HUMAN SUBJECTS RESEARCH FINAL REPORT

Instructions: Principal investigators have the responsibility of informing the IRB when a study has been completed. A study is considered to be open and active until either it is closed administratively by he IRB or the investigator has submitted a Human Subject Research Final Report to the IRB for the applicable study. Complete this form when an approved human participant research project is concluded. Attach a copy of all relevant materials to this form to be reviewed by the IRB.

1. General Information:		
Protocol Title:		
Date of Report:		
2. Principal Investigator:		
Name:		
Email Address:	**Telephone Number:**	**Faculty: ☐ Staff: ☐**
3. Co-Investigator		
Name:		
Email Address:	**Telephone Number:**	**Faculty: ☐ Staff: ☐ Student: ☐**
4. Reason for Closure:		
☐ The only remaining activity involves the analysis of aggregate data sets without individual subject identifiers		
☐ All Research related activities, including data analysis, has been completed		
☐ Study closed at this site by sponsor. Please Explain:		
☐ Other. Please Explain:		
5. Subject Enrollment: Enter '0' where there are no numbers to report. Please do not leave any spaces blank.		
Maximum number of subjects/records approved for enrollment:		
	Since Last IRB Approval[1]	**Since Initial IRB Approval[2]**
Number of subjects screened		
Number of subjects enrolled		
Number of subjects who were dropped		
Number of subjects who voluntarily withdrew		
Number of females enrolled		
Number of males enrolled		
Number of non-binary/third-genders enrolled		
Number of minors enrolled		
6. Criteria for IRB Closure of Research: Please make sure to answer all questions (please respond with N/A or NONE if question is not pertinent to study)		
a. In the past year have there been any of the following?		
• Any expected/unexpected and/or serious/non-serious associated adverse events: ☐ Yes* ☐ No • Unanticipated problems or adverse events involving risks to subjects or others: ☐ Yes* ☐ No • Withdrawal of Subject(s) from the research, including reasons: ☐ Yes* ☐ No • Complaints about this research study: ☐ Yes* ☐ No		
***If the answer is "YES" to any items in 6a, explain each:**		
b. Were all events, problems, withdrawals, or complaints reported promptly to the IRB? ☐Yes ☐No ☐N/A		
***If "NO" to question 6b, explain:**		
c. Provide copies of and/or summarize* below:		
All monitoring reports, Sponsor's reports, preliminary results, abstracts of recent scientific literature with full citation ☐ Attached ☐ N/A		

Any other information that has become available since the last IRB review related to the risks and benefits associated with this study. ☐ Attached ☐ N/A
***Summary: (if applicable)**
d. Please provide a brief summary*, report or abstract of the study findings (if available) ☐ Findings attached ☐ N/A
***Summary: (if applicable)**
e. Did the research consent form include a statement that subjects would be provided with additional information (preliminary and/or study findings, randomization arm, etc.? ☐ YES* ☐ NO ☐ N/A
***If "YES" to Question 6e, have subjects been provided with this information?** ☐ YES (Please include a copy of what was sent to subjects) ☐ NO (Please explain):
f. Are identifiable data still being stored for this study? Identifiable data include:
• Paper or electronic records that are connected to nae, address, email address, phone number, medical record number, student record number or any code that could make it possible to link the data to an individual • Voice or video recordings ☐ N/A (protocol did not include the collection of identifiable data) ☐ YES* ☐ NO-Data has been de-identified as specified by the IRB-approved protocol
***If "YES" to Question 6f, was this approved by the IRB? Explain, in detail, the measures that are being taken to protect the confidentiality of the records/recordings:**
7. Publication and Data Collection
a. Were there any publications, presentations, manuscripts derived from this research? ☐ YES* ☐ NO
***If "YES" to Question 7a, please list or attach findings:**

*Please obtain E-signatures through IRBNet from the following prior to submission:
Principle Investigator
Co-Investigator(s) (if applicable)
Faculty Advisor (for students only if different from PI)

Please contact the office of Research and Sponsored Programs if you need assistance with setting up an account on www.irbnet.org.