**Final Report to the IRB**

**IMPORTANT DEADLINE: Submit at least three (3) weeks in advance of the expiration date of a study.**

**REMINDER: Securely retain data in accordance to Policy IRB-01, IRB approved documents, and sponsor requirements. Do not destroy any research data until required retention periods have passed.**

**NOTES:**

**1) Only include data for sites that have oversight by the Downstate IRB. If this is a multisite study, do not include data for sites outside of the jurisdiction of the SUNY Downstate IRB.**

**2) If the study is completed or only de-identified data is undergoing data analysis, please consider submission of a final report form to the IRB for the purposes of closing the study.**

1. **GENERAL INFORMATION**
2. **Protocol Title:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Principal Investigator (PI):** | |  | | **Dept:** |  | **Box:** | |  |
| 1. **PI Contact Information:** | | **PI Downstate Phone # (required):**  **PI Downstate Email (required):**  **Alternate PI E-mail (optional):** | | | |

1. **If someone other than the PI is the main contact for this study, please provide his/her contact information below:**

|  |  |
| --- | --- |
| **Name (if not PI):**  **Role on Study:** | **Phone:**       **Email:** |

1. **REASON FOR FINAL REPORT:**
2. **Indicate the reason for the final report by checking the appropriate box below:**

No staff or funding to do the study. **If checked,** please explain what will happen to the data that has already been collected?

Analysis or collection of identifiable data has completed.

*Note: If checked, investigators may continue to use de-identified data for manuscript preparation or non-human research activities; however, no new data may be collected or reviewed unless the study is re-opened and approved by the IRB.*

All human research activities, including analysis of identifiable data, are complete.

Sponsor is closing the study to enrollment and no participants have been enrolled at this site.

**B. If you wish to add additional information for the IRB to consider, please add it here:**

1. **dOES THIS STUDY INVOLVE THE PROSPECTIVE ENROLLMENT OF RESEARCH participants?**

**(regardless of whether chart/data review and/or specimen analysis is included)**

Yes Complete Section 4 and Skip Section 5.

No Complete Section 5 and Skip Section 4.

1. **enrollment update:**

Complete this section ONLY when the study involves the prospective enrollment of research participants, regardless of whether chart/data review and/or specimen analysis is included; otherwise, skip to section 5.

1. **Total Number of Participants approved by the IRB:**
2. **Total Number of Participants (not including screen failures or withdrawals) enrolled at this site since project inception:**

If “B” exceeds “A,” submit Protocol Deviation on an “Application for Reportable Event” form.

1. **Indicate the number (not %) of study participants (not including screen failures or withdrawals) that fall into the following categories:**

* Children (under age 18):
* Females:
* Pregnant Women:
* Prisoners:
* Cognitively impaired adults:
* Racial/ethnic minorities:

1. **Total Number of screen failures since project inception:**
2. **Total Number of withdrawals since project inception:**
3. **Number of Participants Withdrawn during the current IRB approval period?       If >0, explain:**
4. **If you wish to add additional information for the IRB to consider, please add it here:**
5. **Is there a Data Safety Monitoring Board (DSMB) for this study?**  Yes  No
   1. **If yes, check all applicable boxes:**

**No DSMB report is due at this time.**

**The most recent DSMB report previously submitted to the IRB.**

**New DSMB report included with this submission.**

**Other, explain:**

1. **If you wish to add additional information for the IRB to consider, please add it here:**

1. **chart, data, or specimen examination update:**

Complete this section ONLY when section 4 does not apply (e.g., the study DOES NOT involve the prospective enrollment of research participants).

1. **Total Number of Participants approved by the IRB:**

**(e.g., number of individuals that pertain to the charts, data, or specimens under examination over the course of the research)**

1. **Total Number of Participants at this site since project inception:**

If “B” exceeds “A,” submit Protocol Deviation on an “Application for Reportable Event” form.

1. **If you wish to add additional information for the IRB to consider, please add it here:**
2. **ADDITIONAL INFORMATION:**
3. **If you wish to add additional information for the IRB to consider, please add it here:**

**The IRBNet package must be electronically signed by the PI before submitting the package to the IRB.**