Appendix 1 – Continuing Review 90 Day 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 for studies operating under the Common Rule pre-2018 requirements

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 Walter Reed Army Institute of Research (WRAIR) Human Subjects Protection Branch (HSPB).

To assure that research under the protocol continues uninterrupted, please submit electronically the following documents to the WRAIR Human Subjects Protection Branch (HSPB) at usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil and me at _____ by _____:

_____

- Continuing review report submitted to the _____Institutional Review Board.
- Cover Memo (signed and dated by both the Branch Director and WRAIR PI/POC)
- The _____ IRB approval for continuation of the protocol
- Copies of the most currently approved versions of the consent form and protocol

If the study has been completed, please contact the HSPB for a copy of the closeout report template.

WRAIR #
Title:

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

Best regards,

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 ___institution____ for ethical review of the protocol listed below; In agreement with the new 2019 Common Rule, the reviewing IRB does not require a continuing review report or similar annual review for this protocol.

To ensure WRAIR records are complete and current, please confirm the current version and version date of the protocol and Informed Consent/Assent 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 HSPB to initiate closing at the WRAIR Site.

WRAIR #
Title:

Best regards,

Reminder Correspondence for Minimum Risk protocols operating under the Common Rule pre-2018 requirements –OR– where the WRAIR IRB determined a Continuing Review (CR) is required

The Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) approval for the protocol listed below will expire on _____. If study activities under this protocol are to continue uninterrupted, a continuing review report must be reviewed and accepted by the WRAIR IRB before that date.

To assure that research under the protocol continues uninterrupted, please submit the following documents to the WRAIR Human Subjects Protection Branch (HSPB) at usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil and me _____ 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/ WRAIR Point of Contact (POC))
- Cumulative deviation log
- Cumulative UAP/adverse event log
- Copies of the most currently approved versions of the protocol, consent form, advertisement and recruitment materials, briefing materials, and data forms
- Translated versions of currently approved study documents listed above, and associated Translation Verification Forms);
- Completed PI Signature Page of the currently approved protocol Current collaborating IRB approvals (list each collaborator, if applicable)
- Current Human Subjects Protection Training Certificates for the Principal Investigator (PI), site PI (or WRAIR POC, if applicable) and the Research/Medical Monitor, if applicable

Please note, submissions received less than 30 days prior to expiration of IRB approval may not receive approval prior to the expiration date, in which case all study activities would need to cease until a new approval is obtained

Please note, if no subjects have yet been enrolled, the study may be eligible for an abbreviated continuing review report. Please contact the HSPB if this situation applies for confirmation and permission to use the abbreviated report. The continuing review report [Appendix 2a] and abbreviated CRR report [Appendix 2b] templates are attached. If the study has been completed, then please contact the HSPB for a copy of the closeout out report template.

WRAIR Protocol #
Title:

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

Best regards,

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 _____. If study activities under this protocol are to continue uninterrupted, a continuing review report must be reviewed and accepted by the WRAIR IRB before that date. Please note that the continuing review report should be submitted to the WRAIR Human Subjects Protection Branch (HSPB) at usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil and me at _____ 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/Directorate and PI/ WRAIR Point of Contact (POC));
- Cumulative deviation log
- Adverse Events Log (to include information across all study sites)
- Current collaborating IRB approvals (list each collaborator, if applicable)
- Copies of the most currently approved versions of the protocol, consent form, advertisement and recruitment materials, briefing materials, and data forms (Including translated versions of these documents and associated translation verification forms);
- Completed PI Signature Page of the currently approved protocol
- Copy of the most currently approved version of the Investigator Drug Brochure (if applicable)
- Monitoring reports/DSMB reports
- Current Human Subjects Protection Training Certificates for the Principal Investigator (PI), site PI (or WRAIR POC, if applicable) and the DoD Research Monitor (if applicable)

Please note, if no subjects have yet been enrolled, the study may be eligible for an abbreviated continuing review report. Alternatively, if all study subjects are in long-term follow-up only, all study related visits are complete, and the study is in data analysis, the continuing review report MAY be reviewed via expedited procedures. Please indicate if any of the situations listed above apply. If you receive confirmation from the WRAIR HSPB that the study is eligible for the abbreviated CRR or expedited review, a copy of the report should be submitted to the WRAIR HSPB (usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil) no later than _____.

Continuing review report [Appendix 2a] and abbreviated CRR report [Appendix 2b] templates are attached. If the study has been completed, then please contact the HSPB for a copy of the closeout out report template.

WRAIR Protocol #
Title:

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