



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

SOP Title	APPEAL OF IRB DECISIONS	SOP No.	UWZ-C-612
		Version	.02
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Signatures and Date

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) documents the procedures used by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) whereby investigators can file an appeal. This process is available to all Investigators and Sponsors/ Contract Research Organizations (CROs) by request.
2. **Responsibilities:** Those taking responsibility for the actions in this SOP are the WRAIR IRB Chair, the WRAIR IRB Members, the WRAIR IRB Administrative Director, Division of Human Subjects Protection (DHSP) Staff, and the Commander, WRAIR (Institutional Official; IO). These persons are responsible for understanding the process outlined in this SOP.
3. **Materials and Equipment:** Not Applicable.
4. **Investigator Guidance:**
 - a. Upon receipt of documentation describing the WRAIR IRB's decision/opinion, including, but not limited to, disapprovals or requested modifications to a research activity, denial of a publication request or disqualification of the credentials of an Investigator, a 30-day appeals window is initiated. This window allows the Investigator to discuss the WRAIR IRB's decision with the research team and/or Sponsors and to prepare a rebuttal, if desired. Appeals after 30 days are generally not considered.
 - b. Investigators are encouraged to have an informal discussion with the WRAIR IRB Chair and WRAIR IRB Administrative Director to provide additional information regarding the context of the IRB's decision.
 - c. Investigators who wish to submit an appeal should do so by submitting a written report to the WRAIR DHSP within 30 days from receipt of the WRAIR IRB's request/determination and provide adequate reasons, or data, for asking the IRB to reconsider its decision(s). Reports can be submitted in person, by fax or by email.
 - d. An Investigator or Sponsor may appeal a determination two times. Additional appeals are rarely granted on a case-by-case basis, and only with compelling justification as determined by the WRAIR IRB Chair or the WRAIR IRB Administrative Director.



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- e. If the study required headquarters-level administrative review (HLAR) by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protections Office (HRPO), the Investigator or Sponsor may ask for a ruling by the USAMRMC ORP HRPO as part of the appeal. The Investigator or Sponsor request for a ruling by the USAMRMC ORP HRPO should be submitted as part of the appeal to the WRAIR IRB and/or the WRAIR IO.

5. Procedures:

- a. When the Investigator or Sponsor notifies DHSP or an IRB member of the intent to appeal, the notification is forwarded to the DHSP protocol point of contact (POC) to assist the Investigator or Sponsor with the processes and timelines documented in this SOP.
- b. Upon receipt of a written appeal or rebuttal, the DHSP staff member notifies the WRAIR IRB Administrative Director and the WRAIR IRB Chair. The DHSP staff member logs the appeal in the database for the study.
- c. The DHSP staff member adds the appeal or rebuttal to the next IRB meeting' agenda, and a time is arranged for the Investigator to present his/her argument to the IRB, if appropriate.
- d. At a fully convened IRB meeting, the IRB Members vote to accept or reject the appeal. They may also ask for additional information before making a final determination (Refer to WRAIR SOPs, IRB Voting Requirements, UWZ-C-610, and WRAIR IRB Meetings, UWZ-C-616). Requests for additional information are documented in the WRAIR IRB minutes and communicated to the Investigator by the DHSP (Refer to WRAIR SOP, WRAIR IRB Meeting Minutes, UWZ-C-625).
- e. When the Investigator or Sponsor requests USAMRMC ORP HRPO review (for studies that required HLAR by the USAMRMC ORP HRPO); the DHSP staff member forwards the appeal or rebuttal and supporting documentation for HLAR review. The USAMRMC ORP HRPO forwards its review, which endorses or denies the appeal, with written justification to the WRAIR IRB for their consideration. The opinion of the USAMRMC ORP HRPO is forwarded to the fully convened WRAIR IRB for consideration.



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- f. If a study is minimal risk and has not been reviewed in any capacity by the USAMRMC ORP HRPO, the WRAIR IRB's decision is final. The determination as to whether to send the appeal forward to the USAMRMC ORP HRPO is made by the fully convened WRAIR IRB and/or the WRAIR IO. If so determined, then all documentation of the appeal and determination(s) by the IRB is forwarded to the USAMRMC ORP HRPO to ensure transparency. The USAMRMC ORP HRPO forwards its review, which endorses or denies the appeal, with written justification to the WRAIR IRB for their re-consideration. The opinion of the USAMRMC ORP HRPO is forwarded to the fully convened WRAIR IRB for consideration.
- g. The Commander, WRAIR (IO) receives the IRB's determination and is the final authority in ensuring action has been taken, if appropriate. The Commander's assessment is sent to the DHSP and the Investigator in writing. The decision of the IRB to approve a study or research activity may be overruled by the Commander, WRAIR (meaning he/she may disapprove a study that has been approved by the IRB), however, neither the Commander, WRAIR, nor Sponsor have the authority to overrule the IRB rejection of a study or activity, or suspension of Investigator credentials.
- h. If the Investigator proceeds with the research in direct violation of the IRB's or Commander's determination, this action is considered serious non-compliance (Refer to WRAIR SOP, Non-Compliance Procedures, UWZ-C-606).
- i. WRAIR DHSP staff ensures that all documentation and communication pertaining to the appeal are archived in the WRAIR IRB meeting and study files.

6. Explanation of Abbreviations and Terms:

Contract Research Organization	A person or organization (commercial academic, or other) contracted by the sponsor to perform one or more of the sponsor's trial-related duties and functions
Division of Human Subjects Protection (DHSP)	Division of Human Subjects Protection, WRAIR, is the administrative branch of the WRAIR IRB.



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Human Subjects Research	Research involving humans as research subjects, or involving data, biological specimens, 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.
Institutional Review Board	(IRB) An ethical review committee that reviews research involving human subjects, as per the cited regulations and policies.
Research	Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Serious Non-Compliance	Serious non-compliance includes intentional departure from established human subject protection or other IRB policies, or rulings of the IRB specific to a research activity; unintentional departure from established human subject protection or other IRB policies, or rulings of the IRB specific to a research activity where the departure seriously jeopardized the rights and/or welfare of the subjects; human subject research conducted without IRB review and approval; human subject research conducted without legally effective informed consent; or substantive modifications to IRB-approved research without IRB approval.
Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
USAMRMC	United States Army Medical Research and Materiel Command serves as the Command Headquarters for the WRAIR.
WRAIR IRB	WRAIR Institutional Review Board reviews research involving human subjects at WRAIR, its CONUS detachments or Overseas Laboratories, or when WRAIR funding, facilities or personnel are involved in conduct of research any way (investigator, medical monitor, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is through WRAIR.



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7. References:

Reference Number or Authors	Document Title
AR-40-68	<i>Clinical Quality Management</i> , 26 February 2004.
AR-70-25	<i>Use of Volunteers as Subjects of Research</i> , 25 January 1990
WRAIR IRB Charter,	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Charter.
ICH-GCP-E6	<i>Guideline for Good Clinical Practice.</i>
OHRP	<i>Guidance on Written IRB Procedures</i> , 15 January 2007, http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm
Titles 21, 32 and 45	<i>Code of Federal Regulations</i>
Amdur, R. J. and Bankert, E. A.	<i>Institutional Review Board Management and Function (2nd Edition)</i> . (2006). Boston: Jones and Bartlett Publishers.
WRAIR SOP UWZ-C-606	<i>Non-Compliance Procedures</i>
WRAIR SOP UWZ-C-610	<i>Institutional Review Board Voting Requirements</i>
WRAIR SOP UWZ-C-616	<i>Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meetings</i>
WRAIR SOP UWZ-C-625	<i>Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meeting Minutes</i>



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8. Forms and Appendices:

Form or Appendix Number	Title
	None

9. Document Revision History:

Version Number	Brief Description of Changes	Effective Date
.00	Original SOP	18 May 2007
.01	Biennial review, to include organization name updates and updates for consistencies with current policies and procedures.	12 Aug 2009
.02	Biennial review, to include minor corrections and clarifications.	SEP 28 2009