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Creating a Research Ethics Consultation Service: *Issues to Consider*

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ABSTRACT This article provides pragmatic advice for organizations interested in creating a research ethics consultation service (RECS). A robust RECS has the potential to build capacity among investigators to identify and consider the ethical issues they encounter while conducting their research. Determining whether to establish an RECS should begin with an institutional-needs assessment that includes three key questions: What are the current resources available to research teams to navigate ethical concerns that arise from their research? Is there a demand or perceived need for more resources? Is there institutional support (financial and otherwise) to establish and maintain an RECS? If this results in the decision to establish the consultation service, relevant institutional stakeholders must be identified and consulted, and personnel with the requisite skills recruited. The next step is to establish an RECS and build the infrastructure to process and respond to requests. The RECS's long-term sustainability will depend on a stable source of funding and a mechanism to receive constructive feedback to ensure that the service is meeting the institutional needs it set out to address.

KEYWORDS human research ethics, research ethics consultation, research ethics consultation service, institutional review board (IRB)

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This article provides pragmatic advice for academic medical centers interested in creating a research ethics consultation service (RECS). We also discuss the use of research ethics consultation in other research settings. An RECS can provide real-time advice to a broad spectrum of institutional stakeholders involved with research (see table 1), with a goal of improving the quality of research that can in turn ultimately benefit society.[1] Previous reports about research ethics consultation show that this type of service provides support to study teams, trainees, institutional review boards (IRBs), and research participants.[2] Consultations are most commonly sought regarding risk-benefit assessment of proposed research, study design, informed consent issues, undue influence in recruiting research participants, and communication of research findings.[3] The number of institutions in the United States that have an RECS has grown over the past twenty years. According to a 2013 survey conducted by McCormick and colleagues, 33 academic medical centers have established such a service, and interest in this type of service continues to grow.[4]

The article is organized around some of the questions most often posed by institutions that are interested in establishing an RECS. We have based our responses to these questions on our experience creating such a service, conducting research ethics consultations, and serving as members of the Clinical Research Ethics Consultation Collaborative (CRECC),[5] which comprises over 60 individuals affiliated with such consultation

services across the United States, Canada, and Australia. We note that our responses to the questions listed below may be biased, as we believe that providing an RECS adds value to an institution committed to facilitating systematic analysis and problem-solving in the context of research.[6]

WHAT IS THE SCOPE OF AN RECS?

The mission and scope of an RECS is often defined by the range of available expertise and the organizational structure already in place at a given institution. Respondents to the McCormick et al. survey reported having between one and eight individuals as core consultants from a range of disciplinary backgrounds, with just under a third having only one to two consultants.[7] A consultation service might consider ethical questions in laboratory research, how to prioritize research topics, how to maintain objectivity in research, how to approach the use of animals in research, and whether there should be limits on the types of research questions that investigators undertake. For example, a consultation might respond to the question about what ethical limits a researcher or institution should consider with respect to research with samples derived from human embryos. An RECS might also assist clinical investigators with identifying the ethical implications of how and to whom to disseminate their research findings, including information related to whether the disclosure of research results could have harmful effects on individuals, groups, or communities and, if so, how to best mitigate these harms. For example, a consultation service could assist investigators with how to engage with key stakeholders in affected communities to obtain their perspectives.

An RECS can also advise on ethical issues that are not directly addressed by consultations arising in translational research phases, including the balance of social value and research risk, implications of data sharing, and social justice considerations such as the allocation of resources.[8] The service can also address questions about data science (e.g., algorithms or artificial intelligence) and implementation science, as well as cross-cutting issues related to research integrity and objectivity in research (i.e., financial and nonfinancial conflicts of interest). And for public health researchers, an RECS can provide input to help balance individual and community interests about proposed research.

Compared to an IRB or an institution's human research protection program (HRPP), both of which limit their review to the conduct of human subjects research, an RECS can extend its scope beyond human subjects research and explore ethical challenges across the research pipeline from basic science at the bench, through clinical testing of interventions, to the dissemination and implementation of research findings.[9] Acting on the advice and guidance an RECS provides may also benefit individual research subjects and study populations as well as researchers, their institution, and the general public.[10]

To date, most of these consultation services are affiliated with academic medical centers and focus on the ethical conduct of human subjects research.[11] For this reason, we focus our attention on this model of research ethics consultation for the remainder of this article.[12]

Table 1.
Institutional Stakeholders

Regulatory review and oversight bodies
• Human research protection programs
• Institutional review boards
• Institutional animal care and use committees
• Institutional biosafety committees
Offices of legal counsel
Ombudspersons
Offices of research integrity
Academic units, including colleges, schools, departments, and divisions
Bioethics programs
Clinical ethics committees
Deans of research
Leaders of large research programs or portfolios
Investigators
Training program directors
Trainees

IS ESTABLISHING AN RECS AT MY INSTITUTION A GOOD IDEA?

A good first step in determining whether an institution should establish an RECS is to conduct an institutional-level needs assessment. The assessment should include at least these three key questions: What are the current resources available to research teams to navigate ethical concerns that arise from their research? Is there a demand or perceived need for more resources? Is there institutional support (financial and other kinds) to establish and maintain the consultation service?

As to the first question, if the current resources meet the demand of research teams, establishing an independent RECS may not be appropriate. The question is not whether the institution currently has any research ethics "issues"—the assumption should be that, at any research institution, there are important research ethics questions. Instead, an institution should look at itself to ask what resources are currently available and whether the supply of these resources meets the demand. This assessment should include at least a scan of current research ethics engagement opportunities available to members of the institution. If, for example, there is little offered beyond the training required by the National Institutes of Health or the National Science Foundation, establishing an RECS might complement efforts to support study teams and IRBs as well as build research ethics expertise across the institution. Put another way, the more the members of the institution know about research ethics, the more they will appreciate the value of having the opportunity to seek advice specific to their research projects. The current availability of ethics expertise and the types of educational offerings available through the institution's IRB or HRPP should also be explored.

The answer to the second question, related to demand for additional resources, will require serious conversations with key stakeholders. In our experience conducting such conversations, stakeholders are often the best source for innovative solutions and for learning about what kinds of resources will be responsive to unique situations and needs. As one example, engagement with faculty stakeholders revealed that they wanted opportunities to seek advice specific to the ethical challenges they encounter in conducting their research, which led to the creation of one of the first research ethics consultation services in the United States.[13] In that case, the faculty had no interest in additional general educational opportunities such as online training or seminars.

Once the expected value of an RECS has been assessed, it is essential to establish whether there is institutional support for it. In some cases, institutional leadership might approach faculty with the relevant expertise to develop a consultation service, thereby conveying a commitment to the enterprise. In other cases, faculty interested in establishing a service will need to assess demand for it. In both cases, interested faculty ought to reach out to relevant institutional stakeholders to outline the role of an RECS in the current ethics and regulatory landscape.

In addition to seeking input and counsel from the relevant stakeholders, those who serve as research ethics consultants must be cognizant of establishing appropriate boundaries among and between relevant offices, building collaborative relationships, and anticipating conflicts across groups.[14] For example, there ought to be a discussion with each stakeholder office about the roles and responsibilities of each group and where an RECS fits into the network of services provided. This conversation should include a consideration of dual roles, as a single individual might be involved in more than one activity related to the conduct of research at a given institution.[15] Such discussions can lead to expectations for handoff and referrals to and from the consultation service. Because disagreements between offices can occur, it is important to identify a process by which any conflicts can be addressed in a fair and civil manner. Additionally, the policies and procedures of an RECS should be vetted by relevant stakeholder groups when relevant and open to review and refinement as the service matures. The long-term success of the consultation service will depend in part on the relationships built and maintained with these individuals and offices.

Another key question in setting up a consultation service that focuses on human subjects research is whether it should be a component of or independent from the institution's HRPP (or a comparable office of which the IRB is a component). The organizational placement of the service is, in part, a practical matter, as it depends on the funding available to support it. An eth-

ics consultation service could be financially and organizationally separate from the HRPP if there is sufficient institutional endorsement of this approach. One major advantage of financial and organizational independence from the HRPP and the IRB is that it might be easier to convey the role and focus of the RECS, which typically consists of advice regarding ethical issues rather than regulatory requirements. Wherever the ethics consultation service is located organizationally, it is important to clarify the relationship between this service and other entities, especially if the individual seeking consultation expects the discussion to be confidential.[16] There might be circumstances in which the consultant might be ethically or legally obligated to share information. For example, a designated research ethics consultant might be required to report a protocol violation in the unlikely event that an investigator reports one during a consultation and, despite being made aware that such a report to the IRB is required, refuses to report the deviation. Additionally, a mechanism for resolving differences in perspective between the consultant and the IRB should be established.[17]

In some circumstances, even when there is no ethical or legal obligation for the consultant to disclose to another party information divulged to them by an investigator, the consultant might feel the challenge of balancing their role as an agent of their institution with their commitment to creating a confidential space in which investigators can seek advice. Most consultation services establish a policy about when confidentiality cannot be maintained and include this policy in information about the service.[18] The level of confidentiality offered is also relevant to determining how consultations are recorded in a database and who has access to the consultation database. In general, it is best to limit the use of personal identifiers, balancing the need to include enough detail to make the database entry understood with the least amount of identifiable information.

WHAT KNOWLEDGE, SKILLS, AND ABILITIES ARE NECESSARY?

To create a successful RECS, it is important to assess whether the institution has (or can hire) the appropriate employees to act in the role of a research ethics consultant. While there is no agreed-upon list of competencies needed for this position, there is a growing concern that more education and training programs are needed to address competency in research ethics.[19] As more of these consultation services are being established in this area, some scholars have argued for the development of standards of excellence akin to the competencies that the American Society for Bioethics and Humanities (ASBH) has outlined for ethics consultants who address ethics issues in the clinical care setting.[20]

The knowledge required for an effective research ethics consultant includes familiarity with dominant ethical theories and ethical concepts that typically emerge in the research enterprise. Additional knowledge requirements include an understanding of fundamental ethical principles related to research with human participants, frameworks for ethical analysis, research regulations, privacy requirements, conflicts of interest, and effective consent for enrolling in research (including concepts such as competence, capacity, and undue influence). Experience serving on bodies with ethical oversight (e.g., an IRB or a committee reviewing protocols for research with human embryonic stem cells) can complement those knowledge requirements. Research ethics consultants should have an understanding of research design and the implementation of study methods, but ought to also anticipate that they will not necessarily have the specific knowledge relevant to all scientific endeavors about which an ethics consultation could be requested. Therefore, the consultation service should plan to include as consultants scientific experts (e.g., those with research methods expertise) who are unaffiliated with the requestor of the consultation. It is also desirable for the consultation service to keep abreast of developments in research fields relevant to the institutions to which they provide services and of institutional policies and guidance. Such knowledge results in more responsive ethical advice, supporting better relationship building and communication between consultee and consultant, but its usefulness will obviously be limited by a service's resources, such as support staff; by the number of consultations; and by the service's ability to distribute consultants' areas of specialty to cover the type of issues brought to it.

One possible way to address these matters is to consider whether a set of competencies that the ASBH has outlined for clinical ethics consultation services ought

to be adapted for research ethics consultation.[21] Using clinical ethics consultation as a model, we envision for research ethics consultation necessary knowledge-based competence as well as skills-based competence in three areas: assessment, process, and interpersonal interactions.[22]

Assessment skills entail, like those for health care ethics consultation, identifying and analyzing the ethical dimensions and value conflicts related to the request, as well as accessing relevant literature, policies, and standards. Additionally, research ethics consultants must be able to differentiate research ethics questions from those regarding clinical ethics; regulatory concerns; culture, customs, or norms; or personal opinions.

Necessary process skills include developing and communicating the mission of a research ethics consultation service and its expectations, leveraging resources, gathering relevant data, conducting ethical analyses and engaging in moral reasoning, facilitating meetings and conducting deliberations, as well as documenting cases and other activities of the consultation service. In addition, the ability to identify systems issues and to improve the quality of the consultations delivered will be beneficial. Understanding the organization in order to navigate it for communication and decision-making is essential.

Interpersonal skills include listening and communication skills that facilitate education about the ethical dimensions of the consultation and elicit relevant information to obtain a full picture of the ethical concerns. Research ethics consultants must maintain openness to multiple perspectives and must communicate clearly across different disciplines with different epistemologies and languages to overcome boundaries in discussions. Consultants must facilitate deliberation, lead productive discussions aimed at conflict resolution, and attend to various relational barriers to communication. Experience with clinical ethics consultation is one avenue through which someone could develop the assessment, process, and interpersonal skills necessary for conducting consultations involving research ethics.

Not every research ethics consultant will have every knowledge- and skills-based competency, but the consultation service will benefit if, together, its consultants can cover all the competencies listed above. If there are areas of limited knowledge or skill, it is important for the consultation service to be aware of and transparent about the limits of its consultants while considering ways to enhance their skills.

WHAT ARE THE KEY COMPONENTS OF AN RECS?

After the steps of conducting a needs assessment, identifying and collaborating with relevant stakeholders and offices at the institution, and identifying personnel with the requisite skills, the next will be to establish the service. Taking this step requires a clear articulation of the mission of the consultation service, creating a record-keeping system, educating relevant stakeholders about the service, and securing necessary support, both fiscal and organizational.

An essential building block of an RECS is the development of a clear mission and values statement. Such a statement is important for setting the basic parameters of what type of services will be offered, conveying what is offered to potential users of the service, and determining benchmarks (such as the number of consults delivered, across a range of departments and offices) to revisit as the service matures.

Regardless of what parts of the research pipeline a particular research ethics consultation can cover, all such services should provide a space to explore ethics that relies on active listening and engagement with individuals seeking consultation. While the ideal way to encourage frank conversation during a consultation would be to guarantee confidentiality, this might not be possible in all settings (for instance, when the service is a component of the institution's HRPP).

The creation and use of a database to document consultations are recommended.[23] A database is useful for tracking the volume of consultations as well as their substantive content, along with relevant demographic characteristics of those who request a consultation. In addition, including recommendations resulting from a consultation can assist the service in building and evaluating consistency across consultations. Such evaluation would consider, for example, whether, in an institution with several consultants, they are using a similar ethical framework to develop options. An annual report of consultations can be circulated to relevant stakeholders to remind them about the service and keep them engaged in refining and supporting its mission. These data, along with user satisfaction data from patients, providers, and

institutional leaders, can help justify the continuation of the service.

Key to the establishment and sustainability of an RECS will be to secure funding.[24] Although institutions might prefer to seek external funds to support all or part of the service, in many cases, some general institutional funds will be required. In addition, while it is not routine for institutions to seek reimbursement from internal users of a consultation service, some institutions have instituted fees for providing consultations to external institutions as a way to fund their internal efforts.

Once the consultation service is established, the next step is to communicate to the stakeholder community within the institution it will serve. Some of this will have occurred during the needs-assessment phase, and such communication should be enhanced in the implementation phase. There are multiple strategies to advertise a service, and the best approach will be dictated by the institution's culture. While general email announcements are an efficient way to convey information to a large group, they are often disregarded or deleted. Creating a website for the service and placing links on other, related sites may draw potential users. Advertising the service could include announcements at faculty meetings or departmental seminars where individuals engaged in human subjects research gather. Reaching out to leaders of research centers or investigators who lead large research programs at the institution and building relationships can also be very helpful. This can lead to invitations to research-group meetings, thus helping the research ethics consultants become aware of a group's work and culture and provide ongoing support. Offering tailored seminars to research groups or hosting more general research ethics education sessions to wider audiences can also increase awareness about the consultation service. Working with clinical ethics committees or services is another way to ensure that clinical ethics consultations that involve a research component have the right kind of expertise on the consultant team. Holding regular office hours in a well-trafficked area can also attract interest or spark a conversation that ultimately develops into a robust consultation.

Initial contact with the RECS should be simple and efficient. Depending on the expected volume, a phone call or short email message to a central contact can be most effective. Establishing a web-based system for the submission of consultation requests provides an efficient way to track and log consultations, but if the system is not easy to locate, this can be frustrating to potential users. Information about how to access the service, including how and when the service is available, must be clear.

Based on our experience, we consider two process features of an RECS worth noting. First, although it can be tempting to address a simple question submitted electronically with an electronic answer, having one or more conversations, including, when possible, face-to-face (or video) meetings, can be helpful. These interactions can illuminate important nuances and build the relationship between the requestor and the consultant.

As more research ethics consultation services are being established, some scholars have argued for the development of standards of excellence akin to the competencies that the American Society for Bioethics and Humanities has outlined for consultants who address ethics issues in the clinical care setting.

It can be useful to consider how to broaden the meeting to include as many relevant stakeholders as the requestor is comfortable including. Second, developing a work plan to include a short narrative summary of the consultation analysis provided to requestors can be helpful. In some cases, sharing a draft is an opportunity to clarify facts and further the substantive discussion. The requester might also find it useful to have a summary to provide to others on the research team and other relevant stakeholders.

Following establishment of an RECS, ongoing process and content evaluations should occur. Establishing a standard documentation format and database can facilitate the evaluation of quantitative process measures

such as the number of inquiries, the turnaround time, and the number of consultant hours. Analysis of consultation types can be used to design institutional training, tools, or in-service sessions for commonly encountered issues. A routine satisfaction survey can provide useful feedback on how to improve and refine the service as well as complement requests for financial and human resources to sustain the service. As the consultation service matures, a substantive evaluation consisting of interviews with those who have sought consultations, for instance, can help shape the future of the service. Measuring the impact of the service would be useful, but impact is hard to quantify. Possible outcomes to document include IRB approvals and funding of grants whose applications are resubmitted after researchers seek advice from the consultation service. As important as these outcomes are, they are unlikely to occur as the direct result of an ethics consultation alone. The larger impact of an RECS on the overall level of knowledge and awareness of research ethics principles at its institution is also important to measure, but such impact is often elusive in the absence of baseline data.

WORK CONTINUES

Our goal in writing this manuscript was to share our combined experience and insight with individuals and institutions considering whether to establish an RECS. A robust service has the potential to build the capacity of investigators to identify and consider the ethical issues they encounter in conducting their research.

Our group (CRECC)[25] is committed to identifying next steps to further advance the delivery of high-quality research ethics consultations. In the near future, we plan to deliberate about what type of knowledge and skills a research ethics consultant ought to have to provide accurate and thoughtful advice, and we will discuss the potential costs and benefits of standardizing these types of skills and knowledge across institutions. We also plan to consider ways to evaluate and measure the impact of an RECS on those seeking consultations and the projects they bring to the table as well as the impact a consultation service can have on the overall culture of an institution. ♦

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