

ORRC Position on What is Considered Research at Howard University

Guided by the OHRP Guidance at 45 CFR 46.102(d); and the FDA Guidance at (21 CFR 50.3(c), 21 CFR 56.103(c), 21 CFR 312.3(b), and 21 CFR 812.3(h)).?

This document is intended to only clarify whether an activity is research. It's not designed to discern the next question of whether the activity includes human subject research. For clarification on this, you may visit the ORRC website at WWW.howard.edu/orrc

Please read the comments below on pages 2 and 3, and then respond **Yes** or **No** to the following questions on page #1.

	Yes	No
Is your activity a systematic investigation?		
Is your activity intended to contribute to generalizable knowledge?		
Does your activity involve the prospective collection of data (qualitative or quantitative)?		
Does your activity involve data analyses to answer a question?		
Is your activity designed/intended to draw general conclusions?		
Is your activity intended to inform policy?		
Is your activity intended to generalize findings beyond a single individual or an internal program?		
Do you intend to publish or present your findings outside of the Howard University community?		
Are you testing an article such as drug, including a biological product for human use?		

If you respond **YES** to any of the above questions, you should submit your grant/activity to the Institutional Review Board (IRB) for assessment to determine whether an IRB review is required.

However, if you already know that your activity is research and requires an IRB review, then proceed to submit the appropriate IRB application. Please visit the ORRC website for additional details.

OHRP Definition and Related View on Research

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Please note that:

- Activities which meet this definition constitute research for purposes of the federal policy.
 - This qualification is regardless of whether an activity is conducted or supported under a program which is considered research for other purposes.
 - For example, some demonstration and service programs may include research activities.
- **Systematic Investigation:** A systematic investigation is an activity that plans (prospectively) to incorporate data collection (quantitative or qualitative) and data analysis to answer a question.
 - Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.
- **Generalizable Knowledge:** Activities designed (with intent) to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publication or presentation).
 - The intent to develop or contribute to generalizable knowledge makes an activity research.
 - Results do not have to be published or presented, to qualify the activity as research.
- **Examples of activities that are typically considered systematic investigations:**
 - Interviews and focus groups
 - Surveys and questionnaires
 - Analysis of data and specimen
 - Observational studies
 - Epidemiological studies
 - Review of medical records as part of systematic investigation
- **Examples of activities that are typically NOT considered systematic investigation:**
 - Training activities when they are **NOT** intended to contribute to generalizable knowledge

- Classroom activities where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods, when the activity is **NOT** intended to contribute to generalizable knowledge
- **Examples of activities that are typically NOT designed to develop or contribute to generalizable knowledge:**
 - Biographies
 - Most oral histories designed exclusively to create a record of specific historical events
 - Service or course evaluations, except they can be generalized to other individuals
 - Services, courses, or concepts where the results are **NOT** intended to be shared beyond the Howard University Community
 - Classroom exercises specifically designed to fulfill course requirements or to train students in the use of specific methods or devices
 - Quality assurance activities designed to continuously improve the quality or performance of a department or program, and there is **NO** intention to share the results beyond the Howard University Community

Food and Drug Administration (FDA) regulations Definition of Research

- The FDA regulation define a clinical investigation as any experiment that:
 - Involves a test article and one or more human subjects, and that
 - Either subject to the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Act, **or**
 - Need not subject to the requirements for prior submission to the FDA under relevant sections of the Act, but the results of which are intended to be later submitted or held for inspection by the FDA as part of an application for a research or marketing permit (21 CFR 50.3(c), 21 CFR 56.103(c), 21 CFR 312.3(b), and 21 CFR 812.3(h)).
- A test article is any drug (including a biological product for human use):
 - Medical device for human use
 - Human food additive
 - Color additive
 - Electronic product, or
 - Any other article subject to FDA regulations.
- **Examples of activities that are clinical investigations:**
 - Clinical trials that involve investigational drugs or devices

Research testing the safety and effectiveness of a device ○ Medical outcome studies comparing approved drugs or devices