**Review Guide: Reportable Event Reviewer Guide**

Date: Click or tap to enter a date.

The purpose of this review form is to evaluate reportable incidences and new information provided by the PI. This review form must be completed by the designated IRB reviewer.

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| **IRB Reviewer:** |  |
| **Principal Investigator (IRB #)** |  |
| **Protocol title:** |  |
| **Sponsor:** |  |
| **Vulnerable populations:** |  |
| **Collaborating sites:** |  |
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| **Definitions:****Non-compliance** is the failure to follow the federal regulations governing human research, requirements, and/or determinations of the IRB. Non-compliance may result from actions or omissions by study personnel and can range from relatively minor or technical deviations to serious deviations that threaten participants’ rights or welfare. It includes failure to follow:* the terms of the IRB approval (outlined in IRB initial and continuing review approval letters and our policies);
* the IRB-approved protocol;
* applicable laws, regulations; AND/OR
* policies related to the conduct of research involving human subjects.

**Serious noncompliance** is any noncompliance that:* increases the risk of harm to subjects or others;
* adversely affects the rights, safety, or welfare of subjects; AND/OR
* adversely affects the integrity of the data and research.

**Continuing noncompliance** is a pattern of repeated noncompliance that continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable timeframe. It includes:* non-compliance that is repeated either on a single protocol or across multiple protocols under an individual investigator or;
* non-compliance which represents a pattern of ongoing activities that indicate a lack of understanding or a willful ignorance of human research requirements that may affect research subjects or the validity of the research.

**Unanticipated Problem**An unanticipated problem is any incident, experience, or outcome that meets all of the following criteria:* unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; *[Note that if the protocol was not being followed as written or the research was not executed according to the IRB approved research plan, then the event is not considered unexpected, rather it should be considered noncompliance per definitions above.]*
* related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
* suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
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**To be completed by the designated IRB reviewer:****SUMMARY OF REPORTED EVENT:**Click here to enter text. |

**EVALUATION OF IMMEDIATE ACTIONS**

Describe the immediate actions taken by the PI to ensure the ongoing safety and protection of research participants.

Click here to enter text.

**ASSESSMENT OF THE EVENT (using the definitions above):**

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| [ ]  | The event does not represent noncompliance, because: Click here to enter text. |
| [ ]  | The event represents noncompliance that is neither serious nor continuing, because: Click here to enter text. |
| [ ]  | The reported problem does not meet the definition of an unanticipated problem, because (check all that apply)

|  |  |
| --- | --- |
| **[ ]**  | The event was expected, because Click here to enter text. |
| [ ]  | The event was not related or possibly related to participation in the research, because: Click here to enter text. |
| [ ]  | The event does not suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized because Click here to enter text. |

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| [ ]  | Is there any additional follow-up required?

|  |  |
| --- | --- |
| [ ]  | Corrective action, Click here to enter text. |
| [ ]  | Modification to the approved protocol, Click here to enter text. |
| [ ]  | Send for full board review |

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| [ ]   | Did this incident occur at a Northeastern University or a site for which Northeastern is the IRB of Record or involve a study participant or employee of the aforementioned? OR |
| [ ]   | If the incident occurred externally, does it have the potential to impact participants at sites where the Northeastern IRB is providing the IRB review? |