Appendix H
Unexpected/Adverse Event Report

Langston University
Institutional Review Board

UNEXPECTED/ADVERSE EVENT REPORT

Send one (1) copy of this form and one (1) copy of the consent form signed by the subject, to the IRB Office. Keep one copy of this form for your files. MUST BE TYPED.

Investigator's Name Position on Grant/Research

Department Address Phone E-Mail

Current IRB Approval Number: _____

Title: _____

Did this event occur to a subject enrolled in your study? ___Yes ___No
Was the event attributable to a study procedure?* ___Cannot be ruled out ___Yes ___No
Was the event unexpected or more serious than expected? ___Yes ___No
Is this kind of adverse event described in the currently approved consent form? ___Yes ___No
Will the event require changes in the consent form or in the research procedures? ___Yes ___No
If yes, attach a copy of the revised consent form with the changes highlighted.
Have you reported this event to the study sponsor? ___Not applicable ___Yes ___No
Has this kind of event happened before in connection with this study? If yes, explain below ___Yes ___No

Who is financially responsible for management of this adverse event? ___Not applicable
___Sponsor: _____
___Subject/subject's insurer: _____
___Other - please explain

Estimate of cost for management: _____ ___Not applicable
If medical care was provided, location of care: _____ ___Not applicable
Subject's name: _____ ___Not applicable
Address: _____ ___Not applicable
Date(s) of occurrence: _____ Location of event: _____ Time (am, pm):_____

Description of adverse effect and action taken (use additional pages, if necessary):

*If any relationship between the event and the study can be ruled out, do not submit this form.

Signature of Investigator _____ **Date** _____

Signature of IRB Chair _____ **Date** _____