

Emergency Unblinding



- TRuST can be accessed through: <https://hicservices.dundee.ac.uk/TRuST>
- There is also a link on the GREAT-2 website staff resources page: <https://sites.dundee.ac.uk/great-2/>
- Login details for unblinding will be different from TRuST access for researchers/pharmacy
- The password can be changed on the TRuST login screen, top right

Training:

- This presentation
- PI and those delegated this task must complete 3 dummy unblindings
- Must be recorded in Training Log in ISF

- Emergency unblinding will be carried out by the PI or delegate.
- Any clinician requiring emergency unblinding of a participant should, where possible, discuss this with the Principal Investigator, however, this should not stall or delay in any way the unblinding of trial participant treatment in emergency situations.
- If unblinding is required, the clinician should contact the local PI or delegate.
- TRuST access will be provided to the local PI for individual participant unblinding in the event of a medical emergency.
- 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.
- Local Clinical Trial Pharmacy will hold unblinded Clinical Trial Request Forms, unblinding **must** be carried out in TRuST. TRuST informs Sponsor, CI and TM
- The CI is also able to unblind all participants across all sites if required.
- Disclosure of the unblinding result should be to individuals involved in the participant's care only.
- Where possible, the participant should remain blinded and remain in the trial and continue with trial visits.



Please enter your name:

- Login to TRuST using emergency unblinding login details
- Enter your name
- Click “Emergency Unblinding”



Project: GREAT-2 Test

TEST SITE

Site: Tayside

EMERGENCY UNBLINDING



University
of Dundee



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 the first pack ID is required, if this information is not available click “no”)

If a participant ID and pack ID are not know 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

Unblinding Result

Participant: 0118
Allocation: Gremubamab 1500mg

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EMERGENCY 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.	1-023-22	EudraCT	2022-003215-28
Chief Investigator	Prof James Chalmers	IRAS	1005993

Person Performing the Unblinding:	great2unblinding - Gillian Martin
Person Requesting the Unblinding:	Gillian Martin
Role:	trial manager
Contact Number:	01382 381955
Email:	gmartin001@dundee.ac.uk
Reason for Unblinding Request:	participant safety
Date of Request:	02/05/2023

Study Participant ID:	0118	Site:	Tayside
Pack ID:	0071		
Date of birth:	17/02/2023	Initials:	JD
		Gender:	Male

Unblinding Result

Gremubamab 1500mg/Gremubamab 500mg/Placebo	Gremubamab 1500mg
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TRuST Unblinding Performed by:

Name:		Designation:	
Signature:		Date:	

GREAT-2 Additional Form V1 04-11-22 Download Date: 02/05/2023 11:39:25

The emergency unblinding results will be visible

- Click “Print Unblinding Form”
- Download & print the record of the unblinding
- Sign & date the emergency unblinding form
- Inform treating clinical 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