Walter Reed Army Institute of Research (WRAIR)
Temporary Transfer
of Study Responsibility

Form Instructions:

- For studies with ongoing subject interactions, as well as, for all FDA regulated studies, the PI-delegate must currently be serving as an Associate Investigator (AI) on the study and have access to all current and previous regulatory and participant file documentation, as applicable. For non-FDA regulated studies with no further subject interactions and no further recruitment (e.g., protocol is in data/specimen analysis only), the PI-delegate does not have to be a current AI on the study.
- Submit this form to the WRAIR Human Subjects Protection Branch (HSPB) prior to the temporary absence of the current PI.
- Please include a copy of the completed form with any other study documents that must be signed by the new PI.
- All submissions must be typed.

Date: [ ]

Principal Investigator: [ ]

WRAIR IRB Protocol #: [ ]

Protocol Title: [ ]

This form is to certify the temporary transfer of responsibility for the conduct of this protocol during the PI's temporary absence starting on **<insert start date>** and ending on **<insert end date>**, at which time the PI will return and resume responsibility for the trial.

By signing this form, the new PI certifies and accepts the following obligations to protect the rights and welfare of human subjects in this study:

- I agree to personally supervise and conduct the investigation in accordance with the protocol version approved by the Institutional Review Boards (IRBs)/Ethical Review Committees (ERCs).
- All the information provided in this application represents an accurate description.
- All project personnel will conduct the study in compliance with all applicable federal, state, and local laws and regulations and all applicable policies and requirements.
- I will not modify the protocol without first obtaining an IRB/ERC approved amendment and new protocol version unless it is necessary to protect the health and welfare of study participants.

- Valid informed consent/assent will be obtained from all research subjects or their legally authorized representatives (as applicable).
- I certify that I, and the study staff, have received the requisite training to conduct this research protocol and are fully aware of their responsibilities relative to obtaining consent/assent according to the WRAIR IRB's policies, state laws, and applicable Department of Defense (DoD) and federal regulations. Only the currently WRAIR IRB approved, consent forms or recruitment scripts will be used.
- I will promptly (within 48 hours) report changes to the research, unanticipated problems, and related serious adverse events/serious adverse device effects to the WRAIR IRB via the WRAIR HSPB at (301) 319-9940 (during duty hours) or to the usarmy.detrick.medcom-wrair.mbx.hspb@health.mil and submit a written report within 10 working days of knowledge of the event.
- The WRAIR IRB will be informed immediately (within 24 hours) of any significant negative changes in the risk/benefit relationship of the research.
- I agree to maintain adequate and accurate records in accordance with IRB policies, Federal, state and local laws and regulations. All required research records will be maintained and made available when requested for Post Approval Compliance Monitoring.
- I will immediately (within 24 hours) report to the WRAIR HSPB of any violations to the DoD, Federal research regulations, U.S. FDA regulations, HIPAA regulations, state and local laws, and WRAIR IRB policies for the protection of human subjects, as applicable, and knowledge of any pending compliance inspection by any outside governmental agency.

If unable to direct this research personally, as when on short term leave or vacation, the PI will arrange for an Associate Investigator to accept responsibility in his/her/their absence.

Print Name of **Delegate** Principal Investigator: _____

Date:_____Signature of **Delegate** PI: _____

Failure to comply with any of the applicable regulations, laws, WRAIR policies, and the provisions of the IRB-approved protocol may result in suspension or termination of this research project and notification by the IRB to appropriate institutional officials, study sponsor, DoD and governmental agencies. In addition to the IRB's actions, the WRAIR Chief Scientific Officer or Commander may impose additional conditions or restrictions.

Print Name of **Current** Principal Investigator:_____

Date:_____Signature of **Current** PI:_____

Directorate/Center/Branch Director Approval:

Does the **Delegate** Principal Investigator have the appropriate qualifications to conduct the study? ☐ Yes ☐ No

Does the **Delegate** Principal Investigator have adequate time to conduct and supervise the study? ☐ Yes ☐ No

Are there any other factors that would limit the **Delegate** Principal Investigator's ability to successfully conduct the study? ☐ Yes ☐ No

Additional Comments:

Print Name of **Directorate/Center/Branch Director:**_____

Date:_____Signature:_____

HSPB Review:

Dated, signed and current (within 2 years of submission) Curriculum Vitae for **Delegate** Principal Investigator provided? ☐ Yes ☐ No

Current Human Subjects Protection Training Certificate for **Delegate** Principal Investigator provided? ☐ Yes ☐ No

Statement of Conflicts of Interest (financial or otherwise) for **Delegate** Principal Investigator provided? (required for studies involving commercial sponsors and/or studies with drugs, biologics, devices, combination products, or development of *in vitro* diagnostics).

☐ Yes ☐ No

Additional Comments:

Print Name of **HSPB Point of Contact:**_____

Date:_____ Signature:_____

WRAIR IRB Chair (or Designee) Review:

Approved ☐

Additional Information Needed ☐

Referred for IRB review at convened meeting ☐

Additional Comments:

Print Name of **WRAIR IRB Chair (or Designee):**_____

Date:_____ Signature:_____