Enhancing the Deviation and CAPA Formulation and Review Process to Improve Compliance, Quality and Principal Investigator Satisfaction

Nicole Ostrowsky-Fabisch, MPH, CCRP
njo1@cinj.Rutgers.edu
Tracie Saunders, RN, MS, CCRC, Karen Jackson, AS, CCRP, Renee' Kurz, DNP, FNP-BC, AOCNP, Ginnette Watkins-Keller, DNP, RN, OCN, NEA-BC, Victor Colucci, RN, Bhavna Shah, PharmD, Andrea Gonzales, RN, MSN, OCN, CCRC, Raheel Anwer, Nicole Caltabellotta, BA, Mohammad Ghalib, MBBS, Lisa Malak, MSN, AGNP-C, Christian Misdary, MBBS, Serban Moroianu, MD, CCRC, Maria Scibilia, BSN, RN, CCRC, Laura Sullivan, DNP, RN, OCN, Elayne Wesolowsky, CCRP

BACKGROUND

Deviations pose risk to the conduct of clinical trials; corrective and preventative action plans (CAPAs) are critical for future mitigation of repetitive deviations. If deviations and CAPAs are not reported in a compliant, comprehensive, and timely manner, there can be extensive internal and external ramifications. Like other cancer centers, the Rutgers Cancer Institute of New Jersey's (RCINJ) Office of Human Research Services (OHRS) has received audit findings of incomplete and poorly written deviations and CAPAs. As a result, the OHRS leadership chartered the Quality Assurance, Improvement and Compliance Committee (QuAICC) in June 2023 to provide quality assurance oversight to the department's Disease Study Groups (DSGs) for deviation composition and CAPA development.

OBJECTIVES

To ensure deviations for patient treatment are appropriately documented, and research compliance through CAPAs are maintained per regulations and institutional policies and procedures, QuAICC is tasked with:

- Improving the investigation, documentation and reporting of deviations and CAPAs
- Reviewing deviations and CAPAs in a collaborative, peer-review format
- Enhancing the overall support the research staff provide to the Principal Investigators (PIs) since they are ultimately accountable and responsible for study conduct, inclusive of deviations and CAPAs.

METHODS

Meetings:

- Occur biweekly and remotely
- Attendance and participation:
  - Leadership in Clinical Operations, Quality Assurance, Information Technology, Education & Training, and Regulatory
  - Research Study Managers
  - Quality Assurance Managers
  - Clinical Trial Specialists, by invitation

A sampling of deviations and CAPAs that have been submitted within the prior two weeks across DSGs are chosen by the Quality Assurance team mostly at random, but sometimes by request of Managers for specific committee feedback.

From August 2023 through April 2024, of a total of 443 deviations were submitted, 49 deviations/CAPAs were reviewed (11%):

During the deviation and CAPA review discussion, the committee ascertains:

?	Was a root cause analysis performed and succinctly documented?
?	Was a realistic corrective action plan implemented and concisely documented?
?	Was a systematic, measurable, and timely preventative action plan proposed, developed and/or implemented, and then properly documented?

After discussion, the committee takes one of the following actions:

Accept
- Accept the deviation/CAPA as written
- No further action required

Revise & Resubmit Internally
- DSG Manager to revise the deviation and/or CAPA based on feedback
- Resubmit to Quality Assurance (QA) and re-present at a future committee meeting

Revise & Resubmit Externally
- DSG Manager to revise the deviation and/or CAPA based on feedback
- Resubmit to Sponsor, QA and/or IRB

OUTCOMES

Inadequately written deviations

Comprehensively & thoughtfully formulated CAPAs seen by OHRS QA, leadership, IRB, Human Research Oversight Committee, Industry and Cooperative Group Sponsors (i.e., NCI, NRG)

Greater satisfaction by PIs with the formulation of CAPAs

Improved skillset and competency in deviation & CAPA development by Research Staff

LESSONS LEARNED/ FUTURE DIRECTIONS

- ☑ The Deviation/CAPA template was revised to guide staff in incorporating all critical elements.
- ☑ Trends (i.e., missing labs, pill diaries, questionnaires) are identified to proactively minimize further recurrence of common deviations.
- ☑ Staff, instead of managers, are encouraged to present their deviations to aide in their understanding of the impact of deviations to patient and study outcomes.
- ☑ Committee to evolve into a broader process improvement committee.
- ☑ Guide re-evaluation of current, and development of new, Standard Operating Procedures