APPENDIX 8: MIRERC UNANTICIPATED EVENTS PROMPT REPORTING FORM

MIRERC STUDY NUMBER:
Date: _____

This form should only be used to report unanticipated problems involving risks to subjects or others (hereafter known as unanticipated problems) and investigator- or sponsor- initiated study suspensions holds. Do not use this form to report noncompliance.
or

Additional Requirements

1. If this report applies to multiple studies, complete a form for each study.
2. Attach any supporting documentation to the report.
3. For external adverse events which require prompt reporting form.

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator: _____

Department: _____ School: _____

Phone: _____ Fax Number: _____ E-Mail: _____

Contact Information:

Name: _____ Address: _____ Phone: _____

Fax: _____ E-Mail: _____

Project Title: _____

Sponsor/Funding Agency: _____

SECTION II: STUDY INFORMATION

This study is:

- ☐ Open to enrollment
- ☐ Closed to enrollment

Number of active subjects:

SECTION III: REPORT TYPE

A. ☐ Adverse Event that meets the following criteria:

- ☐ unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the MIRERC-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- ☐ related or possibly related to participation in the research (i.e., there is a reasonable possibility (more likely than not) that the incident, experience, or outcome may have been caused by the procedures involved in the research);
- ☐ suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Please note that such events routinely warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others;
- ☐ requires changes to the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

If the adverse event does not meet all four (4) criteria listed above, the event should not be reported to the MIRERC on this form. It should, however, be reported at the time of continuing review. Please note that the MIRERC is required to report any unanticipated problem to institutional officials and regulatory agencies (i.e. NACOSTI), as appropriate.

B. ☐ Major Protocol Deviation that meets one or more of the following criteria:

☐ may impact subject safety; and/or

☐ affects the integrity of study data; and.or

☐ may affect a subject's willingness to participate in the study.

Examples: Enrollment of a subject who did not meet all inclusion/ exclusion criteria; performing a study procedure not approved by the MIRERC; drug/study medication dispensing or dosing error; or failure to perform a required lab test or conducting a study visit outside the required timeframe, if, in the opinion of the investigator, may affect subject safety and/or data integrity). Only internal major protocol violations should be reported to the MIRERC.

If the protocol deviation does not meet at least one of the criteria listed above, the event should not be reported to the MIRERC on this form. It should, however, be reported at the time of continuing review.

C. ☐ Change to the MIRERC-approved protocol taken without prior MIRERC review to eliminate apparent immediate hazard to a research subject(s) (e.g. purposeful and for subject safety). Only internal protocol changes should be reported to the MIRERC.

D. ☐ Complaint of a subject that indicates unexpected risks or that cannot be resolved by the research team. Only internal subject complaints should be reported to the MIRERC.

E. ☐ Publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research, in terms of severity or frequency.

F. ☐ Change in labeling or withdrawal from marketing of a drug, device, or biologic used in a research study.

G. ☐ Unanticipated Adverse Device Effect (Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).

H. ☐ Investigator- or Sponsor-initiated study suspension or hold.

I. ☐ Other: Please explain:_____

SECTION IV: REPORT INFORMATION

1. Date of Report:_____ Date Study was Notified of Event:_____

2. Site: ☐ On-site (MUST Teaching Hospital) Participant ID (if applicable):_____
☐ External Site: Specify_____

3. Report: ☐ Initial Report
☐ Follow-up Report

4. Provide a description and explain why it is determined to be an unanticipated problem (i.e. how does it meet the criteria for an unanticipated problem?):

5. Explain the corrective measures taken as a result and the preventive measures to be taken to prevent recurrence in the future (if possible), how this was (or will be) resolved, and whether the sponsor was notified of this (if applicable):

SECTION V: INVESTIGATOR ACTION

Please indicate any actions that will be taken as a result of this report:

1. ☐ The informed consent process/document will be revised. This is required for an adverse event that is not consistent with the current informed consent document and/or available literature (e.g. drug brochure, protocol, publications), including its severity and/or frequency. Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

   ☐ The informed consent document will **NOT** be revised. Please explain:

2. ☐ The protocol will be revised. Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

   ☐ The protocol will **NOT** be revised. Please explain:

3. ☐ Currently enrolled participants will be notified. Please attach a copy of the notification.

   ☐ Currently enrolled participants will **NOT** be notified. Please explain:

4. ☐ Other corrective and/or preventive action will be taken. Please explain:

5. ☐ The event compromised the validity of the data. Please explain:

   ☐ The event did NOT compromise the validity of the data. Please explain:

Statement of Principal Investigator. By submitting this form, the Principal Investigator acknowledges that he/she has personally reviewed this report and agrees with the above assessment.

Recorded in the Minutes of: _____

FOR IREC OFFICE USE ONLY

Unanticipated Problem: In general, includes an incident, experience, or outcome that meets all of the following criteria:

- **a.** unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the MIRERC-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- **b.** related or possibly related to participation in the research (in the SOPs, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures in the research); and
- **c.** suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

☐ 1. Report reviewed by MIRERC Chair.

☐ Report does **NOT** represent an unanticipated problem. Sign report and return to investigator.

☐ Report likely represents an unanticipated problem. **Refer to convened MIRERC**.

Comments/Additional Action:_____

MIRERC Chair Signature:_____ Date:_____

☐ 2. Report sent to convened MIRERC for review.

☐ The report represents an **unanticipated problem**.

☐ Further action is required by the investigator; **see meeting minutes for additional information.**

☐ No further action is required.

☐ The report does **NOT** represent an unanticipated problem.

MIRERC Official Signature:_____ Date:_____

Recorded in the Minutes of: _____