



**Walter Reed Army Institute of Research  
Standard Operating Procedure**



SOP Title	<b>PROGRESS REPORTS AND CONTINUATION DETERMINATION</b>	SOP No.	UWS-HP-638 <b>Appendix A</b>
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**Appendix A – Progress Report 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.*

**Reminder Correspondence when WRAIR relies upon another IRB for review,  
when that institution requires annual reporting**

The \_\_\_\_\_ Institutional Review Board (IRB) approval for the protocol listed below will expire on \_\_\_\_\_. Before that date, a continuing review report or progress report must be approved by the \_\_\_\_\_ IRB and acknowledged by the Walter Reed Army Institute of Research (WRAIR) Human Subjects Protection Branch (HSPB). If a progress report is not required for the IRB of please contact HSPB for instructions.

To assure that research under the protocol continues uninterrupted, please submit electronically the following documents to the WRAIR HSPB ([usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil](mailto:usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil)) and myself by \_\_\_\_\_:

- Progress report or Continuing Review Report submitted to the \_\_\_\_\_ IRB
- The \_\_\_\_\_ IRB approval for continuation of the protocol, including the date the IRB approval expires
- CITI training certificate (dated within 3 years) for the WRAIR PI/POC and Research Monitor, if applicable.

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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**Reminder Correspondence for WRAIR Progress Reports**

The Walter Reed Army Institute of Research (WRAIR) Human Subjects Protection Branch (HSPB) annual progress report for the protocol listed below is due on \_\_\_\_\_. Before that date, the attached progress report (Appendix B) must be reviewed and acknowledged by the WRAIR HSPB.

To assure that research under the protocol is conducted per the approved protocol and governing regulations and policies, please submit electronically to the WRAIR HSPB ([usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil](mailto:usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil)) and me by \_\_\_\_\_:

- Progress report (Signed and dated by both the Branch Director and WRAIR Principal Investigator (PI)/Point of Contact (POC))
- The most current approval(s) from other IRBs, if applicable
- Deviation and unanticipated problem logs
- Cumulative tables summarizing any serious adverse events or unanticipated problems involving risks to subjects or others (UPIRTSO) and any complaints
- CITI training certificate (dated within 3 years) for the WRAIR PI/POC and Research Monitor, if applicable.

If the study has been completed, please notify the HSPB and provide a closeout report (template attached)

**WRAIR #**

Title:

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

Best regards,



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**Request for Study Status when WRAIR relies upon another institution’s IRB for review for studies operating under the 2019 Common Rule requirements and the reviewing institution does not require annual review/continuing review.**

According to the Walter Reed Army Institute of Research (WRAIR) Human Subjects Protection Branch’s (HSPB’s) records, the WRAIR relies on the \_\_\_\_\_ IRB for ethical review of the protocol listed below. Under the new 2019 Common Rule, continuing reviews are not required for certain studies; additionally the reviewing IRB may not require a continuing review report or similar annual review however, to ensure WRAIR records are complete and current, please confirm the version and version date of the protocol and associated protocol documents currently in use. Please also indicate the current status of the research activities under this protocol. Examples include:

- No subjects enrolled
- Active – still enrolling subjects
- Active – ongoing specimen/data analysis (for studies involving no subject enrollment/only biospecimens/data)
- Closed to enrollment but subjects are still undergoing protocol-specific procedures
- Closed to enrollment but follow-up of subjects continues, which include the following activities: \_\_\_\_\_
- Closed to enrollment but analysis of identifiable data and/or biospecimens continues
- Closed to enrollment but analysis continues for data and/or biospecimens that are either anonymized or coded without link to identifiers
- Awaiting final closure by Sponsor (i.e. database lock)

If all study activities have been completed, please submit the close out report and closure acceptance from the \_\_\_ IRB for the WRAIR records/regulatory file. If WRAIR personnel are no longer participating on this study, please contact the WRAIR HSPB to initiate closing at the WRAIR Site.

**WRAIR #**

Title:

Best regards,