INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 01/15/2014
Revision No.: 1
Effective Date: 05/18/2015

TITLE: Institutional Review Board Special Consideration
SC 505 Employees and Students as Research Participants

POLICY STATEMENT: Students and employees recruited as research subjects are more vulnerable to coercion
because of the possibility that they may perceive grades, employment or other benefits as dependent upon their
participation in research. Students and employees are at greater risk of experiencing negative ramifications related
to an inability to maintain strict confidentiality and because more information is known about these individuals than
is collected during the course of the study.

This policy addresses the safeguards that investigators must consider and that the IRB will examine in a submitted
research protocol that includes an employee or student as the research participant to minimize the possibility of
coercion or undue influence for these participants.

GENERAL PROVISIONS: An Investigator’s use of employees, students, or other subordinates as research
participants presents the possibility for coercion or undue influence. The regulatory requirements for IRB review
and approval provide that when some or all of the subjects are likely to be vulnerable to coercion or undue influence,
additional safeguards are needed to protect the rights and welfare of these subjects. (45 CFR 46.111(b) Researchers
who include colleagues or subordinates as research subjects must be able to provide a rationale other than
convenience for selecting them and must show that the recruitment method does not lead colleagues or students to
think they will be compromised by not participating.

The compromised circumstances and fear of retribution, even subtle cues of compromise, can place colleagues,
students or subordinates in a position of involuntary participation in a research project.

Principal Investigators should also adhere to the ethical principles for the protection of human subjects in research as
set forth in the Belmont Report of the National Commission for the Protecor Human Subjects of Biomedical and

Student Participation
Investigators must be mindful of the potential for coercion or undue influence when directly recruiting their own
students as research subjects. In these situations, the IRB will review the following factors:

1. Student participation in research must be voluntary. Students must not be penalized for refusal to participate
   in research.
2. A student’s voluntary decision whether or not to participate will not influence class standing, grades, or any
   other benefit under the control of the researcher.
3. Reasonable levels of extra credit or rewards may be offered for participation; however, students must be
   provided with and informed of non-research alternatives to obtain equivalent credit or rewards.
4. If participation in research is a course requirement, students must be informed of non-research participation
   alternatives.
5. Someone other than the investigator shall obtain informed consent and collect the data when the investigator
   is the student’s instructor. If this is not feasible, there must be a method of obtaining consent and collecting
   data that does not divulge to the investigator whether or not the student agreed to participate until after final
   grades have been assigned for the course.
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6. A “student subject pool” is a recognized approach for identifying students who are generally willing to participate in research. Students must consent to participate in each individual research study, and must be free to decline participation in any available projects without penalty.

Employee Participation

For research where the investigator’s employees or other subordinates are being recruited, the IRB will review the following factors:

1. Employee participation in research must be voluntary. An employee shall not be required to participate in research as a condition of employment.
2. An employee’s voluntary decision whether or not to participate will not affect their employment, performance evaluation, or any other employment practice.
3. Recruitment is conducted through the use of flyers, advertisements, postings, and/or announcements targeted to a larger audience than just to the employees.
4. If employees are specifically targeted, the investigator has provided a rationale other than convenience for selecting this group.
5. Data are collected and stored in a way that protects the privacy of the employee.
6. Someone other than the investigator shall obtain informed consent and collect the data when the investigator is the employee’s supervisor. If this is not feasible, there must be a method of obtaining consent and collecting data that minimizes the possibility of coercion or undue influence.

DEFINITIONS:

Coercion: occurs when a person is compelled to involuntarily behave in a certain way by use of overt or implicit threat of harm, intimidation, or other form of pressure or force. Coercion also occurs when potential subjects perceive pressure or force to participate. For example, an investigator might tell a potential subject that failure to participate will result in the loss of salary or other benefits, or a lowered course grade; or these potential harms may be perceived.

Undue Influence: occurs when a person takes advantage of a position of power by offering excessive or inappropriate rewards for compliance, or, whether intended or not, the person in the position of power undermines the potential subject’s freedom of choice. For example, an investigator might tell a potential subject that the decision to participate will result in a job promotion or better course grade; or the person may perceive s/he lacks the freedom of choice.

REFERENCE:

45 CFR 46.111(b)
45 CFR 46.116(a)(8)
21 CFR 56.111(b)
45 CFR 46.111(b)
OHRP Informed Consent FAQ's http://answers.hhs.gov/ohrp/categories/1566
Belmont Report
OHRP IRB Guidebook, Chapter 6, Special Classes of Subjects, “Students, Employees, and Normal Volunteers.”

ATTACHMENTS:

SC 505-A Worksheet for Review of Research Involving Employees and Students as Research Participants

PROCEDURE: All Mercy Health Campuses

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<th>Responsibility</th>
<th>Action</th>
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<td>IRB Specialist/IRB Coordinator</td>
<td>1. Review submission package and determine if the investigator has proposed the specific inclusion of an employee or student as research participants. If the specific inclusion of these populations are noted in the IRB submission, inform IRB Chairperson of this information.</td>
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<td>2. Prepare review packet as advised by the IRB Chairperson and include the SC 505-A Worksheet for Review of Employees and Students as Research Participants.</td>
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IRB Chairperson (or Designee)

1. Review the submission packet provided by the IRB Clinical Research Assistant or IRB Coordinator.
2. Perform specific review (or designate a reviewer) of the submission for inclusion of the vulnerable populations. Use SC 505-Worksheet for Review of Employees and Students as Research Participants.
3. May return review comments or concerns to the IRB Clinical Research Assistant to forward to the PI to be addressed or may contact the PI with questions.
4. Refer review to the IRB Committee when appropriate or if it is believed a greater than minimal risk is present.

IRB Committee

1. Review studies referred to the full IRB Committee that include students or employees as the research participant. Utilize the completed SC 505 worksheet as a reference during the review process.

CONCURRENT CONSENTS:

Institutional Official

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