

**Institutional Review Board  
(IRB)**

**MPH Capstone Presentation  
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# Types of Capstone Projects

- (Simulated) grant proposal or research plan
  - ✓ not research
- Public Health Program plan
  - ✓ not research
- Research report: data collection and/or analysis
  - ✓ always research, by definition
- Public Health Problem analysis
  - ✓ usually not research



# Types of Review

- Not research (i.e., practice or QA)
- Not human subjects research
- Exempt
- Expedited
- Full committee

# What is Human Subjects Research?

- Living humans
- Participating in formal research protocols
- That seek to test hypotheses or answer scientific questions



# Research vs. Practice

- 45 CFR 46 states that "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."



# CDC Interpretation

- The key word in the regulations' definition of research for the purpose of classifying public health activities as either research or practice is "designed."
- The major difference between research and practice lies in the primary intent of the activity.
  - The primary intent of research is to generate or contribute to generalizable knowledge.
  - The primary intent of practice in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service.



# Research vs. Practice

- A project falls into the category of “practice” (i.e., it’s “not research”) if:
  - The information generated from the project is not generalizable to other populations
  - You plan to disseminate knowledge acquired during the activity only to the sponsoring agency
  - You have no intent to EVER present or publish the information generated by the project



## Example of “Practice” (called “Not Research” by the IRB)

*An evaluation of STD clinic services provided to adolescents through the Baltimore City Health Department. A report would be provided to the Department of Health alone with the intent that the information gathered would benefit future implementation of the STD clinic services in Baltimore. The results would not be generalizable nor would there be any intent to publish the findings.*

# “Not Research” vs. Research

- As stated above, an activity is not “research” if it’s “practice”.
- If an activity **is** “research”, it can still potentially be “not human subjects research”.

# Human subjects research v not HSR:

Not human subjects research is:

Research involving **existing** data, documents, records, specimens if:

1. these sources are publically available  
OR
2. data have been collected in such a way that subjects cannot be identified directly or through links back to the individual

# What is “publically available” data?

- Public use data files are data files prepared by the investigators or data suppliers with the intent of making them available for public use. The data available to the public are not individually identified or maintained in a readily identifiable form.
- Examples include: Census Data, state court records, National Households Survey on Drug Abuse.

# Example of “Not human subjects research”

- *You are conducting a data analysis and preparing a paper using U.S. Census data in which you are examining the relation between zip codes and household density. The data set is publically available, does not contain names and nor would it be possible, based on the information provided, to link a participant to the data provided.*

## If you think your capstone is either “not research” or “not human subjects research:”

- Contact Thomas Bradsher at [tbradshe@jhsph.edu](mailto:tbradshe@jhsph.edu) or 410.502.1881 for additional information or aid in determination if necessary
  - Complete CITI Human Subjects Training
  - Register for electronic submission and submit a new application via PHIRST. The application will be brief. To ensure prompt processing as a Capstone, email Leslie Graf ([lgraf@jhsph.edu](mailto:lgraf@jhsph.edu)) to let her know that you submitted a capstone via PHIRST
- link to PHIRST from website
- You will receive a letter confirming that your research is not human subjects research or not research (i.e., practice).

# Exempt Research

1. Research involving the **prospective** collection and use of testing, surveys, interviews, or observation of public behavior without collection of identifiers (*Identifiers include social security numbers, names, addresses, hospital IDs, etc.*)
2. Research involving **existing** data, documents, records, specimens that do not contain identifiers (if these sources are not publically available) and cannot be linked, **if** any of the investigators was involved in the original data collection.

**Exempt status requires IRB determination that the research is exempt**

# Exempt Example

- *A survey study was recently completed by your capstone advisor in the epidemiology department at Hopkins. They have agreed to let you use the data for your analysis to examine whether there is a link between childhood asthma and certain parental occupations. Participants were interviewed while waiting for asthma treatment at emergency rooms throughout Baltimore. The data set does not contain identifiers.*

# If this sounds like your capstone:

- Complete CITI Human Subjects Training
- If the scope and aims of your data analysis is within a previously approved protocol, ask the PI to add you as a student investigator. This requires submission of a minor amendment to the IRB
  - See amendment request form on website
- If you are mounting your own study of this type, or if the data were collected by a protocol from outside JHMI, register for electronic submission and submit a new application via PHIRST. To ensure prompt processing as a Capstone, email Leslie Graf ([lgraf@jhsphe.edu](mailto:lgraf@jhsphe.edu)) to let her know that you submitted a capstone via PHIRST
  - link to PHIRST from website



# Expedited Review

- Studies qualify for expedited review if the data that are collected contain identifiers and involve no more than minimal risk as defined by a list of minimal risk research categories.



# Minimal Risk

“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.”

# Expedited Example

- *You or your capstone advisor collect(ed) data on 500 pregnant women to evaluate the relationship between psychological stress, stress hormones, and preterm delivery. The study included psychological questionnaires, a blood draw for cortisol analysis, and collection of medical records at birth. You conduct a data analysis on the relation between maternal anxiety and infant birth weight. The data are identifiable.*

# If this sounds like your capstone:

- Complete CITI Human Subjects Training
- If the scope and aims of your data analysis is within a previously approved protocol, ask the PI to add you as a student investigator. This requires submission of a brief amendment to the IRB
  - Use amendment request form on website
- If you are mounting your own study of this type, or if the data were collected by a protocol from outside JHMI, register for electronic submission and submit a new application via PHIRST. To ensure prompt processing as a Capstone, email Leslie Graf ([lgraf@jhsph.edu](mailto:lgraf@jhsph.edu)) to let her know that you submitted a capstone via PHIRST
  - link to PHIRST from website



# Full Committee Review

- Full committee review is required for studies that involve greater than minimal risk (physical, psychological, social, economic) or focus on particular vulnerable populations (e.g., prisoners).

# Example of Full Committee Review

- *You or your capstone advisor are implementing a randomized controlled trial in Ghana on reducing adolescent depression. Participants will be randomized into three arms: a behavioral intervention; an experimental drug treatment; or a control group. Your project involves analyzing whether there is a dose-response relation between the drug therapy and depression symptoms.*

# If this sounds like your capstone:

- Complete CITI Human Subjects Training
- If the scope and aims of your data analysis is within a previously approved protocol, ask the PI to add you as a student investigator. This requires submission of a minor amendment to the IRB
  - Use amendment request form on website
- If you are mounting a new study of this type, or if the data were collected by a protocol from outside JHMI, register for electronic submission and submit a new application via PHIRST. To ensure prompt processing as a Capstone, email Leslie Graf ([lgraf@jhsphe.edu](mailto:lgraf@jhsphe.edu)) to let her know that you submitted a capstone via PHIRST
  - link to PHIRST from website

# Human Subjects Training: CITI

- All student and faculty investigators must take and pass the internet-based human subjects training module
- You can take this at any time
- Take approximately 1 hour
- Instructions for linking to CITI training can be found at: [www.jhsph.edu](http://www.jhsph.edu) → Resources → Institutional Review Board → Education → “click here for instructions”

# Submission Tips

- All new research applications are currently submitted via PHIRST. At some point in late fall/early winter, PHIRST will be replaced with eIRB
- <http://phirst.jhsph.edu> or link to via [www.jhsph.edu](http://www.jhsph.edu) → Resources → Institutional Review board
- Amendments (e.g., being added as a student investigator) are done on paper
- Complete your CITI training prior to submitting either the amendment or new application
- Register on PHIRST. Note that you can create the application but only a faculty member PI can submit it
- Elect “capstone” where indicated in the application.
- Remember to email Leslie Graf ([lgraf@jhsph.edu](mailto:lgraf@jhsph.edu)) when you submit a NEW protocol

# How long does the review process take?

The earlier you submit, and the better prepared your application is, the earlier you'll have a response!

Submit application in January

Being added as a student investigator to an existing JHSPH protocol: ~1 week (highly preferred!)

Not Research, not HSR or Exempt: ~2 weeks

Expedited Review: ~ 3–4 weeks

Full Committee Review: ~ 8 weeks (unlikely for a capstone – if this is your plan, submit soon!)

# Need help or have questions?

- Refer to these materials.
- Work with your advisor or the PI to develop an application if necessary. Experienced investigators will know what type of information the IRB needs for a successful protocol and can save you time and effort.
- Contact the IRB:  
Leslie Graf (443) 287-3929 or [lgraf@jhsph.edu](mailto:lgraf@jhsph.edu)