Coercion and Undue Influence: What is the difference?

Federal regulations require investigators to obtain the voluntary consent of research subjects under conditions that are free of coercion and undue influence. However, the terms coercion and undue influence are not clearly defined and are often mistakenly used interchangeably. Coercion is frequently used to describe all situations in which subjects may be pressured or receive what is perceived to be an excessive reward for their participation in research. Coercion and undue influence are in fact two distinct concepts. The Belmont Report defines coercion as an overt threat of harm intentionally presented to obtain compliance. Undue influence, by contrast, is an offer of an excessive, unwarranted, or inappropriate reward in order to obtain compliance. Coercion requires a threat or the perception of a threat.

To be coerced, a potential subject must be made worse off or made to feel they may be worse off for declining enrollment. Contrary to its frequent association with excessive payment, receiving payment for research is never coercive. No one is ever made worse off or perceives to be made worse off by receiving payment for participation. Incidents of undue influence can be difficult to recognize as there is often uncertainty in applying the definition. Threats are typically verifiable, but this is not always the case for undue influence as it relies on interpretation. What may be perceived as excessive by one individual may not be excessive to another person. Related to subject compensation, it is UI IRB policy that subject compensation be a form of recognition for the investment of the subject’s time or other inconveniences incurred. Therefore, subjects should not be compensated for the level of risk assumed in the study. Undue inducements are cause for concern because offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment and may prompt subjects to conceal information that, if known, would disqualify them from enrolling or continuing as participants in a research study.

HSO Mainline Questions: Alphabet Soup

You mean the HSO is not the IRB? Who are these people? Most researchers are familiar with the acronym “IRB,” but may not know what it means. Although, I have heard it defined as the “Iowa Review Board,” (no, we aren’t really the IRB of record for every research project in Iowa). You might even have a mental image of the IRB at work—a conference of strangers gathered to discuss and vote on human subjects research projects. But wait: you’re supposed to call the HSO with questions about your IRB application? Confused yet? The central purpose of any Institutional Review Board—protecting human subjects—is consistent, yet institutions vary in their regulatory interpretations and requirements. No IRB can function without administrative support. Someone has to coordinate all of those meetings, answer all of those emails, and review all of those projects. The HSO (Human Subjects Office) provides critical support to the three UI IRBs. You can think of the HSO as the skeleton supporting the energy and activity of the IRB muscles. Different institutions give the administrative support scaffold different names (no orderly Linnaean taxonomy here), so your previous experience may not always translate. At the UI, the HSO serves as the human research protection program (HRPP) under the oversight of the Vice President for Research and Economic Development. The HSO aims to protect human research participants. It also has a team dedicated to outreach: the Education and Compliance staff work to educate investigators and research staff about protecting research participants, ethical responsibilities, and regulatory requirements. Together, the HSO and the IRBs help move the body of human subjects research at the University of Iowa.

- Sarah Heady, IRB Assistant
Requirements for Subject Completion of Optional Agreements within the Informed Consent Document

Optional agreements allow subjects to indicate preference for optional research activities or study procedures within the Informed Consent Document (ICD). Optional agreements may be used by investigators who wish to enroll subjects while allowing for individuals to refuse specific aspects of the study. Typically, subjects indicate their preference by placing their initials, checking a box or marking a "yes/no" option. When a subject does not indicate agreement or fails to appropriately mark an optional agreement in the ICD, the optional activity or procedure should not be done. It is the responsibility of the research team to track and honor all optional agreements.

Investigators are encouraged to limit the use of optional agreements in the ICD as it is not always necessary to make certain study procedures optional. Optional agreements must be marked at the time of enrollment (i.e., at the time the subject signs the ICD). Members of the research team should never call subjects to inquire about blank optional agreement and then fill it in based on the subjects' verbal response. A copy of the ICD may be mailed to the subject with instructions for completing blank optional agreements if the research team has IRB approval to do so. If the research team plans to have in-person contact with the subject (e.g., a follow-up study visit), the subject may be asked to complete blank optional agreements at that time.