The Institutional Review Board is responsible for reviewing study recruitment procedures and materials to ensure protection of the rights and welfare of human subjects and equitable subject selection into research [21 CFR 56.107(a), 56.111(a)(3)]. Any method of advertisement must be approved by the IRB before it is implemented. All advertisements must comply with informed consent and subject selection regulations pursuant to 21 CFR 50.20, 50.25, and 56.111(a)(3) as well as the institutional policy described in this document.

Investigators must submit recruitment materials, as they will be implemented, to the IRB for review along with the initial protocol submission, or as an amendment for review through an expedited mechanism.

The IRB requires approval of the following types of advertisements and recruitment materials:
- The final copy of printed materials (ie newspaper, posters, flyers, pamphlets)
- Direct recruitment scripts (ie telephone scripts)
- The final audio and video recruitment materials
- National ad campaigns
- Internet advertising (postings on federally maintained sites such as clinicaltrials.gov do not need prior IRB approval)

All advertisements must not be coercive, must not promise a possibility of benefit beyond what is outlined in the consent and the protocol, must portray accurate information, and must direct potential subjects to proper personnel for further information. This is particularly important when a study involves subjects who may be vulnerable to undue influence. [21 CFR 50.20, 50.25, 56.111(a)(3), 56.111(b) and 812.20(b)(11).]

Recruitment materials should include the following information:
- The name and location of the institution and center/department conducting the research
- The name of the PI or department if appropriate
- The word “research”
- Statement or condition under study and brief description of the purpose of the research
- A brief list of the procedures involved
- A brief summary of the eligibility criteria
- A statement of the approximate time commitment required, if appropriate
- A brief description of the compensation/reimbursement,
- Contact for further information, with telephone number

Recruitment materials should NOT include:
- Exculpatory language
- Any language that would contribute to therapeutic misconception (research subject’s belief that enrolling in study will contribute to direct therapeutic benefit) for example: the use of the words “new treatment,” “new medication,” or “new drug.”
- Claims about the efficacy, safety, or superiority of investigational agents, or the security of confidential information
- Enticing or inducing terms such as “free,” “new,” “exciting,” “opportunity,” “limited opportunity,” “you deserve to feel better.”
- A promise of free treatment when the intent is only to say participants will not be charged for taking part in the investigation.
- Inducing phrases such as “limited enrollment,” “call today” or “study ends soon”
- Overemphasis on compensation but should not emphasize the payment or the amount to be paid by such means as larger or bold type. If the payments will be prorated, the ad should make this clear. For example, instead of stating, $300 compensation,” the ad should state that subjects will receive $50 for each of six completed visits.
- Compensation for participation in a trial offered by the sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- Links to sites/resources that are not IRB approved.
University of Pennsylvania
Department of Neurology
Is Conducting a Research Study on:

Diet and Exercise in Pre-diabetes and Painful Neuropathy

At the University of Pennsylvania Hospital

- If you are between the ages of 35 and 75, and
- Have been diagnosed with pre-diabetes or impaired glucose tolerance, or are at risk, and
- Have pain or numbness in hands and/or feet

You may qualify for a research study examining the effects of diet and exercise on painful neuropathy.

Eligible subjects will undergo neurological evaluations and will receive diet and exercise counseling, 1 hour a week for 8 weeks. Subjects will be compensated for travel.

Principal Investigator: I. Arby Smart, MD
For more information call Ayaar Bee, RN 215-555-555
The UPenn Department of Neurology is conducting a research study on Diet and Exercise in Pre-diabetes and Painful Neuropathy at the University of Pennsylvania Hospital.

- If you are between the ages of 35 and 75, and
- Have been diagnosed with pre-diabetes or impaired glucose tolerance, or are at risk, and
- Have pain or numbness in hands and/or feet

You may qualify for a research study examining the effects of diet and exercise on painful neuropathy.

Eligible subjects will undergo neurological evaluations and will receive diet and exercise counseling, 1 hour a week for 8 weeks.

Subjects will be compensated for travel.

Principal Investigator: I. Arby Smart, MD
For more information call Ayaar Bee, RN 215-555-555