



WALTER REED ARMY INSTITUTE OF RESEARCH
 Human Subjects Protection Branch
 Standard Operating Procedure



SOP Title	INSTITUTIONAL REVIEW BOARD MEETING MINUTES	SOP No. Version	UWZ-C-625 .03
Effective Date	20 April 2015	Page	1 of 10

Signatures and Dates:

Signature on File at HSPB

Author:

Carson M. Cancel, M.A., CIP, CCRP
 Deputy Director

Human Subjects
 Protection Branch

17 April 2015

Date

Signature on File at HSPB

Approving Authority:

Jody L. Ference, M.S., CIP, CCRA, CIM
 Administrative Director

Walter Reed Army
 Institute of Research,
 Institutional Review
 Board

20 APR 15

Date

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
1			
2			
3			
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1. Purpose/Applicability

This Standard Operating Procedure (SOP) outlines the procedures that the Walter Reed Army Institute of Research (WRAIR) Human Subjects Protection Branch (HSPB) uses to prepare, distribute and maintain official copies of the minutes for WRAIR Institutional Review Board (IRB) meetings. This SOP aims to ensure that the IRB meeting minutes are in compliance with applicable federal, Department of Defense (DoD) and Department of the Army regulatory requirements.

This SOP applies to all WRAIR HSPB Staff, WRAIR IRB members, the WRAIR IRB Chair, the WRAIR IRB Administrative Director and the WRAIR Commander (Institutional Official; IO).

2. Responsibilities

a. HSPB Staff:

- 1) Assists in preparing, editing and finalizing the IRB meeting minutes for review and signature by the IRB Administrative Director, IRB Chair and WRAIR Commander.
- 2) Provides the finalized version of the minutes (with signatures, as noted above) to WRAIR IRB members.
- 3) Ensures finalized minutes are properly distributed, stored, and maintained.
- 4) Sends a copy of the finalized minutes to the United States Army Medical and Materiel Command (USAMRMC).

b. WRAIR IRB:

- 1) Receives the final version of the minutes and offers any edits/comments back to the HSPB.
- 2) No vote is recorded, but the submitted meeting minutes are entered into the record.

c. WRAIR IRB Chair and WRAIR IRB Administrative Director:

Review and sign the final version of the minutes.

d. WRAIR Commander (Institutional Official; IO):



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Reviews and signs the final version of the minutes.

3. Materials and Equipment

N/A

4. Procedures

- a. The HSPB Staff shall prepare the IRB Meeting Minutes to include the following as content:
 - 1) Record in the minutes to show the time period of the actual meeting, as well as the separate deliberations, actions, and votes for each protocol/protocol-related document (protocol, continuing review, amendment, Data Safety Monitoring Board report, deviation report, Serious Adverse Event Report, etc.) reviewed/discussed by the convened WRAIR IRB. The content reviewed during an IRB meeting is initially reflected in the WRAIR IRB Agenda that is sent to IRB members in the read-ahead packet. (reference Appendices A & B)
 - 2) Per the Common Rule (32 CFR 219.115), prepare WRAIR IRB meeting minutes to include the following:
 - (a) Attendance at the meetings - A quorum, to include the presence of at least one non-scientist throughout the meeting shall be stated and maintained during the course of the meeting. The list of attendees should also include the names of all non-member persons attending any part of the IRB meeting and may list them as guests, as appropriate.
 - (b) Actions/motions taken by the WRAIR IRB. This may include, but is not limited, to approval, approval with stipulations, tabling and disapproval.
 - (c) Vote on these actions/motions, including the number of members voting *for*, *against*, abstentions and recusals. (reference Voting SOP #UWZ-C-610)
 - (d) The basis for approval or requirement of changes, table/deferral or disapprovals of research.
 - (e) Written summary of the controverted issues and their resolution.
 - 3) Record, in the minutes, the special required considerations, citing the applicable regulations:



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- (a) Approving research with waiver of informed consent.
 - (b) Approving research with waiver of the documentation of informed consent.
 - (c) Approving research involving pregnant women. (Subpart B)
 - (d) Approving research involving prisoners. (Subpart C)
 - (e) Approving research involving children. (Subpart D)
 - (f) Other (e.g., 10 USC 980, applicable FDA regulations, etc.)
- 4) Record in the minutes the risk level determined by the IRB for new, revised or continuing protocols approved by the convened WRAIR IRB.
 - 5) Record in the minutes the term of approval for initial review and continuing review of protocols. The standard term of approval is 12 months. If the IRB recommends a protocol approval period of less than 12 months, include the justification for the shorter term of approval and any requirements to be fulfilled by the investigator by the end of this term.
 - 6) Record in the minutes separate deliberations, actions, and votes for each amendment or sub-study added to a protocol, including any changes to the informed consent arising from such submissions. Document when the WRAIR IRB determines that an amendment or sub-study changes the risk level of the protocol, as well as any change in the approval period.
 - 7) Record in the minutes separate deliberations, actions, and votes for each report of unanticipated problems, protocol deviations, adverse events (AEs), and serious or continuing noncompliance. The minutes shall include the determination of relatedness to the use of the study product (drug or device) or procedure. (references: Safety Reporting for Clinical Trials SOP #UWZ-C-619; Deviation and Unanticipated Problem Reporting SOP #UWZ-C-621; and Non Compliance Procedures SOP #UWZ-C-606)
 - 8) Disclose in the opening section of the meeting minutes all conflicts of interest and the circumstances in which members with conflicts of interest do not participate in the deliberations or voting.
 - 9) Document in the minutes the following, if applicable:
 - (a) IRB continuing education materials distributed



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- (b) Reports from IRB sub-committees
 - (c) Discussion of IRB administrative policies and procedures, including SOPs and training on such
 - (d) Results of any IRB compliance visits or investigation (routine post approval compliance monitoring, report of noncompliance, identified conflicts of interest, complaints, etc.)
 - (e) Expedited review discussions and any actions taken by the WRAIR IRB Chair (or designee)
 - (f) Other review items or information only items, as determined by the WRAIR IRB Administrative Director or WRAIR IRB Chair or his/her designee
- 10) Attach, as an addendum to the WRAIR IRB meeting minutes, a list of actions conducted under expedited review from the previous month: minimal risk approvals, minor amendments, continuing reviews, etc. (reference Appendix C)
- b. The Review and Approval of the WRAIR IRB Meeting Minutes require the following:
- 1) Following the IRB meeting, HSPB staff (or a contracted minutes writer) will prepare a draft version of the "IRB Communication to PI" (referred to as the communication) specific to one of the agenda items reviewed by the IRB, which once finalized, is sent to the PI and other applicable parties. The communication comprises the title of the protocol reviewed, action taken by the Board, summary of any controverted issues, and any stipulations. (See Appendix B)
 - 2) The HSPB staff member sends the draft version of the communication to the IRB Administrative Director and/or HSPB Deputy Director for comment/edits. Noted changes are incorporated into the communication.
 - 3) The HSPB staff member subsequently sends the revised version of the communication to the IRB Chair/Acting Chair and Primary/Secondary reviewers for final comment.
 - 4) Once revised, the HSPB staff member sends the final version of the communication to the PI and any additional applicable parties. The communication is generally sent to the PI within 5 working days of an IRB meeting.



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- 5) The IRB Administrative Director/Designee (or a contracted minutes writer) combines the communications, and finalizes the meeting minutes. (See Appendix B)
 - 6) The IRB Administrative Director/Designee signs the meeting minutes and provides the minutes to the IRB Chair/Acting Chair for review/signature.
 - 7) Once signed by the IRB Chair, the IRB Administrative Director provides the signed meeting minutes to the Commander for his/her review/signature.
 - 8) Relevant sections of the final minutes detailing decisions and requested revisions are sent to other appropriately interested parties (i.e., USAMRMC), upon receiving the Commander's signature on the minutes.
 - 9) Provide the final signed minutes to WRAIR IRB members in the read-ahead packet for the next IRB meeting under 'Old Business'. The committee shall note any changes, and the meeting minutes are then entered into the record.
- c. Maintenance of WRAIR IRB Meeting Minutes:
- 1) HSPB staff shall file the official copy of the WRAIR IRB minutes, meeting Agenda, and expedited review list together electronically, in chronological order (by month and year) in a locked storage room within HSPB. A complete copy of the WRAIR IRB meeting packet is also filed in the locked storage room.
 - 2) An electronic version shall also be maintained on the W:/credentialing drive in the designated meeting minutes folder.
 - 3) WRAIR IRB meeting minutes shall be available for inspection and copying by authorized representatives of the USAMRMC, DoD, or, as applicable, Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS), as appropriate and as determined by the WRAIR IRB Administrative Director.
 - 4) In addition, investigators, representatives from cooperative research groups, and private individuals may request copies of WRAIR IRB minutes under Maryland statute (House Bill 0917) or other applicable Freedom of Information (FOI) laws. Prior to making the minutes of a meeting available, the WRAIR IRB may redact confidential or privileged information (House Bill 0917); this shall be conveyed by the Public Affairs Officer. If rights of access are at all unclear, the Director, HSPB shall consult the Judge Advocate from the Office of The Surgeon General (OTSG).



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- 5) The WRAIR IRB meeting minutes shall be stored in accordance with current applicable regulations.

5. Explanation of Abbreviations and Terms

Abstain	An IRB member who does not have a conflict of interest, but otherwise feels unable to vote (e.g., left the room during the discussion, does not understand the subject matter, or did not read the protocol and supporting documents in advance of the meeting) may abstain from voting. Abstaining members contribute towards the quorum.
AE	Adverse Event
CFR	Code of Federal Regulations
CONUS	Continental United States
Expedited Review	An expedited review is a procedure permitted by 32 CFR 219, 21 CFR 56.102, and 45 CFR 46.102, by which a protocol, amendment or continuing review/final report may be reviewed and approved for human subjects research activities without convening a meeting of a full IRB. A protocol is eligible for expedited review when it meets the requirements set forth in 21 CFR 56.110.
FDA	Food and Drug Administration
HHS	Health and Human Services
HSPB	Human Subjects Protection Branch, WRAIR, is the administrative office of the WRAIR IRB.
IRB	An Institutional Review Board or ethical review committee that reviews research involving human subjects, as per the cited regulations and policies.
Motion	A formal proposal put to the vote after being seconded.
OTSG	Office of The Surgeon General



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PI	Principal Investigator
Recuse	A WRAIR IRB member that has a conflict of interest or other issue pertaining to the review and approval of a protocol must dismiss himself/herself from the meeting room during the closed discussion and vote. Recused members will not contribute towards the quorum.
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
SOP	Standard Operating Procedure
Table	When the IRB reviews a research project at a convened meeting and is unable to approve research because it cannot make the determinations required for approval, the IRB can either disapprove the project, or defer or table the project for further review at a future date. When deferring or tabling the project, the IRB, under its authority to require modifications in order for an investigator to secure approval, may require that the investigator (a) make changes to the protocol or informed consent documents, or (b) submit clarifications or additional documents prior to the next review. If the IRB defers or tables a research project, the research may not proceed until the IRB reviews the revised research project and approves it at a subsequent convened meeting.
USAMRMC ORP HRPO	(U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office) The office responsible to the Surgeon General for headquarters-level oversight of all human subject research conducted or supported by the Army.
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 (investigator, consultant, collaborator, etc.). This



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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	<i>Department of Defense, Protection of Human Subjects</i>
45 CFR 46	<i>Health and Human Services, Protection of Human Subjects</i>
21 CFR 56	<i>Food and Drug Administration, Institutional Review Board</i>
AR 15-1	<i>Committee Management</i>
AR 25-400-2	<i>The Army Records Information Management Systems (ARIMS)</i>
DoD Instruction 3216.02	<i>Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research</i>
AR 40-68	<i>Army Regulation, Clinical Quality Management</i>
AR 70-25	<i>Army Regulation, Use of Volunteers as Subjects of Research</i>
Amdur, R. J. and Bankert, E. A.	<i>Institutional Review Board Management and Function. Boston: Jones and Bartlett Publishers</i>
OHRP	<i>Guidance on Written IRB Procedures, 15 January 2007, http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm</i>
OHRP	<i>Guidance on IRB Approval of Research with Conditions http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html</i>
WRAIR SOP UWZ-C-610	<i>Institutional Review Board Voting Requirements</i>
WRAIR SOP UWZ-C-616	<i>Institutional Review Board Meetings</i>
WRAIR SOP UWZ-C-	<i>Safety Reporting for Clinical Trials</i>



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619	
WRAIR SOP UWZ-C-621	<i>Deviations and Unanticipated Problems Reporting</i>
WRAIR SOP UWZ-C-606	<i>Noncompliance Procedures</i>

7. FHSPBs and Appendices

Form or Appendix Number	Title
Appendix A	WRAIR IRB Agenda Template
Appendix B	WRAIR IRB Minutes Template
Appendix C	WRAIR IRB Expedited Review List Template

8. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New SOP	31 October 2007
.01	Review to include organization name updates and updates for consistencies with current policies and procedures.	11 January 2010
.02	Review to include change in review/approval process and updates for consistencies with current policies and procedures.	04 February 2011
.03	Review to include streamlining of process for consistency with current policies and procedures.	



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Appendix A

Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Agenda Template

This template is meant to be used as a guide when preparing an agenda for an IRB meeting. The agenda is printed on WRAIR letterhead and a signature from the IRB Administrative Director is obtained. The original is maintained with a copy of the WRAIR IRB meeting minutes on file for the record. The items on the agenda can be rearranged/changed or additional items may be added based on level of priority. Italicized statements included in parentheses are intended to be used as instructions for completion.

(LETTERHEAD)

MCMR-UWZ-C

DATE

MEMORANDUM FOR Institutional Review Board, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Ave., Silver Spring, MD 20910-7500

SUBJECT: WRAIR Institutional Review Board Meeting Agenda

The WRAIR Institutional Review Board will meet Wednesday, DATE, in Bldg. 503, Room ____, at **TIME**.

1. Old Business (*This section includes the expedited review list and may also include any finalized minutes and relevant training for the IRB (i.e., IRB training on Standard Operating Procedures.)*)
 - A) *DATE (FINAL) Minutes – for information only
 - B) *DATE Expedited Review List – for information only

*Starred items are for Information Only.



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2. New Business (*This section includes any new protocols, amendments, continuing reviews, deviation reports, unanticipated problems, serious adverse events, etc. that require review or are for information only.*)

A) The following New Protocols are enclosed for your review:

1) WRAIR # (*and any additional identifiers*): "TITLE OF PROTOCOL" (VERSION #, DATE), submitted by NAME OF THE PRINCIPAL INVESTIGATOR (or the WRAIR Point of Contact (POC) for the Protocol), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

PRIMARY REVIEWER: NAME, DEGREE
 SECONDARY REVIEWER: NAME, DEGREE
 HSPB POC: NAME, DEGREE

2) WRAIR # (*and any additional identifiers*): "TITLE OF PROTOCOL" (VERSION #, DATE), submitted by NAME OF THE PRINCIPAL INVESTIGATOR (or the WRAIR Point of Contact for the Protocol), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

PRIMARY REVIEWER: NAME, DEGREE
 SECONDARY REVIEWER: NAME, DEGREE
 HSPB POC: NAME, DEGREE

B) The following Continuing Review Reports are enclosed for your review:

1) WRAIR # (*and any additional identifiers*): "TITLE OF PROTOCOL" (VERSION #, DATE), submitted by NAME OF THE PRINCIPAL INVESTIGATOR (or the WRAIR Point of Contact for the Protocol), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

PRIMARY REVIEWER: NAME, DEGREE
 SECONDARY REVIEWER: NAME, DEGREE
 HSPB POC: NAME, DEGREE

2) WRAIR # (*and any additional identifiers*): "TITLE OF PROTOCOL" (VERSION #, DATE), submitted by NAME OF THE PRINCIPAL

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INVESTIGATOR (or the WRAIR Point of Contact for the Protocol), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

PRIMARY REVIEWER: NAME, DEGREE
 SECONDARY REVIEWER: NAME, DEGREE
 HSPB POC: NAME, DEGREE

C) The following Unanticipated Problem Reports are enclosed for your review:

- 1) WRAIR # (and any additional identifiers): "TITLE OF PROTOCOL" (VERSION #, DATE), submitted by NAME OF THE PRINCIPAL INVESTIGATOR (or the WRAIR Point of Contact for the Protocol), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

PRIMARY REVIEWER: NAME, DEGREE
 SECONDARY REVIEWER: NAME, DEGREE
 HSPB POC: NAME, DEGREE

- 2) WRAIR # (and any additional identifiers): "TITLE OF PROTOCOL" (VERSION #, DATE), submitted by NAME OF THE PRINCIPAL INVESTIGATOR (or the WRAIR Point of Contact for the Protocol), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

PRIMARY REVIEWER: NAME, DEGREE
 SECONDARY REVIEWER: NAME, DEGREE
 HSPB POC: NAME, DEGREE

D) The following *Articles/Educational Items are enclosed for your information:

- 1) Author. "TITLE," SOURCE, VOL., NO., DATE
- 2) Author. "TITLE," SOURCE, VOL., NO., DATE

Please contact the Human Subjects Protection Branch (HSPB) and state by phone (301-319-9940), by fax (301-319-9961), or by email (usarmy.detrick.medicom-wrair.mbx.hspb@mail.mil) whether you will be attending the meeting. Also, if you are aware of a conflict of interest pertaining to one of the protocols on this agenda, please

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acknowledge this when you respond regarding your attendance. It is important to know ahead of time if we have a quorum.

NAME, DEGREE
IRB Administrative Director
WRAIR Institutional Review Board

Encls

- 1 FINAL Minutes (DATE)
- 1 Expedited Review List (DATE)
- 2 New Protocols (WRAIR #s)
- 2 Continuing Review Reports (WRAIR #s)
- 2 Unanticipated Problem Reports (WRAIR #s)
- 2 Articles

*Starred items are for Information Only.



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Appendix B

Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meeting Minutes Template

This template is meant to be used as a guide when preparing the IRB meeting minutes. The meeting minutes are printed on WRAIR letterhead and a signature from the IRB Administrative Director is obtained. Included in the header of pages subsequent to the cover page is the date of the respective meeting. The final signed copy of the meeting minutes is maintained with a copy of the WRAIR IRB agenda on file for the record. Italicized statements included in parentheses are intended to be used as instructions for completion.

(LETTERHEAD)

MINUTES OF THE INSTITUTIONAL REVIEW BOARD MEETING
WALTER REED ARMY INSTITUTE OF RESEARCH

The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) met on **DAY, DATE**, in Room #, Bldg. 503. The meeting was called to order at TIME by IRB CHAIR OR IRB MEMBER PRESIDING OVER THE MEETING, to review:

Old Business

- *DATE FINAL Minutes
- *DATE Expedited Review List

New Business

- 1 New Protocol (WRAIR #)
- 1 Continuing Review Reports (WRAIR #)
- *1 Follow-Up Report (WRAIR #)
- *2 Articles

*Starred items were For Information Only.

Board Members Present *(The IRB Chair is listed first with all other members to follow listed in alphabetical order.) (The full IRB roster is attached for reference.)*

NAME, DEGREE, *(Also note those designated as non-scientists, alternate members or those not counting towards the quorum.)*

Guests *(All guests are listed in alphabetical order.)*



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NAME, DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE

Conflict of Interest Statement *(List all noted conflicts of interest to include the individual's name, the corresponding protocol number, and the rationale for conflict.)*

NAME recused herself/himself from voting on WRAIR # as he/she STATE REASON.

No other conflicts of interest were reported.

Meeting Minutes – For Information Only

Meeting Minutes from *(Date)*

(Include any comments/suggested edits, otherwise note the following.) There were no comments on the Meeting Minutes and it was entered into the record.

Expedited Review List – For Information Only

The Expedited Review List for the period of DATE is summarized as follows:
(Include bulleted summary of actions included in the expedited review list)

There were no other comments on the Expedited Review List and it was entered into the record.



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New Protocol, WRAIR #

The WRAIR IRB reviewed the following New Protocol:

WRAIR #: "STUDY TITLE", submitted by NAME of PRINCIPAL INVESTIGATOR or WRAIR POINT of CONTACT (POC), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

Motion:

To APPROVE/APPROVE WITH STIPULATIONS/TABLE/DISAPPROVE as RISK LEVEL DETERMINATION research for the TERM OF APPROVAL. INCLUDE ANY ADDITIONAL REGULATORY REQUIREMENTS (i.e., REFERENCES TO SPECIFIC REGULATIONS).

Vote:

for, # against, # abstain, # recusal
 JUSTIFICATION FOR ANY VOTES AGAINST/ABSTENTIONS/RECUSALS.

The motion was approved as stated.

(Refer to Appendix 1 for a compilation of the Board's stipulations of approval).

Communication to PI: See the DATE WRAIR IRB Minutes, Appendix 1.



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Continuing Review Report, WRAIR #

The WRAIR IRB reviewed a Continuing Review Report for the following study:

WRAIR #: "STUDY TITLE", submitted by NAME of PRINCIPAL INVESTIGATOR or WRAIR POINT of CONTACT (POC), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

Motion:

To ACCEPT/ACCEPT WITH STIPULATIONS/TABLE/NOT ACCEPT as RISK LEVEL DETERMINATION research for the TERM OF APPROVAL.

Vote:

for, # against, # abstain, # recusal
 JUSTIFICATION FOR ANY VOTES AGAINST/ABSTENTIONS/RECUSALS.

The motion was approved as stated.

(Refer to Appendix 2 for compilation of the Board's stipulations for acceptance.)

Communication to PI: See the DATE IRB Minutes, Appendix 2.



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Follow-Up Report, WRAIR # – For Information Only

The WRAIR IRB was provided a Follow-Up Report for the following protocol:

WRAIR #: "STUDY TITLE", submitted by NAME of PRINCIPAL INVESTIGATOR or WRAIR POINT of CONTACT (POC), DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE.

Background:

SUMMARY OF FOLLOW-UP REPORT

Discussion:

There was no discussion regarding this follow-up report as it was provided for information only.

[USE OF A COMMUNICATION TO PI FOR 'FOR INFORMATION ONLY' ITEMS IS ONLY NECESSARY WHEN THERE ARE REQUESTS/REQUIREMENTS FROM THE IRB; OTHERWISE, USE OF THIS APPENDIX DOES NOT APPLY]



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Articles – presented For Information Only

1. AUTHOR'S NAME (LAST NAME, FIRST NAME). *TITLE OF ARTICLE*. SOURCE. DATE
2. AUTHOR'S NAME (LAST NAME, FIRST NAME). *TITLE OF ARTICLE*. SOURCE. DATE

The meeting was adjourned at TIME.

 NAME DATE
 DEGREE, TITLE
 CHAIR/VICE CHAIR/ACTING CHAIR
 WRAIR IRB

 NAME DATE
 Administrative Director
 WRAIR IRB

Circle Below:
 APPROVED/DISAPPROVED

 NAME DATE
 RANK, DEGREE
 Commander



WALTER REED ARMY INSTITUTE OF RESEARCH
Human Subjects Protection Branch
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APPENDIX 1

From DATE WRAIR IRB Minutes, New Protocol, WRAIR #

Communication to PI, NAME of PRINCIPAL INVESTIGATOR or WRAIR POC, DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE

The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) reviewed the following new protocol:

WRAIR #: "STUDY TITLE", (VERSION #, DATE)

The fully convened WRAIR IRB voted on DATE to APPROVE/APPROVE WITH STIPULATIONS/DISAPPROVE the protocol as a RISK DETERMINATION study for CONTINUING REVIEW PERIOD, at which time a continuing review must be performed before the work can continue. The responses and revised documentation will be forwarded on to the Chair, WRAIR IRB, for expedited review and approval. [INCLUDE ANY BACKGROUND INFORMATION AS NEEDED.]

Please retain a copy of this correspondence in your files. A complete copy of the WRAIR IRB's DATE deliberations are held in the WRAIR's Human Subjects Protection Branch (Room #, Building 503).

The HSPB POC for this action is NAME, EXTENTION #. Please send any responses to usarmy.detrick.medcom-wrair.mbx.hsrb@mail.mil.



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APPENDIX 2

From the DATE WRAIR IRB Minutes, Continuing Review, WRAIR #

Communication to PI, NAME of PRINCIPAL INVESTIGATOR or WRAIR POC, DEGREE, TITLE, DEPARTMENT, BRANCH, INSTITUTE

The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) reviewed the continuing review report (dated) for the following study:

WRAIR #: "STUDY TITLE", (VERSION #, DATE)

The fully convened WRAIR IRB voted on DATE to ACCEPT/ACCEPT WITH STIPULATIONS/TABLE/NOT ACCEPT approve the Continuing Review for CONTINUING REVIEW PERIOD with the following stipulations:

IF APPLICABLE, LIST STIPULATIONS

[INCLUDE ANY BACKGROUND INFORMATION AS NEEDED.]

Please retain a copy of this correspondence in your files. A complete copy of the WRAIR IRB's DATE deliberations are held in the WRAIR's Human Subjects Protection Branch (Room #, Building 503).

The HSPB POC for this action is NAME, EXTENTION #. Please send any responses to usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil.



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Appendix C

Walter Reed Army Institute of Research (WRAIR) Expedited Review List Template

This template is meant to be used as a guide when preparing an addendum (also referred to as an expedited review list) for an Institutional Review Board (IRB) meeting. The addendum is maintained with the WRAIR Human Subjects Protection Branch (HSPB) copy of the IRB packet kept on file for the record. The items included in the addendum can vary on a monthly basis due to the type and volume of submissions to the HSPB. The referenced approval memoranda within the expedited review list are then attached for submission to the WRAIR IRB.

MONTH/YEAR Expedited Review List

ADDENDUM TO THE MINUTES OF
 INSTITUTIONAL REVIEW BOARD (IRB) MEETING
 WALTER REED ARMY INSTITUTE OF RESEARCH (WRAIR)

DATE through DATE

Please See Attached Documents

INITIAL MINIMAL RISK AND GREATER THAN MINIMAL RISK PROTOCOL APPROVALS: #

AMENDMENTS TO GREATER THAN MINIMAL RISK PROTOCOLS AND MINIMAL RISK PROTOCOLS: #

RESEARCH NOT INVOLVING HUMAN SUBJECTS DETERMINATIONS: #

AMENDMENT ACKNOWLEDGEMENTS FOR RESEARCH NOT INVOLVING HUMAN SUBJECTS PROJECTS: #

PROJECT DOES NOT QUALIFY AS A RESEARCH ACTIVITY DETERMINATIONS: #

CONTINUING REVIEW ACCEPTANCES/ACKNOWLEDGEMENTS: #

CLOSEOUT REPORT ACCEPTANCES/ACKNOWLEDGEMENTS: #