# 1 PURPOSE

* 1. The State University of New York at New Paltz supports a wide range of both undergraduate and graduate student research projects using human subjects - from course-related research exercises to master thesis studies.
	2. This policy details SUNY New Paltz's policy on student research involving human subjects and explains the distinctions between student research projects and student research exercises.
	3. All students conducting research (both projects and exercises) with human participants must have a faculty or staff supervisor who is responsible for ensuring that the research is conducted in accordance with SUNY New Paltz human subjects research policy and meets standards for the ethical treatment of human participants.
	4. We believe that explicit recognition of the existence of federal regulations and the work of institutional review boards across the United States, and discussion of research ethics and the role of the HREB here on campus should be an integral part of introducing students to research.
1. CRITERIA FOR STUDENT RESEARCH EXERCISES
	1. The project must meet the definition of classroom research/student research. This is defined as a research study that would meet criteria for Exempt review under 45 CFR 46 and
		1. is a normal part of the student's coursework;
		2. is supervised by a faculty member and the faculty member assumes responsibility for overseeing the project and managing its risks;
		3. has as its primary purpose the development of the student's research skills;
		4. does not present more than minimal risk to participants or to the student investigator;
		5. does not include any persons as research participants under the age of 18;
		6. does not include any persons as research participants who are classified as protected populations or sensitive participants (e.g., economically and educationally disadvantaged persons, fetuses, persons with mental or psychological impairments, prisoners, pregnant women, undocumented individuals, and individuals who are unable to give consent);
		7. is not genuine research and will not result in a degree culminating product (e.g., thesis, dissertation), publication, or some other form of public dissemination (e.g., presentation at external conferences [state, regional, national, and international conferences]);
		8. does not ask participants about illegal activities and which place the data at risk for subpoena and/or the participant at risk for loss of civil liberties; and
		9. does not cause harm:
			1. physical: i.e., sprain, strain, bruise, etc.
			2. psychological: i.e., arousal of distressing memories, increased risk of anxiety/depression
			3. social: i.e., embarrassment
			4. economic: i.e., loss of money, job, or benefits
			5. legal: i.e., problems with the law/police
			6. moral: i.e., damaged reputation
	2. Projects that do not meet the criteria for a research classroom exercise must get HREB approval prior to the start of data collection.
2. RESPONSIBILITY OF FACULTY RESEARCH SUPERVISORS
	1. Faculty members supervising research projects and research exercises are responsible for ensuring the ethical conduct of research conducted by their students.
	2. They must know and understand human subjects research policies and federal guidelines, as well as standards within their own discipline for conducting ethical research. Faculty supervisors must communicate these to their students and assure that research conducted by their students follows these policies and guidelines.
	3. Faculty supervising research exercises assume responsibility for overseeing research conducted by their students and managing its risks.
	4. You are responsible for making the determination of whether your students' study is or is not human subjects research.
	5. At the very least, all faculty supervising research projects and research exercises must complete appropriate CITI training.
3. DEFINITIONS OF HUMAN SUBJECTS RESEARCH
	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.
	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.
	3. Important Definitions
		1. Research: 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. (45 CFR 46 §46.102 (l))
		2. Human Subject: A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46 §46.102 (e)(1))
			1. 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.
			2. Interaction includes communication or interpersonal contact between investigator and subject.
			3. 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).
			4. Identifiable Private Information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (45 CFR 46 §46.102 (e)(5)
4. FOUR CATEGORIES EXPLICITLY DEEMED NOT TO BE RESEARCH

5.1 The final rule includes four categories that are explicitly deemed to be not research (final rule at §ll.102(l)(1)– (4)).

* 1. These categories include:
		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 focuses directly on the specific individuals about whom the information is collected;
		2. (2) certain public health surveillance activities;
		3. (3) certain collection and analysis activities conducted by a criminal justice agency; and
		4. (4) certain activities conducted by a defense, national security, or homeland security authority.
1. Examples of Research that is Not Considered to be Human Subjects Research
	1. Below are some examples of projects that would not be considered human subjects research under the federal definitions:
		1. Case Studies. In general, the review of client (e.g., medical, music therapy, mental health therapy, speech therapy) records for publication of "case reports" of typically three or fewer cases is not considered human subjects research. See more details on the Case Report Policy
		2. 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. 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.
		4. 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.
		5. 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.
		6. Some course-related research exercises. Research exercises, the goal of which is to provide research training are not considered to meet the qualifications for “human subject research” as defined in federal law and college policy. These class assignments are not subject to Human Research Ethics Board (HREB) review. These courses focus on student work in supervised practical applications of theories, research methods and professional research writing styles. They are not meant to add to generalizable knowledge. See more details on Research Exercises vs. Research Projects.
	2. HREB Serves as a Resource
		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 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.
		2. The HREB Chair will respond by e-mail or telephone to the inquiry within 10 days requesting additional information as necessary.
		3. The Chair will copy the HREB Coordinator, the Provost and the Human Protection Administrator on all correspondence.
2. GUIDELINES FOR STUDENT RESEARCH ACTIVITIES
	1. Generally, student research work involving human participants falls into one of two categories, either Research Projects or Research Exercises.
		1. RESEARCH PROJECTS either directed or independent, which employ systematic data collection with the intent to contribute to generalizable knowledge.
			1. These projects require prospective review and approval by the HREB prior to recruitment of or interaction with human subjects.
			2. These projects focus on student-initiated or -conducted research which uses human beings and is undertaken with the intent of contributing to generalizable knowledge.
			3. Undergraduate and graduate theses involving human subjects are always considered research projects.
		2. RESEARCH EXERCISES, the goal of which is to provide research training.
			1. These exercises are not considered to meet the qualifications for “human subject research” as defined in federal law and university policy because they are of limited scope and are not designed to add to generalizable knowledge. Thus, these class assignments are not considered human subjects research and do not need to be submitted for Human Research Ethics Board (HREB) review.
			2. Typically, research exercises are part of the requirements for courses that involve research activities including supervised practical applications of theories, research methods, and professional research writing styles.
			3. In some cases, data collected for research exercises will be collected in the classroom itself and the faculty member will have direct control, and thus greater control over limiting risk to the human participants.
			4. In other cases, data collected outside of the classroom context requires more discretion on the part of student researchers and creates a possibility for greater risk to human participants.
			5. In either case, faculty supervisors must provide students with adequate supervision. Instructors should discuss with the student the particular ethical issues involved in their research, such as the right to volunteer or decline to volunteer, protecting the privacy and confidentiality of participants, the respect for consent, the avoidance of unnecessary discomfort, and data security.
			6. Reports of data collected from research exercises are limited. They cannot be disseminated beyond the SUNY New Paltz community.
3. DISTINGUISHING BETWEEN STUDENT RESEARCH PROJECTS AND STUDENT RESEARCH EXERCISES
	1. Research Projects
		1. Examples that do need HREB approval
			1. Research that requires Expedited or Full Board Approval
			2. Research that involves research participants who are classified as protected populations or sensitive participants (e.g., economically and educationally disadvantaged persons, fetuses, persons with mental or psychological impairments, prisoners, pregnant women, undocumented individuals, and individuals who are unable to give consent)
			3. Research that ask participants about illegal activities and which place the data at risk for subpoena and/or the participant at risk for loss of civil liberties
			4. Research that is above minimal risk and might cause harm as described in 2.1.9.
			5. Research that will be presented in local symposia, either off-campus or for any external audience on campus.
			6. Presentation in regional or national research poster sessions.
			7. Submission of article for competition, e.g., for scholarship competitions.
			8. Submission of research project in full or partial completion of graduate degree requirements.
			9. Intended for contribution to generalizable knowledge. Publication is not the only indicator of generalizability, it also includes:
				1. written dissemination,
				2. reports that are circulated, and
				3. presentations to audiences beyond the New Paltz community.
		2. Retention of Documents:
			1. Manuscript retained by college, school or department so that the document is accessible for review by those outside of the class.
			2. Manuscripts can be prepared for potential publication.
			3. Presentations can be made at professional conferences.
			4. Data retained according to HREB authorization.
	2. Research Exercises
		1. Examples which do not necessarily need HREB approval
			1. Practice with a research technique or professional writing style.
			2. Presentation to classmates and SUNY New Paltz community.
			3. Student research exercises can be disseminated on campus, but not beyond its bounds. Posters based on student research exercises can be posted on campus and students can present at the Student Research Symposium, but not at conferences or meetings held off campus or regional/national conference held on campus directed toward outside constituents.
			4. All materials used to recruit participants for student research exercises (e.g., social media posts, recruitment emails) must clearly indicate that ***“This project is being conducted as a Student Research Exercise and as such, was not subject to SUNY New Paltz HREB review.”***
			5. All posters and presentations presenting the results of student research exercises (those that did not receive Human Research Ethics Board HREB, a group of people who review human ethics research, approval) must be labeled as such. They must include a clearly visible label that says, ***“This project was conducted as a Student Research Exercise and as such, was not subject to SUNY New Paltz HREB review.”***
		2. Sharing of Results/Documents:
			1. Paper or poster may be retained by student and/or faculty member for use as writing samples,
			2. Dissemination beyond the SUNY New Paltz community is specifically not permitted for publication &/or presentation.
			3. Data must be destroyed upon completion of the paper and in accordance with relevant University policy.
		3. Some professors may wish to keep open the possibility that an extraordinary paper submitted in a research exercises course may be submitted to a student competition or presented at a regional, state or national conference. All such proposals must be reviewed and approved according to the HREB’s policies and procedures prior to beginning the collection of data involving human participants as per Federal Law & Regulations and University Policy. (Please note the policy for Exempt review procedures for classes with assigned research exercises.)
4. REVISIONS FROM PREVIOUS VERSION (Needs to be revised)
	1. This document clarifies the criteria for student research exercises in 2 and for distinguishing research exercises (those that can be supervised by the faculty member) from research projects (those that need HREB approval) in 8.1.
5. REFERENCES
	1. None