# Self-Certification Form for Determining Whether Your Proposed Activity is Research Involving Human Subjects

## When to Use this Form

1. If you need documentation for funding agencies, administrators, or collaborators, this self-certification form is provided for your use. Copies of this should be maintained in the PIs research files. Do not submit a copy of this form to the NYU SoM IRB.
2. If you are unsure whether or not you need to submit your project to the IRB
3. If you are unsure if your project is research
4. If you are unsure if your research involves human subjects

**This is not an Exempt Certification or IRB review**

Exemptions are a type of IRB review. If your project meets Exemption criteria you will need to submit the Exemption form to the IRB. Go to the IRB Web site for the Exemption form. The conditions below must be met in order for your research to be determined non human subject research.

## Administrative Information

|  |  |  |  |
| --- | --- | --- | --- |
| Your Name |  | Degree(s) + Institution |  |
| Your Mailing Address |  | Your Phone |  |
|  |  | Your Email |  |
| Study/Grant Title/Award# |  | | |

## Is Your Project “Research”?

**“Research” is defined under 45 CFR 46.102(d) as** 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.

|  |  |
| --- | --- |
| Your proposed activity is a “systematic investigation” | No  Yes  “**Systematic investigation**” is an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.  The systematic investigation will involve a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory.  **Examples of systematic investigations include, but are not limited to**, observational studies, interview (including those that are open-ended) or survey studies, group comparison studies, test development, program evaluation, interventional research. |
| The intent of the data/specimen collection is for the purpose of contributing to generalizable knowledge | No  Yes  Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study which may be applied to populations outside of the specific study population), inform policy, or generalize findings.  To develop or contribute to generalizable knowledge requires that the results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program.  Activities involving human subjects or human subjects data where there is an intention to publish the results in a peer-reviewed journal or to present at a regional or national meeting are generally assumed to be generalizable. In addition, theses or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable. |

If you answered **No** to both questions above, you may stop here. You are not conducting research that needs to be reviewed by the IRB. Otherwise, continue below.

## Does Your Project Involve “Human Subjects”?

Determination of “Human Subject”: 45 CFR 46.102(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

|  |  |
| --- | --- |
| QUESTION 1 Your proposed activity involves “intervention” or interaction with a human subject | No  Yes  “**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. |
| QUESTION 2  Your proposed activity involves access to identifiable “private information” | No  Yes  “**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 be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. |
| QUESTION 3  Your proposed activity collects or receives data/specimens with identifiable private information | No  Yes (answer below)   |  |  | | --- | --- | | QUESTION 3.1  the data/specimens are coded such that a link exists that could allow them to be re-identified | No  Yes | | QUESTION 3.2 there is a written agreement that prohibits you and your research staff access to the link | No  Yes | |

If you answered **No** to Questions 1-3 or **Yes** to Question 3 and **Yes** to both 3.1 and 3.2, you may stop here. You are not conducting research that needs to be reviewed by the IRB.

If you answered in any other combination, your proposed activity may be research that involves human subjects. You must submit an application to the IRB before starting your project. Visit the IRB’s website at <http://irb.med.nyu.edu> or call for further instructions.

## Your Signature

|  |  |
| --- | --- |
| Date |  |
| Print Name |  |
| Signature | I certify that the information I have given above is true and accurate. |

If the results of this form indicate the research does not involve human subjects, consistent with the NYU SoM IRB policy and federal regulations governing human subject research, IRB review is not required.

This document is consistent with NYU SoM IRB policy and may be used as documentation that your research does not involve human subjects and does not require IRB review.