

	RECRUITMENT & ADVERTISEMENT FOR SUBJECTS			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	7.04	06.27.2020	7.04	02.07.2020

RECRUITMENT

Each protocol submitted must explain how subjects will be identified and recruited for the study. The recruitment method(s) should respect an individual's reasonable expectation of privacy and should be done so as to avoid coercion or harassment of subjects. The study should be introduced in a manner that does not put undue pressure on subjects to enroll in the study. General considerations include who makes the request, how the request is made and when it is made. The number of attempts to contact the prospective subject (typically no more than three attempts) should be limited and inducements to enroll should not be excessive. Subjects should be provided sufficient time to make a decision. When recruiting vulnerable populations, the study team must take into consideration the regulations at 45 CFR 46, Subparts B, C, or D for determining the most effective recruitment method(s).

Acceptable methods for recruitment include but are not limited to:

1. Use of advertisements and media which must be approved by the IRB (*see below for more details*);
2. Direct recruitment of unknown potential participants using random digit dialing or social media;
3. Using a separately maintained, IRB-approved database of potential participants;
4. Giving Providers an IRB-approved letter to share with their patients that explains how to contact the study team if interested;
5. Sending an IRB-approved letter to providers asking for referrals of eligible patients; or,
6. Approaching the investigator's own patients, students, or employees in a way that does not unduly influence or mislead the potential participant.

ADVERTISEMENT

If notices are posted or other advertising is used for recruitment of volunteers to participate in the research, the specific advertisement and methods of recruitment must be approved by the IRB prior to use. Any type of advertising for research subjects that is intended to be seen or heard by prospective subjects is considered as part of the informed consent and subject selection process. Since this may be the initial contact by the investigator with the subject, the IRB must ensure that the information is not misleading to subjects. This is especially important when a study may involve subjects who are likely to be vulnerable to undue influence, for example, financially-impaired subjects.

When advertising is to be used, the IRB must review both the information contained in the advertisement and the mode of its communication in order to determine that the procedure for recruiting subjects is not coercive and that the recruitment 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.

Advertising for recruitment of participation into investigational drug, biologic or device studies should not use terms such as "new treatment" or "new medication" without explaining that the test article is investigational.

A phrase such as "you will receive new treatments" incorrectly implies that all study subjects will be receiving newly-approved products of proven worth. Advertisements should not promise "free medical treatment" when the reality is only that subjects will not be charged for taking part in the investigation.

If an investigator decides to begin advertising for subjects after the study has received IRB approval, the advertising is considered as an amendment to the on-going study and must be reviewed by the IRB. When such advertisements are easily compared to the consent, the IRB will review and approve the advertisement using expedited procedures. When the comparison is not obvious or other complicating issues are involved, the advertisement will be reviewed at a convened meeting.

Generally, advertisements should be limited to the information the prospective subjects need in order to determine their eligibility and interest. The following items must be addressed in order for the advertisement to qualify for review:

1. The name of the investigator, the name and phone number of the contact person for the study and the name of the institution (e.g., LSU Health Sciences Center in New Orleans)
2. The purpose of the research (e.g., the condition under study or the goal of the project)
3. The eligibility criteria (which may be in summary form, or listed as bullets or points)
4. The time-frame required for participation
5. A short list of benefits (Note that payments to subjects for participation are not benefits. The payment may be mentioned; however, it cannot be emphasized.)

Investigators who require assistance with advertisement formatting or composition should contact the LSUHSC-NO Director of Information Services at 504-568-4806. This office must be contacted if the recruitment material will appear in print media, be presented on television or radio, or placed on the internet.

Regarding acceptable and unacceptable payment arrangements for the sponsor, organization, researcher, and those referring research participants, all financial issues related to research projects supported by a sponsor must be detailed in the payment schedule associated with the clinical trial agreement. Such payments may include all costs associated with the research including time and effort for the principal investigator and study team members. However, note that so called “finder’s fees” or “referral fees” in exchange for referrals or recruitment of research participants are not allowed. Similarly, payments to individuals designed to accelerate recruitment are not allowed and any such arrangement for the institution will be examined very closely for potential influence on subject selection at the time of clinical trial agreement negotiation.