

# 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 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 must be downloaded from TASC website each time it is required, to ensure you are using correct version
- The form can be found under TASC SOP59:

<https://www.dundee.ac.uk/tasc/policies-sops-templates/study-progress>

- Email copy of breach report form to [tascpotentialbreach@dundee.ac.uk](mailto:tascpotentialbreach@dundee.ac.uk) & copy in [GREAT-2-TM@dundee.ac.uk](mailto:GREAT-2-TM@dundee.ac.uk)
- Every breach must be documented on the Breach Log in the site file

## Part A

<b>Project details</b>
Protocol title:
IRAS number:

<b>Name and contact details of person reporting/completing the form</b>
Name:
Role within project if relevant:
Email:
Tel:

<b>Details of Site where breach occurred</b>
Name of <u>Site</u> :
Site Number <u>  </u> (If not single centre):
Name of Principal Investigator:
Email of PI:
Number of breaches reported at this site, including this one <i>(information from Site's Breach Log)</i> :

<b>Have you informed any other parties? If so, who and when? <i>Do NOT enter names, only the date when informed. Add rows as required.</i></b>		
	<b>Date</b>	<b>Method i.e., email, phone, verbal</b>
Has the person who may have committed the breach been notified? <i>(If different from person reporting the breach)</i>		
Principal Investigator		
REC		
Funder		
<u>Other</u> <i>(Identify all, but if none, then enter n/a under space for date)</i>		

<b>Timeline</b>
Date breach identified:
Date breach occurred:
Date of notification to Sponsor:
Provide brief explanation if not same date:

<b>Summary of breach</b>
<i>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.</i>

<b>Actual impact</b> <i>(select all that apply if known at this time.)</i>
Patient Safety, physical or mental integrity <input type="checkbox"/> Data Integrity (scientific value of the <u>trial</u> ) <input type="checkbox"/> No significant impact <input type="checkbox"/>

<b>Corrective action taken</b>
<i>Provide details of action taken to correct this breach. If none, you must explain why not.</i>

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

<b>Send to the Sponsor/Breach Team</b>
<i>Please forward this form to <a href="mailto:tascpotentialbreach@dundee.ac.uk">tascpotentialbreach@dundee.ac.uk</a></i>

## 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 & to [great-2-tm@dundee.ac.uk](mailto:great-2-tm@dundee.ac.uk) and documented on the Breach Log
- If you are unsure, report anyway