

Study Completion or Closure Form

|  |
| --- |
| **Study Title:**  |
| **IRB Number:** |

1. **Principal Investigator**

|  |  |
| --- | --- |
| **PI Name**  | **Date:** Click here to enter a date. |
| Protocol Title  | WMed IRB #:      *(for IRB Office use only)* |

|  |  |
| --- | --- |
| [ ]  Faculty [ ]  Other:       | Department/Unit:  |
| Address:  |
| Email:  | Phone Number:  |

1. **Verification of Closure**
2. Reason for Closure:
3. Study completion date:Click here to enter a date.
4. Verify the following by checking each both:

[ ] The research is permanently closed to enrollment.

[ ] Collection of identifiable private information is completed.

[ ] Analysis of identifiable private information is completed.

[ ] All participants have completed all research-related interventions. [ ] NA

[ ] FDA Regulated Diagnostic Devices: Testing utilizing human specimens and analysis of data are completed. [ ] NA

[ ] For multi-center studies, continuing review of the research by the WMed IRB no longer required after all human subjects research activities have been completed locally, even if (i) interactions or interventions with subjects may be occurring at other study sites; or (2) data analysis of identifiable private information is ongoing at another central site that collects and analyzes data from all study sites. [ ]  NA

1. **Subject Enrollment**
2. Number of subjects enrolled (or charts/records reviewed) locally since last IRB review:
3. Total number of subjects enrolled (or charts/records reviewed) since study start:
4. Total number of subjects withdrawn from the study:
	1. Explain/Summarize the withdrawals:
5. Provide the cumulative accrual by race/ethnicity and gender for this study:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **American Indian or Alaska Native** | **Asian** | **Black or African American** | **Hispanic or Latino** | **Native Hawaiian or Other Pacific Islander** | **White** | **Totals** |
| **Men** |       |       |       |       |       |       |       |
| **Women** |       |       |       |       |       |       |       |
| **Totals** |       |       |       |       |       |       |       |

[ ] Race/ethnicity and gender not collected for this study.

# Interim

1. Since the last IRB review, have there been any problems with or changes in the research:

[ ] No

[ ] Yes\* *(provide a summary of problems or changes):*

\*If yes, was this information reviewed by the IRB?

[ ] Yes

[ ] No *(please explain):*

# Findings

1. Please summarize your findings to date; including results (preliminary or final) where available *(State if there are no findings to date)*:

1. Since the last IRB review, have there been any publication or presentations resulting from this research?

[ ]  No

[ ] Yes *(list and include a copy of all publications):*

# Signature

I certify that the information provided in this application is complete and correct.

Signature of Principal Investigator Date

**HRPP/IRB USE ONLY**

1. **Reviewer Conflict of Interest**

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study?

[ ]  Yes\*\*  [ ]  No

\*\*If yes, please do not perform the review and contact the HRPP/IRB Office at 269-337-4345

1. **Determination**

[ ]  Acknowledge study closure

[ ]  Additional information is needed:

|  |  |
| --- | --- |
| **Signed** | **Dated** |