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| BRANY file # | INVESTIGATOR’S OR SPONSOR’S study identifier: |
| STUDY TITLE: | |

## **Instructions for Study Sponsor, Lead Investigator, or Master Site PI**

A representative of the Study Sponsor, the Lead Investigator, or the Master File Site PI for a multi-center study must complete this form, or provide the information requested in another format.

* Return the completed form to the local site Principal Investigator under BRANY IRB purview to be included with the application for continuing approval to BRANY IRB.
* For Lead Investigators of Multi-center studies or Master File Site PIs for which BRANY IRB is serving as the single IRB, return the completed form directly to BRANY IRB.

## **Frequently Asked Questions about this Form**

Q: What is the purpose of this form?

A: The purpose of this form is to obtain a summary of study-wide data for multi-center studies so BRANY IRB can compare the progress of the PI under its purview to all sites involved in the study.

Q: Is this form mandatory for Continuing Approval from BRANY IRB?

A: Yes, it required per BRANY IRB policy. Return the completed form to the PI under BRANY IRB purview so it can be included with the PI’s application for continuing approval.

## **COMPLETE THE QUESTIONS BELOW**

1. Number of subjects accrued across all participating sites thus far:
   1. Race/ethnic classifications (total should match number entered above):

# african-american # middle eastern

# caucasian # hispanic

# pacific islander # asian

# native american/first nations # other (specify):

* 1. Gender distribution (total should match number entered above):

# female # male

* 1. Summarize any withdrawals of subjects, including reasons for withdrawal if known:

1. Summarize any unanticipated problems involving risks to participants or others. Append supporting documents as necessary. If none, state:

1. Provide a summary of adverse events, or indicate whether adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure/safety profile information that was already provided to the IRB.

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| Adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure/safety profile information that was already provided to BRANY IRB. | NOTE: If this research is a clinical trial that is subject to oversight by a monitoring entity (e.g., the research sponsor, a coordinating or statistical center, or a DSMB/DMC), a current report (within 60 days) from the monitoring entity may be provided. The report must include:   * + 1. a statement indicating what information (e.g., study-wide adverse events, interim findings, and any recent literature that may be relevant to the research) was reviewed by the monitoring entity,     2. the date of the review, and     3. the monitoring entity’s assessment of the information reviewed. |
| **OR** |
| Summarize adverse events. Append supporting documents as necessary. If none, state: |

1. Summarize any complaints from research subjects about their rights or welfare, or complaints from subjects or research subjects or research staff about the conduct of the study. Append supporting documents as necessary. If none, state:

1. Summarize any recent literature that may be relevant to the research. Append supporting documents as necessary. If none, state:

1. Provide any relevant multi-center trial reports (reports that summarize study-wide progress and/or results not already provided to the IRB) Append supporting documents as necessary. If none, state:

1. Provide any other relevant information, especially information about risks associated with the research. Append supporting documents as necessary. If none, state:

1. Provide any other interim findings since the last IRB review (not already reported to BRANY IRB). Append supporting documents as necessary. If none, state:

1. Based on study results thus far, provide a current risk-potential benefit assessment. Append supporting documents as necessary.

## **SIGNATURE OF PERSON COMPLETING THE FORM**

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|  |  |  |  |
| **Printed Name** | **Signature** | **Title & Organization** | **Date** |