Subject Recruitment Plans: Key Concepts for IRB Review

The key to any study's success often lies in the study team's ability to recruit and enroll subjects. Meeting that challenge requires considerable planning prior to the initiation of a study and, while IRB review and approval is only one step in the process of developing a subject recruitment plan, it's an important one. Consider the following key concepts regarding IRB review and approval of subject recruitment plans: selection of subjects must be equitable; plans must be free of undue influence and coercion; and subject privacy must be protected.

Selection of Subjects Must Be Equitable

In determining whether the selection of subjects is equitable consider whether the criteria for selecting the study population are directly related to the goal of the research:

- Is the study population the population that will most likely benefit from the research or is the population selected out of convenience?
- Does the eligibility criteria appropriately protect subjects by eliminating those that may be at increased risk?
- If you require the enrollment vulnerable subjects to address your study question, have you explained why this is required? Have you justified the burden of participating in the research in consideration of other burdens that may already be placed on the population?

Case Study: A colleague at a peer institution initiates a multi-study to evaluate the use of a contrast agent in a population undergoing routine MRI imaging. While the contrast agent is approved by the FDA, it is not approved for use in the study population. Rather than randomize individual subjects, the investigator plans to randomize by enrolling sites (e.g., subjects enrolled a Site A will receive routine care while subjects at Site B will receive the investigational contrast agent). Is the selection of subjects equitable, if the burden of risk is not evenly distributed across enrolling sites?

OHSP Response: No, this study would not likely be approvable in its current form, as subjects enrolling at the institution administering the investigational contrast agent would unduly carry the burden of risk.

Plans Must Be Free of Undue Influence & Coercion

Undue influence and coercion can be introduced via multiple avenues in subject recruitment. Consider how:

- A pre-existing relationship with a potential subject may affect their decision-making process;
- The material is conveyed in a study advertisement or recruitment letter (including the method of communication, information included, and visual effects); and
- Subject payments and other forms of compensation may be interpreted by the study population.

Case Study: A longitudinal, observational study for which a large sample size is required is initiated by several faculty in the Cancer Center. In addition to posting advertisements in local newspapers, leadership within the Cancer Center present the study at various faculty, lab and staff meetings to aid in the recruitment of healthy controls. How might the presentation of this study affect the willingness of potential subjects to enroll?

OHSP Response: In this scenario, the presentation of the study by senior leadership to recruit junior faculty, employees, students (potentially including medical students, residents, graduate and post-doctoral students), etc., would be viewed as potentially coercive. Undue influence and coercion could be minimized by having an individual who is not in a position of authority present the study and enroll these potentially vulnerable subjects (while explicitly expressing the voluntary nature of the research).

Subject Privacy Must Be Protected

Only Investigators with routine access to their prospective subjects (or subject records) may recruit these individuals directly (i.e., contact in-person or via phone/writing). "Routine access" means the Investigator already has a clinical/academic reason for knowing the subject or reviewing a subject's record. Investigators who wish to recruit subjects from populations where they **do not have routine access** (e.g., patients of another physician), may not contact potential subjects directly; alternative methods for identifying and contacting these subjects must be formulated.

Case Study: A faculty member and graduate student in the Department of Clinical & Social Sciences in Psychology have initiated a new study on individuals with low back pain. Recruitment flyers have been placed in public locations but enrollment has been slow. To address this, the study team would like to recruit patients from local physical therapy clinics. What would be the best approach for recruiting these subjects?

OHSP Response: As the study team does not have routine access to these subjects, the initial point of contact must come from someone within the physical therapy clinic in order to maintain patient privacy. Appropriate methods of recruiting these subjects would include providing recruitment brochures to physical therapy clinics for providers to give to potential subjects or drafting a recruitment letter that includes study team contact information for providers to mail to potential subjects.

ADDITIONAL RESOURCES:

- OHSP Policy 703 Recruitment Materials and Subject Payment
- OHSP Guideline for Recruitment Methods and Materials
- OHSP Guideline for Subject Payment
