BOWIE STATE UNIVERSITY
1865

OFFICE OF RESEARCH & SPONSORED PROGRAMS
BSU-INSTITUTIONAL REVIEW BOARD (IRB)

Charlotte Robinson Hall, Suite 110
14000 Jericho Park Rd, Bowie, MD 20715
P 301-860-4326
F 301-860-4390
bowiestate.edu

REPORTABLE EVENTS

To ensure the protection of research participants, federal regulations and the Bowie State University IRB (BSU-IRB) require study teams to submit reportable events to the BSU-IRB for review. The BSU-IRB has the authority to suspend or terminate approval of research that has been associated with unexpected serious harm to participants.

REPORTABLE EVENT DEFINITIONS

Adverse Event: An unfavorable *medical* occurrence, which may include abnormal signs (such as abnormal physical exam or laboratory finding),symptoms, or disease, temporarily associated with, but not necessarily considered related to, the subject's participation in the research study.

Unexpected Adverse Event: An adverse event that was not previously identified in nature, severity, or frequency in the investigator's brochure, sponsor protocol or current IRB-approved research protocol or Informed Consent Document, taking into account the characteristics of the subject population being studied.

Non-compliance: Failure on the part of the Principal Investigator or any member of the study team to follow the terms of IRB approved protocol or failure to abide by applicable laws or regulations or Human Research Protection policies. This includes protocol deviations.

Continuing Non-compliance: Non-compliance that has been previously reported or a pattern of non-compliance that,as determined by evaluation of the BSU-IRB, significantly affects the safety, rights or welfare of human research subjects or significantly compromises the quality or integrity of the research data (i.e. negatively impacts the ability to draw conclusions from study data).

Serious Non-compliance: Non-compliance that, as determined by evaluation of the BSU-IRB, significantly adversely affects the safety, rights or welfare of human research subjects or significantly compromises the quality or integrity of the research data (i.e. negatively affects the ability to draw conclusions from study data).

Examples of Serious Non-compliance include, but are not limited to:

- Performing non-exempt human subject research without obtaining prospective IRB approval;
- Implementing substantial modifications to a research study without obtaining prospective IRB approval;
- Failure to obtain research subjects' informed consent as required by the IRB approved study application; Failing to adhere to IRB-approved study applications where subject

safety or the quality or integrity of the research data may be significantly and negatively impacted; and
- Failing to comply with federal, state, or local regulations governing human subjects protections (this includes activities of the IRB and/or Human Research Protections (IRB) staff.

Unanticipated Problem Involving Risk to Human Subjects or Others: Any accident, experience, new information or outcome that meets the following criteria:

- Unexpected in terms of nature, severity, or frequency;
- Related or possibly related, to a subject's participation in the research; and
- Places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

NOTIFICATION: REPORTABLE EVENTS

To notify the BSU-IRB of reportable events, The Principal Investigator is required to submit a Reportable Event Form to the BSU-IRB. The Reportable Event Form should be submitted via email at the following email address: irb@bowiestate.edu. The form must be submitted within 10 days of the occurrence or on the date of the discovery of the occurrence. A Copy of the Reportable Event Form is listed on the following page.

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REPORTABLE EVENT FORM

The Reportable Event Form should be submitted via email at the following email address: irb@bowiestate.edu. The form report must be submitted within 10 days of the occurrence or on the date of the discovery of the occurrence.

Name of Principal Investigator (First, Last):	
Name of Primary Contact (First, Last):	
E-mail Address of Primary Contact:	
Phone Number of Primary Contact:	
Protocol Number:	
Study Title:	
IRB Approval Expiration Date:	
Date Form Completed:	

Event Summary:

Date or period of time when event occurred:	
Date or period of time when event was identified:	
Description of event and how it was identified, and root cause, if known:	

Study Enrollment Status:

☐ Study has not begun (no subjects consented)
☐ Open to subject enrollment
☐ Closed to subject enrollment

Current Enrollment:

Total number of subjects consented:	
Total number of active subjects:	
Total number of subjects in follow up:	

Assessment of Impact to Subjects/Participants:

Indicate the number of subjects affected by the event and the current status of those participants (active/completed/or follow up). Provide detail for consideration, if applicable. Use a separate sheet if necessary.

Did the event adversely affect the *rights* of participants? Yes ☐ No ☐ Why or why not? Provide detail for consideration, if applicable. Use a separate sheet if necessary. These rights include answering the following questions: - Did participants have enough time to decide whether or not to participate in the study and enough time to make that decision without pressure? - Did participants have the right to refuse to participate and stop participation at any time? - Did participants receive a copy of the study consent form? - Did participants have an opportunity to ask questions about the study?

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Assessment of Impact to Subjects/Participants:

Did the event adversely affect the scientific integrity of the study? Yes ☐ No ☐ **Why or why not? Provide detail if applicable, use a separate sheet if necessary.**
If yes, what is the plan to account for the reportable event in the study's analysis of data. Provide detail if applicable, use a separate sheet if necessary.

Attachment A: Corrective Action Plan: Discuss the corrective action plan taken or planned by the site to correct this deviation in a separate attachment submitted with this form. The attachment should be labeled "Reportable Event: Attachment A - Corrective Action Plan" Discuss any preventive actions taken or planned to prevent this occurrence in the future in the document. Contact the BSU-IRB Administrator for technical assistance, if applicable.

Attachment B: Communication Plan: Discuss plans to communicate information about this event to the study participants in a separate attachment submitted with this form. The attachment should be labeled "Reportable Event: Attachment B - Communication Plan" Contact the BSU-IRB Administrator for technical assistance, if applicable.

Submitted by:

Principal Investigator Name (Printed):	
Principal Investigator Signature:	
Date:	

FOR BSU-IRB USE:

Acknowledged/Corrective Action Plan approved and expedited

Acknowledged/Referred for Convened Board Review

Reviewer Notes: