Determining the Necessity of IRB Review

INSTRUCTIONS: Not all research involving humans will require IRB submission or approval. Only those activities that meet the regulatory definitions of **(a)** "**research**" and **(b)** "**human subjects**" and where **(c)** 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 **(1)** to help you determine whether or not you need to file an application for review to the NJCU IRB and/or **(2) to request** documentation of formal notice from the NJCU IRB that NJCU is not "engaged" in "human subjects research" requiring NJCU IRB review/approval.

SECTION 1: DETERMINATION OF "RESEARCH"

Research–"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"

RESEARCH	NOT RESEARCH
Activities "designed to develop or contribute to generalizable knowledge" and to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings. The project may be "research" if it: • intends to advance general knowledge in the academic, scientific, or professional community; • is conducted using a research design that will lead to scientifically valid findings; • involves subjects who are not expected to benefit personally from the knowledge gained; • is completed to obtain a Baccalaureate, Master's, or Ph.D. degree.	Projects may be systematic but not "research." Some examples of "not research" include: • classroom projects undertaken solely to fulfill course requirements with no intention of sharing the results beyond the University community; • Quality Improvement (QI)/Quality Assurance (QA) or Program Evaluation activities designed to improve the quality or performance of a department or program with no intention of sharing the results beyond the local community (Please see QI/QA and Program Evaluation questions below.); • projects during which most of the subjects who participate are expected to benefit from the knowledge gained and the main goal of the project is to improve services; • most oral history activities, which, in general, are designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge. Only those conducting oral history projects that conform to the regulatory definition of research need to submit their research protocols for IRB review.

Use the information above to answer the following questions.

1. Do the proposed activities involve a systematic approach? A "systematic" approach involves a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or specimens and analysis.

   [__] YES **[__] NO**

   If NO, please explain why the proposed activities do not involve a systematic approach:
   <Type Here>

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 YES to 1 and 2, these activities constitute research. Proceed to Section 2.**

 **If NO to 1 and 2**, 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	**E 1.** The evaluation is being initiated based on the request and needs of a partner organization or department for internal purposes only. [__] YES [__] NO
QI 2. The study is NOT designed to expand knowledge of a scientific discipline or scholarly field. [__] YES [__] NO	**E 2.** The intent of the evaluation is to improve a specific program and/or to meet funder requirements. [__] YES [__] NO
QI 3. All activities are "routine care" or "standard practice" and will be conducted by staff where the project will take place. Untested methods and/or interventions are NOT being evaluated. [__] YES [__] NO	**E 3.** The program being evaluated is evidence-based (already shown to be effective). Untested services, programs and/or interventions are NOT being evaluated. [__] YES [__] NO
QI 4. The project does NOT involve a control group or randomization or blinded interventions. [__] YES [__] NO	**E 4.** The evaluation does NOT involve randomization of participants, but may involve comparison of variations in programs. [__] YES [__] NO
QI 5. The project is NOT externally funded. [__] YES [__] NO	
QI 6. NO drugs, biologics and/or devices without FDA approval are being used in the project or being used for a non-FDA approved purpose. [__] YES [__] NO	

 If all QI/QA or all Program Evaluation questions are answered "**YES**," the criteria for research are not met and a project is considered Quality Improvement/Quality Assurance or Program Evaluation. **Proceed to Section 4.**

 If any QI/QA or Program Evaluation question is answered **"NO," 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 (i.e., 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 identity 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 (i.e., medical or educational record information). Private information must be *individually identifiable* through the use of identifiers (name, date of birth, social security numbers) 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 when 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 NJCU 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	NOT ENGAGED
NJCU is considered to be engaged in human subjects research if NJCU or NJCU personnel are involved in **any** of the following activities under **NJCU Auspices**:	NJCU is considered to not be engaged in human subjects research if NJCU or NJCU personnel are:

• direct awardee of a federal grant, award, or contract; • obtaining informed consent; • performing invasive or noninvasive procedures with subjects; • intervening for research purposes with any subjects by manipulating the environment; • interacting for research purposes with any subject (e.g., conducting research interviews or administering questionnaires); or • obtaining private identifiable information.	• solely performing services that do not merit professional recognition or publication privileges or are typically performed by those institutions for non-research purposes; • are not administering any study intervention being tested or evaluated under the protocol; • only informing (e.g., providing a copy of the informed consent document, information about contacting the investigator, and/or seeking or obtaining the prospective subjects' permission for investigators to contact them) prospective subjects about the availability of the research but not obtaining subjects' consent for the research or acting as representatives of the investigators; or • releasing identifiable private information/specimens pertaining to the subjects of the research.

Use the preceding information to answer the following question.

1. Is NJCU engaged in human subjects research?

   [__] YES **[__] NO**

   If YES or NO, please explain why NJCU **IS** or **IS NOT** engaged in human subjects research:
   <Type Here>

2. Is any non-NJCU IRB involved in reviewing this project?

   [__] YES* **[__] NO**

   ***If YES,** please list/name those IRB(s) and include the status of IRB approval(s):
   <Type Here>

 **If YES to 1, NJCU is engaged. Proceed to Section 4.**  **Otherwise, NJCU is not engaged. Proceed to Section 4.**

SECTION 4: YOUR PROTOCOL IS HUMAN SUBJECTS RESEARCH AND NJCU IS ENGAGED

If your responses in Sections 1, 2, and 3 determine that your study activities constitute research **and** involve human subjects **and** that NJCU is engaged, then an IRB review and approval of your study is required before any study activities can begin. To request an IRB review, please complete and submit an application for review to the NJCU IRB. The application is available on the NJCU IRB website, which is accessible online from the main page of the Office of Research Grants and Sponsored Programs. If you have any questions, please email irb@njcu.edu**.**

If your responses in Sections 1, 2, and 3 indicate that NJCU is **not engaged** in **human subjects research**, you are **not required** to submit an IRB application. If you would like confirmation and documentation from the IRB that your proposed activities do not constitute NJCU being engaged in human subjects research, or if you are uncertain if your study meets the definition of human subjects research, please complete this form, including Sections 5-6, and submit it as an MS Word document to irb@njcu.edu .

SECTION 5: STUDY INFORMATION

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>

IRB DETERMINATION OF NJCU ENGAGEMENT IN HUMAN SUBJECTS RESEARCH	
Researchers do not complete this section. This section is for **IRB staff only.**	
[__] The activities as described **DO NOT** constitute NJCU being engaged in Human Subjects Research. Submission of an IRB Application to NJCU is not required. **[__]** The activities as described **DO** constitute NJCU being engaged in Human Subjects Research. Submission of an NJCU IRB Application **IS REQUIRED**. IRB Approval must be obtained before the research can begin.	
_____ IRB Chair	_____ Date