**HUMAN RESEARCH DETERMINATION FORM**

**INSTRUCTIONS:**

* Prior to initiation, investigators are required to submit and the IRB is required to review Human Research for which Northwestern University is engaged.
* The term “Human Research” is defined below for you to consider in Section 1.0.
* Section 2.0 contains examples of activities that are generally considered not to be Human Research.
* If, after reading through Sections 1.0 and 2.0, you are not certain whether your activity is Human Research **or** you would like for the IRB Office to determine that for you and provide documentation of that determination, complete the information on page 2 and in Section 3.0. The IRB Office uses “WORKSHEET: Human Research Determination” (HRP-310) to make its Human Research determinations. Please consult that worksheet as a guide for the information you provide in Section 3.0.
* After completing Section 3.0, create a new study in eIRB+ and upload the entire document in lieu of an Investigator’s Protocol and submit the study for IRB Office review.
* If, while reviewing this determination form, you discover that an activity is Human Research, consult the “Investigator Manual” (HRP-103) for further instructions.
* If you need assistance, contact one of the offices below:

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| --- | --- |
| **Social and Behavioral Research**  Chambers Hall, 2nd Floor 600 Foster St. Evanston, IL 60208 Phone: (847) 467-1723 [irb@northwestern.edu](mailto:%20irb@northwestern.edu) | **Biomedical Research**  Arthur Rubloff Building, 7th Floor 750 N. Lake Shore Dr. Chicago, IL 60611 Phone: (312) 503-9338 [irb@northwestern.edu](mailto:irb@northwestern.edu) |

**ACTIVITY TITLE:**

Include the full protocol title as listed in the [IRB System] (include link).

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**VERSION DATE:**

Include the date of submission.

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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:

* **“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 (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

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:

* **“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. A human subject includes an individual on whose specimen a medical device is used.

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

1. **If your activity does not meet either DHHS or FDA definitions for “Human Research”, then you do not need to submit anything to the IRB Office for review. Consult “WORKSHEET: Human Research Determination (HRP-310)” for further clarification if needed.**

# Examples of activities that are generally considered not to be Human Research

The following are examples of activities that are generally considered not to be Human Research according to the definitions in Section 1.0. If your activity is 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 **publication is not a determining factor** for whether an activity is Human Research.

* 1. **Grant-only Submission:** The submission includes a grant (without an accompanying protocol) for which you would like acknowledgement of receipt by the IRB Office. Examples include Umbrella Grants, Training Grants, etc., that themselves do not include all elements..
  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.  
       
     Note that an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities, but may still not meet one of the definitions for Human Research in Section 1.0.
  3. **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.
  4. **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 Office for review.
  5. **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).
  6. **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. Please consult “WORKSHEET: Human Research Determination (HRP-310)” for clarification and contact the IRB Office with any questions regarding research with data.
  7. **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.

2.8 **Instrument Development:** This activity involves projects where the focus is on the development and construction of a data collection tool. The research team may interact with people in order to obtain feedback on the types of items or questions that could be used to develop an instrument but the focus in on the instrument, not on the people who are providing the feedback on the instrument being developed. Projects where the instrument development process will apply to many aspects of reliability and validity testing of the instrument are typically not human research. However, it is possible that once the process gets to the level of testing discriminant, concurrent and / or predictive validity, the project may need to be reclassified as human research.

# Description of Activity

* 1. If, after reviewing the information above, (1) you are unclear as to whether your activity is Human Research and would like for the IRB Office to make a determination for you; or (2) you believe that your activity is not Human Research and would like for the IRB Office to provide documentation that it agrees with your assessment, then please complete the information below.
  2. **Purpose**  
     Briefly describe the purpose, specific aims, or objectives of the study.
  3. **Procedures**Briefly 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 will be asking survey questions or interviewing people, include the questions you plan to ask.
  4. **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.
     + **Data and/or Specimen Collection and Analysis**  
       Describe the data and/or specimens you will collect and how they will be analyzed.
     + **Data and/or Specimen Collection Method**Describe how you will obtain the data or specimens. (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?)
     + **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), 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).