman Institute of Bioethics (BIB) and expertise in research ethics, we were asked by our IRB institutional official to learn more about what types of research ethics capacity development initiatives would be of use to the faculty. We were given time on the agendas for departmental faculty meetings in the five JHSPH academic departments that conduct the majority of human subject research within the school and at school-wide “faculty senate” meetings to solicit suggestions and feedback on prioritizing research ethics “continuing education” initiatives that would be helpful to them. A consulting service whereby faculty could, in real-time, discuss challenging ethics issues at various stages of their research, consistently received the greatest support.

A proposal for a research ethics consulting service that would be staffed by the two of us was presented to and approved by the Executive Committee (EC) of the Office of Research Subject (ORS), JHSPH (consisting of the institutional official, IRB chairs, and the associate dean for research). Funds were allocated to develop and initiate a 6-month pilot of the service, with the understanding that, if successful, the school would consider making a longer term commitment to the service beyond the initial support provided by the external grant from the National Institutes of Health (NIH, Bethesda, MD). The EC allocated the

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necessary funds to support the development of a web-based interface through which consults would be requested. As noted in Cho and colleagues (2008), our service was built on a platform already in use for the placement and management of computer related “help calls” by JHSPH faculty, staff, and students. (BMC Software 2006).

The RECS was launched in March of 2005. As of April 2005, we have received and responded to 72 consults. In the terms used by Cho and colleagues (2008) we have adopted a “hybrid” model closer to the “‘single expert’ biostatistics” model than to the current Stanford model. From this point forward, we will limit our discussion of the service to two issues: managing conflicts of interest and competencies for providing the service.

MANAGING CONFLICTS OF INTEREST

Cho and colleagues (2008) conclude that the location and funding source raise potential financial and non-financial conflicts of interest for research ethics consultation services. In reference to location, Cho and colleagues (2008) conclude, and we agree, that “consultation groups are best situated locally.” (4) As we discuss in the core competencies section of this article, we believe being locally situated is essential to the provision of a high quality consult. It may be that as research ethics consultation spreads and matures, outcomes across sites could be compared to assess the role of location and non-financial conflicts. In reference to financial conflicts, Cho and colleagues (2008) recommend that research ethics consultation ought to be funded by sources “outside the institution” (4) and “from sources that do not support the research that is discussed in consultation” (4) to avoid the potential for bias in the provision of a consult: consultants favoring the study proposed despite ethical reservations. In the short term, our efforts were supported by OHRP/DHHS funds, arguably meeting both these criteria. But the only way to assure the sustainability of the service was for JHSPH to make a commitment to provide core support the service once the OHRP/DHHS funds ran out (i.e., provide salary support to REC faculty staffing service). As a result of our anticipated funding arrangement, in consultation with our BIB colleagues and the EC, we identified possible real or perceived conflicts that might arise as well as means to manage them. Two types of potential conflicts were raised: 1) in guaranteeing confidentiality to the researcher bringing the consult, we might learn information that, in good conscience, we think must be disclosed to the IRB; 2) because both faculty members (article authors Taylor and Kass) staffing the service also sat on JHSPH IRBs, there was a possible conflict of becoming so invested in our resolution of an ethics quandary that we would be less objective as an IRB member or reviewer when the study came before the IRB.

How Much Confidentiality to Guarantee the Researcher?

When our service started, we envisioned that the RECS would be not only a venue for identifying best practices for current and future studies, but would also be a “safe place” for investigators to disclose past actions that raised ethics questions in order to talk through how such actions should be addressed and/or avoided in the future. As such, we wanted to guarantee to researchers that consults would be kept completely confidential. However, we recognized that, in rare circumstances, we might be told information that we did not, ethically, believe we *could* keep confidential from regulatory authorities. Indeed, in determining whether our service should be presented as being independent from the ORS that oversees our IRBs, or part of the ORS infrastructure, we opted ultimately for the latter and chose then to concentrate on making this relationship transparent to researchers requesting a consult. To this end we agreed that all information regarding the consult will remain confidential with the following of caveats:

- If a consult is sought on a protocol that has already been reviewed and approved by the IRB, a note summarizing the consult will be forwarded to the director, ORS to be included in the protocol file.
- If information is provided to RECS staff that constitutes a grave moral and/or regulatory violation, and the investigator is unwilling to disclose it him/herself to the IRB and/or institutional officials, RECS staff reserve the right to do so.
- RECS staff may communicate with each other about a particular case in order to provide the best possible response to the investigator.
- RECS staff may discuss the generalities of the case (i.e., no personal or protocol details that would easily identify the investigator) with colleagues who are members of the Program in Research Ethics, BIB.¹

The primary disadvantage of this arrangement is that investigators may be reluctant to seek out a consult believing that they risk being “caught” doing something unethical and reported to the IRB. That investigators have in fact used the service and a number have returned for second and third consults suggests many researchers are not deterred by this policy, although, we have not attempted to assess whether investigators have avoided using the service for this reason.

Research Ethics Consulting Service Staff Also Serving As Institutional Review Board Members

When the RECS was established, the two faculty staffing the RECS both served as ‘ethicist’ members of the JHSPH IRBs.² An additional set of actions and policies were developed to promote transparency and minimize conflicts of interest between our work as IRB members and staffing the RECS:

- Investigators seeking consults are reminded that seeking a consult will not substitute for a sound IRB review.
- RECS faculty do not serve as primary IRB reviewers research protocols that had previously been submitted to the RECS.
- RECS faculty will disclose to the IRB the projects for which they had previously consulted when those projects are brought before the IRB. In the course of such disclosure, RECS faculty, or other IRB members, may conclude that the extent of RECS faculty involvement in the protocol under review may constitute a significant enough conflict of interest to warrant being recused from IRB review of that protocol.
- IRB members are encouraged to voice concerns about protocols that have gone through the RECS just as they would if the investigator had not pursued a consult.

We believe these policies have served the IRBs and RECS well. To date we have disclosed to the IRB a number of times when we provided a consult on a protocol before the IRB and neither of us felt the need recuse ourselves from the deliberations about the protocol nor been asked to recuse ourselves by other IRB members.

¹The Program in Research Ethics (PRE) is comprised of faculty of the Berman Institute of Bioethics who serve on one of the seven IRBs serving the JHU Schools of Medicine and Public Health, as well as Berman Institute of Bioethics faculty who engage in significant research and/or teaching related to research ethics. PRE brings these faculty together monthly to discuss challenging issues in research ethics and/or IRB function; to identify and collaborate on scholarly projects related to research ethics; and to provide service with regard to research ethics policies and/or IRB procedures to the JHU Schools of Medicine and Public Health.

²In addition to providing start up funds for the RECS, funds from the OHRP/DHHS were also used to fund the placement of an Berman Institute of Bioethics faculty member on all IRBs serving the JHU Schools of Medicine and Public Health.

CORE COMPETENCIES

We would also like to briefly comment on Cho and colleagues' (2008) proposed set of core competencies for staffing a research ethics consultation service. Based on our experience we would argue that research ethics knowledge is necessary but not sufficient to provide high-quality research ethics consultation. That is, there is a limit to how far generic research ethics knowledge and a "basic understanding of the research," (Cho 2008, 4) can go in providing a sophisticated resolution to a highly complex research ethics problem. In addition, we assert that, in order to engage in high quality consultation, the ethicists involved should have: a reasonable amount of substantive knowledge in the field in which investigators seeking consults are working; practical experience in applying moral reasoning to human subject research; and some experience conducting human subject research themselves. In our own service, we find that it is consistently helpful that both RECS faculty have doctoral level training in public health. Many of consults submitted through our service require a sophisticated understanding of the differences among different public health study designs (e.g., nested case controls, community randomized trials), or balancing public health research interests with individual duties, an ongoing ethical tension for public health. Related, much of the research conducted at JHSPH is global in nature, and both of us have conducted research ethics work both domestically and in resource-poor countries. In addition, both RECS faculty have served for many years on IRBs in a variety of public and private settings, providing practical experience on how other cases have been resolved. In addition, we bring extensive knowledge of the culture of and expertise available at our home institution. While it may be too high a standard for all research ethics consultants to acquire this "competency", having it ourselves turns out to be helpful in drawing other experts into a consult or picking up the phone to discuss a particular issue with a known staff member at the IRB. As more and more institutions, including our own, adopt or expand on models of research ethics consultation with funds provided by the Clinical and Translational Science Awards (CTSA), the ability of ethicists to meet these competencies—and overlap with the substantive expertise of their consulting investigators—will make the difference between an adequate and high quality service.

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