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| **Instructions** | |
| * This template should be completed by the study team when reporting a subject complaint. * 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 9-4, Subject Complaints for more information. | |
| **Complete Questions 1 – 4.** | |
| 1 | Study title. |
| 2 | Who received the complaint? |
| 3 | Describe any action or changes the investigators are making in response to this subject complaint. |
| If revisions or changes to the study are needed, submit a Modification submission to request the change. |
| 4 | Describe any action or changes that 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 submission to request the change. |