

Institutional Review Board

Unanticipated Risk/Adverse Event Form



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| --- | --- | --- | --- | --- |
| Date | Title of Research Project | | | |
| Project IRBNet ID | | | | |
| Principal Investigator/Project Director | | Department | Phone | Email |
| Co-Investigator/Student Investigator | | Department | Phone | Email |
| Co-Investigator/Student Investigator | | Department | Phone | Email |

|  |  |  |
| --- | --- | --- |
| Grant affiliation (if none, put “NA”) | | |
| Other organizations and/or agencies, if any involved in the study | | |
| Name of Contact | Department/Position | Email |

Date of original approval:

Type of Review (as determined by IRB): ☐ Exempt ☐ Exempt, Limited Review ☐ Expedited ☐ Full Review

**Unanticipated Risk/Adverse Event Report**

Please describe fully and completely the unanticipated risk or adverse event. Be as specific as possible.

Click here to enter text.

Describe the course of action taken, to date.

Click here to enter text.

Describe the proposed course of action, to follow.

Click here to enter text.

How many participants have participated thus far, and of these, how many have experienced a similar risk/event?

Click here to enter text.

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:**

**Please check to acknowledge acceptance of the following policies:**

☐ As one engaged in investigation utilizing human participants, I acknowledge the rights and welfare of the human participants involved and agree to protect them.

☐ As PI, I/we certify that this report is accurate and complete.