Research Ethics Consultation

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Background

• Evidence in literature from 20 years ago but most recent set of articles on experience from a number of institutions in last 10 years

• Most recent interest in Research Ethics Consultation has come with creation of CTSAs directing applications to importance of research ethics related resources

Beskow et al, IRB 2009
National Collaborative

• National Survey
  – 46 CTSA institutions responded
  – 33(70%) had established a consultation service
    • 9 of the 33 initiated a consultation service prior to CTSA funding
      – 2 of the 9 had been in existence for 6 years or more

McCormick et al, Clinical and Translational Research 2013
A consultation on a research ethics related matter is an advisory activity available throughout the lifecycle of a study. It involves interaction between researchers or other stakeholders in the research enterprise and one or more individuals knowledgeable about the ethical considerations in research, including concerns related to any aspect of planning, conducting, interpreting, or disseminating results of research broadly related to human health and well being. The purpose of the interaction is to provide information; identify, analyze, and/or deliberate about ethical issues; and recommend a course of action through informal or formal mechanisms.

A research ethics consultation service is an individual or established group of individuals that is formally tasked with providing consultations to anyone involved in research activities who has research questions or concerns. Furthermore, an existing and publicized mechanism is in place by which investigators can contact a research ethics consultant in order to identify, analyze, and/or deliberate about ethical issues as well as to discuss a course of action.
Research Ethics Consulting Service

• Component of ICTR Research Participant Recruitment and Retention Core
  – Research Ethics Achievement Program
    • Research Ethics Workshops About Responsibilities and Duties of Scientists (REWARDS)
    • Research Ethics Consult Service (RECS)

• Established in 2008 (services available to JHSPH since 2005)
Research Ethics Consulting Service

• **Goal:** To help raise awareness of and to assist investigators in resolving issues of ethics in human subject research throughout research process.

• Service is open to anyone in Hopkins community (i.e. anyone with a JHED ID).
Research Ethics Consulting Service

• Link to ICTR Connection Request.
  – http://ictr/johnshopkins.edu/connection/

• Connections will be handled by appropriate BI faculty
CONNECTION REQUEST

Welcome to the ICTR's Connection Request System.
You can use this system to:
• submit requests for ICTR services
• ask for help from any of our consultants
• submit questions, comments, or complaints
• apply for ICTR grant programs.

This is your one-stop shop for everything the ICTR has to offer.
To log in with your JHED ID and connect with one of the ICTR programs listed below, Click Here

ICTR Connection Request Service List:

• Ask an ICTR Navigator

The Navigators are here to help direct investigators to the ICTR services they need and advise them on “next steps” in the clinical and translational research enterprise at Johns Hopkins. If you’re not sure where to start, click here to ask a Navigator!
ICTR Translational Laboratory Core [Website]

The Translational Laboratory Core is made up of ICTR supported labs that provide coordinated consultative help across several related programs, all focused on the foundational components required to effectively translate new drugs, biologics, vaccines, devices, biomarkers and diagnostics into clinical trials and eventually clinical practice. Supported labs include: 1) Drug Analysis Unit, 2) Drug Screening Library Unit, 3) Medicinal Chemistry Unit, 4) Drug Development Unit, 5) Biologics Translational Program, 6) Genetics Translational Technology Program, 7) Proteomic Biomarker Development Program, 8) Imaging Translational Program, and 9) Metabolomics Program. For more information, click on Translational Laboratory Core website. Click here to apply.

Nexus Grant Program

The Nexus Grant Program is sponsored by the ICTR Translational Research Communities. The deadline for applications is October 1, 2014.

Research Data Collection and Storage (RDCS)

The ICTR offers consulting and, in some cases, direct assistance with research data collection and storage issues. Among the services provided by RDCS are: advice on database construction, design, and remote data access; web-based and teleform data collection; and secure storage and backup for data associated with clinical research studies. Click here to apply.

Research Ethics Consulting Service (RECS)

RECS provides advice and support for investigators as they address ethical questions that arise during study design and execution. Click here to apply. [More information ...]

The Office of Recruitment and Retention (ORR) Consult Service [Website]

The ORR consult service offers consultations and expert advice on the recruitment of research participants. Click here to apply. [More information ...]
• ICTR Translational Laboratory Core [Website]

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Password

Login

The purpose of Johns Hopkins Enterprise Authentication is to provide a single sign-on functionality for our customers to access many applications with just one login.

First time JHED User?  Forgot Password?  Change Password?

Login Problems?  Frequently Asked Questions

Johns Hopkins Enterprise Authentication - V6.6.2.21
Use of the Johns Hopkins Enterprise Directory (JHED)

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Research Ethics Consulting Service (RECS)

General Information

Welcome to the ICTR Research Ethics Consulting Service. The purpose of this service is to provide assistance to the Johns Hopkins research community. The service is available to help individuals from Johns Hopkins consider and address ethical issues or situations that may arise in the development, execution, or analysis of a research study.

Students are welcome to use this service, but their requests should be placed through their faculty advisors or P.I.s.

General Information

An ethics consultation is an advisory service to assist the Johns Hopkins University research community in considering ethical challenges that arise in the design and conduct research. The information provided is intended to serve as information only, which requires further evaluation by the investigator or authorized representative.
General Information

An ethics consultation is an advisory service to assist the Johns Hopkins University research community in considering ethical challenges that arise in the design and conduct of research. The information provided is intended to be educational and helpful in decision-making processes. However, the ethics consultants will not make decisions for the investigators. Investigators remain responsible for their choices. Regardless of whether an ethics consultation has been sought, faculty and student researchers must obtain formal approval from the relevant University oversight committee(s) (e.g., IRB, IACUC, or ESCRO) before initiating any research project. None of the University oversight committees are bound by the options presented by the consultants. The alternatives presented by the consultants are not institutionally or legally binding.

Confidentiality

Research ethics consultants may disclose project-specific information to the appropriate Johns Hopkins institutional oversight body if, a researcher/study team member discloses information revealing what appears to be a significant ethical or regulatory violation, including risks to subjects that have not already been reported to the appropriate oversight body by the research/study team member. If a study team member (other than the Principal Investigator) provides information indicating a problem that he or she is not comfortable sharing with the PI, the consultant will direct that person to report the information using confidential institutional reporting channels.

Conflicts of Commitment

To avoid conflicts of interest, consultants who also serve on oversight committees will inform the relevant oversight committee if they are asked to review a protocol as part of their committee service on which they also have consulted. Further, oversight committee members, including consultants themselves, may conclude that a consultant should recuse her/himself from a committee vote to avoid a conflict of interest.

1. IRB/ESCRO/IACUC Protocol Number (if available):

2. This consult is primarily about research with:
2. This consult is primarily about research with:
   - Select One

2a. If 'Other':

3. Research Type:
   - Select One

3a. If 'Other':

3b. If clinical trial, what phase? (check all that apply):
   - First-in-Human
   - Phase I
   - Phase II
   - Phase III
   - Phase IV
   - n/a

4. Number of Study Sites:
   - Single
   - Multiple

5. Research Setting:
   - Select One

5a. If 'Other':

6. Project Phase:
   - Select One

6a. If 'Other':
6. Project Phase:
   - Select One

   6a. If "Other":
      
7. Select the category that best describes your query.
   - Select One

   7a. If "Other":
      
8. How did you hear about our service?
   - Select One

   8a. If "Other":
      
9. Were you referred to our service? If so, by whom?
   
10. What is your question for the research ethics consultation team? *
Public Health Experience

• Between 2005-2007: 72 consults
• Most (70%) placed by faculty
• Within JHSPH, 42% of consults came from Department of International Health
• Consults were:
  - 19% regulatory
  - 81% ethical
# Stage of Study

<table>
<thead>
<tr>
<th>Stage</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Development</td>
<td>35 (52)</td>
</tr>
<tr>
<td>Under JHSPH-IRB Review</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Preparation for Data Collection</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Data Collection Underway</td>
<td>17 (25)</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>6 (9)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Missing Value</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>72 (100)</td>
</tr>
</tbody>
</table>

Taylor & Kass, *IRB 2009*
## Content of Consults (Top 10)

<table>
<thead>
<tr>
<th>Topic</th>
<th>Ethics</th>
<th>Regulatory</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>20</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>20</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>Risk/Benefit Assessment</td>
<td>17</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td>Study Design</td>
<td>13</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>Human Subject Research?</td>
<td>7</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Secondary Data Analysis</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>IRB Application</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Disclosure of Test Results</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Data Monitoring Committees</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Study Procedures</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>84</td>
<td>14</td>
<td>98</td>
</tr>
</tbody>
</table>
Sample Consult

• Investigators are planning to conduct a mineral supplementation trial in a resource limited setting. Limited evidence already exists from another resource limited setting on another continent indicating that supplementation is beneficial. Investigator wants help in thinking through whether clinical equipoise exists and whether it is ethical to conduct the planned trial.

– Codes assigned: Risk/Benefit Assessment, Study Design
Sample Consult

• Investigators are conducting a cancer screening study in a rural area in South Asia. The women enrolled in the study are refusing the standard therapy and requesting a riskier, clinically non-indicated procedure.

  – Codes assigned: Population, Risk/Benefit, Subject Request for “Unnecessary” Treatment
Typical Consultation

• Acknowledgement of consult in 24 hours
• Resolution
  – By e-mail
  – In-person
  • Phone
  • Meeting
    – PI
    – Study Team
RESEARCH ETHICS Consulting Service

http://ICTR.JohnsHopkins.edu/ResearchEthicsConsult

A FREE service offered through the ICTR.
Questions