Instructions: Use this form to report Reportable New Information for a p-Site. Send this completed form to the overall study/lead UMN PI or their designee. As the p-Site PI, you must complete and send this form to the overall study/lead UMN PI **no later than 5 business days** of you becoming aware of the information. The overall study/lead UMN PI will submit the report on your behalf within **5 business days of becoming aware of the event** to the UMN IRB and will serve as a liaison for the p-Site with the UMN IRB see sIRB Manual (HRP-803) for more information.

1. **UMN IRB Study Number:** Click or tap here to enter text.
2. **Local Site ID Number:** Click or tap here to enter text.
3. **Today’s Date:** Click or tap here to enter text.
4. **RNI Short Title:** Click or tap here to enter text.
5. **Date the event occurred:** Click or tap here to enter text.
6. **Date you became aware of the information:**
7. **The UMN IRB defines prompt reporting to be within 5 business days. If you did not report this new information within 5 business days, please explain why the delay in reporting occurred, and how prompt reporting will be ensured in the future:**

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| Click or tap here to enter text. |

1. **Identify the categories that represent the new information:**

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|  | **Unexpected Death:** Unexpected death of a locally enrolled participant whether considered related to the research or not. Death is considered unexpected if the risk of death is not listed in the consent form or is not listed in the Investigator’s Brochure. |
|  | **Risk:** Information that indicates a new or increased risk, or a safety issue. For example:   1. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk. 2. An adverse event that indicates a potential increase in risk or reduction in benefit (such as those that may prompt a change to the protocol or consent form). 3. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk. 4. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol. 5. Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm. 6. Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm. 7. Any changes significantly affecting the conduct of the research. |
|  | **Harm**: Any harm experienced by a participant or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures.   1. A harm is “unexpected” when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population. 2. A harm is “probably related” to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm. |
|  | **Non-compliance**: Non-compliance with the federal regulations, state laws or UMN policies governing human research, or with the requirements or determinations of the IRB, or an allegation of such non-compliance. |
|  | **Audit**: Audit, inspection, or inquiry by a federal agency (e.g. FDA Form 483). |
|  | **Report**: Written reports of study monitors, Data Safety Monitoring Board reports, or other sponsor reports (e.g. FDA non-approval letters). |
|  | **Researcher error**: Failure to follow the protocol due to the action or inaction of the investigator or research staff. |
|  | **Confidentiality**: Unauthorized disclosure of confidential information. |
|  | **Protocol Deviation**: Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a participant. |
|  | **Incarceration**: Incarceration of a participant in a study not approved by the IRB to involve prisoners. |
|  | **Complaint**: Unresolved participant complaint. |
|  | **Suspension**: Suspension or premature termination by the sponsor, investigator, institution or other IRB. |
|  | **Unanticipated adverse device effect**: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants. |
|  | **Disqualification / Termination**: Change in qualification of any member of the study team based on state medical board, hospital medical staff action, or other disqualification by professional board or employer. |

***Important! Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.***

1. **Describe the nature and severity of the event:**

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| Click or tap here to enter text. |

1. **Describe the likely impact of the event on risk to the study participants or others:**

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| Click or tap here to enter text. |

1. **What actions, if any, have been taken to address the situation? If none, explain why:**

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| Click or tap here to enter text. |

1. **In the submitter's opinion:**

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| 1. Does this information indicate a new or increased risk, or a safety issue?   Yes  No   1. Does the study need revision, either study-wide or locally?   Yes  No   1. Does the consent document need revision, either study-wide or locally?   Yes  No   1. Do research participants need to be notified?   Yes  No |