**CONFIDENTIAL**

Study Review: Principal Investigator Response Form

|  |  |
| --- | --- |
| Principal Investigator: |  |
| Protocol Number: |  |
| Protocol Title: |  |
| **PI Response Due Date:** |  |

**Instructions:**

**1. The PI must review, address and respond to each Required Action and Recommended Action as outlined. PLEASE DO NOT INCLUDE ANY DIRECT IDENTIFIERS IN THIS REPORT. USE INITIALS OR STUDY ID NUMBERS.**

Part A. Required Actions: *all actions must be addressed promptly* to meet federal regulations, guidelines and VCU/VCUHS policies. If the required action is not possible or cannot be completed, please provide reason.

Part B. Recommended Actions: *consider all recommended actions*. While not mandatory, it is strongly encouraged to consider the recommendations, evaluate them in terms of your program/study procedures and to incorporate as deemed helpful.

Please respond to each recommendation with one of the following actions:

|  |  |
| --- | --- |
| 🡪 Accept Action | Recommendation deemed useful and action implemented. Please explain how. |
| 🡪 Postpone Action | Recommendation deemed useful, but action will be implemented later in this study and/or will be applied to future studies. |
| 🡪 Decline Action | Recommendation deemed impractical or unfeasible for this study as well as future studies. |
| 🡪 Acknowledge | As applicable, an observation may be noted in which no follow-up action is necessary, but PI will be asked to acknowledge or clarify. |

**2. Once this form is complete, please sign below and return (PDF by email, or by interoffice mail) to** [viragoea@vcu.edu](mailto:viragoea@vcu.edu) **or at the ORSP office, MCV Campus, BioTech One, Room 3033, 800 E Leigh St., PO Box 980617, Richmond, VA 23298-0617 by the due date noted above.**

This signature indicates the Principal Investigator has reviewed this report, shared findings and provided copies to appropriate research staff and addressed all *Required and Recommended Actions*.

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator (Printed): |  |  |  |
| Principal Investigator Signature: |  | Date: |  |

**Part A. REQUIRED ACTIONS: *all actions must be addressed promptly***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Ref.** | Required Action | PI Response | EXPLAIN RESPONSE | | ***PAMQuIP Use Only*** |
| COMPLETED: | If no changes, no response required |
| OTHER/NO ACTION: | Why alternative or no action taken |
| ACKNOWLEDGED: | As applicable, acknowledge or clarify |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| A1 |  | COMPLETED  OTHER/NO ACTION | Response: |  |
| A2 |  | COMPLETED  OTHER/NO ACTION | Response: |  |
| A3 |  | COMPLETED  OTHER/NO ACTION | Response: |  |
| A4 |  | COMPLETED  OTHER/NO ACTION | Response: |  |
| A5 |  | COMPLETED  OTHER/NO ACTION | Response: |  |

**Part B. RECOMMENDED ACTIONS: *consider all recommendations.***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Ref.** | Recommended Action | PI Response | EXPLAIN RESPONSE | | ***PAMQuIP Office Use Only*** |
| ACCEPT: | Describe action taken and when |
| POSTPONE: | Why action will be implemented in future. |
| DECLINE: | Why action not taken |
| ACKNOWLEDGE: | As applicable, acknowledge or clarify |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| B1 |  | ACCEPT  POSTPONE DECLINE | Response: |  |
| B2 |  | ACCEPT  POSTPONE DECLINE | Response: |  |
| B3 |  | ACCEPT  POSTPONE DECLINE | Response: |  |
| B4 |  | ACCEPT  POSTPONE DECLINE | Response: |  |
| B5 |  | ACCEPT  POSTPONE DECLINE | Response: |  |

This program is intended to help investigators meet and understand the regulations that apply to their research, as well encourage improvements that maximize the protection of human subjects. Your participation is appreciated and your input useful. Please provide any additional suggestions, concerns, and comments that you feel might help.