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

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|       |       |       |
| 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

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| **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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |