

INSTITUTIONAL REVIEW BOARD

ADVERSE EVENT / DATA BREACH FORM

|  |
| --- |
| **ADVERSE EVENT: an undesirable and unintended, although not necessarily unexpected, result of intervention in this research**. |

|  |
| --- |
| **Date of form completion:** |
| **PROJECT IDENTIFIERS** |
| IRB Protocol Number: |
| IRB Approval Expiration Date:  |
| **Project Title:** |

|  |
| --- |
| PRINCIPAL INVESTIGATOR |
| Principal Investigator *(Must be a faculty/staff member at the University of New Haven)*:  |
| Title:  |
| Department/Division:  |
| Phone:  | UNH Email: |

|  |
| --- |
| Project Affiliation |
| [ ]  UNH Faculty | [ ]  Undergraduate Student*Name of Faculty Advisor:* |
| [ ]  UNH Staff |
| [ ]  UNH Administration | [ ]  Other *(Explain):**Name of UNH faculty Co-PI:* |
| [ ]  Graduate Student*Name of Faculty Advisor:* |

**Summarize the circumstances of the adverse event or data breach using the questions below. Use as much space as you deem necessary to provide a clear picture of the incident (attach additional pages as necessary). Be as specific as possible. Remember to include pertinent dates, times, names, and locations. Include any procedures undertaken to ameliorate the negative consequences of the events (e.g., contacting police, medical personnel, psychological personnel etc…) as well as modifications undertaken to reduce the probability of a repetition of the event/breach.**

|  |
| --- |
| **Please check all that apply. Explain all checked materials. If necessary, attach more pages.**  |
| [ ]  The adverse event/ data breach was related to the procedures associated in the project protocol: |
| [ ]  The risk of this adverse event/data breach is contained in the current consent form: |
| [ ]  The risk of this adverse event is contained in other literature distributed to research participants prior to their participation in the study: |
| [ ]  The consent form or a portion of the study should be revised as a result of this adverse event. (If so, submit a “Request for Revision” form and other pertinent documents to the IRB): |
| [ ]  Current research participants will be notified of this adverse event. If yes, describe the method of notification. If no, explain why not: |
| [ ]  Modifications have been undertaken to reduce the probability of a repetition of the event/breach. If yes, describe. If no, explain why not: |

|  |  |
| --- | --- |
| **PI Signature:** | **Date:** |

**Please email this form and supporting documents to:**

**Dr. Alexandria E. Guzmán, IRB Chair at** **IRB@newhaven.edu**

|  |
| --- |
| **FOR IRB USE ONLY:** |
| Date Received:  |
| Protocol #:  |
| Action Taken: |
| Comments:  |
| Decision (if any):  |
| Date Completed:  |