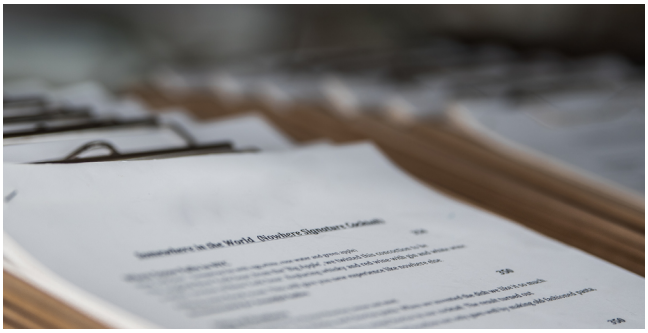
Corrective and Preventive Action (CAPA) Plans

Northwestern University
NUCATS
Clinical and Translational Sciences Institute

We're human. Sometimes things go wrong.

As clinical research professionals, we strive for consistency and alignment throughout the lifecycle of our studies. However, despite our best attempts, we will have things go wrong on a study and in our day-to-day research operations. Like many things in life, how we appropriately respond to things that go wrong is more important than what went wrong.



Protocol Deviations & Notes-to-File

Site staff routinely run across individual instances during a study that deviate from the research protocol. These are documented as protocol deviations and are usually one-time occurrences that do not compromise subject safety or widespread data integrity. Common protocol deviations include out-of-window visits or minor data omissions (like a missing blood pressure reading during a routine follow-up visit). A similar practice in regulatory documentation is a one-time note-to-file to indicate a discrete documentation issue like a missed signature, etc.

Corrective and Preventive Action Plans

In other cases, patterns of protocol deviations (sometimes called protocol violations) begin to emerge. Or, more severely, significant operational problems are identified that compromise data integrity or jeopardize the rights, welfare, and/or safety of participants. Sometimes these problems or patterns are raised internally by staff or externally by study monitors and inspectors. If you become aware of a deviation or unexpected event that endangers the rights, welfare, or safety of participants and others, you must first take immediate corrective actions without first obtaining IRB approval. The NU IRB outlines some appropriate responses.

Problematic patterns or practices must be immediately corrected and prevented from harming research subjects, study personnel, or the public. This process of correction and mitigation is outlined in a Corrective and Preventive Action (CAPA) Plan.

General Rule

If study operations (or an oversight in operations) result in Reportable New Information, it likely requires a CAPA Plan.

CAPA plans are comprised of a corrective component and a preventive component, both of which are critical to ensuring compliance with GCP and research best-practices.

One central component of a CAPA plan is a root-cause analysis. There may be multiple reasons or causes that contribute to a problem. Eliminating or mitigating the root cause should prevent a recurrence of the issue. In addition to the NU IRB, the Society of Clinical Research Associates (SOCRA) provides guidance and a case study on conducting a CAPA-related root cause analysis.

Who writes CAPA plans?

Usually, an experienced coordinator or research manager writes a CAPA once a problem is identified. The PI (and other impacted investigators) may contribute or review the CAPA as well.