

	<b>SOP: Student Research Exercises and Not Human Subjects Research Policy</b>			
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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.
- 1.3 Important Definitions
  - 1.3.1 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))
  - 1.3.2 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))
  - 1.3.3 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))

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 This document was updated to reflect the new Common Rule.

## 3 UPDATE TO THE COMMON RULE

- 3.1 The final rule includes four categories that are explicitly deemed to be not research (final rule at §II.102(l)(1)– (4)).
- 3.2 These categories include:
  - 3.2.1 (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;
  - 3.2.2 (2) certain public health surveillance activities;
  - 3.2.3 (3) certain collection and analysis activities conducted by a criminal justice agency; and
  - 3.2.4 (4) certain activities conducted by a defense, national security, or homeland security authority.

## 4 FURTHER INFORMATION

- 4.1 Below are some examples of projects that would not be considered human subjects research under the federal definitions:
  - 4.1.1 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 patients is not considered human subjects research. See more details on the Case Study Policy below.

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- 4.1.2 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.
- 4.1.3 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.
- 4.1.4 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.
- 4.1.5 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.
- 4.1.6 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.

4.2 HREB Serves as a Resource

- 4.2.1 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.
- 4.2.2 The HREB Chair will respond by e-mail or telephone to the inquiry within 10 days requesting additional information as necessary.
- 4.2.3 The Chair will copy the HREB Secretary, the Provost and the Human Protection Administrator on all correspondence.

**5 GUIDELINES FOR STUDENT RESEARCH ACTIVITIES**

- 5.1 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.
- 5.2 Generally, student research work involving human participants falls into one of two categories:
  - 5.2.1 RESEARCH PROJECTS either directed or independent, which employ systematic data collection with the intent to contribute to generalizable knowledge.
    - 5.2.1.1 These projects require prospective review and approval by the HREB prior to recruitment of or interaction with human subjects.

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5.2.1.2 These courses focus on student-initiated or -conducted research which uses human beings and is undertaken with the intent of contributing to generalizable knowledge.

5.2.2 RESEARCH EXERCISES, the goal of which is to provide research training.

5.2.2.1 These exercises 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.

5.2.2.2 Typically, research exercises are part of the requirements for courses that involve research activities that are part of supervised practical applications of theories, research methods, and professional research writing styles.

5.2.2.3 Although the HREB does not necessarily review such class projects, we strongly encourage instructors to become familiar with each student’s project(s), and to discuss it with the student. The majority of research complaints we have received have taught us that time spent with students discussing matters such as courtesy, and avoidance of unnecessary discomfort or invasion of privacy, will be time well spent. 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 methodologies.

5.2.2.4 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 in a recognized forum. 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.)

## **6 CRITERIA FOR DISTINGUISHING BETWEEN STUDENT RESEARCH PROJECTS AND STUDENT RESEARCH EXERCISES**

### 6.1 Research Projects

6.1.1 Examples that do need HREB approval

6.1.2 Goals for Students:

6.1.2.1 Participation in local symposia, either off-campus or for any external audience on campus.

6.1.2.2 Presentation in regional or national research poster sessions.

6.1.2.3 Submission of article for competition, e.g., for scholarship competitions.

6.1.2.4 Submission of research project in full or partial completion of graduate degree requirements.

6.1.2.5 Intended for contribution to generalizable knowledge (Publication is not the only indicator of generalizability, it also includes:

6.1.2.5.1 written dissemination,

6.1.2.5.2 reports that are circulated, and

6.1.2.5.3 presentations to audiences beyond the New Paltz community.

6.1.3 Retention of Documents:

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6.1.3.1 Manuscript retained by college, school or department so that the document is accessible for review by those outside of the class.

6.1.3.2 Data retained according to HREB authorization.

## 6.2 Research Exercises

6.2.1 Examples which do not necessarily need HREB approval

6.2.2 Goals for Students:

6.2.2.1 Practice with a research technique or professional writing style.

6.2.2.2 Presentation to classmates and SUNY New Paltz community.

6.2.2.3 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.

6.2.2.4 Student research exercises (those that did not receive HREB approval) must be labeled as such on all posters and in all presentations. 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."

6.2.3 Retention/Excision of Documents:

6.2.3.1 Manuscript or paper may be retained by student and/or faculty member, but is not accessible for review by those outside of the class with the exception of accrediting/auditing bodies.

6.2.3.2 No other dissemination beyond the SUNY New Paltz community is permitted.

6.2.3.3 Data must be destroyed upon completion of the paper and in accordance with relevant University policy.

## 7 CASE REPORT POLICY

7.1 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 patients requires submission of a request for a "Not Human Subjects Research Determination" (see the SUNY New Paltz--Not Human Subjects Research Determination guidelines).

7.2 This is because case reporting on a small series of patients/clients does not usually involve the formulation of a research hypothesis that is subsequently investigated prospectively and systematically for publication or presentation. This policy may also be relevant to case reports in other disciplines (e.g., education, business), please contact the HREB chair (HREBChair@newpaltz.edu) for more information.

7.3 When investigators report on larger series of cases, they usually begin to ask specific research questions and formal systematic collection of data occurs, moving these activities closer to prospectively designed research. The boundaries between case reporting and formal records research may be unclear for a series of one's own patients and/or clients. Researchers are advised to consult with the HREB or submit an HREB proposal for larger case series reports when uncertainty exists about whether a full application is necessary.

7.4 It should also be noted that teaching, and soliciting colleagues' advice on clinical care of a specific patient/client or groups of patients/clients during presentation of a case at departmental conferences DOES NOT require HREB review. Generalized commentary by a clinician on the outcome of their clinical care of patients/clients in accepted venues for discussion of clinical management is also not considered research requiring HREB review.

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This type of communication may occur at hospital, clinics, or practice meetings, where the comments are explicitly identified as personal experience and not formal clinical research.

- 7.5 Confidentiality: Patient confidentiality should be respected in all clinical situations involving identifiable health information from patients/clients. All clinicians are reminded of the following points:
- 7.5.1 Names, dates of birth, social security numbers, and other "codes" or combinations of identifiers, which might easily allow someone to identify a subject, should never be used in publications or external presentations.
  - 7.5.2 Unique family trees or pedigrees should be masked or disguised when such information could identify individuals or kindreds.
  - 7.5.3 Photographs should be appropriately masked to preclude identification of subjects.
- 7.6 It is strongly recommended that patients/clients provide written consent to allow publication or electronic dissemination of pictures or other information (e.g. videos, voice recordings, transcripts), which might in any way identify them. Contact the HREB, as appropriate, for example non-research consent forms.
- 7.7 When reporting on cases, you should be sensitive to the "small cell problem," that is that the uniqueness or unusual details of a case might make it possible for others (e.g., patients, friends, and family members) to identify the individual based upon the information provided in the case description.
- 7.8 Differentiating Between Case Reports and Research
- 7.8.1 Case Reports
    - 7.8.1.1 Not Human Subjects Research Determination Needed
    - 7.8.1.2 Record review of three or fewer patients/clients.
    - 7.8.1.3 Clinical treatment: Each patient/client is treated as clinically indicated - treatment is not directed by a research protocol nor are specific research interventions/interactions involved.
    - 7.8.1.4 No HIPAA review/approval required provided patient confidentiality is protected.<sup>i</sup>
    - 7.8.1.5 NOT GENERALIZABLE or scientifically rigorous. Information is educational describing a very limited number of interesting cases (3 or less) and how they were treated.
  - 7.8.2 Research
    - 7.8.2.1 HREB approval needed
    - 7.8.2.2 Record review of four or more patient/client records appears to meet the federal definition of research (systematic investigation intended to contribute to generalizable knowledge).<sup>ii</sup>
    - 7.8.2.3 Clinical treatment: If research protocol dictates how the patients/clients/subjects will be treated and/or specific research interventions/ interactions are scheduled.
    - 7.8.2.4 Need either: (1) signed HREB approved Informed Consent forms from all participants that includes HIPAA Authorization OR (2) an HREB approved Waiver of (a) Informed Consent AND (b) HIPAA Authorization.
    - 7.8.2.5 GENERALIZABLE. Hypotheses can be proved/disproved. Data is collected and analyzed in a rigorous manner (may include statistics).

## 8 REFERENCES

- 8.1 None

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<sup>i</sup> HIPAA regulations permit case reports provided patient confidentiality is protected. This means that your case report cannot contain any information that would identify the patient, including but not necessarily limited to:

- Names, dates of birth, social security numbers, and other "codes" or combinations of identifiers, which might easily allow someone to identify a subject, should never be used in publications or external presentations.
- Unique family trees or pedigrees should be masked or disguised when such information could identify individuals or kindreds.
- Photographs should be appropriately masked to preclude identification of subjects or only be used if patients/clients provide written consent to allow publication or electronic dissemination of pictures or other information (e.g. videos, voice recordings, transcripts), which might in any way identify them.
- Clinicians/Therapists should be sensitive to the "small cell problem," that is that the uniqueness or unusual details of a case might make it possible for others (e.g., patients, friends, and family members) to identify the individual based upon the information provided in the case description.

<sup>ii</sup> Review of more than 3 patients/clients usually involves the clinician/therapist/investigator asking specific research questions which lead to formal systematic collection of data, moving these activities closer to prospectively designed research. The boundaries between case reporting and human subjects research may be unclear for a series of one's own patients/clients. Researchers are advised to consult with the HREB or submit larger case series reports for HREB review when uncertainty exists about whether formal and systematic collection of human subjects research is occurring.