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| **Instructions** | |
| * Use when Question 4 items were left unchecked on the Continuing Review / Study Closure Information SmartForm. * CLICK™ IRB   + Include template with the Continuing Review or the Modification and Continuing Review Submission.   + Upload completed template to Continuing Review / Study Closure Information SmartForm, Question 5. * See HRPP Manual 8-7, Renewed Approval. | |
| **Complete Questions 1 – 2.** | |
| 1 | Study title. |
| 2. | Select item(s) that apply to the study and complete the related questions. |
|  | Subjects experienced unexpected harm. |
| Submit a Reportable New Information in CLICK IRB, provide RNI ID. |
| * As part of the RNI submission, complete the HRP-531- Template - Unanticipated Problem Involving Risk to Subjects or Others. |
|  | Anticipated adverse events have taken place with greater frequency or severity than expected. |
| Submit a Reportable New Information in CLICK IRB, provide RNI ID. |
| * As part of the RNI submission, complete the HRP-531- Template - Unanticipated Problem Involving Risk to Subjects or Others. |
|  | Subjects withdrew from the study. |
| Number of subjects who withdrew. |
| Provide a summary, including the reason(s) for withdrawal. |
|  | Unanticipated problems involving risks to subjects or others. |
| Submit a Reportable New Information in CLICK IRB, provide RNI ID. |
| * As part of the RNI submission, complete the HRP-531- Template - Unanticipated Problem Involving Risk to Subjects or Others. |
|  | Complaints about the study. |
| Submit a Reportable New Information in CLICK IRB, provide RNI ID. |
| * As part of the RNI submission, complete HRP-533 - Template - Subject Complaint. |
|  | Publications in the literature relevant to risks or potential benefits. |
| Provide a summary of the publications in the literature that are relevant to risks or potential benefits. |
| CLICK IRB: Upload literature as appropriate to the Continuing Review / Study Closure Information SmarForm page, Question 5. |
|  | Interim findings. |
| Provide a summary of the interim findings. |
|  | Multi-center trial reports. |
| CLICK IRB: Upload multi center trial reports to the Continuing Review / Study Closure Information SmartForm page, Question 5. |
|  | Data safety monitoring reports. |
| CLICK IRB: Upload data safety monitoring reports to the Continuing Review / Study Closure Information SmartForm page, Question 5 |
|  | Regulatory actions that could affect safety and risk assessments. |
| Submit a Reportable New Information in CLICK IRB, provide RNI ID. |
| * As part of the RNI submission, upload any documents relevant to the regulatory actions. |
|  | Other relevant information regarding this study, especially information about risks. |
| Describe the other relevant information regarding this study. |
|  | In the opinion of the PI, the risks and potential benefits are changed. |
| Explain why the risks and potential benefits are changed. |
| Submit a Modification if changes are needed. If modification submitted, provide MOD ID. |
|  | All modifications to the protocol have NOT been submitted to the IRB. |
| Please explain why all modifications to the protocol have not been submitted to the IRB. |
| Submit a Modification in CLICK IRB, provide MOD ID. |
|  | All problems that require prompt reporting to the IRB have not been submitted. |
| Please explain why all problems that require prompt reporting to the IRB have not been submitted. |
| Submit a Reportable New Information in CLICK IRB, provide RNI ID. |