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The Emergence of Clinical Research Ethics Consultation: Insights from a National Collaborative

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In the past five decades, a system of review and oversight of human subjects research has been established that focuses primarily on institutional review boards (IRBs) and their interpretation and implementation of federal regulations. Earlier this year, the Department of Health and Human Services issued a revision to the Common Rule thereby modifying the existing regulatory landscape (U.S. Department of Health and Human Services 2017). However, the new Rule will not fully address the increasing complexity of the ethical issues faced by researchers and regulators. Growth in the number and size of multi-site trials, investment in comparative effectiveness research, and advances in genomics and biologics have introduced novel ethical issues that will remain challenging

Over the last decade, this complex research agenda has prompted researchers, as well as IRBs, to seek a forum in which to discuss novel or unresolved issues (McCormick, Boyce and Cho 2009). Research ethics consultation (REC) has become such a forum in which to address these issues (Beskow et al. 2009; Cho et al. 2008; Emanuel 1998). More than three dozen academic institutions in the U.S. have established REC services (McCormick et al. 2013) to advise research teams, regulators and administrators, and sometimes research participants, in their navigation of ethical issues related to planning, conducting, interpreting, or disseminating results of research, as well as recommending practical strategies for managing these issues (Beskow et al. 2009; Sharp et al. 2015). The typical REC service provides *a systematic approach to providing consultation advice that includes publicized access to the service, documentation of recommendations, and institutional accountability* (Danis et al. 2012; McCormick et al. 2013). Thus researchers now have the opportunity to benefit from access to similar sorts of assistance surrounding ethical

deliberation that many clinicians have had access to for over three decades through clinical ethics consult services (Fox, Myers and Pearlman 2007).

The Clinical Research Ethics Collaborative (“Collaborative”) is a nationwide group of research ethics consultants that was formed to share practices and experiences related to clinical research ethics consultation, to enhance understanding of the complex ethical dilemmas that emerge with advancing translational science, and to improve the quality of clinical research ethics consult advice (Clinical Research Ethics Consultation Collaborative 2016s). Fifty four members representing 35 institutions currently participate in the Collaborative. The Collaborative evolved out of the Clinical Research Ethics Key Function Committee of the Clinical and Translational Science Award (CTSA) program supported by the NIH from 2008–2014.

The Collaborative has fostered a number of efforts that document the breadth and depth of ethical issues faced by investigators at academic medical centers across the U.S., as well as at the NIH, deemed significant enough to warrant ethics consultation. These efforts have allowed the collaborative members to better understand how existing consult services are utilized and to appreciate the range of approaches to the most challenging consultation requests. First, in 2012, we established a research ethics consultation repository to systematically collect and characterize key information from consultations completed by REC services across the country. Second, in 2013, we implemented monthly Collaborative case discussions and subsequent publication of case commentaries.

In this paper, we describe our collective experiences with research ethics consultations, illustrated by the repository and the case discussions, and then consider the implications of what we have learned for bioethicists and institutions that are considering developing such services. The role of IRBs remains crucial to the protection of human subjects and the question remains as to how research ethics consultation can best complement the existing framework (Beskow et al. 2009). Our experiences have led us to appreciate that research ethics consultation can be a valuable resource for institutions engaged in biomedical research that pushes the boundaries of existing ethical and regulatory frameworks. Furthermore, professional bioethics training programs should consider research ethics consultation as an important focus for training the future workforce to meet institutional needs. We highlight stages and types of research for which REC services can complement the work of IRBs and expand the forum for ethical deliberation involving the design and conduct of human subject research.

Research Contexts and Ethical Concerns in the Consultation Repository

Ten institutions contributed data to the repository: nine academic medical centers and the NIH Clinical Center. These represent public and private institutions, geographic diversity, and a wide range of consultation volume. The Collaborative developed a set of key domains to be collected for each consult and entered into the repository, including some focused on the research project (research activities, research stage, translational research phase, and research context), and others focused on the consultation request (ethical concern, amount of interaction, and additional services provided) (for definitions of the categories described, see

Cho et al. 2015). These are a subset of 35 fields proposed by the Collaborative for REC services to consider collecting for internal use (Cho et al. 2015).

During 2012 and 2013, 359 consults were entered into the repository, 158 from nine academic medical centers and 201 from the NIH Clinical Center. For these academic medical centers, the number of consults per institution ranged from two to 44 with a median of 12.5.

Challenging and Novel Cases

Approximately six times per year, the Collaborative hosts web-based meetings during which a consultant shares a particularly challenging or interesting consultation request that has come through their REC service, usually initially requested by investigators at the consultant's home institutions. Cases presented often address novel or complex issues that benefit from additional reflection. The Collaborative discusses and analyzes the range of ethical issues involved and in conclusion the consultant presents the actual resolution of the case. Two of these cases, along with three commentaries each, are subsequently published semi-annually in the *American Journal of Bioethics* (AJOB) as part of a recurring series entitled *Challenging Cases in Research Ethics* in order to contribute to the field of research ethics in areas where regulations and ethical analysis have not previously provided clear guidance or resolution.

Sixteen cases and 48 commentaries have been published since October, 2013. Table 3 presents the key ethical question raised by these 16 cases and addressed by each set of commentaries. The key ethical questions are drawn from the discussion on the Collaborative call and refined by the editors of the case series (HAT and BSW) and commentators themselves.

Four Contexts Where Research Ethics Consultation Services Add Value

In reflecting on the experience of the Collaborative, considering the repository data and challenging cases, and research ethics consultation in general, we found that research ethics consultation can be a resource that complements the work of IRBs to promote ethically sound human subject research. Research ethics consultation can be valuable in the following four contexts: 1) as a resource for investigators before and after the regulatory review; 2) as an additional resource for investigators, IRBs and other research administrators facing challenging and novel ethical issues; 3) to assist IRBs and investigators with the increasing challenges of informed consent and risk/benefit analysis; and 4) as a flexible resource that can provide collaborative assistance to overcome study hurdles, mediate conflicts within a team, or even directly engage with research participants.

First, one value of research ethics consultation is its availability to researchers during all stages of a project. Consultation requests often occur outside the regulatory review stage of a research project. Ethics consultants address issues that arise during initial study design development, recruitment, study participation, termination, and reporting of the research. In fact, approximately half of the consults in our repository (54%) occurred during the data collection phase, after the research had already been approved by an IRB. In these cases, the

regulatory requirements for human subjects protection were met, yet ethical concerns still arose. In addition, 11% occurred after data collection was completed.

Second, consultation requests are often made for particularly challenging or novel issues. Some of these issues occur in specific research contexts. For example, in the repository, 18% involved pediatrics and 11% involved human biological samples (see Table 1). Other requests also involved research context such as innovative treatments (8%), randomized control trials (6%), international research (4%), community-engaged research (3%), and human stem cells (3%). Some of these requests, such as those regarding pediatric research and research with biological samples, are illustrative of contemporary research contexts about which there is insufficient regulatory guidance. Additionally, the consults in the repository reflect contemporary ethical concerns that have surfaced recently enough such that investigators find advice helpful, such as the disclosure of results to participants (Wolf et al. 2008), which was a concern in 11% of consults, and the complexity of integrating research into the clinical health care delivery systems (Faden et al. 2013), which was an issue in 16% of the repository cases (see Table 2). Examples of novel issues that may not have been previously seen by a particular investigator or IRB are illustrated by the questions discussed by the collaborative (see Table 3). One example dealt with obligations to inform a patient about clinically actionable information identified when population-based research is conducted on aggregate electronic health record data (American Journal of Bioethics 2016a; Crites et al. 2016; Swirsky and Boyd 2016; Whicher and Evans 2016) and another considered questions about using social media to locate research subjects lost to follow-up (Farnan 2014; Parsi and Elster 2014; Swirsky, Hoop and Labott 2014; Taylor, Kuwana and Wilfond 2014).

Third, while informed consent and risk/benefit analyses are issues commonly addressed by IRBs, they are becoming increasingly complex and consults services can provide assistance. Informed consent continues to vex researchers, as illustrated by the fact that nearly half of the consultations in the repository involved issues related to that topic (49%). In today's research environment, it is generally taken for granted that consent will be obtained unless there is good justification to do otherwise. Still, there is ongoing debate about how best to communicate with participants to assure adequate understanding and when consent can be waived (Grady 2015). Furthermore, interesting complexities and challenges can be encountered. For example, in one of the cases the collaborative discussed, researchers struggled to determine whether the parents who initially consented for their newborn's participation or the now-adult child should be the first point of re-contact (Melvin et al. 2015; McKinney 2015; Paquette and Ross 2015; Taylor, Kuwana and Wilfond 2015c). Assessment of research risk and benefit was the second most common ethical concern about which a consult was requested (16%), suggesting that the determination of risk and benefit is not as simple as it may seem. In contemporary analyses of research ethics, many more stakeholders and perspectives are taken into account, such as in another collaborative case dealing with the impact of genetic research on family members and communities (Milner, Liu and Garrison 2013; Rothstein 2013; Shah et al. 2013; Taylor and Wilfond 2013a). REC services can provide additional support to researchers and IRBs in thinking through these unresolved issues.

Fourth, REC services can adopt a flexible approach, going beyond providing ethical advice to actively engaging with study team members, and in some circumstances even engaging directly with research participants. A number of the consults in the repository involved the provision of additional services such as assessment of capacity of a potential research participant to consent (14%); assistance with study design (7%), the consent process (5%), or regulatory review (4%); and conflict mediation (4%). REC can facilitate communication between research participants, investigators and IRBs to ensure that the interests and concerns of all parties are addressed. It is important to highlight that some consults services are available for consults directly from research participants and their families who can benefit from having a resource available when they encounter ethical challenges (Collier and Danis 2017; Doussau and Hanmer 2017; Wetmore 2017; Wilfond, Morales and Taylor 2017). Finally, while most REC services focus on ethical questions related to projects conducted at their own intuitions, a few will work with researchers at others organizations including patient advocacy organizations or biotechnology companies who may otherwise not have access to ethical advice.

We acknowledge that the Collaborative's repository of ethics consultations and the Collaborative case presentations do not reflect the full range and frequency of ethical issues facing investigators and IRBs. Only those ethical questions that rise to the level of attention and concern sufficient to trigger a consultation request are in the repository. Ethical quandaries that investigators resolved on their own, ethical concerns related to research misconduct that might be directed toward an office of research integrity, and regulatory questions that might be brought directly to an IRB or other institutional human research protection programs are not captured. However, the picture illustrated by the repository and the engagement between colleagues made possible through Collaborative activities represents a bellwether of cutting edge and unresolved ethical questions pertaining to clinical research. They signal the ethical issues perceived by researchers and IRBs to benefit from research ethics consultation.

The Emerging Role of Research Ethics Consultation in Research Organizations

The IRB system remains the foundation for the ethical review of research, but our experience with the Collaborative has led us to conclude that research ethics consultation can be a valuable service for organizations that conduct research and particularly useful in the four contexts described above. We encourage institutions that do not have such services, especially those with a high volume of research, to develop REC services. However, we do not think that REC should be mandatory for all research prior to IRB review. Routinely required consultation would likely be an unnecessary and inefficient use of this consultative function and would slow down the review process. However, research ethics consultation can be particularly useful in challenging and novel cases like those presented in Table 3. Furthermore, there are often few individuals at institutions that can serve as consultants and many of them have limited time available for this activity. Over time, we hope that bioethics training programs will provide the foundational knowledge and experience to better prepare the next generation of scholars and consultant to address these issues.

For those institutions that have established or plan to establish REC services, there are several steps that may be taken to improve access to, and quality of, the service, based on the experience of the Collaborative members. Research ethics consultation services should work to raise the visibility of their services among local investigators and institutional bodies responsible for research policy. RECS should have open communication with clinical ethics consult services, as many issues occur at the interface between clinical care and research, and some requestors may be more familiar with clinical consult services. Further, REC services can learn from the clinical ethics consultation field and begin to develop ways to evaluate the quality of the ethical advice given as well as gauge the quality of the experience for consult requestors (Fins et al. 2016; Pearlman et al. 2016). One pragmatic approach that can begin to address access and quality is to establish a research ethics advisory committee. Such a committee of stakeholders, including IRB staff, biostatisticians, investigators, research coordinators, research participants and administrative officials, could provide diverse perspectives to review the recommendations of research ethics consultants, and as they become more familiar with the service, to provide appropriate referrals.

The experiences of the Collaborative convey a research landscape that is undoubtedly complex. While the role of IRBs remains unquestioned, research ethics consultation can complement and add to resources already available. Half a century ago, Henry Beecher's landmark article in the *New England Journal of Medicine* identified "intelligent, informed, conscientious, compassionate, responsible investigators" as a key component of the ethical conduct of human subjects research (Beecher 1966). Research ethics consultants can help researchers in their efforts to meet this ideal. Ethics consultation has the potential to improve the capacity of researchers and IRBs to address the issues they face today as well as the new issues that will inevitably continue to emerge.

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Table 1:

Specific Research Contexts in Research Ethics Consultations (N=359)

No Specific Context	185 (52%)
Pediatric Population	63 (18%)
Human Biological Samples	40 (11%)
Innovative Treatment	27 (8%)
Randomized Control Trials	22 (6%)
International Research	14 (4%)
Community Engaged Research	11 (3%)
Human Stem Cells	10 (3%)
First-in-Human Trials	8 (2%)
Quality Improvement Research	7 (2%)
Emergency Research	5 (1%)

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Table 2:

Specific Ethical Concerns in Research Ethics Consultations that Involve (N=359)

Informed Consent	175 (49%)
Research/Clinical Practice Relationships	57 (16%)
Benefit/Risk Assessment	57 (16%)
Subject Selection/Recruitment	49 (14%)
Disclosure of Incidental Findings/Research Results	41 (11%)
Privacy/Confidentiality	40 (11%)
Study Design	39 (11%)
Research Integrity	37 (10%)
Legal	36 (10%)
Undue Influence/Exploitation	30 (8%)
Socially or Economically Vulnerable Subjects	28 (8%)
Conflict of Interest	21 (6%)
Community Considerations	21 (6%)
Communication of Findings	19 (5%)
Broader Social Impact	13 (4%)
Ancillary Care	11 (3%)
Study Withdrawal/Termination	8 (2%)
Other	12 (3%)

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Table 3:**Novel and Complex Ethical Questions in Research Ethics Consultation**

CLINICAL/RESEARCH RELATIONSHIPS
Should a patient with myelofibrosis, who is an undocumented immigrant with limited English proficiency and financial resources and would otherwise be offered hospice care, be informed about a clinical trial involving bone marrow transplant that has a 30% five year survival? (Taylor, Morales and Wilfond 2016)
Is it ethical to conduct a randomized study on the effect of clinicians offering financial incentives to encourage the uptake of Hepatitis B vaccine in a community clinic? (Wilfond, Morales and Taylor 2016)
What are the responsibilities of clinicians not engaged in a research project that links patient reported data with their electronic health records to review the patient reported data to identify clinically relevant and/or potentially actionable information? (American Journal of Bioethics 2016a)
Should a cancer patient with cholangiocarcinoma be required to undergo standard chemotherapy with limited benefit before being eligible for a novel Phase I immunotherapy clinical trial? (Wilfond, Morales and Taylor 2017)
Does the sponsor of an open-label extension study for a pulmonary hypertension drug have an obligation to allow participants in a subgroup for which the drug was not ultimately approved to remain in the study in order to receive the drug at no cost? (Taylor, Kuwana and Wilfond 2014b)
What is the extent of professional confidentiality in a research institution when a student reveals research misconduct to a university affiliated mental health professional during the course of a clinical counseling session? (Taylor and Wilfond 2013b)
GENETICS
Do the researchers studying an autosomal dominant syndrome have an ethical obligation to disclose the risk of a novel mutation to the descendants of deceased research participants? (Taylor and Wilfond 2013a)
Is it deceptive to conduct genotype-driven recruitment based on fragile X gene mutation status found among participants in a population biorepository cohort study without disclosing to participants that they were selected based their genotype? (Taylor, Morales and Wilfond 2017)
How ought researchers recruit participants to a randomized, placebo-controlled trial of an investigational Alzheimer's prevention agent from two large family cohorts without inadvertently disclosing their mutation status? (Taylor, Kuwana and Wilfond 2015b)
PEDIATRICS
What obligations do researchers have to meet when statutory sexual abuse is disclosed during the course of a study to improve adolescent parenting skills? (Taylor, Kuwana and Wilfond 2014c)
Is it acceptable to conduct a pediatric autism spectrum disorder study using enrollment criteria that favor economically advantaged patients? (American Journal of Bioethics 2016b)
Is it acceptable for the attending neonatologist to obtain parental permission to enroll a newborn in a clinical trial for an investigational drug that must be administered within 24 hours after birth? (Taylor, Kuwana and Wilfond 2015a)
RECRUITMENT AND CONSENT
Is it ethically appropriate to directly recontact and recruit young adults (over 18) who were enrolled in neonatal herpes simplex virus research as infants? (Taylor, Kuwana and Wilfond 2015c)
Should researchers be allowed to enroll cognitively impaired adults in research that poses more than minimal risk and offers no prospect of direct benefit? (Taylor, Kuwana and Wilfond 2015d)
Is it ethically appropriate for researchers to disclose that the drug under investigation is FDA approved for other indications and may be prescribed for "off-label use" by other physicians? (Taylor, Kuwana and Wilfond 2014a)
SOCIAL MEDIA RESEARCH
How should researchers meet their obligations to participants in healthcare research if they are studying social media behavior or recruiting through social media? (Taylor, Kuwana and Wilfond 2014d)