|  |
| --- |
| **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. |