



# Researcher Guidance for Non-Human Subjects Research (NHSR)

Office of Research Integrity & Compliance

Version 2

Updated: June 21, 2017

This document is intended for investigators who are creating a Non-Human Subjects Research (NHSR) protocol for submission to the WVU IRB for review. This guidance document presents the criteria that must be met in order for a study to be considered human subjects research. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at [IRB@mail.wvu.edu](mailto:IRB@mail.wvu.edu).

## Requesting WVU+kc Access

Anyone who needs to create or edit an IRB protocol needs to request access from ITS. To submit the request, please follow the steps under the *Training* section of the [WVU+kc page](#) of the ORIC website. There will be a short tutorial video on how to use and navigate the electronic submission system. **It is highly recommended that new users watch this video.**

## 3 Criteria for Human Subjects Research

If the answer is “No” to any one of the three criteria listed below, an NHSR protocol submission may be appropriate.

### 1. Does the study fulfill both definitions of research?

- a. The activity is a systematic investigation, including research development, testing, and evaluation; AND
- b. The activity is designed to develop or contribute to generalizable knowledge.

**Note:** Research means a systematic investigation designed to develop or contribute to generalizable knowledge. Most case reports and most oral histories are not generalizable and, therefore, not research. Many classroom projects, if not intended to be published, are also not considered research. Many quality improvement or program evaluation studies are not research.

### 2. Is the data the investigator is planning to obtain about living individuals?

**Note:** According to federal definitions, a human subject is a living individual. If the research does not include living individuals, the project is not “human subject research” and should not be submitted for evaluation. Please be aware that if the study involves the collection of protected health information (PHI), even if the records are from deceased individuals, a Decedent HIPAA waiver may be required for your study. The use of a Decedent HIPAA waiver must be justified and its use must be approved by the IRB even if the study itself is not “human subject research”.

### 3. Does the study involve individually identifiable private information?

- a. Data is gathered by any of the following means:
  - i. Physical procedures performed on individuals
  - ii. Manipulations of individuals
  - iii. Manipulation of individuals' environment
  - iv. Interpersonal contact with individuals
- b. The data is private because:
  - i. The information is about behavior that occurs in context in which an individual can reasonably expect that no observation or recording is taking place; OR
  - ii. The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (i.e. medical records).
- c. The data is individually identifiable because:
  - i. The identity of the participant is or may be readily ascertained by the investigator; OR
  - ii. The identity of the participant is or may be readily associated with the information.

In order to be considered human subject research, individually identifiable private information must be obtained or used in the research. If there is no individually identifiable private information involved, the project is not human subject research and does not require being submitted to the Office of Research Compliance. Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or someone else associated with the information) in order to constitute research involving human subjects.

**Note:** Anonymous surveys and individual medical records where no identifiable data is being recorded are considered individual information and not considered appropriate for NHR review.