

Incident Reporting

Any deviations from the protocol, study procedures, Good Clinical Practice (GCP) or regulatory requirements must be reported as incidents to the BASE study team, using the BASE Incident and Deviation Reporting Form. Any member of the team can report incidents.

Incidents should be reported as soon as practical and can be reported by either:

1. **Completing the Incident & Deviation Reporting Form** (available as editable PDFs and as hard copies in BASE Documents Box).

Paper version: Please fill in all documentation clearly and legibly. If you make a mistake, please cross through this with a single line and put your initials and date next to it. Once completed, scan and send to BASE study team by email (base@npeu.ox.ac.uk) or via the study upload tool

PDF version: Enter data onto editable PDF, save, and email to BASE study team.

If applicable, for the purpose of anonymity, all paperwork should have the Study number only and no further identifiable information.

OR

2. **Verbally via phone.** However, this must be followed up in writing.

If you are unable to complete the 'resolution' section of the form in the first instance, send the partially completed form and re-send the form with 'resolutions' at a later date.

Copies of all incident reports should be kept in the ISF.

Serious Breaches

Incidents and protocol deviations may be defined as a serious breach if there is a breach of GCP or protocol which is likely to affect to a significant degree either:

- The safety, physical or mental integrity of the subjects of the study.
- The scientific value of the study.

The BASE study team will conduct an assessment of all reported incidents to determine if they could be classified as a serious breach.