The Human Research Protection Program

Presented by Adrienne Meyer, MPA, CIP

9:30am-10:30am

UW Husky Union Building

Room 145

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

The Human Research Protection Program

Cultivating a Partnership with Your IRB

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Learning Objectives

- Discuss the dynamic relationship of the IRB and research staff in the regulatory compliance environment
- Describe, and possibly begin to create a strategy for how to plan a response to the IRB
- Identify the location of resources for partnering with the IRB

There is nothing insignificant in the world. It all depends on the point of view.

-- Johann Wolfgang von Goethe

If you wish to please people, you must begin by understanding them.

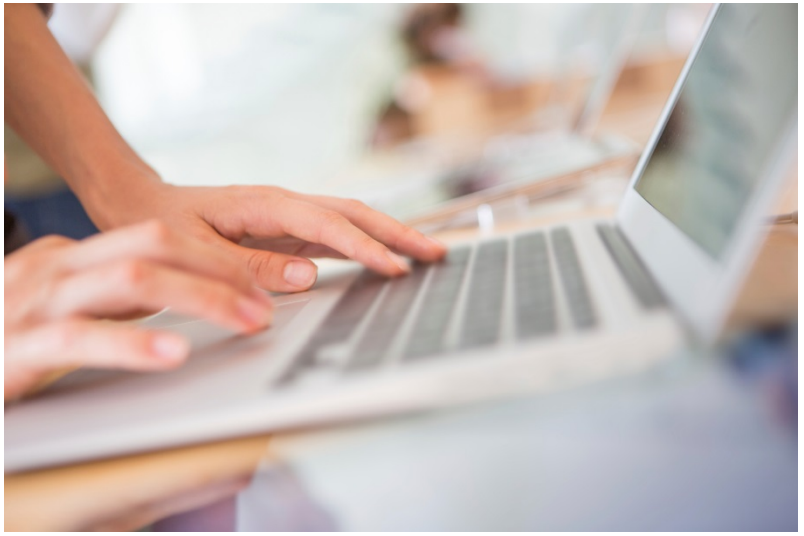
– Charles Reade

What role does the IRB play?

The primary purpose of the IRB is to protect the rights and welfare of human subjects involved in research activities being conducted under its authority.

The IRB primarily does this by reviewing research protocols before they are implemented and assessing them against:

- Federal Regulations
- State Laws
- Institutional Requirements



Federal Regulations

- Common Rule (45 CFR 46)
- FDA Regulations (21 CFR 50 and 21 CFR 56)
- HIPAA Privacy Rule
- Family Educational Rights and Privacy Act (FERPA)*
- Protection of Pupil Rights Amendment (PPRA)*

Example: Federal Criteria for IRB Approval

- Risks to subjects are minimized using
  - procedures consistent with sound scientific design and which do not unnecessarily expose subjects to risk
  - whenever appropriate by using procedures already being performed on subjects for diagnostic or treatment purposes
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable (no groups are being exploited)
- Informed consent will be obtained or meets criteria for being waived
- Informed consent will be documented or meets criteria for being waived
- Privacy and confidentiality will be protected as appropriate to the study
- Data and safety monitoring provisions are appropriate to the study
- Additional protections for vulnerable populations such as children and prisoners

State and Other Laws

APPLICABILITY OF THESE LAWS DEPENDS ON LOCATION OF RESEARCH AND OTHER FACTORS SPECIFIC TO THE RESEARCH

- WA State Law → additional considerations for use of medical records
- CA State Law → additional requirements for consent information presented
- Various → age of majority, mandatory reporting

Institutional Requirements

- Training and qualifications of research team
- Coordination with other review offices
  - Office of Sponsored Programs (OSP)
  - Radiation Safety
  - Institutional Biosafety Committee
  - Financial Conflict of Interest Review
- Policies about how recruitment or other aspects of the study must be carried out
- Metrics and reporting requirements for the institution

The IRB Needs Information

- Initial Application
- Requests for additional information
  - Pre-Review
  - Deferral
  - Conditional Approval
- Status Reports
- Modifications
- Reports of New Information

Empowered Responses to IRB Requests Consider Four Things

- What information does the IRB want?
- Why does it want that information? (What is it trying to determine or decide?)
- What is the best source for that information?
- How should we respond?

Exercise: What does the IRB want and why?

The committee is not clear as to whether children will be enrolled because guidelines for children are described as part of the exclusion criteria for population 1 in section 2.2 of the IRB Protocol.

- Please clarify whether children will be enrolled either as part of population 1 or 2?

- If not, please delete references to children in 2.2 and references to assent in 2.2 and 5.1.

- The committee suggests that you consider that the inclusion of children in population 2 may increase the scientific validity of your data. If you would like to do so, you can either revise the application now to include children or submit a subsequent modification.

Activity: What information does the IRB want and what is the best source for the information?

- **Refer to handouts**

But why, why, why can't people just say what they mean?

– Graeme Simsion

In terms of asking questions, I plead guilty. I ask a hell of a lot of questions. That's my job.

-- Dick Cheney

The Study Team Needs Information Too

The Research Coordinator should play a key role in obtaining information for the study team:

- What information about the study is the IRB going to need? Do we have it all?
- What are the most likely concerns that the IRB will have? Can we address them ahead of time?
- Do we clearly understand what the IRB is asking? Do we need to request clarification?
- Are there any special considerations for this study? What do we do about that?

Activity:
What information do you need and how will you get it?

Preparing Effective Responses

- Write in lay language
- Address *every* request in each question
- Address *every* question
- Format for readability
- Be courteous and professional

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