The ITHS Research Bioethics program provides a forum for discussion and analysis of ethical issues in clinical and translational research. Our team can help address ethical questions in areas such as:

**Study Development**
- What if informed consent is not practical for my study?
- When is a placebo-controlled study design ethically appropriate?

**Study Implementation**
- Can I withdraw participants against their wishes?
- What must I do if my participants need medical care or other help?

**Study Analysis**
- Should I tell participants about the research findings?
- What if participants request their data be withdrawn?

**Community Engagement**
- How should I negotiate disagreements with community stakeholders?
- How should I share the research data with the community?

**Research Bioethics Consultants**
- Ellen Kuwana, MS, ITHS Bioethics Program Manager
- Ann Melvin, MD, MPH, Seattle Children’s
- Kathryn Porter, JD, MPH, Seattle Children’s
- Mark Stein, PhD, ABPP, Seattle Children’s
- Benjamin Wilfond, MD, Seattle Children’s

**The Consultation Process**
ITHS offers research bioethics consultations to researchers, trainees, research staff, and personnel involved in the protection of human subjects. Discussions with consultants can take place by telephone or in person. There is generally no charge.

Bioethics consults are advisory and provide a forum for in-depth conversation and analysis of ethical issues in clinical and translational research. Recommendations are supplemental to the authority and oversight of review groups such as an Institutional Review Board or Data Monitoring Committee.

To ensure a balanced understanding of the facts or to facilitate resolution of a conflict, the consultant is available to talk with others involved in the issue if the requestor so desires.

In some cases, the issue may warrant referral to offices such as the institutional ombudsperson, human resources, or legal counsel.

In rare cases, consultants have obligations to share consult information with others. Examples include significant concerns about safety, sexual harassment, research misconduct, or research non-compliance where participant safety is at stake.

**The Post-Consultation Process**
- Requestors will receive a written report summarizing the consultation. We will also request feedback from the requestor to inform improvements to the Research Bioethics Consultation Service.
- ITHS may contact requestors annually to collect information about ITHS services that have assisted the researchers in submitting grants and publications.
- The consultation will be entered into a database. Access to this database is restricted to the bioethics consultants and ITHS administrative staff.
- Hourly charges can be included in grant applications for projects that anticipate the need for regular consultation or collaboration in the future.

**Contact Us**
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- Web: iths.org/bioethics

ITHS is supported by grants UL1TR000423, KL2TR000421, and TL1TR000422 from the NIH National Center for Advancing Translational Sciences through the Clinical and Translational Science Awards Program (CTSA).