Guidelines Subject Recruitment Advertisement

Federal Regulations require that the IRB review and approve methods used to recruit subjects, which includes various types of advertisements and forms of media. As such, all recruiting material that may be seen or heard by subjects must be reviewed and approved by the McLaren Health Care Institutional Review Board (MHC IRB) prior to distribution, posting, publication, or broadcasting. In addition to flyers, brochures, study identification cards, etc.; the IRB must also review study information to be provided via newspaper, radio, TV, bulletin boards and the internet/world wide web.

When submitting your recruitment materials to the IRB for review:

- Include information as to where the material is going to be placed/posted
- Submit printed ads exactly as they will appear in print (or as close as possible) so the reviewer can assess the visual impact, emphasis and graphic message
- Submit the full text of radio or television ads

DO:

Include the following in advertisements:

- Adequate information regarding eligibility, significant study procedures, and time commitment to allow prospective subjects to make an informed decision regarding possible participation:
  - Basic inclusion / exclusion criteria
  - Study procedures: x-rays, MRIs, exercise testing, overnight stays, frequent blood sampling, etc.
  - Time commitment: number / length of visits, expected overall length of participation
- The word "research" (someplace prominent)
- The term "healthy volunteers" rather than "normal volunteers"; "investigational " rather than "experimental"; "at no cost" rather than "free"
- Simple lay language; generally understood terms
- Minimal use of abbreviations / acronyms (NOTE: If acronyms can't be avoided, spell them out the first time they appear in the document)
- Names of drugs if they are commonly known to the public (i.e. Aspirin, St. John's Wort, etc.)
- Name of the facility where research will be conducted
- Purpose of the research
- Basic eligibility criteria
- Compensation, if any (NOTE: Compensation should not be promoted as a benefit)
- Local contact information

DO NOT:

Include the following in advertisements:

- Claims that the test article (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
- References to "new treatment", "new medication" or "new drug" without explaining that the test article is investigational
- Emphasis on monetary compensation (i.e. making money appear to be a benefit; using bold, italic, or large font) Misleading terms, such as "Study" or "Treatment Study"
- Monetary compensation as a lead in before the description of study purpose and procedures
- Statements that imply treatment benefit if the primary focus of the study is safety and tolerability rather than efficacy
- Emphasis on "no cost treatment" if a placebo is involved (NOTE: you don't need to explicitly state that placebos are used in ads) and/or the protocol involves drugs, biologics, or devices not FDA approved for the condition under study
- Detailed lists of risks and benefits