

4.7 Research Involving Employees of the Organization and Students as Subjects

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for IRB review and approval of research involving employees of the Organization, and/or students as subjects. These persons are considered vulnerable because of the potential for undue influence or coercion.

2.0 Policy

- **2.1.** It is the policy of the Organization that students, and employees of the Organization, may be recruited for research participation. To the extent that these subjects are vulnerable, the research plan must include additional safeguards to protect the rights and welfare of these subjects.
 - **2.2.** It is the policy of the Organization that the recruitment of employees working directly for, or under the supervision of, the PI or other study personnel, is discouraged.
 - **2.3.** It is the policy of the Organization that the recruitment of students taking classes from the PI or other study personnel, is discouraged.
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3.0 Students as Research Participants

- **3.1.** Students (for example, undergraduates, graduate students, medical students, residents, fellows, doctoral students) may be recruited for research participation.
- **3.2.** A student may not be required to participate in research without a comparable non-research alternative offered as a course requirement.
- **3.3.** Students (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion
- **3.4.** Recruitment of students taking classes from the PI or other study personnel is strongly discouraged; when such recruitment is scientifically justified and important to the conduct of the research, there must be additional safeguards in place to reduce the risk of undue influence or coercion.

- **3.5.** A student's decision about research participation may not affect grades or other such assessments of opportunities for the student.
 - **3.6.** Attention must be paid by the investigator to the risks to the student's privacy, since the classroom situation may make it difficult to keep an individual's participation confidential
 - **3.7.** Use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA) at 34 CFR 99
 - **3.8.** Research involving surveys with students in elementary and secondary schools that receive funding from the Department of Education must also comply with the Protection of Pupil Rights Amendment (PPRA) at 34 CFR 98.
 - **3.9.** UNO Students may participate in the SONA Research Participation System. All preceding requirements must be met. Any other student database or registry used for recruitment purposes must have procedures in place to exclude students that have enacted a FERPA hold on their registry information.
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4.0 Research Involving Employees of the Organization as Research Participants

- **4.1.** Employees (full-time, part time or student) of the Organization may be recruited for research participation.
 - **4.2.** An employee may not be required to participate in research as a condition of employment.
 - **4.3.** Employees should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion
 - **4.4.** Recruitment of employees under the supervision of the PI or other study personnel is strongly discouraged; when such recruitment is scientifically justified and important to the conduct of the research, there must be additional safeguards in place to reduce the risk of undue influence or coercion.
 - **4.5.** An employee's decision about research participation may not affect performance evaluations or other such assessments or opportunities for the employee.
 - **4.6.** Attention must be paid by the investigator to the risks to the employee's privacy, since the workplace situation may make it difficult to keep an individual's participation confidential
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5.0 IRB Review

- **5.1.** Research involving employees of the Organization, or students may be reviewed by the full convened IRB (as per HRPP policy 2.2) or using an expedited procedure (as per HRPP policy 2.3). The IRB application must clearly address:
 - **5.1.1.** Justification of the need to recruit the particular subject population
 - **5.1.2.** A description of any additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- **5.2.** If an investigator proposes to recruit employees working for, or under the supervision of, the PI or other study personnel; or students taking classes from the PI or other study

personnel, the IRB application must clearly address:

- **5.2.1.** The nature of the professional relationship.
 - **5.2.2.** Justification of the need to recruit the particular subject population. This justification must be particularly strong for any study which involves greater than minimal risk procedures.
 - **5.2.3.** The plan for minimizing the risk of undue influence and/or coercion is the process of recruitment and consent.
 - **5.2.4.** A description of any additional safeguards have been included in the study to protect the rights and welfare of these subjects.
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