

Research Subject To Human Subjects Regulations

All faculty, staff, and students at SUNY New Paltz must get research conducted with human participants approved prior to conducting their research. There are no retroactive approvals. You are responsible for making the determination of whether your study is or is not human subjects research.

The common rule defines what is meant by research and what constitutes a human subject. (See the definitions below.) Research and other projects that do not satisfy **both** parts of the definitions are excluded from HREB review.

45 CFR 46, Section 102

46.102 (d)

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

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 an individual, or
- 2) Identifiable private information.

Below are some examples of projects that would **not** be considered human subjects research under the federal definitions:

Program evaluation. Program evaluation is not considered human subjects research because it is not intended to contribute to generalizable knowledge. The purpose is for local use and is intended for program assessment and improvement purposes. For example, an assessment project intended to gauge the satisfaction of alumni with their educational experience in a particular department at SUNY New Paltz.

Oral history. Collecting stories about a person's experience during a particular moment in history. The purpose is to record the stories and not to make generalizations, develop policies, or test theories.

Studies not about people. Studies designed to collect information about an object, process, or event that do not focus on the person's reaction or response. For example, asking an organization what type of accounting system it uses or what water policy a municipality uses.

Art projects. Art projects that include performing or showcasing music, art, dance, or drama are typically not considered human subjects research unless they include the following elements: a research question, methods for data collection and analysis, and plans for disseminating the research results. Keep in mind, there may be additional legal and regulatory standards that apply to your research. You should follow industry and discipline policies regarding the use of images, video and voice recordings, and other media capture of individuals.

The HREB is here as a resource and we encourage you to ask questions regarding your projects. Though not required, if you would like confirmation that your study is excluded from HREB review prior to beginning data collection, you can contact the Chair of the HREB. Send an e-mail to the HREB Chair (hrebchair@newpaltz.edu) with a description of the proposed research project giving a rationale for designation of research as not subject to regulation, i.e., not human subject research as defined in 45 CFR 46. A full description of the type of data to be collected should be included. If you are conducting a survey, a copy of the survey items should also be included.

The HREB Chair will respond by e-mail or telephone to the inquiry within 10 days requesting additional information as necessary.

The Chair will copy the HREB Secretary, the Provost and the Human Protection Administrator on all correspondence.