



TASC
Tayside Medical Sciences Centre

Recording and Reporting Breaches

STAR COVID-19



What is a Breach?

Any departure from:

- The approved protocol
- The principles of GCP
- Written procedures (such as SOPs)
- Regulatory requirements
- Confidentiality and data protection (GDPR)
- *Has to be a breach of something....*

How to Record and Report

Contact trial team: star-covidTM@dundee.ac.uk
with the following information:

- What was breached- the Protocol? GCP? GDPR?
- How it happened and how it was discovered
- Who or what was affected; include anonymous Subject ID
- What was the impact on personal safety
- Which staff were involved; roles only, no names
- What has been done to correct it
- Record the same information in the Breach Log
- Do not delay in reporting- information can be updated
- Follow instructions from the trial team



Are they always serious?

- No.
- The majority are technical breaches that do not result in harm to the trial subjects 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 documented on the Breach Log and reported to the Trials Unit





Examples of Serious Breaches

- Failure to obtain informed consent
- No evidence of medical assessment of eligibility of participant
- Subject does not meet the eligibility criteria for the study
- Failure to report SAEs in line with the protocol and sponsor SOPs
- Cumulative effect of non-serious breaches





Examples of potentially non-serious breaches

Every other deviation from....

- The approved protocol

- The principles of GCP

- Written procedures (such as SOPs)

- Regulatory requirements

- Confidentiality and data protection (GDPR)

There are no waivers.

All breaches must be recorded and reported



Corrective And Preventive Action CAPA

Corrective

- Can you fix it?
- How did it happen?
- What can you do to stop it happening again?

Preventive

- Preventive action is to stop the problem from returning at the original Site or occurring at others

- **If you are unsure, report anyway**
- **Don't delay**
- **Complete the Breach Log**

