

Criteria & Application for Non-Human Subject Research (NHSR) Certification

Review the criteria below and then complete Part 1 – Application for Non-Human Subject Research (NHSR) Certification. CITI is not required for NHSR Certification.

NOTE: The IRB can only make a NHSR determination **PRIOR** to the beginning of the activity. The IRB will not make a NHSR determination after the activity has already begun.

NOT ELIGIBLE FOR NHSR CONSIDERATION:

1. Student projects or class assignments conducted to fulfill course requirements designed to teach students research methods except for the following: Doctoral dissertations; Master's theses, and honors theses.
2. Human stem cell research is not eligible for NHSR consideration. Human stem cell research includes all research involving human embryonic stem cells (hESC), induced pluripotent stem (iPS) cells, neural progenitor cells, human embryos, human gametes and other potentially pluripotent cells.

Research refers to a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Generalizable refers to studies where the findings can be applied to broader populations beyond the specific sample studied. That is the results are relevant and applicable to a larger group, not just the individuals directly involved in the research.

Human subject is a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research Criteria Groups eligible for NHSR Certification

1. Research collecting or receiving unidentifiable/de-identified or coded private information or biological specimens is not human subjects research because the investigator cannot readily ascertain the identities of the individuals to whom the data or samples belong and does not have access to the code linking the data to the identities.
2. Research with publicly available data, with or without personal identifiers, from sites that are freely accessible.
3. Research involving interviews or asking subjects about non-private/non-personal information such as appraising art, assembly line processes, traffic flows, or consumer trends.
4. Research for oral history, journalism, biography, literary criticism, legal research, and historical scholarship, directly concerning specific individuals such as a scientist that is not for generalizable research.
5. Program evaluation or quality assurance/improvement activities that are required by an institution to directly affect institutional projects, programs, or policies and not designed to contribute to generalizable research. (*Findings may be shared or presented to a wider audience with the intent to demonstrate potentially effective models, strategies, assessment methods or to provide benchmarks.*)

Program evaluation is a systematic method for collecting, analyzing, and using information to answer questions about the effectiveness and efficiency of a project, policy, or program.

Quality assurance/improvement is a systematic pattern of actions to optimize productivity, communication, and value within an organization for the purpose of improving the quality of a service, project, program, or process, etc.

Part 1 – Application for Non-Human Subject Research (NHSR) Certification

The Application for NHSR Certification has two parts.

Part 1 is to determine if your proposed research is eligible for the NHSR Certification. To be eligible at least one condition of the seven conditions below must be checked “YES – **THIS IS NHSR**”.

If eligible, **Part 2** has instructions for preparing and submitting the application for NHSR Certification.

Verify that your research meets one or more of the following conditions for NHSR certification.

1. Does your research involve data that is completely de-identifiable about private information¹ collected from living individuals through intervention or interaction with the individuals?
☐ YES – **THIS IS NHSR – GO TO PART 2** ☐ NO – **GO TO #2**
2. Is your research considered quality assurance/improvement or program evaluation for internal use and not for generalizable research?
☐ YES – **THIS IS NHSR – GO TO PART 2** ☐ NO – **GO TO #3**
3. Does your research involve interviews or asking subjects about non-private/non-personal information?
☐ YES – **THIS IS NHSR – GO TO PART 2** ☐ NO – **GO TO #4**
4. Is your research oral history, journalism, biography, literary criticism, legal research, and historical scholarship, that is directly concerning specific individuals and is not for generalizable research?
☐ YES – **THIS IS NHSR – GO TO PART 2** ☐ NO – **GO TO #5**
5. Will you collect or receive de-identified data or specimens or access publicly available data?
☐ YES – **THIS IS NHSR – GO TO PART 2** ☐ NO – **GO TO #6**
6. Will you receive coded data/specimens AND one or more of the following in **a.** through **d.** apply?
(**CHECK BOX FOR EACH THAT APPLIES**):
 - a. ☐ The code link to subject identifiers is destroyed before the research begins, **OR**
 - b. ☐ The PI & holder of the code link enter into an agreement to prohibit release of the link under any circumstances, **OR**
 - c. ☐ There are IRB-approved written policies for the repository or data source that prohibit the release of the link, **OR**
 - d. ☐ There are other legal requirements prohibiting the release of the code link under any circumstances.
7. Is at least one option a. through d checked? ☐ YES – **THIS IS NHSR – GO TO PART 2** ☐ NO – **STOP**

IF YOUR RESEARCH IS NOT ELIGIBLE FOR NHSR CERTIFICATION PLEASE SUBMIT AN APPLICATION FOR EXEMPT DETERMINATION OR APPLICATION FOR EXISTING AND SECONDARY DATA OR APPLICATION FOR EXPEDITED AND STANDARD REVIEW. THE APPLICATIONS AND GUIDANCE ARE AT [CSULB IRB](#).

¹ 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. Information provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Part 2 –Application for Non-Human Subject Research (NHSR) Certification

Only complete Part 2 – Application for NHSR Certification if the response to any of your answers in Part 1 was “Yes - THIS IS NHSR – GO TO PART 2”

Instructions:

1. Create a New Project in [IRBNet](#).
2. Student PIs must share their New Project package with their Faculty Advisor via IRBNet.
3. Upload this “Application for NHSR Certification” in the New Project package.
4. Upload applicable documents (i.e., Faculty Advisor/Mentor Letter, permission letter from provider of de-identified data, data collection materials, and recruitment/consent forms for proposed research that fits Research Criteria Group #3 on 1st page).

Project Title (Use Uppercase for Key Word in Title):

For your proposed research, enter the number for the “Research Criteria Group” under “Research Criteria Groups Eligible for NHSR Certification” on the 1st page:

Enter a brief description of your proposed project purpose and project activities, a description of participants, and upload any applicable documents:

Principal Investigator: ☐ Faculty **OR** ☐ Student (Provide Faculty Advisor/Mentor details in “Other Investigator”)

Last Name, First Name:

Department/College:

CSULB E-mail address:

Other Investigator: ☐ Faculty Advisor/Mentor (upload Faculty Advisor/Mentor letter) **OR** ☐ Co-PI **OR** ☐ N/A

Last Name, First Name:

Department/College:

CSULB E-mail address:

Study/Grant Title/Award No. (IF NOT APPLICABLE ENTER N/A):