**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.**