Minimal Risk Research
Presented by Melinda Allie and Stacie Fujisaki
Topics for today

• Minimal Risk Research
• Exempt Research
• Non-Human Subjects Research
• Anonymous, coded, and identifiable data
• Basic Submission Requirements
• Questions and Answers
*Just a few comments*

- Minimal risk, exempt, and non-human subjects research do not required full board review. They are reviewed in the office by the analysts and then sent to the chairs for review.
- It is a rare occurrence for one of these studies to go to the chair without being returned first for changes, questions, clarifications, so expect to get it back at least once.
- The IRB reserves the right to request a higher level of review at its discretion.
Minimal Risk or Expedited Studies

• What does the term minimal risk mean? 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 or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)).
More information on making the minimal risk determination:

Ethical considerations other than determining if the research is minimal risk can be found in the Federal Regulations

Exempt Research

• Only the IRB can determine that if your study falls under an exempt review category.

• Exempt does not mean that the research activity is exempt from state laws, and it does not mean that the research need not conform to the principles of sound research ethics.

• Although consent is not required by law, the OHSU IRB reserves the right to request an information sheet.
Exempt and HIPAA

- If the IRB determines that your study qualifies as exempt, and the proposed research involves Protected Health Information (PHI), HIPAA regulations still apply.
  - Waiver of authorization for chart review.
  - Decedents form for research on dead people.
  - Data use agreement if sharing or receiving a limited data set (LDS).
Exempt and Ongoing Review

• The OHSU IRB requires annual continuing review of exempt studies to re-evaluate the exempt status of the study.
• Proposed changes to an exempt study, that could potentially affect the study’s exempt status, must be submitted to the OHSU IRB for review via modification.
Non-Human Subjects Research

What is human subject research? The Code of Federal regulations defines Human Subjects as:
"...living individual(s) 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)]
NHS continued

Research as:

"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)]
**NHS continued**

- The most common example of an NHS review study: Receiving data with no identifiers or coded with no link back.
- When completing the “request for determination” in the eIRB and the response states “most likely to be determined human subjects research”, start the application over as a “new study” submission.
Not Engaged in Research

• The Office for Human Subjects Protections (OHRP) has issued guidance on helping researchers determine whether or not their role in a research project would be considered Engaged in Research. This guidance can be found on the OHRP website.

• Google “engaged in research” and you will be directed to this 2008 guidance.
Not Engaged in Research and HIPAA

• If the IRB determines that you are not engaged in the proposed research but includes Protected Health Information (PHI), HIPAA regulations still apply.
Anonymous and Anonymized Data

• What is anonymous? You are receiving or recording data without any of the 18 HIPAA identifiers.

• Anonymized? The data is stripped of all 18 HIPAA identifiers and there is no way for you to be able to link the data back.
Coded with a Unique Identifier

• Coded?
  ▪ identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individuals to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
  ▪ a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
Coded with a Unique Identifier cont.

- Subjects initials, D.O.B, or MRN#s do not qualify as coded data. The use of any of these makes the data fully identifiable.
- A code is NOT anonymous, anonymized, or de-identified. It is coded period.
- Some exceptions: if you the code is random and not linking back to subjects, or do not have access to, or are destroying the code.
Basic Submission Requirements

• PPQ – fully signed, please... yes we know that an email from the dean’s office can be uploaded in lieu of signature but it must be uploaded to the eIRB. The study will not be approved until this has been uploaded. If is it fully electronic, tell us that, please.

• Lay Protocol Summary

• Protocol and/or Grant
Basic Submission Requirements Cont.

If applicable to your study:
• Consent form or information sheet
• Surveys, questionnaires
• A copy of the data collection sheet or list of ALL variables for chart review studies
• Focus group/interview questions.
• HIPAA forms (waiver of authorization, decedent form, data use agreement)
Summary

• Make sure your documents and the IRQ are consistent about what you are doing!
• Questions?
Mark your calendars!

Next Brown Bag Session is March 22
PI Eligibility and Research Collaborations
11:30 a.m. to 12:30 p.m. MacDonald Auditorium
Andrea Johnson and Kara Drolet
This session will address various issues that arise in developing collaborative research projects, both within and outside OHSU.

Visit our website for more information:
www.ohsu.edu/researchintegrity