

**Adverse Event Form**

<b>Project Title</b>	Click here to enter text.
<b>Principal Investigators</b>	Click here to enter text.
<b>Contact Address</b>	Click here to enter text.
<b>Telephone</b>	Click here to enter text.
<b>Email (Regis Email)</b>	Click here to enter text.
<b>Research Advisor (student projects)</b>	Click here to enter text.
<b>Research Advisor CITI Training expiration date</b>	Click here to enter text.
<b>Student Researcher CITI Training expiration date</b>	Click here to enter text.

- 1. Please describe the unexpected event(s). Include all details such as the number of events, the dates of occurrences, number of participants involved, known or potential impact on participants, and any other relevant information.**

- 2. Please describe the known or possible cause(s) for the event(s).**

- 3. Please describe the actions, if any, that you, members of your research team, and/or others took in response to the event. Include the dates of those actions as well as who took them.**

- 4. Have you submitted or do you plan to submit for IRB review, an amendment as a result of the expected event? If yes, please describe the amendment briefly. If no, please explain why you believe that an amendment is not required.**

- 5. Will you inform the participants who are already enrolled in your study about this unexpected event or any safety or procedure related information as a result of this unexpected event? If yes, describe what will be communicated, and when and how it will be communicated. If the communication will be in writing, please provide the text of the communication to the IRB.  
If no, please explain.**

