**Recruitment Guidance**

**Recruitment is an important aspect of human subject research because it is considered part of the consent process. The information participants are given during the recruitment phase can make a huge impact on their decision to participate, thus, recruitment should be approached with care. All recruitment efforts must respect personal rights to privacy and confidentiality, be compliant with HIPAA regulations and avoid coercion or undue influence.**

**Please note that the investigator is responsible for ensuring the recruitment materials follow all institutional guidelines.**

**This document is intended to provide general guidance on various recruitment strategies as well as what should be included within recruitment materials. Because there are a wide array of recruitment modalities that are rapidly evolving, the general guidance provided below is not intended to encompass all scenarios. Please note that for sponsored (industry) clinical trials, it is possible that the sponsor’s materials will need to be made to the site-specific documents to include all the necessary elements.**

**Should you wish to discuss your recruitment method(s) with the IRB, please fill out an** [**Initial Consult Request Form**](https://www.unthsc.edu/north-texas-regional-irb/request-a-consultation/) **to request a meeting with IRB staff.**

**Investigators (Physicians/Clinicians/Health-Care Providers) Who Want to Contact Prospective Subjects Who Were Identified From Medical Records**

* An investigator (physician/clinician/health-care provider) may approach a potential participant about participating in an IRB-approved study. The investigator should ensure that that the potential participant understands their agreement to participate in the project will not affect the clinical care that they receive or their relationship with the facility or their physician/clinician/health-care provider.
* Clearly describe the recruitment process in the protocol synopsis. How will the potential subjects be contacted (by phone, by email, etc.)? Who, among the members of the research team, will be contacting the potential subjects?
* Submit a copy of all recruitment materials that will be used to contact the potential subjects (e.g., phone scripts, email scripts, letters, etc.).

**Recruitment using social media or online advertising**

* The use of social media and online advertising techniques are becoming more popular; however, this type of recruitment must be approached with caution.
* The IRB must review and approve **all** recruitment procedures, including social media and online advertising, before the recruitment procedures can be implemented.
* Describe (in the protocol synopsis) the specific online/social media platforms that will be used for recruitment. If a wide-range of online/social media platforms will be used, incorporate language (in the protocol synopsis) that allows for flexibility in the platforms that will be used.
* Provide (in the submission) a copy or screen shot of the ad or post, including any text, images, tags, etc. that may accompany the advertising. If hashtags will be associated with the post, please include (in the submission) a document that includes a list of the hashtags that will be used.

**Recruitment using flyers/brochures/posters**

* Recruitment materials such as flyers/brochures/posters must receive IRB review and approval prior to implementation in order to ensure they follow federal regulations, as well as any institutional policies/practices, and are not coercive, misleading or unduly influential.
* The IRB may require changes in wording, therefore it is recommended that investigators wait until IRB approval is provided before making copies for distribution. (Note: The IRB-approved version will also include the IRB approval stamp.)
* The protocol synopsis should describe where the flyers/brochures/posters will be displayed or disseminated.
* Please note that researchers must obtain appropriate authorizations to display or disseminate the recruitment materials (e.g., if the flyer will be posted in a clinic, researchers should obtain permission from the appropriate authority at the clinic prior to posting these flyers). This also includes ensuring all institutional approvals for posting recruitment materials has been received.

**Recruitment over the phone or email**

* Some researchers may choose to contact participants over the phone or through the mail.
* Please ensure the protocol describes the way in which the contact information for the potential participants will be obtained. Every effort should be made to reduce any “cold call” effects.
	+ Cold calling includes reaching out to potential participants when they have no knowledge about the project
* Include (in the submission) a copy of all materials (phone scripts, email scripts, letters, etc.) that will be used during recruitment. These materials must receive IRB review and approval prior to implementation.

**Guidance on what to provide (and what not to include) in recruitment materials:**

**Recruitment materials should include the following information:**

* The word “research”
* Brief description of the purpose of the research
* Brief summary of the eligibility criteria
* Brief list of the procedures involved
* A statement of the approximate time commitment required
* May include graphics or pictures appropriate to the purpose of the study
* The name and location of the institution and department conducting the research
* Contact person for further information, including telephone number
* When appropriate (and IRB approved), compensation for time and travel expenses (no specific dollar amounts)

**Recruitment materials should not include the following information:**

* Terms such as “new treatment”, “new medication” or “new drug” without explaining that the drug or device is investigational. A phrase such as “receive new treatments” leads study subjects to believe they will be receiving newly improved products of proven worth. An “IRB friendly” way to say this is: *Volunteers with a diagnosis of (target disease) are being sought to participate in a research study testing an investigational drug.*
* Promise of “free medical treatment” when the intent is only to say subjects will not be charged for taking part in the study. Ads may state that subjects will be “compensated for their time and travel expenses”. An “IRB friendly” version would be: *Qualified volunteers will receive all study-related exams and lab tests at no charge and will be compensated for their time and travel expenses.*
* Enticing or inducing terms or phrases such as “free”, “new”, “exciting”, “limited enrollment”, “help us help you”, “you deserve to feel better”
* Emphasizing the payment or the amount to be paid, by such means as larger or bold type
* Links to sites/resources that are not IRB approved