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| **Instructions** | | |
| * Complete this template when reporting protocol deviations or violations. * CLICK™ IRB   + Do not include any protected health information.   + Include the template with a Reportable New Information Submission.   + Upload the completed template to the Reportable New Information SmartForm, Question 7. * See HRPP Manual 9-8, Protocol Deviations or Violations, for more information. | | |
| **Complete Questions 1 – 5.** | | |
| 1 | Study title. | |
| 2 | Did the deviation/violation affect subject safety? | No  Yes |
| Please explain your answer. | |
| 3 | If the study is externally sponsored, was the sponsor notified? | No  Yes  Not externally sponsored |
| If you answered yes or no, please explain you answer. |  |
|  | If you answered yes, also upload the sponsor response to the Reportable New Information SmartForm, Question 7. | |
| 4 | Was the subject informed of the deviation/violation? | No  Yes |
| Please explain your answer. |  |
| 5 | Describe what will be done to prevent future occurrences (e.g. what corrective actions have been taken or will be taken). If revisions or changes to the study are needed, submit a “Modification” to request the change(s). | |