# Breach Reporting

## What is a breach?

- Any departure from:
  - Approved Protocol.
  - Conditions of approvals.
  - Principles of Good Clinical Practice (GCP).
  - Written procedures (SOPs).
  - Regulatory requirements.
  - Contractual obligations.
  - Confidentiality and General Data Protection Regulation (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 & copy in the Trial Management Team using sophist-trial@dundee.ac.uk
- Every breach must be documented on the Breach Log in the Investigator Site File (ISF).

Part A

| **Project details** |
|---|
| Protocol title: |
| IRAS number: |

| **Name and contact details of person reporting/completing the form** |
|---|
| Name: |
| Role within project if relevant: |
| Email: |
| Tel: |

| **Details of Site where breach occurred** |
|---|
| Name of Site : |
| Site Number –(If not single centre): |
| Name of Principal Investigator: |
| Email of PI: |
| 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.*

| | **Date** | **Method** *i.e., email, phone, verbal* |
|---|---|---|
| Has the person who may have committed the breach been notified? *(If different from person reporting the breach)* | | |
| Principal Investigator | | |

| **Timeline** |
|---|
| Date breach identified: |
| Date breach occurred: |
| Date of notification to Sponsor: |
| Provide brief explanation if not same date: |

BREACH REPORT- NHS Tayside/University of Dundee

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

| **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:*<br>***A timeline for implementation, detail who is responsible for each action and provide information on how this will be included in final report*** |

| **Send to the Sponsor/Breach Team** |
|---|
| *Please forward this form to tascpotentialbreach@dundee.ac.uk* |

## Summary of Breach

- Detail what has been breached e.g. GCP, protocol, SOP, GDPR.
- Explain the breach in layman's terms and what has happened.
- Include any background information and context to understand the incident.
- Do not include any participant identifiable data except participant trial ID number.
- Do not include the names of any staff, just their role in trial.

# 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 breaches must be reported to Sponsor & to SOPHIST-trial@dundee.ac.uk and documented on the Breach Log.
- If you are unsure, report anyway.