

	SOP: Research Subject To Human Subjects Regulations			
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1 PURPOSE

- 1.1 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.
- 1.2 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.

2 45 CFR 46.102

- 2.1 46.102 (l)
 - 2.1.1 Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:
 - 2.1.1.1 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.
 - 2.1.1.2 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).
 - 2.1.1.3 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.
 - 2.1.1.4 Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- 2.2 46.102 (e)
 - 2.2.1 (1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
 - 2.2.1.1 (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - 2.2.1.2 (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
 - 2.2.2 (2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

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- 2.2.3 (3) Interaction includes communication or interpersonal contact between investigator and subject.
- 2.2.4 (4) 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 (e.g., a medical record).
- 2.2.5 (5) 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.
- 2.2.6 (6) 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.
- 2.2.7 (7) Federal departments or agencies implementing this policy shall:
 - 2.2.7.1 (i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of “identifiable private information,” as defined in paragraph (e)(5) of this section, and “identifiable biospecimen,” as defined in paragraph (e)(6) of this section.

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

- 3.1 **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.
- 3.2 **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.
- 3.3 **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.
- 3.4 **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.

4 HREB HELP

- 4.1 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 submit a request for “Not Human Subjects Research Determination” through the SUNY Pre-award and Compliance System (PACS). Please attach a file that includes: a description of the proposed research project giving a rationale for designation of research as not subject to regulation, a full description of the type of data to be collected, and if you are conducting a survey, a copy of the survey items. For more information about PACS, visit [Sponsored Programs](#).

5 REFERENCES

- 5.1 45 CFR 46.102