Signatures and Dates:

Author:

QA Review:

Approving Authority:

Signatures on file

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
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1. Purpose and Applicability

This Standard Operating Procedure (SOP) covers the process used to conduct reviews of progress reports for protocols that do not require continuing review under the Revised Common Rule (2018 requirements). **Institutional progress reports will be required for all human subjects research protocols not requiring annual (Continuing Review Report) review by an Institutional Review Board (IRB).**

This SOP applies to the Walter Reed Army Institute of Research (WRAIR) IRB Administrative Director, the Human Subjects Protection Branch (HSPB) staff, and Principal Investigators (PI)/WRAIR Points of Contact (POC). A template for the Progress Report Form (Appendix B) is available on the WRAIR HSPB website and WRAIR intranet.

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 progress report or continuing review is processed by the WRAIR HSPB or WRAIR IRB, respectively.

Human research at WRAIR is governed by various regulations, to include Title 32 Code of Federal Regulations (CFR) 219, Protection of Human Subjects.

Per §32 CFR 219.109(f)(1): Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for review via expedited review procedures in accordance with §32 CFR 219.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in §32 CFR 219.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Continuing review of research by the WRAIR IRB is required if the protocol is subject to the U.S. Food and Drug Administration (FDA) regulations or the WRAIR IRB determines so, regardless if the protocol meets the eligibility criteria listed above. Please refer to SOP UWS-HP-618, Continuing Review and Continuation Determination.

Protocols approved prior to 21 January 2019 and the implementation of the 2018 Common rule (i.e. operating in accordance with the Pre-2018 Common Rule), may be eligible to submit a progress report instead of a continuing review report. Investigators interested in operating their research study under the rule changes, should contact the HPSB POC to determine what, if any, changes need to be made to the protocol and/or informed consent documents to be in accordance with the new requirements. The determination on whether such a protocol is eligible to be governed under the 2018 Common Rule, rests with the IRB Chair (or designee) in consultation with the HSPB Director (or designee).

Eligibility of expedited continuing review, limited review or progress reporting does not preclude investigators from required reporting of various incidents to the IRB, such as Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs), or seeking prospective approval from the IRB for amendments to the research. As part of the WRAIR IRB's responsibility to confirm research is being conducted in a manner where the conditions of the federal regulations, DoD Instruction, IRB and Institutional policies are being met, protocols may be selected for Post Approval Compliance Monitoring. Refer to WRAIR SOPs: UWS-HP-621 Deviations and Unanticipated Problem Reporting, UWS-HP-615 Amendments to Human Subjects Research Protocols, and UWS-HP-634 Directed-Monitoring of Human Subjects Research.

Changes to the protocol (e.g. risks to subjects, addition of FDA regulated products) may result in a different category of annual review process necessary to fulfill the regulatory requirements.

Other protocol lifecycle actions, such as amendments or extension requests, may be submitted with, but not as part of the progress report packet. The IRB reviews these protocol lifecycle actions, as separate items in accordance to SOP UWS-HP-615, Amendments to Human Subjects Research Protocols. Items submitted with, or at similar time as, the progress report will be processed separately, with different processing timelines. It is the responsibility of the PI to ensure extension requests are submitted with enough time to be processed and approved prior to the protocol closeout date.

3. Responsibilities

Those taking responsibility for the actions in this SOP are the WRAIR IRB Administrative Director, HSPB staff, and the PIs/WRAIR POCs. These persons are responsible for understanding the processes outlined in this SOP.

a. WRAIR IRB Administrative Director or designee responsibilities:

Review acknowledgement memos for quality and federal regulations.

b. HSPB staff responsibilities:

1) Send 90-day progress report notifications (Appendix A).

2) Review progress report and supporting documents for completeness, and contact study team/investigator for additional information/documentation, as needed.

3) Develop and issue the annual review acknowledgement to the PI/WRAIR POC and forward the acknowledgement and supporting documents to any other reviewing institutions (e.g. United States Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP) Human Research Protection Office (HRPO) and institutions that rely on WRAIR for review).

4) Update the database with any communication and new approval dates.

5) File the progress report packet, correspondence between the WRAIR HSPB and the investigator, a copy of the progress report acknowledgement or suspension/termination communication to the PI and, as applicable, a copy of the WRAIR IRB meeting minutes relating to that protocol in the HSPB regulatory files. A copy of the Progress Report Acknowledgment will be added to the monthly Expedited Review Listing.

c. PI/WRAIR POC responsibilities:

1) Track all IRB approvals, to include those from collaborating institutions, as applicable, to ensure that they are all submitted in a timely manner to avoid expiration of the study. Note: The PI is responsible for submitting the progress report to the WRAIR HSPB regardless of whether a 90-day progress report notification is sent. If feasible, 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 progress report is submitted to all reviewing IRBs. Additionally, the PI is responsible for reporting to the HSPB any lapse(s) in approval.

2) Submit the required progress report, and associated documents, to the HSPB via the electronic mailbox (usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil) and the HSPB POC, allowing sufficient time (30 days) for review and acknowledgment prior to the established expiration date. The PI or WRAIR POC is required to respond to all requests for information/additional documents from the HSPB and comply with any determinations made by the HSPB regarding the progress report.

3) Select a cutoff date for the progress report reporting period to achieve the submission deadline described in the point above. The next progress report reporting period should start on the day following the cutoff for the previous progress report period to ensure a continual review of protocol activities by the WRAIR HSPB.

4) If PIs do not comply with the progress report reporting requirements or research is suspended due to a lapse in the non-WRAIR approval, the study is considered to be in non-compliance with WRAIR requirements. Refer to WRAIR SOP UWS-HP-606 Non-Compliance Procedures.

Note: The WRAIR HSPB will apply the Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP) timelines for continuing reviews to the progress reporting. When the WRAIR HSPB staff completes review of and acknowledges the progress report within 30 days before the due date, the previously established expiration date for the protocol will be retained. If the progress report acknowledgment occurs prior to 30 days before the anniversary date, a new due date will be established.

5) Maintain a regulatory file, inclusive of the progress report and corresponding documentation for the timeframe specified per his/her institutional requirement.

4. Procedures for Conducting Progress Report Reviews

a. As a courtesy, HSPB sends out progress report notifications approximately 90 days prior to the expiration date of a study. The notification is sent out via email to the PI/WRAIR POC; additional POCs may be included on the correspondence (Appendix A).

b. The investigator prepares and submits the progress report to the HSPB inbox using the corresponding WRAIR forms as needed (Appendices B-D). Should the protocol be a collaborative effort, other institution's progress report/annual review templates may be used if the report contains all requested information contained in the WRAIR Progress Report Form.

c. The progress report packet is subsequently forwarded to the appropriate HSPB POC, who:

1) Checks the progress report packet for completeness, particularly noting the version of the protocol and informed consent(s)/assent(s) currently in use.

2) Verifies that the training of the PI/WRAIR POC and the Research Monitor, as applicable, is current in accordance with the WRAIR Training policy "Initial and Continuing Human Subjects Protection Education and Training Requirements" or 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 HSPB, but are documented in the submission packet to the HSPB.

4) Contacts the PI/WRAIR POC to complete any deficiencies noted in the review packet. Any responses or remaining questions/concerns identified by HSPB are included with the progress report packet provided to the HSPB Director or designee.

d. Review of progress reports conducted by the WRAIR HSPB Director or designee results in either:

1) Acknowledgement of the progress report; or

2) Recommendations to the IRB Chair for review of the report by the WRAIR IRB Chair or designee or by the fully convened WRAIR IRB.

This may be prompted by indications of non-compliance, over enrollment, etc.

e. Once a final continuation determination by the HSPB Director or designee has been made and documented, it is returned to the HSPB POC who will issue the acknowledgement communication to the PI/WRAIR POC.

f. Review of Progress Reports when WRAIR relies on another IRB

When the WRAIR IRB relies on another IRB for review and when that local IRB does not require that an annual progress report be submitted (e.g. minimal risk research), the HSPB POC will contact the study's WRAIR POC each year at the anniversary of the WRAIR Commander's approval, to request an update on whether WRAIR is still engaged in that research activity (Appendix A). This update can be provided via email communication.

g. Non-Receipt of a Progress Report

Protocols that require a WRAIR Progress Report may be placed on hold due to non-receipt or untimely receipt of the required documents, the HSPB Progress Report POC will:

1) Inform the HSPB Director or designee about the impending lapse.

2) Inform PI/WRAIR POC by email of points 3 and 4, below.

3) After 30 days of non-receipt, notify the IRB Chair and Branch/Center Director of non-compliance.

4) After 60 days of non-receipt, notify the Chief Science Officer, Deputy Commander and Commander, who may require the WRAIR personnel cease all study activities or the study go on hold.

h. Closeouts

Once all study activities have ceased, to include data analysis, a closeout report or notification must be submitted by the PI or WRAIR POC to the HSPB for acknowledgment. See SOP UWS-HP-637 Closeout Reporting and WRAIR Commander's IRB Policy Memorandum #07 Human Subjects Research Protocol Closure Policy.

i. Suspension or Termination of Research

There may be circumstances, under which the WRAIR IRB or Commander/ Institutional Official (IO) may determine that a protocol needs to be suspended or terminated for cause. The PI and/or the WRAIR 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 USAMRDC ORP HRPO, and, if applicable, other collaborating IRBs' officials, and the Sponsor are notified.

5. 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-Conducted and -Supported Research, 15 April 2020
FDA Guidance	IRB Continuing Review after Clinical Investigation, February 2012 Approval
Titles 21, 32 and 45	Code of Federal Regulations
63 Federal Register (FR) 60364-60367	National Institutes of Health. Protection of Human Subjects: Categories that May Be Reviewed by the Institutional Review Board through an Expedited Review Procedure, 9 November 1998
WRAIR Commander's IRB Policy Memorandum #03	Initial and Ongoing Human Subjects Protection Education and Training Requirements
WRAIR Commander's IRB Policy Memorandum #07	Human Subjects Research Protocol Closure Policy
WRAIR HSPB Document	Master List of Definitions, Draft
WRAIR SOP UWS-HP-606	Non-Compliance Procedures
WRAIR SOP UWS-HP-615	Amendments to Human Subjects Research Protocols

WRAIR SOP UWS-HP-618	Continuing Review and Continuation Determination
WRAIR SOP UWS-HP-621	Deviations and Unanticipated Problem Reporting
WRAIR SOP UWS-HP-634	Directed-Monitoring of Human Subjects Research
WRAIR SOP UWS-HP-637	Closeout Reporting

6. Appendices and Attachments

Appendix or Attachment Number	Title
UWS-HP-638-A	Progress Report Notifications
UWS-HP-638-B	Progress Report Form
UWS-HP-638-C	Adverse Event Log (Optional)
UWS-HP-638-D	Deviation Log (Optional)

7. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	Original SOP	04 Dec 2020