Undue Influence and Coercion in Protocol Consent

The Cal Poly Pomona IRB prohibits undue influence or coercion of participants in human studies. The IRB is especially vigilant of the risks of undue influence and coercion during the consenting process. The definitions of undue influence and coercion based on the Department Health & Human Services **(DHHS-Office for Human Research Protections**) regulation **Title 45**: *Public Welfare Department of* *Health and Human Services*, **Part 46***: Protection of Human Subjects,* ***Section 116****:* General requirements for informed consent:

“An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence” ([45 CFR 46.116](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116)). This requirement applies to all nonexempt human subjects’ research not eligible for a waiver of the consent requirements.”

Furthermore**, OHRP** defines **undue influence** and **coercion** as:

**Undue influence:** often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise a student extra credit *only* if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

In addition to undue influence that can arise with the offering of rewards, undue influence also can be subtle. For example, subjects might feel obligated to participate in research if there is a preexisting relationship with the investigator. Also, intentional or non-intentional peer pressure of subjects into consenting is also considered inappropriate. Because influence is contextual it is at the discretion of the IRB when determining which circumstances give rise to undue influence on a case per case basis.

**Coercion:** occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

Citation:

What Does It Mean to Minimize the Possibility of Coercion or Undue Influence?" *Human Research Protections Informed consent FAQ’s:* Department of Health and Human Services. Web. 03 July 2019.

**Protocols with undue influence or coercion must be addressed and corrected by the investigators. Inappropriate consents may delay the IRB approval process. Some examples of inappropriate language to be used on the consent the IRB would deem unsatisfactory are written below:**

1. **This study involves research with the Business Department; *your participation is needed for my graduation*.**
2. **You are invited to participate in a study for the Biology department, *please participate in my study so that I may graduate*.**
3. **I am doing a research project, *so that I can graduate* from Cal Poly Pomona. *I am asking for you to be part of this research project.***
4. *As a student in my class, you need to fill out this questionnaire for my study. Students need to participate in my study*.

To avoid inappropriate consent the Cal Poly Pomona IRB has provided the following **acceptable** example statements for investigators to model. When crafting the informed consent form, ensure it’s appropriate for the respective protocol (note: *Italics* represent example entries):

1. This study involves research with *Education*, *and is a component of the Master Degree**program* at California State Polytechnic University, Pomona.
2. *You are invited to participate in a research study*. The study is in partial completion of the Master degree undertaken by Business department at California State Polytechnic University, Pomona.
3. *You are invited to participate in a research study being conducted by Suzie Student, an undergraduate student* at California State Polytechnic University, Pomona, in the Psychology department.
4. *You are invited to participate in a research project for the Civil Engineering program* at California Polytechnic University of Pomona, in partial fulfillment of degree requirements.
5. *I am currently a Master student at California Polytechnic State University of Pomona. You are invited to participate in a study in partial fulfillment of my degree requirements.*
6. *Students participating in this study will receive one credit of research participation.* (*The amount of credit given is at the discretion of the principal investigator.)*

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