Winship Clinical Trials Office CAPA Review Process
CAPA Review Team

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Purpose

To assess the design, implementation and effectiveness of corrective and preventative action plans (CAPA) developed to address significant deviations and non-compliance in the conduct of cancer-related treatment clinical trials by Winship faculty. The CAPA Review Team performs assessments of CAPA plans to ensure the CAPA is appropriate, feasible and realistic and monitor CAPA implementation and effectiveness.

Scope

The CAPA Review Team is designed to ensure that the CAPA is 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.

Deviations Review

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.

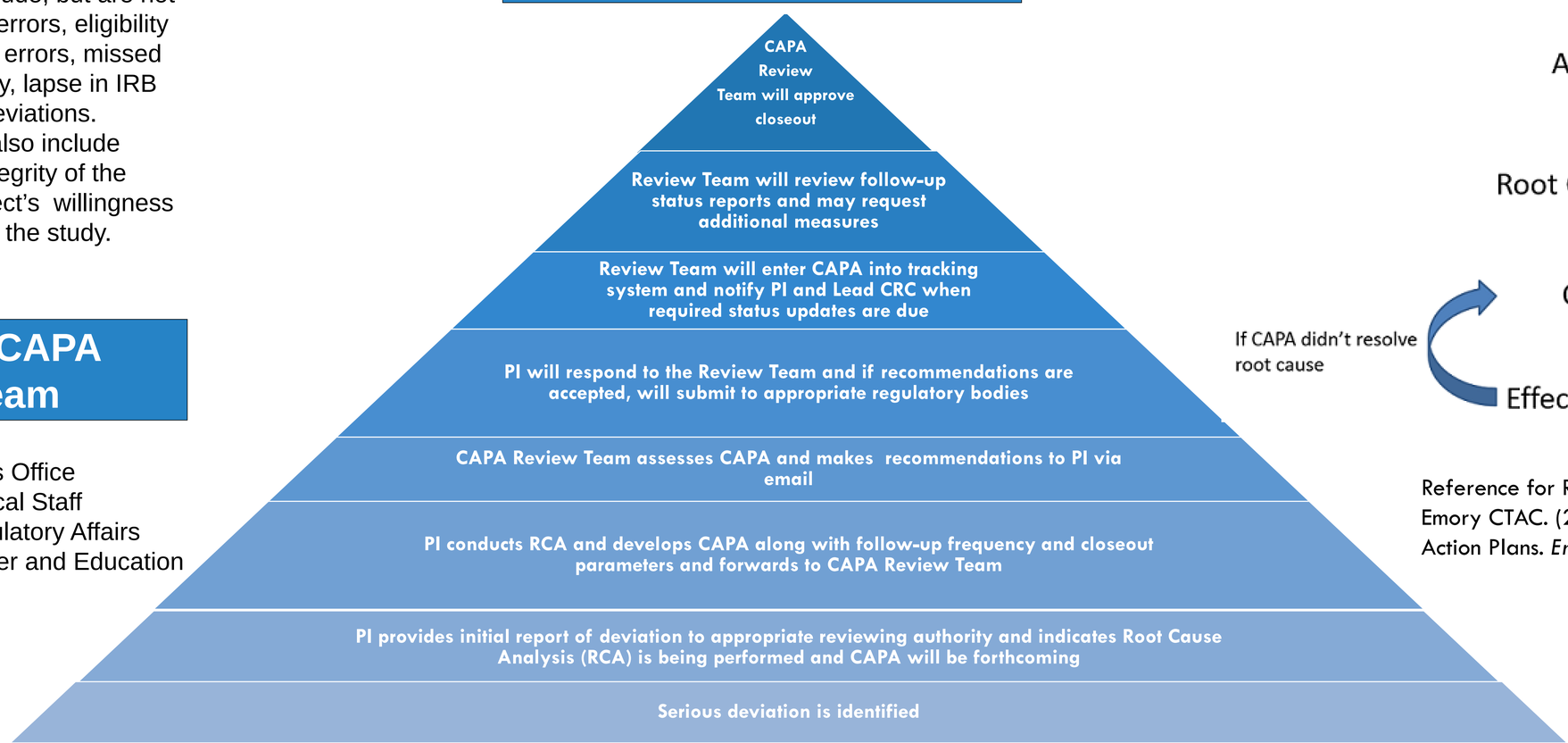
Members of CAPA Review Team

Director of the Clinical Trials Office
Assistant Directors for Clinical Staff
Assistant Directors for Regulatory Affairs
Manager for Quality Manager and Education
Manager for DSMC

Objectives

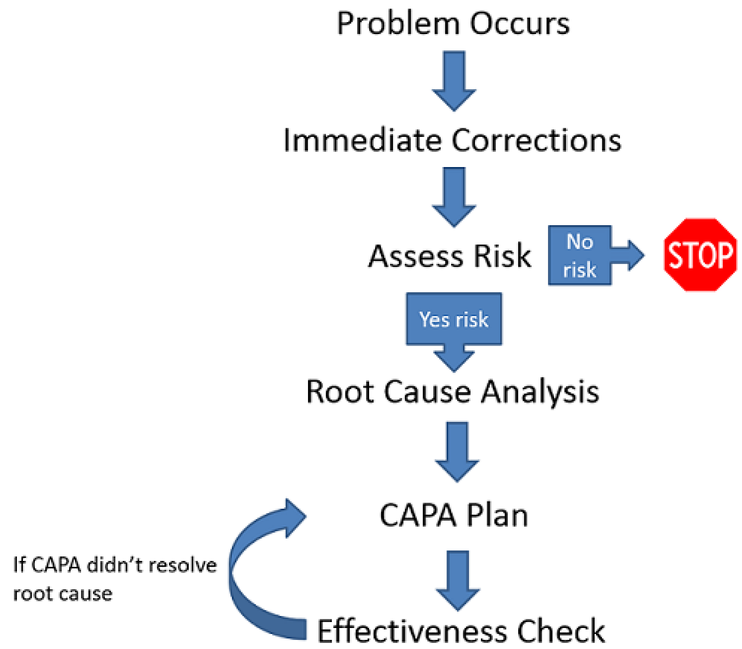
The CAPA Review Team reviews the CAPA for all deviations occurring in treatment interventional trials including pharmaceutical, investigator-initiated and NCTN trials. The scope also encompasses the review of major deviations for major audits and inspections, and minor deviations where trends are seen. The focus is to provide the PI a review of a CAPA before the final version is submitted to a reviewing authority, including the IRB, sponsors or other external reviewers.

CAPA Review Process



CAPA Tracking

CAPAs are tracked on a shared spreadsheet, and reviewed periodically to verify they are followed and determine when they can be closed.



Reference for RCA diagram.
Emory CTAC. (2020). Corrective and Preventive Action Plans. *Emory University.*