

The background features a repeating pattern of stylized green leaves. In the center, a magnifying glass is positioned over a dictionary page. The magnified text includes the definition of 're-search' and the words 'research into' and 'student'.

# WHICH PROJECTS DO – AND DO NOT – REQUIRE IRB REVIEW?

*A Brief Overview of the Types of  
Projects Which Need IRB Oversight*

*Melanie Locher, B.S., CIP*

# Back to Basics...

- Anyone engaged in human subjects research at UVM or UVMMMC is bound to comply with regulations and policies for protecting participants.

*These include but are not limited to:*

- [45 CFR 46](#), DHHS
- [21 CFR 56](#), [21 CFR 50](#), [21 CFR 312](#), [21 CFR 812](#), FDA
- UVM and UVMMMC's Committee Operating Procedures
- Ethical Principles in the Belmont Report

# Back to Basics...

- The IRB exists to protect human research participants, but there are many projects for which the regulations do not require IRB review
- We try to limit our scope to what is required by the regulations

# The Big Question

- The rules only apply to certain projects, so...

**What types of projects must the IRB review?**

- When does my project require compliance with all those human subjects research regulations?

# Human Subjects Research

- Research is “a systematic investigation designed to contribute to generalizable knowledge.”

(paraphrased from [45 CFR 46.102](#))

- *Systematic Investigation?*
  - Methodical exploration of a question or theory
  - Typically includes data collection and analysis
  - Includes development, design, and testing phases

# Human Subjects Research

- Typically Includes:
  - Interviews, surveys, chart reviews, epidemiological studies, observational studies
- Typically does **NOT** include:
  - Training others on how to use a device, provided activities do not include data collection/analysis

# Human Subjects Research

- *Designed to be Generalizable?*
  - Difficult to define, but typically designed to be generalizable if:
    - Aims to draw conclusions about people or practices beyond a specific individual or internal program
  - The **intent** to generalize makes it research, whether results are published or presented does not matter
  - Just because you publish does not make it automatically research!

# Human Subjects Research

- Typically does **NOT** include:
  - Quality Assurance/Quality Improvement
  - Public Health Practice
  - Individual Case Reports
  - Academic Course Evaluations
  - Program/Curriculum Evaluation

# Human Subjects Research

## *DHHS Definition:*

- A Human Subject is a living individual about whom an investigator obtains:
  1. Data through intervention or interaction; or
  2. Identifiable private information
    - Identifiable if identity can be ascertained (e.g. 18 HIPAA identifiers)
    - Private means a reasonable expectation that no recording is taking place, and information is used for intended purposes

[45 CFR 46.102](#)

# Human Subjects Research

- Typically does **NOT** include human subjects:
  - Analysis of deidentified dataset
  - Research with deidentified samples
    - Exception for FDA definition, in which it is a clinical investigation involving human specimens
  - Deceased individuals



# EXAMPLES

# Clinical Trials

- A clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- Yes, it's research; and Yes with human subjects.
- Submit the "Human Research Protocol" Data Management and Security Plan and a consent form.

# Data or Tissue Repositories

- Repositories housed at UVM/UVMMC containing any identifiers, would require IRB review
  - A repository can collect and contain solely identifiable data  
and/or
  - Identifiable data and biological specimens
  - This includes banked specimens such as blood, tissue and DNA and banked data referring to HIPAA identifiers, pathology tissue and radiology reports
- Yes, it's *future* research; and Yes with human subjects.
- Submit the Biological Specimen/Data Repository Protocol Form

# Blood Collection Protocol for Non-Clinical Laboratory Research

- Researchers conducting bench science often times require human cells for their laboratory research.
- Healthy research subjects will donate blood for these scientific purposes.
- While the activity of drawing blood is not a “research protocol”, the collection of the cells is for research, and therefore requires IRB review.
- No Protected Health Information (PHI) may be collected on this protocol.

Yes, it's future research; and Yes with human subjects.

Submit [The Blood Collection Form](#)

# Retrospective Chart Review (exempt #4)

- Involves reviewing patient medical charts, or portions thereof, from specific, prior time period
- Key is determining intent:
  - Might be reviewing your own patients, but research aims makes it research
  - Chart review for internal QA/QI purpose not likely research (not generalizable)
  - Retrospective data collection only
- Yes, it's research; and Yes with human subjects because the data will be identifiable.
- Submit the Exempt #4 Determination Form

# Surveys

- May be online surveys or in-person, designed to gather and analyze data to investigate a question
- What if it's anonymous?
  - Still involves human subjects, because it meets the interaction element, whether it has identifiable information doesn't matter
  - It might, however, have an impact on the type of IRB review it has
- Yes, it's research; and Yes with human subjects.
- Submit the Exempt #2 Determination Form

# De-identified Dataset

(not human subject determination)

- Analyzing data collected previously, stripped of all possible identifiers
- Neither study team nor any collaborators have identifiers or a linking code
- Yes, it's research; but No human subjects because no interaction/no intervention/no identifiable info.

# Note on “ De-identified ”

- To the IRB, deidentified means:
  - No one on the study team has access to identifiers *at any time*
  - For research at a UVMCMC covered entity, all 18 HIPAA identifiers are removed
  - For research at an outside covered entity, it means that there is no feasible way to identify someone from the data (directly or via code)

Check “ NO ” to question #8 on the Study Scope page when submitting in UVMClick

# Program Evaluation

- Typically an evaluation of a UVM/UVMMC program or class
- Look at intent and aims; designed to be generalizable?
- Publication doesn't necessarily imply *research*
  
- No, not research if not designed to be generalizable
- Nothing formally to submit to the RPO office

# Quality Assurance / Improvement

- Designed to improve a specific program or process
  - Often includes obtaining data to measure effectiveness
  - e.g. customer surveys, effectiveness of in-house initiatives, course evaluations, curriculum development
- May look exactly like scientific method behind research, the distinction can be tricky
  - Consider *specificity* of project
  - Publication does not necessary imply research
- No, not research if not designed to be generalizable
- Nothing formally to be submitted to the RPO office

# Public Health Practice

- Purpose is to improve health (preventing disease or injury) or to improve a public health program
- Key is the *intent*; designed to be generalizable?
  - Opportunity for *research* may arise, concurrent with the practice
  - Collaborators' affiliation can be clue (e.g. health dept/ministry/bureau)
- No, not research if not designed to be generalizable
- Nothing formally to be submitted to the RPO office

# Not Research Self-Determination Tool

**For Assessing Projects such as Quality Assurance, Quality Improvement, Program Evaluation, or Public Health Practice**

Determining whether a project constitutes human subjects research rather than quality improvement or program evaluation involves multiple factors. The federal definition of research is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." In contrast, quality improvement projects or program evaluation projects systematically collect data for administrative, clinical, or reporting purposes, but are not designed to contribute to, or to advance generalizable knowledge. Instead, they are designed to develop or contribute to knowledge relevant to the organization.

# Not Research Self-Determination Tool

- The IRB Office has often been asked to provide a determination on whether a project is research under the Federal regulations or is rather program evaluation or quality improvement.
- Formal IRB determinations are requested in anticipation of such documentation being required for journals, conferences, funding sources and others.
- The following IRB self-determination tool guides whether the project is quality improvement versus research requiring IRB review.

<https://www.uvm.edu/rpo/forms/determination-not-research>

# Not Totally Clear? We Agree!

- The regulations leave plenty of ambiguity and whether a particular project needs IRB oversight is not obvious
- Depends on particularities, often there are exceptions

## TAKEAWAY:

- If you have questions about this determination form, then please contact your IRB Research Analyst for assistance
- <https://www.uvm.edu/rpo/contact-us>
- Submit your project to the IRB for an official determination