Template for Not Human Subject Research (NHSR) Determination Requests

**INSTRUCTIONS:**

* *Use this template to prepare a document with the information from the following sections to request a determination of Not Human Subjects Research from the VCU IRB.*
* *Depending on the nature of your activity, some sections may not be applicable to your project. If so, mark as “NA.”*

**PROJECT TITLE:**

*Include the full project title*

**PROJECT LEAD(S):**

*Name*

*Department*

*Telephone Number*

*Email Address*

**NOTES:**

* The IRB can only make this determination prior to the beginning of the research activity. The IRB will not make a determination after the activity has already begun.
* The IRB Office uses HRP-310 - WORKSHEET - Human Research Determination to make its Human Research determinations. Please consult that worksheet as a guide for the information you provide in Section 3.0 if you choose to submit to the IRB.
* Complete Section 3.0 below and create a new study in RAMS-IRB. Upload this completed template in lieu of a Protocol and submit for IRB Office review.
* If, while reviewing this determination form, you discover that an activity is Human Research, consult HRP-103 - Investigator Manual for instructions on how to submit a new study to the VCU IRB.

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# Definitions for Human Research

Review the following definitions to determine whether your activity is Human Research. Note that publication is not a determining factor for whether an activity is Human Research requiring review and approval by the IRB.

1. **“Human Research”** (according to DHHS): The definition includes two components:
   1. “Research”: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
   2. Human Subject”: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:
      1. Intervention: Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
      2. Interaction: Communication or interpersonal contact between investigator and subject.
      3. Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
      4. Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
      5. Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

If your activity does not meet both of these components, then it is not Human Research according to DHHS. Please see below for the FDA definition.

1. **“Human Research”** (according to FDA): The definition includes two components:
   1. **“Research”**: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:
      1. Must meet the requirements for prior submission to the US Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
      2. Must meet the requirements for prior submission to the US Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
      3. Any activity the results of which are intended to be later submitted to, or held for inspection by, the US Food and Drug Administration as part of an application for a research or marketing permit.
   2. **“Human Subject”:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

If your activity is not research or is research that does not involve human subjects, it is not Human Research according to FDA.

If your activity does not meet either DHHS or FDA definitions for “Human Research” you are not required to submit to the IRB Office for review or approval. See the appendix for examples of activities that are generally considered not to be Human Research. If you are unsure whether your activity constitutes Human Research, or require documentation of the IRB’s determination of research, complete and submit this template via RAMS-IRB.

# Description of Activity

|  |  |
| --- | --- |
| **Project Information** | **Description** |
| **Brief background and Rationale for the non-research project.** |  |
| **Purpose (may include goals and objectives) of the activity** |  |

# Type of Project

* + Quality Improvement / Quality Assurance / Lean Six Sigma
  + Program Evaluation
  + Evidence-Based Practice
  + Course-related Activity
  + Case Report
  + Oral History
  + Scholarly Activity (e.g., journalism, biography, literary criticism, legal research, historical scholarship)
  + Other or Uncategorized (please specify):

# Procedures

*4.1 Describe the procedures used to obtain information from the individuals with whom*

*you will interact or intervene for this activity, including communication or*

*interpersonal contact with individuals and physical procedures, if any.*

# Data and/or Specimen Collection

* 1. *Describe the data/specimens you will collect and how they will be analyzed, if applicable. Specify whether the data/specimens may be directly linked to individuals, indirectly linked through a code, or not linked at all to individuals (you will not have a link to the code).*
  2. *Describe the procedures used to obtain the data/specimens, if applicable.*

# HIPAA

*6.1 Indicate which of the following applies to this project concerning protected health information (PHI):*

* Not applicable: I am not using or accessing PHI for this project
* I am requesting a **waiver** of HIPAA authorization for this **research** activity that **does not involve human subjects** or their identifiable private information per HHS regulations (for example, research on data using a limited data set that is considered PHI under the Privacy Rule); see 1.1.b.

Justification for waiver of HIPAA authorization (see HRP-441 - CHECKLIST - HIPAA Waiver of Authorization):

* *Describe the PHI to be used or accessed for the study.*
* *Describe your plan to protect identifiers from improper use and disclosure.*
* *Describe your plan to destroy identifiers at the earliest opportunity consistent with the conduct of the study, or provide the health or legal justification for retaining.*
* *Confirm the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.*
* *Confirm the study could NOT practicably be conducted without the waiver or alteration.*
* *Confirm the study could NOT practicably be conducted without access to and use of the protected health information.*
* I am using PHI consistent with VCU’s Notice of Privacy Practices for treatment, payment or health care operations purposes

# Appendices

* 1. Examples of activities that are generally considered not to be Human Research. Note that publication is not a determining factor for whether an activity is Human Research.

**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.

Note: The purpose of a QA study 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 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.

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

Will you simply monitor an existing process for which there will be no manipulation of the existing process?

For biomedical or Social Behavioral QA or PE studies, will physicians or caregivers (parents, teachers, therapists, etc.) provide usual and customary care regardless of the conduct of the study?

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?

Note that 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 Research in Section 1.0.

**Case Report:**

A case report is a detailed report of the diagnosis, treatment, response to treatment, and follow-up after treatment of an individual patient. A case series is group of case reports involving patients who were given similar treatment. Case reports and case series usually contain demographic information about the patient(s), for example, age, gender, ethnic origin.

When information on more than three patients is included, the case series is considered to be a systematic investigation designed to contribute to generalizable knowledge (i.e., research), and therefore submission is required to the IRB. Note that HIPAA or other state or local laws may still apply to this activity.

**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 and otherwise do not meet either of the definitions of Human Research in Section 1.0.

Note that 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 for review.

**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.

**Research Using De-identified Information:**

The activity is limited to analyzing private data that have been provided to the investigator without any accompanying information by which the investigator could identify the individuals. Note that HIPAA regulations still apply to limited data sets that may not otherwise be considered identifiable per DHHS regulations.

**Research Using Health Information from Deceased Individuals:**

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

Note that deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. Please review the definitions above 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.

**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/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 that 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.