Request for Human Subjects Research Determination

**Instructions**: Use this form if you need to determine if your project is human subjects research. Keep a copy of this form in your project file. Submit this form to [hrpp@newschool.edu](mailto:hrpp@newschool.edu) if you would like the HRPP/IRB to determine whether or not your project is human subjects research.

If you have questions about whether an activity is human research, contact [hrpp@newschool.edu](mailto:hrpp@newschool.edu)for guidance.

|  |  |
| --- | --- |
| Project Title: | Date: |

1. **Applicant Information**

|  |  |
| --- | --- |
| **Name:** | |
| Faculty  Student  Part-time Faculty  Full-time Staff | |
| Division/Department: | Email: |

**Faculty Advisor** *(if appropriate)* NA

*Students may serve as the applicant with authorization from their faculty advisor.*

|  |  |
| --- | --- |
| Name: | Division/Department: |
| Email: | |

1. **PROJECT DESCRIPTION**

**Summary.** Provide a summary of the proposed project. The summary should describe the objectives of this project, the procedures to be used, and the population(s) involved. Alternatively, a narrative or protocol may be attached and submitted.

# COMMON RULE DETERMINATION

# Is the project limited to any of the following activities?

# *(If this research is funded by* [*DOJ*](https://www.nij.gov/funding/humansubjects/Pages/welcome.aspx)*/*[*NIJ*](https://www.nij.gov/funding/humansubjects/Pages/welcome.aspx)*/*[*OJP*](https://www.ojp.gov/funding/explore/legaloverview2021/researchrelatedrequirements)*, check here and proceed to question 2 below )*

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** | **Activities deemed to not to be “research” in the Common Rule** |
|  |  | **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, **that focus directly on the specific individuals about whom the information is collected.**  The objective of the activities in this category is to provide an accurate and evidence-based portrayal of the individuals involved, and not to develop generalizable knowledge. |
|  |  | **Public health** surveillance activities, including the collection and testing of information or biospecimens, **conducted, supported, requested, ordered, required, or authorized by a public health authority**. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).   * Is this an NIH-supported or conducted activity?   No  Yes – Documentation of the NIH determination must be included.  *Note: NIH issues determinations about whether NIH-supported or conducted activities qualify as public health surveillance activities deemed to be “not research”. Investigators and institutions may not make their own determinations.* |
|  |  | Collection and analysis of information, biospecimens, or records by or for a **criminal justice agency for activities authorized by law or court order solely** for criminal justice or criminal investigative purposes. |
|  |  | **Authorized operational activities (as determined by each agency)** in support of intelligence, homeland security, defense, or other national security missions.  *(This category is for national security missions authorized by federal agencies, which are not considered to be human subject research.)* |
| * If you answered YES to any of the above, Skip to Section IV*, you do not need to complete questions 2 & 3 below.* The proposed activity is not human subjects research according to the Common Rule. * If you answered NO to all the above, proceed to question 2 below. | | |

# Is the activity “research”?

As defined by Department of Health and Human Services (DHHS) regulations: *“Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”* 45 CFR 46.102(l)

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| --- | --- | --- |
| **Yes** | **No** | **Research** |
|  |  | 1. Does the activity involve a **systematic investigation?**   *(i.e., an activity that involves a prospective plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a question)* |
|  |  | 1. Is the activity is designed to develop or contribute to **generalizable knowledge?**   *(i.e., conclusions drawn from the data analysis will be applied to populations outside of the specific study population. In other words, if the results of the systematic investigation are expected to be generalized to a larger population beyond the site of data collection and replicated in other settings, then the knowledge is generalizable.)*   |  | | --- | | **Examples of activities that generally are not designed to develop or contribute to generalizable knowledge** | | **Program Evaluation/Quality Improvement/Assurance Activities**  Program Evaluation, Quality Assurance and Quality Improvement Activities are considered research only when they are intended to contribute to generalizable knowledge or there is a possibility that the resulting data will be used to contribute to generalizable knowledge.  When the purpose of an activity is to ONLY assess the success of an established program in achieving its objectives and the information will be used to provide feedback to improve that program, the activity is not human subjects research.  When the evaluation is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is research.  . | | **Student Course Assignment/Project**  Activities that are designed as part of a course requirement for purposes of learning experience only and are not “designed to develop or contribute to generalizable knowledge” are done so with the intent to satisfy the curriculum requirements of a course, are not intended for use outside of the classroom, and are typically concluded at the end of the relevant semester.  For more information, see [The New School RCR Policy: Course Related Student Projects](https://docs.google.com/document/d/1RbYiDFmqaS1ZB1pdPAKjVxv2k-DdkD8GFVKPjAnXkP8/edit).  **Note: Some student course assignments and projects may meet the definition of human subjects research.** For example, a student may be conducting the activities with the intent to conduct further investigation or analyses in order to contribute to generalizable knowledge. If this is the case, IRB review and approval or determination is required prior to the conduct of such activities.  **Studies intended to result in a dissertation or thesis DO NOT fall under this description of student course assignments/projects.** | |
| * If you answered NO to either 2a or 2b, Skip to Section IV, *you do not need to complete question 3 below.* This activity does not meet the definition of research according to the Common Rule. * If you answered YES to both 2a and 2b, Complete question 3 below. This activity meets the definition of research in the Common Rule. | | |

1. Does the activity involve **“human subjects”**?

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** | **Human Subjects** |
|  |  | 1. Will you be gathering information or biospecimens **about** **living individuals**?   *Collecting facts (such as how many chairs are in a room) is not about the person providing the information. If the question is “How many chairs do you think are in that room?” to measure a person’s observational skills or memory, then that data would be about the person being asked.* |
|  |  | 1. Will you obtain information or biospecimens through **intervention** with living individuals, and use, study, or analyze the information or biospecimens?   This *includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Manipulations may be physical, social, psychological, or emotional. "Environment" includes an individual's social and virtual environments as well as physical environment.* |
|  |  | 1. Will you obtain information or biospecimens through **interaction** with living individuals and use, study, or analyze the information or biospecimens?   *This includes communication or interpersonal contact between researchers and subjects, including indirect interaction such as via a web-based survey.* |
|  |  | 1. Will you obtain, use, study, analyze, or generate **identifiable private information** or **identifiable biospecimens**?   ***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 that 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 or education record).*  ***Identifiable private information*** *is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.*  ***An identifiable biospecimen*** *is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.*  *Note: When data or specimens are* ***coded****, and the investigator has access to the key or another means to re-identify, the data is identifiable. Consult with the IRB Office for questions on this topic.* |
| * **If you answered YES to 3a and YES to either 3b, 3c, or 3d**, **STOP!** This project involves Human Subjects Research. Do not submit this form to the IRB. Instead, use Cayuse to submit a New Project for IRB review. IRB Approval is REQUIRED before you may conduct any study related activities. * **If you answered No to 3a**, **Complete Section IV of this form.** * **If you answered Yes to 3a but No to 3b, 3c, and 3d**, **Complete Section IV of this form.** | | |

# ADDITIONAL INFORMATION

# Describe any plans for the use and/or dissemination of results internally and/or externally:

1. Provide any additional information that you believe may be relevant for this determination:

1. **SIGNATURE**

I will conduct the activities identified above in the manner described on the attached narrative. If I decide to make any changes, I will submit the proposed changes to The New School HRPP/Institutional Review Board, for confirmation that the activity remains “not human subjects research”.

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Investigator Signature Date

**IF THE INVESTIGATOR IS A STUDENT, A FACULTY ADVISOR MUST SIGN BELOW:** I have read this application and approve of this project.

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Faculty Advisor Signature Date

**HRPP/IRB USE ONLY**

1. **Reviewer Conflict of Interest**

Do you have any interests, financial or otherwise, related to this submission that could present a conflict of interest?

Yes. Please do not conduct this review, contact the IRB office so that this submission can be reassigned.

  No

1. **Determination**

The activity **is not** research.

The activity **does not** involve human subjects.

The activity **does** involve human subjects research per the:  Common Rule  FDA

An application to the IRB is required.

Additional information is needed (see “Changes, Modifications, and Clarifications” below)

**Reviewer Notes:**

**Changes, Modifications, and Clarifications**

|  |  |
| --- | --- |
|  | |
| **Reviewer Name:** | **Date:** |