



WHICH PROJECTS DO AND DO NOT REQUIRE IRB REVIEW?

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

Melanie Locher, B.S.,
CIP

Governing Principles

The Committees are governed by the basic principles regarding experimentation on humans which have their origins in the Nuremberg Code, the Belmont Report, and the Declaration of Helsinki and are consistent with federal regulations governing research with human subjects.

- 45 CFR 46 of the Code of Federal Regulations
- FDA , 21 CFR 50 and 21 CFR 56



The Big Question

- The federal guidelines only apply to certain projects, so...

What types of protocols 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, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

(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

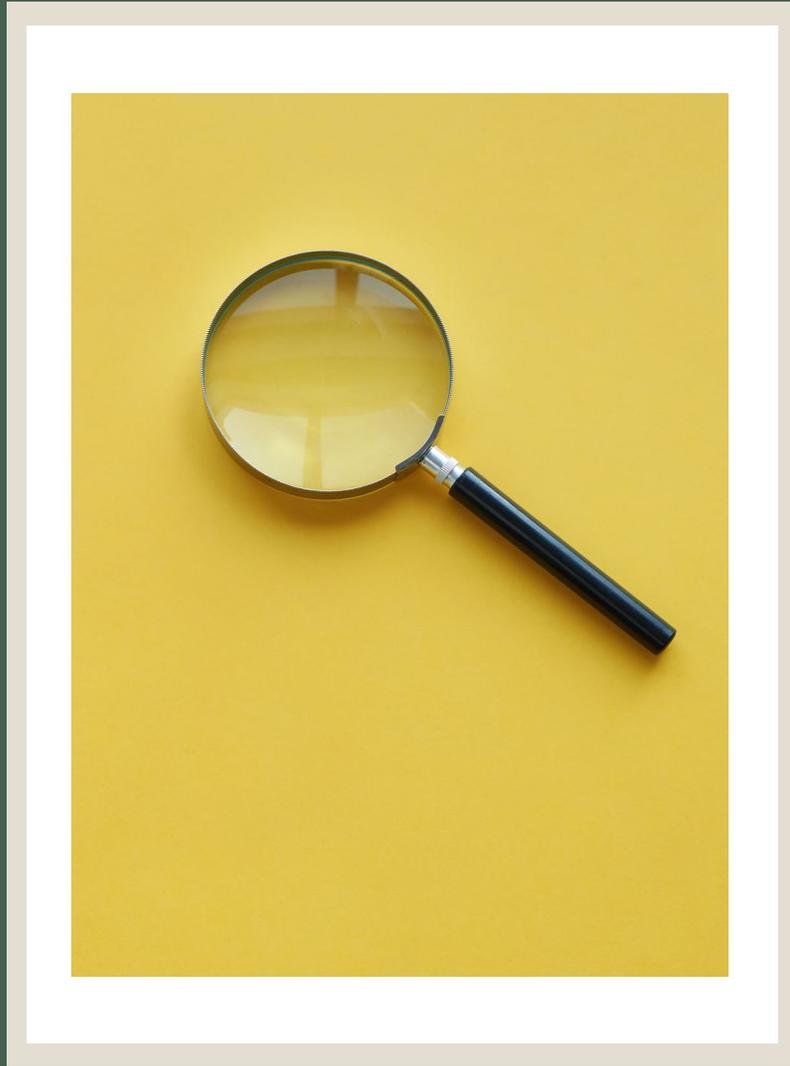
Systematic Investigation

Typically Includes:

- surveys and questionnaires
- interviews and focus groups
- observational studies
- analysis of existing data or biological specimens
- evaluations of social or educational programs
- medical chart review studies
- group comparison studies
- interventional research

Typically, does **NOT** include:

- Training others on how to use a device, provided activities do not include data collection/analysis



Designed to be Generalizable?

Generalizable knowledge
is information that expands
the knowledge base of a
scientific discipline or other
scholarly field of study.

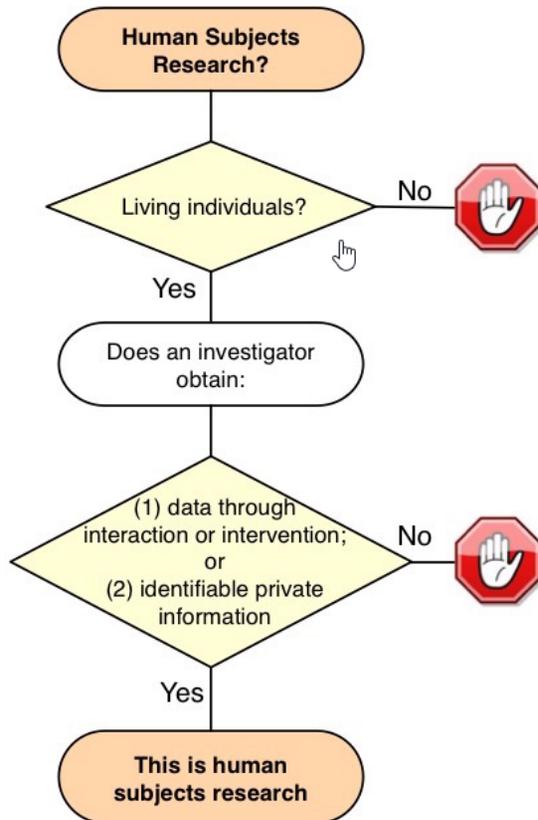


Typically, does **NOT** include:

- Quality Assurance/Quality Improvement
- Public Health Practice
- Individual Case Reports
- Academic Course Evaluations
- Program/Curriculum Evaluation
- Implementation projects

Human
Subjects
Research

Who is a Human Subject?



OHRP Definition of Human Subject: a living individual about whom an investigator (whether professional or student) is conducting research

- 1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- 2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

[45 CFR 46.102](#)

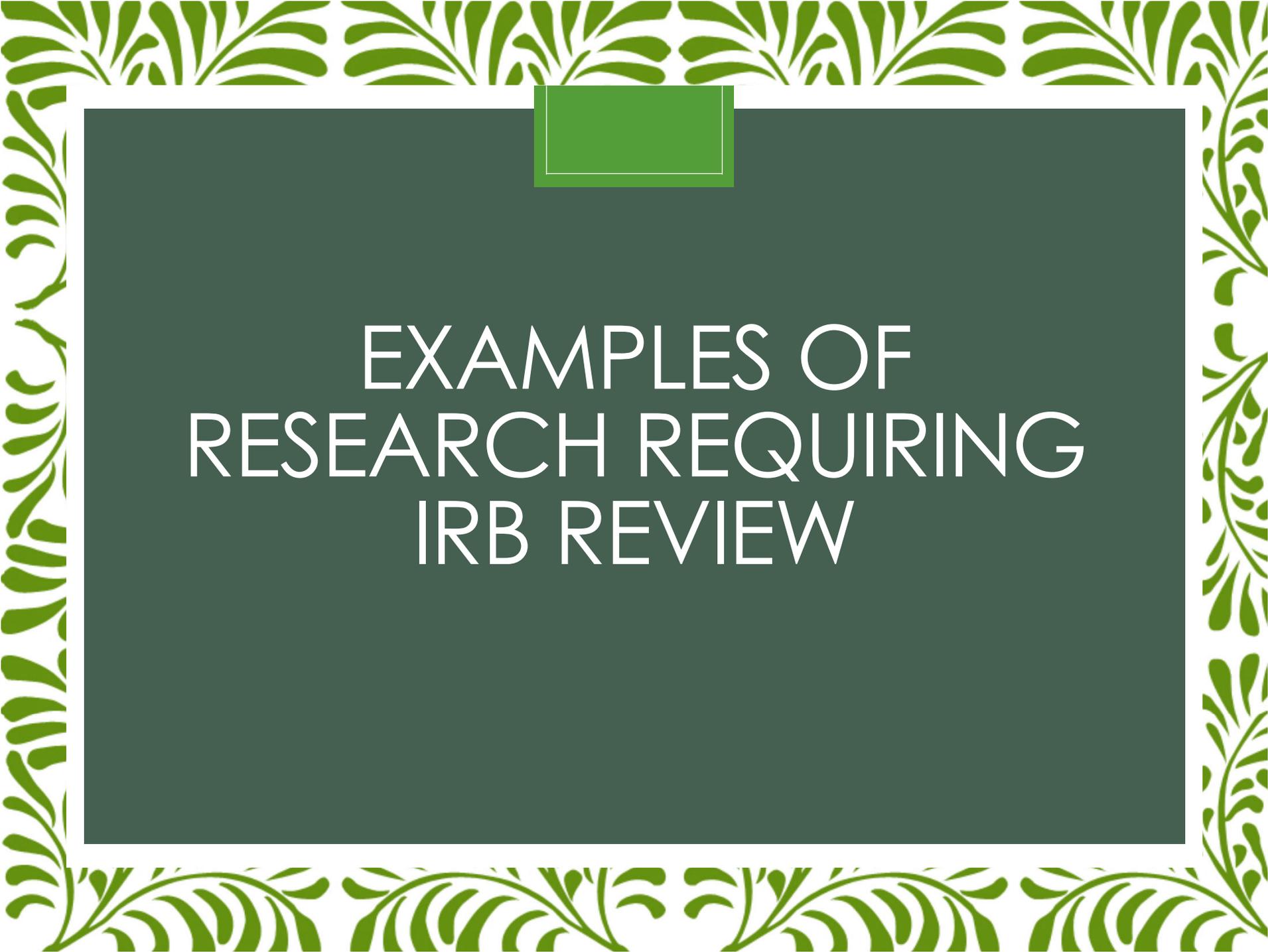
Who is NOT
a Human
Subject
under the
federal
regulations?

Decedents

Individuals Not Readily Identifiable: De-identified data and individuals who are not readily identifiable are not human subjects.

Inanimate Objects: The subject of the research could be about institutions, programs, or hospitals and not about the individuals who are in those programs.

**Not Human Subjects
Research:
IRB Review is NOT
Required**



EXAMPLES OF RESEARCH REQUIRING IRB REVIEW

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, human subjects.

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 research; and Yes with human subjects.

Coded Data

- Identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- Yes, it's research; and Yes with human subjects.



EXAMPLES OF
RESEARCH NOT
REQUIRING IRB REVIEW

De-identified Dataset (not human subject determination)

- Analyzing data collected previously, stripped of all possible identifiers (18 HIPAA identifiers)
- Study team has no identifiers or a code to link to the data
- **Not coded data**, you can never re-identify the dataset
- Generally, involves the use of an honest broker

- Yes, it's research; but No human subjects because no interaction/no intervention/no identifiable info.
- NO IRB review required

SELF-DETERMINATION OF RESEARCH NOT INVOLVING HUMAN SUBJECTS

- Research projects that do not involve human subjects do not require submission to the IRB for review.
- To reduce researcher burden, the IRB has developed this easy self-determination tool to allow researchers to make their own determinations as to whether the proposed activity involves human subjects and thus needs IRB review.
- No formal UVMClick submission needed
- https://qualtrics.uvm.edu/jfe/form/SV_4NNHtCBa35POswm



Other Types of Research not requiring IRB Review

- Quality Assurance/Quality Improvement
- Public Health Practice
- Individual Case Reports
- Academic Course Evaluations
- Program/Curriculum Evaluation
- Implementation projects
- Public Health Surveillance Activities

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



USE THE NOT
RESEARCH SELF
DETERMINATION
TOOL

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

Public Health Surveillance Activities

- In general, public health surveillance involves collecting, testing, analyzing, and using information or biospecimens to improve public health and prevent disease. It provides timely and useful evidence, and it enables public health authorities to be more effective in their efforts to protect and promote public health. Thus, public health surveillance is an important element of public health practice.
- ***the difference between public health surveillance and research in this context is that the purpose of the surveillance is to inform the decisions or actions that must be made by a public health authority.***

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 always obvious
- Often there are exceptions

TAKEAWAY:

- If you have questions about the self-determination tools, please contact your IRB Research Analyst
- We're happy help