

GUIDELINES FOR RECRUITING RESEARCH SUBJECTS

The Main Line Hospital Institutional Review Board (MLH IRB) is responsible for reviewing study recruitment plans and materials to ensure protection of the rights and welfare of research subjects [21 CFR 56.107(a) & 56.111].

In accordance with the MLH IRB policy **ALL proposed recruiting tools** associated with a recruitment plan in a research study must be reviewed and approved by the MLH IRB. These tools include but are not limited to:

- Printed advertisements (ie, newspaper, posters, flyers, pamphlets, bulletin boards or brochures)
- Direct recruitment scripts (ie telephone scripts, receptionist scripts)
- Audio/video materials (ie final draft radio, TV scripts)
- Internet & web postings (final draft) no IRB review required on federally maintained sites such as clinicaltrials.gov, the NIH

All advertising is reviewed to assure that it is not unduly coercive and does not promise a benefit beyond what is outlined in the consent and the protocol.

Recruitment materials should be written in a simple language and limited to the information the prospective subjects need to determine their eligibility and interest and should **INCLUDE**:

- The name and address of the principal investigator and location of the research
- The condition under study (explanation or purpose of research)
- A brief summary of eligibility criteria
- A statement as to time or other commitment required of subject (number of visits, procedures, duration of study, etc.)
- A specific reference to “research study”
- Contact information to learn more about the study (telephone number)
- A brief list of participation benefits

No claims should be made explicitly or implicitly, that a 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 drug, biologic or device.

Recruitment materials should **NOT**:

- Use terms such as “new treatment”, “new medication” or “new drug” without explaining that the test article is investigational
- Emphasize monetary compensation (larger, italicize, bold type)
- Imply treatment benefit if the study is designed as safety & tolerability, drug kinetics or basic physiological processes rather than efficacy
- Use inducing terms such as “free”, “unique opportunity”, “exciting”, “cutting edge”, “limited offer”
- Promise free medical treatment when the intent is only to say subjects will not be charged for taking part in the research
- Imply research is recommended by Main Line Health or linked to quality of care subjects receive at Main Line Health