UNANTICIPATED PROBLEM REPORT FORM

*Any adverse events or unanticipated problems during approved research involving human subjects must be reported immediately to the IRB using this form. For a definition of these two terms, see the FAQ section at utica.edu/irb. You can type your answers on this form, and the lines and box will expand to fit additional text as needed.*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IRB Number:** |  | | |  | | | | |
| Title of Research: | | |  | | | | | |
| Principal Investigator’s Name: | | | | |  | | | |
| E-mail Address: | |  | | | | | Preferred Phone Number: |  |
| Date and Place of Problem/Event: | | | | | |  | | |

Did the problem or event result in physical, psychological, social, financial, legal, or other harm?

YES  NO  UNKNOWN

|  |
| --- |
| Description of the unanticipated problem or adverse event as determined by the Principal Investigator: |
|  |

***Classification of Event:*** *Please check one box only, indicating relationship of event to research and severity of the event.*

***ATTRIBUTION OF EVENT SEVERITY OF EVENT***

|  |  |  |  |
| --- | --- | --- | --- |
|  | Mild | Moderate | Serious |
| Not or Unlikely Related to Research Procedure |  |  |  |
| Unknown |  |  |  |
| Probably or Definitely Related to Research Procedure |  |  |  |

Signature of Principal Investigator:

*Signature Date*

***Submit this completed form to the Utica University IRB at irb@utica.edu.***

***IRB Use Only***

\_\_\_\_\_\_\_ Continue study as submitted and approved by IRB. No changes needed.

\_\_\_\_\_\_\_ Discuss with Principal Investigator

\_\_\_\_\_\_\_ Changes recommended in protocol or consent form.

\_\_\_\_\_\_\_ Place study on hold. Discuss with Principal Investigator.

\_\_\_\_\_\_\_ Report to Institution officials: (Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of IRB Chair:

*Signature Date*