

**OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)**

**Issues Report Form**

PROTOCOL #:

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| This form should be submitted when you need to report issues that occur during research conduct. Issues that require OHRA review include events / occurrences that may affect the safety, rights or welfare of participants or study staff. Issues that may negatively affect the data integrity of the study should also be reported. Additional guidance about appropriate issues reporting is available on the OHRA website.  **REQUIREMENTS FOR ISSUES REPORTING:**  - Completed Issues report form  - All OHRA submissions must include a complete list of documents being submitted for review. Each listed item must include the name of the document, version identifier and date (e.g., Study Protocol version 7, dated 9/26/2017)  - If this issue was reported to or reviewed by any other entities besides the OHRA, please include a copy of any reporting forms / correspondences  - Any other supplemental reports or communications related to the issue (if applicable). If additional information is expected but still pending at the time of OHRA submission, please clearly note this somewhere in the form. |

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| 1. **Oversight Entity Input:** Please address the following related to this issue: | |
| 1. Has the sponsor been notified of this issue? | YES  NO  N/A |
| 1. Has the Medical Monitor been notified of this issue? | YES  NO N/A |
| 1. Have other entities (FDA, etc.) been notified of this issue? | YES  NO N/A |
| ***For all entities marked “Yes,”******please submit copies of this correspondence.*** | |
| 1. Please provide the list of documents submitted in support of this report: | |
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| 1. **Issue Details:** Please provide the following details for the issue being reported. If there was a significant delay in reporting from the time of identification, please describe the reason for this delay. | |
| 1. Date or period of time when the issue occurred: |  |
| 1. Date or period of time when the issue was identified: |  |
| 1. Description of the issue and how issue was identified: | |
| 1. Please provide a summary with the following details:    1. Root cause of the issue / reason the issue occurred    2. Parties involved    3. Please discuss whether the potential for the nature, severity, and frequency of this issue was expected or anticipated during the project development or explain why this issue is completely unexpected.    4. Please provide your assessment of whether this issue is directly related to participation in the research or could be attributed to factors outside of the research context. | |
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| 1. Please discuss the corrective action plan taken or planned by the site to address/correct this issue. Please also discuss any preventative actions taken or planned to prevent this issue from occurring in the future:   *Please Note: If a protocol amendment is planned to address this issue, please provide reference to this and when the amendment will be submitted or if it has been submitted.* | |
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| 1. Plans for communicating information about this issue to participant(s), if applicable:   *Please Note: If an addendum consent form or telephone script has been created to communicate information about the issue to the participant, please note this here and attach a copy of the relevant document(s)* | |
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| 1. **Assessment of the Issue’s Effects**   *Note: It is insufficient to answer “No” without any rationale or explanation for the questions below.* |
| 1. Did this issue adversely affect the **scientific integrity** of the study?    1. Why or why not?    2. If yes, what is the plan to account for this in the analysis? |
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| 1. Did this issue adversely affect the **welfare or safety** of participant(s)?    1. Why or why not?    2. Describe any actual harm experienced as well as any potential for harm.    3. Comment on the severity of potential or actual harm.    4. Comment on whether this issue may represent increased risks to participants in general |
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| 1. Did this issue adversely affect the **rights\*** of participant(s)? Why or Why not?   \*These rights include:   * *Having time to decide whether or not to be in the research study and to make that decision without pressure.* * *Refusing to be in the study at all, and to stop participating at any time.* * *Being informed of all the applicable required elements of consent.* * *Receiving a copy of the consent form* * *Asking questions* |
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| 1. Did this issue affect the **participant’s willingness to participate** in the research? Why or Why not? |
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| 1. **Recurring Issues Assessment** | |
| 1. Is this issue a recurrence of an issue previously reported on this protocol? | YES  NO |
| 1. **\*If “Yes,”** please identify when the previous occurrence was received and processed by the OHRA: | |
| 1. **\*If “Yes,”** please explain how will the revised corrective action plan prevent this event from repeating: | |