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| **Institutional Review Board Office**  Phone: 410-955-3193  Toll Free: 1-888-262-3242  Email: [bsph.irboffice@jhu.edu](mailto:bsph.irboffice@jhu.edu)  Website: [www.bsph.edu/irb](http://www.bsph.edu/irb) | **UNANTICIPATED PROBLEM/EVENT/NON-COMPLIANCE REPORT**  ***DO NOT USE THIS REPORT FOR ANTICIPATED EVENTS OR MINOR/ADMINISTRATIVE PROTOCOL DEVIATIONS (they may be reported with your continuing review/progress report)***   * Use this report for prompt reporting of any **problem/event** that: 1) poses a greater harm or risk of harm to subjects or others than was previously known or recognized; 2) is unanticipated (in terms of nature, severity or frequency given the description in the research plan and consent forms); and 3) is potentially/conceivably, even remotely, related to the study procedures. If uncertain as to relatedness, please submit a report. * Use this form to report any **protocol non-compliance**, i.e.a significant failure to follow the IRB approved research procedures, federal, state, or local laws and regulations, or institutional policies.   ***NOTE: “Prompt reporting” means submission as soon as possible after discovery, but within 10 working days of learning about the unanticipated problem/event/non-compliance*** |

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| IRB Number: |  | Principal  Investigator: | | |
| Phone: |  | | | E-mail: |
| Study Title: |  | | | |
| Sponsor: |  | | Has JHSPH deferred review to an external IRB?  Yes  No | |

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| **I. Type of Reportable Event: Please answer the questions and describe the reportable problem/event/non-compliance in the text boxes under Sections A. and/or B. below.** |
| 1. **Unanticipated Problem**: The reportable problem/event is not a failure to follow IRB approved study procedures, laws and regulations or JHU policies. The reportable event involves (check all that apply): |
| 1. Unanticipated increased harm or risk of harm to **individual participants** connected with their study participation. Complete Section II, if appropriate.  2. Social/political developments beyond the PI’s control that pose harm or risk of harm to participants or to study staff. Describe below and provide details about any steps taken to minimize risk.  3. Other problem/event not associated with study participation that poses harm or risk of harm to study staff or study integrity (e.g., loss of study data, transport accidents, etc.) Describe below and provide details about any steps taken to minimize risk.   |  | | --- | |  | |
| 1. **Non-Compliance:** Describe the protocol non-compliance below. Explain whether you think this non-compliance poses potential or actual harm to participants or to their rights and welfare or compromises the integrity of the study or the JHU human subjects protection program.   *Note: In contrast to “serious non-compliance”, a protocol deviation is a minor or administrative departure from approved study procedures made without prior IRB approval. In this context, “minor or administrative” protocol deviations are defined as those that do not “affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects.” Examples include follow up visits that occur out of window or blood samples obtained at times close to, but not precisely within, the time points specified in the protocol.* *Deviations may be reported annually. An ongoing pattern of protocol deviations could constitute reportable “continuing non-compliance.”* |
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| **II. If the reported problem/event/non-compliance affected an individual study participant or other (study staff, family member, etc.) describe the problem/event/injury below. For multiple individuals, attach a table with the information below, if known. You may supplement this information as you learn more over time.** | | | | | | |
| Participant ID  (if relevant) | | Age | Gender:  Male/Female/  Non-Binary | Date of Event | Date Event Discovered | Site of the Event |
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| 1. Briefly describe the problem/event/non-compliance *(Use as much space as you need. Box will expand.)* | | | | | | |
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| 2. Did the problem/event/non-compliance cause harm or place the individual at increased risk of harm? **IF YES**, describe below; attach redacted clinical information if relevant. | | | | | | Yes  No |
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| 3. Does the study include a drug or device used in a clinical investigation?  **IF YES**, provide name of drug or device, when the drug or device was started, and if it was stopped. | | | | | | Yes  No |
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| 4. Describe your corrective action plan, including any actions you have taken to date.  Include any changes to study procedures that you have taken without prior approval by the IRB. | | | | | | Yes  No |
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| 5. Describe the current status of your study: are you still enrolling? Are participants still actively involved with study procedures or follow-up? | | | | | |  |
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| **III. Attribution (For Unanticipated Problems Only) and Notifications** | |
| 1. Please assess below the **relatedness of the unanticipated problem event** to participation in the research. If you select:   * 'Definitely not related,' you are indicating that there is no possibility of a connection between the event and study participation. * 'Definitely related,' you are indicating that the connection between the event and study participation is certain. JHU attribution standards may not be the same as your Sponsor’s; you must comply with both. | |
| Definitely not related  Probably not related  Possibly related  Probably related  Definitely related | |
| 2. Have any of the following entities been notified about the problem/event/noncompliance?  **IF YES**: check which have been notified: | Yes  No |
| Sponsor  FDA  External IRB (If JHU defers to an External IRB)  DSMB Medical Monitor |  |