

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.







- 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.



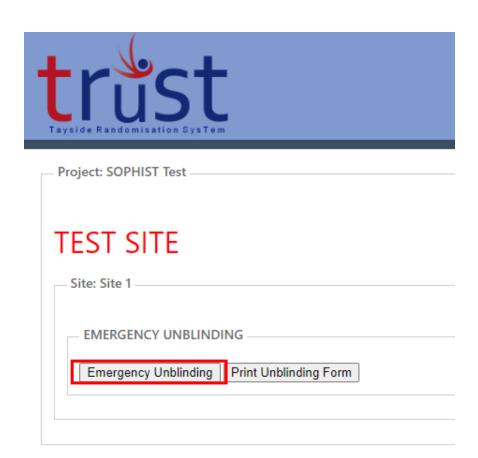




- Login to TRuST using emergency unblinding login details.
- Enter your name.



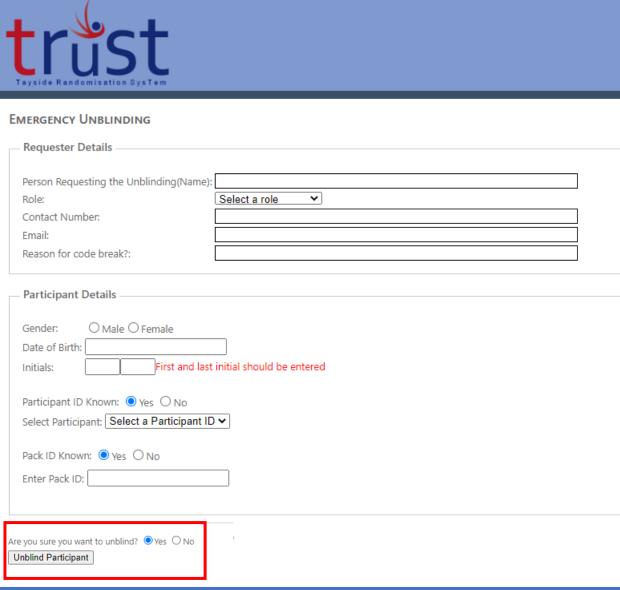
• Click "Emergency Unblinding".











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"











EMERGENCY UNBLINDING FORM

EMERGENCY UNBLINDING

Participant: 01010 Allocation: Placebo

Unblinding Result

Return to Main Menu Print Unblinding Form

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

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

Person Performing the Unblinding:	sophistUnblind - Joel Rocha
Person Requesting the Unblinding:	
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

Sotagliflozin/Placebo 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 <u>SOPHIST-trial@dundee.ac.uk</u>

NHS Tayside Clinical Trial Pharmacy: 01382 632969 <u>Tay.clinicaltrials@nhs.scot</u>

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





