**Instructions:** Use this form to report all adverse events, all internal unanticipated problems involving risks to subjects or to others (UPIRSOs), follow-up reports to adverse events, safety notice/reports from Sponsor or IRB of Record, and reports from a Data and Safety Monitoring Board or equivalent. Please read [IRB SOP: Requirements for Reporting to the IRB](https://www.campbell.edu/about/leadership/provost/institutional-review-board/for-investigators/policies-procedures/) prior to completing this form.

The IRB requires Principal Investigators to submit reports of adverse events, UPIRO’s or other safety issues meeting the definition of ***prompt*** (the event increased risk of harm to participants or others) within 5 days of the time the event becomes known to the project team. If the event did not increased risk of harm to participants or others, report as soon as the event is discovered or at the time of progress report, continuing review, or closure of the protocol, as appropriate.

*Please note that a single Reportable Event Submission 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 clear of identifiable subject information.\*\*\*

Attach this form to the [IRB Electronic Reportable Event Form](https://cphsadmin.wufoo.com/forms/zchj38n0ie50md/).

|  |  |
| --- | --- |
| **Section 1: Project Information** | |
| IRB Protocol Number: | Number |
| Protocol Title: | *Title* |
| Principal Investigator: | Name |
| Campbell email: | Name |
| Phone number: | Phone |
| School/Department: | School/Department |

|  |  |
| --- | --- |
| **Section 2: Submission Type** | |
| * Definitions: * Adverse Event (AE): An AE in research can be any unfavorable or unintended event, including abnormal laboratory findings, symptom or disease, temporarily associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation and does not necessarily have to be caused by any identifiable aspect of the research. * External Serious Adverse Event: An Adverse Event that occurs at any outside location and does not involve a CU research subject that (1) results in death, (2) is lifethreatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) results in persistent or significant disability/incapacity, (5) results in a congenital anomaly/birth defect, or (6) is an important medical event that jeopardizes the subject or requires medical intervention to prevent one of outcomes listed above. * Serious Adverse Event (SAE): An Adverse Event that (1) results in death, (2) is lifethreatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) results in persistent or significant disability/incapacity, (5) results in a congenital anomaly/birth defect, or (6) is an important medical event that jeopardizes the subject or requires medical intervention to prevent one of outcomes listed above. * Unanticipated Adverse Event (UAE): An Adverse Event that is not consistent in nature, frequency, or severity with the current IRB approval protocol, investigator’s brochure, device manual/instructions for use, or consent form. * Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO): Any information, including any incident, experience, or outcome that meets ALL three of the following conditions: (1) is unanticipated (in terms of nature, severity, or frequency) given (a) the research procedures described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, Instructions for Use/Device Manual and/or Investigator’s Brochure; and (b) the characteristics of the subject population being studied; (2) is related or possibly related to participation in the research (in this document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) or test article; and (3) suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred. | |
|  | All Internal unanticipated problems involving risks to subjects or others (UPIRSO), unless reported as an adverse event. This includes unanticipated problems that increase risks or decrease potential benefits. *Complete Section 3.* |
|  | Report from a Data and Safety Monitoring Board (DSMB or Equivalent) *Complete Section 4.* |
|  | Safety Notice/Report from Sponsor or IRB of Record *Complete Section 5.* |
|  | Adverse events that meet all of these criteria: (a) internal, (b) unexpected, (c) serious, (d) possibly, probably, or definitely related to the research project, and (e) experienced by participants or others. *Complete Section 6.* |
|  | Follow-up Report to: (a) internal, (b) unexpected, (c) serious, (d) possibly, probably, or definitely related to the research project, and (e) experienced by participants or others. *Complete Section 6.* |

|  |  |  |
| --- | --- | --- |
| **Section 3: Internal Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO)  NA** | | |
| 3.1 | Date(s) of UPIRSO: | Enter date(s) here |
| 3.2 | Describe as completely as possible the nature of the unanticipated problem:  Click or tap here to enter text. | |
| 3.3 | Describe as completely as possible how this problem resulting in increased risks or negative consequences to participants or others:  Click or tap here to enter text. | |
| 3.4 | Describe the measures that have been taken or planned to reduce the likelihood that similar problems will occur in the future:  Click or tap here to enter text. | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 4: Submission of a Report from a DSMB or Equivalent  NA** | | | |
| 4.1 | Date the report was received by the Investigator: | | Click or tap to enter a date. |
| 4.2 | Attach a copy of the DSMB report to the electronic submission form:  Name of file attached | | |
| 4.3 | Does the information in the DSMB report indicate any increased risks to the participant population?  Yes  No | | |
|  | 4.3.1 | If yes, indicate the actions that will be taken, if any, to protect or inform the research participants (select all that apply):  Suspend project enrollment  Revised protocol (if this is checked, please submit an amendment for the revised protocol)  Revised informed consent document (if this is checked, please submit an amendment for the revised consent form)  Addendum to the informed consent document for current participants (if this is checked, please submit an amendment for the additional form)  Other: Click or tap here to enter text. | |

|  |  |  |
| --- | --- | --- |
| **Section 5: Safety Notice/Repot from Sponsor or IRB of Record  NA** | | |
| 5.1 | Date the report was received by the Investigator: | Click or tap to enter a date. |
| 5.2 | Attach the safety notice/report from the sponsor or IRB of record:  Name of file attached | |
| 5.3 | Describe the measures that have been taken or planned to address the concerns described in the report:  Click or tap here to enter text. | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 6: Internal, Serious, Unexpected, and Reasonably Related Adverse Event or Follow-up  NA** | | | |
| 6.1 | Date(s) of Adverse Event: | Enter date(s) here | |
| 6.2 | Date Adverse Event(s) Reported to PI: | | Enter date(s) here |
| **This form is for reporting internal, serious, unexpected, and possibly, probably, or definitely related adverse events. These events must be reported to the IRB within 5 days of learning of the event. If the event increased risk of serious harm to participants or others, report in 72 hours. All other adverse events do not require prompt reporting but should be reported as soon as possible or with a progress report or continuing review, if required.** | | | |
| 6.3 | Why is this event considered serious and unexpected? (check the appropriate boxes if any of the following apply)  Unexpected event based on the protocol, investigator’s brochure, and/or consent form  Anticipated event that exceeds the frequency described in the protocol, investigator’s brochure, and or consent form  Anticipated event that exceeds the severity described in the protocol, investigator’s brochure, and/or consent form  Death occurred while the participant was in the study or within 30 days of active participation in the project  In patient hospitalization or prolongation of an existing hospitalization  Life-threatening reaction  Persistent or significant disability/incapacity, or a permanent harm or disability, wither physical or psychological  Inability to carry on normal activities, and required medical or surgical intervention  Congenital anomaly/birth defect in the offspring of a participant  Secondary cancer  Important medical event that jeopardized the participant and require medical intervention to prevent on of the outcomes listed above. | | |
| **If none of the above applies in section 6.3, this event does not meet the requirement for a reportable event. STOP. Please email the IRB with a brief description of the event and you will receive an email acknowledgement.** | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section 6.4: Type of Event and Current Enrollment** | | | | |
| 6.4.1 | | Indicate if the event was (select all that apply)  Medical (completed section 6B)  Psychological, Psychiatric or Behavioral (complete section 6C)  Other (e.g., economical, social, etc.): specify other. | | |
| 6.4.2 | | Current number of participants enrolled in the study at Campbell University: Number | | |
| 6.4.3 | | Current project-wide number of participants enrolled in the study: Number | | |
| **Section 6.5: Description of Medical Event** | | | | |
| 6.5.1 | | Indicate the relationship of the event to the project:  Definitely Related  Probably Related  Possibly Related  Not Related | | |
| 6.5.2 | | Provide a narrative description of each of the following: | | |
|  | 6.5.2.1 | | | The adverse event:  Click or tap here to enter text. |
|  | 6.5.2.2 | | | The treatment/intervention provided and the outcome:  Click or tap here to enter text. |
| *Continue to Section 6.6, if applicable or skip to section 6.7* | | | | |
| **Section 6.6: Description of Psychological, Psychiatric or Behavioral Event** | | | | |
| 6.6.1 | | Indicate the relationship of the event to the project:  Definitely Related  Probably Related  Possibly Related  Not Related | | |
| 6.6.2 | | Provide a narrative description of each of the following: | | |
|  | 6.6.2.1 | | | The adverse event:  Click or tap here to enter text. |
|  | 6.6.2.2 | | | The treatment/intervention provided and the outcome:  Click or tap here to enter text. |
| **Section 6.7: Information Regarding the Unexpected/Unanticipated Aspects of this Event** | | | | |
| 6.7.1 | | Describe how the event exceeds the nature, severity or expected frequency described in the protocol:  Click or tap here to enter text. | | |
| **Section 6.8: Adverse Event Monitoring** | | | | |
| 6.8.1 | | Indicate who is responsible for monitoring the implications of adverse events (click all that apply):  Principal Investigator  Data and Safety Monitoring Board  Sponsor  Principal Investigator at IRB of Record (if a multi-site project)  Other: Click or tap here to enter text. | | |
| **Section 6.9: Risk/Benefit Analysis** | | | | |
| 6.9.1 | | In your opinion, is the overall risk-benefit relationship of the research still acceptable in light of the event?  Yes  No  NA (for multi-site project ONLY): | | |
|  | | 6.9.1.1 | Rationale:  Click or tap here to enter text. | |
| **Section 6.10: Protocol/Investigator Brochure** | | | | |
| 6.10.1 | | Is the possibility of the event listed in the current protocol and/or Investigator Brochure?  Yes  No | | |
|  | | 6.10.1.1 | | If yes, copy the description form the current protocol and or investigator brochure into the section below:  Click or tap here to enter text. |
| 6.10.2 | | Are protocol changes needed as a result of this event?  Yes  No  NA (for multi-site project ONLY) | | |
|  | | 6.10.2.1 | | If yes, briefly indicate the changes here and submit an amendment to modify the protocol.  Click or tap here to enter text. |
| **Section 6.11: Consent Form** | | | | |
| 6.11.1 | | Is the possibility of the event describe in the informed consent document?  Yes  No | | |
|  | | 6.11.1.1 | | If yes, copy the description from the current consent form into this section:  Click or tap here to enter text. |
| 6.11.2 | | Are any changes needed to the informed consent document(s) to better inform the participant?  Yes  No  NA (for multi-site project ONLY) | | |
|  | | 6.11.2.1 | | If yes, briefly indicate the changes here and submit an amendment to modify the consent form(s).  Click or tap here to enter text. |
|  | | 6.11.2.2 | | If no, provide rationale:  Click or tap here to enter text. |
| **Section 6.12: Currently Enrolled Participants and Former Participants** | | | | |
| 6.12.1 | | Do currently enrolled participants need to be informed of this event?  Yes  No  NA (for multi-site project ONLY) | | |
|  | | 6.12.1.1 | | If yes, describe the method of notification (e.g., letter, addendum to the consent form) and submit an amendment for the additional materials:  Click or tap here to enter text. |
|  | | 6.121.2 | | If no, provide rationale for not informing the currently enrolled participants:  Click or tap here to enter text. |
| 6.12.2 | | Do former participants need to be informed of this event?  Yes  No  NA (for multi-site project ONLY) | | |
|  | | 6.12.2.1 | | If yes, describe the method of notification (e.g., letter, addendum to the consent form) and submit an amendment for the additional materials:  Click or tap here to enter text. |
|  | | 6.12.2.2 | | If no, provide rationale for not informing the currently enrolled participants:  Click or tap here to enter text. |

|  |
| --- |
| **Section 7: Please list attached documents** |
| (Corrective Action Plan, Sponsor Reports, DSMB reports, other documents listed in previous sections, etc.) |
| Click or tap here to enter text. |

**Principal Investigator:**

I verify that the information provide in this reportable event submission form is accurate and complete.