**Guidance: Recruitment Strategy**

**Policy:**  The investigator may use only the recruitment strategies approved by the CPHS for the research study.

**Key Terms**

**Exclusion Criteria:** A list of criteria, any one of which excludes a potential subject from participation in a research study.

**Inclusion Criteria:** The criteria that potential participants must meet to be eligible for participation in a research study.

**Randomization:** The process of assigning research participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

**Recruitment:** The process that employs inclusion and exclusion criteria and is used by investigators to enroll appropriate participants into a research study.

Successful study recruitment involves development and implementation of a well-coordinated plan that may require the efforts of the entire research team. Once in place, subject recruitment efforts must be constantly assessed, with new strategies implemented as necessary. The study team may use only the recruitment strategies approved by the CPHS for the research study.

**Developing Recruitment Plan -** Based upon the specific inclusion/exclusion criteria for a study, the study team should establish a suitable recruitment plan. The plan may be as simple as identifying potential participants within the practices of the members of the research team or a multi-pronged comprehensive plan incorporating various methods of direct advertising. The plan should be outlined in the CPHS application. The research team should continually monitor progress in enrollment and develop appropriate alternative strategies, if necessary. Some strategies for recruitment include:

* **Direct Advertising** – Direct advertising for research participants, i.e., advertising that is intended to be seen or heard by prospective participants to solicit their participation in a study includes, but is not necessarily limited to: newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective participants. FDA considers direct advertising for study participants to be the start of the informed consent and subject selection process.

When direct advertising is to be used, the information contained in the advertisement and the mode of its communication should not coercive and should not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

The final copy of printed advertisements must be reviewed and approved by CPHS. When advertisements are to be taped for broadcast, the CPHS must review and approve the final audio/video tape. The study team may submit wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.

Advertising for recruitment into investigational drug, biologic or device studies:

* Should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" leads study participants to believe they will be receiving newly improved products of proven worth.
* Should not promise "free medical treatment," when the intent is only to say participants will not be charged for taking part in the investigation.
* Should not emphasize the payment or the amount to be paid, by such means as larger or bold type, advertisements may state that participants will be paid.
* Should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It should be noted, however, that FDA does not require inclusion of all of the listed items.
  1. the name and address of the clinical investigator and/or research facility;
  2. the condition under study and/or the purpose of the research;
  3. in summary form, the criteria that will be used to determine eligibility for the study;
  4. a brief list of participation benefits, if any (e.g., a no-cost health examination);
  5. the time or other commitment required of the participants; and
  6. the location of the research and the person or office to contact for further information.

Only flyers that have been approved and stamped by CPHS may be used. Flyers may only be placed within designated areas. Flyers must not be pasted on walls, lobbies, elevators, restrooms and other public areas. <who gives permission for pasting flyers?>

* **UT Health Clinical Trials Page –** CPHS maintains a webpage on the UT Houston website that lists research studies that are open for enrollment. Research studies are listed by disease areas. The request to add a research study on this list should be sent to the CPHS office. Basic information on the trial including title, brief description of eligibility criteria and contact information should be provided.
* **Texas Medical Center Clinical Trials Website** – The Texas Medical Center website has a database of ongoing research studies. At <http://texasmedicalcenter.org/root/en/QuickLinks/Research/SearchResearch.htm> The request to add a research study on this list should be sent to the <to find out> . Basic information on the trial including title, brief description of eligibility criteria and contact information should be provided.
* **Clinical Trials Registry –** ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov contains information about a trial's purpose, who may participate, locations, and phone numbers for more details. Registration of certain clinical trials is mandatory. Research staff should contact the Clinical Trials Resource Center at [clinicaltrials@uth.tmc.edu](mailto:clinicaltrials@uth.tmc.edu) for registration information.
* **Research Match -** ResearchMatch is a recruitment tool that helps connect volunteers with researchers who are searching for appropriate volunteers to be placed in their research studies. Researchers at participating sites will be given access to register through the ResearchMatch system.  Upon registration, researchers may request either feasibility or recruitment access.  The ResearchMatch database will send invitation notices to volunteers who match the eligibility criteria for the research. To gain Recruitment Access, the study team may contact the UT Houston’s institutional liaison at [clinicaltrials@uth.tmc.edu](mailto:clinicaltrials@uth.tmc.edu).
* **Study Website** - Study teams may set up a website for the research study. This is especially helpful for large scale multi-center studies. Paying search engines like Google to place the research study at the top of the search list as a ‘sponsored link’ helps direct interested potential participants to the study website.
* **Dear Doctor Letters –** It is sometimes helpful to send information about the research study to physicians who might see potential participants in their practice. These letters should include a brief description of the research study, eligibility criteria, location of the study and contact information for the physician to call if they need more information and to refer the potential participant. Communications directed to colleagues do not require IRB approval, but this method of recruitment should be stated in the protocol.
* **Dear Patient Letters -** The PI may ask physician colleagues to send out general “Dear Patient” letters describing the study. The PI may draft the letter to be signed by the treating physician’s signature, but may not have access to the patient names or the mailing addresses. If the PI wants the letters to be individualized for the patients, the personalized information would have to be entered by the treating physician.
* **Community Outreach –** There are several organizations that offer support to patients with specific diseases. Many of these groups offer a variety of resources and services to patients. The study team may work with the support group relevant to their research and place direct advertising in the group’s website or newsletter. If the investigator is planning to use a business, listserv, school, agency, etc. to recruit subjects, the IRB will need to see a letter from that organization giving the investigator permission to recruit.

**Enrollment Plan -** With prior CPHS approval of waiver of authorization, the study team may conduct a preliminary screening to identify potential participants by reviewing medical records or databases. Apre-screening checklist with the study inclusion/exclusion criteria may help screen potential participants.

If the screening involves any procedures, these may be carried out only after informed consent is obtained. And enrollment packet helps to ensure that all the necessary paperwork has been completed. This packet may include the following documents:

* Eligibility checklist
* Consent form
* HIPAA Authorization form
* Study Flowsheets or Worksheets

The study team must maintain a record of all individuals who consented to participate in the study in a Screening Log. The study team should maintain a list of all potential participants who were approached for the study regardless of whether they signed the informed consent document or not in the pre-screening log.

A list of potential participants who meet eligibility criteria should be maintained in the enrollment log or study schedule log. If the subject was not enrolled into the study, the screening log should document the reason why the subject was not enrolled.

**Accessing Medical Records -** Persons who have access to medical records for the patients’ clinical care are said to have ‘ethically permissible access’ to the patients’ health information. Only persons with ethically permissible access are allowed to access medical records for research without the patient’s authorization unless the CPHS has approved waiver of authorization.

1. All healthcare professionals involved in the clinical care of a patient can be said to have ethically permissible access to the patient medical records
2. A staff working in a clinic may be said to have ethically permissible access to the patients attending that clinic.

**Contacting Potential Participants** - Only persons with ethically permissible access may make the first contact with patients either in the form of a letter of invitation or a telephone invitation to participate in a research. If the researcher does not have ethically permissible access to these patients, the researcher should work with individuals with ethically permissible access to make the first contact.

**Monitoring Enrollment:** During the course of the study, the study coordinator should regularly update the study team with electronic newsletter or email updates with status of study enrollment including data on enrollment at other sites may help to keep the team motivated. This would also help remind the study team of the eligibility criteria. The PI should arrange for the study team to have regular meetings. One of the agenda items at these study meetings should be to discuss the status of study enrollment and discuss strategies to improve enrollment. The study coordinator should consider distributing pocket sized index cards with eligibility criteria printed to the entire study team to help quickly identifying potential participants.

**Applicable Regulations and Guidelines**

# FDA Information Sheet - Recruiting Study Subjects - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

**Applicable Institutional Policies and Procedures**

* None

**Attachments**

* Template Flyer
* Advertisement guidelines

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