Glasgow Clinical Trials Unit
NHS GG&C Clinical Research Facility

MANDATORY

GUI 57.003A: GCRF Non-compliance and CAPA Report

Forms of non-compliance are described as critical, major and other: this in the line with internal audit categorisations as detailed in SOP 57.003, GCRF Internal Audit.

Procedure

1. Non-compliance

Non-compliances may be identified during a sponsor monitoring or audit visit, by regulatory inspection or internal audit. All non-compliances will be investigated by GCRF Quality Assurance Lead (QA Lead) or representative.

When cases of non-compliance have been identified by external monitoring or audit the Lead Study Nurse must notify the relevant Research Nurse Manager and QA Lead or QA representative. The initial notification must include an outline of the non-compliance and any immediate corrective action that has been or will be taken. Evidence of several non-compliances may result in escalation of categorisation. It is important to recognise that deviations may not be deliberate or intentional but action must be taken to prevent future repeats.

The QA Lead or representative must categorise the non-compliance following SOP 57.003. R&D Governance must be notified of Critical Non-compliances following SOP 51.008, Handling non-compliance with GCP and or/trial protocol in clinical research.

2. Corrective Action Preventative Action

A Corrective Action and Preventative Action (CAPA) report may be completed for each non-compliance, although it is acceptable to use one report for multiple items when more than one non-compliance is identified. Non-compliance may be identified during an internal audit and reported on the internal audit report.

i. Completion of CAPA Report

The sponsor may provide a CAPA report template and advise on the action, however when not available template Form 57.003D must be used. The identified non-compliance must be recorded as clearly as possible. It may be necessary to split the non-compliance into smaller areas particularly when a complex issue. QA Lead or representative may assist in completion of the CAPA report, assessing root cause and action.

Once identified, the QA Lead or representative will:

- Categorise the non-compliance, or assist with this if identified during an internal audit.
- Record details of the non-compliance on CAPA Summary Report.
- Identify or assist to identify appropriate corrective and preventative action.
- When identified internally the study sponsor may be notified.
- May assign a member of the GCRF Internal Audit team to support the research study team.

ii. Progressing the CAPA

The study team will work to complete actions within CAPA timelines, identifying and addressing the root cause to prevent future occurrences. Details of corrective action must be clearly documented in the report, including completion date. Categorisation of the non-compliance may be escalated if not closed in a timely manner.

Final CAPA Report must be submitted to QA Lead or representative for review. When appropriate the QA Lead or representative will confirm CAPA closure date to study team, updating details on CAPA Report and CAPA Summary Report.

The QA Lead or representative will present all non-compliances quarterly to the GCRF GCP Compliance Committee.

Document History

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Version	Date	Description
1.0	08/08/17	Creation of Guidance document
2.0	11/12/2018	• Change category Minor to Other in line with MHRA categorisation • Addition of GCRF QA Representative