
Tayside Randomisation System

Unblinding Users Guide

Contents

1	Introduction to TRuST	2
2	Getting Started.....	3
2.1	Logging in	3
2.2	Logging out.....	4
3	Unblinding a Participant	4
4	Trouble Shooting & Contacts	7
4.1	Unblinding by Participant Identifiers	7
4.2	Unable to Access TRuST.....	7
4.3	Contacts	7

1 Introduction to TRuST

TRuST is the web based randomisation system being used by both Research Nurses and Clinical Trial Pharmacy Staff for all sites participating in the STOP-COVID19 trial. The Clinical Trial Manager and study monitors will have access to TRuST to enable them to check randomisation and drug accountability remotely.

The TRuST system can also be used for unblinding participants if required.

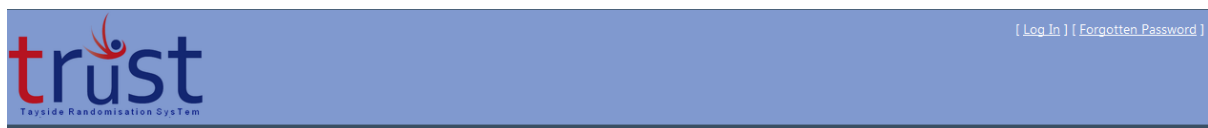
Emails generated by TRuST should either be printed and filed in the ISF or held electronically with a file note in the ISF stating where they are held.

2 Getting Started

- Training should be completed by the PI including a test unblinding before unblinding is carried out on the live system.
- Go to:
<https://hicservices.dundee.ac.uk/TRuST>

2.1 Logging in

- Enter **username** & **password** provided on the Emergency Unblinding Procedure (this can be found in section 9 of ISF)



Log IN

Please enter your username and password.

Account Information

Username:

Password:

- You will be asked to enter your name



The screenshot shows the TRuST logo and the text 'Please enter your name:'. Below this is a text input field with a red box around it, and a 'Go' button to its right.

2.2 Logging out

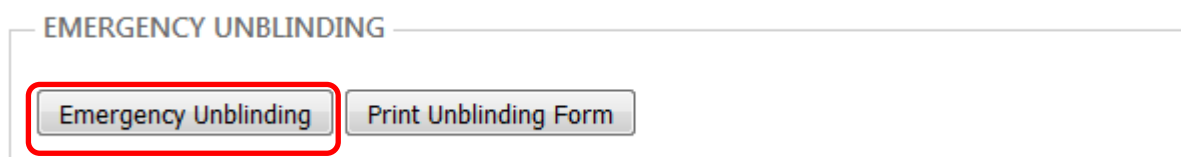
- Click [Log out](#) when finished.



The system will automatically log out the user if there has been no activity for 10 minutes.

3 Unblinding a Participant

- From the Main Menu select [Emergency Unblinding](#).



EMERGENCY UNBLINDING

Requester Details

Person Requesting the Unblinding(Name):

Role:

Contact Number:

Email:

Reason for code break?:

Complete:
➤ [Requester Details](#)

Participant Details

Gender: Male Female

Date of Birth:

Initials: *First and last initial should be entered*

Participant ID Known: Yes No

Pack ID Known: Yes No

Complete:
➤ [Participant Details](#) if known
➤ [Participant's ID](#) if known (drop down menu)
➤ [Pack ID](#) if known

Are you sure you want to unblind? Yes No

Complete:

- Select **yes** if you are sure you have the correct details and wish to unblind

Are you sure you want to unblind? Yes No

Unblind Participant

“Unblind participant” button appears

- [Click](#) unblind participant

- The Unblinding result will be given, select [Print Unblinding Form](#)
- If no match found, or more than one match is found, ‘unable to unblind unless Patient ID or bottle number known’ will be displayed.

EMERGENCY UNBLINDING

Unblinding Result

Participant: 01025

Allocation: Placebo 25mg once daily

[Return to Main Menu](#)

[Print Unblinding Form](#)

- Completed Emergency Unblinding Form will generated.
- Check all details are correct
 - Print form off
 - Complete 'Performed by' section at end of form
 - Place in sealed envelope labelled with Participant's number and "Emergency Unblinding Details – do not open unless information required for clinical purposes".
 - File in ISF Section 9.2.

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.	2016RC27	EudraCT	2018-001590-24
Chief Investigator	Prof James Chalmers	IRAS	252929

Person Performing the Unblinding:	uVitalBE - M Band
Person Requesting the Unblinding:	M band
Role:	CI
Contact Number:	01382 383097
Email:	m.band@dundee.ac.uk
Reason for Unblinding Request:	Medical emergency
Date of Request:	30/07/2019

Study Participant ID:	01678	Site:	Royal Brompton
Pack ID:	Not Provided		
Date of birth:	08/07/2019	Initials:	qw
		Gender:	Male

Unblinding Result

Cayston three times per day/Cayston twice per day/Placebo three times per day/Placebo twice per day	Cayston twice per day
---	------------------------------

TRuST Unblinding Performed by:

Name:		Designation:	
Signature:		Date:	

Download Date: 30/07/2019 16:44:38

4 Trouble Shooting & Contacts

4.1 Unblinding by Participant Identifiers

If the participant ID and Pack ID are not available, unblinding can be performed using participant identifiers, [gender](#), [DOB](#) and [Initials](#).

4.2 Unable to Access TRuST

If internet access is possible but the TRuST system is not working please contact the Clinical Trial Manager or Chief Investigator during working hours. Out with working hours please contact NHS Tayside On-call Pharmacist. See section 4.3 below for details.

Sites will be informed of any planned downtime for TRuST.

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.

4.3 Contacts

Clinical Trial Manager
stop-covid19@dundee.ac.uk

Chief Investigator – Prof James Chalmers
0774 0124 122
j.chalmers@dundee.ac.uk

NHS Tayside On-Call Pharmacist
Ninewells Hospital switchboard
01382 660111 ask for on call Pharmacist