IRB Red Flags
How to Know When IRB Review May Be Needed

Human Research Protection Program

Presented by
Aline Lovings, MA, CIP
HRPP Interim Director
Federal Regulations

- 45 CFR 46 – Basic Department of Health and Human Services Policy for Protections of Human Research Subjects
  - Definitions of Research and of Human Subjects
  - Criteria for review of Human Subjects Research
- Additional Regulations from other Federal Agencies
Basic Ethical Principles

• Respect for Persons
  ▪ autonomy of subject

• Beneficence
  ▪ benefits outweigh risks

• Justice
  ▪ selection of subjects is equitable
Institutional Rule

- Research conducted (1) by or using Texas A&M faculty, staff, and/or students and/or (2) on Texas A&M property must be reviewed by the TAMU IRB.
Is it Research?

• The federal regulations define research as:
  ▪ “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(d)).
Is It a Human Subject?

"a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 CFR 46.102(f)(1),(2))

- **Intervention** includes physical/psychological procedures, manipulations of the subject, or manipulations of the subject’s environment for research purposes.
Red Flags List

- human samples, cells, tissues;
- research on education instructional strategies;
- research on involving normal educational practices;
- research involving educational tests, surveys, interviews, observation of public behavior;
- research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;
- research and demonstration projects designed to study, evaluate, examine public benefit or service programs;
- taste and food quality evaluation;
- consumer acceptance studies;
- research on drugs;
- research on medical devices;
- collection of blood samples;
- collection of biological specimens;
- collection of data routinely employed in clinical practice;
Red Flags List (continued)

• x-ray;
• microwave;
• collection of data from voice, video, digital, or image recordings made for research purposes;
• research on individual or group characteristics or behavior;
• research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior;
• survey;
• interview;
• oral history;
• focus group;
• program evaluation;
• human factors evaluation;
• quality assurance methodologies
Where do I start?

• CITI Training
  ▪ Must be renewed every five years
  ▪ Web-based ethics course
  ▪ All study personnel must complete CITI training with a minimum score of 90 percent.
  ▪ www.citiprogram.org
  ▪ More information available at: http://rcb.tamu.edu/humansubjects/training
Submission Process for Research with Human Subjects

1. Submit Required Documentation
2. Pre-review
3. Review by Committee
4. Communicate Outcome
5. Conduct Research
How to Submit Your Project

Online system – iRIS
 http://imedris.tamu.edu

Information
 –Help line (979.845.4969)
 –HELP button
 –FAQs on the website:
  http://rcb.tamu.edu/humansubjects/faqhumansubjects
Submission Process for Research with Human Subjects

1. Submit Required Documentation
2. Pre-review
3. Review by Committee
4. Communicate Outcome
5. Conduct Research
Submission Process for Research with Human Subjects

1. Submit Required Documentation
2. Pre-review
3. Review by Committee
4. Communicate Outcome
5. Conduct Research
### Categories of IRB Review

<table>
<thead>
<tr>
<th>EXEMPT</th>
<th>EXPEDITED</th>
<th>FULL BOARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>No/minimal risk</td>
<td>Minimal risk</td>
<td>Greater than minimal risk</td>
</tr>
<tr>
<td>Existing data</td>
<td>Prospective data</td>
<td>Annual continuing review</td>
</tr>
<tr>
<td>5-year continuation</td>
<td>Annual continuing review</td>
<td>Review by two IRB members</td>
</tr>
<tr>
<td>HRPP staff</td>
<td>Single IRB member</td>
<td>then IRB</td>
</tr>
</tbody>
</table>

- **EXEMPT**
  - No/minimal risk
  - Existing data
  - 5-year continuation
  - HRPP staff

- **EXPEDITED**
  - Minimal risk
  - Prospective data
  - Annual continuing review
  - Single IRB member

- **FULL BOARD**
  - Greater than minimal risk
  - Annual continuing review
  - Review by two IRB members then IRB
Eight Ethical Assessment Criteria

- Risks are minimized
- Risks are reasonable vs. benefits
- Selection is equitable
- Informed Consent is obtained
- Participation is voluntary
- Data and Safety are protected/monitored
- Privacy and confidentiality are upheld
- Vulnerable population protections are enhanced
Vulnerable Populations

- Additional safeguards must be implemented for populations in which research may pose additional and/or unknown risks.
- For example
  - Pregnant Women, Human Fetuses, and Neonates
  - Prisoners
  - Children
  - Economically disadvantaged
  - Socially disadvantaged
  - Educationally disadvantaged
  - Cognitively impaired
  - Disabled
Submission Process for Research with Human Subjects

1. Submit Required Documentation
2. Pre-review
3. Review by Committee
4. Communicate Outcome
5. Conduct Research
Submission Process for Research with Human Subjects

1. Submit Required Documentation
2. Pre-review
3. Review by Committee
4. Communicate Outcome
5. Conduct Research
How will I know when I can begin?

- Official approval letter sent through iRIS
- Use stamped recruitment documents

Am I done with the IRB?

*Not quite! Keep us informed!*

- Submit any desired project changes to the protocol or study documents for review
- Report any adverse events or deviations
Questions?

Human Subjects in Research Resources

- [http://rcb.tamu.edu/humansubjects](http://rcb.tamu.edu/humansubjects)
- 979.458.4067

Online system – iRIS
- [http://imedris.tamu.edu](http://imedris.tamu.edu)

iRIS Support Team
- outreachrcb@tamu.edu
- 979.845.4969

TAMU IRB Liaisons by College and Department
Amy Donnellan, Denise Puga, Jennifer Rau-Hug and Graeme Wright

HRPP Interim Director
Aline Lovings
aloavings@tamu.edu
979.458.4117