AAHRPP DOCUMENT # 102

UNIVERSITY OF ALABAMA
HUMAN RESEARCH PROTECTION PROGRAM

FORM: Report of Study Problem

NOTE: Use this form for all reportable problems. See POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems and Adverse Events for definitions, reporting procedures, timeframes, and IRB processes. If you need assistance in deciding whether to report an event or in completing this form, please contact a Research Compliance Specialist at 8-5069 (Medical IRB) or 8-6457 (Non-Medical IRB).

NOTE: Timeframes for Reporting: All deaths related to the study procedures must be reported immediately or within no more than 48 hours after the death. Initial reports of participant deaths may be made by telephone, e-mail, or in person, followed by the completed appropriate form. Events involving unanticipated life-threatening experiences must be reported with 7 calendar days of the investigator’s receipt of the information. All other serious and unanticipated problems—short of death or life-threatening experiences—must be reported within 14 calendar days of the investigator’s receipt of the information.

Date: ______________________

1. UA PROTOCOL IDENTIFICATION
   a. IRB Number
   b. Title:
   c. Principal Investigator:
   d. Sponsor (if any):
   e. OSP number (if any):
   f. Protocol approval expiration date:

2. CONTACT PERSON REGARDING THIS REPORT
   a. Name:
   b. Title/Role:
c. Telephone and FAX:
d. E-mail:

3. LOCATION OF RESEARCH:  € UA  € Other site _____________

4. FDA STATUS:  € Not applicable  € Approved Drug/Device
                € UA PI holds IND/IDE  € Sponsor holds IND/IDE

5. PROTOCOL STATUS:  € Open to Enrollment  € Closed to Enrollment
                      If CLOSED, choose one of the following:
                      € Participants still on therapy/receiving interventions
                      € Participants off therapy/intervention, in long term follow up only
                      € Participants off study therapy/intervention, in data analysis only

PROBLEM INFORMATION

6. Date of problem:

7. Date you learned of this problem:

8. How did you learn of this problem (e.g., report from sponsor, report from study personnel, personal experience with participants, etc.):

9. What is your appraisal of the type of problem? Check all that apply. (The IRB will make the final decision.)
   € A. Protocol Deviation
   € B. Adverse Event
   € C. Serious Adverse Event
   € D. Unanticipated Problem
   € E. Not sure/Precautionary Report
10. Subject Identifier: ____________________ Age; ________ Sex __________

11. DESCRIBE THE PROBLEM. For medical studies, discuss the medical nature of the problem, including background/history, concurrent medications, treatments and their dates. For nonmedical studies, discuss the nature of the problem, including the situation that led to the problem, individuals present, referrals for medical or psychological care.

12. What was the outcome(s) of this problem? Check all that apply.

   a. Death
   b. Life-threatening complication
   c. Initial or prolonged hospitalization
   d. Required intervention to prevent permanent damage
   e. Disability
   f. Significant dosage or protocol error
   g. Participant withdrawn from study
   h. Breach of participant confidentiality
   i. Other (describe):
   j. Resolved
   k. Outcome not yet known

13. Is this the first event of this kind in this study? € Yes  € No
   a. If NO, how many others have there been?
   b. What was done about the previous event(s)?
RELATION OF PROBLEM TO PROTOCOL

14. Is the problem related to the study procedures/protocol? € Yes € No € Unknown
   a. If YES, is the relationship € Possible € Probable € Definite?

15. Is the problem described in the study protocol? € Yes € No

16. Is the problem described in the informed consent? € Yes € No

17. Does the problem change the previous risk/benefit ratio? € Yes € No
   If YES, what is your estimation of the new risk/benefit ratio?
   a. € Minimal risk (Potential harm/discomfort not greater than those encountered in everyday life or during routine physical or psychological examinations)
   b. € Greater than minimal risk (circle: Moderate High) but has potential direct benefit
   c. € Greater than minimal risk (circle: Moderate High) and no direct benefit but with potential to yield generalizable knowledge about the subjects’ disorder or condition.
   d. If risk is greater than minimal, are the risks reasonable in relation to the potential benefits? € Yes € No Please explain.

CORRECTIVE ACTIONS

18. Should the protocol be changed to reflect this problem? € Yes € No

19. Should the consent form be changed to reflect this problem? € Yes € NO

2. Should previously enrolled participants be given information about the problem?
   € Yes € No
   If YES, how? (Informational letter, telephone call, etc.)
21. Should previously enrolled participants be asked to reconsent? € Yes € No

22. Does the information in this report require that the research be suspended or closed? € Yes € No

23. Has any corrective action or measure besides those described in 18-22 been taken to address this problem and prevent future problems? € Yes € No

For all questions answered YES, see POLICY: Modification of Approved Protocol. Complete FORM: Modification of Approved Protocol and attach other needed materials (e.g., revised consent document, clean copy of original application) as directed.

REPORTING

24. Was a Medwatch Report submitted? € Yes € No If YES, attach a copy.

25. Have you reported this event to anyone else? € Yes € No

If YES, to whom?

_____________________________________________   _____________

Investigator's Signature Date

ORC USE ONLY

1. The information in this report was UNANTICIPATED given the nature of the research and the study population. € True € False

2. The information in this report suggests that the research places subjects or others AT GREATER RISK of harm or discomfort than was previously known. € True € False

3. If the event reported is an adverse event, then is at least POSSIBLY related to the research. € True € False

4. This is a SERIOUS problem. € True € False

5. This report was submitted within the appropriate TIMEFRAME. € True € False

6. This problem was an € INTERNAL € EXTERNAL € Event

Recommendation:

The reported problem represents or may represent (check all that apply):

€ A protocol deviation
An adverse event

A serious adverse event

An unanticipated event without risk to participants or others

An unanticipated event with risk to participants or others

Action

- Refer to convened IRB for review.
- Treat by expedited review procedures.

______________________________________________
Signature of DRC/IRB Chair/Designee

_________________
Date