**CAPA Review Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date:** |  | **Submitter:** | |  |
| **Site** |  | **UNC PI or Site PI (if M/C)** | |  |
| Protocol #: |  | | | IRB # |
| Protocol Title: |  | | | |
| Date of Audit Letter: | | | | |
| Observation Category: | | | Finding Section Number: | |
| Date(s) of Incident: | | | | |
| Date(s) reported to IRB: | | | Date approved by IRB: | |
| UPIRSO, Serious or Continuing Noncompliance: **No** **Yes** Describe: | | | | |
| **Audit Finding:** | | | | |
| **Root Cause Analysis:** | | | | |
| **CAPA:** | | | | |
| **Effectiveness Check:** | | | | |

**Attachment: ☐Audit Report ☐PRI ☐Other** ☐**N/A**

**Response/s**

|  |  |  |
| --- | --- | --- |
| **Did the response (attached documentation)** **include…** | **Y** | **N** |
| 1. A brief description of the issue? |  |  |
| 1. A root cause analysis? |  |  |
| 1. A description of corrective and preventative actions taken or planned? |  |  |
| 1. If so, did it outline by whom and a date of completion |  |  |
| **Comments/Notes:** | | |
|  | | |

**☐IRB Approval** ☐**OCT Approval** ☐**Other (e.g., LCCC Approval)**

**Is this part of a CPO wide CAPA?** ☐ **Yes** ☐ **No**

**Please complete a separate report for each CAPA. Please include all documentation with the submission including audit report, all PRIs, IRB responses, stipulations, OCT responses and/or any other pertinent documents.**