Papworth Hospital NHS Foundation Trust CTBI: Corrective and Preventive Action (CAPA) Guidance

PURPOSE

To define the process to report quality system nonconformities, investigate their root cause, and prevent them from occurring (for preventive action) or recurring (for corrective action). In the context of this document, non-conformity can be any of the following but not limited to:

- Protocol non-compliance
- Protocol deviation
- Non-compliance with departmental SOPs
- GCP non-compliance
- Serious breaches of GCP
- Any of the above arising from inadequate training/experience of personnel
- Any of the above arising from procedural or logistical issues

For the purpose of Papworth Hospital NHS Foundation Trust CAPA, nonconformities could be highlighted via any of the following means (but not limited to):

- Internal monitoring
- Internal auditing
- Externally requisitioned audit
- Regulatory inspection
- Mock inspections

PROCEDURE

1. Identify and recording of the non-conformity on the CAPA database:

- The QA team runs three separate CAPA databases:
  - CAPA database – AUDIT
  - CAPA database – MONITORING
  - CAPA database – MHRA inspections
- All non-conformities must be recorded by the QA team onto the relevant CAPA database and, once agreed as detailed below, all further information must be entered in due course.

2. Root cause analysis and determination of actions required:

Root cause analysis:

- Analysis must be undertaken by the persons responsible for the trial and the QA team to clarify the finding
- Discussion must agree all actions to be completed as detailed below
- The person responsible for completing agreed actions must be identified
- The deadline for completion of all actions must be agreed
- All findings/actions and dates are to be entered onto the CAPA database by the QA team

***Corrective action*:**

- All actions that are required to ***correct*** the detected non-conformity or other undesirable situation found at Audit/Monitoring/Inspection.
- Includes investigation and correction of occurrences, there may be more than one cause of a non-conformity.

Preventative action:

- All actions that are required to ***prevent re-occurrence of*** the cause of a non-conformity or any other undesirable situation.
- There could be more than one cause for a potential non-conformity.

Communication:

- The non-conformity is reported formally to the required personnel in the form of an audit or monitoring report or using the CAPA process form for root cause analysis with clear instructions to be included within this report as to the person/s responsible for undertaking the corrective and/or preventive action with deadlines for actions to be completed (see Audit: Research and Development Good Clinical Practice (GCP) Audit (SOP 063) and Monitoring Papworth Sponsored Studies (SOP 016)).

3. Review and implement:

- Once the responsible person/s has completed all actions, the QA team must update the relevant CAPA database and mark the entry as complete.
- If it is felt necessary to re-audit/re-monitor in order to ensure that the actions have been implemented into practise as preventative measures, then this will be discussed, agreed, and recorded on the database as being required.

4. Re-audit/re-monitoring:

- Any required re-auditing/re-monitoring must be completed as agreed above and recorded in the database. This may either be a stipulation of the original CAPA database entry in which case the re-audit/monitoring must be undertaken before the entry can be marked complete. However, the requirement to re-audit/monitor may also be agreed as a separate event that can be recorded on the CAPA database as a new event.

ROLES/RESPONSIBILITIES

Role	Responsibility
QA team	• Maintain oversight of auditing and monitoring processes • Maintain all three CAPA databases and ensure up-to-date at all times • Liaise with relevant research teams to ensure the procedure outlined above is followed, recorded and completed

	• Escalate any concerns to the senior management team
Research team	• Liaise with QA team to ensure timely and effective completion of the process as outlined above • Ensure all preventative actions are incorporated into practise
Senior Management	• Liaise with QA team to maintain programs of audit and monitoring • Attend QA meetings to ensure QA departmental oversight • Work with the QA team to address any findings escalated to senior management and report to RDD as necessary