APPENDIX 10: MIRERC
CLOSE PROJECT REPORT FORM

IRB STUDY NUMBER: _____

Please type only in the gray boxes. To mark a box as checked, double-click the box, select "checked", and click "OK".

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator:
Name *(Last, First, Middle Initial)*:
Department: _____ Phone: _____ E-Mail: _____

Additional Study Contact:
Name: _____ Phone: _____ E-Mail: _____

Project Title:
Sponsor/Funding Agency: _____ Sponsor Number: _____

SECTION II: CURRENT STUDY STATUS

☐ Study will not be initiated:
Explain and skip to Section IV: _____

☐ Study closed prior to completion
Date closed:_____
Explain: _____

☐ Study completed Date completed:_____

NOTE: This study can only be closed under the following circumstances and conditions:

1. No further interaction/intervention with subjects, including follow-up, or access to subjects' personally identifiable information for the purpose of research data collection.

   AND

2. ***Either*** of the following (*mark the appropriate box*)

   ☐ All data analysis involving the research site(s), under the MIRERC approval, is complete.

   OR

   ☐ Data has been de-identified, with no codes or keys that would allow for the potential of identifying individuals in the future. Note: This typically applies to multi-center research where de-identified data is provided to the sponsor and the sponsor authorizes MIRERC closure.

If applicable, explain what will happen to samples/tissues/data collected as part of the research study: _____

SECTION III: SUBJECT SUMMARY

☐ Check here if your study utilizes records or specimens versus human subjects. When the form asks for the number of subjects, document the number of subjects for which data/specimens have been collected.

☐ Check here if the MIRERC has approved a waiver of consent for your study. When the form asks for the number of subjects, document the number of records that have been reviewed.

1. SUBJECT SUMMARY TABLE

Date first subject was enrolled: _____

		On-Site
Since last MIRERC review	Total number of subjects **CONSENTED**	
	Total number of subjects who **FAILED SCREENING** (e.g. found ineligible to participate)	
	Total number of subjects who have **WITHDRAWN** from the study	
Since beginning of study	Total number of subjects **CONSENTED**	
	Total number of subjects who **FAILED SCREENING** (e.g. found ineligible to participate)	
	Total number of subjects who have **WITHDRAWN** from the study	
Number of subjects who have **COMPLETED** the study		

If necessary, please provide further explanation regarding the subject summary: _____

2. WITHDRAWAL

Have any subjects withdrawn from the study since the last MIRERC review?

☐ No

☐ Yes, state the reasons for withdrawal:_____

3. **Vulnerable Populations**. Are any of the subjects who have consented or enrolled in the study members of a vulnerable population?

☐ No.

☐ Yes.

☐ Has the MIRERC previously approved enrollment of these subjects?

☐ Yes. Continue to Question 4.

☐ No. **You must submit an amendment to the MIRERC to request the inclusion of these subjects.**

Subjects in the following vulnerable populations were enrolled without MIRERC approval.

☐ Children ☐ Pregnant Women and Human Fetuses

☐ Prisoners ☐ Students

☐ Cognitively/Mentally Impaired

4. Is this study conducted at, funded by, or recruiting from the vulnerable population (VP)?

☐ No

☐ Yes. In the table below, please indicate the total number of VP subjects enrolled in the study and indicate in which categories those subjects fall and how many represent each category indicated.

Total number of VP subjects:

☐	Children:	_____
☐	Cognitively Impaired:	_____
☐	Pregnant Women and Fetuses:	_____
☐	Prisoners:	_____
☐	Students:	_____

SECTION IV: PROTOCOL EVENT SUMMARY

1. **Since the last MIRERC review**, did any unanticipated problems, including adverse events, protocol deviations, or subject complaints, or noncompliance occur that required prompt reporting to the MIRERC?
   - ☐ No.
   - ☐ Yes. Were these events reported previously to the MIRERC and VP, if applicable?
     - ☐ No. Please explain why these events were not previously reported: _____
     - ☐ Yes. Provide a **summary** of these events:_____
       - ☐ Check here if the **summary** is attached.

2. **Since the last MIRERC review**, did any protocol-related adverse events, subject complaints, or protocol deviations occur involving a MIRERC-approved performance site that did **not** require prompt reporting to the MIRERC?
   - ☐ No.
   - ☐ Yes. Provide a **summary** of these events:_____
     - ☐ Check here if the **summary** is attached.

3. Is there a data safety monitoring plan for this study?
   - ☐ No. This study is minimal risk (exempt or expedited).
   - ☐ Yes. Summarize the findings of the data safety monitoring since the last MIRERC review, explain why findings are not available, or indicate that a summary has been attached: _____

4. Describe the progress of the research, including any observations and information about study results or trends: _____

5. Have subjects experienced any **direct** benefit(s) from their participation in the study?
   - ☐ No. Please explain: _____
   - ☐ Yes. Please describe: _____

6. Choose any of the following which have occurred since the last MIRERC review.
   - ☐ Literature publication which demonstrates a significant impact on the conduct of the study or the well-being of subjects
   - ☐ Audits from federal agencies conducted since the last MIRERC review that identified unanticipated problems involving risks to subjects or others or noncompliance
   - ☐ Events which affected the validity of the data
   - ☐ Increase in risk to subjects or others
   - ☐ Increase in frequency or severity of adverse events
   - ☐ Protocol deviations, problems, or complaints
   - ☐ Change in the risk-to-benefit assessment
   - ☐ None of the above

   Provide an explanation of any options checked above and submit any relevant documents: _____

NOTES:

- Incomplete submissions will result in a processing delay, which could result in study expiration.

SECTION V: INVESTIGATOR STATEMENT OF COMPLIANCE

By submitting this form, the Principal Investigator assures that all information provided is accurate. He/she assures that no further research activities will occur, including enrollment of new subjects, interaction with or intervention on current subjects, and analysis of identifiable data.