Study Closure Form

**PRINCIPAL INVESTIGATOR & STUDY INFORMATION**

|  |  |
| --- | --- |
| **PI Name** | **Date** |
| Study Title/Study Number | |

|  |  |
| --- | --- |
| ☐ Faculty ☐ Fellow ☐ Other: | Department/Unit: |
| Address: | |
| Email: | Phone Number: |

**Faculty Advisor** *(if appropriate)* **☐** NA

**NOTE*:*** *A Faculty Advisor is required if the PI is a fellow and the Faculty Advisor MUST sign this study application.*

|  |  |
| --- | --- |
| Name: | Department/Unit: |
| Address: | |
| Email: | Phone Number: |

1. **Verification of Closure**
2. Reason for Closure:
3. Study completion 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 NJH 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 Total number of subjects withdrawn from the study: 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/ethnic group and gender of this study:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | African  American | American  Indian | Asian | Caucasian | Hispanic  - White | Hispanic  - Black | Others | Totals |
| Men |  |  |  |  |  |  |  |  |
| Women |  |  |  |  |  |  |  |  |
| Totals |  |  |  |  |  |  |  |  |

**☐** Gender and minority status not collected for this study. *(reason:      )*

# 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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator Signature Date

**IF THE INVESTIGATOR IS A FELLOW, A FACULTY ADVISOR MUST SIGN BELOW** ☐ NA

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Faculty Advisor Signature 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 NJH HRPP/IRB Office at 303-398.1477].

1. **Determination**

☐ Acknowledge study closure

☐ Additional information is needed:

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