



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



SOP Title	INSTITUTIONAL REVIEW BOARD MEETING MINUTES	SOP No. Version	UWZ-C-625 .02
Effective Date	FEB 04 2011	Page	1 of 10

Signatures and Dates:

Author:

QA Review:

S. Q. V.

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			
2			
3			
4			



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1. Purpose/Applicability

This Standard Operating Procedure (SOP) outlines the procedures that the Walter Reed Army Institute of Research (WRAIR) Division of Human Subjects Protection (DHSP) 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 DHSP Staff, WRAIR IRB members, the WRAIR IRB Chair, the WRAIR IRB Administrative Director and the WRAIR Commander (Institutional Official; IO).

2. Responsibilities

a. DHSP 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 stored, maintained and distributed.
- 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 DHSP.
- 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 DHSP 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.) 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 - The list of attendees needs to include the names, earned degrees, and institutional affiliations of participating individuals and guests. Note: 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. This includes acknowledging within the minutes the times that IRB members and guests (excluding DHSP staff) enter and exit the room. 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, if 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, abstaining and recusals. (reference Voting SOP #UWZ-C-610)
 - (d) The basis for approval or requirement of changes, table/deferral or disapprovals of research.



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- (e) Written summary of the discussion of controverted issues and their resolution.
- 3) Record, in the minutes, the special required considerations, citing the applicable regulations:
- (a) Approving research with waiver of informed consent.
 - (b) Approving research with waiver of the documentation of informed consent.
 - (c) Approving research involving prisoners.
 - (d) Approving research involving children.
 - (e) Approving research involving pregnant women.
 - (f) Other.
- 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. (reference Safety Reporting for Clinical Trials SOP #UWZ-C-619)
- 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.



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- 9) IRB members are only identified by name and title in the attendees section of the minutes. Within the discussion and voting portion of the minutes, IRB members are not identified by name or title. This includes members who did not participate in the deliberations or voting (recusals and abstentions), or who voted against an action.
 - 10) Document in the minutes the following, if applicable:
 - (a) IRB continuing education materials distributed
 - (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 (conflict of interest, report of noncompliance, 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
 - 11) 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) Prepare a draft version of the minutes (usually done by a contracted minutes writer) for review by DHSP Staff, the WRAIR IRB Administrative Director, and applicable parties, as appropriate. The draft minutes are modified to include any corrections requested by the DHSP Staff and/or the Administrative Director.
 - 2) Send a copy of the draft and final versions of the "Communication to Principal Investigator (PI)" (an excerpt of the meeting minutes) and any other relevant sections of the meeting minutes, detailing requested revisions, if any, to the PI and other appropriate parties. Draft sections are written/provided in the same format as finalized versions, are reviewed by the WRAIR IRB Administrative



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Director (or designee) , IRB Chair, and/or IRB primary/secondary reviewers prior to distribution to the PI,, and are generally provided within 5 working days following an IRB meeting.

- 3) Provide the draft version of the IRB meeting minutes with incorporated changes to the IRB Chair or Acting IRB Chair.
- 4) Modify the draft minutes to include any corrections requested by the WRAIR IRB Chair and/or WRAIR IRB Administrative Director, and re-submit to both the WRAIR IRB Chair and WRAIR IRB Administrative Director for signature.
- 5) Provide the WRAIR Commander with the minutes, signed by the WRAIR IRB Chair and WRAIR IRB Administrative Director, for review and signature. Note: The version of the minutes signed by the WRAIR Commander is considered the final version.
- 6) Send relevant sections of the final minutes detailing decisions and requested revisions to the PI and other appropriately interested parties (i.e., USAMRMC), upon receiving the signature of the Commander on the minutes.
- 7) Provide the official minutes to WRAIR IRB members in the read-ahead packet under 'Old Business' for the next WRAIR IRB meeting. The committee shall note any changes, and the meeting minutes are then entered into the record.

c. Maintenance of WRAIR IRB Meeting Minutes:

- 1) DHSP staff shall file the official hard copy of the WRAIR IRB minutes, meeting Agenda, and expedited review list together in a binder, in chronological order (by month and year) in a locked storage room within DHSP. 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



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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, DHSP shall consult the Judge Advocate from the Office of the Surgeon General (OTSG).

- 5) The WRAIR IRB meeting minutes shall be retained permanently.

5. Explanation of Abbreviations and Terms

AE	Adverse Event
CFR	Code of Federal Regulations
CONUS	Continental United States
DHSP	Division of Human Subjects Protection, WRAIR, is the administrative office of the WRAIR IRB.
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
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
PI	Principal Investigator



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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
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 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>



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AR 15-1	<i>Committee Management</i>
AR 25-400-2	<i>The Army Records Information Management Systems (ARIMS)</i>
DoD Directive 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>
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>
WRAIR SOP UWZ-C-610	<i>Institutional Review Board Voting Requirements</i>
WRAIR SOP UWZ-C-619	<i>Safety Reporting for Clinical Trials</i>

7. FDHSPs 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	Biennial review to include organization name updates and updates for consistencies with current policies and procedures.	



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.02	Biennial review to include change in review/approval process and updates for consistencies with current policies and procedures.	<i>FEB 04 2011</i>
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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, DIVISION, INSTITUTE.

DHSP 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, DIVISION, INSTITUTE.

DHSP 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, DIVISION, INSTITUTE.

DHSP 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, DIVISION, INSTITUTE.

DHSP POC: NAME, DEGREE

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

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- 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, DIVISION, INSTITUTE.

DHSP 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, DIVISION, INSTITUTE.

DHSP POC: NAME, DEGREE

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

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

Please contact the Division of Human Subjects Protection (DHSP) and state by phone (301-319-9940), by fax (301-319-9961), or by email (wrairdhsp@amedd.army.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 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. In addition to the below, notations are added to the minutes when investigators/guests/members leave/enter the room. It is important to note the absence of investigators to ensure a quorum is maintained throughout the 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 (WRIAR #)
- *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.)*

NAME, DEGREE, TITLE, DEPARTMENT, DIVISION, INSTITUTE *(Also note those designated as alternate members or those not counting towards the quorum.)*



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

NAME, DEGREE, TITLE, DEPARTMENT, DIVISION, 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, DIVISION, INSTITUTE.

Background:

SUMMARY OF STUDY

Discussion:

SUMMARY OF REVIEW

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, DIVISION, INSTITUTE.

Background:

SUMMARY OF STUDY/REPORT

Discussion:

SUMMARY OF REVIEW

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, DIVISION, INSTITUTE.

Background:

SUMMARY OF FOLLOW-UP REPORT

Discussion:

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

Communication to PI: See the DATE IRB Minutes, Appendix 3.



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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



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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, DIVISION, 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, WRAIRIRB, for expedited review and approval.

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

The DHSP POC for this action is NAME, EXTENTION #. Please send any responses to WRAIRDHSP@amedd.army.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, DIVISION, 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

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

The DHSP POC for this action is NAME, EXTENTION #. Please send any responses to WRAIRDHSP@amedd.army.mil.



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



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APPENDIX 3

From the DATE WRIAR IRB Minutes, Follow-Up Report WRAIR #

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

The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) reviewed a follow-up report (dated) as information only for the following study:

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

The WRAIR IRB acknowledged the Follow-Up report (DATED). No further action is required.

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

The DHSP POC for this action is NAME, EXTENTION #. Please send any responses to WRAIRDHSP@amedd.army.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 Division of Human Subjects Protection (DHSP) 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 DHSP. 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

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: #

PROJECT DOES NOT QUALIFY AS A RESEARCH ACTIVITY DETERMINATIONS: #

CONTINUING REVIEW ACCEPTANCES/ACKNOWLEDGEMENTS: #

CLOSEOUT REPORT ACCEPTANCES/ACKNOWLEDGEMENTS: #