IRB REVIEW OF RECRUITMENT PLANS AND MATERIALS

Recruitment Activities: Activities intended to provide prospective study participants with their first introduction to the research study by providing study related information. Recruitment is considered part of the informed consent process.

Recruitment Materials: Information potential subjects will see or hear that is used as part of the research recruitment process, including but not limited to websites, flyers, posters, newspaper ads, television or radio ads, brochures, doctor-to-patient or Investigator-to-subject letters, and social media ads.

Recruitment Methods: Methods used to identify potential research subjects, or to draw a potential research subject's attention to participation in research, including but not limited to identification through records review, in-person discussion, and use of recruitment materials.

Recruitment Plan: A section that must be included in the protocol which describes the "Who, What, Where, When and How" details of the proposed recruitment process.

IRB REVIEW PROCESS: The IRB reviews the recruitment plan along with all recruitment materials. Most recruitment materials cannot be used until approved by the IRB. The IRB must ensure that the recruitment plan and/or materials:

- Are consistent, complete and clear
  - Recruitment plan is consistent with the recruitment materials that are submitted for review
  - Recruitment materials should be written using clear and understandable language and without medical jargon
  - Materials provide enough information so prospective participants can decide if they are eligible and interested
- Promote fair and equitable participant selection
  - Recruitment plan should be based on the scientific question that the research will address
  - Plan should focus on those groups affected by the disease being studied
  - Specific groups should not be unfairly targeted nor excluded
- Take into consideration local social and cultural practices, as applicable
- Are translated into relevant language if research has planned enrollment of specific non-English speaking individuals
- Include provisions to protect prospective participants' privacy and confidentiality
- Are not likely to result in undue influence especially for potentially vulnerable populations
- Do not state or imply a certainty of favorable outcome or benefits beyond that in the protocol and consent forms
- Do not emphasize payment or amount to be paid (e.g., use of larger bold type font) or describe payment as a benefit

CONTENT FOR RECRUITMENT MATERIALS: The IRB reviews materials that may include some of the information below:

- Research title or identifier
- Identify that the study is a <u>research</u> study (must include the word "research")
- Purpose of the study
- Summary of eligibility criteria
- What is involved (e.g., study duration and location, number of visits, procedures and, if applicable, research intervention(s))
- If compensation will be provided
- Name of the investigator and their NIH IC affiliation
- Who to contact for more information
- Technical specifications: NIH/IC logo unless prohibited by 3rd party; footer with protocol #, version and date; and pagination, if applicable
- If applicable, brief lists of significant risks and possible benefits as well as compensation information
- For clinical trials that are FDA regulated, additional requirements apply:
  - Must state that the drug, biologic and/or device being studied is <u>investigational</u>
  - Not claim, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that it is known to be equivalent or superior to any other drug, biologic or device
  - Not use the terms "new treatment," "new drug," or "new medication" without explaining that the test article is investigational