



**Walter Reed Army Institute Of Research
Division of Human Subjects Protection
Standard Operating Procedure**



SOP Title	WAIVER OR ALTERATION OF INFORMED CONSENT FOR MINIMAL RISK RESEARCH	SOP No.	UWZ-C-617
		Version	.01
Effective Date	APR 06 2011	Page	1 of 10

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

	Author/Date	QA Review/Date	Approving Authority/Date
1			
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1. Purpose/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(d), 117(c) and 45 CFR 46.116(d), 117(c). The IRB may waive documentation of consent (i.e. not obtain a signed consent form for some or all subjects) or waive the consent process entirely or in part. The criteria described in this SOP also apply to a waiver or alteration of parental permission or of child assent. Waiver of informed consent, waiver of parental permission, 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 prisoners or nonviable neonates (Refer to SOP UWZ-C-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 applies to Principal Investigators (PIs) or WRAIR Points of Contacts (POCs), WRAIR DHSP 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 or alteration of the consent process.
- b. The DHSP staff provides assistance to PIs regarding the requirements for a waiver or alteration of the consent process and documents waiver determinations.
- c. The WRAIR IRB Chair (or designee) and WRAIR IRB members review and recommend approval, if appropriate, of a waiver or alteration of the consent process in accordance with this SOP.



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

3. Materials and Equipment

N/A

4. Procedures

- a. The PI or WRAIR POC:

- 1) Requests a waiver/alteration of the consent process from the WRAIR IRB in accordance with this SOP.
- 2) If requesting a waiver of the consent process, provides a clear and complete description of the following:
 - (a) How the waiver will not adversely affect the rights and welfare of subjects in the local context.
 - (b) Why the research could not practicably be conducted without a waiver or alteration.
 - (c) If appropriate, whether and how subjects will be provided additional pertinent information after participation.
- 3) If requesting a waiver of documentation only, provides a clear and complete description of the following:
 - (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; 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.



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b. The DHSP Staff:

- 1) Forwards 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.
- 2) Notifies 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 the convened WRAIR IRB recommends approval to the WRAIR Commander (IO) and the Commander approves implementation of the waiver.
 - (b) Request for additional information - A written request from the IRB Chair 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.
- 3) Notifies the WRAIR IRB of waivers approved via the expedited review procedure in accordance with SOP UWZ-C-613, Expedited Human Subjects Research Protocol Review.
- 4) Documents the determinations and decisions regarding waivers/ alterations of informed consent in the protocol file and DHSP database.
- 5) Ensures 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 UWZ-C-625, WRAIR IRB Meeting Minutes.



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c. The WRAIR IRB Chair (or designee):

- 1) Recommends approval 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 UWZ-C-613), provided the Chair (or designee) finds that:
 - (a) The local context, the rights, and welfare of subjects are taken into account and are not adversely affected by the waiver or alteration, and
 - (b) The research could not be practicably carried out without the waiver or alteration.
- 2) Recommends approval of a waiver of consent documentation, provided the Chair (or designee) finds that:
 - (a) The only record linking the subject to the research is the consent form, and the potential risk of harm to the subject could result from a breach of confidentiality; OR
 - (b) The research involves no procedures for which written consent is normally required outside of the research context.
- 3) May require that other conditions be met if a waiver of consent or of consent documentation is granted (e.g., the IRB may require the investigator to provide subjects with a written statement regarding the research).

d. The fully convened WRAIR IRB:

- 1) Recommends approval 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 in its entirety meets the definition of minimal risk,
 - (b) The local context, the rights, and welfare of the subjects are taken into account and are not adversely affected by the waiver or alteration, and



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- (c) The research could not be practicably carried out without the waiver or alteration.
- 2) Recommends approval of a waiver of the requirement for the PI to obtain a signed consent form if it determines that either:
 - (a) The research in its entirety meets the definition of minimal risk, and the research does not involve procedures for which informed consent is normally required outside the research context; OR
 - (b) The only record linking the subject and the research would be the consent document, and the potential risk of harm could result from a breach of confidentiality if the consent documents were disclosed.
- 3) May require that other conditions be met if a waiver of consent or consent documentation is granted.
- 4) 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 WZ-C-625, WRAIR IRB Meeting Minutes.
- e. WRAIR Commander (IO) reviews and approves for implementation or disapproves a waiver/alteration of informed consent.



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5. Explanation of Abbreviations and Terms

- 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
- DHSP** Division of Human Subjects Protection, WRAIR, is the administrative support to the WRAIR IRB.
- DoD** Department of Defense
- FDA** 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 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.
- 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.



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IO	Institutional Official
IRB	An Institutional Review Board or ethical review committee that reviews research involving human subjects, as per the cited regulations and policies.
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 or WRAIR POC
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
WRAIR	Walter Reed Army Institute of Research
WRAIR IRB	WRAIR Institutional Review Board (IRB), the ethical review committee or IRB 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 (i.e. investigator). This includes protocols for which recruitment of subjects is being performed at WRAIR.



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6. References

Reference Number or Author	Document Title
32 Code of Federal Regulations (CFR) 219	<i>Department of Defense, Protection of Human Subjects</i>
45 CFR 46	<i>Health and Human Services, Protection of Human Subjects</i>
21 CFR 50	<i>Food and Drug Administration, Informed Consent of Human Subjects</i>
Amdur, R.J. and Bankert, E. A.	<i>Institutional Review Board Management and Function. Boston: Jones and Bartlett Publishers.</i>
AR 70-25	<i>Use of Volunteers as Subjects of Research, 25 January 1990</i>
10 USC 980	<i>Limitation on Use of Humans as Experimental Subjects</i>
DoD Directive 3216.02	<i>Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research</i>
WRAIR SOP UWZ-C-608	<i>Waiver of Informed Consent in Greater than Minimal Risk Emergency Research</i>
WRAIR SOP UWZ-C-613	<i>Expedited Review of Human Subjects Research</i>
WRAIR SOP UWZ-C-625	<i>WRAIR IRB Meeting Minutes</i>



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7. Forms and Appendices

N/A

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	APR 06 2011