**Institutional Review Board**

Old Vet Quad, Suite 151E, 3800 Spruce Street

Philadelphia, PA 19104

Phone: 215-573-2540

**Deviation Report Form**

FULL PROTOCOL TITLE**:**

PROTOCOL #:

PENN PRINCIPAL INVESTIGATOR:

IRB APPROVAL EXPIRATION DATE:

DATE FORM COMPLETED:

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| *A deviation is an unintentional action or process that departs from the IRB approved study protocol, involving one incident and identified retrospectively, after the event occurred. It may occurrence once or multiple times.* *Use this form to report a single protocol deviation. Please note that a single protocol deviation can affect multiple subjects. If you need to report multiple, different protocol deviations, please utilize the Corrective and Preventative Action Plan (CAPA) Template that is available on the IRB forms page:* [*https://irb.upenn.edu/forms*](https://irb.upenn.edu/forms) *under Supplemental Forms.**Deviations are reportable to the IRB* ***within 10 business days*** *from the time the event becomes known to the study team only when*1. *They may adversely affect:*
* *the rights and welfare of participants, including actual or potential substantive harm, OR*
* *the scientific integrity of the study*
1. *It reflects a pattern of repeated noncompliance including inadequate efforts to take corrective actions within a reasonable timeframe.*

*Expedited reporting is not required for minor protocol deviations that patently do not meet the criteria outlined above.* **Before completing this deviation report, please see: [deviation reporting guidance and definitions.](https://irb.upenn.edu/Deviation)** **DOCUMENTS REQUIRED FOR DEVIATION REPORTING: Please provide one copy of the following:**-Completed deviation report form -If this deviation was reported to or reviewed by any other entities besides the IRB, please include a copy of those reporting forms/correspondences.-Any other supplemental reports or communications related to the deviation (if applicable)- All IRB submissions for Greater Than Minimal Risk research must include a complete list of documents being submitted for review as they should appear in your determination letter (document name, version #, date). |

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| **Background Information**  |
| 1. **Who should the IRB contact with questions?** *Note: If Penn is serving as the Single IRB (IRB of Record) for a multi-site protocol, please list the name and contact information for the designated Point of Contact who is creating and submitting this deviation in HSERA.*
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| Name:  | Telephone:  |
| Email:   |
| 1. Is this a multi-site study where Penn is serving as the Single IRB or IRB of Record for external sites?
 | [ ]  **YES** [ ] **NO** |
| ***If Yes,*** please identify the site where the deviation occurred in the text box below and provide the names, email addresses & phone numbers for the site Investigator and Study Contact that the IRB can contact with questions related to the substance of the deviation. |
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| 1. Please note the study Enrollment Status:

[ ]  Study has not begun (no subjects consented)[ ]  Open to subject enrollment[ ]  Closed to subject enrollment |
| 1. Please note the current enrollment ***at the site where the deviation occurred***:
2. Total number of subjects consented:
3. Number of active subjects:
4. Number of subjects in follow up:
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| 1. **Oversight Entity Input:** Please address the following related to this deviation:
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| 1. Has the sponsor been notified of this deviation?
 | [ ] YES [ ] NO [ ] NA |
| 1. Has the Medical Monitor been notified of this deviation?
 | [ ] YES [ ] NO [ ] NA  |
| 1. Have other oversight entities (FDA, DSMB Etc.) been notified of this deviation?
 | [ ] YES [ ] NO [ ] NA  |
| ***For all above entities marked “Yes,”******please submit copies of this correspondence.*** |
| 1. **Please utilize the space below to provide the list of documents being submitted for review.**
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| 1. **Deviation Summary:** Please provide the following details for the deviation being reported. If there was a significant delay in reporting from the time of identification, please describe the reason for this delay.
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| 1. Date or period of time when the deviation occurred:
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| 1. Date or period of time when the deviation was identified:
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| 1. Description of protocol deviation and how deviation was identified:
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| 1. Please detail the root cause of the deviation (reason the deviation occurred, and parties involved).
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| 1. Please discuss the corrective action plan taken or planned by the site to correct this deviation. Please also discuss any preventative actions taken or planned to prevent this deviation from occurring in the future.

*Please Note: If a protocol amendment is planned to address this deviation, please identify the confirmation code or note when the amendment will be submitted.*  |
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| 1. Plans for communicating information about this deviation to participant(s), as applicable.

*Please Note: If an addendum consent form or telephone script has been created to communicate information about the deviation to the participant, please note this here and attach a copy of the relevant document(s)*:  |
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| 1. **Deviation Assessment:** To determine the level of review required please address the following:

*Note: It is insufficient to answer “No” without any rationale or explanation in the questions below.*  |
| 1. Please indicate the number of subjects affected by the deviation **and** the current status of those subjects (e.g. active/in follow up/completed). In doing so, please confirm that the study records have been reviewed to ascertain whether any other subjects were impacted by similar deviations.
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| 1. Did this deviation adversely affect the **welfare or safety** of participant(s)? Address the prompts below in your response:
	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. If applicable, comment on whether this deviation may have increased risks to participants directly unaffected by this deviation.
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| 1. Did this deviation adversely affect the **scientific integrity** of the study? Address the prompts below in your response:
	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 deviation adversely affect the **rights\* of participant(s)?** Why or Why not?

\*These rights include: * *To have enough time to decide whether or not to be in the research study and to make that decision without any pressure.*
* *To refuse to be in the study at all, and to stop participating at any time.*
* *To be informed of all the applicable required elements of consent.*
* *To receive a copy of the consent form*
* *To ask questions*
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| 1. Did this deviation affect the **subject’s willingness to participate** in the research? Why or Why not?
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| 1. Is this deviation a recurrence of a deviation(s) previously reported to the IRB on this protocol?
 | [ ] YES [ ] NO  |
| 1. **If “Yes,”** please identify the confirmation code(s) under which the deviation was submitted:
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| 1. **If “Yes,”** how will the revised corrective and preventative action plan prevent this event from being repeated in the future?
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| **Completion of Deviation: (This section not required if submitting via HSERA)**By signing this form, the principal investigator and the person completing the form (if other than the investigator) certify that he/she has disclosed to the IRB all relevant information that might affect the risk to benefit analysis of this study. |

Name of person completing this form:

Signature of person completing the form:

Principal Investigator Name:

Principal Investigator Signature:

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| **For IRB use only** |

[ ]  ACKNOWLEDGED/ CORRECTIVE ACTION PLAN APPROVED EXPEDITED

[ ]  ACKNOWLEGED/REFERRED FOR CONVENED BOARD REVIEW

Final reviewer notes:

Signature of Final Reviewer: DATE: