CAPE FEAR VALLEY HEALTH	**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 information (data)*, or are not purposed to support the marketing of an FDA-regulated drug, biologic, or device product.

If your activity is limited to one of the categories below, then it is likely Non-Human Subjects Research which would not need oversight by the IRB. **Publication is not necessarily a determining factor** for whether an activity is Human Subjects Research.

Categories of Non-Human Subjects Research

1. 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 to be Research: 2018 Requirements please visit the OHRP website.

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.

2. 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 usually meet the federal definition of research because it is not "generalizable."**

> *Note: The purpose of a Quality Improvement (QI) is for improving the quality of a service, program, process, etc. The purpose of a Quality Assurance (QA) project is to assure a known quality. A QI/QA project should present NO CHANGE in RISK to participants. These projects 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. These projects are not research and must not be presented as research.*

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

- Is the intent of the project to implement knowledge, improve a practice or process within an institution, ensure it confirms with established/accepted standards or evaluating a program operation(s) and/or evaluating its impact?
- Does not include randomization, but may involve comparison of variations in programs?
- 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 project?

- Are the findings of the project shared with stakeholders within the institutions with the aim to improve processes or programs?

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.

Improvement or assurance project designed specifically for a setting may yield useful information for similar entities and may still not meet one of the definitions for Human Subjects Research.

For detailed information on determining if your project is research or a QI/QA/PE project, see the following guidance documents ***IRB Guidance: Comparison of Characteristics of Research/QI/QA/PE Projects*** which can be found on the IRB website. Use the ***IRB: QI/QA/PE Form*** for submission these projects.

IRB review and determination are required for this type of research

NOTE: Although IRB oversight for QI/QA/PE projects is required, investigators are still required to protect participants private identifiable information, ethically conduct projects, and apply all other relevant regulations (e.g., FERPA, HIPAA) and Institutional Policies.

3. Case Study/Series

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.

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, tattoos, or unique markings. For further information please see ***IRB Guidance: Case Studies/Series*** which can be found on the IRB website. Use the ***IRB: Case Study/Series Form*** for submission to the IRB.

NOTE: Although IRB oversight for case reports/series is required, investigators are still required to protect participants private identifiable information, ethically conduct projects, and apply all other relevant regulations (e.g., FERPA, HIPAA) and Institutional policies. A clinical site letter is requested to document support and agreement with this project by individuals engaged in direct clinical care at the site where the study activity is to occur.

IRB review and determination are required for this type of research.

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

The activity is limited to analyzing data and/or biospecimens about living individuals:

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

If data/biospecimens provider has access to the identity of the subjects, the investigator must enter into an agreement with the data/specimen provider stating under no circumstances will the identity of the subjects be released to the investigator.

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/biospecimens. The IRB has provided a list of ***IRB Designated Public Data Sets*** which can be found on the IRB website. If the data set you wish to use is not on the list, please contact the IRB.

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

5. 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 for clarification. 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.

6. Course-Related Activity

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.

Some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB Office for review.

IRB review and determination may or may not be required for Course Related Activities. Please contact the IRB office to discuss your project prior to submitting any forms.

7. Instrument/Questionnaire Development

This activity is limited to interacting with individuals 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. 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 project, 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.

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 Application Form***, except for QI/QA/PE and Case Study/Series projects, which can be found on the IRB website.

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