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| **Instructions** | | | | | | | | | |
| * Complete this template when reporting events that may constitute an unanticipated problem involving risks to subjects or others; for urgent situations, please contact the HRPP office. * CLICK™ IRB   + Do not include any protected health information.   + Include the template with the Reportable New Information Submission.   + Upload the completed template to the Reportable New Information SmartForm, Question 7. * See HRPP Manual 9-1, Unanticipated Problems Involving Risks to Subjects or Others for definitions such as an adverse event, reporting requirements, etc. | | | | | | | | | |
| **Complete Questions 1 – 8.** | | | | | | | | | |
| 1 | Title. | | | | | | | | |
| 2 | Please explain how the event may be unexpected (in terms of nature, severity or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, and the characteristics of the subject population being studied. | | | | | | | | |
| 3 | Please explain how the event may be related or possibly related to participation in the research. Possibly related means there is a reasonable probability that the incident, experience, or outcome may have been caused by the procedures involved in the research. | | | | | | | | |
| 4 | Will currently enrolled subjects be provided an informational letter or be asked to sign a new consent form? | | | | | | | No  Yes | |
| If yes, submit a Modification to request changes. | | | | | | | | |
| 5 | Does the information in these documents require that the research be suspended or closed? | | | | | | | No  Yes | |
| 6 | Describe any action or changes the investigators are making in response to this unanticipated problem. | | | | | | | | |
| If revisions or changes to the study are needed, submit a Modification to request the change. | | | | | | | | |
| 7 | Describe what will be done to prevent future occurrences (e.g. what corrective actions have been taken or will be taken) or explain why correction actions are not needed. | | | | | | | | |
| If revisions or changes to the study are needed, submit a Modification to request the change. | | | | | | | | |
| 8 | Could the unanticipated problem also be an adverse event? | | | | | | | No  Yes | |
| If you answered yes, complete 8A, 8B, 8C, and 8D. | | | | | | | | |
| 8A | Was the unanticipated problem a serious adverse event? | | | | | | | No  Yes | |
| 8B | What was the outcome? (select all that apply) | | | | | | | | |
| Death  Life-Threatening  Hospitalization – Initial or Prolonged  Disability  Required intervention to prevent permanent damage  Study drug withdrawn temporarily | | | | Discontinued from study  Significant dosage or protocol error  Resolved  Outcome not yet determined  Other, | | | | |
| 8C | How related is the unanticipated problem to the following: | | | | | | | | |
| Subject’s underlying disease process or condition | Unrelated | Unlikely | Possible | | Probable | Definite | | Unknown |
| Please explain your answer: | | | | | | | | |
| Study’s procedure | Unrelated | Unlikely | Possible | | Probable | Definite | | Unknown |
| Please explain your answer: | | | | | | | | |
| Study’s drug/device | Unrelated | Unlikely | Possible | | Probable | Definite | | Unknown |
|  | Please explain your answer: | | | | | | | | |
| 8D | Was a MedWatch Report submitted? | | | | | | | No  Yes | |
| If yes, upload a copy to the Reportable New Information SmartForm, Question 7. | | | | | | | | |