

RESEARCH

@ SINGHEALTH DUKE-NUS
ACADEMIC MEDICAL CENTRE

Implementing a CAPA Plan

Implementing a Corrective Action and Preventive Action (CAPA) plan for issues identified during the conduct of research will help to improve quality of research and prevent recurrence of issues.



Corrective Action (CA)

Immediate action(s) taken to eliminate/address/correct a issue that has already occurred or has been identified.

Preventive Action (PA)

Action(s) taken to eliminate the root cause of a potential issue, as well as to prevent occurrence and recurrence of existing issues.



EXAMPLE OF CAPA

Issue: Pre-filled dates on Informed Consent Form (ICF)

IMMEDIATE ACTIONS REQUIRED OF PRINCIPAL INVESTIGATOR (PI)

- Refer to SHS-RSH-ORIC-CWP-201 CAPA Plan for Research on Docupedia
- Perform Root Cause Analysis (RCA) e.g. site staff unaware that ICF should not be pre-filled with the dates
- Prepare and implement CAPA Plan



Proposed Corrective Action

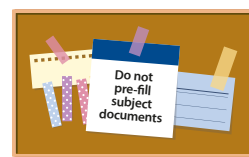


Discard all pre-filled documents



PI, research participant and/or witness must sign & date personally

Proposed Preventive Action



Use of study tools as reminders



Re-training of Study Team