Signatures and Dates:

Author:	Signature on file	Human Subjects Protection Branch	Date
Author:		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

This Standard Operating Procedure (SOP) provides guidance on obtaining a waiver or alteration of informed consent and describes the criteria and processes by which the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) may waive or alter informed consent requirements, as permitted by 32 Code of Federal Regulations (CFR) 219.116(f), and 117(c) and 45 CFR 46.116(f) and 117(c). The IRB may waive documentation of consent (e.g. not obtain a signed consent form for some or all subjects), waive the requirement to obtain informed consent, or alter elements of informed consent. Waiver of informed consent and waiver of documentation are not permitted under the United States Food and Drug Administration regulations (except as provided in 21 CFR 50, sections 23 and 24) or for research involving nonviable neonates (refer to SOP UWS-HP-608, Waiver of Informed Consent in Greater than Minimal Risk Emergency Research).

Per Title 10 United States Code (USC) 980, a waiver of informed consent is not permitted for “research involving experimental subjects”. Department of Defense (DoD) Directive 3216.02 defines “research involving experimental subjects” as activities where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction.

This SOP does not describe procedures for waiver or alteration of consent in research involving public benefit and services programs conducted by or subject to the approval of state or local officials described at 32 CFR 219.116(e) and 45 CFR 46.116(e).

This SOP applies to Principal Investigators (PIs) or WRAIR Points of Contact (POCs), WRAIR Human Subjects Protection Branch (HSPB) Staff, WRAIR IRB members, the WRAIR IRB Chair (or designee), and the WRAIR Commander (Institutional Official; IO).

2. Responsibilities

a. The PI or WRAIR POC requests approval from the WRAIR IRB for a waiver of the requirement to obtain informed consent, waiver of documentation of consent, or alteration of elements of informed consent.

b. The HSPB staff provides assistance to PIs/WRAIR POCs regarding the requirements for a waiver of the requirement to obtain informed consent, documentation of consent, or alteration of elements of informed consent, and documents waiver determinations.

c. The WRAIR IRB Chair (or designee) and WRAIR IRB members review and approve, if appropriate, a waiver of the requirement to obtain informed consent,

documentation of consent, or alteration of elements of informed consent, in accordance with this SOP.

d. The WRAIR Commander (IO) approves implementation of a waiver/alteration of consent or disapproves implementation, in accordance with this SOP.

3. Materials and Equipment

Not Applicable

4. Procedures

a. The PI or WRAIR POC:

1) Requests a waiver/alteration of consent from the WRAIR IRB in accordance with this SOP.

2) If requesting a waiver of consent, provides a clear and complete description of the following in the protocol, Informed Consent section, or appropriate supporting documentation:

(a) Why the research involves no more than minimal risk to subjects;

(b) Why the research could not practicably be conducted without a waiver or alteration of consent;

(c) If the research involves identifiable biospecimens or identifiable private information, why the research could not practicably be carried out without using the information or biospecimens in an identifiable format;
(d) How the waiver will not adversely affect the rights and welfare of subjects (including local context considerations); and

(e) Whenever appropriate, whether and how subjects or LAR will be provided with additional pertinent information after participation.

3) If requesting a waiver of documentation, provides a clear and complete description of the following in the protocol, Informed Consent section, or appropriate supporting documentation:

(a) The only record linking the subject to the research is the consent form, the principal risk to the subject would be potential harm resulting from a breach of confidentiality, and state that each subject [or legally authorized representative (LAR)] will be asked whether he/she wants documentation

that he/she is linked with the research and the subject's wishes will govern; OR

(b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; OR

(c) If the subject or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to the subjects and there is an appropriate alternative mechanism to document that informed consent was obtained.

4) When research meets the definition of "experiment" per 10 USC 980 and the subject will not grant prospective consent, the PI must describe how the research will benefit each subject or apply for a 10 USC 980 waiver of consent through the Secretary of Defense.

b. The HSPB Staff:

1) Review the request for a waiver of consent, alteration of consent, or waiver of documentation of consent to ensure that it contains the elements required by 32 CFR 219.116, .117, and 10 USC 980, as applicable.

2) Forward requests for waiver/alteration of the informed consent process to the WRAIR IRB Chair or fully convened WRAIR IRB, as appropriate, for review and determination.

3) Notify the PI in writing of any of the following WRAIR IRB determination(s) with regard to waiver/alteration of informed consent requests:

(a) Approval – The IRB Chair (or designee) or the convened WRAIR IRB approves the waiver/alteration request and the IO approves implementation of the waiver/alteration.

(b) Request for additional information – A written request from the IRB Chair (or designee) or the convened IRB for additional information to resolve issues prior to further action.

(c) Disapproval – A written communication to the PI that includes the reason(s) for the disapproval.

4) Document the determinations and decisions regarding waivers/alterations of informed consent in the HSPB database.

5) Ensure that the determinations and decisions of the WRAIR IRB, with respect to waiver/alteration requests requiring review by the fully convened WRAIR IRB, are included in the IRB meeting minutes according to WRAIR SOP UWS-HP-628, Review of Human Subjects Research by the Fully Convened WRAIR IRB.

c. The WRAIR IRB Chair (or designee):

1) Approves of a waiver/alteration of informed consent for research qualifying for the expedited review procedure authorized by 32 CFR 219.110(b) and 45 CFR 46.110(b) (Refer to WRAIR SOP UWS-HP-613), provided the Chair (or designee) finds that:

(a) The research involves no more than minimal risk to subjects;

(b) The research could not practicably be conducted without a waiver or alteration;

(c) If the research involves identifiable biospecimens or identifiable private information, the research could not practicably carried out without using the identifiable private information or identifiable biospecimens;

(d) The waiver or alteration will not adversely affect the rights and welfare of subjects in the local context;

(e) Whenever appropriate, subjects or LAR will be provided additional pertinent information after participation; and

(f) That the requirements of 10 USC 980 have been met or a waiver is provided from the Secretary of Defense.

2) Approves of a waiver of documentation of informed consent, provided the Chair (or designee) finds that:

(a) The only record linking the subject to the research is the consent form, and the principal risk to the subject would be potential harm resulting from a breach of confidentiality and that the subject will be asked whether he/she wants documentation that he/she is linked with the research and the subjects' wishes will govern; OR

(b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; OR

(c) If the subject or LARs are members of a distinct cultural group/community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to the subjects and there is an appropriate alternative mechanism to document that informed consent was obtained.

3) May require that other conditions be met if a waiver of consent or of documentation of consent is granted (e.g., the IRB may require the investigator to provide subjects with a written information sheet regarding the research).

d. The fully convened WRAIR IRB:

1) Approves of a waiver/alteration of informed consent for research that does not qualify for the expedited review procedure if it finds that:

(a) The research involves no more than minimal risk to subjects;

(b) The research could not practicably be conducted without a waiver or alteration;

(c) If the research involves identifiable biospecimens or private information, the research could not practicably be carried out without using the identifiable private information or identifiable biospecimens;

(d) The waiver will not adversely affect the rights and welfare of subjects in the local context;

(e) Whenever appropriate, subjects will be provided additional pertinent information after participation; and

(f) That the requirements of 10 USC 980 have been met or a waiver is provided from the Secretary of Defense.

2) Approves a waiver of the requirement for the PI to obtain a signed informed consent form for all or some subjects if it determines that either:

(a) The only record linking the subject to the research is the consent form, and the principal risk to the subject would be potential harm resulting from a breach of confidentiality and that the subject will be asked whether

he/she wants documentation that he/she is linked with the research and the subjects' wishes will govern; OR

(b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; OR

(c) If the subject or LARs are members of a distinct cultural group/community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to the subjects and there is an appropriate alternative mechanism to document that informed consent was obtained.

3) May require that other conditions be met if a waiver of consent or documentation of consent is granted.

4) May not waive consent for the storage, maintenance or secondary research use of identifiable private information or identifiable biospecimens if an individual refused to provide broad consent of that information or biospecimens.

5) Ensures that the determinations and decisions of the WRAIR IRB with respect to the waiver are included in the IRB meeting minutes according to WRAIR SOP UWS-HP-628, Review of Human Subjects Research by the Fully Convened WRAIR IRB.

e. The WRAIR IO reviews and approves for implementation or disapproves a waiver/alteration of informed consent.

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

Alteration	Permission from the IRB and its Designees for a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in the Common Rule section 46.116, paragraphs (b) and (c).
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.
HSPB	Human Subjects Protection Branch, WRAIR, provides administrative support to the WRAIR IRB.

DoD	Department of Defense
FDA	United States Food and Drug Administration
Full Board Review	Review of proposed research at a convened meeting at which a majority of the membership of the IRB is present including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
Human Subject	A living individual about whom an investigator conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes, the information or biospecimens; or obtains uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.
Identifiable biospecimen	A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
Identifiable private information	Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
Informed Consent	A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. The informed consent document (consent form) communicates the necessary information in a meaningful, understandable way. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.
IRB	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. Selection for the board is in accordance with Federal guidelines outlined in 21 CFR 56.107, 32 CFR 219, and 45 CFR 46.
LAR	Legally authorized representative
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests.
PI	Principal Investigator
POC	Point of Contact
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Risk	The probability of harm or injury (physical, psychological, social, legal, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."
SOP	Standard Operating Procedure
USC	United States Code
Waiver	Permission from the IRB and its Designees to eliminate completely the requirement of consent ([waiver of consent) or the requirement to obtain written documentation of consent (waiver of documentation of consent).
WRAIR	Walter Reed Army Institute of Research
WRAIR IRB	WRAIR Institutional Review Board (IRB), the committee 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 at WRAIR, its CONUS and OCONUS Directorates, or when WRAIR funding, facilities or personnel are involved in any way (i.e. investigator). This includes human subjects research 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
45 CFR 46	Health and Human Services, Protection of Human Subjects
21 CFR 50	Food and Drug Administration, Protection of Human Subjects
10 USC 980	Limitation on Use of Humans as Experimental Subjects
DoD Directive 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
WRAIR SOP UWS-HP-608	Waiver of Informed Consent in Greater than Minimal Risk Emergency Research
WRAIR SOP UWS-HP-613	Expedited Review of Human Subjects Research
WRAIR SOP UWS-HP-628	Review of Human Subjects Research by the Fully Convened WRAIR IRB

7. Appendices and Attachments

Appendix or Attachment Number	Title
None	

8. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New	16 April 2007
.01	Updated names and titles, replaced PI responsibilities/procedures with guidance for PI	06 April 2011
.02	Review and revisions to incorporate updated guidance, policies and regulations	