**A. Study Information**

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| --- | --- |
| IRB Study #:       | Date:       |
| Project/Study Title:       |
| Principal Investigator:       | Phone:       |
| IRB Contact Person:       | Phone:       |

**B. Definitions**

**Unanticipated Problem** – 1) Incident, experience, or outcome is unexpected; 2) incident, experience, or outcome is related or possibly related to participation in the research; 3) incident, experience, or outcome placed the study participant(s) or others at a greater risk of harm.

**Serious noncompliance** - is noncompliance that adversely affects the rights and welfare of study participants or results in any untoward medical occurrence that meets the criteria of “serious” or significantly impacts the integrity of study data. Serious is defined as side effects that may require hospitalization or may be irreversible, long-term, life-threatening, or fatal.

**Continuing noncompliance** - A pattern that, if unaddressed, could jeopardize the rights and welfare of research participants or the integrity of the study data due to noncompliance with the protocol, Federal regulations, and/or the requirements of the CIRB.

**C. General Information:**

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| Enter each study's Protocol Version Date associated with the incident, experience, or outcome. |  |
| Enter the Study Participant(s) Registration Number(s), if the incident, experience, or outcome involved a study participant(s). |  |

**D. Description of Incident, Experience, or Outcome**

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| Enter the date incident, experience, or outcome occurred. |  |
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| Describe the incident, experience, or outcome and/or add an attachment: |
|  |
| Attachment provided:**[ ]  Yes****[ ]  No** |
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| 3. Has the Cooperative Group/sponsor, the Study Chair, or a Federal agency been notified of this incident, experience, or outcome?**[ ]  Yes****[ ]  No**If Yes, identify those notified (Attach a copy of the notification and any response(s) received from those notified) |
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| Did the incident, experience, or outcome occur while the CIRB-approved protocol was followed as written?**[ ]  Yes** (If Yes, complete Section E: Unanticipated Problem)**[ ]  No** (If No, complete Section F Serious or Continuing Noncompliance) |

**E. Potential Unanticipated Problem**

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| Is this incident, experience, or outcome unexpected?**[ ]  Yes****[ ]  No** |
| If Yes, describe how the incident, experience, or outcome is unexpected and/or add an attachment. |
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| Is this incident, experience, or outcome related or possibly related to participation in the research?**[ ]  Yes****[ ]  No** |
| If Yes, describe how the incident, experience, or outcome is related or possibly related to participation in the research and/or add an attachment. |
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| Did the incident, experience, or outcome place the study participant(s) or others at a greater risk of harm?**[ ]  Yes****[ ]  No** |
| If Yes, describe how the incident, experience, or outcome placed the study participant or others at a greater risk of harm and/or add an attachment. |
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| Describe any action the Principal Investigator and/or Signatory Institution has taken, is taking, or is planning to take, to address the incident, experience, or outcome. (Add an attachment, if applicable) |
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F. Potential Serious or Continuing Noncompliance Report

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| Is the incident, experience, or outcome potential serious noncompliance?**[ ]  Yes****[ ]  No** |
| If Yes, describe how the incident, experience, or outcome is potential serious noncompliance and/or add an attachment. |
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| Is the incident, experience, or outcome potential continuing noncompliance?**[ ]  Yes****[ ]  No** |
| If Yes, describe how the incident, experience, or outcome is potential continuing noncompliance and/or add an attachment. |
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| Does the incident, experience, or outcome affect the study participant’s continued participation in the study?**[ ]  Yes****[ ]  No** |
| If Yes, describe how the study participant’s continued participation is the study is affected and/or add an attachment. |
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| Describe the management plan, including any corrective action, the Signatory Institution and/or Principal Investigator has taken, is taking, or is planning to take, to address the incident, experience, or outcome?Add an attachment, if applicable. |
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**For IRB/HSPP use only:**

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| **Institutional Official Determination (check all that apply):**[ ]  Reportable to PedCIRB as:  [ ]  Potential Unanticipated Problem  [ ]  Potential Serious Non-compliance  [ ]  Potential Continuing Non-compliance[ ]  Not Reportable to PedCIRB | Initials:      Date Determination Made:       |