

Emergency Unblinding

Emergency unblinding: Procedures

- Emergency unblinding should only be carried out where a physician considers that it is necessary for participants clinical safety/medical emergency.
- If emergency unblinding is required, the clinician should contact the local PI or delegate that will have a login to the interactive web-based randomisation system, TRuST, for 24-hour emergency unblinding (only for their site).
- Responsibility of the local PI to ensure that adequate training and instructions are given for anyone delegated this role to enable them to access and perform the emergency unblinding procedure.
- Emergency unblinding **must** be carried out in TRuST system. TRuST informs Sponsor, CI and TM.
- The CI is also able to unblind all participants across all sites if required.
- The date, reason and result must be documented and signed by the person carrying out the unblinding. This must be stored in a sealed envelope in the ISF.
- Disclosure of the unblinding result should be to individuals involved in the participant's care only.
- Where possible, the participant should remain blinded and continue with trial visits.

Emergency unblinding: Requirement

- Being PI or delegated to emergency unblinding on Delegation Log.
- Emergency unblinding training completed:
 - This presentation.
 - PI and those delegated this task must complete 2 dummy emergency unblindings.
 - Must be recorded in Training Log in ISF.
- TRuST log-in.
- Requester details (i.e. name, role, contact details) and reason for emergency unblinding.
- Gender, date of birth and initials of participant to be unblinded. Participant ID and a Pack ID should also be used but emergency unblinding is still possible if latter two are not known.
- Printer.

Emergency unblinding: TRuST System

- TRuST can be accessed through: <https://trust.hicservices.dundee.ac.uk>
- There is also a link on the SOPHIST trial website resources page: <https://sites.dundee.ac.uk/sophist-trial/sophist-trial-resources/>
- Login details for emergency unblinding are different from TRuST access for randomisation by research team/nurses.
- The password can be changed on the TRuST login screen, top right.

Emergency unblinding: TRuST System

- Login to TRuST using emergency unblinding login details.
- Enter your name.



The screenshot shows the TRuST login interface. At the top is the TRuST logo with the text 'Tayside Randomisation System'. Below the logo is a text input field with the placeholder text 'Please enter your name:' and an 'Ok' button to its right.

- Click “Emergency Unblinding”.



The screenshot shows the TRuST system menu. At the top is the TRuST logo with the text 'Tayside Randomisation System'. Below the logo, the 'Project' is set to 'SOPHIST Test'. The main heading is 'TEST SITE' in red. Underneath, the 'Site' is set to 'Site 1'. There is a section for 'EMERGENCY UNBLINDING' which contains two buttons: 'Emergency Unblinding' (highlighted with a red border) and 'Print Unblinding Form'.

Emergency unblinding: TRuST System



EMERGENCY UNBLINDING

Requester Details

Person Requesting the Unblinding(Name):

Role:

Contact Number:

Email:

Reason for code break?:

Participant Details

Gender: Male Female

Date of Birth:

Initials: *First and last initial should be entered*

Participant ID Known: Yes No

Select Participant:

Pack ID Known: Yes No

Enter Pack ID:

Are you sure you want to unblind? Yes No

Enter:

- Requester Details
- Participant details:
 - Gender
 - Date of birth (using format dd/mm/yyyy)
 - Participant initials
 - Participant ID
 - Pack ID (only one of the pack IDs is required, if this information is not available click “no”)

If a participant ID and pack ID are not known unblinding can still occur with only gender, date of birth and initials completed (unless there is more than one participant at your site with the same details)

- Answer “yes” to Are you sure you want to unblind?
- Click on “Unblind Participant”



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Emergency unblinding: TRuST System



EMERGENCY UNBLINDING



EMERGENCY UNBLINDING FORM

Unblinding should only occur when patient safety is compromised. Ensure there is a genuine need to perform unblinding

Unblinding Result

Participant: 01010
Allocation: Placebo

Return to Main Menu

Sponsor	University of Dundee and NHS Tayside		
Protocol No.		EudraCT	
Chief Investigator	Dr Ify Mordi	IRAS	1007807

Person Performing the Unblinding:	sophistUnblind - Joel Rocha		
Person Requesting the Unblinding:	Joel Rocha		
Role:	Trial Manager		
Contact Number:	01382 388596		
Email:	jrocha001@dundee.ac.uk		
Reason for Unblinding Request:	Allergic reaction		
Date of Request:	04/07/2024		

Study Participant ID:	01010	Site:	Site 1
Pack ID:	1004		
Date of birth:	07/01/1960	Initials:	JR
		Gender:	Male

Unblinding Result	Placebo
Soatagliflozin/Placebo	

TRuST Unblinding Performed by:	
Name:	Designation:
Signature:	Date:

Download Date: 04/07/2024 14:09:54

When emergency unblinding results are visible:

- Click “Print Unblinding Form”.
- Download & print the record of the unblinding.
- Sign & date the emergency unblinding form.
- Inform treating clinician of unblinding result.
- Document unblinding date and reason for unblinding in the participant’s medical records.
- The result should not be documented so not to unblind research team.
- File emergency unblinding form in a sealed envelope in the ISF.
- Sponsor, CI and PI will be notified of emergency unblinding occurring, but not of result, by automatic email from TRuST.

Emergency unblinding: If TRuST is not working

- Sites will be informed of any planned downtime for TRuST or, if unplanned, the Clinical Trial Manager will inform sites as soon as they are aware that TRuST is down and will notify them when this is corrected.
- If, during normal working hours, internet access is possible but the TRuST system is not working please inform the Clinical Trial Manager and contact the NHS Tayside Clinical Trial Pharmacy for emergency unblinding.
- If, TRuST is down outside normal working hours please contact NHS Tayside On-call Pharmacist for emergency unblinding.

Clinical Trial Manager: Joel Rocha 07386657801 SOPHIST-trial@dundee.ac.uk

NHS Tayside Clinical Trial Pharmacy: 01382 632969 Tay.clinicaltrials@nhs.scot

NHS Tayside On-Call Pharmacist (Ninewells Hospital): Call switchboard on 01382 660111 and ask for on call Pharmacist.