

Research Ethics Collaborative: Requestor Information

Effective ethics consultation services can promote ethical research and support investigators, study teams, regulators, and research participants in their aligned mission of advancing knowledge to improve health.

The Clinical Research Ethics Consultation Collaborative is made up of approximately 45 members affiliated with various research ethics consultation services across the United States.

The Collaborative's mission is to:

- Share practices and experiences related to clinical research ethics consultation.
- Enhance understanding of the complex ethical dilemmas that emerge with advancing translational science.
- Improve the quality of clinical research ethics consult advice.

Our activities build on the work of the Clinical Research Ethics Consultation Working Group of the Clinical and Translational Science Awards program from the National Center for Advancing Translational Sciences.

The Collaborative has three major initiatives that involve consult requestors:

1. Collaborative Consultation (described on page 2)

2. Case Webinars: Each quarter, a member presents a case to the entire group during the monthly meeting. This case is one that the presenter was directly involved with, and the requestor can be invited to participate in the webinar. The format is:

1. The presenter explains the background of the case and the primary questions (15 minutes).
2. The group discusses the case and exchanges thoughts and ideas (30 minutes).
3. The presenter shares what actually happened as far as advice and follow up (5 minutes).
4. The group discusses the case outcome and recommendations (10 minutes).

The presenter generally uses PowerPoint slides to convey key points of the presentation.

3. Case Publications: Some case presentations are published in the *American Journal of Bioethics* as part of a twice-yearly series, "Challenging Cases in Research Ethics Consultation."

The case presenter drafts a summary of the ethics case (500 words). Case summaries do not make specific mention of where the consultation took place, the requestor's name, or full details. The summary is then circulated to the entire group in order to solicit three commentaries (800-1200

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words). The case presenter (often in collaboration with the consult requestor) routinely submits one of the three commentaries.

Participating in a Clinical Research Ethics Collaborative Consultation

Thank you for requesting a research ethics consultation with our group. The information below will help you understand our process. There are two key points to keep in mind:

1. The collaborative consultants' comments, suggestions, and recommendations are advisory.
2. You should still use discretion in discussing highly sensitive information, even though the consultants have agreed to keep the conversation confidential.

Before the Call:

You will be given biosketches so you can be aware of which members are participating. We typically have 5 to 10 members on a call.

During the Call:

1. The consultant will ask you to introduce yourself and anyone on your team, and then will do a roll call of the collaborative consultants on the call.
2. The consultant will ask you to present the background and clarify the question(s) you would like addressed.
3. The consultant will ask any clarifying questions and then ask if the collaborative consultants have any additional clarifying questions.
4. The consultant will discuss the issues with you and then ask the collaborative consultants if they have additional comments.
5. The consultant will finalize the recommendations with you and then ask the collaborative consultants if they have any final comments.

After the Call:

1. You will receive a consult report. Some consultants will send you a draft to review, depending on their usual practice. The consultant may also send the draft report to the collaborative consultants for their feedback in preparation of the final report.
2. The final report will be sent to you and to the collaborative consultants.
3. You might receive a request for feedback about the collaborative consultation experience. Feedback will be shared with the group.

Confidentiality

Collaborative consultants are expected to keep the details of the discussion confidential. Each consult service has its own guidelines for limits of confidentiality and reporting obligations. Those outside of the initiating institution are expected to not make disclosures to the requestor's institution or to their own.