**Human Research Determination Form**

**INSTRUCTIONS:**

* Prior to the initiation of any human research activity, 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.
* In addition, Section 2.0 below contains some 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 review your protocol (Section 3.0 below) and evaluate your research and provide documentation of that the IRB agrees your study is not human research, complete the information in Section 3.0.

Note: 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 “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 if you choose to submit to the IRB.

* 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:

|  |  |
| --- | --- |
| **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) |

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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 (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 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.

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

**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. **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:

1. Will you simply monitor an existing process for which there will be no manipulation of the existing process?
2. 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?
3. 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.

* 1. **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.
  2. **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.
  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.
  4. **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.
  5. **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.

2.7 **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. 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: 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.

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 but would like for the IRB Office to provide documentation that it agrees with your assessment, then please complete the information below.

# Description of Activity (Delete the instructions below when providing your information)

**ACTIVITY TITLE:**

Include the full protocol title as listed in the eIRB+ System.

**PRINCIPAL INVESTIGATOR:**

Dr. Jason D. Hartline

McCormick Computer Science Department

+1 847 467 0280

hartline@northwestern.edu

**VERSION DATE:**

7/23/20

* 1. **Purpose**

This project compares Northwestern’s existing course allocation mechanism to alternate course allocation mechanisms in order to identify mechanisms that would more equitably balance the capacity of over-demanded courses.

The data collected from surveying students is for evaluating course allocation mechanisms and is not of interest itself.

* 1. **Procedures**

The project will collect data on what Computer Science courses students want to take, which courses they enroll in Fall quarter, and current course capacities for these courses.

# The data will be collected via a survey that will be sent out to all Computer Science majors, minors, and master’s students via email that will survey their interests in courses for next fall. Students will receive contact information from the project team and a brief explanation of the purpose for the survey. They will then quantify how much they want to take each Computer Science course next quarter on whatever scale they wish. Because the student’s preferences need to be paired with the courses they are actually enrolled into, the survey results will not be initially anonymous; this is so that survey results can be paired with actual fall enrollments. Once these pairs (course preferences and enrollments) are attained, the data will be deidentified. The current course capacities for next quarter will be obtained from the CS department.

* 1. **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**

The students’ preferences for Computer Science courses next quarter and the Computer Science courses that each student is assigned will be collected. Because each student quantifies this using his/her own scale, these scales will be normalized. This data will be used to test Course Assignment mechanisms.

* + - **Data and/or Specimen Collection Method**

The students will be surveyed for their course preferences, as described above, and the responding student’s student IDs will be used to collect data on which courses they were able to enroll in via the CS department. The CS course capacities will be obtained from the CS department as well.

* + - **Identifiability of Data or Specimens**

Each individual’s course preferences need to be linked to the courses he/she enrolls in. Each individual that responds to the survey will provide a student ID and name that will be used to pair their reported course preferences with the courses they actually enroll in. When all of this data is obtained, it will be deidentified.

3.4 Protected Health Information (if applicable):

If you are requesting the use of protected health information, the Northwestern 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, the Privacy Board will consider the following:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements. Describe:
2. Your plan to protect the identifiers from improper use and disclosure.
3. 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.
4. Written assurance that 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.
5. The research could NOT practicably be conducted without the waiver or alteration.
6. The research could NOT practicably be conducted without access to and use of the protected health information.