# SOP09 Corrective Action Preventative Action for Research Sponsored by De Montfort University.

1. **Introduction**

This Standard Operating Procedure (SOP) describes the process to be followed when breaches/deviations of research protocol, Good Clinical Practice in research (ICH GCP), Sponsor/Host Standard Operating Procedures or agreements have been identified. The severity of the breach/deviation is irrelevant and this procedure must be the basis for root cause analysis and preventative action.

A Corrective Action, Preventative Action plan (CAPA) must be completed on each occasion, although it is acceptable to use a CAPA Plan for multiple items when more than one breach is identified. It is important to recognise that breaches/deviations may not be deliberate or intentional, but action must be taken to prevent future repeats.

Where it is identified that a breach/deviation necessitates an amendment to the protocol, the amendment itself will form part of the CAPA plan.

1. **Procedures**

A potential breach/deviation may be identified by any individual. An individual does not have to be associated with a research study to identify and escalate potential breaches.

On finding a potential breach/deviation, the individual must notify the Sponsor in the first instance.

In all cases a named individual must be nominated by the Chief Investigator/Principal Investigator (CI/PI) to lead communication with the Sponsor.

 It is expected that the CAPA form will be used (Annex A).

**Completion of the CAPA**

The identified breach/deviation must be written down as clearly as possible. It may be necessary to split the breach up into smaller parts, particularly where it is a complex issue. It is important to be clear but concise and factual. Each section of the CAPA form must be completed.

On first identifying the breach/deviation the CAPA must be opened. The Sponsor will categorise the breach adhering to the definitions Critical/Major/Near Miss.

Progress during completion of the CAPA will be monitored by the Research Governance Office using the ethics breach log. The lead individual will be responsible for ensuring that all actions identified are completed in accordance with the CAPA plan. Failure to comply will result in the non-compliance SOP process being implemented. A final version of the CAPA plan must be sent to the Sponsor to close the breach.

1. **Doccument Control**

|  |
| --- |
| **DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT** |
| **Author:** Douglas Gray | **Job Title:** Faculty Head of Research Ethics (HLS) |
| **Approved by:** University Research Ethics Committee | **Date Approved:** 14/04/2021 |
| **REVIEW RECORD** |
| **Date** | **Issue****Number** | **Reviewed By** | **Description of Changes (If Any)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **DISTRIBUTION RECORD:** |
| **Date** | **Name** | **Dept** | **Received** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |