Status Report Update for Studies Not Requiring

IRB Continuing Review

*Note: This form can be used for both IRB annual status check in as well as for projects overseen solely by the R&D Committee*

**. 1. Project Identification**

|  |  |
| --- | --- |
| 1. Title of Project |  |
| 1. Study Number |  |
| 1. Date of last update or approval (may be an amendment approval date) |  |
| 1. Principal /Co-Principal Investigator (PI)   *If more than two Co-PIs, add additional rows.* | PI Name:       Phone:  VA E-mail:    Co-PI Name:       Phone:  VA E-mail: |
| 1. PI VA Medical Facility Location | Name:  Location (City): |
| 1. Person Providing Information | Name:  Study Role:  Location:  Phone:  VA E-mail |

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***Attach a list of all study personnel and check one of the boxes below indicating accuracy of the list, along with any changes.*** | | | | | | | |
|  | 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 project*** | | | | | | | |
| **Name** | | | **Project Role** | | | **Date Departed** | |
|  | | |  | | |  | |
|  | | |  | | |  | |
| ***List all personnel who have joined the project since the last update or amendment adding them.*** | | | | | | | |
| **Name** | | **Project Role** | | **Date Added** | **Obtaining IFC** | | **VA E-mail** |
|  | |  | |  |  | |  |
|  | |  | |  |  | |  |
|  | |  | |  |  | |  |

**III. Current Project Status**

|  |  |
| --- | --- |
| **The PI/SC *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 at all sites; participants continue to undergo interventions per protocol.   **Date Closed to Enrollment:** |
|  | 1. Closed to enrollment at all sites; participants are in follow-up only 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 at any sites; data analysis of private identifiable information only ongoing.   **Date Follow-up Ended**: |
|  | 1. Study is a data analysis only study; there are no interventions and data analysis is ongoing |

**IV. Reminders**

|  |  |
| --- | --- |
| **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 |
|  | All PI, LSI, and Investigator additions have been submitted to the IRB/R&DC and received IRB/R&DC approval |