



WALTER REED ARMY INSTITUTE OF RESEARCH  
Division of Human Subjects Protection  
Standard Operating Procedure

SOP Title	<b>REVIEW OF RECRUITMENT PROCESSES AND MATERIALS</b>	SOP No.	<b>UWZ-C-627</b>
Effective Date	FEB 18 2011	Version	.01
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**Signatures and Dates:**

Author:

QA Review:

For signatures, please see original in the  
Division of Human Subjects Protection

Approving  
Authority:

**Review/Approval for unchanged documents**

Date	Author	QA Review	Approving Authority



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## 1. Purpose and Applicability

The following Standard Operating Procedures (SOP) relays the process for submission and review of recruitment material submitted to the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB).

This SOP applies to the Principal Investigators (PIs)/WRAIR Point of Contact (POC), the WRAIR DHSP staff, the WRAIR Institutional Review Board (IRB), and the WRAIR IRB Chair (or designee).

### Background:

Federal regulations require that an IRB review and have authority to approve, require modifications, or disapprove all research activities covered by the IRB regulations [45 CFR 46.109, 32 CFR 219.109, 21 CFR 56.109]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46, 32 CFR 219, 21 CFR 56.107 and 56.111]. In fulfilling these responsibilities, an IRB is expected to review the methods, materials, procedures, and tools that investigators intend to use to recruit potential research subjects prior to the implementation of a study, as well as, throughout the course of the study.

Subject recruitment is considered the first step in the informed consent process and subject selection process. Reviewing recruitment methods provides an "additional opportunity for oversight bodies to monitor the actual content of the consent process" (Office of the Inspector General, Recruiting Human Subjects: *Pressures in Industry Sponsored Clinical Research*, DHHS, June 2000).

The ethical issues of greatest concern relative to recruitment are: consent (on-going, continuing), coercion (of medium or message), confidentiality (and privacy), and completeness (accuracy, truthfulness vs. deception).

Direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study, must have IRB approval prior to initiating the study. Some acceptable forms of direct advertising include, but are not limited to, the following:

- Posters
- Flyers
- Brochures
- Media Advertisements (Newspaper, Magazine, Journal, Radio, Internet, Television)
- Social networks (Facebook, Twitter, LinkedIn, etc.) Screening and phone scripts



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- Receptionist scripts (including the script a receptionist or first contact point follows to determine basic eligibility of prospective study participants)
- Audio, videotapes, & DVDs
- Bulletin boards

Recruitment materials that are not recognized as acceptable forms of direct advertising for study volunteers include:

- No promotions in news stories requesting volunteers, unless an approved method of advertising per the protocol. No compensation amounts (per visit or total) should be displayed on flyers & posters.
- With Military Treatment Facilities (MTFs)/hospitals/clinics - No letters from a researcher without filtering through the patients' physicians.

For internet listing of clinical trials, WRAIR IRB review and approval is not required when the system format limits the information displayed to basic clinical trial information, such as: study title, purpose, protocol summary, basic eligibility criteria, study location, and contact information.

- The clinical trials listing services that do not require IRB review and approval are the Clinicaltrials.gov, National Cancer Institute's cancer clinical trial listing and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).
- Internet listings of clinical trials should never assert or imply certainty of cure or benefit to subjects beyond what is described in the approved protocol and consent form.

In an effort to protect the privacy and confidentiality of research subjects, data obtained during recruitment must either be destroyed at regular intervals or the subject must be told that his/her data will be maintained (example: for up to a year) without additional consent.

Recruitment within the PI's department is generally not acceptable, unless this is an approved study population due to specific requirements (Example: entomology collections). For all WRAIR military staff members, an approved Supervisor's Form is required. This is strongly encouraged for civilian and contractor employees.

Information and data containing personal identifiers should not be provided to any third party without the subject's written permission. Any financial or other gains to any party (Investigator, Sponsor, etc) that may affect the subject's willingness to release the information must also be disclosed prior to obtaining consent (examples: in the briefing and consent form).



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As of 2010, advertisements may state that subjects will be paid, but should not emphasize the intention to pay through the use of dollar signs, larger font size, or bold type, and should not include the amount to be paid to subjects.

## 2. Responsibilities

a. The PI/WRAIR POC is responsible for:

- 1) Submitting all forms of recruitment material with the initial protocol application, that will be utilized in the study [refer to Appendix A: Guidance for Investigators Recruiting Subjects through Advertising];

**Note:** Recruitment material can be submitted to the IRB at the time of initial submission or any time after IRB approval. Any changes in recruitment proposed after the initial protocol has been approved, must be reviewed and approved by the WRAIR IRB as an amendment to the protocol [refer to SOP UWZ-C-615];

- 2) Revising recruitment material according to the recommendation(s) of the WRAIR IRB and/or the WRAIR DHSP reviewer;
- 3) Providing a clean version and track changes version of any revised recruitment material to the WRAIR DHSP; and,
- 4) Assuring that the recruitment process is not conducted prior to approval for implementation.

b. The WRAIR DHSP staff is responsible for:

- 1) Ensuring all forms of recruitment materials referenced in the protocol are available for review;
- 2) Ensuring the review of all recruitment material is accomplished and in accordance with Federal regulations and with the procedures in this SOP, and when appropriate, ensuring translations and translation verifications are provided;
- 3) Communicating with the PI/WRAIR POC any revisions required to the recruitment material, if applicable;
- 4) Documenting the review of recruitment materials;
- 5) Maintaining a file of all necessary documents and any correspondence with the investigator; and
- 6) Providing approvals/disapprovals to PI/WRAIR POC and others.



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- c. The WRAIR IRB/Chair (or designee) is responsible for:
- 1) Receiving and reviewing all recruitment material submitted with a protocol application and determining if the documents and the mode of communication are acceptable methods of recruitment;
  - 2) Communicating and documenting any concerns to the PI/WRAIR POC and the DHSP reviewer; and
  - 3) Ensuring recruitment materials are in compliance with applicable regulations and guidelines.

### 3. Materials and Equipment

N/A

### 4. Procedures

- a. The PI/WRAIR POC should:
- 1) Provide all forms of recruitment material to the WRAIR DHSP for review and approval, as identified in the protocol [refer to Appendix A: Guidance for Investigators Recruiting Subjects through Advertising and Appendix B: DHSP Recruitment Material Checklist];
  - 2) Obtain approval from all applicable participating institutions listed on the protocol and from the various sites where the advertisements will be placed. This may be needed before implementation can be granted (rolling starts may be permitted);
  - 3) Address any concerns from the WRAIR IRB or WRAIR DHSP review in a timely manner, until the recruitment material is in an IRB-approvable format;
  - 4) Provide a tracked change and clean version of any revised recruitment material, to include updated version number and date, to the WRAIR IRB for review;
  - 5) Submit any audio and DVD/ videotapes that will be used for recruiting along with the text of the message for review;
  - 6) Ensure that no recruitment activities associated with the protocol begin until approval to implement the protocol and recruitment material is received from the WRAIR Commander; and,
  - 7) Understand and adhere to the protocol and the procedures outlined in this SOP.



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b. The WRAIR DHSP staff:

- 1) Receives and reviews the recruitment materials with the initial submission of the protocol. If the material is being submitted after the protocol has been approved, then a tracked change version of the material, clearly identifying the changes must be provided;
- 2) Confirms that all methods of recruitment material are consistent with the protocol (flyers, brochures, etc.);
- 3) Ensures the recruitment material is in accordance with the protocol's stated objectives;
- 4) Uses the DHSP Recruitment Material Checklist [Appendix B] (as a guide) to ensure the appropriate elements are included and addressed;
- 5) Communicates to the PI/WRAIR POC the need to address and correct any missing elements required for the review. Any revisions to the submitted document(s) will require a new version number and date;
- 6) Once complete, forwards all recruitment materials to either the WRAIR IRB Chair (or designee) for expedited review or the WRAIR IRB for full board review, depending on the appropriate review pathway for the protocol [refer to SOP UWZ-C-603, SOP UWZ-C-613 and SOP UWZ-C-615];
- 7) Generates approval memoranda for the WRAIR IRB Chair (or designee) and Commander to review and sign (initial approval or amendment);
- 8) Stamps the IRB approved version of the recruitment documents (i.e., flyers, posters, brochures, and phone scripts) in accordance to SOP UWZ-C-635 [Stamping of Protocol Materials]. Note: The aforementioned recruitment materials may only be used with a valid stamp;
- 9) Forwards any approval documentation or correspondences to the PI/WRAIR POC; and,
- 10) Maintains an IRB file on the protocol, with copies of all versions of the recruitment material, as well as documentation of any communication with those involved with the protocol, its submission, review(s) and approval.



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c. The WRAIR IRB Chair (or designee):

- 1) Performs an expedited review (see SOP UWZ-C-613), in accordance with 21, 32, & 45 CFRs, of all recruitment material submitted to the WRAIR DHSP not undergoing review by the fully convened WRAIR IRB
- 2) Reviews, recommends revisions, and approves recruitment materials for research;
- 3) Forwards any recruitment material to the fully convened WRAIR IRB, should any doubts or complicated issues arise regarding the recruiting process, as appropriate;
- 4) Reviews all recruitment material to ensure that the rights and welfare of potential volunteers are protected by making sure the following elements are addressed:
  - a) Any references to the inclusion and exclusion criteria, description of the study, and compensation to study participants in the recruitment material is accurate and balanced by the requirements outlined in the research protocol and informed consent form;
  - b) Language is not coercive;
  - c) The word "new" is not used in relation to the investigational product.
  - d) The word "free" is not emphasized with either text size or the number of times the word is repeated;
  - e) There is not an emphasis on "benefits" without balancing the risks of the research;
  - f) Any description of procedures required for the study is identified as "study-related";
  - g) All text and graphics are of relative size and legible
  - h) Advertisement clearly states that the study is research
  - i) Advertisement does not promise a cure or benefit beyond what is described in the protocol and informed consent form;
  - j) Advertisements may state that subjects will be paid, but should not emphasize the intention to pay through the use of dollar signs, larger font size, or bold type and should not include the amount to be paid to subjects; The advertisement does not offer to pay an excessive amount of money to research subjects;
  - k) If audio and DVD/ videotapes will be used for recruiting, the DVD and/or text of the message must be provided for review to ensure that it is not coercive and that the wording and terminology is appropriate.

Additional considerations for recruitment material involving investigational new drugs/devices:



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- l) Advertisements should not use terms such as “new drug”, “new treatment”, or “new medication”, without explaining that the test article is investigational;
  - m) No claims should be made and implied that the drug, biologic, or device is “safe” and “effective” or that the test article is known to be equivalent or superior to any other drug or device;
  - 5) Forwards any review questions and/or concerns to the PI/WRAIR POC and DHSP POC; and,
  - 6) Provides approval recommendation for recruitment process/materials.
- d. The WRAIR IRB:
- 1) Reviews all recruitment processes and materials for research in accordance with applicable regulations and guidelines;
  - 2) Discusses any additional concerns about the recruitment methods and material and recommends any changes required to the protocol’s recruiting process; and,
  - 3) Establishes a review recommendation to approve, disapprove, table/defer or approve pending changes to the protocol and recruitment material.



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**5. Explanation of Abbreviations and Terms**

CFR	Code of Federal Regulations
DHSP	Division of Human Subjects Protection, WRAIR, is the administrative support to the IRB.
DOD	Department of Defense
Expedited Review	A protocol is eligible for expedited review when it meets the requirements set forth in 21 CFR 56.110, 32 CFR 219.110, 45 CFR 46.110, and AR 70-25
FDA	Food and Drug Administration
GTMR	Greater Than Minimal Risk
Human Subjects Research	Research involving humans as research subjects, or involving biological specimens, data, specimens from repositories or anatomical substances of human origin. This includes the administration of questionnaires or surveys, as well as research done in an educational setting.
IRB	WRAIR Institutional Review Board, the ethical review committee for research involving human subjects at WRAIR its continental U.S. detachments or Overseas Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (investigator, medical monitor, consultant, etc.). This includes protocols for which recruitment of subjects is through WRAIR.
Minimal Risk	A protocol constitutes minimal risk to subjects if the probability of harm or discomfort anticipated in the research is not greater than that encountered in daily life or during a routine physical or psychological examination.
PI	Principal Investigator
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.



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WRAIR Walter Reed Army Institute of Research

**6. References**

Reference Number or Authors	Document Title
Titles 21, 32, and 45	Code of Federal Regulations
	Food and Drug Administration, Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators
AR 70-25	Use of Volunteers as Subjects of Research
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Management and Function (2 <sup>nd</sup> Edition). Boston: Jones and Bartlett Publishers, 2006.
	OHRP Guidebook on Written IRB Procedures, July 11, 2002.
WRAIR SOP UWZ-C-603	Conducting Initial Protocol Review
WRAIR SOP UWZ-C-613	Expedited Review
WRAIR SOP UWZ-C-615	Amendments to Human Subjects Research Protocols
WRAIR SOP UWZ-C-618	Continuing Review and Continuation Determination
WRAIR SOP UWZ-C-635	Stamping of Protocol Materials
DHHS, June 2000	Office of the Inspector General, Recruiting Human Subjects: <i>Pressures in Industry Sponsored Clinical Research</i> ,



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**7. Forms and Appendices**

<b>Form or Appendix Number</b>	<b>Title</b>
Appendix A	Guidance for Investigators Recruiting Subjects through Advertising
Appendix B	DHSP Recruitment Materials Checklist



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**8. Document Revision History**

Version Number	Brief Description of Changes	Effective Date
.00	New	2 November 2007
.01	Periodic review, including updates to organization name changes, references, and provide clarifications regarding procedures and definitions.	<i>FEB 18 2011</i>

# **UWZ-C-627.01 - 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), Division of Human Subjects Protection (DHSP).

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 and the internet/world wide web. Advertisements developed by coordinating centers for multicenter study recruitment also require IRB approval. Notices directed to clinical colleagues seeking study referrals 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 and address of PI
- Title of Research Study (abbreviated is acceptable)
- 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
- Condition under study
- Brief list of procedures involved
- Whether there is any kind of compensation or reimbursement for participation
- 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
- Version number and date of protocol

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

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should be tastefully composed and not include monetary amount. 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. Division of...)
- In your cover memo, indicate where the ad is going to be placed/posted, 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)

## Don't:

- Put the monetary amount.
- Bold, italicize, underline or enlarge fonts on type describing monetary 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 not FDA approved for the condition under study

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- Provide detailed lists of risks and benefits (this should be done in person)
- "Hype" the study with overly optimistic or effusive language implying benefit (commercially designed radio ads occasionally do this)
- Use words describing 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
- Use catchy acronyms for the study title, such as "HELP" or "PATRIOT".

**\*NOTE: Recruitment material must include a valid IRB stamp, as appropriate (see SOP UWZ-C-635, Stamping of Protocol Materials).**

**UWZ-C-627.01 - Appendix B: DHSP Recruitment Materials Checklist**

WRAIR # \_\_\_\_\_

Date Checklist Completed: \_\_\_\_\_

PI: \_\_\_\_\_

Date Checklist Updated: \_\_\_\_\_

Reviewer's Signature: \_\_\_\_\_

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
A. Local IRB reviewed and approved the Ad for initial review or as an amendment to the protocol. (32 CFR 219.109; 32 CFR 219.111; 21 CFR 56.109 a; 21 CFR 56.110 (b)(2))				Date of IRB Approval:
B. An acceptable form of advertisement is being used, such as:				
1. Posters/Flyers				
2. Newspaper Ad				
3. Magazine or Journal Ad				
4. Radio or TV Ad				
5. The Internet				
6. Audio or Videotapes				
7. Phone Scripts				
8. Bulletin Boards (				
9. Social Networking Sites (i.e., Facebook, Craig's List)				
C. Recommended elements for Ads: (Inclusion of all listed items is not required)				
1. Title of study				
2. Purpose of the research				
3. Summary of basic eligibility criteria				
4. Procedures and/or activities required for subject participation				
5. Brief list of benefits from participation				
6. Time commitment required of subjects				

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WRAIR # \_\_\_\_\_

Elements	Is Element Addressed?			Comments
	Yes	No	N/A	
7. Name and address of Principal Investigator				
8. Location of the research				
9. Name of person or office to contact for further information				
<b>D. Additional Required Elements for IND or Investigational Device Ads</b>				
1. The Ad states that the drug, treatment or device is investigational. (FDA Information Sheet, 1998 Update)				
2. No claims are made that the investigational product is safe and effective for the purposes of the study. (21 CFR 312.7 (a); 21 CFR 812.7 (d))				
<b>E. Other elements to consider for all Ads:</b>				
1. Does the Ad promise a cure or benefit beyond what is mentioned in the protocol or consent form?				
2. Are the font of the text and other visual effects reasonably sized?				
3. If the subjects will be paid, is the amount of payment in bold type, larger than other text, or otherwise over-emphasized?				
4. Is the payment to subjects an excessive amount such that it is unduly coercive in obtaining subjects' consent to participate?				
5. Does the Ad promise "free medical treatment" which is not the true intent?				
6. If audio/video tapes are being used, has the text of the message been provided for review?				
7. If subjects are recruited by telephone, has the phone script been provided for review?				