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Defining the Scope and Improving the Quality of Clinical Research Ethics Consultation: Response to Open Peer Commentaries about the National Collaborative

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Abstract

The Open Peer Commentaries on “The Emergence of Clinical Research Ethics Consultation: Insights from a National Collaborative201D highlight the many ways in which the practice of ethics consultation for clinical research can be further advanced. We respond here to a number of key considerations highlighted by commentators, including the role and scope of research ethics consultation (REC), relationships with other institutional services and programs, efforts to ensure the quality of consultations provided, and the feasibility of widespread REC services.

Role and Scope

Fost (2018) argues that REC services are unnecessary and that the best mechanism for bioethics scholars to engage research ethics issues is through an institutional review board (IRB), which ought to be the institutional entity to address ethical issues in clinical research. While we agree that the work of the IRB includes the ethical assessment of each protocol it reviews and that bioethics scholars can address ethical challenges within the context of IRB responsibilities, the scope of REC sometimes extends beyond protocol review and beyond the reach of the IRB. REC requests pertain to issues that occur during the entire timespan of a research protocol, from the formulation of a research question to the dissemination of results. Further, the REC is uniquely situated to address ethical questions that arise outside of research that is reviewed by IRBs (such as research that is conducted by academic scientists but at private companies licensing technologies from universities, or translational

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research that does not involve human subjects). We appreciate Fost's worries that investigators pursuing ethics consultation outside the IRB for those consults that are related to a specific protocol that will also be reviewed by the IRB can be problematic. However, we believe that the role of the consultant, even for research that is reviewed by an IRB, is not to supplant the work of the IRB but rather to complement it. We note that on occasion, IRBs refer researchers to REC services or even request consults themselves. In our experience, the REC can be a valuable forum for researchers and IRBs to discuss ethical challenges and scientific responsibility of emerging fields and research practices. The opportunity for discussion not bounded by features of a particular study frames REC interactions in a way that focuses on ethical considerations, rather than meeting institutional requirements.

Arnold et al. (2018) and Paquette and Ross (2018) raise related questions about how consultants should do their job in cases of conflicting recommendations from REC services and regulatory bodies such as IRBs, particularly situations where the IRB has approved a protocol as permissible from a regulatory standpoint that a REC service "finds impermissible based on their ethical analysis" (Paquette and Ross 2018). We acknowledge that the IRB does have regulatory authority, and consultations are advisory. However, collaborative and respectful engagement between IRBs, RECs, and investigators provides opportunities to consider when decisions are within the zone of discretion or push the boundaries. We agree that the community of research ethics consultants and other stakeholders need to further address these process issues (Beskow et al. 2009; Sharp et al. 2015).

Master et al. (2018) recommend an expansion of the scope of the REC into the area of research integrity. We have found in the delivery of research ethics consults that there is sometimes an unclear distinction between research ethics and research integrity. For this reason we agree with Master et al. (2018) that there can be some overlap between the two areas. We also agree that it is very important for research ethics consultants to be aware of the institutional resources available to support research integrity in order to make appropriate referrals in the case of research or professional misconduct. When concerns squarely in the realm of research integrity arise during a consultation, investigators should be referred to the institutional resource established to manage and oversee such issues for two primary reasons. First, REC services do not have the capacity to fully investigate these concerns and second, it is important for REC services to avoid any oversight role so that consult requestors can continue to assume that the consultation service provides a safe space for reflection.

Partnerships

Cho et al. (2018) promoted the formation of partnerships between research ethics consultation and clinical ethics consultation services. We agree. Many of the consults that Collaborative members have received to date relate to navigating the boundaries between clinical research and clinical care. It is also the case that some research ethics consultants have prior or concurrent responsibilities on clinical ethics consult services. Along these lines, we note that some institutions have consolidated administrative and information technology resources for management and tracking of both clinical and research

consultations. Thus, partnership and interaction with clinical ethics consultation programs is probably an important aspect of establishing and sustaining a REC service in an institutional setting.

Training and Quality

Arnold et al. (2018), Paquette and Ross (2018), and Fost (2018) raise questions and concerns about how clinical research ethics consultants should be trained. This is a fundamental question that needs attention. It has been instructive for us to reflect on the evolution of clinical ethics consultation and the articulation of core competencies by the American Society for Bioethics and Humanities (ASBH) and further efforts to ensure quality (ASBH 2011). While the field of research ethics consultation is a long way from any effort toward professionalization, in 2017, the Collaborative facilitated the establishment of the ASBH Clinical Research Consultation Affinity Group. We anticipate this group might be the locus of efforts to consider whether there is a set of core competencies any individual consultant or an institutional service ought to meet.

Feasibility

Finally, Greenbaum (2018) raises the concern that “not every research institution needs to have the research-related infrastructure of their largest peers,” and proposes regional research ethics consultation services to address this problem. We agree with his concerns for two primary reasons. First, the supply of experienced consultants is limited. Second, the establishment of a REC at every institution that conducts human subject research does not make economic sense. In an effort to address this, the Collaborative currently offers a national resource for consultation with the goal of providing access to expertise to supplement the existing ethics expertise available at research institutions. That is, a Collaborative member affiliated with an REC that is relatively new or encounters a particularly complex case can initiate a Collaborative Consult and invite Collaborative members to join in on the consult in real time. These ad hoc calls are in addition to quarterly calls the Collaborative sponsors at which members present and discuss complex or novel cases that have been closed by the respective service but presented with the goal of cross institutional knowledge and capacity building. In addition, while most RECs are institutional resources and serve their institutional community only, a few offer consultation to outside institutions/organizations (https://www.ctsabioethics.org). Expanding access to these consultation resources may be a first step in determining whether there is a demand for a regional service.

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