Montclair State University IRB Guidance Document

Coercion and Undue Influence

Considerations for research involving real or perceived authority, undue influence or coercion over participants (please see definitions below).

Authority: Authority implies a power relationship and a person having power or control over another person (e.g. doctor/patient; teacher/student). Persons in authority may be perceived as coercive to the participant. Subsequently the authority relationship needs to be addressed in order to mitigate coercion.

Undue Influence: An offer of excessive or inappropriate reward in order to obtain compliance or participation. For example, a researcher might offer a \$500 gift card for one-hour of participation. Because the level of compensation could induce subjects to participate against their better judgment, this offer might present undue influence.

Coercion: An overt or implicit threat of harm or negative consequences presented by one person to another in order to obtain compliance. For example, an instructor might tell prospective subjects in a class that they will lose grade points if they do not participate in the research – this situation would be coercive. Students may also perceive coercion, even if it is unintended by a faculty member, if they know that the faculty member will be aware of their willingness to participate in the faculty member's research while that person is in a position to assign them grades. Compensation for research is not coercive in and of itself, since it does not involve a threat of harm.

When some or all of the subjects, such as students, children, employees or others, are likely to be vulnerable to coercion or undue influence, the MSU IRB shall consider whether additional safeguards have been included in the study to protect the rights and welfare of these subjects and mitigate the potential for coercion. [§46.111(a)(7)(b)].

The following are selected approaches the IRB suggests in order for the PI to minimize the risk of coercion or undue influence. Each protocol is unique and variations on the procedures below may also be considered.

I. Research with MSU Students currently enrolled in the PI's or Co-PIs own course(s).

NOTE: If the PI's own students are used as subjects, the investigator must explain within the application why he or she cannot use another instructor's students

- 1. One way to reduce the potential for students to experience coercion is to design the study so that PI as the instructor are "blind" to who is participating in the research (at least until after grades are submitted). To accomplish this, the PI can:
 - a. Use a third party for recruiting subjects, obtaining consent, and collecting data (including interviewing). For example, the PI as instructor would leave the room while a third party without connection to the class explains the study and then distributes and collects signed consent forms from those students who wish to participate.
 - b. Have the third party hold the data from the instructor until the course is completed and grades are submitted. The third party may be another colleague, department administrator or graduate assistant. If the data are already part of the course, then the PI would still be able to handle the data but should not

Version date: 11/17/2014 Page 1

- be able to infer who has given consent to participate. The third party should be added as a research team member on the application.
- c. Have the consent document inform potential subjects that the instructor will not know who did and who did not participate (or will not know until after grades have been submitted).

OR

2. Another approach is to make the entire study anonymous. In such a study, no signatures or identifiers of any kind are obtained. A third party passes out an informed consent document to the class. A survey is handed out to everyone or a survey link is shared for an online instrument. The third party then tells the class that if anyone would like to complete the survey, they may do so outside of class time and/or leave the physical survey in a designated location other than the classroom. The instructor is allowed to introduce the study but should not be part of the consent process. This requires the PI to request a waiver of documentation (signature) of consent with the IRB application.

OR

3. If data for the research will be the assignments that are already part of normal educational practice, then the instructor may request from each student permission to use the student's work AFTER the course is completed and grades are submitted.

II. Research involving the Employer/Employeeⁱ

An employee may not be required to participate in research as a condition of employment. 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). 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).

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.

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, online and/or outside of regular work hours when possible to minimize potential risks.

III. Research with students (K-12)

For research with students in grades K-12 where the teacher is involved in the research, the following option may be considered to minimize coercion. The potential for coercion may not apply when the research activities do not involve the teacher or when the teacher is simply collecting the consent forms for the researcher. (e.g., an after school survey conducted by PI who is not also the students' teacher). Other options to minimize coercion may be considered on a protocol by protocol basis.

1. The teacher and/or the PI would be blind to who ends up participating in the research (at least until grades are submitted or the school year is over). To accomplish this:

Version date: 11/17/2014 Page 2

- a. A third party may be used for recruiting subjects, obtaining consent, and collecting data (including interviewing).
- b. The data would be held by the third party and not given to the teachers. If the data are already part of the class and the normal educational practice, then the teacher would still be able to handle the data for research purposes only once it is de-identified, so they should not be able to infer who is participating in the research. Data may also still be handled if it is part of normal educational practice within the classroom.
- c. Potential subjects and their parents would be informed in the consent and assent documents that the teacher will not know who did and who did not participate (if applicable). The parental consent would explain that "the decision on participation in the research will in no way change the education or services provided to their child." The assent document would make a similar statement in language appropriate to the age of the students.

Version date: 11/17/2014 Page 3

ⁱ University of Pittsburgh http://www.irb.pitt.edu/content/research-involving-employees-research-participants