

Research & Innovation Arrangements over the festive period

R&I office

During the festive period the R&I office will be **closed** between **25th December 2017** and **1st January 2018 inclusive**.

SAE reporting

During the period between 23rd December and 1st January inclusive, please follow this process to report an SAE:

If you need to report an SAE, please email it to research@uhbristol.nhs.uk In this event, ensure **one** of the following is done:

1. Scan and attach to the email a hard copy of the SAE report which the PI has signed.

OR

2. Send the SAE report from the PI's email address to confirm signature electronically.

OR

3. Send an unsigned copy of the SAE report by email, followed up by a signed copy as soon as possible.

If the PI is unavailable and there is a delegated clinician, please send a copy of the SAE report signed by the delegated clinician, by email as described above (1&2).

Fatal/life threatening SUSARs will be reported onwards by R&I to the MHRA using the e-submission reporting function within 7 days.

The research team should report the SUSAR to the REC within 7 days of the report to us.

If a SUSAR is not fatal or life threatening the reporting period is 15 days.

Standard Operating Procedure

Refer to the **SOP 'Research Safety Reporting'** for detailed process and timelines.

More information can be found on our website [http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/what-to-do-when-approval-is-received/safety-reporting-\(adverse-events\)/](http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/what-to-do-when-approval-is-received/safety-reporting-(adverse-events)/)

Contact

If you need any advice/guidance on safety reporting during this period please email research@uhbristol.nhs.uk