## Types of IRB Review

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Not Research / No Human Subjects</strong></td>
<td>- Letter may be necessary at sponsor’s request or for journal publication</td>
</tr>
<tr>
<td><strong>Exempt</strong></td>
<td>- Federal regs do not apply to certain categories, ensure relevant protections</td>
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<tr>
<td><strong>Expedited Review</strong></td>
<td>- <em>Minimal risk</em> research that falls in certain categories under regulation</td>
</tr>
<tr>
<td><strong>Full Board Review</strong></td>
<td>- Greater than minimal risk research or research that cannot be expedited</td>
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</table>
Example: Receiving completely anonymous data from a national study

- Local research team not involved in the original study in any way (no interaction / intervention)
- Local research team not receiving identifiers and will not be able to link the data to identifiers in any way (not identifiable)
Example: Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens

- Information must be recorded with no codes or other identifiers
- In existence at the time of the IRB submission
Exempt

- Anonymous surveys with adults
- Surveys on non-sensitive information (adults)
- Curricular evaluation studies in regular educational settings
- Interviews
- Observation of public behavior
Minimal Risk

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population) or during the performance of routine physical or psychological examinations or tests.
Collection of blood samples, with restrictions
Non-invasive biological specimen collection
  ◦ Urine, saliva, hair, nails
Non-invasive data collection
  ◦ MRI, EEG, no x-rays or CT
Materials collected for non-research purposes
  ◦ Medical, employee or school records
Data from audio/video files for research purposes
Interviews, focus groups, surveys
Greater than minimal risk research
Research that cannot be expedited
Research sent by IRB staff discretion

Possible voting outcomes:

- Full Approval
- Approved Subject to Modifications
- Reconsideration
- Disapproval
IRB Members have access all approved studies:

Through Agenda:

“My Home” OSIRIS Page:
Road to IRB Review

Mentor for Students

Scientific Review

Ancillary Committees

IRB Queue

Assignment to a reviewer (Expedited and Exempt) or to a Committee (Full Board)
Notifications & Ancillary Review

- UPMC Research Fiscal Review
- Investigational Drug Service (IDS)
- Office for Investigator-Sponsored IND and IDE support (O3IS)

Ancillary Review

- Mentor
- Scientific Review
- Radiation Safety
- Biosafety Committee (rDNA)
- Conflict of Interest
- SCRO (stem cell)
All studies involving human subjects must undergo departmental scientific review except:
- research qualifying for “exempt” review
- research reviewed by a peer scientific review committee as a condition of research funding (e.g., NIH/NSF sponsored research)

Department of Defense studies must have departmental review
Possible questions from AAHRPP

- Can you give examples of a study that could be expedited? Exempt?
- How is it determined that the research does not involve human subjects?
- When is scientific review necessary?
- What is the IRB’s role in scientific review?
Of course the IRB Reviews the Science!

...in the context of risk minimization and protection of the rights and welfare of the research participants

- Risks to study participants are minimized
- Potential benefit justifies potential risk
Criteria for IRB Approval

- Risks to study participants are **minimized**
- Risks are **reasonable** in relation to anticipated benefits
- Selection of subjects is **equitable**
- **Informed consent** is obtained and appropriately documented
- Adequate provisions for **monitoring** collected data to ensure safety of subjects
- **Privacy** of participants and **confidentiality** of data are protected

-46 CFR 46.111, 21 CFR 56.111
<table>
<thead>
<tr>
<th>Privacy</th>
<th>Individuals’ right to control access to their information and body</th>
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<tr>
<td>Confidentiality</td>
<td>How private information provided by individuals will be protected by the researcher from release</td>
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Meeting preparation:

- Review prior to the meeting and troubleshoot any issues
- Discuss the protocol with investigator if you are comfortable or have the IRB staff facilitate the dialog
- Informed the Vice Chair or IRB coordinator of any issues prior to the meeting
Possible questions from AAHRPP

- Do you know how to access the checklists provided? Do you use them?
- How do you prepare for your reviews?
- What aspects do you consider when you review a protocol?
- How is risk determined?
- How does your committee discuss the criteria for IRB approval (.111 criteria)?
Questions?

Specialized education available upon request: askirb@pitt.edu