

## **Winship Clinical Trials Office CAPA Review Process – CAPA Review Team**

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### **1. Background**

The Corrective and Preventative Action (CAPA) Review Team was originally developed in March 2018. The Winship Clinical Trials Office (CTO) needed a method to assess the design, implementation and effectiveness of CAPAs developed to address significant deviations and non-compliance in the conduct of cancer-related treatment clinical trials.

### **2. Goals**

- Review all CAPAs to ensure they are appropriate, feasible and realistic.
- Identify trends in deviation reporting.
- Increase number of CAPAs successfully closed.

### **3. Solutions and Methods**

The CAPA Review Team is designed to ensure that CAPAs are appropriately developed based on a root cause analysis for significant findings, defined as deviations that require reporting to the IRB, other regulatory bodies or sponsor.

The CAPA Review Team reviews CAPAs for all significant deviations occurring in interventional treatment trials including pharmaceutical, investigator-initiated and NCTN trials. The scope also encompasses the review of trends in deviation reporting.

There are two levels of review: Significant deviations and less serious deviations.

Significant deviations that impact subject rights, safety, or welfare include, but are not limited to, consent process errors, eligibility process errors, drug dosing errors, missed safety labs, poor data quality, lapse in IRB approval and other major deviations. Significant deviations may also include deviations that affect the integrity of the research data and the subject's willingness to continue participation on the study.

Significant protocol deviations are submitted and reviewed at the regularly scheduled CAPA Review Team meetings. The full review and any recommendations are captured in the meeting minutes.

Less serious deviations are reviewed by the team quarterly to track for trends in deviation reporting. The review and approval is presented quarterly at CAPA Review Team meetings.

### **4. Outcomes**

*Category: Clinical Trials Operations - Completed Project*

In response to a recent NCI audit, Winship CTO created two CAPAs which focused on pharmacy orders to identify missing safety and protocol-specific laboratory values, as well as a pregnancy test audit to evaluate for testing compliance.

A recent FDA audit resulted in a classification of No Action Indicated (NAI) with a special mention from the auditor of Winship CTO lab compliance. The CAPA Review Team believes that this success can be attributed to effective CAPA development and implementation.

**5. Lessons Learned**

- Additional training is required on CAPA creation and root cause analysis.
- Once a CAPA is implemented, an assessment needs to be performed to determine the effectiveness of the CAPA. If not effective, a revision to the CAPA may be necessary.
- CAPAs need deadlines to ascertain if they can be closed out.
- The deviation reporting and assessment process needs to be streamlined. The team is currently investigating IT solutions.