SOP Title	**REVIEW OF RECRUITMENT PROCESSES AND MATERIALS**	SOP No.	**UWS-HP-627**
		Version	.02
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Signatures and Dates

Author:	Signature on file	Human Subjects Protection Branch	Date
QA Review:		Human Subjects Protection Branch	Date
Approving Authority:		Human Subjects Protection Branch	Date

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
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1. **Purpose and Applicability**

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

This SOP applies to the Principal Investigators (PIs)/WRAIR Points of Contact (POCs), the WRAIR Human Subjects Protection Branch (HSPB) staff, the WRAIR 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 network posts (Facebook, Twitter, LinkedIn, etc.)
- Screening, email and phone scripts
- Receptionist scripts (including the script a receptionist or first contact point follows to determine basic eligibility of prospective study participants)
- Digital media, audio files and DVDs
- Bulletin boards

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

- Promotions in news stories requesting volunteers, unless an approved method of advertising per the protocol. Compensation amounts (per visit or total) may be displayed on flyers and posters with a justification provided by the research team
- Within Military Treatment Facilities (MTFs)/hospitals/clinics - 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. Specifically, 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) only. 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. It is best practice that these sites be listed in the recruitment section of the protocol or site specific addendum.

Data obtained during recruitment (contact information, basic demographic information, etc.) must not be recorded or kept without obtaining the informed consent of the subject. Screening data must only be collected after obtaining the informed consent of the subject. A waiver of informed consent for this purpose may be considered by the IRB or designated reviewer in limited circumstances. Recruitment within the PI's department is generally not recommended, 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 prior to participation. Supervisor's approval prior to participation in a research study is strongly encouraged for both civilian and contractor employees while on duty status.

Per the DOD Instruction 3216.02, superiors of military and civilian personnel may not be present at recruitment sessions for personnel whom they supervise. When possible, supervisors should be presented with separate recruitment sessions for their own participation in the research. For greater than minimal risk research when recruitment occurs in a group setting, an ombudsman must be appointed and listed in the protocol. This designated individual should not be associated with the research in any other way and should be present at the recruitment activities to enforce the voluntary nature of the research. The ombudsman may be the same individual as the research monitor.

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, recruitment bonus for the referring subject, 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).

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 unless a justification is provided and is specifically approved by the IRB.

Internet-based procedures for advertising and recruiting potential participants must follow the requirements that apply to any traditional media, such as flyers and newspaper ads. Like traditional media, personally identifying information should be kept confidential, to the extent possible. Names of internet personas, avatars, gamer handles, etc. are all considered identifying information, and often, may be used to ascertain an individual's legal name or location.

In certain situations, without face-to-face or voice interaction, it is difficult to ascertain that potential participants responding to recruitment ads are not misrepresenting themselves. Investigators should discuss screening measures to authenticate subjects. For example, screening measures could include providing each participant with a personal identification number (PIN) or using internet monitoring software, such as SafeSurf or Adult Check, to screen out minors. A risk-based assessment should be made in order to determine whether this is necessary.

When conducting recruitment activities in an online group setting, such as on a disease-specific patient forum, the activities should not disrupt normal group activity. When determining recruitment strategies, the research team should consider how the recruitment or presence of the researchers in the forum may be perceived by the members of the online community. Researchers should announce their presence in a chatroom or forum, and clearly state the reason for observing or participating in the

chat room. Exceptions to this may be reviewed and approved by the IRB, when deemed appropriate; however, this deception may necessitate a waiver of consent elements. When navigating a chatroom, it is important that those present are able to let the researcher know if they are not comfortable with the researcher's presence and that the researcher respects these wishes. The plan to allow members to decline to interact with the researchers as well as contingency plans should be outlined in the protocol.

Investigators should ensure that recruitment plans do not violate the terms and conditions of the website to which the recruitment will be posted. For example, the terms and conditions of a social media site or dating website may not allow research teams to create a "fake" profile for the purpose of advertising research opportunities.

When using subjects' social media networks to recruit study participants, plans to ensure the subjects' confidentiality (e.g. medical diagnosis, sexual orientation, or serostatus) as well as the confidentially of their social media contacts must be described in the protocol.

2. Responsibilities

a. The PI/WRAIR POC is responsible for:

1) Submitting to HSPB all forms of recruitment materials that will be utilized in the study, with the initial protocol application [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 UWS-HP-615]. Internet recruitment documents must note the website to which the document/language will be posted and include the terms and conditions or privacy policy of the website, when possible.

2) Revising recruitment material according to the recommendation(s)/stipulations(s) of the WRAIR IRB and/or the WRAIR HSPB reviewer.

3) Providing both a clean and tracked changes version of any revised recruitment material to the WRAIR HSPB, and ensure version control.

4) Assuring that the recruitment process is not conducted prior to approval for implementation.
5) Providing the terms of service or privacy policies of the internet sites, to which recruitment material will be posted (if applicable), for review.

b. The WRAIR HSPB 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) Ensuring recruitment materials do not violate the terms of service or privacy policies of the internet sites to which recruitment material will be posted (if applicable).

4) In the case of social network recruitment activities, ensuring adequate protections for subjects' and potential subjects' confidentiality are addressed in the protocol.

5) Communicating with the PI/WRAIR POC any revisions required to the recruitment materials.

6) Documenting the review of recruitment materials.

7) Maintaining a file of all necessary documents and any correspondence with the investigator.

8) Providing approvals/disapprovals to PI/WRAIR POC and others.

c. The WRAIR IRB/Chair (or designee) is responsible for:

1) Receiving and reviewing all recruitment materials 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 HSPB reviewer.

3) Ensuring recruitment materials are in compliance with applicable regulations and guidelines, as well as ethical standards, especially with regards to confidentiality and reducing undue influence.

3. Materials and Equipment

Not Applicable

4. Procedures

a. The PI or WRAIR POC:

1) Provides all forms of recruitment materials to the WRAIR HSPB for review and approval, as identified in the protocol [refer to Appendix A: Guidance for Investigators Recruiting Subjects through Advertising and Appendix B: HSPB Recruitment Materials Checklist].

2) Describes the full recruitment plan in the protocol and/or site specific addendum.

3) Obtains approval from all applicable participating institutions listed on the protocol and from the various sites where the advertisements will be placed or leaders/stakeholders from any social media groups/forums (including providing terms of service or privacy policy statements from internet or social media sites). This may be needed before implementation can be granted (rolling starts may be permitted).

4) Addresses any concerns from the WRAIR IRB or WRAIR HSPB review in a timely manner, until the recruitment materials are in an IRB-approvable format.

5) Provides both a tracked changes and clean versions of any revised recruitment materials, to include an updated version number and date, to the WRAIR IRB for review.

6) Submits any digital media, audio and/or DVDs that will be used for recruiting along with the text of the message for review.

7) Ensures that no recruitment activities associated with the protocol begin until approval to implement the protocol and recruitment materials is received from the WRAIR Commander.

8) Understands and adheres to the protocol and the procedures outlined in this SOP.

b. The WRAIR HSPB staff:

1) Receives and reviews the recruitment materials with the initial submission of the protocol. If the materials are being submitted after the protocol has been approved, ensures a tracked changes version of the materials, clearly identifying the changes is provided.

2) Confirms that all methods of recruitment are consistent with the protocol and WRAIR policy, ethical standards, and normative expectations of privacy.

3) Ensures the recruitment material is in accordance with the protocol's stated objectives.

4) Uses the HSPB 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 (tracked and clean versions) to either the WRAIR IRB Chair (or designee) for expedited review or the fully convened WRAIR IRB for full board review, depending on the appropriate review pathway for the protocol [refer to SOP UWS-HP-603, SOP UWS-HP-613 and SOP UWS-HP-615].

7) Generates approval memoranda for the WRAIR IRB Chair (or designee) and WRAIR Commander to review and sign (initial approval or amendment).

8) Forwards any approval documentation or correspondences to the PI/WRAIR POC.

9) Maintains an IRB file on the protocol, with copies of all versions of the recruitment materials, as well as documentation of any communication with those involved with the protocol, its submission, review(s) and approval.

c. The WRAIR IRB Chair (or designee):

1) Performs an expedited review (see SOP UWS-HP-613), in accordance with 21 CFR 50, 32 CFR 219, & 45 CFR 46, of all recruitment material submitted

to the WRAIR HSPB not undergoing review by the fully convened WRAIR IRB.

2) Reviews, recommends revisions, and approves recruitment materials for research.

3) Forwards any recruitment materials to the fully convened WRAIR IRB, should any doubts or complicated issues arise regarding the recruiting process, as appropriate.

4) Reviews all recruitment materials to ensure that the rights and welfare of potential volunteers are protected by making sure the following elements are addressed:

   a) References in the recruitment material to the inclusion and exclusion criteria, description of the study, and compensation to study participants are accurate and balanced by the requirements outlined in the research protocol and informed consent form.

   b) The language used in the recruitment material is not coercive or appears to create undue influence.

   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 and should say “at no cost to you.”

   e) Advertisement does not promise a cure or benefit beyond what is described in the protocol and informed consent form.

   f) There is not an emphasis on “benefits” without balancing the risks of the research.

   g) Any description of procedures required for the study is identified as “study-related.”

   h) All text and graphics are legible and appropriately emphasized (i.e. not in bold or big fonts).

   i) Advertisement clearly states that the study is research.

j) Advertisements may state that subjects will be paid (compensation amounts may be included with justification provided by the investigator), but should not emphasize the intention to pay through the use of dollar signs, larger font size, or bold type.

k) If online recruitment will occur, website terms and conditions and/or privacy policies are not violated by the recruitment plan, as well as, the website terms and conditions or privacy policy will not store data that may compromise the confidentiality of subjects.

l) If online recruitment will occur, the protocol must address plans to ensure confidentiality of all identifying information including internet pseudonyms, a plan to confirm age/eligibility, a plan to announce the research group's presence as well as allow members of online forums/social media groups to opt out of the interaction.

m) If digital media, including text messaging, audio files and/or DVDs will be used for recruiting, these items must be provided for review to ensure that they are not coercive or appear to create undue influence, and that the wording and terminology are appropriate.

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

n) Advertisements should not use terms such as "new drug", "new treatment", or "new medication", without explaining that the test article is investigational.

o) 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 HSPB POC.

6) Provides approval 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 materials and recommends any changes required to the protocol's recruiting process.

3) Establishes a review recommendation to approve, disapprove, table/defer or approve pending changes to the protocol and recruitment materials.

5. **Explanation of Abbreviations, Acronyms, and Definition of Terms**

Abbreviations and acronyms have been defined in the text at the time of first use.

HPSB	Human Subjects Protection Branch, WRAIR, is the administrative support to the IRB.
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
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, A committee that has been formally designated to review, approve, and monitor biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects (see Army Regulation 70-25, Appendix C-1). Selection for the board is in accordance with Federal guidelines outlined in 21 CFR 56.107, 32 CFR 219, and 45 CFR 46.
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.
Principal Iinvestigator	The individual who is responsible and accountable for conducting a research study. This individual will have the appropriate scientific and ethics training and

	experience to assume full responsibility and accountability for the scientific integrity of the research data and results. The PI is the individual responsible and accountable for designing, conducting, and monitoring the research study, and has access to the data. For studies involving human research subjects, the PI, as the leader of the research study team, assumes full responsibility for the medical care and evaluation of subjects, either directly or indirectly (designee of a healthcare provider). The PI also is responsible for protecting the rights and welfare of human subjects and is responsible for carrying out sound ethical research consistent with research plans in a protocol approved by a properly-constituted IRB. The PI may formally delegate roles and responsibilities to other members of the research study team, as appropriate, but retains full responsibility for the conduct of all study activities.
Research	A systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge.

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
DODI 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research

Amdur, R. J. and Bankert, E. A.	Institutional Review Board Management and Function (2nd Edition). Boston: Jones and Bartlett Publishers, 2006.
DHHS	OHRP Guidebook on Written IRB Procedures, July 11, 2002.
WRAIR SOP UWS-HP-603	Conducting Initial Protocol Review
WRAIR SOP UWS-HP-613	Expedited Review
WRAIR SOP UWS-HP-615	Amendments to Human Subjects Research Protocols
DHHS, June 2000	Office of the Inspector General, Recruiting Human Subjects: *Pressures in Industry Sponsored Clinical Research*
Committee for Protection of Human Subjects, University of California, Berkley	Committee for the Protection of Human Subjects Guidelines – Internet-Based Research. (2016, June). Retrieved from https://cphs.berkeley.edu/internet_research.pdf.
Committee for Protection of Human Subjects, University of California, Berkley	Committee for the Protection of Human Subjects Guidelines – Subject Recruitment. (2013, April). Retrieved from https://cphs.berkeley.edu/recruitment.pdf.
Harvard Catalyst Regulatory Foundations,	The use of social media in recruitment to research: A guide for Investigators and IRBs. (Accessed 1 Dec 2016). Retrieved from https://catalyst.harvard.edu/pdf/regulatory/Social_Media_Guidance.pdf

Ethics, and Law Program	
WRAIR Policy 2019-49	Staff as Research Volunteers

7. **Appendices and Attachments**

Appendix or Attachment Number	Title
Appendix A	Guidance for Investigators Recruiting Subjects through Advertising
Appendix B	HSPB Recruitment Materials Checklist

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.	6 April 2011
.02	Periodic review, including updates to organization name changes, references, and provide clarifications regarding procedures and definitions.	