UNANTICIPATED PROBLEMS INVOLVING RISK TO SUBJECTS OR OTHERS AND (REPORTABLE) ADVERSE EVENT REPORT FORM

An unanticipated problem is any incident, experience or outcome that meets these three criteria: (1) is unexpected, (2) is related or possibly related to the research, and (3) suggests that the research placed subjects or others at risk of harm. An adverse event is any untoward or unfavorable occurrence in a human subject (abnormal sign or symptom) associated with the subject's participation in the research. Reportable adverse events are those that meet the three criteria above.

TITLE OF STUDY:	CURRENT DATE:
SPONSOR	APPLICATION NO.

PRINCIPAL INVESTIGATOR:	
University Status (Faculty, Staff, Post-doc.):	Telephone Number:
Email Address:	Dept.:

COORDINATOR/CONTACT:	
University Status (Faculty, Staff, Student, etc.):	Telephone Number:
Email Address:	Dept:

1. Indicate the type of unanticipated problem or reportable adverse event.
   - ☐ Unanticipated problem/adverse event that was : (1) unexpected and (2) related/likely related to the research as determined by the principal investigator.
   - ☐ Specific protocol-defined events that require prompt reporting to the sponsor
   - ☐ Breach of confidentiality
   - ☐ Incarceration of a participant in a protocol not approved to enroll prisoners
   - ☐ An accidental or unintentional deviation to the HSC-approved protocol that involved risks
   - ☐ An emergency protocol deviation taken without prior HSC review to eliminate an apparent immediate hazard to a research participant
   - ☐ A complaint of a participant that indicates an unanticipated risk or any complaint that cannot be resolved by the research staff
   - ☐ Information that indicates a change to the risks or potential benefits of the research. For example,
     - An interim analysis or safety monitoring report indicating that frequency or magnitude of harms or benefits may be different than initially presented to the HSC; **OR**
     - A paper published from another study indicating that the risks or potential benefits of the research may be different than initially presented to the HSC.
   - ☐ Change in FDA labeling or withdrawal from marketing of the study drug, device or biologic used in this research protocol
   - ☐ Sponsor imposed suspension for risk
2. Location of event:

- ☐ At University of North Alabama campus.
- ☐ At another site in a multicenter study in the protocol of report
- ☐ Other → Explain:

3. Is the study permanently closed to enrollment?
   - ☐ Yes
   - ☐ No

4. Is anyone at this site still on study treatment (drugs, device, intervention)?
   - ☐ Yes
   - ☐ No

5. Indicate the type of report:
   - ☐ Initial report
   - ☐ Follow-up report

6. Date of problem/event:

7. Date of discovery of problem/event, if applicable:

8. Identify drug, biologic, device, treatment, intervention, etc., if applicable:

9. Briefly describe the problem/event:

10. Has the same problem/event occurred previously in this study?
    - ☐ No
    - ☐ Yes → What is the number of times this event has occurred study-wide?

11. Is the problem/event ongoing?
    - ☐ Yes
    - ☐ No
      - ↳ Date the problem/event ended.
      - ↳ Outcome of the problem/event (Check all that apply)
        - ☐ Participant was not adversely affected by the problem/event
        - ☐ Resulted in prolonged hospitalization
        - ☐ Resulted in permanent disability
        - ☐ Resolved spontaneously
        - ☐ Resolved with treatment
        - ☐ Participant discontinued study intervention
        - ☐ Participant withdrew from the study
        - ☐ Other → Specify. If problem involved breach of confidentiality, please specify the nature of data involved:

12. Are the specificity, frequency and severity of this problem/event consistent with the study and consent document?
    - ☐ Yes
    - ☐ No → Explain why not:

13. Based on your analysis of this event, should the consent document be revised?
    - ☐ No
    - ☐ Yes → Submit a revised consent document and a *Request for Modification* letter with this report.

14. Based on your analysis of this event, should the protocol be revised?

☐ No
☐ Yes → Submit a revised protocol and a *Request for Modification* letter with this report.

15. Based on your analysis of this event, should the research be suspended or terminated?
☐ No
☐ Yes → Describe the procedures for orderly suspension or termination of the research.

16. Should currently enrolled participants be notified about this problem/event?
☐ No
☐ Yes → Explain how they will be notified. If an addendum to the consent document will be used, submit this document and a *Request for Modification* letter with this report.

17. Should past participants be notified about this problem/event?
☐ No
☐ Yes → Explain how they will be notified. If an addendum to the consent document will be used, submit this document and a *Request for Modification* letter with this report.

Comments:

Principal Investigator Certification: My signature certifies that all necessary information has been assessed and the risk-to-benefit ration continues to be acceptable.

_____ _____ Principal Investigator's
Signature Date

Submit to Office of Sponsored Programs.

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For Committee Use Only

_____ Report Acknowledged/accepted without recommendation.
_____ Report Acknowledged/accepted pending receipt of additional information. To be submitted to the HSC.
_____ Protocol requires full review (disseminate all UP/AE materials to each HSC member).

Comments:

Committee Review Signature _____ Date _____