Standard Operating Procedure
Walter Reed Army Institute of Research

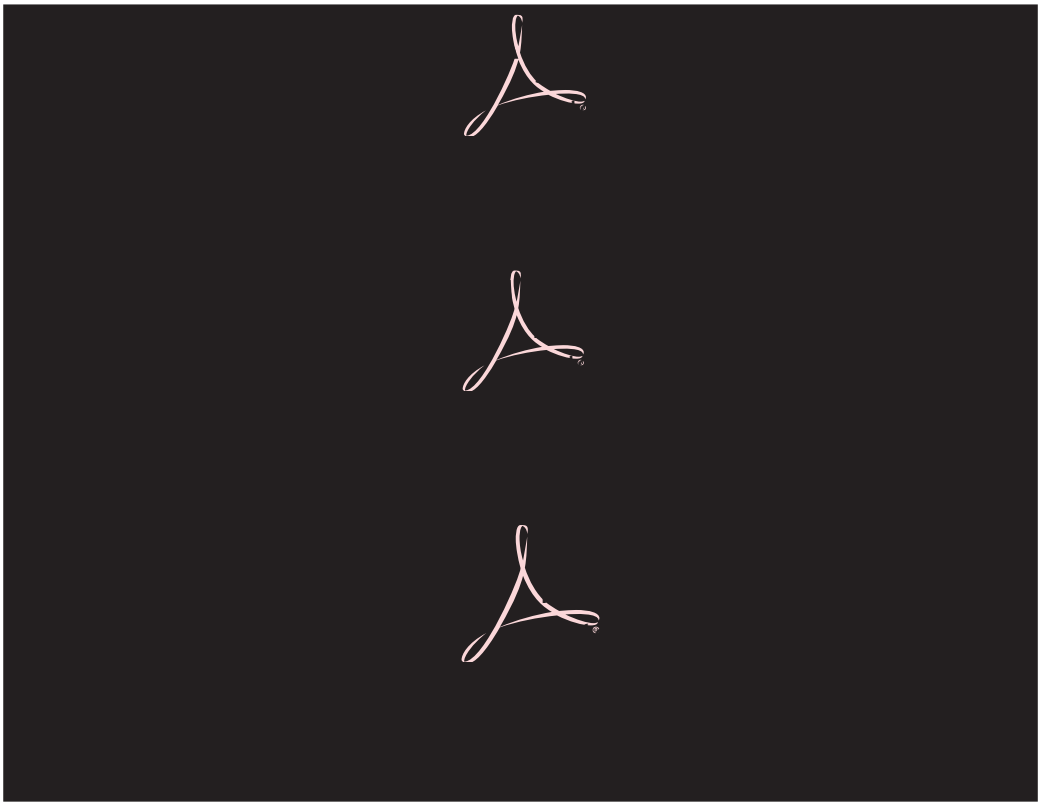
SOP:	APPEAL OF IRB DECISIONS	**SOP No.:**	UWS-HP-612
		Version:	.05
Effective Date:	21 June 2024	**Page:**	1 of 6

Signatures and Dates:

Author:

QA Review:

Approving Authority:



Review/Approval for unchanged documents

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1. Purpose and 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. Roles & Responsibilities

Those taking responsibility for the actions in this SOP are the WRAIR IRB Chair, the WRAIR IRB Members, the WRAIR IRB Administrative Director, Human Subjects Protection Branch (HSPB) Staff, and the WRAIR Commander (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, suspensions, terminations, or requested modifications to a research activity or disqualification of the credentials of an investigator, a thirty (30) calendar day window is initiated, in which an investigator may appeal the WRAIR IRB's decision. This window allows the investigator to discuss the WRAIR IRB's decision with the research team and/or Sponsor(s) and to prepare a rebuttal, if desired. Appeals after thirty (30) days will only receive consideration in rare circumstances and are at the discretion of the Commander, WRAIR, or IRB Chair.

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 appeal/rebuttal to the WRAIR HSPB within thirty (30) calendar 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). Rebuttals/appeals can be

submitted in person or by email. If submitted by email, receipt of the report will be acknowledged by a HSPB staff member.

d. An Investigator, Sponsor, or CRO (serving on behalf of the Sponsor) may appeal a determination two times. Additional appeals are granted on a case-by-case basis, and only with a compelling, strong justification as determined by the WRAIR Commander or WRAIR IRB Chair. If an additional appeal request is granted, the fully convened IRB has the final authority to approve or deny the additional appeal request. In the case of a decision by the IRB to disapprove, suspend, or terminate a protocol, the decision cannot be reversed by the WRAIR Commander.

5. Procedures

a. When the Investigator, Sponsor, or CRO notifies the HSPB or an IRB member of the intent to appeal, the notification is forwarded to the HSPB Human Subjects Protection Scientist (HSPS) to assist the Investigator or Sponsor with the process and timelines documented in this SOP.

b. Upon receipt of a written appeal or rebuttal, the HSPB staff member notifies the WRAIR IRB Administrative Director and the WRAIR IRB Chair. The HSPS member logs the appeal or rebuttal in the database for the study.

c. The HSPS member adds the appeal or rebuttal and supporting documentation to the next IRB meeting agenda, and a time is arranged for the Investigator to present his/her rebuttal/additional information for consideration 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 SOP UWS-HP-610, IRB Meetings and Voting Requirements). Requests for additional information are documented in the WRAIR IRB meeting minutes and communicated to the Investigator by the HSPB (Refer to WRAIR SOP UWS-HP-628, Review of Human Subjects Research by the Fully Convened WRAIR IRB).

e. The WRAIR Commander receives the IRB's determination and is the final authority in ensuring any required actions have been taken. The Commander's

assessment is submitted to the HSPB and the Investigator in writing. The decision of the IRB to approve a study or research activity may be overruled by the WRAIR Commander (meaning he/she may disapprove a study that has been approved by the IRB); however, neither the WRAIR Commander nor the Sponsor/CRO have the authority to overrule the IRB's disapproval, suspension, or termination of a study or activity, or suspension of investigator credentials.

f. If the investigator proceeds with the research in direct violation of the IRB's and/or Commander's determination, this action is considered serious non-compliance (Refer to WRAIR SOP UWS-HP-606, Non-Compliance Procedures).

g. The WRAIR HSPB HSPS ensures that all documentation and communication pertaining to the appeal are archived in the WRAIR IRB meeting and study files.

h. Results of the appeal will be provided to the PI and his/her Branch Director and Center Director, in writing, by the HSPS, the WRAIR Administrative Director, or the WRAIR IRB Chair.

i. If a research protocol/project is terminated, or suspended, this will be reported to the U.S. Army Medical Research and Development Command (USAMRDC) Office of Human and Animal Research Oversight (OHARO) Office of Human Research Oversight (OHRO) as per USAMRDC Command Policy 17.

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

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

7. References

Reference Number or Author	Document Title
AR-70-25	Use of Volunteers as Subjects of Research, 25 January 1990
WRAIR IRB Charter	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Charter

ICH-GCP-E6	Guideline for Good Clinical Practice.
OHRP Guidance	Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs, May 2018
Titles 21, 32, and 45	Codes of Federal Regulations
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Management and Function (3rd Edition). (2021). Boston: Jones and Bartlett Publishers.
WRAIR SOP UWS-HP-606	Non-Compliance Procedures
WRAIR SOP UWS-HP-610	Institutional Review Board Voting Requirements
WRAIR SOP UWS-HP-616	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meetings
WRAIR SOP UWS-HP-625	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meeting Minutes
USAMRDC Policy 17	Event Reporting Requirements for Human Subjects Research Conducted by the USAMRDC

8. Appendices and Attachments

Appendix or Attachment 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 August 2009
.02	Biennial review, to include minor corrections and clarifications.	28 September 2011
.03	Review and revisions to include updated guidance, policies and regulations, and minor corrections and clarifications.	01 September 2020
.04	Clarification on the additional appeals and the Commander's role as per the AHRPO Audit report and removal of HRPO review of appeals.	24 August 2022
.05	Reformatted using new WRAIR SOP template and other minor administrative and editorial changes.	21 June 2024