Status Report Update for Studies Not Subject to

IRB Continuing Review

IRB# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ CPA# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1. Study Identification**

|  |  |
| --- | --- |
| 1. Title of Study |  |
| 1. Study Number |  |
| 1. Date of last update or approval (may be an amendment approval date) |  |
| 1. Principal Investigator | PI Name:       Phone:  VA E-mail:       Alternate E-mail |
| 1. Person Providing Information | Name:  Study Role:  Location:  Phone:  VA E-mail  Alternate E-mail |

**2. Verification of Investigators/Study Coordinators**

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| --- | --- | --- | --- | --- | --- |
| ***List of all study personnel*** | | | | | |
| ***Name*** | | | ***Study Role*** | | |
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|  | The list is accurate and there are no changes. | | | | |
|  | There have been changes and these are annotated below | | | | |
| ***List all personnel who have left the study*** | | | | | |
| **Name** | | **Study Role** | | **Date Departed** | |
|  | |  | |  | |
|  | |  | |  | |
| ***List all personnel who have joined the study since the last update or amendment adding them.*** | | | | | |
| **Name** | | **Study Role** | | | **Date Added** | |
|  | |  | | |  | |

**III. Current Study Status**

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| **The person completing the report *must* check one of the following to indicate the overall status of the study:** | |
|  | 1. Study not yet open to enrollment |
|  | 1. Open to enrollment; no participants enrolled. |
|  | 1. Active and open to enrollment; participants are undergoing interventions per approved project. |
|  | 1. Closed to enrollment; participants continue to undergo interventions per protocol.   **Date Closed to Enrollment:** |
|  | 1. Closed to enrollment; participants are in follow-up only (e.g. survival) and data being accessed is only from interventions as part of regular clinical care   **Date Participant Intervention Ended**: |
|  | 1. No further patient interventions or follow-up; data analysis of private identifiable information only ongoing.   **Date Follow-up Ended**: |
|  | 1. Data collection and analysis study only; there are no interventions and data analysis is ongoing |

**IV. Assurances**

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| **The person completing the report needs to acknowledge and check each of the following** | |
|  | All amendments have been reviewed and approved by the IRB/R&DC before implementation (or none submitted) |
|  | All reportable events have been reported, reviewed and acknowledged by the IRB/R&DC |
|  | PI and Investigator additions have been submitted to the IRB/R&DC and received IRB/R&DC approval |