Albany State University

IRB Protocol Close-out Report

1. PROJECT TITLE	ASU PROTOCOL NUMBER (IRBNet)

2. PRINCIPAL INVESTIGATOR (or Advisor)

Name (Last, First, MI): _____ E-mail: _____

KEY PERSONNEL Name (Last, First, MI):

_____ _____ _____ _____

_____ _____ _____ _____

3. RESEARCH STATUS

Check all that apply to the research:

- ☐ Research was never initiated.
- ☐ No research participants were ever enrolled (or participant records, specimens, etc. obtained).
- ☐ Research has been discontinued, and there will be no further data collection (including long term follow-up or re-contact) or analysis of identifiable/coded data.
- ☐ Sponsor is discontinuing the research.
- ☐ Principal Investigator and/or Co-Investigator are leaving the University.
- ☐ Other, specify: _____

4. RESEARCH PROGRESS

a. Summarize the results of the study, including any plans for scholarly/scientific presentations or publications.

b. Summarize any IRB-approved amendments or changes made to the research since last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation.

c. Discuss whether any significant new findings or other information should be provided to past participants.

d. Discuss what will happen to the identifiable/coded data, if any, at the end of the study.

5. NUMBER OF PARTICIPANTS

The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all did not prove eligible or complete the study.

a. Is this a multi-site study?

- ☐ Yes → Indicate the total number of participants enrolled across all sites: _____
- ☐ No

b. For research approved by ASU IRB, provide:

1) IRB approved number of participants (or records, specimens, etc.): _____

2) Total number of participants enrolled in the research to date: _____

3) Number of participants enrolled since last IRB review (initial or continuing): _____

c. If actual total enrollment to date (5b.2) is significantly different (over or under) from IRB approved number (5b.1), provide an explanation:

d. If applicable, did participants complete consent forms prior to participation in research.

☐ N/A
☐ Yes
☐ No → **# research participants** _____
 # consented _____

6. RISK ASSESSMENT

a. Since the last IRB review (initial or continuing), did any unanticipated problems involving risks to subjects or others or adverse events occur in research at ASU or at a site(s) approved by an ASU IRB?

☐ No

☐ Yes → Provide a summary of risk(s) information. ***Do not list each event separately or include participants' personally identifiable information.***

7. PARTICIPANT COMPLAINTS & VOLUNTARY WITHDRAWALS

a. Have any participants made complaints about the research since last IRB review?

☐ Yes
☐ No

If Yes → List and describe each **complaint** and any **actions taken** to resolve the complaint(s).

b. Have any participants voluntarily withdrawn from the research since last IRB review? ***Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.***

☐ Yes
☐ No

If Yes → List and describe each **withdrawal** and any **actions taken** (e.g., changes to the research or consent process) in response to the withdrawal(s).

8. PRINCIPAL INVESTIGATOR'S ASSURANCE

I have followed all applicable policies and procedures of The Albany State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as with professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- Performed the research as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- Promptly reported to the IRB events that may represent unanticipated problems involving risks to subjects or others;
- Maintained research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Retained research- related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;

- Obtained IRB approval or exemption before initiating any new research activities involving human subjects; and
- Informed all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

I verify that the information provided in this Close-out Report is accurate and complete.

Printed name of Principal Investigator (or Advisor)	**Date**