



## IRB Guidance: Non Human Subjects Research (NHSR) Categories

**Non Human Subjects Research (NHSR)** are projects that do not fit the definition of research, do not actively involve human subjects, do not access private, identifiable human data, or are not purposed to support the marketing of an FDA-regulated drug, biologic, or device product.

The following are examples of activities that are generally considered not to be Human Subjects Research. If your activity is limited to one of the examples below, then it is likely not Human Subjects Research which would not need to be reviewed by the IRB. Note that **publication is not necessarily a determining factor** for whether an activity is Human Subjects Research.

### Research Using Public or Non-Identifiable Private Information about Living Individuals

The activity is limited to analyzing data about living individuals:

1. Where the data have been retrieved by the investigator from public, non-restricted data sets; or
2. Where the private data have been provided to the investigator without any accompanying information by which the investigator could identify the individuals.

**Note:** that “de-identified data” according to HIPAA may be identifiable according to the DHHS definition of “Human Subjects”. Please consult the **Human Subjects Research Determination Worksheet** for clarification and contact the IRB Office with any questions regarding research with data.


***The IRB requires investigators at Campbell University submit their research using public non-identifiable information about living individuals to the IRB for a determination of non-human subject research.***

## Categories of Non Human Subjects Research

### 1. Program Evaluation/Quality Assurance Review/Quality Improvement Project

The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting. **This type of project does not meet the federal definition of research because it is not “generalizable”.**

*Note: The purpose of a Quality Assurance (QA) project is to assure known quality. The purpose of Program Evaluation (PE) is to assess that a program is doing what it is intended to do. Generally Quality Improvement (QI) is designed for the purpose of improving the quality of a service, a program, a process, etc. A QA, QI or PE study should present NO CHANGE in RISK to participants. These studies are mechanisms to assure that a service, a program or process functions optimally. Such projects are usually for internal auditing purposes only, and not to be shared with the public (i.e. publication or presentation).*

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If you can answer "yes" to all the following questions, the activity is most likely **not** human subjects research:

- a) Will you simply monitor an existing process for which there will be no manipulation of the existing process?
- b) For biomedical or Social Behavioral QA/QI or PE studies, will physicians or caregivers (parents, teachers, therapists, etc.) provide usual and customary care regardless of the conduct of the study?
- c) Does the study involve collection of data to which the investigator routinely has access as part of his or her responsibilities within the institution to monitor data associated with, for example: treatment, cost containment, performance, or compliance?
- d) Are the findings of the project shared with stakeholders within the institutions with the aim to improve processes or programs?

Note that a project may have both a QA/QI/PE focus as well as a research focus. These projects will need to be submitted to and be approved by the IRB.

For further information, see [IRB Guidance: Comparison of Characteristics of Research/QI/PE](#), [IRB Guidance: QI/PE Decision Tree and Explanation](#), which can be found on the IRB website.

**Note:** an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities and may still not meet one of the definitions for Human Subjects Research.

IRB review and determination are highly recommended for QA/QI/PE. Please contact the IRB office to discuss your project prior to submitting any forms.

Although there is no IRB overview for QA/QI/PE projects, investigators are still required to protect participants private identifiable information, ethically conduct studies, and apply all other relevant regulations (e.g., FERPA, HIPAA).

## 2. Case Report

The project consists of a case report or series (less than three subjects/records) which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

**Note:** HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.



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Note: Consent is generally required for case reports. In addition, the investigators should never share personal identifiable information directly or indirectly (by combining certain other information) even if the participant consents to this. Pictures involving persons, should never include identifying information, such as (parts of) their face.

IRB review and determination are not required for case report research.

### 3. Journalistic or Documentary Activity (including Oral History)

The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium, e.g., print newspaper, documentary video, online magazine. For detailed information regarding [Scholarly and Journalistic Activities Deemed Not be research: 2018 Requirements](#) please visit the [OHRP website](#).

IRB review and determination are not required for Journalistic or Documentary Activity.

### 4. Research Using Health Information from Deceased Individuals

This activity is limited to analyzing data (identifiable or not) about deceased individuals.

**Note:** deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. Please review the definitions of human subjects research defined, previously, for clarification. Note also that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.

IRB review and determination may or may not be required for this type of research. Please contact the IRB office to discuss your project prior to submitting any forms.

### 5. Course-Related Activity



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The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments, are not shared beyond the classroom, and otherwise do not meet either of the definitions of Human Subjects Research.

### ***Do I need IRB review for classroom based research projects conducted by students?***

*CU recognizes that some student projects conducted to fulfill course requirements involve activities which, in a different context, might meet the definition of human subjects research. See, **IRB SOP: Classroom Projects for Educational Purposes Only**, found on the IRB website. In the circumstance of a classroom assignment that might otherwise constitute human subjects research the IRB will make the final determination if the project requires IRB review.*

*However, there are some student human subject research projects that will always require IRB review: Doctoral dissertations; funded research; research conducted through collaborations external to Campbell, Masters theses, Honors theses and other undergraduate research funded projects. All of these must be reviewed and approved by the IRB before students may begin their research. If you have any questions about whether student projects need IRB review, contact the IRB Office.*


IRB review and determination may or may not be required for Course Related Activities. For detailed information regarding classroom research see, [IRB SOP: Undergraduate Classroom Projects for Educational Purposes Only](#). Please contact the IRB office to discuss your project prior to submitting any forms.

## **6. Instrument/Questionnaire Development**

This activity is limited to interacting with individuals in order to obtain feedback on the types of questions which could or should be used to develop an instrument or questionnaire. The focus is on the development and construction of a data collection tool and not on the individuals who are providing the feedback on the questions being developed. This will be true even when the feedback may be specifically sought from an identified group of people most likely to be affected by the topic of the instrument, survey or questionnaire. The instrument or questionnaire development process will apply to many aspects of reliability and validity testing of the instrument or questionnaire. Note that once the process gets to the level of testing discriminant, concurrent or predictive validity, the activity may need to be reclassified as human subject research.

**Note:** If the participant is asked to provide additional information unrelated to instrument/questionnaire construction, such as, demographic information that will be analyzed as part of a research study, the project may need to be submitted to the IRB for review.

IRB review and determination highly recommended for Instrument/Questionnaire Development. Please contact the IRB before submitting any forms.

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To apply for review and determination of these types of research, please follow the instructions above. As indicated complete and follow the instructions for submission of the [NHSR Protocol Submission Form](#) which can be found on the IRB website.

**Please note:** The NHSR Submission Form does not replace submission of an IRB application to the Campbell University IRB. Investigators who intend to conduct activities that might involve human subject research must submit a formal application to the Campbell University IRB Office for determination.