Process Change

Research – IRB Review Not Required

Go Live: 2/17/25

Please Note:

- Protocol submissions are not required today for projects that do not meet the federal definition of research and human subjects.
- The new process provides an easy way to obtain documentation (Letter of Determination) for publication purposes.
- Flex/NHSR is combined as one submission type in WVU+kc due to system limitations. Note that they are two separate and distinct protocol types.
  - NHSR is not human subjects research
  - Flex IS human subjects research and is subject to IRB oversight
- Protocol submissions are required for all human subjects research projects (flex, exempt, expedited, full board).

Outline

1. Overview
    1. **HHS Federal Definitions**
    2. Overview of IRB Requirements
    3. Differences: Not Research & NHSR & PI Decisions
    4. Institutional requirements: All types of projects
2. Current Process
3. Flex Stays the Same
4. New Process
    1. Data Protection Form becomes DP & Determination Form
    2. Form will determine whether submission to IRB is required

Dept of Health & Human Services (HHS) Definitions

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

A **human subject** is a living individual about whom an investigator conducting research:

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

Overview: IRB Requirements

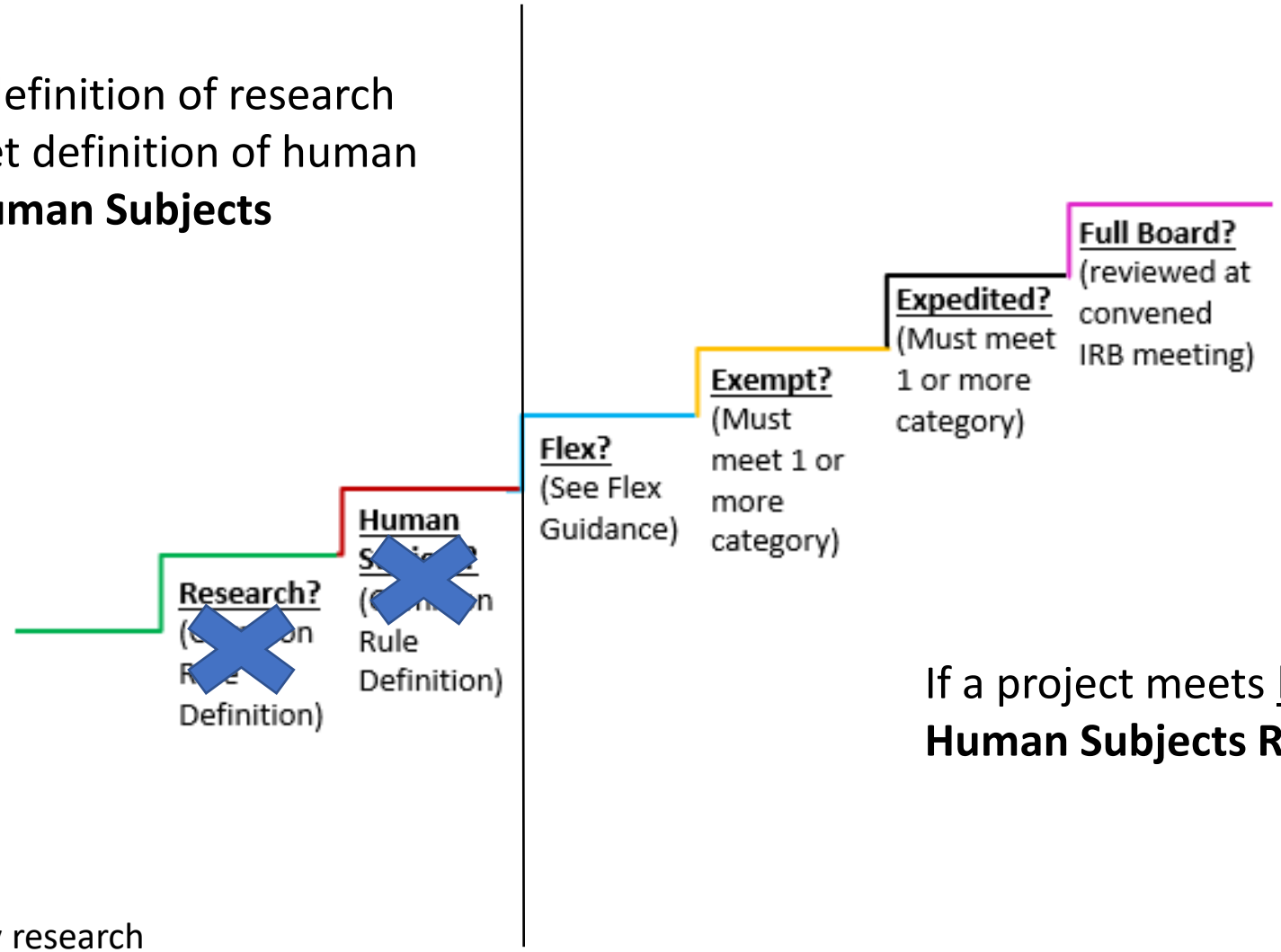
- Get Started Page
- For an IRB review to be required both must be true:
  - Must meet federal HHS definition of *research*
  - Must meet federal HHS definition of *human subjects*
  - Not Research/Not Human Subjects Research
- If both are true = Flex, Exempt, Expedited, or Full Board protocol

If project does not meet definition of research = **Not Research**

If project meets definition of research but does not meet definition of human subjects = **Not Human Subjects Research**

"Not Research" examples:
QA/QI
Program Evaluation
Evidence Based Practice
Oral History
Public Health Surveillance

NHSR examples:
Decedent Data
Publicly Available Data
Specific subset of secondary research



If a project meets <u>both</u> definitions = **Human Subjects Research**

Examples: NR/NHSR vs HSR

Not Research/Not Human Subjects Research:

IRB review <u>not required</u>

- Quality Improvement
- Quality Assurance
- Program Evaluation
- Evidence Based Practice
- Decedent Data
- Publicly available data
- Case Study (5 or fewer EMRs)

Human Subjects Research:

IRB review <u>required</u>

- Retrospective chart reviews
- Clinical trials
- Surveys/interviews for research purposes
- Interaction and/or intervention for research purposes

Important Considerations for PIs

PIs must evaluate and determine whether the project meets the HHS federal definition of research:

❖Some activities that are often categorized as "Not Research" *may* reach the threshold of human subjects research.

❖Often, methodologies for QA/QI, public health surveillance, program evaluation, etc., and human subjects research are similar and *the scope/intent is the deciding factor.*

NHSR and FLEX are *Different*

WVU+kc currently groups NHSR and FLEX in one submission type: NHSR/FLEX

TWO DISTINCT SUBMISSION TYPES

- NHSR = No IRB review required
- Flex = IRB review always required
  - Meets definition of Research and Human Subjects
  - Conducting a Flex study without IRB approval = NONCOMPLIANCE

FLEX submissions will continue in WVU+kc

NO CHANGE TO THE FLEX PROCESS

Please Take Note:

If you are uncertain about whether a project is Human Subjects Research (Flex, Exempt, Expedited, Full Board), please contact irb@mail.wvu.edu

The IRB cannot provide a determination **retrospectively**, or after the research has started. Conducting Human Subjects Research without IRB approval constitutes *noncompliance* and may result in *required reporting* to federal OHRP or the FDA.

Institutional Requirements

IRB review may not be required, but there are additional institutional policies:

- The Responsible Entity may not be the university:
  - Example: Conducting QA/QI on behalf of the Health System requires Health System approvals
- HIPAA may apply
- Data Agreements may be required
- Adherence to university requirements for participant payment
- Adherence to university requirements for data and information security and approved technology
- Conflict of interest disclosure

Why is the process changing?

Capture only the required information about projects that do not require IRB review

Clarify the delineation between Not Research/NHSR and human subjects research to ensure compliance is focused on HSR

Clarify institutional expectations by project type - eliminate “one-size fits all”

Streamlined process for investigators

- Still able to receive documentation for journals
- OHRP/IRB and others are able to dedicate resources to human subjects research

How will the new process work?

The Data Protection Process will be modified to include a decision tree and will produce the Letter of Determination for projects that qualify.

Answer questions about the project to determine if it is Not Research or NHSR

If the project does not meet federal definition of research:

- The Data Protection process will not be invoked, and a Letter of Determination will automatically be sent within 30 minutes. No reviews.
- Institutional policies must be followed for data and technology.
- You may receive follow-ups for some projects.
- A Letter of Determination rather than a Data Protection Certificate is sent after approvals.
- An IRB Protocol Submission is not required and cannot be accepted.

If the project is Research but is not human subjects research:

- Normal Data Protection process
- Auto-determination for NHSR – The Letter of Determination will be automatically sent for **most** NHSR projects.
- A Letter of Determination rather than a Data Protection Certificate is sent after approvals.
- An IRB Protocol Submission is not required and cannot be accepted.

Will old/pending submissions be affected?

- Submissions in WVU+kc that have received an “IRB review not required” determination will not be affected and do not need to take any action
  - Will still be available to access to download letter/view submission

- **Action needed:** Any new and pending NHSR protocol submissions should be submitted by Friday, January 24, 2025, to allow for sufficient time for processing ahead of the Monday, February 17 transition date. WVU+kc will not accept NHSR protocol submissions on/after Monday, February 17.

Data Protection & Determination: Decision Questions

Is your project research?

For assistance with these questions, please contact irb@mail.wvu.edu

Are you conducting a systematic investigation? *

This Question was added

A systematic investigation uses a methodical procedure and plan, is theoretically grounded, and specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods.

Essentially, you are conducting a systematic investigation if the activity is planned in advance and uses data collection/analysis to answer a question. [No Title]

- ◯ Yes
- ◯ No

Will your project contribute to generalizable knowledge? *

This Question was added

Generalizable knowledge is information that is expected to expand the knowledge base of a scientific discipline or another scholarly field of study and yields one or both of the following:

1. Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
2. Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

Note that publication or other dissemination of findings does not in and of itself make the activity "research."

The following are examples of projects that do not contribute to generalizable knowledge:

1. Student projects that will not be published. (Please note: If the thesis or capstone will be made available via WVU Libraries, this would be considered published and has the potential to be generalizable depending on the project.)
2. Projects that intend to improve or affect an internal or local policy only.

- ◯ Yes
- ◯ No

Data Protection & Determination: Decision Questions = Not Research

Is your project research?

For assistance with these questions, please contact irb@mail.wvu.edu

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- ○ Yes
- ◉ No

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2. Projects that intend to improve or affect an internal or local policy only.

- ○ Yes
- ◉ No

This project is considered to be Not Research under the federal definition of research.
Continue to determine the category of Not Research for this project.

Section Added

Answer to Questions:
Both = No
One = No

Respond to a few more questions and receive the Letter of Determination within 30 minutes. (No approvals or reviews)

Data Protection & Determination: Decision Questions = Not Research Category Determination

Does the activity fit in any of the following categories federal OHRP listed in 45 CFR 46 as not requiring IRB review?

Oral History - Interviews concerning the past that collect and interpret the voices and memories of people as a method of historical documentation and that are preserved by placement in some form of repository or archive for access by other researchers. **This includes the collection and use of information that focus directly on the specific individuals about whom the information is collected without extending that information to draw generalizations about other individuals or groups. 45 CFR 46.102(l)(1)**

Scholarly and Journal/Documentary Activities - Activities that focus on collecting, verifying, reporting, and analyzing information or facts on current events, newsworthy issues, or stories about people or events. There is no intent to conduct a systematic investigation and does not test a hypothesis. 45 CFR 46.102(l)(1)

Public Health Surveillance - Activities that focus on collecting, verifying, reporting, and analyzing information or facts on current events, newsworthy issues, or stories about people or events. There is no intent to conduct a systematic investigation and does not test a hypothesis. 45 CFR 46.102(l)(1)

- ○ Oral History
- ○ Scholarly and Journal/Documentary
- ○ Public Health Surveillance
- ◉ None of the Above

Are you doing a retrospective case study with 5 cases or fewer? A case study is an article that describes and interprets an individual case (or less than five total), often written in the form of a detailed story.

- ○ Yes
- ◉ No
- ○ My case study is prospective / Retrospective with more than 5 records

Is the project intended to improve or evaluate a practice, process, or specific program within an institution (for quality improvement/assurance or a program evaluation)?

- ○ Yes
- ◉ No

Is the project evaluating evidence-based practice?

Evidence-based practice (EBP) is the process of collecting, processing, and implementing research already conducted and shown to be effective to improve clinical practice.

- ○ Yes
- ◉ No

Is this project being done for a class project or research methods course?

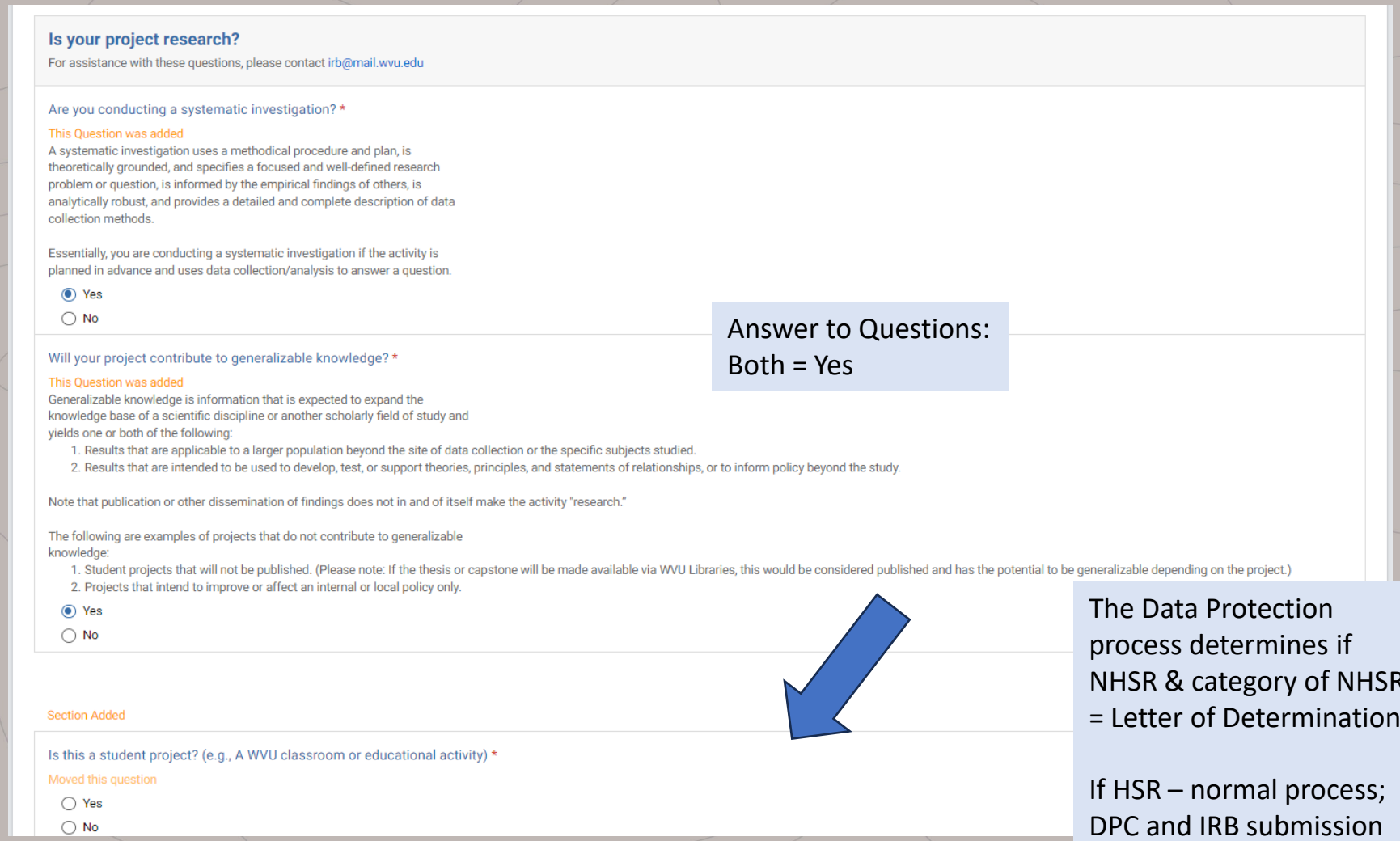
- ○ Yes
- ◉ No

Based on your responses, your project did not meet the definition of research but did not fit in any category. Please start over or contact us at irb@mail.wvu.edu for further guidance.

Suggestion: Tell the user to start over and answer both screening questions answered Yes.

This shows the questions and the result if answered incorrectly.

Data Protection & Determination: Decision Questions = Research (including NHSR)



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Essentially, you are conducting a systematic investigation if the activity is planned in advance and uses data collection/analysis to answer a question.

- (●) Yes
- ( ) No

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This Question was added

Generalizable knowledge is information that is expected to expand the knowledge base of a scientific discipline or another scholarly field of study and yields one or both of the following:

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2. Projects that intend to improve or affect an internal or local policy only.

- (●) Yes
- ( ) No

Section Added

Is this a student project? (e.g., A WVU classroom or educational activity) *

Moved this question

- ( ) Yes
- ( ) No

Answer to Questions:
Both = Yes

The Data Protection process determines if NHSR & category of NHSR = Letter of Determination

If HSR – normal process; DPC and IRB submission

WVU Office of Human Research Protections

Determination Letter

Letter# 0054

As a result of your responses and attestation on the Data Protection Form, this project **does not meet the federal definition of research and therefore does not require an IRB review**.

AN IRB PROTOCOL IS NOT REQUIRED AND CAN NOT BE ACCEPTED BY THE SYSTEM. There may be additional institutional requirements for the project, please see guidance and link below.

Project Category

Oral History and Scholarly and Journal/Documentary Activities: This project has been deemed not human subjects research because it is a scholarly/journalist activity that does not focus directly on the specific individuals about whom the information is collected. (45 CFR 46.102(l)(1)

If you have questions regarding this determination, please contact the WVU Office of Human Research Protections (OHRP) at IRB@mail.wvu.edu

Keep this document with your project records and send a copy to the PI if applicable. Use this page of the document to meet publisher requirements

If the details of the project change and the project no longer fits into the category listed above, a new Data Protection Request form must be completed by the PI.

Next Steps

- Please visit {website} for data storage and information security guidance and other applicable institutional requirements.
- You are responsible for ensuring your project is conducted in compliance with all institutional requirements (University or WVU Health System IT and information security policies).
- For assistance regarding data storage and information security, contact your department IT Support

WestVirginiaUniversity.

WVU Research Office

Determination of Not Human Subjects Research

Letter# 0051

As a result of your responses and attestation on the Data Protection Form, this project is considered by the WVU IRB to be **Not Human Subjects Research (NHSR) and, therefore, does not require an IRB review.**

AN IRB PROTOCOL IS NOT REQUIRED AND CAN NOT BE ACCEPTED BY THE SYSTEM. There may be additional institutional requirements for the project, please see the guidance and link in the Next Steps section.

NHSR Category:
Publicly Available Data: This project has been deemed not human subjects research because it involves **publicly** available data and therefore, does not meet the definition of human subjects. Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable **private** information or identifiable biospecimens.

If you have questions regarding this determination, please contact the WVU Office of Human Research Protections (OHRP) at IRB@mail.wvu.edu.

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Resources

Data Protection Process

researchdataprotectionsupport@mail.wvu.edu

irb@mail.wvu.edu

Thank You

Questions ?

Go Live: 2/17/25

Presenters:
Kasandra Lambert – Research Office – Assistant Director of OHRP
Nancy McGill – Continuous Quality Improvement and Education Coordinator of OHRP