**Reportable New Information, Incident, or Adverse Event Form**

Before completing this application, please familiarize yourself with the [*Policies and Procedures for Human Research Protections*](https://research.northeastern.edu/hsrp/hsrp-manual/) to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants.

**Please submit this form along with any relevant materials** [**IRBReview@northeastern.edu**](mailto:IRBReview@northeastern.edu)**.**

**PROTOCOL INFORMATION**

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| **Principal Investigator:** Click or tap here to enter text. |
| **Student Investigator [if applicable]:** Click or tap here to enter text. |
| **Protocol Title:** Click or tap here to enter text. |

**FUNDING INFORMATION**

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| **Funding agency/source [NU if no external funding source]:** Click or tap here to enter text. |
| **Grant Title:** Click or tap here to enter text. |
| **Grant ID:** Click or tap here to enter text. |

1. **INCIDENT SUMMARY**

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| **Summarize the event/incident:**  Include details of the incident along with the location of the incident. Include what happened, when and where. Please also provide a timeline including the time of the incident and when the incident was discovered.  **­­­­­­­­­­­­­­** Click or tap here to enter text. |
| **Provide the date the information/incident was reported to the Investigator/Research Team (or when the information was received by the Investigator):**  Click or tap here to enter text. |
| **Describe the scope or magnitude of the incident:**  Include how many participants were impacted and the status/outcome of the incident for each participant.  Click or tap here to enter text. |
| **Summarize any risks or harms that resulted or might result in the future from the incident:**  Please address where these risks or harms were already identified in the IRB approved protocol and describe the magnitude of risk or harm.  Click or tap here to enter text. |
| **Provide the current status of the study:**  Open for enrollment  Closed to enrollment but study procedures are on-going  Closed to enrollment and study procedures are completed  Enrollment on hold |
| **What is being reported:**  Possible unanticipated problem (e.g., adverse event, breach of confidentiality or privacy, participant complaint, other problems/incidences)  Possible serious or continuing non-compliance (e.g., protocol deviations or violations)  Information (e.g., new information, incarceration of participant, data safety monitoring report) |

1. **INCIDENT RESPONSE**

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| **Summarize any immediate actions that were taken:**  This includes any steps taken to ensure the ongoing safety and protection of participants.  Click or tap here to enter text. |
| **Describe whether participants were or will be notified of the incident:**  Outline any plans to do so. Provide copies of any correspondence you used or will use.  Click or tap here to enter text. |

1. **INCIDENT CAUSE**

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| **Summarize why you think the incident occurred:**  Describe whether the incident reflects a failure to follow the IRB approved procedures. Please be specific regarding which procedures were not followed and provide your best understanding of why any procedures were not followed. If the incident occurred while following approved procedures, please give a summary of why you think it occurred.  Click or tap here to enter text. |
| **Describe if you feel the event/incident resulted from any research procedures and/or is related to participation in the research study:**  Please be specific about why or why not.  Click or tap here to enter text. |

1. **CORRECTIVE ACTION PLAN AND REPORTING REQURIEMENTS**

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| **Describe any modifications or changes you plan to make to your procedures to prevent this from occurring again:**  Note that a formal modification will need to be submitted to the IRB for any changes to ongoing or approved studies.  Click or tap here to enter text. |
| **Does the study involve any non-Northeastern relying sites that need to be notified of the incident? Does the study involve a sponsor or other stakeholders that require notification?** Click or tap here to enter text. |

1. **DOCUMENTS AND ATTACHMENTS**

List all documents that are being submitted to facilitate review of the incident. Please include any materials that were used or will be used to notify participants.

|  |  |  |
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| Document Name | Description of document use | Version Date |
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**PRINCIPAL INVESTIGATOR ASSURANCE**

I have reviewed the contents of this form, with attachments and certify the information provided is complete and accurate

Signature: Date:

*Principal Investigator / Faculty Advisor*

Signature: Date:

*Student Investigator*