Grand Canyon University
Office of Academic Research
College of Doctoral Studies
3300 W. Camelback Road
Phoenix, AZ 85017
Phone: 602-639-7804

Procedure for the Recruitment of Subjects

I. Applicability: This procedure defines the standards and parameters for the recruitment of research study subjects for biomedical, behavioral and social science research.

II. Definitions:

Advertisements: An announcement to the public using a printed notice, voice or data broadcast that describes a research study and includes contact information. Used for recruitment purposes for a research study.

Bonus Payment: Compensation tied to the rate or timing of recruitment. An example of bonus payment would include a study sponsor offering financial incentives to study site that meets or exceeds enrollment targets within a specified time frame.

Coercion: The act of compelling by force of authority. To force to act or think in a certain way by use of pressure, threats, or intimidation.

Finder's Fee: Payment of any type (cash, educational stipends, gift certificates, or anything else of value) to an individual or department made in exchange for referral or recruitment of a participant to a research study.

Recruitment: Seeking individuals to enroll or participate in a research project.

Therapeutic misconception: A phrase used to define the experience of patients who tend to interpret information about clinical research, if presented to them by their healthcare provider, as being beneficial to them directly even if they are told that the study has no guaranteed benefit to them.

III. Procedure Statement:

Recruitment of research subjects will be conducted ethically and with sensitivity to the individual subject's rights and expectations. The framework for an ethical recruitment strategy requires that 1) subjects' privacy is protected, 2) subjects are not unduely pressured to participate and 3) information presented to the subjects is accurate and balanced without misleading statements. A description of the proposed recruitment methods to be used in any given study will be included in protocol submitted to GCU IRB for review and approval.

A. Privacy

1. Researchers must ensure that recruitment strategies both protect and respect the privacy of all potential research subjects. This includes the manner in which contact is made with subjects as well as the manner in which subjects are identified for recruitment.

2. Privacy protection is an especially sensitive issue when potential subjects are also medical patients and it is their medical condition that makes them eligible as potential subjects. In general, their medical records and identifiable health information should not be accessed by individuals not directly involved in their care and researchers will not contact potential research subjects unless they are directly responsible for care of that individual and have access to such identifiable health information as a result of that relationship. It is always preferable if potential subjects are contacted by people directly involved in their care and not by unknown researchers. In the event that the researcher intends to recruit potential subjects with whom s/he has no professional relationship, either the patients physician should request permission from the patient to release his or her name or the patient's physician will provide introductory information about the study to the potential subject so that s/he can contact the investigator if interested in enrolling.
3. Information about potential subjects who refuse to participate may not be kept unless the individual has expressly consented to allowing even this limited information to be kept by the investigator.

B. Pressure to Participate

An individual's decision to participate in research must be free from coercion or undue influence. The Principal Investigator (PI) must ensure that subjects be given sufficient time to consider the decision to enroll in a research study. All reasonable steps must be taken to ensure that the recruitment method or material does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol and minimize therapeutic misconception.

C. Students and Employees as Participants

Principal Investigators should recognize that directly approaching students or staff for the purposes of research participation may be considered coercive, as it may be difficult for the prospective participant to refuse the investigator's request. The prospective participant may also believe that the investigator will look favorably upon them should they agree to participate in the research study. Therefore PI's must carefully consider their ability to influence others when designing study recruitment methods. Investigators must specify in the protocol how the recruitment method will eliminate possible coercion when recruiting these populations. For instance, such individuals may participate in research if they approach the research team and initiate enrollment on their own behalf (see separate Procedure on Students and Employees in Research).

D. Data Base and Repository Recruitment

Investigators may request to use recruitment screening methods of certain databases to look for potential participants that may be eligible for their research projects (e.g., disease, age, sex, etc.).

E. Inclusion of Women, Children and Minorities

The inclusion of women, children, and minorities or other vulnerable populations in research is important, both to ensure that they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. Investigators will include the widest possible range of population groups to ensure the appropriate generalization of research results and to

further ensure that individuals who could potentially benefit from the research are given the opportunity to participate.

F. Unbiased Presentation

All information presented to potential subjects will be accurate and free from misleading emphasis that would make the study overly appealing. Such information includes that contained in the consent form as well as introductory letters to subjects, recruitment scripts, advertisements or web postings. Advertisements will be reviewed by the IRB before being implemented. Information contained in advertisements should be limited to:

1. The name and address of the PI
2. The purpose of the research
3. A brief description of eligibility criteria
4. A description of the incentives for subject participation
5. The study location
6. Study personnel or office to contact for information
7. Time or other commitment required to participate

G. Acceptable Recruitment Methods

The following acceptable recruitment methods must be approved by GCU's IRB before being implemented:

1. Information that is presented to the public and potential subjects should contact the investigator directly. Examples: Print, radio and television advertisements; e-mail solicitations; social media and Internet websites; texts.
2. Investigator contacts previous research subject who has given consent to be contacted in the future. Former research subjects must have previously consented to future contact.
3. Investigator seeks to identify potential subjects through school or organization records or other records that are either not under her/his purview or are not public records. The investigator must obtain permission to access the records from either the organization or individual responsible for the records as well as a waiver of consent/authorization from the IRB. In all such cases the investigator must accept responsibility for maintaining subject confidentiality. In such cases, the record review should be limited to the minimum information necessary to identify potential subjects.
4. Investigator requests a Waiver of Consent/Authorization for recruitment purposes. In all such cases the waiver must be justified in the protocol and approved by the IRB. Such a waiver will only be applicable in the following situations:
    a. Minimal risks studies in which subjects will not be contacted (e.g., database, school records chart review)
    b. Potential subjects can only be identified through medical record review. Once identified, potential subjects will then be contacted and informed about the study. The justification for the waiver to review the medical records must show why the research could not be done without the waiver.

H. Authority to Recruit

The PI or other members of the study team who have sufficient information about the study to answer questions may recruit study subjects. Also, if potential subjects are being recruited through a treating physician, the subjects may be approached and referred to the study investigator by other individuals involved in the patient's care who have permitted access to the patient's protected health information.

I. Finder's Fees and Bonus Payments

Research sponsors may offer to pay the PI, study personnel or departments an additional fee to encourage the recruitment of subjects and the timely or accelerated opening or completion of research studies. GCU does not permit these types of payments. Other types of compensation that are not related to participant enrollment or the subject's completion of the study may be permissible. These payments will be reviewed by GCU IRB for appropriateness.

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