



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
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Signatures and Dates;

*[Handwritten signature]*

For signatures, please see original in the  
Division of Human Subjects Protection

Review/Approval for unchanged documents

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



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



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## 1. Purpose/Applicability

This Standard Operating Procedure (SOP) outlines the procedures used to conduct continuing review (CR) and continuation determination of human subject research protocols by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB), previously known as the Human Use Review Committee (HURC). 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 protocols reviewed by the WRAIR IRB until an official final closure has been granted.

This SOP applies to the WRAIR IRB Members, the WRAIR IRB Chair, the WRAIR IRB Administrative Director, and the Division of Human Subjects Protection (DHSP) Staff. The Continuing Review Cover sheet/Checklist and Template will be posted on the WRAIR DHSP website.

## 2. Background

The sponsor/funding agent of the study, collaborating institutions with or without IRBs, and the risk level of the study all contribute to how the continuing review is handled by the WRAIR IRB. Notable, for all studies funded or sponsored by the U.S. Army Medical Research and Materiel Command (USAMRMC) or other Army funding agencies (intramural research), the WRAIR IRB serves not only as the IRB of record for the WRAIR investigators engaged in research, but also serves as the review authority to ensure that Army- and Department of Defense (DoD)-specific requirements are met by all parties engaged in research (unless a headquarter's level administrative review is required). As such, the WRAIR IRB oversees the conduct of the entire study. Generally, when there is more than one DoD IRB reviewing the study, the DoD IRB of record should be the one serving the Institution of the Principal Investigator (PI) and that IRB assumes responsibility to ensure that DoD-specific requirements are met. If this is not the WRAIR IRB, its review only serves the ongoing participation of WRAIR staff engaged in research.

For extramural research (funded by another DoD department, 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.



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### **3. Responsibilities**

Those taking responsibility for the actions in this SOP are the WRAIR IRB Chair, the WRAIR IRB Members, the WRAIR IRB Administrative Director, Division of Human Subjects Protection (DHSP) Staff, and the Commander, WRAIR (Institutional Official; IO). These persons are responsible for understanding the procedures outlined in this SOP.

### **4. Investigator Guidance**

a. The PI is expected to:

- 1) Submit the required continuing review report and associated documents to the DHSP via the DHSP electronic mailbox (WRAIRDHSP@amedd.army.mil) and the DHSP 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 from the WRAIR IRB or DHSP, and complies with any determinations made by the WRAIR IRB regarding the continuing review
- 2) Select a cutoff date for the CR period to achieve this deadline. The next CR 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
- 3) Submit the CR report/application 60-90 days before the established continuing review date. However, the timeliness of the WRAIR IRB review is dependent on the timing and completeness of the submission of the completed CR application by the PI or PI's POC. Ideally, the WRAIR IRB review begins approximately 30-60 days before the protocol continuing review date
- 4) Ensuring that no human subjects research, including data analysis, is conducted on the protocol until WRAIR IRB continuation is granted if the IRB approval lapses without continuing review approval. The only exception to this is when stopping the protocol would compromise the safety of the research subjects, and this exception must be acknowledged by the IRB Chair. 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



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study is considered in non-compliance. (Refer to WRAIR SOP, Non-Compliance Procedures, UWZ-C-606)

- 5) Track IRB approvals from the collaborative institutions if the research is collaborative in nature to ensure that they are all submitted in a timely manner. In collaborative research with two or more IRB reviews, it is ideal to have all IRBs communicate and agree on a single anniversary date to simplify the review process for the investigator. DHSP can give guidance to assist in this scenario. Ideally, the same CR report is submitted to all reviewing IRBs

**5. General Guidance**

- a. Explanation of the Timelines Pertaining to the WRAIR IRB Continuing Review Process:

All IRBs must approve the CR by their established anniversary date, or their 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 continuing review prior to issuance of the WRAIR IRB CR approval letter. Likewise in international research, the host nation's IRB CR approval is required to continue research with its citizens. In this fashion, the WRAIR IRB CR approval letter serves as an equivalent for continuation to the command implementation letter issued at the start of the research. Communication with IRBs at other collaborating institutions is critical to ensure effective review.

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.

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 (Refer to WRAIR SOP, Amendments to Human Subjects Research, UWZ-C-615).

- b. Types of Continuing Review



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- 1) There are three types of continuing review processes conducted by the WRAIR IRB or DHSP
    - a) Fully convened WRAIR IRB review (approval resulting in an acceptance)
    - b) Expedited review by the WRAIR IRB Chair (or designee) (approval resulting in an acceptance)
    - c) 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)
  - 2) Each human subjects research protocol undergoes a review depending on the WRAIR IRB determined risk level to the subjects, review requirements imposed by the DoD, sponsor, funding agency, and location of the study, and collaborative research arrangements with other DoD or non-DoD IRBs
  - 3) If it is discovered during an ongoing continuing review that the protocols has changed the risk status of the study or collaborative arrangements change the determination (i.e., exempt or research not involving human subjects, refer to WRAIR Policy Letter #08-03), then this change may result in a different category of continuing review process requirements necessary to fulfill the regulatory requirements
- c. Responsibilities based on the types of continuing review for research conducted by the WRAIR IRB
- 1) The fully convened WRAIR IRB
    - a) Conducts continuing review on WRAIR greater than minimal risk studies that require full board review. These studies were originally submitted to the full WRAIR IRB for review and initial approval
    - b) Reviews any studies that need additional input from the full WRAIR IRB as determined during expedited review by (Refer to WRAIR SOP, Expedited Review of Human Subjects Research, UWZ-C-613) the WRAIR IRB Administrator, WRAIR IRB Chair (or designee)
    - c) Provides instructions to investigators regarding the status of the protocol's continuing review submission, and additional documentation necessary for its approval



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- d) Reviews and ensures the adequacy of the informed consent document(s) and process
  - e) Determines if compliance monitoring is warranted to verify from sources other than the investigator that no material changes have occurred since the previous WRAIR IRB review (See WRAIR SOP, Directed-Monitoring of Human Subjects Research, UWZ-C-634)
  - f) Approves, approves with stipulations, suspends, or terminates the research or revokes continuation of any protocol under its review
  - g) Establishes the next continuing review date and risk category for the continuing review period
  - h) Documents in the meeting minutes the status of the continuing review package, the continuation determination and any stipulations that need to be addressed. The minutes reflect separate deliberations, actions and votes for each protocol undergoing continuing review
- 2) The WRAIR IRB Chair (or designee)
- a) May delegate his/her responsibility to a qualified voting WRAIR IRB member
  - b) Conducts continuing review on all minimal risk studies, unless the IRB requests a convened board continuing review
  - c) Provides instructions to investigators regarding the status of the continuing review submission, and additional documentation necessary for its approval
  - d) Approves or approves with stipulations the continuation of a protocol under review; OR refers to the fully convened WRAIR IRB any continuing review that is not eligible for expedited review
  - e) Establishes the next continuing review date and anticipated category of continuing review required
- 3) The WRAIR IRB Administrative Director (or designee)
- a) Reviews continuing review and IRB approval conducted by the USAMRMC Human Subjects Research Review Board, or another IRB



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under an IRB Authorization Agreement (IAA) (See WRAIR SOP, Working with Other Institutions Engaged in Research [Assurances, IAAs & Deferrals], UWZ-C-624). Resolves questions from the IRB review as they pertain to WRAIR engagement in the research

- b) Provides instructions to investigators regarding the continuing review submission
- c) Issues an acknowledgement memorandum on behalf of the DHSP

4) Signatures

- a) The WRAIR IRB Chair, or WRAIR IRB member designee, on behalf of the fully convened WRAIR IRB, reviews and signs the continuing review report acceptance letters for CR completed by the full board
  - b) The WRAIR IRB Chair or WRAIR IRB member designee reviews and signs the continuing review reports eligible for expedited review or downgraded to exempt or research not involving human subjects
  - c) The WRAIR IRB Administrator or designee reviews and signs continuing review submission acknowledgement letters for the studies conducted under another institution's IRB for studies not originally reviewed by the WRAIR IRB
- 5) The WRAIR IRB or Institutional Official (IO) may determine in rare cases that the protocol needs to be suspended or terminated for cause. The PI and/or the PI's POC is notified promptly of a WRAIR IRB suspension or termination of the protocol with an explanation of the determination as per WRAIR SOP, Protocol Closure, Suspension, Reinstatement, and Extension UWZ-C-622. In addition, the WRAIR IO, management, 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
- 6) Procedures for notifying the full WRAIR IRB of continuing review determinations conducted by expedited review (refer to WRAIR SOPs, Expedited Review of Human Subjects Research, UWZ-C-613, and WRAIR HURC Meeting Minutes, UWZ-C-625)

Documentation is included in the WRAIR IRB monthly meeting minute's addendum (expedited review list) regarding the status of the continuing



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reviews and continuation determinations conducted via expedited review, including changes required as part of previous provisional approvals. The specific expedited review category must be included in the documentation

7) 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 DHSP

**6. Procedures for conducting continuing review**

- a. The investigator prepares and submits the continuing review packet using the Application to the WRAIR IRB for Continuation of Human Subjects Research and Continuing Report Review (Appendix 1) or comparable templates from other IRBs
- b. The continuing review packet is sent to the appropriate Human Subject Protection Scientist, who
  - 1) Prepares the DHSP and WRAIR IRB Member Continuing Review Worksheet (Appendix 2)
  - 2) Checks the continuing review packet for completeness in accordance with Appendix 2, with attention to the version of the protocol, consent, and advertisements in current use
  - 3) Verifies that the training of the PI, medical monitor and any investigators listed on the protocol is up-to-date as per the education policy (WRAIR Policy Letter #08-07)
  - 4) Verifies the status of all other IRB submissions and approvals in the case of collaborative research with oversight by more than one IRB. Pending approvals will not delay submission to the WRAIR IRB, but must be documented in the submission packet to the IRB
  - 5) Contacts the PI or WRAIR POC to complete any deficiencies noted in the review packet
  - 6) Contacts the WRAIR IRB Chair with a recommendation to submit the continuing review packet to expedited review or the fully constituted WRAIR IRB



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- a) If eligible for expedited review, sends a copy of the packet and Continuing Review Worksheet to the IRB reviewer
- b) If going to the full IRB, request that the CR be reviewed at the next IRB meeting and provide the documentation in the electronic meeting folder on the DHSP drive. Preliminary review by the IRB Chair or designated 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 forwarded to the WRAIR IRB Administrative Director for
  - 1) Due diligence review
  - 2) Adequate documentation of IRB actions
- c. The IRB reviewer(s) conducts a review of the continuing review package as follows
  - 1) Verifies that the investigator has provided adequate background information for the continuation of the research by assessing if
    - a) The number of subjects screened and enrolled corresponds to the numbers approved by the IRB
    - b) The research project and progress to date are described adequately
    - c) Serious and unanticipated adverse events for the whole study are summarized adequately and have been submitted in a timely manner to the IRB, and any concerns have been sufficiently resolved by the investigator for the Sponsor and/or IRB
    - d) Other safety reports from the Sponsor or safety monitoring committee/data and safety monitoring board have been reviewed
    - e) The following information since the last IRB review is described adequately
      - (1) Unexpected adverse experiences and unanticipated problems involving risks to subjects and others
      - (2) Withdrawal of subjects
      - (3) Complaints



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- (4) Protocol deviations and corrective actions taken
  - (5) New information provided in the protocol reports and recent literature review (preferably with search terms included)
  - (6) Data and Safety Monitoring Board or Safety Monitoring Committee Reports (as applicable)
- 2) Establishes whether the investigator has submitted sufficient information to determine that the following regulatory criteria have been satisfied
- a) Risks remain minimized through sound research design
  - b) Risks remain reasonable in relation to anticipated benefits
  - c) Selection of subjects remains equitable
  - d) The informed consent process is adequate (or has been previously waived by the WRAIR IRB)
  - e) Documentation of informed consent is adequate (or has previously been waived by the WRAIR IRB)
  - f) Safety monitoring is adequate and appropriate. When a medical monitor is designated, he/she is engaged and is completing requested functions as designated by the IRB
  - g) Provisions for the protection and privacy of subjects and the confidentiality of data/records remain adequate and appropriate
  - h) Safeguards for vulnerable subjects remain adequate
  - i) Research project and progress to date are described adequately
- 3) Makes a determination whether a protocol needs verification from sources other than the investigator that no material changes have occurred since the previous WRAIR IRB review. This may include, but is not limited to
- a) Requesting the PI to contact the Sponsor / Contract Research Organization for verification of protocol/consent versions
  - b) DHSP/WRAIR IRB compliance monitoring of the site prior to the expiration of approval, or as a requirement for re-approval after expiration (refer to WRAIR SOP, Directed Monitoring of Human



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Subjects Research, UWZ-C-634 for summary of scenarios that may require directed-review, or monitoring)

- 4) The CR 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
- d. Once the IRB reviewer(s) has completed their review, a determination of the protocol is made as follows
  - 1) Reviews conducted by the fully convened WRAIR IRB
    - 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
        - (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. 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 requires re-submission to the full WRAIR IRB, which after deliberation of the same issues, may
      - (a) Approve the protocol for continuation as written



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- (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
  - (d) Disapprove/Terminate the protocol
  - (4) Determination of the period of WRAIR IRB approval must also be documented, but may be no more than 12 months. 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 to exempt, research not involving human subjects, minimal risk or greater than minimal risk.
- 2) 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
      - (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. Once the PI has complied with those modifications, depending on the substantive nature of the changes, a final determination is made either by the WRAIR IRB Chair or is referred to the fully convened WRAIR IRB
- (3) If the determination is non-approval then this requires submission to the full WRAIR IRB, as in 6d above



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- b) Determination of the period of WRAIR IRB approval is documented, but may be no more than 12 months
- c) A risk determination for activities in the coming CR review period is made as follows
  - (1) Level of Risk to Subjects: remains the same or has changed to exempt, research not involving human subjects, or minimal risk
  - (2) If the level of risk is determined to be greater than minimal risk, then the next continuing review will be referred to the fully convened WRAIR IRB
- 3) Reviews conducted by the Director, DHSP (or designee) results in either:
  - a) Acknowledgement of the other institution's IRB approval
  - b) Recommendation to the WRAIR Commander (IO) to dissolve the IAA, and submission of a full CR packet to the WRAIR IRB
- e. Procedures for notifying the PI of the continuing review determination
  - 1) Once a final continuation determination by the IRB, IRB Chair, (or Director, DHSP for acknowledgements) has been made and documented, it is returned to the DHSP
  - 2) An official acceptance or acknowledgement letter, and the WRAIR IRB draft meeting minutes of the continuing review (as applicable) will be communicated to the PI or the PI's POC notifying them that the protocol continuation has been approved or provisionally approved (with provisions listed). The next date of continuing review is documented within the letter or minutes
    - If provisionally approved, changes are re-submitted to the DHSP and the IRB for review
  - 3) Official letters are generated, using the models identified in Appendices 3 and 4. Alterations to the models may be needed to fit individual circumstances

**7. Explanation of Abbreviations and Terms**

CONUS

Continental United States



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- DHSP** Division of Human Subjects Protection, WRAIR, is the administrative branch of the WRAIR IRB.
- DoD** Department of Defense
- 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** A protocol has reached its projected ending date.
- Expedited Continuing Review** Continuing review of research previously approved by a convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for the long term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis. Additionally, continuing review of research not conducted under an investigational new drug application or investigational drug exemption where expedited review categories two thru eight (21 CFR 56, 32 CFR 219, 45 CFR 46) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- 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 includes 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



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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
- 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	<i>Use of Volunteers as Subjects of Research, 25 January 1990</i>
WRAIR IRB Charter	Walter Reed Army Institute of Research Institutional Review



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	Board (WRAIR IRB)
WRAIR HRPP	WRAIR Human Research Protection Program (HRPP)
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 2007	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 #08-07	Initial and Ongoing Human Subjects Protection Education and Training Requirements
WRAIR Policy Letter #08-03	Determination that an Activity is Research Involving Human Subjects
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-622	Protocol Closure, Suspension, Reinstatement, and Extension
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

**9. Forms and Appendices**

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UWZ-C-618-A-1	Application to the WRAIR IRB for Continuation of Human Subjects Research and Continuing Report Review
UWZ-C-618-A-2	DHSP and WRAIR IRB Member Continuing Review Worksheet
UWZ-C-618-A-3	WRAIR IRB Acceptance Model (for studies reviewed by the WRAIR IRB)
UWZ-C-618-A-4	CR Acknowledgment Model (for studies where WRAIR did not originally review the protocol)
UWZ-C-618-A-5	CRR Notification Memos

**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	

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**Appendix 1 - Application to the WRAIR IRB for Continuation of Human Subject Research and Continuing Report Review**

**Instructions:** Please submit this completed memorandum for all research involving human subjects to the WRAIR Division of Human Subjects Protection (DHSP). Please contact DHSP if you have any questions at (301) 319-9940 or by email at [WRAIRDHSP@amedd.army.mil](mailto:WRAIRDHSP@amedd.army.mil).

**Continuing Review:** 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. Continuing review will be conducted by the convened WRAIR 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 WRAIR IRB with the necessary information to make the Federally required determinations codified at 32 CFR 219, 21 CFR Parts 50,54, & 56, and 45 CFR 46 Subparts B,C, and D. Incomplete answers may result in the WRAIR IRB requesting additional information or clarification. An alternate IRB template form may be used if the information is equivalent.

Requests for amendments to the protocol must be submitted separately from this request for continuation of your human research protocol.

**Reporting Timeline:** To ensure timely review 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. CR submission less than 30 days prior to the established expiration date are consider delinquent, and will prompt command notification. Protocol closeout reports are due 30 days following study completion.

Contact the DHSP at 301-319-9940 or by email at [WRAIRDHSP@amedd.army.mil](mailto:WRAIRDHSP@amedd.army.mil) if questions arise.

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MCMR-UWZ-~~xx~~

date

MEMORANDUM THROUGH DIRECTOR, DIVISION OF ~~xxx~~

FOR Director, Division of Human Subjects Protection, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Ave., Silver Spring, MD 20910-7500

SUBJECT: Submission of Protocol Continuing Review for **WRAIR #~~xxx~~**

1. The following continuing review for the WRAIR protocol listed below is submitted to the WRAIR IRB for action.

2. **Protocol Title:**

**Dates of Reporting Period:** \_\_\_\_\_

**Principal Investigator/WRAIR POC:** \_\_\_\_\_

**Sponsor:**  WRAIR  USAMMDA  Other DoD  Other: \_\_\_\_\_  N/A

**Risk Level:**  Minimal Risk  Greater than Minimal Risk

**IRB Approval Expiration Date:** dd/mmm/yy

3. The following required documents are enclosed in the continuing review report package:

- Continuing Review Report
- Currently approved protocol  Version # \_\_\_\_\_ Date \_\_\_\_\_
- Currently approved consent forms  Version # \_\_\_\_\_ Date \_\_\_\_\_
- Currently approved advertising  Version # \_\_\_\_\_ Date \_\_\_\_\_
- Current Investigators Brochure  Version # \_\_\_\_\_ Date \_\_\_\_\_
- DSMB or Independent Safety reports (if applicable)  Date \_\_\_\_\_

I certify that all investigators listed on the protocol are current in their human subjects protection training in accordance with the current WRAIR DHSP Training Policy.

4. The point of contact for this action is undersigned at ~~phone number~~ and ~~Email~~.

PI or WRAIR POC Name  
Title  
Department/Division

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(Date)

SUBJECT: Continuing Review Report for Human Subjects Research Protocol WRAIR #~~xxxx~~

1. PROTOCOL NAME:

WRAIR IRB#:

MRMC HSRRB/HRPO Log #(if applicable):

DATES COVERED BY THIS REPORT:

2. IS THIS A COLLABORATIVE RESEARCH STUDY?:      Yes                      No

Other institutions participating:

Institutional IRB/ERC

CR Approval Date

- 1.
- 2.
- 3.
- 4.

3. RESEARCH OBJECTIVES: (Describe the protocol objectives in 1-2 sentences.)

4. SUBJECTS/SPECIMENS: (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: (Tell how many subjects were authorized to be enrolled, and how many have actually been enrolled into the protocol thus far. If any subjects withdrew/were withdrawn, state how many and why.)

Enrollment Status:

Category	Total Number this Reporting Period	Cumulative Total
Number of Subjects Originally Authorized to screen: XXXXX enroll: XXXXX		
Number Briefed:		
Number Screened:		
Number Enrolled:		
Number Lost (deaths, other) and reason for each:		
Number Withdrawn by Investigator and reason for withdrawal(s) of each:		
Number Withdrawn (drop		

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outs – subject withdrew him/herself) and reason for withdrawal(s) for each:		
Number Active Subjects:		
Number 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?

NUMBER OF SPECIMENS AUTHORIZED/UTILIZED: (Tell how many subjects were authorized to be enrolled, and how many have actually been enrolled into the protocol thus far. If any subjects withdrew/were withdrawn, state how many and why).

Status:

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

**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.

5. STUDY STATUS: [Describe the current status of the study: Study not started, Open and enrolling, Enrollment closed (include date of closure) subjects in follow-up phase, all follow-ups completed, study in specimen or data analysis; awaiting final closure by Sponsor]

6. CHANGES TO STUDY DOCUMENTS IN REPORTING PERIOD: List any amendments to the protocol, consent, advertising or case report forms in the past reporting period. Ensure version numbers are included.

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7. **CURRENT LITERATURE:** Provide Database and search terms, and dates reviewed

(If there have been any relevant publications, provide a brief summary and any impact that 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. If applicable, attach copies of publications, presentations, and abstracts that have resulted from the research.)

8. **UNANTICIPATED PROBLEMS OR UNEXPECTED ADVERSE EVENTS:** (Give a brief description of the side effects observed and their severity. Detail and explain any unexpected side effects, toxicities, or unanticipated problems involving risks to subjects and others that have occurred since the last continuing review. State 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. Also include a summary of any Safety Monitoring Committee or DSMB/DMC report, if applicable.)

9. **SUMMARY OF RESULTS TO DATE:** (Give a brief summary of your results in 1-2 paragraphs.)

10. **COMPLAINTS:** Were any complaints or grievances received about this study?

11. **DEVIATIONS:** (If any deviations from the protocol occurred, they should be described and discussed, and the corrective action taken should be provided. A copy of the original report describing the deviation from the protocol may be attached if it was not originally submitted. Minor deviations should be reported in the continuing review reports and major deviations should have been reported as stated in the protocol and they must also be summarized in the continuing review report.)

12. **FUTURE PLANS:** (What activities are planned for the protocol during the coming year? Continued collection of data? Analysis of data? Completion of the protocol? Submission of a new protocol or modification to the current protocol to expand on results?)

**NOTE:** Any proposed modifications should be mentioned, but the request to modify the protocol should be submitted separately to the Division of Human Subjects Protection.

13. Please contact the undersigned (Explain how someone would contact the PI in case of questions.) for additional information of clarification.

(Signature of PI)  
(Signature block of PI)

(Signature of the Division Director)  
(Signature block of the Division Director)

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**Appendix 2 – DHSP and WRAIR IRB Member Continuing Review Worksheet**

**COVER SHEET**

**WRAIR Protocol #:** \_\_\_\_\_ **Protocol Approval Thru-Date:** \_\_\_\_\_

**HSRRB/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	<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"/>

Initial Review Date: \_\_\_\_\_

CR Package Complete Date: \_\_\_\_\_

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 have been satisfied

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

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

**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):  **N/A - Closeout**

- 12 months**
- 6 months**
- Other: \_\_\_\_\_**

\_\_\_\_\_  
**Signature of Reviewer**

\_\_\_\_\_  
**Date**

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**Part D—WRAIR IRB Administrative Director Recommendations Summary**

**IRB OF RECORD 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/prospect of direct benefit to individual subjects**

-----  
**RECOMMENDED DHSP ACTION** (check one):

(To be completed by the CR Reviewer)

- Acknowledge as submitted**
- Acknowledge pending minor clarifications described below:**
- Recommendation to the Commander to dissolve the IAA, and request submission of a full continuing review packet to the WRAIR IRB:**

**Comments:**

**Recommended Approval Period for next Continuing Review by IRB of Record** (check one):

- 12 months**
- 6 months**
- Other: \_\_\_\_\_**

\_\_\_\_\_  
**Signature of Reviewer**

\_\_\_\_\_  
**Date**

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**Appendix 3-WRAIR IRB Acceptance Model (for studies reviewed by the WRAIR IRB)**

MCMR-UWZ-C

DATE

MEMORANDUM FOR Director, Division of Human Subjects Protection, Walter Reed Army Institute of Research, 503 Robert Grant Ave., Silver Spring, MD 20910

SUBJECT: Continuing Review Report Acceptance for WRAIR#, HSRRB/HRPO Log #

1. The continuing review report for WRAIR#, HSRRB/HRPO Log #, protocol entitled " \_\_\_\_\_," submitted by \_\_\_\_\_, is accepted. The ongoing research is approved as \_\_\_\_\_ (minimal risk or greater than minimal risk).
2. The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) approval for this protocol now expires on DATE. For the research to continue thereafter, a new continuing review report should be submitted in time to be reviewed and accepted by the IRB by this date.
3. The Point of Contact (POC) for this action is XXXXX , (301) 319-XXXX.

NAME  
COL, MC  
IRB Chair  
Walter Reed Army Institute of Research

CF:  
PI/WRAIR POC  
PI's/WRAIR POC's Division Director  
MCMR-ZB-PH (if applicable)

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**Appendix 4 – CR Acknowledgment Model (for studies where WRAIR did not originally review the protocol)**

MCMR-UWZ-C

DATE

MEMORANDUM FOR Principal Investigator or Point of Contact, Address

SUBJECT: Continuing Review Report Acknowledgement for WRAIR#, HSRRB Log #

1. The continuing review report for the WRAIR#, HSRRB Log #, protocol entitled " \_\_\_\_\_", is acknowledged.
2. The \_\_\_\_\_ Institutional Review Board (IRB), approved this report on DATE. The ongoing research is approved as \_\_\_\_\_ (minimal risk or greater than minimal risk).
3. IRB approval for this protocol expires on DATE. For the research to continue, a new continuing review report should be submitted in time to be reviewed and approved by the IRB of Record, before the expiration date. Once this approval is obtained, it is requested that the Principal Investigator (PI)/point of contact (POC) submit all required documents to the WRAIR Division of Human Subjects Protection for review and acknowledgement.
4. The Point of Contact (POC) for this action is XXX X XXXXX, (301) 319-XXXX.

NAME  
Director  
Division of Human Subjects Protection  
Walter Reed Army Institute of Research

CF:  
WRAIR POC/PI  
POC's/PI's Division Director  
MCMR-ZB-PH (if applicable)

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## Appendix 5 – CRR Notification Memos

### One-Month Continuing Review Notification Memo

Dear \_\_\_\_\_,

This is your third notification that a continuing review report will be due for **WRAIR#** \_\_\_\_\_ entitled, “\_\_\_\_\_,” on \_\_\_\_\_. The WRAIR Institutional Review Board (IRB) now considers this continuing review submission delinquent, and the WRAIR chain of command has been notified.

Please note the attached continuing review packet submission requirements below. Templates and guidance instructions may be found at: <https://www.wrairdhsp.com>. Also attached for your reference is the Commander’s Guidance on Human Use Protocol Continuing Reviews. If you have any questions or need any additional information, please do not hesitate to contact me. Thank you for your time and assistance in advance.

Best regards,

[NOTE: This notification should be included as a forwarding of the 2-month continuing review notification so that the submission requirements and the previous notification will be listed below.]

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## Two-Month Continuing Review Notification Memo

Dear \_\_\_\_\_,

This is your second reminder that a continuing review report will be due for **WRAIR#** \_\_\_\_\_ entitled, "\_\_\_\_\_" on \_\_\_\_\_. The Institutional Review Board (IRB) will need up to 30-60 days, depending on the type of review required, to process and approve the completed continuing review packet.

Please note the continuing review packet submission requirements below. Templates and guidance instructions may be found at: <https://www.wrairdhsp.com>. Thank you for your time and assistance in advance.

Best regards,

[NOTE: This notification should be included as a forwarding of the 3-month continuing review notification so that the submission requirements will be listed below.]

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## Continuing Review Expiration Notification Memo

Dear \_\_\_\_\_,

This is a warning letter that the protocol **WRAIR#** \_\_\_\_\_ will **expire on** \_\_\_\_\_ . This means that until the continuing review report has been reviewed and approved/accepted/acknowledged by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB), no work can be done by research staff covered under the WRAIR Human Research Protection Plan after this date, to include data analysis.

Please note that we cannot give extensions with regard to continuing review. If you feel that suspension of research activities will pose a harm to study volunteers, please speak to the WRAIR IRB Chair (**name, phone and Email**) **immediately**. Research activities conducted otherwise during a lapse in IRB approval is serious non-compliance and must be reported to higher headquarters. If the continuing review report has not been approved by the expiration date listed above, an official memo will be sent from the Commander suspending the work on this protocol at WRAIR.

Also attached for your reference is the Commander's Guidance on Human Use Protocol Continuing Reviews. If you have any questions or need any additional information, please do not hesitate to contact me. Thank you for your time and assistance in advance.

Best regards,

[NOTE: This notification should be included as a forwarding of the 1-month continuing review notification so that the submission requirements and the previous notifications will be listed below.]

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**Greater than Minimal Risk Notification Letter where the WRAIR IRB  
originally reviewed the protocol where there are multiple Institutional  
Review Boards**

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 submitted to the \_\_\_\_\_ IRB(s) and 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 Division of Human Subjects Protection, WRAIR by \_\_\_\_\_ in order for it to go before the \_\_\_\_\_ full WRAIR IRB meeting.

One (1) hard copy and one electronic copy of the following documentation are required:

- Continuing review report (signed and dated by both the Division Director and PI/POC)
- Copy of the most currently approved consent form
- Copy of the most currently approved version of the protocol
- Other IRB approvals for continuation of the protocol, including the date the IRB approvals expire
- Current Human Subjects Protection Training Certificate for the principal investigator (current within the last year)
- Current Human Subjects Protection Training Certificates for all other investigators listed on the protocol (current within the last three years)
- The Principal Investigator's current Good Clinical Practices (GCP) Training Certificate (current within the last three years)

If this protocol is still open for data analysis only and no new subject enrollment and/or intervention has taken place in the past year, the continuing review report is eligible for expedited review by the WRAIR IRB Chair, and one copy of the report should be submitted to the WRAIR Division of Human Subjects Protection by \_\_\_\_\_.

If the study has been completed, then please submit 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 Letter Where the WRAIR IRB did not originally review the protocol where there are multiple Institutional Review Boards**

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 approved by the \_\_\_\_\_ IRB and acknowledged by the WRAIR IRB.

To assure that research under the protocol continues uninterrupted, please submit one electronic copy and one hard copy of the following documents to the WRAIR Division of Human Subjects Protection by \_\_\_\_\_:

- Continuing review report (signed and dated by both the Division Director and PI/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
- Copy of the most currently approved version of the Investigator Drug Brochure (if applicable)
- Current Human Subjects Protection Training Certificate for the principal investigator (current within the last year)
- Current Human Subjects Protection Training Certificates for all other investigators listed on the protocol (current within the last three years)
- The Principal Investigator's current Good Clinical Practices (GCP) Training Certificate (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 #**

Title:

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

Best regards,

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### WRAIR Minimal Risk Notification Letter

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 one electronic copy and one hard copy of the following documents to the WRAIR Division of Human Subjects Protection by \_\_\_\_\_:

- Continuing review report (signed and dated by both the Division Director and PI/POC)
- 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 year)
- Current Human Subjects Protection Training Certificates for all other investigators listed on the protocol (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,

SOP Title	<b>CONTINUING REVIEW AND CONTINUATION DETERMINATION</b>	SOP No.	UWZ-C-618
		Version	.01
Effective Date	AUG 12 2009	Page	7 of 8

### **WRAIR Greater than Minimal Risk Notification Letter**

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 WRAIRIRB if research on the protocol is to continue uninterrupted. Please note that the continuing review report should be submitted to the Division of Human Subjects Protection, WRAIR by \_\_\_\_\_ in order for it to go before the \_\_\_\_\_ full IRB meeting.

One (1) hard copy and one electronic copy of the following documentation are required:

- Continuing review report (signed and dated by both the Division Director and PI/POC)
- 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)
- Current Human Subjects Protection Training Certificate for the principal investigator (current within the last year)
- Current Human Subjects Protection Training Certificates for all other investigators listed on the protocol (current within the last three years)
- The Principal Investigator's current Good Clinical Practices (GCP) Training Certificate (current within the last three years)

If this protocol is still open for data analysis only and no new subject enrollment and/or intervention has taken place in the past year, the continuing review report is eligible for expedited review by the WRAIR IRB Chair, and one copy of the report should be submitted to the WRAIR Division of Human Subjects Protection by \_\_\_\_\_.

If the study has been completed, then please send a final report.

Continuing review report and final report templates/models are attached here.

**WRAIR Protocol #**

Title:

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

Best regards,

SOP Title	<b>CONTINUING REVIEW AND CONTINUATION DETERMINATION</b>	SOP No.	UWZ-C-618
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**Minimal Risk Notification Letter Where There Are Multiple Institutional  
Review Boards**

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 approved by the \_\_\_\_\_ IRB(s) and accepted by the WRAIR, IRB.

To assure that research under the protocol continues uninterrupted, please submit one electronic copy and one hard copy of the following documents to the WRAIR Division of Human Subjects Protection by \_\_\_\_\_:

- Continuing review report (signed and dated by both the Division Director and PI/POC)
- The \_\_\_\_\_ IRB approval(s) for continuation of the protocol, including the date the IRB approval(s) expire(s)
- 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 year)
- Current Human Subjects Protection Training Certificates for all other investigators listed on the protocol (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,