CTO Protocol Deviation Form

**Study Number:**

**Patient ID:**

**Site:**

**Principal Investigator:**

**Date Protocol Deviation Occurred:**

**Date Site Became Aware:**

## **Type of Protocol Deviation (please select from drop-down below):**

Choose an item.

## **Detailed Description of Protocol Deviation (what happened at which timepoint?):**

## **Corrective Action Plan (what will be done to ensure the deviation does not happen again?):**

## **Did this deviation compromise the rights/welfare of a patient OR damage data integrity in any way?**

YES (if yes, the event MUST be reported to the NU IRB within 10 days of discovery)

NO

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Reporter (print) | **Reporter Signature** | **Date** |
|  |  |  |
| Principal Investigator (print) | **Principal Investigator Signature** | **Date** |

For NU IITs: Please submit completed form to your assigned Northwestern University Quality Assurance Monitor at [croqualityassurance@northwestern.edu](mailto:croqualityassurance@northwestern.edu)

|  |  |
| --- | --- |
| **Northwestern University Quality Assurance Use Only** | |
| Type of Review Required: | QA Review, Date:\_\_\_\_\_\_\_\_\_\_ QA Initials:\_\_\_\_\_\_\_\_\_\_  DMC Review, Date: \_\_\_\_\_\_\_\_\_\_ |
| Type of Deviation: | Incomplete Documentation  Patient Non-Compliance  Screening Error  Study Procedure Error  Treatment Error  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |