IRB Review

Types of IRB Review

Not Research / No Human Subjects	• Letter may be necessary at sponsor's request or for journal publication
Exempt	• Federal regs do not apply to certain categories, ensure relevant protections
Expedited Review	• Minimal risk research that falls in certain categories under regulation
Full Board Review	• Greater than minimal risk research or research that cannot be expedited

Not Research / No Human Subjects

- 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)

Exempt

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.

Expedited

- 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

Full Board

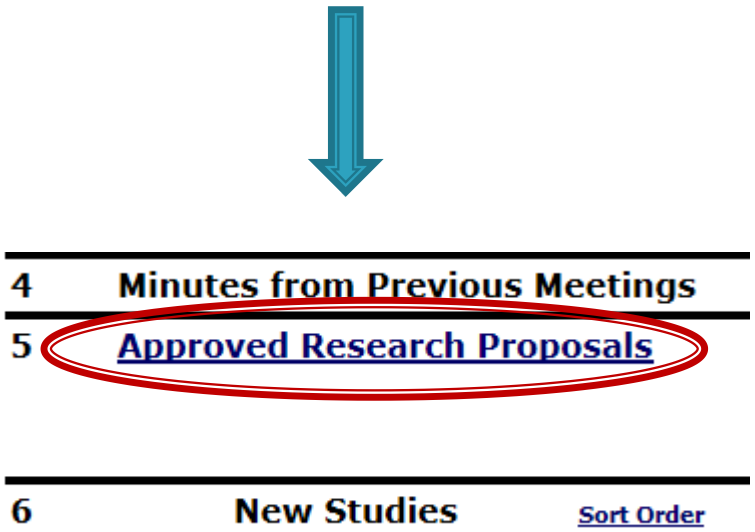
Greater than minimal risk research
Research that cannot be expedited
Research sent by IRB staff discretion

Possible voting outcomes:

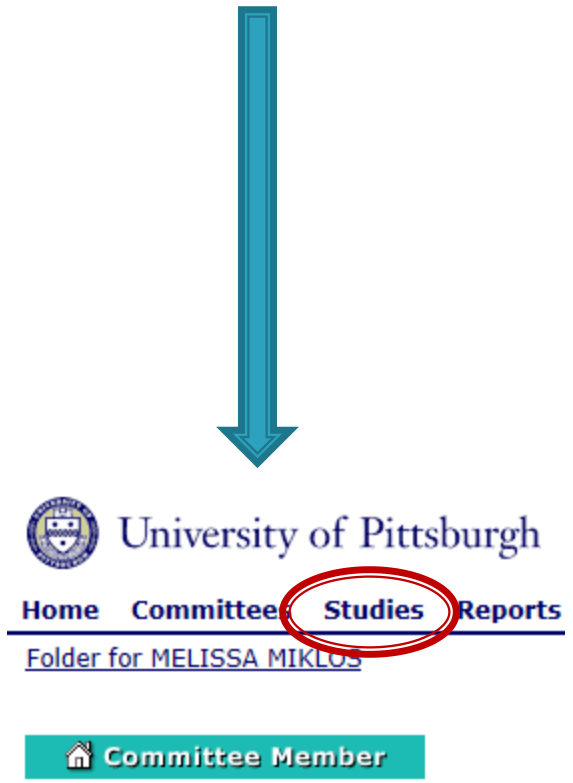
Full Approval	**Approved Subject to Modifications**
Reconsideration	**Disapproval**

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

Ancillary Review

- Mentor
- Scientific Review
- Radiation Safety
- Biosafety Committee (rDNA)
- Conflict of Interest
- SCRO (stem cell)

Notifications

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

Scientific Review

- 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

Privacy	**Individuals' right to control access to their information and body**
Confidentiality	**How private information provided by individuals will be protected by the researcher from release**

Tools for Review

Current State

Assigned To Agenda

View Study

Reviewer Version

My Activities

Submit CM Document(s)

Send Comments To Study Team

Designated Reviewer Checklist

Non-Scientific Checklist
Size:156 KB

Scientific Checklist
Size:178 KB

University of Pittsburgh
Institutional Review Board
IRB Checklist for Consent Form Reviewers
Revised May 2008

NSENT FORM CONSIDERATIONS	YES	NO	N/A
se, non-technical language used throughout?	☐	☐	☐
UPPORT	YES	NO	N/A
f financial support for the study listed and consistent with section 7.2?	☐	☐	☐
RIPTION	YES	NO	N/A
t the subject is participating in a research study?	☐	☐	
r statement of the purpose of the study?	☐	☐	
dures that are experimental clearly identified?	☐	☐	☐
mate number of subjects to be studied noted?	☐	☐	☐
of each subject's participation included?	☐	☐	☐
lures accurately described as either research related or completed as	☐	☐	☐

University of Pittsburgh
IRB Checklist for Scientific Reviewers
Revised May 2008

OSIRIS SECTION				
	TRIAGE	**YES**	**NO**	**NA**
T 3.0	Is risk level noted by investigators consistent with risks the study poses to subjects?	☐	☐	
	COVER SHEET	**YES**	**NO**	**NA**
CS 9.0	If not already listed, does this study require an IND or IDE?	☐	☐	☐
	OBJECTIVE, AIMS, BACKGROUND AND SIGNIFICANCE	**YES**	**NO**	**NA**
1.4	Is the research design adequate to yield scientifically sound data?	☐	☐	
	RESEARCH DESIGN AND METHODS	**YES**	**NO**	**NA**
2.1	Is the duration of the study drug intervention limited appropriately to that which is minimally necessary to evaluate efficacy?	☐	☐	☐
2.18	Is there a statistical justification for the sample size?	☐	☐	☐
2.18	Is the proposed statistical treatment of the data appropriate for the design of the study?	☐	☐	☐
2.3.1	Is a placebo being used where an effective treatment exists?	☐	☐	☐

Forms, Templates and Checklists

Documentation Forms

Title

- Child Form
- Department of Defense Checklist
- Device Documentation Form
- Documentation of Expedited Review
- Fetal Tissue Form
- HIPAA waiver of Authorization
- IND or IDE Checklist
- International Exempt Checklist
- International Greater than Minimal Risk Checklist
- International Non-Exempt Checklist
- Neonate Form
- Pregnancy Form
- Prisoner Form
- Unanticipated Problem Checklist
- Waiver of Consent & HIPAA for RetroStudy
- Waiver of Consent to Identify Subjects
- Waiver of Emergency Research
- Waiver of HIPAA Exempt
- Waiver of HIPAA for Recruitment
- Waiver of Informed Consent
- Waiver to obtain a signed consent

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