

Breach Reporting



What is a breach?

- Any departure from:
 - Approved Protocol
 - Conditions of approvals
 - Principles of GCP
 - Written procedures (SOPs)
 - Regulatory requirements
 - Insurance cover
 - Contractual obligations
 - Confidentiality and GDPR
- Our Sponsor does not recognise deviations – all deviations should be classified as potential breaches and reported

Breach reporting

- Breach reporting is the responsibility of the site team
- Breach reporting is made directly to the Sponsor
- Online breach reporting form:
<https://www.dundee.ac.uk/tasc/policies-sops-templates/breach-report-form>
- The Trial management team should be notified of breaches and copied into correspondence with the sponsor
- Every breach must be documented on the Breach Log in the ISF

Project details

Project title *

IRAS number *

Name and contact details of person reporting/completing the form

Name *

First name

Last name

Role within the project if relevant *

Email *

Telephone

Details of site where breach occurred

Name of site *

Site number (if not single centre) *

Name of Principal Investigator *

First name

Last name

Email of Principal Investigator *

Number of breaches reported at this site, including this one (information from Site's Breach Log) *

Have you informed any other parties? If so, who and when? Do NOT enter names, only the date when informed. Add rows as required.

Has the person who may have committed the breach been notified? (If different from person reporting the breach) *

Timeline

Date breach identified *

Day Month Year

Date breach occurred *

Day Month Year

Date of notification to Sponsor *

Day Month Year

Provide brief explanation if not same date

Summary of breach

Detail what has been breached- i.e., GCP, Protocol, SOPs, GDPR Explain the breach in layman's terms and what has happened. Include any background information and context to understand the incident. *

Actual impact

Actual impact (select all that apply if known at this time.) *

- Patient Safety, physical or mental integrity
- Data Integrity (scientific value of the trial)
- No significant impact

Corrective action taken

Provide details of action taken to correct this breach. If none, you must explain why not. *

Preventative action proposed

Provide a clear measurable plan on what is being put in place to stop this happening in the future. Must include: A timeline for implementation, detail who is responsible for each action and provide information on how this will be included in final report *

Submit

Corrective And Preventive Action (CAPA)

- **Corrective**
 - What did you do to fix it?
- **Preventive**
 - Preventive action is to stop the problem from happening again or to stop other sites doing the same
 - What can you do to stop it happening again?

Are breaches always serious?

No.

- The majority are technical breaches that do not result in harm to the trial participants or significantly affect the scientific value of the reported results
- But...several non-serious breaches can become one Serious Breach as collectively they do have a detrimental impact
- Therefore ALL must be reported to Sponsor, copied to the Trial Management Team and documented on the Breach Log
- If you are unsure, report anyway
- Always complete the Breach Log