

**Institutional Review Board**

3800 Spruce Street First Floor Suite 151E

Philadelphia, PA 19104-6006

Phone: 215-573-2540

**Reportable Event Form**

FULL PROTOCOL TITLE**:**

PROTOCOL **#:** IRB APPROVAL EXPIRATION DATE**:**

PENN PRINCIPAL INVESTIGATOR**:**

DATE FORM COMPLETED:

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| Please use this form to report the following types of events:   * Medical adverse events (any untoward medical occurrence in a subject participating in a research protocol) OR * Non-medical reportable events (see the [Reportable Events Guidance page](https://irb.upenn.edu/reportable-event) for examples of such events).   This form should be used when the reportable event is both **unexpected** AND **probably or definitely related\*\*** to research procedures.  The IRB requires researchers to submit reports that meet the above criteria **within 10 business days** of the time the event becomes known to the study team, with one exception.  If the adverse event involved the unforeseen death of a subject, report **within 3 calendar days.**  ***If the event does not meet the reporting criteria above, please refer to the table on the*** [***Reportable Events Guidance***](https://irb.upenn.edu/reportable-event) ***page regarding whether the event is reportable to the IRB, and if so, when it should be reported.***  *\*\*NOTE:* ***Possibly related events******do not require expedited submission******UNLESS******the event suggests that the research places subjects at greater risk******than*** *was* ***previously known*** *(i.e.,* ***changes to the study conduct and/or documents are required*** *to mitigate risk and/or* ***participants’ willingness to participate may be adversely impacted****). If the event suggests that the research places subjects at greater risk than was previously known, the event may be an unanticipated problem and requires assessment by the IRB.*  **This form should not be used to submit deviations.** Please utilize the deviation form to submit deviations (including deviations on the part of the subject). Additional information on reportable events can be found in the [IRB SOPs](https://irb.upenn.edu/mission-institutional-review-board-irb/irb-policies) on the IRB website.  *Please note that a single Reportable Event Form can be completed for multiple subjects if the subjects were affected by the same event. If you need to report multiple, separate Reportable Events, please contact the IRB in advance to determine the best way to draft your report(s).*  \*\*\***The IRB should not receive any identifiable subject information**. All supporting documentation should be de-identified prior to submission. Additionally, when emailing with the IRB about any reportable event, please ensure that all email correspondence is devoid of identifiable subject information. \*\*\*  **DOCUMENTS REQUIRED FOR REPORTING: Please provide one copy of the following:**   * Completed reportable event form * If this event 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 event (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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| 1. **Study Contact:** In addition to the Principal Investigator, who should the IRB contact with questions about the event?*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 event in HSERA.* | | |
| 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,*** *did the event occur at Penn or at a site that is relying on Penn as the IRB of record?* | | **YES  NO** |
| ***If yes,*** please identify the site where the Event 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 Event. | | |
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| 1. **Report Type & Review Status-** responses to this section will dictate the information needed in following sections. | |
| * 1. Please indicate the type of event being reported | Medical / Clinical Event  Non-Medical Event |
| * 1. Is this a new event or a follow up to a previously reported event? | Initial Report  Follow-up Report – Please provide confirmation code(s) from previous reports and date(s): |
| * 1. Is the event considered resolved? | Resolved  Unresolved |
| * 1. Has the sponsor been notified of this event? | YES NO  NA |
| * 1. Has the Medical Monitor been notified of this event? | YES  NO NA |
| * 1. Have other oversight entities (Lead site PI, CRO, FDA, DSMB, Funding Agency, Another IRB, etc.) been notified of this event? | YES - please specify:  NO NA |
| ***For all entities marked “Yes,”******please submit copies of any supporting documentation and event-related correspondence*** *(e.g. MedWatch reports, SUSAR reports, email-based discussions of the event with the medical monitor or sponsor, DSMB assessments of the event, etc.).* | |
| * 1. **Please utilize the space below to provide the list of documents being submitted for review.** | |
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| 1. **Event Summary** |
| * 1. Please provide a brief narrative summary of the event that occurred. The summary should include the following elements: * The date the event occurred; * The date the team became aware of the event; * A description of the event and subject relevant information (e.g., medical history); and * A description of the immediate and follow up actions that were taken in response to the event. If the event is unresolved, please indicate what additional actions will be taken to resolve the event.   *Note: It is insufficient to refer to an attached SUSAR or MedWatch form.* |
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| * 1. **If this is a follow up report:** please summarize what has changed since the initial report.   *Note: It is insufficient to refer to an attached SUSAR or MedWatch form.* |
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| 1. **Is the event unanticipated or unexpected**? An event is unanticipated or unexpected if it is not accurately reflected in the protocol-related documents. Note: An event can also be considered unexpected if it is not listed at the specific *frequency* or *severity* that has been previously observed and described in the protocol-related documents.   The following are factors that should be considered when making this assessment:   * Is the event or problem described in the study documents (such as the IRB-approved research protocol, the investigator’s brochure/package insert, the device investigational plan, or the current IRB–approved informed consent document)? * Is the event or problem accurately described in the study documents (i.e. frequency, severity or some other parameter is not currently represented)?   + Has the event occurred with ***greater severity*** than was previously known?   + Has the event occurred with ***greater frequency*** or duration than was previously known? | | |
| * 1. Does the Principal Investigator assess this event as unexpected or unanticipated?   *\*If you are reporting an event that occurred at an external site or a site that is relying on Penn as the IRB of record, please provide the local PI’s assessment rather than the Penn PI’s assessment\** | | YES  NO |
| * 1. Please provide a narrative summary of the Principal Investigator’s rationale for this unanticipated/unexpected assessment. *Note: It is insufficient to refer to an attached SUSAR or MedWatch form.* | | |
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| * 1. If this event is described in any study documents (e.g., protocol, IB, or ICF), please direct the IRB to the appropriate document and the specific section and/or page numbers where the event is described: | | |
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| * 1. Has the sponsor assessed the event as unanticipated/ unexpected? | YES NO Pending | |
| ***If yes,*** *please identify the page number and the attached document in which the sponsor’s assessment is located.* | | |
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| 1. **Is the event considered related to the research?** An event is considered related to the research if the cause of the event is deemed related to the investigational product/intervention or a procedure that was performed for the purposes of the research.   The following are factors that should be considered when making a relatedness assessment:   * The IRB requires expedited reporting of events that are **probably or definitely related**. *If the event is not probably or definitely related*, please refer to the guidance on the [Reportable Events Guidance page](https://irb.upenn.edu/reportable-event) regarding whether the event is reportable to the IRB, and if so, when it should be reported. * The IRB considers an event to be probably related when it is probable that a causal relationship exists between the event and some aspect of research participation | | |
| * 1. Does the Principal Investigator assess this event as **related** to the research?   *\*If you are reporting an event that occurred at an external site or a site that is relying on Penn as the IRB of record, please provide the local PI’s assessment rather than the Penn PI’s assessment\** | | YES  NO |
| * 1. Please provide a narrative summary of the Principal Investigator’s rationale for this relatedness assessment. *Note: It is insufficient to refer to an attached SUSAR or MedWatch form.* | | |
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| * 1. Has the sponsor assessed the event as **related**? | YES NO Pending | |
| ***If yes,*** *please identify the page number and the attached document in which the sponsor’s assessment is located.* | | |
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| 1. **Risk/Benefit Assessment** |
| Please re-assess the study overall and **provide your rationale** regarding:   * + - whether **risks** to subjects **remain reasonable** **in relation to** the anticipated **benefits**.     - **whether** the event suggests **subjects are at greater risk** than was previously known or recognized. |
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| 1. **Response to the Event** | |
| * 1. Does the event(s) require any changes to the currently approved study conduct or document(s)? Have you been informed that revisions to study documents are planned (i.e. from the Sponsor)? | **YES** **NO** |
| ***If Yes****, please submit an amendment to the IRB or clarify when the amendment will be submitted.*  ***If No****, please explain why these events do not warrant revision of the current study conduct and/or document(s):* | |
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| * 1. Do current and/or past subjects need to be notified of this event? | **YES** **NO** |
| ***If Yes****, please briefly describe how you intend to accomplish this and provide a timeline for notification*  ***If No****, please provide justification for not notifying subjects* | |
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| * 1. **If this event involved a subject enrolled at Penn (or a site that is relying on Penn as the IRB of record)**: please provide a description of what information has been shared with the subject and whether this communication has been documented. Please also detail what actions may still be taken with the subject in response to the event (e.g. subject will be withdrawn, additional follow-up procedures, additional monitoring will occur, etc.) | |
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| **Completion of Reportable Event**: Please attach this completed form a Reportable Event application in the HSERA system along with the other requirement documents and submit for IRB review. |

By submitting this completed 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 re-approval of this study. ([Click to review PI responsibilities](http://www.upenn.edu/IRB/mission-institutional-review-board-irb/guidance/agreements))