

# Determining Whether Your Project Meets the Definition of Research

Julie M. Eiserman, MA, CCRP

Team Lead, Office of IRB Operations, OHSRP

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# Background

- The DHHS Regulations for the Protection of Human Subjects Research ([45 CFR 46](#)) went into effect beginning July 14, 2009.
- Subpart A of these regulations is also referred to as “the Common Rule”.
  - This subpart was revised and required compliance as of January 21, 2019.
  - The [2018 Common Rule](#) (or the Revised Common Rule), includes a list of activities that are deemed not to be research.

# Is the Activity Research?

- Does the activity meet the DHHS/ Common Rule Definition for Research?
- “Research means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”. (45 CFR 46.102(I))

# Four Categories Deemed “Not Research” under 2018 Common Rule

- Scholarly & journalistic activities
- Government functions:
  - **Public health surveillance activities**
  - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes and analysis of information
  - Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other security measures.

# Public Health Surveillance Activities

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
  - Those necessary to allow a public health authority to identify, monitor, assess, or investigate potential **public health signals, onsets of disease outbreaks, or conditions of public health importance**, including trends, signals, risk factors, patterns of diseases, or increases in injuries from using consumer products.
  - Does not apply to public health surveillance research!

# Other Examples of Activities which **May Not** Be Considered Research under the Common Rule

- Quality Assurance/Quality Improvement (see [QA/QI vs. Research](#))
- Program Evaluation (see [Program Evaluation vs. Research](#))
- Clinical Consulting
- Evidence-Based Practice
- Use of an existing sample(s) to validate an assay
- A Case Report involving three or less patients, where data were initially collected for the purposes of diagnosing an individual's condition or for instructional purposes

What Are the Basic Questions that You Need to Ask to Determine if the Activity Involves Research?

# Question 1: Systematic

- Is the activity a systematic investigation? Is the planned activity systematic?
  - Is the activity conducted in a **systematic** fashion, i.e., done or acted according to a fixed plan or system; methodical in procedure or plan?

# What is a Systematic Investigation?

- An activity that is methodologically driven
- Involves a prospective plan
- Has a hypothesis
- Data or information is collected in an organized and consistent way.
- The data or information is analyzed in some way, usually quantitatively or qualitatively
- Conclusions can be drawn from the results

# Must be Systematic to be Research

- If activity is not considered to be a “systematic investigation”, then the activity is not “research” even if other criteria exist (i.e., it is generalizable.)
- An activity can be approached systematically and still not be research.

## Question 2: Purpose

- What is the intent/purpose of the activity?
  - Are there different/multiple intents/purposes?
- Does the project include a **research objective or a hypothesis**?
- Would the project be conducted as proposed if you knew that you would never receive any form of professional recognition for the project, including publication of results or presentation at a professional meeting?

# Question 3: Generalizable

- Will the activity contribute to “generalizable knowledge”?
- Is the activity designed to develop or contribute to generalizable knowledge? Within the institution, outside the institution, outside the system?
  - Does the **design** allow the results to be **generalized** to a population beyond just those who were included in the project?
  - Is the purpose of the project to contribute to **generalizable knowledge** about certain class or category of subjects in the U.S. or world?

# Definition of Generalizable Knowledge #1

- Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, advance scientific knowledge, or generalize findings beyond a single individual or an internal program.

# Definition of Generalizable Knowledge #2

- To be considered "generalizable knowledge," the activity would include the following concepts:
  - Knowledge contributes to a theoretical framework of an established body of knowledge
  - Results are expected to be generalized to a larger population beyond the site of data collection or population studied
  - Results are intended to be replicated in other settings

# What about Publication?

- Note: Office for Human Research Protection (OHRP) states that OHRP does not consider intent to publish to be a reliable indicator of whether an activity involves research
- Publication “alone” does not automatically make an activity “research”

# Quality Assessment/ Quality Improvement

See [QA/QI vs. Research: Do I Need to Submit for an Exemption or IRB Approval?](#)

# No HRPP Requirements for “Not Research”

- If an activity falls into the category of “not research”, **then there are no regulatory or policy requirements\***.
  - The investigator does not need to submit for a formal determination or IRB review.
  - Investigators are allowed to make these determinations themselves but should consult with the IRB, if there is any question.

\*Note: The one exception is if the investigator is conducting a public health surveillance activity. Determinations that these types of activities are not research must be made by the Office of Science Policy. Please contact the IRB for more information and see the following notice.

# Submitting for a Determination of “Not Research” or “Not Human Subjects Research”

- If you need a formal determination that your project is “Not Research”, submit a request in the eIRB system, PROTECT.
- Complete the [Not Human Subjects Research Application](#).
- The lead researcher will need to be an NIH FTE and have a PROTECT account. Requests for new accounts can be obtained [here](#).
- Select “Create New Study” in [PROTECT](#) and answer all the questions
  - Upload the NHSR Application where it says “Protocol” and be sure to include “NHSR” when naming the document.
- For more information, please see [Not Human Subjects Research](#) on the OHSRP website.

# Questions

For questions, please contact [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov) or the IRBO at [IRB@od.nih.gov](mailto:IRB@od.nih.gov) or (301) 402-3713. You can also find helpful information on the [OHSRP website](#).