**Instructions:** Use This form to report non-compliance. Non-compliance is (intentional or unintentional) failure to comply with Campbell University HRPP/IRB policies and procedures or failure to follow the requirements and determinations of the IRB including significant or planned protocol deviation or violation (e.g., not following procedures in the IRB approved protocol). 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 researchers to submit reports of non-compliance 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/).

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| --- | --- |
| **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** | |
|  | Non-Compliance with IRB Policies and/or Procedures - *Complete section 3.* |
|  | Significant or Planned Protocol Deviation or Violation *(a planned protocol deviation needs to be submitted to the IRB prior to being implemented) -Complete section 4.*   * *Planned protocol deviation is when you know a protocol deviation will occur in advance, such as a subject’s second study visit being missed because they are on vacation.* |

|  |  |
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| **Section 3: Non-Compliance with IRB Policies and/or Procedures  NA** | |
| Date(s) of Non-Compliance : | Enter date(s) here |
| Describe as completely as possible the nature of the non-compliance:  Click or tap here to enter text. | |
| Describe as completely as possible what actions have been taken to correct this occurrence of non-compliance:  Click or tap here to enter text. | |
| Describe the measures to reduce the likelihood that similar non-compliance will occur in the future:  Click or tap here to enter text. | |

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| **Section 4: Protocol Deviation or Violation  NA** | |
| Date(s) of Protocol deviation or violation: | Enter date(s) here |
| Describe the deviation or violation:  Click or tap here to enter text. | |
| Did the deviation/error result in any increased risk of harm or negative consequences to the participant?  Yes  No  If yes, describe and indicate the steps that have been taken to address the issue with the involved participant:  Click or tap here to enter text. | |
| Describe the measures that have been taken to reduce the likelihood that similar deviations or violations will occur in the future:  Click or tap here to enter text. | |
| Was the deviation due to:  Participant error  Staff error  Circumstance | |

|  |
| --- |
| **Section 5: 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.