**Guidance and Application Form for “Not Human Research” (NHR) Determination – Includes QA/QI/PE Studies**

Instructions: Prior to the initiation of any human research activity, investigators are required to submit, and the IRB is required to review and approve research with human subjects for which RFUMS is engaged.Please review how “Human Research” is defined below in Section A. Also, examine Section B for examples of activities that are generally NOT considered to be Human Research. If you are uncertain about whether your activity is human research or not, or you would like the IRB to formally evaluate your proposed study and provide a written determination that your study is NHR, please complete the information in Section C and submit to the IRB.

**The IRB will only make this determination prior to the beginning of the research activity. The IRB will not make a Not Human Research determination or issue a formal letter in that regard after the activity has already begun.**

**A. Definitions for Human Research**

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

**1. Human Research - (according to HHS) includes two components**:

 “Research*” =* a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

“Human Subject” = a living individual about whom an investigator 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:

* 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.
* Interaction: Communication or interpersonal contact between investigator and subject.
* 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).
* 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.
* 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 either of these components, then it is not Human Research according to DHHS. However, also see below for the FDA definition (if relevant to your work.)

**2. Human Research - (according to FDA) includes two components:**

“Research” = any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

* 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;
* 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
* 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.

“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 does not meet either HHS or FDA definitions for “Human Research”, then you do not need to submit anything to the IRB Office for review, unless you want an official determination of not human subject research.**

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# B. Examples of activities that are generally considered NOT Human Research (NHS)

If your activity is entirely limited to one of the examples below, then it is likely Not Human Research which, would need to be reviewed by the IRB. Note that intent to publish is not a determining factor for whether an activity is Human Research requiring review and approval by the IRB.

**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.

*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 and are typically NOT considered human research by HHS or FDA definition (above).*

***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, teachers, or caregivers (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, student learning/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 A (above)

**2. Case Report**: The project consists of a case report or series 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 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.

**3. 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 A above. 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 Office for review.

**4. 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.

**5. 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” above.

**6. 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.

**7. 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.. **Once the process gets to the level of testing reliability or validity, the activity may need to be reclassified as human subject research, depending on what is being done.** 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.

*You may also wish to examine the “CHECKLIST: Is this a Quality Assessment (QA), Quality Improvement (QI) or Process Evaluation (PE) Study and “Not Human Research”? that is posted on*

*the IRB website (Guidance for Researchers section).*

**IRB Application for Proposed “Not Human Research” Activity**

*(Complete and submit only this completed section to IRB only if you wish to obtain a formal determination on whether this can be considered “Not Human Research”).*

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| **Title of Activity** |  |
| PI Name, Title |  |
| Dept. & College at RFUMS |  |
| Email |  |
| Phone |  |
| Date of Submission |  |

**1. Purpose** (Briefly describe the purpose, specific aims, or objectives of the study. Please describe how the study fits the “not human research” designation):

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**2. Procedures (**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. If you are using pre-collected data, describe the circumstances under which that data was collected. i.e., as part of routine clinical care):

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**3. Data and/or specimens** (Describe the data and/or specimens that you will gather about individuals, including names of datasets you will access, and links to data sources.)

**a. Data and/or Specimen Collection and Analysis** (Describe the data and/or specimens you will collect and how they will be analyzed).

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**b. Data and/or Specimen Collection Method** (Describe how you will obtain the data or specimens. For example, are you obtaining them from another researcher? Are you pulling data from directly from a medical record? Are you pulling leftover samples from a lab?)

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**c. Identifiability of Data or Specimens** (Indicate whether the data or specimens you collect for this activity can be directly linked to individuals, (e.g., the dataset includes names or other identifiable information like email, address), indirectly linked through a code (e.g., the dataset includes a code and you have the key to the code), or not linked at all to individuals (e.g., the dataset includes a code, but no one but the person giving you the data or specimens has the key to the code).

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**4. Protected Health Information (PHI), if applicable:**

If you are requesting the use of PHI, the RFUMS IRB in its role as the Privacy Board will need to consider if a HIPAA Authorization is required or if it can be waived. In order to make that decision, they will consider the following information:

**a. That the use or disclosure of PHI involves no more than a minimal risk** to the privacy of individuals, based on, at least, the presence of the following elements. Please describe:

(1) Your plan to protect the identifiers from improper use and disclosure.

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(2) Your plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

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(3) Written assurance that the PHI will not be reused or disclosedto 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.

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**b. That the research could NOT practicably be conducted without the waiver** or alteration.

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**c. That the research could NOT practicably be conducted without access to and use of the PHI.**

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**5. Family Education Rights and Privacy (FERPA), if applicable**. (If the project involves educational records, describe the ways in which your project will adhere to the FERPA guidelines here)

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***SIGNATURE:***

 Attestation of Principal Investigator

**Name/Signature of PI Date**

*Please save a copy of this completed form and send it electronically to IRB@rosalindfranklin.edu. After review, IRB will issue a determination letter if it finds this to be Not Human Research.*