SOP 10.01 – Subject Recruitment and Study Advertising

1. Objective

The purpose of this SOP is to describe the review requirements and recommendations for recruitment of study subjects, and for study advertisements to help ensure equitable selection of subjects. All recruitment procedures and materials for non-exempt research studies must be reviewed and approved by the IRB before they can be used to recruit potential participants.

2. General Description

The recruitment of study subjects is considered the beginning of the informed consent/assent process, and the IRB must review and approve recruitment of subjects to ensure that the proposed recruitment methods are not coercive, or present undue influence and that the confidentiality and privacy of potential subjects are protected. In order to fulfill the responsibility of protecting the rights and welfare of human subjects, the IRB reviews the methods, materials, procedures, and tools use to recruit potential study subjects.

The IRB considers important elements of any recruitment strategy to be the content presented, the mode that the content is presented, the comprehensibility of the content, and the voluntariness of the recruitment setting.

3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Research Team Members, IRB, IRB Chair, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

4. Procedures

The IRB reviews the recruitment process and materials with consideration to the desired subject population, recruitment setting(s), and study purpose, methods and procedures.

Every protocol proposal submitted for review must include a recruitment section that clearly describes:

- how potential subjects will be identified;
- how, where, and by whom subjects will be approached about participation;
- when informed consent is obtained in relation to enrollment and the start of the study procedures; and
- if applicable, whether third parties will assist with recruitment of subjects and how.

Every proposal submitted for review must include any study advertisements (printed, audio, and/or video) intended for use. Materials such as flyers, posters, brochures, media advertisements, recruitment letters/emails, word of mouth recruitment, are all subject to review and approval prior to use.

Recruitment materials should minimally include the following information:

- name of the principal investigator;
- name of the institution or facility conducting the research;
- a statement that a proposed activities are 'research;'
- statement of the purpose of the research;
- the study eligibility (inclusion/exclusionary criteria);
- a brief list of benefits to subjects (if any);
- time and other commitment costs to subjects;
- any compensation or remuneration provided to subjects;
- where the research activity will take place; and
- the person(s) or office to contact to obtain more information about or to sign up for the study. *Contact information does not have to be explicitly stated at the time of approval provided that the contact information is directed toward an approved member of the research team.

Additional suggestions include:

- use simple lay language
- use the phrase 'at no cost' rather than 'free'
- use the word 'investigational' rather than 'experimental'
- use the phrase 'healthy volunteers' rather than 'normal volunteers'

Recruitment materials should *not*:

- state or imply a certain favorable outcome or other benefits beyond those outlined in the protocol proposal and informed consent materials;
- include any exculpatory language, or language that could be perceived as contractual in nature;
- emphasize payment or incentives for participation (e.g. bold, underlined, italicized, or oversized font);
- promises of 'free treatment,' 'free testing (or medications),' 'free counseling';
- use phrases such as 'new treatment,' or 'new drug,' etc. without clarifying that 'new' means 'investigational;'
- make claims or imply that an experimental drug, device, intervention, program, etc. is safe or effective for the purposes under investigation;
- make claims or imply that the experimental drug, device, intervention, program, etc. is comparable or superior to another drug, device, etc.;
- include misleading or inaccurate information,
- contain links to sites/resources that are not IRB approved, or
- contain language or graphics that appeal directly to the sensibilities of children.

Once the necessary information has been provided, the IRB will seek to determine and document where necessary that:

- recruitment strategies and advertisement content is appropriate for the desired subject population(s);
- advertisement content is consistent with the information in the protocol proposal and informed consent materials;
- materials contain the study relevant content,
- materials are free from bias, and do not coerce or unduly influence potential participants,
- materials do not overly emphasize incentives or compensation,
- materials appropriately reference compensation, and alternatives when applicable.

Considerations for researchers who want to enroll their own students

When the sample population includes students who receive instruction directly from one or more researchers, recruitment strategies must be designed to ensure voluntary participation. Students' decisions about research participation may not affect (favorably or unfavorably) grades, performance evaluations, or other opportunities or decisions made by instructor/researcher. Generally, it is preferable for a person other than the instructor/researcher to conduct the recruitment and informed consent process. Also, see SOP 7.05 - Students as Research Subjects.

Finder's fees, referral fees, and referral bonuses

A finder's or referral fee is a payment from the Researcher or Sponsor to a person who refers a prospective subject. Recruitment bonuses are payments from the Sponsor to a researcher or organization based on the rate or timing of recruitment.

Acceptable payment arrangements among sponsor, organization, researcher, and those referring research subjects will largely be determined on a case by case basis and with close attention to how those arrangements may affect equitable selection of subjects. Payment arrangements that are determined to adversely affect the equitable selection of subjects are unacceptable and will not be approved. Where federal health care programs are involved in the course of a research study, finder's and referral fees, and referral bonuses are prohibited.

Special considerations for Department of Justice (DOJ) regulated research

Finder's and referral fees, and recruitment bonuses are prohibited unless they are judged not to interfere with providing prospective subjects with sufficient opportunity to consider whether to participate and do not increase the possibility of coercion or undue influence on researchers or subjects.

Special considerations for Department of Defense (DOD) regulated research

Officers and senior non-commissioned officers may not be present at the time of recruitment.

5. References

45 CFR 46.111, 45 CFR 46.116
21 CFR 50.20, 21 CFR 50.25, 21 CFR 56.107(a), 21 CFR 56.111(a)(3)
UNLV SOP 7.05 – Students as Research Subjects
Institutional Review Board Management and Function, Bankert & Amdur – Chapter 5-6, 5-7
AAHRPP Element II.3.C.1