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The Challenges of Incorporating Research Ethics Consultation into Institutional Human Subjects Protections Program

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Porter et al. describe their experience with a national collaborative for research ethics consultation (REC), highlighting four contexts in which REC can be valuable and encouraging institutions without a REC service to consider developing one to complement other human subjects' protections oversight programs such as those that manage conflicts of interest, enforce HIPAA and evaluate protocols for scientific and ethical merit. (Ross et al. 2010) We agree that REC can be an important resource in identifying and managing research ethics concerns, but we also recommend that before doing so, that institutions proactively consider how best to implement a REC service and how to relate this service into existing human subjects' protections programs.

First, institutions will need to determine what function REC will serve. Ethical—and, in particular, regulatory—oversight for research should occur during institutional review board (IRB) review. However, in areas where there is no regulatory guidance, the IRB, and research teams may turn to REC to help identify and manage ethical issues arising in the design and conduct of research. Institutions will need to decide how to incorporate input from REC activities into general research oversight. As Porter and others describe, research ethics consults may be requested at any point in the research process, from the planning of a study through its execution to data analysis and dissemination, both before and after IRB review. (Porter et al. 2017; Beskow et al. 2009) When consultation occurs prior to or concurrent with IRB review, it may provide additional insights that aid in project approval or disapproval at the IRB-level. When REC occurs following IRB approval, however, institutions will need to determine whether REC recommendations are enforceable or merely advisory and who has the authority to make that decision. Another question is the permissibility of overlapping membership on REC services and IRBs, and how to separate these roles such that authority is clearly identified and distinguished.

A related, but distinct, issue arises when the recommendations of REC are in conflict with regulatory determinations by an IRB. Individuals may differ in their interpretation of regulatory requirements or regulations may be silent in areas with distinct ethical implications, particularly for research in emerging areas where regulations have not been

developed. In these situations, research ethicists can provide important guidance in helping researchers and institutions to consider the ethical implications of their work. However, institutions will need to consider what to do in the setting of research that is permissible from a regulatory standpoint, and so approved by the IRB, which a research ethics consultant finds impermissible based on their ethical analysis. The research ethics consultant may be considering group or social implications that are proscribed from IRB consideration. Under CFR 46.111.2, IRBs are instructed “not [to] consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.” (Protection of Human Subjects. Subpart A - Basic HHS Policy for Protection of Human Research Subjects 2009) While these are undoubtedly important considerations, particularly as community engaged research continues to grow, (Ross et al. 2010) institutions will need to have a mechanism by which disagreements between IRB and REC review will be addressed and potentially resolved. Similarly, in the setting of multisite research, a single IRB may be the site of regulatory review, but REC may be requested at any of the individual sites, and potentially more than one site. Research teams and single IRBs assuming regulatory responsibility for the proposed research will need to develop mechanisms to incorporate feedback that may vary between institutions.

Institutions will also need to consider whether they will permit researchers to seek REC services outside of the institution in which the IRB review will occur. In some instances, individuals on an IRB may not have the requisite expertise to consider all of the human subjects concerns relevant to a proposed research study. In these situations, in order to ensure the most thoughtful ethical review, consultation may be sought outside of the home institution. In addition to determining what weight to assign to external review, particularly if it conflicts with IRB perspectives within the institution, important privacy and intellectual property concerns may arise. In order to conduct thorough research ethics consultation, a consultant will need to know specific details about the planned research. Institutions will need to determine how to ensure confidentiality with respect to research information and intellectual property.(Taylor and Kass 2009). Institutions will also need to determine how they will ensure the privacy of individual participants if the consult requires sharing of this information.(Sharp et al. 2015) In structuring relationships with consultants external to the institution, both parties should also consider under what circumstances the research ethics consultant may feel compelled or reticent to disclose information learned as a result of conducting a REC.(Cho et al. 2015; Resnik 2008)

A fourth consideration for REC services is how REC should be performed. Similar to clinical ethics consultation, different models may exist in different institutions for conducting REC. (McCormick et al. 2013) In some institutions, a single individual may review a case referred for consultation; in other institutions, cases may be reviewed by a collaborative team. While either form of review has the potential to identify ethical issues in conducting the proposed research, a team approach may be more likely to uncover areas where reasonable individuals may disagree in their ethical assessment.(Kelley et al. 2008) Particularly in cases where the REC might yield different conclusions about the permissibility of research than an IRB, it may be useful to utilize a team approach to REC, to identify whether different individuals reviewing the study from an ethical perspective

come to similar conclusions about its ethical permissibility. When an institution lacks the resources to conduct such a collaborative review, institutions may need to go outside of their institution, raising again the issues of information sharing.

An additional issue that needs to be considered by the wider scientific and ethics communities is what constitutes adequate training and competency to perform REC, (McCormick et al. 2013; Cho et al. 2008) particularly because the triggers for research ethics consultation may be quite diverse.(Havard, Cho, and Magnus 2012) While some regulatory knowledge is essential, we do not believe that research ethics consultants need to have Certified IRB Professional training. Coursework, IRB experience or other professional training in research ethics and human subjects protections should be adequate. Additionally, regulatory knowledge alone is insufficient for conducting a research ethics consultation because it does not include the non-regulatory elements of research ethics consultation, including how to consider group, rather than individual, harm, how to measure social good in the local and broader contexts, and how to contemplate areas in which no regulatory guidance exists. REC programs should have the capacity to incorporate local considerations much in the same way that local considerations are incorporated into IRB review.(Office of Human Subjects Protections 2016; Secretary's Advisory Council for Human Research Protections 2013) A research ethics consultant who lacks this knowledge must have access to the resources needed to ensure an accurate assessment of the issues for the organizations and communities served.

Finally, research ethics consultants need a working knowledge of scientific research processes. Although REC began in the late 1980s, (Singer et al. 1988; Singer et al. 1989) it became more commonplace with the establishment of a REC component to the original Clinical and Translational Science Award (CTSA) programs established by the National Center for Research Resources (NCRR). The association with the CTSA ensured a strong foundation not only in the regulations governing research, but also in the ethics of research methodology and clinical trial design. As research ethical issues may arise secondary to issues with the validity of the scientific approach or analysis, research ethics consultants arguably ought to have some training and/or experience within these areas, in addition to regulatory knowledge and core ethics training. The lack of ongoing funding for an ethics function through CTSA's under the National Centers for Advancing Translational Sciences (NCATS) may result in institutions foregoing an independent REC service. While Porter et al. describe a well-established REC collaborative that started within the CTSA network, it is likely that more informal REC occurs at many institutions with clinical ethics teams potentially being called upon to perform REC even though the clinical ethics team members may not have requisite regulatory knowledge, training in research ethics and human subjects protections, or experience with research design and methodology.

Seventy years following the Nuremberg Code, the scientific community, research oversight programs including IRBs, and ethicists still continue to struggle with ethical issues in the conduct of research. REC offers an important resource to address ethical issues that may not be captured in traditional research oversight.(McCormick, Boyce, and Cho 2009) Yet, as Porter et al. call for an increase in the availability of REC, scientists, ethicists and others responsible for research oversight will need to consider important questions about the proper

function and scope of RECs, what represents adequate training to RECs, and how to integrate a REC function within an institution's existing human subjects' protections program.

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