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**Institutional Review Board (IRB)**

**GUIDELINES FOR RESEARCH INVOLVING STUDENTS AND EMPLOYEES**

1. **Introduction**

Research involving potentially vulnerable populations must include additional protections to minimize the possibility of coercion or undue influence. Federal regulations provide specific protections for pregnant women and fetuses, prisoners, and children; however, considerations may also be necessary for other potentially vulnerable groups, such as students and employees.

The purpose of these guidelines is to outline additional protections that investigators and IRBs should consider for research involving students and employees.

1. **Definitions**

**Student** refers to a person who is studying at a school or college, including undergraduates, graduate students, medical students, residents, fellows, doctoral students, etc.

**Employee** refers to a person employed for wages or salary, including full-time, part-time, temporary, visiting, student employee appointments, etc.

**Coercion** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.

**Undue Influence** occurs when the amount or nature of inducements for research participation have the potential to alter a subject’s decision-making process such that he or she may not appropriately consider the risks of participating in the research.

**3. Students as Research Participants**

Students and advisees, in particular, may volunteer to participate in research in an effort to please a teacher, mentor, or advisor in hope that it could positively impact grades or position or in fear that failure to participate will negatively affect their relationship or standing. Students’ cultural or religious backgrounds (e.g., requiring deference to authority figures) may also influence their choices. As such, student populations are susceptible to coercion or undue influence to participate in research in which they’d not otherwise take part.

Students may be recruited for research participation; however, a student may not be required to participate in research (without a comparable non-research alternative offered) as a course requirement. A student’s decision about research participation may not affect (favorably or unfavorably) grades, potential letters of recommendation, or other opportunities or decisions made by teacher-investigators.

Recruitment of students as research participants must be designed to minimize the possibility of coercion or undue influence. Students (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion. Additionally, potential participants should be solicited from a “broad base” of individuals meeting the conditions for study, rather than by personal solicitation of specific students when possible.

Strategies to Reduce Potential for Coercion or Undue Influence

Investigators and IRBs must consider strategies to ensure voluntary participation when the subjects of research include students who receive instruction directly from the investigator(s). Strategies to minimize the potential influence of an investigator when recruiting students include recruitment by general announcements, postings or sign-up sheets, recruitment by research team members with no relationship to students or other methods that have the ability to minimize potential coercion.

Except in unusual circumstances, investigators should not enroll students from their own classes when the research involves greater than minimal risk without the prospect of direct benefit. Such studies should proceed only when the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and the research is of significant importance and cannot be conducted without the enrollment of these students.

Additional Privacy Considerations

Additional safeguards may be needed to protect the privacy interests of research participants when the participants are students. Classroom conditions may make it difficult for investigators to keep an individual’s participation confidential, which could pose risks to participants (e.g., when stigma is associated with the condition or question under study or when peer-pressure is a component of the research). In such situations, consideration should be given to whether conducting the research off-site and/or outside of regular school hours may minimize potential risks.

Protecting the confidentiality of research participants’ personal information when the participants are students may also present additional challenges. The extent to which personal information and/or research data may be accessible to parents, teachers, or others not directly involved in the research must be considered and disclosed to potential participants and their parents/guardians (as applicable) in the informed consent and assent processes.

Other Special Considerations

In cases where regular classroom activities are also the topic of research, investigators must clarify for potential research participants (and/or their parents, as applicable) those activities that are optional and distinct from required classroom activities that would take place even without the research. When access to students, educational records, or school facilities is needed for recruitment and/or research activities, a letter of support from an individual authorized to speak on behalf of the school/district (e.g., principal or superintendent) is generally required.

Certain additional protections for students and parents are provided by federal regulations. The proposed use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA). Research involving surveys with students must comply with the Protection of Pupil Rights Amendment (PPRA).

Offering Course Credit or Payment for Student Participation

Students should not be required to participate in research studies in order to fulfill course requirements without having alternative ways to fulfill those requirements. Alternatives that are offered must be comparable in terms of time, effort, and fulfillment of course requirements. Examples may include reading and/or writing research papers, attending research presentations offered by faculty, or observing performance of research studies.

Researchers should be sure that payments to students, SLU student workers in particular, are done in accordance with the SLU Policy on Participant Payments within Research and/or Sponsored Activities. Specifically, there may be limitations on the methods of payment that can be used.

Withdrawal from Participation

All research participants, including students, must be free to withdraw from participation at any point in a study without penalty. Students who withdraw from a research study (e.g., if upset by the intervention and want to discontinue) should still receive credit for participation. When payment is offered, it should be prorated and earned as the study progresses (as appropriate to the research) and not contingent upon the student completing the entire study.

**4. Employees as Research Participants**

Employees are also subject to potential coercion or undue influence if being asked to participate in research by a supervisor, mentor, or employer. They may take part in hope that it could positively impact their employment or in fear that failure to participate will negatively affect their employment or standing.

Employees, including university employees may be recruited for research participation; however, an employee may not be required to participate in research as a condition of employment. An employee’s decision about research participation may not affect (favorably or unfavorably) performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors.

Recruitment of potential participants who are employees must be designed to minimize the possibility of coercion or undue influence. Employees (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion. In general, potential participants should be solicited from a “broad base” of individuals meeting the conditions for study, rather than from individuals who report directly to the investigator(s) when possible.

Strategies to Reduce Potential for Coercion or Undue Influence

Investigators and IRBs must consider strategies to ensure voluntary participation when the subjects of research include employees who are directly supervised by the investigator(s). Strategies to minimize the potential influence of an investigator when recruiting his/her own employees include recruitment through a third party unassociated in a supervisory relationship with the employee, postings or sign-up sheets, or other methods that require an employee interested in participation to initiate contact with the investigator(s).

Except in unusual circumstances, investigators should not enroll employees under their direct supervision when the research involves greater than minimal risk without the prospect of direct benefit. Such studies should proceed only where the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and the research is of significant importance and cannot be conducted without the enrollment of these employees.

Additional Privacy Considerations

Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions may make it difficult for investigators to keep an individual’s participation confidential, which could pose risks to participants (e.g., when stigma is associated with the condition or question under study or when peer-pressure is a component of the research). In such situations, research should be conducted off-site and/or outside of regular work hours when possible to minimize potential risks.

Protecting the confidentiality of research participants’ personal information when the participants are employees may also present additional challenges. The extent to which medical information and/or research data may be accessible to supervisors or others not directly involved in the research must be considered and disclosed to potential participants in the informed consent process.

Other Special Considerations

In cases where regular workplace activities are also the topic of research, investigators must clarify for potential research participants those activities that are optional and distinct from any mandatory workplace activities that would take place even without the research. When access to individuals or the facilities of the site is needed for recruitment and/or research activities, a letter of support from someone authorized to speak on behalf of the employees/site may be required.

Offering Payment for Employee Participation

Researchers should be sure that payments to SLU employees are done in accordance with the SLU Policy on Participant Payments within Research and/or Sponsored Activities. Payments to University employees are taxed and reported on the annual W-2, and the University will calculate the tax withholdings on the research participant payment. The [Research Participant Payments to SLU Employees](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/consent_addendum_employee_payment.docx) addendum consent document can be used to explain these considerations to research participants who are SLU employees.

Withdrawal from Participation

All research participants, including employees, must be free to withdraw from participation at any point in a study without penalty. When payment is offered, it should be prorated and earned as the study progresses (as appropriate to the research) and not contingent upon the employee completing the entire study

**5. References**

21 CFR 56.111

45 CFR 46.111

AAHRPP, Inc. Elements II.3.F, II.4.A