**Appendix A: Guidance for Investigators Recruiting Subjects**

**Through Advertising**

Note: The following guidance provides some helpful hints for investigators submitting recruitment materials to the Walter Reed Army Institute of Research (WRAIR), Human Subjects Protection Branch (HPSB).

The text of all direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects, must be reviewed and approved by the WRAIR Institutional Review Board (IRB) prior to distribution, posting, publication, or broadcasting. Direct advertising includes, but is not limited to, notices aimed at recruiting research subjects that investigators intend to place in newspaper, radio, TV, bulletin boards, social networks sites, and the internet. Advertisements developed by coordinating centers for multicenter study recruitment also require IRB approval. These include, but are not limited to, letters, electronic and other postings, or notices in professional publications.

Advertisements should include:

* Name of research facility and/or name of Principal Investigator
* Title of Research Study (abbreviated is acceptable)
* Condition/treatment under study
* Purpose of the research and eligibility criteria (briefly stated)
* Time or other commitment required for participation (e.g. number of visits, total duration including follow-up visits, etc.)
* Contact person for more information
* The word “research” prominently written in the advertisement
* Location of the study
* Brief list of procedures involved
* Whether there is any kind of compensation or reimbursement for participation, amount can be included with case by case approval by WRAIR IRB
* Inclusion/exclusion criteria in summary form
* Brief list of benefits, if any (e.g. a no-cost health examination)
* Name of person or office to contact for additional study-related information
* Text and graphics that are legible
* WRAIR protocol number

Advertisements should not include: (1) claims, explicit or implicit, that the drug, biologic or device is safe or effective for the purposes under investigation or that the test article (drug, biologic, device) is known to be equivalent or superior to any other drug, biologic or device; and (2) references to "new treatment", "new medication" or "new drug" without explaining that the drug, biologic or device is investigational. All advertisements should be tastefully composed and may include monetary amount with justification. If you wish to use WRAIR logos, contact the WRAIR Public Affairs Officer for relevant guidelines.

**Do:**

* USE THE WORD "RESEARCH" in your advertisement, the terms "Study" or "Treatment Study" do not convey the same message.
* Provide information prospective subjects need to determine interest, such as eligibility, significant study procedures, and time commitment.
* Include information on if males, females, adults, and/or children will participate, the specific age range, and if certain medications are prohibited, etc.
* Include information on x-rays, MRIs, exercise testing, overnight stays, and frequent blood sampling, etc.
* Provide information on the duration of the study, number of visits and/or length of visits, if only one or two visits are needed, etc.
* Use "healthy volunteers" instead of "normal volunteers"
* Use simple lay language without acronyms or abbreviations unless these are well known to the public or to the special patient group you are targeting, e.g., patients with ALS or women with PMS will understand these abbreviations.
* Provide simple symptom complexes if you are looking for subjects who do not already carry the diagnosis.
* Provide basic exclusion criteria whenever possible to reduce unnecessary calls.
* Use the word "investigational" rather than "experimental."
* Name drugs used if approved and/or known to the public, e.g., Aspirin, St. John's Wort.
* Use the words "at no cost" rather than "free" where relevant.
* Specify affiliation (e.g. Branch of...)
* In your cover memo, indicate where the ad is going to be placed/posted, and if the same text will be used for email, newspaper, etc.
* Submit printed ads 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 (we'll even take a DVD).
* Submit the privacy statement or confidentiality statement when advertising on internet websites.
* Address confidentiality during recruitment in the protocol and/or site specific addendum when the recruitment strategy involves advertising for subjects utilizing subjects’ social networks, or offering recruitment bonuses to subjects.
* Use pictures in advertising that is appropriate to the targeted subject populations (e.g., Do not solely use pictures of Caucasian children for a recruitment presentation to be given to parents in Southeast Asia).

**Do Not:**

* Bold, italicize, underline or enlarge fonts on type describing compensation.
* Imply treatment benefit if the primary focus of the study is safety and tolerability, drug kinetics, or basic physiological processes rather than efficacy.
* Imply treatment benefit for chronic problems if the study involves only short-term interventions.
* Emphasize no cost treatment if a placebo is involved (you don't need to explicitly state that placebos are used in ads) and/or the protocol involves drugs, biologics, or devices that not U.S. FDA approved for the condition under study.
* Provide detailed lists of risks and benefits (this should be done in person).
* "Hype" the study with overly optimistic or effusive language overemphasizing benefit Emphasize broader affiliations (e.g., "Harvard researchers" or "Harvard Medical School Study") which tend to mistakenly convey endorsement and/or direct oversight of study treatments and procedures by the university or medical school.