

Corrective Action Preventative Action (CAPA) Template
Sponsor Reference Number:

CAPA Completion Guidelines

This form should ideally be completed electronically, but can be hand written. The form can be used to capture single or multiple breaches, when more than one breach is identified at a time.

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|--------------|-----------------------------|---|
| 1. The Title | | Complete Sponsor reference number and short study title. |
| 2. Column 1 | Number | Enter number of finding referred to on this form (i.e. 1 if singular or 2 etc. if multiple findings recorded). |
| Column 2 | Category | Enter Critical, Major or Other. A full explanation of these three definitions can be found on the CAPA form and in the non-compliance Standard Operating Procedure SOP S-1012 UoL. If further advice is required contact the Sponsor. |
| Column 3 | Date | Enter the date of the event. |
| Column 4 | Finding | Provide a brief description of the finding. Additional supporting documentation can be Supplied (please ensure any identifiable information is removed). |
| Column 5 | Immediate Action | Enter the details of the immediate action taken with regards to the breach (i.e., what you have done straight away to mitigate any risk/resolve the problem identified). |
| Column 6 | Corrective Action | Enter the details of the corrective actions put in place following the breach (i.e., what you have done to resolve the problem identified in the short-term). |
| Column 7 | Preventative Action | Enter details of what processes have been reviewed/updated to ensure there is no repeat of the breach. |
| Column 8 | Expected date of completion | Expected date of completion for individual findings entered on the CAPA. |

3. The Chief/Principal Investigator must print their name and sign and date the form.

| No | Category As below | Date | Finding | Immediate Action | Corrective Action | Preventative Action | Expected Date of completion |
|----|----------------------|------|---------|------------------|-------------------|---------------------|-----------------------------------|
| 1 | | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |

| Category definition: CRITICAL | Category definition: MAJOR | Category definition: OTHER |
|---|---|--|
| <ul style="list-style-type: none"> • The safety, wellbeing or confidentiality of participants has been jeopardised. • Reported data are unreliable or absent • Inappropriate, insufficient or untimely corrective action has taken place regarding a major non-compliance • Where there are a number of major non-compliances across areas of responsibility, indicating a systematic quality assurance failure • Provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the Regulations | <ul style="list-style-type: none"> • Significant and unjustified non-compliance with relevant legislation or Good Clinical Practice (ICH GCP). • A number of breaches of legislation or GCP within one area, indicating systematic quality assurance failure • A failure to comply with legislative requirements including annual reporting requirements | <ul style="list-style-type: none"> • Findings that are neither critical nor major |

P.I. Name (Print)

P.I. Signature.....

Date.....

For serious breaches and if requested the completed form should be sent by email to the Sponsor for the attention of the Research Governance Manager, email to rgosponsor@le.ac.uk