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 |