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Beyond Open Communication: A Call for Partnership Between Clinical Ethics and Research Ethics Committees

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Abstract

In proposing strategies to improve access to and quality of research ethics consultation (REC) services, Porter and colleagues (2018) call for “open communication” between REC and clinical ethics consultation (CEC) services. The authors believe this proposal provides a means for addressing ethical issues occurring at the intersection of research and clinical care, as well as an opportunity for REC services to learn from quality improvement strategies of CEC services. We agree with the premises of this suggestion, yet propose that direct partnership, rather than simply open communication, between REC and CEC services can provide further benefits, including protecting patient-subjects, improving the quality of research ethics consultations, and increasing the visibility of REC services.

OVERLAP OF CLINICAL AND RESEARCH ETHICS

Although the role of REC services has developed to be distinct from the role of CEC services (McCormick et al. 2013), it is important to recognize that clinical ethics and research ethics often overlap and sometimes come into conflict. We recognize that clinical research and clinical care are guided by different ethical principles and responsibilities (Beauchamp and Saghai 2012). However, investigators do have some clinical responsibilities toward the welfare of their patient-subjects when they conduct research (Emanuel, Wendler, and Grady 2000; Danis et al. 2012, 122). Because of these responsibilities, ethical issues in research may overlap with researchers’ clinical obligations toward their patient-subjects. For example, many contend that clinician-investigators sometimes have a duty to provide ancillary care to their patient-subjects (Dickert and Wendler 2009). In other cases, clinical

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ethics and research ethics may conflict. For example, in order to maintain a clinical research protocol's scientific validity, an investigator may struggle with when it is acceptable to withhold clinically indicated treatments from some of her subjects (Danis et al. 2012, 124).

Recent developments in clinical research design have further blurred the boundaries between clinical practice and clinical research, highlighting the frequent overlap between research ethics and clinical ethics. First, rapid advances in medicine, including the development of genomic technologies, robotic procedures, and translational medicine, may bring novel treatments into the clinic before their systematic assessment, such that their use in the clinic bridges both treatment and research (Faden et al. 2013). As another example, in medical specialties like oncology, physician-investigators are encouraged to advertise clinical trials for their patients as "the preferred treatment choice" after standard therapies (Institute of Medicine 2010). A final example is the growth of pragmatic clinical trial designs, which are conducted in practice settings with patients, or the medical records of patients, and often involve comparing standard of care treatments (Ford and Norrie 2016; Patsopoulos 2011). In all of these cases, either research takes on a distinctly clinical bent, or clinical care incorporates elements of research, or both. With continuous changes in both medicine and clinical research, the overlap between these two practices seems only to increase.

A PROPOSAL FOR DIRECT PARTNERSHIP/COLLABORATION

Because of the significant and growing overlap between clinical care and research, we propose a more direct partnership between REC and CEC services. This partnership could take many forms, each of which goes beyond Porter and colleagues' call for "open communication." First, REC and CEC services could share resources. For example, clinical ethics consultants might train REC team members about the clinical ethics issues that arise in research ethics consultations and strategies appropriate for addressing such problems from a clinical ethics angle. CEC and REC services might share other resources such as consult reports, quality improvement reports, and consultation guidelines so that each service can learn from what works and what does not work in the other service. Second, the two services could share members with expertise in both clinical and research ethics. Alternately, REC services could invite a member of a CEC team to participate in consultations that entail clinical ethics issues. Consultation team members with expertise in clinical ethics could ensure that those topics are appropriately addressed in research ethics consultations when necessary. Third, each service could develop guidance to address common issues at the interface of clinical research and practice, such as when providing ancillary care is indicated and how to determine when it might be acceptable to withhold medically indicated treatment for research purposes. Fourth, REC and CEC services could advertise themselves together or as related consultation services. The services might share an intake number so that consult requests could be routed to the appropriate service, or they might create an efficient means of providing joint consultations. Fifth, REC and CEC services could merge into a single consultation service; academic medical centers might be places where this deep integration would be appropriate. This proposal might resemble the Bioethics Consultation Service at the National Institutes of Health (NIH) Clinical Center, which combines research and clinical ethics.

Our proposal applies primarily to academic medical centers that have already established or are considering establishing REC services. However, we also believe that large academic medical centers should have RECs—or, at the very least, invest in creating a subcommittee within the CEC infrastructure dedicated to research ethics—given the complex and specialized nature of clinical research ethics. For these academic medical centers, greater collaboration between REC and CEC services could carry several benefits:

1. REC and CEC services in collaboration could appropriately address the ethical considerations relating to both research and clinical care in a way that neither service may be equipped to do alone. Given the aforementioned overlaps and possible tension between research and clinical ethics, this ability to address all ethical issues in a consult, regardless of the research/practice distinction, seems a necessary feature.
2. The enhanced ability to address the full range of ethical issues through REC–CEC partnerships could better protect research participants' interests. By further incorporating clinical ethics, joint REC–CEC services highlight the unique relationship of the clinician-investigator and patient-participant, and encourage further consideration of the participant's interests for whom the consultation was called.
3. A partnership between REC and CEC services could improve efficiency and consistency of the respective consultations services, for example, through the creation and use of guidance for common areas of clinical care and research overlap. Investigators may also find the services easier to reach if the two services share an intake number or consultations.
4. A potential benefit to collaboration between RECs and CECs is increased visibility of RECs, which are newer and likely less prominent than CECs (McCormick et al. 2013). This also addresses the concern of underutilization raised by Porter et al. (2018).

CASE STUDY

To illustrate possible benefits of collaboration between REC and CEC services, we describe a bioethics consultation from the National Institutes of Health Clinical Center's Bioethics Consultation Service.

A potential research participant is a medically appropriate candidate for an NIH oncology study, but has an extensive history of noncompliance with her previous treatments and only sporadically complies with her psychiatric medications. Although her medical condition is serious, the researchers are concerned about this participant's ability to comply with an exceptionally rigorous protocol. The team was split on whether they thought enrolling her was ethically appropriate. Thus, they approached the NIH Bioethics Consultation Service for an ethics consultation.

The NIH Clinical Center's Bioethics Consultation Service recognized a conflict between the ethics of clinical research and clinical practice. On one hand, enrolling this participant could jeopardize the patient's safety and the goals of the study. If she were not able to comply and

dropped out midway through the trial, she would not only risk her own health, but would also use up valuable resources and impact study results. On the other hand, denying her participation in the research would be akin to denying her otherwise difficult-to-attain medical care for a serious and likely otherwise fatal condition.

As a joint REC and CEC service, the NIH Bioethics Consultation Service was able to address both realms thoroughly. Although it was acknowledged that the researchers could exclude this patient due to her history of noncompliance complicated by her psychiatric condition, the consultation team ultimately recommended accommodating the participant because of her “need[ed] emergent cancer treatment ... [and the benefits of] high-quality care at the NIH.” The consult team also offered specific strategies to ensure the participant’s understanding of the research protocol and to support her compliance, including communication with her primary physician and significant other, evaluation of possible substance use and behavior throughout the study, and ongoing support from social services and the Psychiatric Consultation Liaison Service. In the end, the participant successfully completed the trial and is in full remission.

This example illustrates the power of a direct partnership between RECs and CECs. Without considering the clinical obligations to the research participant and her clinical needs, as well as her dual role as patient and participant, an REC’s advice might have been that it was ethically permissible not to enroll her in the clinical trial. However, direct collaboration of REC with CEC encompassed both perspectives and allowed the establishment of a comprehensive plan that protected both the interests of the patient-participant and the validity of the research.

CONCLUSION

In conclusion, while we acknowledge the distinction between clinical and research ethics, it is important to thoroughly address ethical issues spanning the domains of both REC and CEC services. The current state of clinical research demands an increasingly multidisciplinary approach to answer research ethics questions that incorporate issues of clinical obligations and patient welfare. We appreciate that Porter and colleagues recognized the need to address these overlaps, and suggest that further collaboration and partnerships beyond open communication could carry additional benefits for research ethics consultation services.

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DISCLOSURES

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References

- Beauchamp TL, Saghai Y. The historical foundations of the research–practice distinction in bioethics. *Theoretical Medicine and Bioethics*. 2012; 33(1):45–56. DOI: 10.1007/s11017-011-9207-8 [PubMed: 22258893]

- Danis, M., Largent, E., Wendler, D., et al. Clinical research consultation: A casebook. Oxford, UK: Oxford University Press; 2012.
- Dickert N, Wendler D. Ancillary care obligations of medical researchers. *Journal of the American Medical Association*. 2009; 302(4):424–28. DOI: 10.1001/jama.2009.1076 [PubMed: 19622821]
- Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *Journal of the American Medical Association*. 2000; 283(20):2701–11. DOI: 10.1001/jama.283.20.2701 [PubMed: 10819955]
- Faden RR, Kass NE, Goodman SN, Pronovost P, Tunis S, Beauchamp TL. An ethics framework for a learning health care system: A departure from traditional research ethics and clinical ethics. *Hastings Center Report*. 2013; 43(s1):S16–27. DOI: 10.1002/hast.134
- Ford I, Norrie J. Pragmatic trials. *New England Journal of Medicine*. 2016; 375(5):454–63. DOI: 10.1056/NEJMra1510059 [PubMed: 27518663]
- Institute of Medicine. A national cancer clinical trials system for the 21st century: Reinvigorating the NCI Cooperative Group Program. Washington, DC: National Academies Press; 2010. <https://doi.org/10.17226/12879>
- McCormick JB, Sharp RR, Ottenberg AL, Reider CR, Taylor HA, Wilfond BS. The establishment of research ethics consultation services (RECS): An emerging research resource. *Clinical and Translational Science*. 2013; 6(1):40–44. DOI: 10.1111/cts.12008 [PubMed: 23399088]
- Patsopoulos NA. A pragmatic view on pragmatic trials. *Dialogues in Clinical Neuroscience*. 2011; 13(2):217–24. [PubMed: 21842619]
- Porter K, Danis M, Taylor H, Cho M, Wilfond B. The emergence of clinical research ethics consultation: Insights from a national collaborative. *American Journal of Bioethics*. 2018; 18(1): 39–45.