



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



SOP Title	CONTINUING REVIEW AND CONTINUATION DETERMINATION	SOP No. UWZ-C-618
		Version .02
Effective Date	15 January 2016	Page 1 of 14

Signatures and Dates:

Authors:

Please see HSPB

29 December 2015

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

Human Subjects
Protection
Branch
Date

Please see HSPB

31 Dec 15

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

Human Subjects
Protection
Branch
Date

Please see HSPB

15 Jan 2016

Approving
Authority:

Shon A. Remich, COL, MC
Chair

WRAIR IRB
Date

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
1			
2			



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1. Purpose/Applicability

This Standard Operating Procedure (SOP) outlines the process used to conduct continuing review (CR) and continuation determination of non-exempt human subject research protocols. The WRAIR IRB is required to conduct substantive and meaningful continuing review of human subjects research not exempt from 32 CFR 219 (Common Rule) at intervals appropriate to the degree of risk, but not less than once per year. Continuing review and continuation determination are required for all non-exempt human subjects research protocols reviewed by the WRAIR IRB until an official final closure has been granted.

This SOP applies to the WRAIR Institutional Official (IO), WRAIR IRB Members, the WRAIR IRB Chair, the WRAIR IRB Administrative Director, the Human Subjects Protection Branch (HSPB) Staff and Principal Investigators. The Continuing Review Report/Application Template is available on the WRAIR HSPB website.

2. Background

The sponsor/funding agent of the study, collaborating institutions with or without IRBs, additional Department of Defense (DoD) review requirements, study location, and the risk level of the study all contribute to how the continuing review is handled by the WRAIR IRB. Given these factors, the WRAIR IRB generally oversees the conduct of an entire study. However, there are instances where the WRAIR IRB may only review the participation of WRAIR-affiliated staff engaged in research. For extramural research (funded by another DoD component, or non-DoD agency), the WRAIR IRB serves as the IRB of record for its staff engaged in research, but there are no additional duties to ensure that Army- and DoD-specific requirements are met unless delegated this responsibility. For collaborative extramural research, each IRB serves as the IRB of record for its investigators engaged in research, unless IRB agreements are negotiated.

All IRBs must approve the CR by their established anniversary date, or WRAIR staff engaged in research must stop participation. For research sponsored by the WRAIR or sponsored by another DoD agency relying on the WRAIR IRB to ensure compliance with DoD regulations, collaborative IRBs must approve the CR prior to issuance of the WRAIR IRB CR acceptance memorandum. Communication with IRBs and collaborators at other institutions is critical to ensure effective review.

There are three types of continuing review processes conducted by the WRAIR IRB or HSPB: 1) Fully convened WRAIR IRB review (approval resulting in an acceptance from the IRB); 2) Expedited review by the WRAIR IRB Chair (or Designee) (approval



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resulting in an acceptance from the IRB Chair/Designee); and 3) WRAIR IRB Administrative Director (or designee) review of CRs performed by other institutions' IRBs where the WRAIR IRB defers review of the protocol (approval resulting in an acknowledgement by HSPB). If it is discovered during an ongoing continuing review that the risk status of a study has changed or collaborative arrangements change the determination, then this change may result in a different category of continuing review process necessary to fulfill the regulatory requirements.

Other protocol lifecycle actions such as amendments may be submitted with but not as part of the continuing review packet. The IRB reviews other protocol lifecycle actions, such as amendments, as separate items.

3. Responsibilities

Those taking responsibility for the actions in this SOP are the WRAIR IO (Commander), WRAIR IRB Chair/Designee, the WRAIR IRB Members, the WRAIR IRB Administrative Director, HSPB Staff, and Principal Investigators. These persons are responsible for understanding the process outlined in this SOP.

4. Investigator Requirements

a. The PI is expected to:

- 1) Track all IRB approvals, to include those from the collaborating institutions, as applicable, to ensure that they are all submitted in a timely manner. In collaborative research with two or more IRB reviews, it may be preferable to have all IRBs communicate and agree on a single anniversary date to simplify the review process for the investigator. HSPB can give guidance to assist in this scenario. Ideally, the same CR report is submitted to all reviewing IRBs. Of note, it is the responsibility of the PI to know all continuing review dates associated with a specific study and ensure continuing review reports are submitted in a timely fashion to avoid expiration of the study. Additionally, the PI is responsible for reporting to the HSPB/IRB any lapse(s) in approval.
- 2) Submit the required continuing review report and associated documents to the HSPB via the electronic mailbox and the HSPB Point of Contact (POC), allowing sufficient time for review and continuation determination prior to the established continuing review date. The PI responds to all requests for information/additional documents from the HSPB and/or



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WRAIR IRB, and complies with any determinations made by the WRAIR IRB regarding the continuing review.

- 3) Select a cutoff date for the CR reporting period to achieve this deadline. The next CR reporting period should start on the day following the cutoff for the previous CR period so as to ensure a continual review of protocol activities by the WRAIR IRB.
- 4) For those protocols requiring full board review, submit the complete CR report/application 60-90 days before the established continuing review date; and for those protocols that qualify for expedited review, submit the CR report/application 30-60 days before the established continuing review date. Consult HSPB to ensure appropriate submission timelines are met. Protocols received inside of 30 days are considered to be delinquent.
- 5) If IRB approval lapses, ensure no human subjects research, including data analysis, is conducted on the protocol until WRAIR IRB continuation is granted. The only exception to this is when stopping the protocol would compromise the safety of the research subjects, and this exception must be approved by the IRB Chair/Designee. Enrollment of new subjects cannot occur during the lapse of WRAIR IRB approval.

If investigators do not comply with the continuing review reporting requirements or suspension of research due to a lapse in the approval, the study is considered in non-compliance. (Refer to WRAIR SOP, Non-Compliance Procedures, UWZ-C-606)

5. OHRP Guidance

a. Determining continuing review dates:

The WRAIR IRB recognizes the Department of Health and Human Services (DHHS) Office of Human Research Protection (OHRP) timelines for CR review and approval. When the WRAIR IRB completes and approves the continuing review within 30 days before the WRAIR IRB approval period expires, the WRAIR IRB may retain the previously established anniversary date for the protocol. If the CR approval occurs prior to 30 days before the anniversary date, a new CR date must be established.

b. Multisite research:



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Continuing review of a multicenter research project by the local IRB must occur at least annually as long as the institution remains engaged in human subjects research activities involving the project. Once the institution is no longer engaged in human subjects research activities under the project, there is no regulatory requirement for continuing review by the local IRB, even if human subjects research activities are occurring at other institutions. A site closeout report will need to be submitted.

c. Expedited review of greater than minimal risk research:

A study initially reviewed and approved as greater than minimal risk may qualify for expedited review under category 8. Application of category 8 to greater than minimal risk research is determined by the status of the study at the time the continuing review is submitted. For example, if a continuing review report for a greater than minimal risk study reports that subjects participated in study interventions during the reporting period, but at the time the report is submitted, all interventions/interactions are complete, and the study is limited to data analysis, the continuing review may be reviewed under expedited review category 8.

6. Procedures for conducting continuing review

- a. As a courtesy, HSPB sends out continuing review notifications approximately 90 days prior to the expiration date of a study. The notification is sent out via email to the Principal Investigator/WRAIR point of contact; additional points of contact may be included on the correspondence. (See Appendix 1)
- b. The investigator prepares and submits the continuing review packet to the HSPB inbox using the Application to the WRAIR IRB for Continuation of Human Subjects Research and Continuing Report Review (Appendix 2) or comparable templates from other IRBs.
- c. The continuing review packet is subsequently forwarded to the appropriate HSPB POC, who:
 - 1) Checks the continuing review packet for completeness and prepares the HSPB and WRAIR IRB Member Continuing Review Worksheet (See Appendix 3), particularly noting the version of the protocol, consent, and advertisements in current use.



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- 2) Verifies that the training of the PI and the Research Monitor, as applicable, are current in accordance with their respective institutional training policies.
 - 3) Verifies the status of all other IRB approvals and assurances in the case of collaborative research with oversight by more than one IRB. Pending approvals will not delay submission to the WRAIR IRB, but are documented in the submission packet to the IRB.
 - 4) Contacts the PI or WRAIR POC to complete any deficiencies noted in the review packet. Any responses or remaining questions/concerns identified by HSPB are included with the continuing review packet provided to the IRB Chair/Designee/IRB.
 - 5) Provides the WRAIR IRB Administrative Director or designee with the continuing review packet and a recommendation to submit the continuing review packet via expedited review or to the fully constituted WRAIR IRB:
 - a) If eligible for expedited review, the packet and completed Continuing Review Worksheet are provided to the IRB Chair/Designee for review.
 - b) If full IRB review is required, the CR is scheduled for review at the next IRB meeting and the documentation is placed in the electronic meeting folder on the HSPB drive. Preliminary review by the IRB Chair or designated reviewing IRB member is strongly encouraged.
 - c) If the CR packet was not originally reviewed by the WRAIR IRB and is approved by another institution's IRB, the packet is reviewed WRAIR IRB Administrative Director or designee for subsequent acknowledgement.
- d. For both expedited and full Board review, the IRB reviewer(s) conducts a review of the continuing review package as follows:
- 1) Verifies that the investigator has provided adequate background information regarding the research project and progress to date for the continuation of the research, per the completed reviewer worksheet. (See Appendix 3)
 - 2) Establishes whether the investigator has submitted sufficient information to determine that the applicable regulatory criteria have been satisfied (e.g. 32 CFR 219.111, 45 CFR 46.111, 21 CFR 56.111, as well as, any applicable Subparts and additional regulations).



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3) The IRB reviewer(s) communicates with the PI regarding any questions or clarifications that arise during the review process; this communication is documented and retained in the WRAIR IRB protocol file.

e. Once the IRB reviewer(s) has completed their review, a determination of the protocol is made as follows:

1) Reviews conducted by the WRAIR IRB Chair or Designee via expedited review:

a) The WRAIR IRB Chair or Designee makes one of the following continuation determinations regarding the research based on their review:

(1) Approve the protocol for continuation as written.

(2) Approve the protocol for continuation with modifications:

(a) Minor (non-substantive) changes: changes of this nature are not required to secure continuation approval and may be addressed prior to the next continuing review date.

(b) Substantive changes: these changes are communicated to the PI/WRAIR POC prior to issuing approval of the continuing review. If the IRB Chair/Designee considers the responses to the stipulations to be inadequate, additional follow-up with the PI/WRAIR may occur, or the continuing review will be sent to the fully convened IRB.

(3) If the determination is non-acceptance then the continuing review is submitted to the full WRAIR IRB.

b) Determination of the period of WRAIR IRB approval is documented, but may be no more than 12 months. Justification is documented and relayed to the PI/WRAIR POC when the approval period is determined to be less than 12 months.

c) A risk determination for activities in the coming continuing review period is made, noting that the risk/engagement remains the same or has changed, identifying the new risk assessment.

d) The review/approval by the IRB reviewer is documented on the Continuing Review Report Application. (See Appendix 2)

2) Reviews conducted by the fully convened WRAIR IRB:



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- a) The reviewer presents the continuing review to the full WRAIR IRB.
- b) The WRAIR IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the committee. (32 CFR 219.107)
- c) Based on the reviewer's recommendations, the WRAIR IRB makes one of the following continuation determinations regarding the research:
 - (1) Approve the protocol for continuation as written;
 - (2) Approve the protocol for continuation with stipulations:
 - (a) Minor (non-substantive) changes ; or
 - (b) Substantive changes

When this action is selected and the modifications require changes by the PI, those required modifications are communicated to the PI or PI's POC following the IRB meeting by HSPB (generally within 5 business days). Once the PI has complied with those modifications, depending on the substantive nature of the changes, a final determination is made either by the fully convened WRAIR IRB or by the WRAIR IRB Chair when the convened WRAIR IRB remands the determination to the WRAIR IRB Chair
 - (3) Non-approval requiring re-submission to the full WRAIR IRB, which after further deliberation may:
 - (a) Approve the protocol for continuation as written;
 - (b) Approve the protocol for continuation with modifications:
 - (1) Minor (non substantive) changes
 - (2) Substantive changes, subject to review and re-approval as above;
 - (c) Suspend the protocol; or
 - (d) Disapprove/Terminate the protocol.



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- (4) Determination of the period of WRAIR IRB approval must also be documented, but may be no more than 12 months. A justification for an approval period of less than 12 months will be documented and provided to the PI/WRAIR POC. Additionally, for collaborative research with multiple IRB reviews, consideration is made to the synchronization of dates whenever feasible.
 - (5) The WRAIR IRB makes a risk determination for activities in the upcoming CR review period determining whether the level of risk to subjects remains the same or has changed.
- 3) Reviews conducted by the Director, HSPB (or designee) results in either:
- a) Acknowledgement of the other institution's IRB approval;
 - b) Recommendations to the IRB/Human Protections Administrator of the other Institution; or
 - c) Recommendation to the WRAIR Commander (IO) to dissolve the IAA, and submission of a full CR packet to the WRAIR IRB.
- e. Once a final continuation determination by the IRB, IRB Chair/Designee, or Director, HSPB (for acknowledgements), has been made and documented, it is returned to the HSPS who:
- 1) For protocols reviewed via expedited review, will generate an official continuing review acceptance memorandum for the IRB Chair/Designee to sign and send to the PI/WRAIR POC via email. (See Appendix 4)
 - 2) For protocols reviewed by the fully convened IRB, will send a communication to the PI following the meeting, summarizing the approval and any stipulations. Additionally, an official acceptance letter, signed by the WRAIR IRB Chair or Designee, will be sent to the PI/WRAIR POC. (See Appendix 4) For those studies approved with stipulations, the review of the stipulations may be addressed under separate cover.
 - 3) For protocols reviewed by the HSPB Director, will issue the acknowledgement communication to the WRAIR POC. (See Appendix 4)
- f. Closeouts
- 1) Once all study activities have ceased, to include data analysis, a closeout report is submitted by the Principal Investigator to HSPB. (See Appendix 5)



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- 2) HSPB will review the report, and provide it to the IRB Chair/Designee for WRAIR IRB-reviewed studies, or to the Director, HSPB, for studies reviewed by another IRB, along with a corresponding closeout report acceptance memo or acknowledgement memo/correspondence.
- 3) Once signed/review, the memo/correspondence will be sent to the Principal Investigator and/or WRAIR point of contact for that study.

g. Suspension or Termination of Research

There may be circumstances, under which the WRAIR IRB or Institutional Official (IO) may determine that a protocol needs to be suspended or terminated for cause. The PI and/or the PI's POC are notified promptly of a WRAIR IRB suspension or termination of the protocol with an explanation of the determination. In addition, the WRAIR IO, WRAIR Leadership, the Army Human Research Protections Office (AHRPO), the USAMRMC Office of Research Protections (ORP) Human Research Protection Office (HRPO), and, if applicable, other collaborating IRBs' officials, and the Sponsor and U.S. Food and Drug Administration are notified.

h. Storage of records documenting the WRAIR IRB continuing review

The protocol continuing review package, correspondence between the WRAIR IRB and the investigator, a copy of the acknowledgement/ acceptance or suspension/termination communication to the PI and, as applicable, a copy of the WRAIR IRB meeting minutes relating to that protocol are filed in the HSPB.

The Principal Investigator is required to maintain a regulatory file, inclusive of the continuing review and corresponding documentation.

7. Explanation of Abbreviations and Terms

- CONUS** Continental United States
- HSPB** Human Subjects Protection Branch, WRAIR, is the administrative support of the WRAIR IRB.
- DoD** Department of Defense



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- Exempt** A protocol is exempt from Human Subjects Review when it meets the requirements set forth in 32 CFR 219.101 and 45 CFR 46.101.
- Expiration** IRB approval of the protocol has lapsed and the study cannot continue unless reinstated.
- Expedited Review** An expedited review is a procedure permitted by 32 CFR 219.110, 21 CFR 56.110, and 45 CFR 46.110, by which a protocol, amendment or continuing review/final report receives IRB review and approved for human subjects research activities without being reviewed at a fully convened meeting of an IRB.
- FDA** Food and Drug Administration
- HQ** Headquarters
- Human Subjects Research** Research involving humans as research subjects, or involving biological specimens, specimens from repositories or anatomical substances of human origin. This may include the administration of questionnaires or surveys, as well as research done in an educational setting.
- WRAIR IRB** WRAIR Institutional Review Board (IRB), the ethical review committee or institutional review board, for research involving human subjects at WRAIR, its CONUS detachments or Overseas Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (investigator, medical monitor, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is being performed at WRAIR.
- IAA** Institutional Review Board Authorization Agreement
- IO** Institutional Official
- Minimal Risk** Research in which the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests.
- OCONUS** Outside of the Continental United States



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OHRP	Office of Human Research Protection
POC	Point of Contact
PI	Principal Investigator
Research	Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Sponsor	An individual, company, institution or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
SOP	Standard Operating Procedure
Suspension	An official action by the IRB to suspend the conduct of a study. Suspension does not include protocol-planned suspension (e.g., for interim data analysis).
USAMRMC	U.S. Army Medical Research and Materiel Command

8. References

Reference Number or Authors	Document Title
AR-70-25	Use of Volunteers as Subjects of Research, 25 January 1990
DoDI 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, 8 November 2011
FDA Guidance	Guidance on Continuing Review
WRAIR IRB Charter	Walter Reed Army Institute of Research Institutional Review Board (WRAIR IRB)
WRAIR HRPP	WRAIR Human Research Protection Program (HRPP)



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ICH-GCP-E6	<i>Guideline for Good Clinical Practice.</i>
Titles 21, 32 and 45	<i>Code of Federal Regulations</i>
OHRP Guidance Number Jan 2010	Guidance on Continuing Review
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Management and Function. Boston: Jones and Bartlett Publishers, 2006
WRAIR Policy Letter #11-49	Initial and Ongoing Human Subjects Protection Education and Training Requirements
WRAIR Policy Letter #12-09	Determination that an Activity is Research Involving Human Subjects
WRAIR Policy Letter #12-12	Human Subjects Research Protocol Closure Policy
WRAIR SOP UWZ-C-606	Non-Compliance Procedures
WRAIR SOP UWZ-C-613	Expedited Review of Human Subjects Research
WRAIR SOP UWZ-C-615	Amendments to Human Subjects Research Protocols
WRAIR SOP UWZ-C-624	Working with Other Institutions Engaged in Research (Assurances, IAAs, & Deferrals)
WRAIR SOP UWZ-C-634	Directed-Monitoring of Human Subjects Research
WRAIR SOP UWZ-C-625	WRAIR IRB Meeting Minutes

9. Forms and Appendices

Form or Appendix Number	Title
UWZ-C-618-A-1	Continuing Review Notifications



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UWZ-C-618-A-2	Continuing Review Application
UWZ-C-618-A-3	HSPB and WRAIR IRB Member Continuing Review Worksheet
UWZ-C-618-A-4	Continuing Review/Closeout Acceptance and Acknowledgement Templates
UWZ-C-618-A-5	Closeout Report Template

10. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	Original SOP	01 Feb 2008
.01	Re-organization of SOP outline for readability, update SOP and appendices with current WRAIR policies and procedures	12 Aug 2009
.02	Revise SOP in accordance with existing OHRP guidance and DoD policies and procedures	15 January 2016

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Appendix 1 – Continuing Review Notifications

Instructions: The example correspondences below are sent via email from the Human Subjects Protection Branch to the Principal Investigator or WRAIR point of contact approximately 90 days prior to the expiration date. Additional relevant parties are copy furnished on the email.

Acknowledgement Correspondence

The _____ Institutional Review Board (IRB) approval for the protocol listed below will expire on _____. Before that date, a continuing review report must be approved by the _____ IRB and acknowledged by the WRAIR HSPB.

To assure that research under the protocol continues uninterrupted, please submit electronically the following documents to the WRAIR Human Subjects Protection Branch (HSPB) by _____:

- Continuing review report (signed and dated by both the Branch Director and WRAIR POC)
- The _____ IRB approval for continuation of the protocol, including the date the IRB approval expires
- Copies of the most currently approved versions of the consent form and protocol

If the study has been completed, please notify the HSPB and provide a closeout report, if available.

WRAIR #

Title:

If you need any assistance, please feel free to contact me.

Best regards,

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Minimal Risk Notification Correspondence

The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) approval for the protocol listed below will expire on _____. Before that date, a continuing review report must be accepted by the WRAIR IRB if research on the protocol is to continue uninterrupted.

To assure that research under the protocol continues uninterrupted, please submit electronically the following documents to the WRAIR Human Subjects Protection Branch by _____. If these documents are not received 30 days prior to the expiration date, the continuing review will be considered delinquent:

- Continuing review report (signed and dated by both the Branch Director/Directorate and PI/POC)
- Collaborating IRB approvals (list each collaborator, if applicable)
- Copies of the most currently approved versions of the consent form and protocol
- Current Human Subjects Protection Training Certificate for the Principal Investigator (current within the last three years)
- Current Human Subjects Protection Training Certificate for the Research Monitor, if applicable (current within the last three years)

If the study has been completed, then please send a closeout report. Continuing review report and closeout report templates/models are attached here.

WRAIR Protocol #

Title:

If you need any assistance, please feel free to contact me.

Best regards,

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Greater than Minimal Risk Notification

The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) approval for the protocol listed below will expire on _____. Before that date, a continuing review report must be accepted by the WRAIR IRB if research on the protocol is to continue uninterrupted. Please note that the continuing review report should be submitted to the Human Subjects Protection Branch (HSPB), WRAIR by _____ in order for it to go before the _____ full IRB meeting.

An electronic copy of the following documentation are required:

- Continuing review report (signed and dated by both the Branch Director and PI/POC)
- Collaborating IRB approvals (list each collaborator, if applicable)
- Copy of the most currently approved consent form
- Copy of the most currently approved version of the protocol
- Copy of the most currently approved version of the Investigator Drug Brochure (if applicable)
- Deviation Log
- Adverse Events Log (to include information across all study sites)
- Current Human Subjects Protection Training Certificates for the Principal Investigator and the Research/Medical Monitor (current within the last three years)

If the study has been completed, then please send a closeout report. Continuing review report and closeout report templates/models are attached here.

WRAIR Protocol #

Title:

If you need any assistance, please feel free to contact me.

Best regards,

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Continuing Review Report (CRR)

WRAIR#:

(MRMC HRPO Log #:)

Continuing Review Number *(provide sequential report number):*

Instructions: Please submit this completed application and continuing review memorandum for all research involving human subjects to the Walter Reed Army Institute of Research (WRAIR), Human Subjects Protection Branch (HSPB) mailbox @ usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil. An alternate CRR template form may be used if the information is equivalent.

Continuing Review: The WRAIR Institutional Review Board (IRB) is required to conduct "substantive and meaningful" continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Continuing review will be conducted by the convened IRB unless the research falls into one or more of the categories appropriate for expedited review.

The information requested in this application is designed to provide the IRB with the necessary information to make the federally required determinations codified at 32 CFR Part 219, 21 CFR Parts 50, 54, & 56, and 45 CFR Part 46 Subparts B, C and D.

Incomplete answers may result in the IRB requesting additional information or clarification. Requests for amendments to the protocol must be submitted separately from this application.

Reporting Timeline: To ensure timely review and approval and avoid a lapse in the IRB approval for the protocol, it is recommended that the submission of a complete continuing review packet is made 60 - 90 days prior to the established expiration date. Protocol closeout reports are due to the WRAIR HSPB 30 days following study completion.

Additional Forms: This report should be accompanied by a Submission Memorandum as well as the applicable documents listed in part J of this report template.

Please contact the HSPB with any questions at (301) 319-9940 or by email at usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil.

Part A – Background Information

1. **Date:**
2. **Protocol Title:**
3. **WRAIR Principal Investigator/WRAIR Point of Contact *(name, title, Department/Division):***
4. **Principal Investigator, if different from above *(name):***
5. **Research Monitor, if applicable *(name, affiliation):***
6. **Sponsor or Executive Authority *(name):***
7. **Funding Source:**
8. **If the WRAIR IRB did not review this study, please identify the institutional affiliation of the reviewing *(name of institution):***
9. **Dates of this reporting period *(if the 2nd or greater report, start with the day after the last date of the previous reporting period):***
10. **Date of WRAIR IRB approval expiration:**
11. **If this is a collaborative research study list the Collaborating Institutions, their Federal Wide Assurance# and Expiration Date, and Continuing Review Approval Date**

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a. *(Name of Institutional Review Board/ERC)(FWA # and expiration date) (Continuing Review Approval Date)*

b.

c.

Part B – Current Status of Research

1. Study initiation date:

2. Study completion date (or estimated date if study still ongoing):

3. Current Status of the approved study:

- No subjects enrolled
- Active – still enrolling subjects
- Active – ongoing specimen/data analysis (for studies involving no subject enrollment/only specimens/data)
- Closed to enrollment but subjects are still on the protocol regimen
- Closed to enrollment but follow-up of subjects continues
- Closed to enrollment but analysis of specimens continues
- Closed to enrollment but analysis of identifiable/coded data continues
- Awaiting final closure by Sponsor

4. Research Risk level as determined by the IRB:

- Minimal Risk Greater than minimal risk

5. Research Sites (check all that apply):

- WRAIR facilities i.e. Bldg 503, AFRIMS, USAMRD-W, USAMRU-K, USAMRU-G (list):
- Multi-center clinical trial (list all sites):
- Other collaborating institutions (provide all institution names):

Part C – Update on Research Design and Procedures

1. Please state the objectives of the research, a summary of the research plan and methods, and summarize your findings to date, including preliminary results where available:

2. Briefly summarize any study-wide reports, monitoring reports, preliminary results or any other information that has become available since study initiation (if first CRR) or the last continuing review and that may affect the IRB's deliberations about the risks or benefits associated with the research:

3. Describe the results of the current literature search, along with the search terms and the date conducted. If there is any new and relevant information, published or unpublished, since study initiation (if first CRR) or the last continuing review, provide a brief summary and any impact that it may have to your

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research. If there has been no literature, include a statement indicating that a search of the literature revealed no new information for this subject matter. Please feel free to include as an attachment:

4. Please describe any problems with or changes in the research since study initiation (if first CRR) or the last continuing review, including the following: subject recruiting; advertising; subject compensation; inclusion or exclusion criteria; costs to subjects; investigator inducements; informed consent; documentation of informed consent; privacy or confidentiality protections; safety monitoring; vulnerable subject protections:
5. Were all changes described above prospectively reviewed and approved by the IRB and WRAIR Command prior to implementation?
 Yes No (If no, please explain):
6. Describe the activities that are planned for the protocol during the coming year (any proposed modifications should be mentioned):

Part D – Update on Subject Selection and Recruitment

1. Number of subjects approved for this study (all sites):
2. Number of subjects enrolled in this study to date (all sites):
3. Number of subjects enrolled since the end of the reporting period of the last IRB continuing review report:
4. Number of additional subjects to be enrolled in this WRAIR approved study:
5. Have any subjects been withdrawn from this WRAIR approved study to date?
 No Yes (If yes, please explain how many and why):
6. Have any subjects been excluded on the basis of race, ethnic group, understanding of English, socioeconomic status, education, gender, or pregnancy?
 No Yes (If yes, please explain):
7. **Summary Tables:** (Please complete the appropriate table(s) as they relate to the study. For example, if human subjects are being enrolled and specimens collected, then complete table 1 only. For studies solely working with specimens, then complete table 2 only).

NUMBER OF SUBJECTS ENROLLED/WITHDRAWN/APPROVED:

Table 1

Category	Total Number this Reporting Period	Cumulative Total
Number of Subjects originally authorized to screen: to enroll:		
Number Briefed:		

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Number Consented & Screened:		
Number Enrolled or Randomized:		
Number Lost (deaths, other) and reason for each:		
Number Withdrawn by Investigator and reason for withdrawal(s) of each:		
Number Withdrawn (drop outs – subject withdrew him/herself) and reason for withdrawal(s) for each:		
Number Active Subjects during this reporting period:		
Number Active Subjects at the end of this reporting period:		
Number who completed all study activities:		

Note: The sum of Subjects Active, Subjects Withdrawn, Subjects Lost, and Subjects Completed must equal Subjects Enrolled

Provide a brief description of the demographics of the subjects enrolled (e.g., groups, gender, age, ethnicity, special populations). Are there any changes from the anticipated population?

THIS SECTION IS TO BE USED FOR DATA/SPECIMEN ANALYSIS PROTOCOLS, ONLY. IF YOUR STUDY INVOLVES/INVOLVED THE ENROLLMENT OF SUBJECTS, ONLY USE THE TABLE ABOVE.

NUMBER OF SPECIMENS AUTHORIZED/UTILIZED:

Table 2

Category	Total Number this Reporting Period	Cumulative Total
Number of Specimens originally authorized to screen: Number Actually Utilized:		
Number Not Viable or Usable:		
Number Active:		
Number Completed All Study Activities:		

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Note: The sum of Specimens Utilized must equal the number of Specimens Not Usable, Specimens Active, and Specimens Completed.

Provide a brief description of the use of the specimens, origin, and comment on whether there were any non-usable specimens and why there were not usable:

8. Number of subjects enrolled:

Adults (as defined by local law):

Children (as defined by local law):

9. This study involves (check all that apply):

- | | |
|---|---|
| <input type="checkbox"/> Male | <input type="checkbox"/> Female |
| <input type="checkbox"/> U.S. Active Duty Military | <input type="checkbox"/> Foreign Active Duty Military |
| <input type="checkbox"/> Employees of the WRAIR/WRAIR Laboratories | <input type="checkbox"/> Healthy volunteers |
| <input type="checkbox"/> Pregnant Women, Human Fetuses, or Neonates | <input type="checkbox"/> Lactating Women |
| <input type="checkbox"/> Human Placental or Fetal Material, Embryos, or Stem Cells | <input type="checkbox"/> Children |
| <input type="checkbox"/> Non-English Speaking Persons (list languages): | |
| <input type="checkbox"/> Prisoners or Juvenile Offenders | |
| <input type="checkbox"/> Persons with Acute/Severe Mental/Physical Disabilities (describe): | |
| <input type="checkbox"/> Persons in a Sedated/Traumatized/Crisis State (describe): | |
| <input type="checkbox"/> Persons with Cognitive, Social, Economic, or Educational Disadvantages (describe): | |

10. Please describe any changes in the inclusion/exclusion criteria for the study, explaining any changes since the last review:

11. Are subjects or treating physicians, clinicians, or researchers being compensated or paid an incentive for referring or enrolling subjects?

- No Yes (If yes, please explain):

Part E – Update on Research Risks

1. Please describe what risks, side effects or discomforts (i.e., physical, psychological, social, and economic) have been observed since initiation (if first CRR) or the last continuing review report:

2. Please summarize any serious adverse events or unanticipated problems involving risks to subjects or others occurring since study initiation (if first CRR) or the last continuing review report, including their nature, severity, frequency, and resultant changes to the research or consent process:

a. Were all such events or problems previously reported as required to the IRB?

- Yes No (If no, please explain):

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3. Please describe any (i) unexpected adverse events and their likely cause; (ii) withdrawal of subjects from the research; or (iii) complaints about the research occurring since study initiation (if first CRR) or the last continuing review report:

a. Have these events, withdrawals, or complaints altered the conduct of the study?

4. Please describe and discuss any deviations and the corrective action plan taken since study initiation (if first CRR) or the last continuing review report. A copy of the original report describing the deviation from the protocol may be attached if it was not previously submitted. Minor deviations should be reported with the continuing review report and major deviations should be reported when they are identified and should also be summarized in this continuing review report:

5. Was/ should the protocol be changed in light of any of these events, problems, withdrawals or complaints?

No Yes (If yes, please explain):

Part F – Multi-Center Study

1. Is this a multi-center study? No Yes (If yes, please provide a brief summary of the number of subjects screened and enrolled, withdrawals, and the number and type of adverse events, unanticipated problems and deviations for each site. Please add extra columns for additional sites). This may require assistance from the study Sponsor:

Information	(Site A name)	(Site B name)
Number of Subjects originally authorized to screen:		
Number Screened:		
Number Enrolled:		
Number Withdrawn by Investigator and reason for withdrawal(s) of each:		
Number Withdrawn (drop outs – subject withdrew him/herself) and reason for withdrawal(s) for each:		
*Number of Related Adverse Events:		
*Number of Related Serious Adverse Events:		
*Number of Deaths:		
*Number of Deviations:		

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*Number of Unanticipated Problems:		
------------------------------------	--	--

* List the types of adverse events, deviations, and unanticipated problems that have occurred.

Part G – Additional Information

1. Please list any other information specific to this study that you believe the IRB should consider:
2. As the Principal investigator/WRAIR POC, do you believe that continuation of the research is justified in light of the above information?
 Yes No (If no, please explain):

Part H– Changes to Study Documents In Reporting Period

List any amendments to the protocol, informed consent forms, assent forms, investigator brochure, advertising or case report forms in the past reporting period. Ensure version numbers are included:

Part I – Update on Conflict of Interest Disclosure

Significant Financial Interests: A Significant Financial Interest is defined as an interest valued at greater than \$10,000 or an equity ownership of more than 5% held by an investigator and/or the investigator's spouse and/or dependent children.

Financial Interests (check all that apply):

- Members of the investigative team have no significant financial interests related to this research
- Members of the investigative team are disclosing the following significant financial interests (check all that apply):
 - Salary or other payment for services (e.g., consulting fees or honoraria)
 - Equity interests (e.g., stocks, stock options, or other ownership interests)
 - Intellectual property rights (e.g., patents, copyrights, or royalties from such rights)
 - Other significant financial interest that could affect, or be perceived to affect, the results of the research or educational activities funded or proposed for funding

Other Conflicts (check all that apply):

- Organizational/Institutional
- Professional/Relational
- Other: _____

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Part J – Attachments

1. Please attach the following items as applicable and check those attached:

- Current IRB approved protocol with version annotated
- Completed Principal Investigator Signature Page for the current approved protocol
- Data Monitoring Committee or Data Safety Monitoring Board report(s) during this reporting period (to be included whether or not they were previously submitted to the IRB)
- Current IRB approved Informed consent/assent/parental permission document(s) with version annotated (clean version, to be stamped)
- Current Clinical investigator’s brochure, package insert, PDR monograph, labeling information, where applicable
- Results of the current literature search, along with the search terms and the date conducted
- All advertisements, announcements, letters, or other recruiting materials
- All scales, survey instruments, questionnaires, interview scripts, etc. currently in use
- Serious Adverse Event and Deviation reports if not already submitted to the IRB.
- Copy of collaborating IRB or ethical review board approvals
- Any government, sponsor, or other audit or monitoring report during this reporting period for WRAIR/WRAIR sites
- Any available publications, presentations, abstracts, or progress reports during this reporting period that have resulted from this research
- Other (e.g., tables of study data, figures, etc.):

Part K– Principal Investigator Statement

- I certify that all investigators listed on the protocol are current in their human subjects protection training in accordance with the current WRAIR Policy: Initial and Continuing Human Subjects Protection Education and Training Requirements.

The point of contact for this action is the undersigned at () - and @ .

PI or WRAIR POC
Title
Department/Branch
(Date)

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Appendix 3 – HSPB and WRAIR IRB Member Continuing Review Worksheet

Instructions: The Cover Sheet and Part A are to be completed by WRAIR HSPB. Parts B & C are to be completed by the IRB Reviewer. Part D is only applicable when IRB review has been deferred to another institution, and is to be completed by the WRAIR HSPB Director or Designee.

COVER SHEET

WRAIR Protocol #: _____ Protocol Approval Thru-Date: _____

HRPO Log # (if applicable): _____ Dates Covering the Reporting Period: _____

Title of Protocol: _____

Risk Level: Minimal Risk Greater Than Minimal Risk

Acknowledgement (Part A & D) Acceptance (Part A, B, & C)

Continuing Review Submission Received Date: _____

Principal Investigator (name): _____

WRAIR POC (name, if different than the PI) _____

CR POC (name): _____

HSP Scientist (name): _____ IRB Reviewer (name): _____

Sponsor (name and POC, if applicable): _____

Funding Organization: _____

Collaborating Institutions (if any):

Name	Current Assurance #	Assurance Expiration Date

Collaborating IRBs:

Name	CR Approved and Date	CR Submitted	IRB Registration #

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Part A – Background Information

1. Please verify that the investigator has provided adequate information for the continuation of the proposed research.

	YES	NO	NA
a. Investigator has been using the current, approved protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Investigator has been using the current, approved informed consent/assent documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Investigator has been using the current, approved advertising	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. The investigator has signed the protocol compliance agreement page of the current protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Training is current for all investigators listed on the protocol, as verified by the PI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. The number of subjects screened and enrolled or samples collected corresponds to the number approved.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Serious and unanticipated adverse events for the whole study are summarized adequately.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. The following information since the last continuing review is provided:			
1) Unexpected adverse events and unanticipated problems involving risk to subjects or others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) Withdrawal of subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) Complaints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) Protocol Deviations and Corrective Actions Taken	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5) New information provided in study reports and recent literature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6) Updated Investigator's Brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7) Independent Safety Committee or DSMB/DMC Reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. IRB approval of Continuing Review from all collaborating institutions/host nations obtained for the CR period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Recommend monitoring visit and/or independent verification of documents (if yes, see comments below)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Initial Review Date: _____

CR Package Complete Date: _____

Recommend

Comments or Concerns:

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Part B – IRB Review of Continuing Review

Regulatory Criteria: The WRAIR IRB is required to conduct **substantive and meaningful continuing review** of research at intervals appropriate to the degree of risk, but not less than once per year. In order to approve continuation of the research, the WRAIR IRB must have sufficient information to determine that the eight required criteria codified at 32 CFR 219.111 have been satisfied.

Please verify that the investigator has submitted sufficient information to determine and the response satisfies the IRB that:

	Yes	No
a. Risks remain minimized through sound research design	<input type="checkbox"/>	<input type="checkbox"/>
b. Risks remain reasonable in relation to anticipated benefits	<input type="checkbox"/>	<input type="checkbox"/>
c. Selection of subjects or samples is equitable	<input type="checkbox"/>	<input type="checkbox"/>
d. The informed consent process is adequate (or has previously been waived by the WRAIR IRB)	<input type="checkbox"/>	<input type="checkbox"/>
e. Documentation of informed consent is adequate (or has previously been waived)	<input type="checkbox"/>	<input type="checkbox"/>
f. Safety monitoring remains adequate and appropriate	<input type="checkbox"/>	<input type="checkbox"/>
g. Provisions for the protection of privacy of subjects and the confidentiality of data/records are adequate and appropriate	<input type="checkbox"/>	<input type="checkbox"/>
h. Safeguards for vulnerable subjects are adequate	<input type="checkbox"/>	<input type="checkbox"/>
i. The research project and progress to date are described adequately.	<input type="checkbox"/>	<input type="checkbox"/>
j. Recommend monitoring visit and/or independent verification of documents (if yes, see comments below)	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

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Part C—IRB Reviewer Recommendations Summary

LEVEL OF RISK (please check):

- Remains as:**
- Minimal Risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)
 - Greater Than Minimal Risk**

- OR has changed to:**
- Exempt**
 - Research Not Involving Human Subjects**
 - Minimal Risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)
 - Greater Than Minimal Risk**

Device Category (please check one): **Not applicable** **Significant Risk** **Non-significant risk**

- Child Category** (see also Attachment 1)
- Not applicable**
 - Cat. 1 (45 CFR 46.404) minimal risk**
 - Cat. 2 (45 CFR 46.405) greater than minimal risk w/ the prospect of direct benefit to individual subjects**

Additional Regulations

- 21 CFR**
- 10 USC980**
- Other (Subpart, local, etc.)**

Independent Verification of No Material Changes Since Previous IRB Review (check one):

Not Recommended **Recommended (please comment):**

RECOMMENDED WRAIR IRB ACTION (check one):
(To be completed by the CR Reviewer)

- Approve as submitted**
- Approvable pending minor non-substantive changes described below:**
- Referral to the Fully Convened WRAIR IRB with recommendations to:**
 - Consider major substantive changes described below:**
 - Disapprove for the reasons described below:**

Comments:

Recommended Approval Period for next Continuing Review (check one):

12 months **6 months** **Other: _____** **N/A - Closeout**

Signature of Reviewer

Date

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Appendix 4 – CRR Acceptance & Acknowledgement Templates

Instructions: The continuing review/closeout acceptance memoranda templates are a word documents that are generated in hard copy/electronically for signature. The acknowledgement templates provided include text which is sent via email to the WRAIR point contact.

Continuing Review Acceptance Memorandum Template

MCMR-UWZ-C

DATE

MEMORANDUM FOR Director, Human Subjects Protection Branch (HSPB), Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Avenue, Silver Spring, Maryland 20910-7500

SUBJECT: Continuing Review Report Acceptance for the <RISK LEVEL> Human Subjects Research Protocol, WRAIR #XXXX, RV #, HRPO Log #, etc. (if applicable)

1. The continuing review report, dated <XX MONTH YEAR>, for the protocol WRAIR #XXXX entitled, "PROTOCOL TITLE" (Protocol Version X, dated <XX MONTH YEAR>), submitted by INVESTIGATOR NAME, CREDENTIALS, INSTITUTIONAL AFFILIATION is accepted.
2. The continuing review report covers the reporting period from XX MONTH YEAR through XX MONTH YEAR. STATUS OF ENROLLMENT (i.e., the study is now closed to enrollment, as of 03 June 2010).
3. INCLUDE A STATEMENT REFERENCING APPROPRIATE REGULATIONS FOR EXPEDITED REVIEW, OR INFORMATION REGARDING REVIEW DURING AN IRB MEETING. ALSO INCLUDE REFERENCES TO ANY APPLICABLE SUBPARTS REQUIRED DUE TO PARTICIPATING VULNERABLE POPULATIONS. (EXAMPLE: As this is a minimal risk protocol, the continuing review report was reviewed by expedited review procedures according to 32 CFR 219.110, 45 CFR 46.110, 21 CFR 56.110 (as applicable). This study continues to meet the requirements under 32 CFR 219.111, 45 CFR 46.111, 21 CFR 56.111 and 45 CFR 46.404, as children are participating in this minimal risk study.)
4. IF APPLICABLE, INCLUDE A STATEMENT REGARDING ANY OUTSTANDING ITEMS (i.e., stipulations, other supporting documents).
5. IF APPLICABLE, INCLUDE A STATEMENT(S) REGARDING OTHER IRB APPROVALS FROM PARTICIPATING INSTITUTIONS STATING DATE OF APPROVAL.
6. This study is sponsored by NAME OF SPONSOR and funded by NAME OF FUNDING.
7. The following documents are approved for continuation <LIST MAIN STUDY DOCUMENTS>:
 - a. Continuing Review Report, dated XXXX

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- b. Protocol, version X, dated XXX
- c. Informed Consent, version X, dated XXXX
- d. Investigator's Brochure, version X, dated XXXX

8. Per the current WRAIR Policy #11-49, "Initial and Continuing Human Subjects Protection Education and Training Requirements", an 80% grade on each individual module must be obtained. The Principal investigator is responsible for ensuring each research team member's, to include those listed on the protocol, as well as those who are not explicitly listed but may be providing study/laboratory support, human subjects protection training is current. Additionally, the PI must maintain records of documentation of this training (i.e., a staff log and training files).

9. The expiration date of this study at the WRAIR is XX XXXX 201X. The PI is responsible for submitting a continuing review report to the WRAIR Institutional Review Board (IRB) and the [NAME OF OTHER IRBS/ERCS] in time for the report to be reviewed and accepted/approved prior to the respective expiration dates to avoid an interruption in work. A closeout report or a request for an extension must be submitted to the WRAIR HSPB no later than five (5) years from the anniversary date of approval (i.e., XX XXX 201X). No changes, amendments, or addenda may be made to the protocol without prior review and approval by the WRAIR IRB, [NAME OF OTHER IRBS/ERCS].

10. The point of contact for this action is NAME OF POC, at CONTACT INFORMATION.

NAME OF IRB CHAIR Credentials
Chair (Designee), Institutional Review Board
Walter Reed Army Institute of Research

CF:
PI
PI's SUPERVISOR (DEPT & DIV)
COLLABORATORS
REGULATORY PERSONNEL
MCMR-RP
OTHERS

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Continuing Review Acknowledgement Template

LTC XXXX:

This is to acknowledge the continuing review report, dated XXXX, for the greater than minimal risk protocol, WRAIR #XXXX; HRPO Log #A-XXXX, entitled, "*Title*," version XX, dated XXXX, submitted by *Name, Rank, Title, Institution*. The XXX Institutional Review Board (IRB) approved the study for continuation on XXXX, with an expiration date of XXXX.

In accordance with the existing Institutional Agreement for IRB Review (IAIR) between the Walter Reed Army Institute of Research (WRAIR) and XXXX, WRAIR defers IRB review to XXXX. WRAIR Commander Approval Authorization will be required for each amendment and continuing review reports must be submitted to the WRAIR Human Subjects Protection Branch (HSPB) for acknowledgement.

The expiration date of this study is XXXX, per the XXXX IRB. The Principal Investigator (PI) is responsible for submitting a continuing review report to the XXXX IRB, in time for the report to be reviewed and accepted prior to the respective study expiration dates. The WRAIR POC is responsible for submitting these documents to the WRAIR HSPB for acknowledgement prior to the expiration date. No changes, amendments, or addenda may be made to the protocol without prior approval from the XXXX IRB, as well as WRAIR Commander Approval Authorization and XXXX Commanding Official Approval, as appropriate.

Best wishes,

*WRAIR HSPB POC, Credentials
Contact Info*

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Closeout Report Acceptance Template

MCMR-UWZ-C

DATE

MEMORANDUM FOR Director, Human Subjects Protection Branch (HSPB), Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Avenue, Silver Spring, Maryland 20910-7500

SUBJECT: Closeout Report Acceptance for the <RISK LEVEL> Human Subjects Research Protocol, WRAIR #XXXX, RV #, HRPO Log #, etc. (if applicable)

1. The closeout report, dated <XX MONTH YEAR>, for the protocol WRAIR #XXXX entitled, "PROTOCOL TITLE" (Protocol Version X, dated <XX MONTH YEAR>), submitted by INVESTIGATOR NAME, CREDENTIALS, INSTITUTIONAL AFFILIATION is accepted.
2. The primary objective of this study was [INCLUDE A STATEMENT REGARDING THE PRIMARY OBJECTIVE].
3. INCLUDE A STATEMENT(S) REGARDING DISPOSITION OF THE SPECIMENS/DATA.
4. IF APPLICABLE, INCLUDE A STATEMENT(S) REGARDING OTHER IRB APPROVALS FROM PARTICIPATING INSTITUTIONS STATING DATE OF APPROVAL.
5. This study is sponsored by NAME OF SPONSOR and funded by NAME OF FUNDING.
6. The study is now closed. Please note that the PI is responsible for notifying all investigators, collaborators, and study and laboratory personnel that the study is now closed. No further use of specimens or data can occur until a new protocol is approved and authorized by the WRAIR.
7. The point of contact for this action is NAME OF POC, at CONTACT INFORMATION.

NAME OF IRB CHAIR Credentials
Chair (Designee), Institutional Review Board
Walter Reed Army Institute of Research

CF:
PI
PI's SUPERVISOR (DEPT & DIV)
COLLABORATORS
REGULATORY PERSONNEL
MCMR-RP
OTHERS

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Closeout Report Acknowledgement Template

LTC XXXX:

This is to acknowledge the closeout report, dated XXXX, for the greater than minimal risk protocol, WRAIR #XXXX; HRPO Log #A-XXXX, entitled, "*Title*," version XX, dated XXXX, submitted by *Name, Rank, Title, Institution*. The XXX Institutional Review Board (IRB) approved the closeout report on XXXX, and the study is now closed.

Please note that the Principal Investigator (PI) is responsible for notifying all investigators, collaborators, and study/laboratory personnel that the study is closed. No further use of specimens or data can occur until a new protocol is reviewed and approved by all applicable Institutional Review Board (IRBs) or their corresponding regulatory offices.

Please keep a copy of this email with your regulatory file. Should you have additional questions regarding this action, please feel free to contact me.

Best wishes,

*WRAIR HSPB POC, Credentials
Contact Info*

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(Office Symbol)

(Date)

MEMORANDUM THRU Director, NAME OF BRANCH

FOR Director, Human Subjects Protection Branch, Walter Reed Army Institute of Research, Silver Spring, MD 20910-7500

SUBJECT: Closeout Report for Human Subjects Research Protocol (Insert Protocol Name, WRAIR #, HSRRB Log # - This report should be 1-2 pages in length. It should include a brief abstract as well as the approximate start and end dates of actual data collection)

1. **RESEARCH OBJECTIVES:** (Describe the protocol objectives in 1-2 sentences. Add dates that are covered by the report. Also, include the approximate dates data collection started and data collection ended).

2. **NUMBER OF SUBJECTS ENROLLED/WITHDRAWN/APPROVED:** (Tell how many subjects have been enrolled into the protocol. If any subjects withdrew/were withdrawn, state how many and why. Also, state the number of subjects that was originally approved. If modifications have been approved increasing the sample size, please state this and provide dates of approval.)

3. **CURRENT LITERATURE:** (If there have been any publications, provide a brief summary and any relevance it may have to your research. If there has been no literature, include a statement indicating that a search of the literature revealed no new information of this subject matter. Please include the keywords used to conduct the literature search and any database searches.)

4. **SIDE EFFECTS:** (Give a brief description of all the side effects observed and their severity. Did any adverse effects occur, and were they expected or unexpected? If any unexpected side effects occurred, state what they are, whether they were reported as required, and if a protocol modification has been/will be submitted to add the side effects to the consent form for future subjects.)

5. **SUMMARY OF RESULTS TO DATE:** (Give a brief summary of your results in 1-2 paragraphs. If any deviations from the protocol occurred, they should be described and discussed in a separate paragraph under this section of the report. A copy of the original report describing the deviation from the protocol may be attached.). Copies of publications and presentations from this study may be included as attachments.

6. **SPECIMEN AND DATA MANAGEMENT:** (Give a brief description of how specimens and data are managed. The following items should be addressed: (1)

SOP Title	CONTINUING REVIEW AND CONTINUATION DETERMINATION	SOP No.	UWZ-C-618 Appendix 5
		Version	.02
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Specify if specimens are currently being stored; (2) If yes, identify where the specimens are being stored and the length of time specimens will be kept; (3) Identify where the database is being kept and by whom; and, (4) Describe the provisions in place in assuring subject confidentiality is maintained.

7. FUTURE PLANS: (Analysis of data? Submission of a new protocol to expand on results?)

8. Be sure to include short summary of the protocol.

(Signature of PI)
(Signature block of PI)