

Not all research involving humans will require IRB submission or approval. Only activities that meet the regulatory definitions of "research" and "human subjects" and where New Jersey City University (NJCU) is engaged in the conduct of human subjects research require NJCU IRB review and approval.

This form may be used as to help you determine whether or not you need to file an application for review to the NJCU IRB and/or documentation of formal notice of IRB.

2. Is the intent of the proposed activities to *develop or contribute to generalizable (scholarly) knowledge*?

YES

NO

If NO, please explain the intent of the proposed activities and explain how the proposed activities are not intended to contribute to generalizable knowledge:

<Type Here>

If to , these activities constitute research. Proceed to Section 2.

If to , these activities may be considered a *Quality Improvement/Quality Assurance or Program Evaluation project*. Please confirm by answering the following QI/QA and Program Evaluation questions.

Quality Improvement/Quality Assurance

Program Evaluation

QI 1. The project is being initiated/conducted based on the request and needs of a department, institution, or organization for internal purposes only.

YES

NO

If any QI/QA or Program Evaluation question is answered, the activities constitute research. Proceed to Section 2.

### SECTION 2: DETERMINATION OF "HUMAN SUBJECT"

*Human subject*-a living individual about whom an investigator (faculty, student, or staff) 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 (venipuncture) and manipulations of the subject or the subject's environment for research purposes

*Interaction* is communication or interpersonal contact between researcher and subject

*Identifiable* is when it is possible for the researcher to identify the subject, even if only through associated information

*Private information* is 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 (e., medical or educational record information). Private information must be individually identifiable through the use of identifiers (name, date of birth, social security number) or through the use of a code.

Use the definitions above to answer the following questions.

### SECTION 3: DETERMINATION OF "ENGAGED"

**Engaged** An institution considered to be engaged in research if certain federal criteria are met may be subject to IRB review/approval.

**NJCU Auspices** NJCU personnel (student, faculty, or staff) who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities

**Non-NJCU researchers** wishing to conduct human subjects research using NJCU personnel as subjects or its facilities are not considered to be engaged. This document is for the determination of IRB review only and researchers are expected to obtain other permission as necessary. For example, the NJCU IRB does not have authority to grant the release or use of NJCU listservs, equipment, or facilities

#### ENGAGED

NJCU is considered to be engaged in human subject research if NJCU personnel are involved in any of the following activities under NJCU Auspices

#### NOT ENGAGED

NJCU is considered to not be engaged in human subject research if NJCU personnel are:

- x direct awardee of a federal grant, award, or contract;
- x obtaining informed consent;
- x performing invasive or noninvasive procedure with subjects;
- x intervening for research purposes with any subjects by manipulating the environment;
- x interacting for research purposes with any subject (e.g., conducting research interviews, administering questionnaires); or
- x obtaining private identifiable information.

x sole

1. Describe the purpose of the proposed activities. State the overall objectives and specific aims. Provide a brief description of the procedures. <Type Here>
2. Describe the subject population or the type of data and/or specimens to be studied. <Type Here>
3. Describe how the data and/or specimens will be obtained. <Type Here>

<b>IRB DETERMINATION OF NJCU ENGAGEMENT IN HUMAN SUBJECTS RESEARCH</b>
Researchers do not complete this section. This section is for IRB staff only
<input type="checkbox"/> The activities as described DO NOT constitute NJCU being engaged in Human Subjects Research. Submission of an IRB Application to NJCU is not required.
<input type="checkbox"/> The activities as described DO constitute NJCU being engaged in Human Subjects Research. Submission of an IRB Application IS REQUIRED. IRB Approval must be obtained before the research can begin.

IRB Chair \_\_\_\_\_