Health
Hunter New England
Local Health District

SOP 100: HNELHD Research Office - Corrective & Preventive Action (CAPA) Plan for Site Authorisation Breach

Purpose: To explain the process for completion of a CAPA plan after an identified breach of site authorisation for research conducted within Hunter New England Local Health District (HNELHD)

Scope: This Standard Operating Procedure (SOP) applies to the project Coordinating Principal Investigators (CPI) and HNELHD site Principal Investigators (PI) involved in research within HNELHD

Responsibility:

- The site Principal Investigator (PI) is responsible to ensure all project activity is ceased at site, until appropriate site authorisation has been received.
- The site Principal Investigator (PI) with the assistance of the project Coordinating Principal Investigator (CPI) is responsible for the completion of the CAPA. This task may be delegated to another suitably trained individual, but the responsibility remains with the Site PI and the project CPI.
- HNE Research Governance is responsible for oversite of the CAPA and ensuring the approving HREC committee receive notice of the site authorisation breach.
- Approving HREC committee is responsible for reviewing/noting the CAPA at next HREC meeting and deciding on the use of existing data/samples collected prior to the identification of site authorisation breach.
- The site PI and project CPI are responsible for implementing and amending processes in accordance with the root cause analysis.
- The site PI and project CPI are responsible for ensuring appropriate research governance authorisation (site authorisation) is received prior to recommencing the research within the HNELHD site.

Guidance on Completing the CAPA:

- **Description of site authorisation breach:** The description of the site authorisation breach should be as accurate and complete as possible. Key factors including who, what, when, where, how and why the event occurred. Another important component is to determine the level of risk in the situation, as this will drive CAPA timelines for resolution.
- **Description of the progress at site at the time the breach was identified:** A full description of the progress of the research at site is to be detailed, including any data or samples collected.

- Description of immediate action: A full description of the immediate action taken once the site authorisation breach was identified, this will assure the Research Governance and HREC teams that the research was ceased at site the moment the breach was identified.
- Find the Root Cause: An investigation that results in the identification of the actual cause, or cause(s) of the problem that resulted in the non-compliance. Root Cause Analysis (RCA) is a method or methodology used to investigate an incident to assist in the identification of system failures that may not be immediately apparent at initial review. The purpose of an RCA is to identify issues that contributed to or resulted in the incident occurring and to provide recommendations on actions to be taken to prevent or minimise a recurrence of a similar incident. It is interdisciplinary in nature and uses a structured process which endeavours to answer three questions: • What happened? • Why did it happen? • How can it be prevented from occurring again? Importantly, an RCA is not used to assign blame, but a tool designed for learning and improving the quality at the site. After identifying the root cause(s), break the solution into discrete, measurable actions that address the root cause(s):• What will be done – identify action(s) needed to correct and prevent recurrence (e.g. amending documents, changing systems, staff training)• Who will make amendments/perform the corrective actions and when?• Establishing an achievable target date for completion. Describe the procedures implemented to resolve the problem and indicate who is responsible for the procedure. Indicate an achievable date for the corrective action.
- Proposed Action for Long Term Solution: Corrective and preventive actions are considered long-term solutions to resolve or eliminate the cause of the non-compliance. This process is initiated to address the root cause, which can include the following; • Review of workplace procedures • staff training as appropriate • work process modifications • review of resource allocation and/or requirements • re training in the specific investigator site file to ensure authorisation is received prior to starting on site.
    - The PI or Delegate will track the progress towards completion of all required actions and evaluate whether the implemented actions have successfully addressed the issues.

Submission:

- The completed CAPA (signed by the PI/CPI and site HOD) is to be submitted to HNELHD-ResearchOffice@health.nsw.gov.au by the Site PI or Project CPI
- If the CAPA is unacceptable, the PI will be notified and will need to provide an appropriate response within the given timelines.

- The site PI must ensure the completed CAPA documentation is stored within the specific Investigator Site file

Once the CAPA has been acknowledged by the HNE Research Governance and HREC and returned to the site PI or project CPI, the appropriate site authorisation is to be sought prior to the recommencement of the project within the HNELHD site.