

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



SOP Title	STAMPING OF PROTOCOL MATERIALS	SOP No.	UWZ-C-635
			Version .01
Effective Date	FEB 18 2011	Page	1 of 7

Signatures and Dates:

Author:

QA Review:

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

Approving
Authority:

Change Control: Review/Approval for unchanged documents

Date	Author	QA Review	Approving Authority



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



SOP Title	STAMPING OF PROTOCOL MATERIALS	SOP No.	UWZ-C-635
			Version .01
Effective Date	<i>FEB 18 2011</i>	Page	2 of 7

1. Purpose/Applicability:

This Standard Operating Procedure (SOP) is intended to ensure that only current, Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) approved documents, are presented to volunteers, by describing the process for stamping documents. Recruitment materials (for example, posters and brochures) are covered by this SOP, as subject recruitment is considered part of the informed consent process. This SOP applies to the following types of approved documents that are commonly stamped and may only be used with a valid stamp:

- a. Consent documents,
- b. Consent form addenda,
- c. Assent documents,
- d. Information sheets associated with the informed consent process, and
- e. Advertisement/subject recruitment materials reviewed and approved by the WRAIR IRB, IRB Chair or designee.

Standard forms that are not protocol specific (for example, Maryland State HIV testing consent form or Supervisor/Commander's Approval Form for Active Duty Military Volunteers) are commonly approved with the protocol submission, but not stamped. Standard forms that are protocol specific may be stamped if requested by the Principal Investigator (PI) or other appropriate parties (for example, the study sponsor), however stamping is not usually required, unless explicitly stated.

This SOP applies to protocols conducted under the WRAIR Human Research Protection Program (HRPP), to include protocols conducted by the U.S. Army Medical Research Unit-Europe (USAMRU-E). Protocols conducted at other OCONUS Detachments and non-WRAIR sites are subject to the stamping requirements of the local IRB. This SOP applies to all personnel covered under the WRAIR HRPP.

2. Responsibilities:

WRAIR DHSP is responsible for:

- a. Upon IRB approval, ensuring that documents are stamped with a valid stamp and provided to the PI, and
- b. Checking for valid stamps during monitoring visits. *Note: At continuing review, a copy of stamped materials may be requested from the PI/WRAIR point of contact (POC) for verification (see SOP UWZ-C-618).



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



SOP Title	STAMPING OF PROTOCOL MATERIALS	SOP No.	UWZ-C-635
			Version .01
Effective Date	<i>FEB 18 2011</i>	Page	3 of 7

WRAIR DHSP Director is responsible for:

- a. Ensuring compliance with this SOP
- b. Ensuring training on this SOP
- c. Providing resources for compliance with this SOP

3. General Guidance:

A WRAIR IRB approval stamp affixed to a document indicates that the document has been reviewed and approved by the IRB, IRB Chair, or designee. It also serves as a reminder of the requirement for continuing review and re-approval. The WRAIR IRB approval stamp shows the protocol number, protocol expiration date, and document version number and date. The stamp is only applied to finalized, IRB approved documents and appears on each page of the document.

4. Materials and Equipment:

N/A

5. Procedures:

a. The DHSP:

1) Informs the PI/WRAIR POC of the following requirements:

a) Use the stamped consent/assent form and recruitment materials to make copies of the document for enrolling/recruiting study participants.

b) Retain stamped documents in the study regulatory file.

c) Submit a clean copy of revised document(s) at the time of an amendment for IRB review/approval and stamping before the amendment is implemented.

d) Submit a clean copy of the current document(s) at the time of continuing review for IRB review/approval and stamping before it is accepted.

2) Stamps the IRB approved version of the document. Documents covered by this SOP are stamped following initial approval, continuing review approval, and approval of modifications to the documents (See SOP UWZ-C-615).

3) Sends the stamped copy to the PI/WRAIR POC.

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



SOP Title	STAMPING OF PROTOCOL MATERIALS	SOP No.	UWZ-C-635
			Version .01
Effective Date	FEB 18 2011	Page	5 of 7

WRAIR

Walter Reed Army Institute of Research



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



SOP Title	STAMPING OF PROTOCOL MATERIALS	SOP No.	UWZ-C-635
			Version .01
Effective Date		Page	6 of 7

FEB 18 2011

WRAIR IRB

WRAIR Institutional Review Board, the ethical review committee for research involving human subjects at WRAIR its CONUS detachments or OCONUS Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (investigator, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is being performed at WRAIR.

6. References:

Reference Number or Authors	Document Title
32 Code of Federal Regulations (CFR) 219	Department of Defense, Protection of Human Subjects
	OHRP Guidebook on Written IRB Procedures, 11 July 2002.
UWZ-C-633	Routine Monitoring of Human Subjects Research Compliance SOP
UWZ-C-634	Directed Monitoring of Human Subjects Research SOP
UWZ-C-615	Amendments to Human Subjects Research Protocols SOP
UWZ-C-618	Continuing Review and Continuation Determination SOP
UWZ-C-627	Review of Recruitment and Advertising Material SOP

7. Forms and Appendices:

N/A



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



SOP Title	STAMPING OF PROTOCOL MATERIALS	SOP No.	UWZ-C-635
			Version .01
Effective Date		Page	7 of 7

FEB 18 2011

8. Document Revision History:

Version Number	Brief Description of Changes	Effective Date
.00	Original document	20 June 2008
.01	Biennial Review; updated for consistency with current policies/procedures.	FEB 18 2011