



EXCALIBUR Unblinding Process

This service is provided by Southampton Clinical Trials Unit (SCTU)

023 8120 5154

Unblinding for EXCALIBUR is only available **Monday-Friday 9am-5pm**

Requests for unblinding should only be from a healthcare professional and will only be approved if certain criteria are met

Healthcare professional contacts the Quality & Regulatory Team (QRT) at SCTU to unblind a patient randomised in the HATRIC study



The QRT will establish the reason why unblinding is being requested and will discuss the unblinding request with the Chief Investigator (CI) or delegate.



The reason for requesting unblinding will be documented by the QRT and will proceed depending on the criteria below:-

UNBLINDING WILL PROCEED IF:-

- A potential SUSAR is received (either confirmed by PI or Clinical review).
- There are extraordinary circumstances (after authorisation from the CI or delegate)

UNBLINDING WILL NOT PROCEED IF:-

- The patient has died (it will not influence the management of the patient)
- The patient is pregnant. Pregnancy is not itself a criterion for codebreak. Unblinding in this situation will only occur if authorised by the CI or delegate.



The QRT will unblind the patient by contacting the Statistical Team at the SCTU. In order to unblind the patient it will be necessary to provide the **patient pack number or participant ID**. The QRT will not disclose the unblinding information to the trial team at the SCTU.

In the case of a potential SUSAR, the QRT will then report to the MHRA & REC as required following regulatory timelines.



On completion of the unblinding a member of the QRT will inform the caller of the patient's treatment allocation. An email notification that the patient has been unblinded will be sent to the EXCALIBUR Team, but this will not include details of the patient's treatment allocation.

Patients randomised into the EXCALIBUR study will be provided with a treatment card detailing contact numbers for their local site. In addition each card has the direct number for the SCTU should this be required by a healthcare professional. **Patients must be advised to carry the EXCALIBUR treatment card with them at all times.**