At times it is difficult to determine if a project constitutes research under the federal definition of research in 45 CFR 46. The purpose of this form is to solicit sufficient preliminary information from the project staff for the IRB to provide a determination regarding whether the federal human subjects protection regulations apply to the project.

Please refer to the flow chart on page 5. This flowchart was prepared by the federal Office for Human Research Protections to assist in determining if a project meets the regulatory definition of research.

Research is defined in the regulations (45 CFR 46.102(d)) as follows:

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subject is defined in the regulations (45 CFR 46.102(f)) as follows:
(f) **Human subject** means 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.

**Intervention** includes both 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** includes communication or interpersonal contact between investigator and subject. **Private information** includes 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 which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

By providing the information requested on the following pages, the IRB or the CUNY Office of Research Conduct will be able to make a determination as to whether the project meets the above federal regulatory definition of research. Please answer all questions.

If the project does not involve research, no further involvement by the IRB will be necessary for this project. If the project meets the definition of research and living human subjects are involved, you will be advised to file an application for IRB review.

If your campus is using IRBManager, please submit this request through IRBManager. If you are submitting this form in hardcopy, please submit two copies and include a copy of the completed form in Word. **For all campus-based projects, please submit this form to your campus IRB.**

For CUNY Central Administration projects, please indicate “CUNY Central Administration” in the space for CUNY College on page 1 and submit this form through IRBManager to the CUNY Office of Research Conduct. If you need help, call 212.794.5504.
PART I: PROJECT INFORMATION

A. Duration of Project:

B. Description of Project: Please describe briefly (one page or less) the scope and intent of the project. Provide a description of how the data will be collected and analyzed, whether data about living human subjects are involved, and what the end product will be (such as internal document, teaching materials, electronic or print publication, etc.).

C. Description of Potential Human Subjects, and Human Subjects Data to be Collected:

D. Recruitment Plan:

E. Comments:

PART II: SIGNATURES

A. Required Signatures

The above information concerning the proposed project is correct. If the project is judged to involve human subjects research, I will seek and obtain IRB approval prior to beginning the project.

Project Director’s Original Signature:

Signature of Project Director:

Date:
PART III: OFFICE USE

FOR IRB OFFICE USE:

☐ The IRB has determined that this project does not constitute research with human subjects. No further IRB review is necessary.

☐ The IRB has determined that this project does constitute research. Further IRB review is necessary. Please prepare an IRB application package and submit it to the IRB office.

____________________________________                     ____________
IRB Chair                                                                                  Date

OR

FOR OFFICE OF RESEARCH CONDUCT USE:

☐ The Office of Research Conduct has determined that this project does not constitute research. No further IRB review is necessary.

☐ The Office of Research Conduct has determined that this project does constitute research. Further IRB review is necessary. Please prepare an IRB application package and submit it to the IRB office.

____________________________________                         ____________
Director, Office of Research Conduct                                                                 Date
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here.

Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge? [45 CFR 46.102(d)]

- **NO** Activity is not research, so 45 CFR part 46 does not apply.
- **YES** Activity is research. Does the research involve **obtaining** information about living **individuals**? [45 CFR 46.102(f)]

- **NO** The research is not research involving human subjects, and 45 CFR part 46 does not apply.
- **YES** Does the research involve **intervention** or **interaction** with the individuals? [45 CFR 46.102(f)(1), (2)]

- **NO** Is the information **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]
  - **NO** BUT
  - **YES** Activity is research involving human subjects. Is it **conducted or supported by HHS**? [45 CFR 46.101(a)(1)]
    - **NO** BUT
    - **YES** Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?
      - **YES** Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.
      - **NO** Go to Chart 2

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]