Working Practice Document: **RANDOMISATION**		
CURRENT VERSION WPD: CHIP-BCIS3 WPD/03/02		
Current version date:	07 Jun 2024	
Review date:	07 Jun 2027	
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Revision chronology:

Version number	Effective date	Reason for change
1	18 Jun 2021	Scheduled review; updated section 2 (to include Randomisation accounts) & added in section 5.2 (randomised in error)
2	07 Jun 2024	

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1. Purpose of this document

The purpose of this document is to give an overview of the online randomisation system for the CHIP-BCIS3 trial: **C**ontrolled trial of **H**igh-risk coronary **I**ntervention with **P**ercutaneous left ventricular unloading.

2. Accessing the system

The only staff that will be granted access to the randomisation system from the sites are the staff undertaking randomisation procedures. They will be issued 'Investigator' or 'Randomisation' accounts as required, which allow them to randomise patients, view the randomisation data for their site, and generate queries. In addition 'Investigator' accounts enable delegated site personnel to edit, add and view eCRF forms as well as upload attachments. These account types may be provided to a range of staff (e.g. research nurses, pharmacists, or clinicians) as needed.

Staff at the London School of Hygiene and Tropical Medicine (LSHTM) Clinical Trials Unit (CTU) will have 'Administrator' accounts, which allow them to create accounts and view the data for all sites.

Access to the randomisation system is via https://www.sealedenvelope.com/access/ and users must log in with their email address and password before access is granted (see Figure 1).

*Note*: the screenshots shown below are taken from the testing site which uses dummy data.

Figure 1:

If a user does not have an account, or provides an incorrect password, they will not be allowed access. Investigator and Randomisation accounts will be set up by a member of the CTU team. This will only occur once the appropriate training has taken place and the training and delegation logs have been signed.

When a user has logged in their name and unique user ID is always shown at the top of every page in the navigation bar.
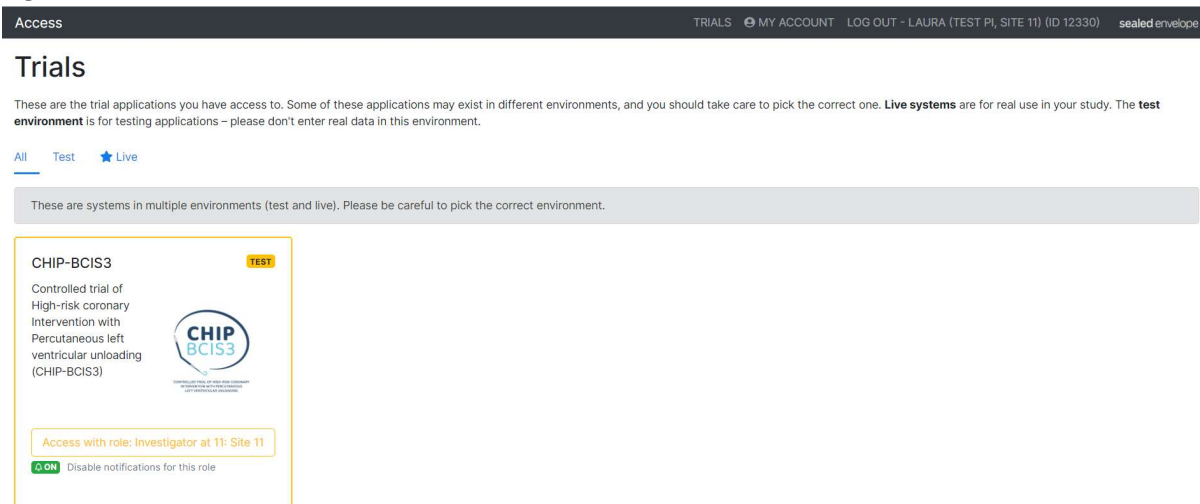
After logging in for the first time the user will see Figure 2 (the "Access" page) and this will show a message that reads 'You have an invitation'. The user should click on this link and accept the invitation, this will add the trial to their access page.

Figure 2:
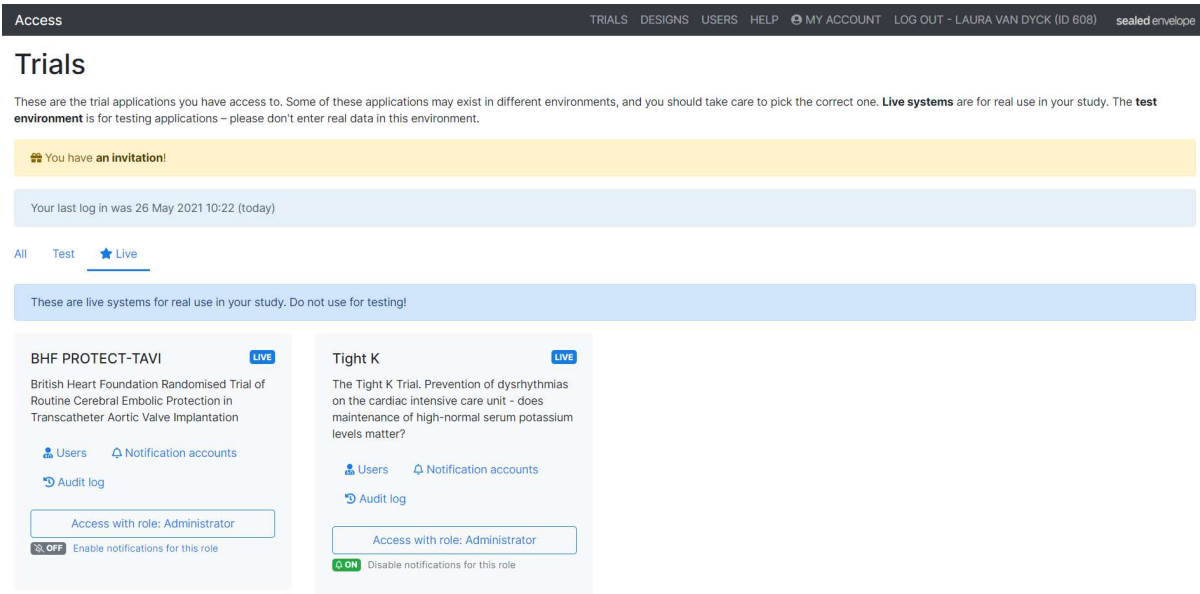
The user should then click on the "Access with role" link to enter the study, as shown in Figure 3.

Figure 3:

Once a user has finished using the database application, it is good practice to log out. This is particularly important if the user is using a shared computer or a computer that is not their own. To log out, click on the "Logout" link in the navigation bar at the top of the page.

Note: To comply with good clinical practice (GCP), it is very important that users do not share accounts or allow others to access their accounts, even temporarily. If a user has forgotten their details or is unable to log in, please refer to section 3 for more information.

3. Passwords

3.1 Forgotten passwords

Forgotten passwords can be reset by users by clicking the "Forgot your password?" link on the login page. This can only be done if they have set up a recovery email address (different to the account email address) or mobile phone number. If a user forgets their password but has not set up recovery contact details, they should contact the CHIP-BCIS3 CTU and the user's password will be reset. This sends out a new password by email to the account holder.

It is highly recommended that users provide recovery details on their user account.

Requests for password resets made by investigators to Sealed Envelope will be referred to the CHIP-BCIS3 CTU to ensure the validity of the request. Note: there is no way to see a user's current password – they are stored in an encrypted format that not even Sealed Envelope* staff can decrypt.

*Sealed Envelope is the organisation responsible for developing and maintaining the CHIP-BCIS3 data management systems (https://www.sealedenvelope.com/).

3.2 Changing a password

If a user would like to change their password, click on the "My Account" link at the top of the screen. This link directs the user to the screen shown in Figure 4 below. To change a password it is necessary for the user to enter their existing password. New passwords must be at least 8 characters long. It is advisable to avoid using passwords that are obvious or easily guessed.

Passwords expire after 180 days, after which point a user is forced to change their password. Users with expired passwords have no access to the system except for the change password screen. From this screen it is also possible to update your email address, and add (or update) a back-up email address or mobile phone number.

Figure 4:

4. Auto time-out

After a set period of inactivity (15-20 minutes), the user is automatically logged out of the system.

5. Randomisation Procedure

5.1 Randomising patients

Randomising will be done only by the member of staff whom has been delegated this responsibility by the principal investigator as evidenced by documentation in the delegation log.

We do not mandate a specific time period between randomisation and treatment. However, we recommend that randomisation should be done as close to the PCI procedure as possible, to minimise the chance of events occurring during this time period.

To randomise a patient to the CHIP-BCIS3 trial:

1. Log in to the system (https://www.sealedenvelope.com/access)
2. Click the "Randomise" link on the top left hand side of the screen on the navigation bar, which will open the randomisation data entry screen
3. Use the "Randomise" screen to enter the inclusion/exclusion criteria (see Figure 5) and click "Randomise"

Figure 5:

4. After submitting the randomisation data, the user will be asked to review it as changes will not be allowed after confirming. If you need to amend any of the details hit the "Back" button.
5. In order to complete randomisation of the patient you will have to enter your password and click "Confirm".
6. The patient is now in the CHIP-BCIS3 trial and a pop up (Figure 6a) followed by the confirmation screen will appear (see Figure 6b). This will confirm the CHIP-BCIS3 patient ID number, randomisation details and treatment allocated.
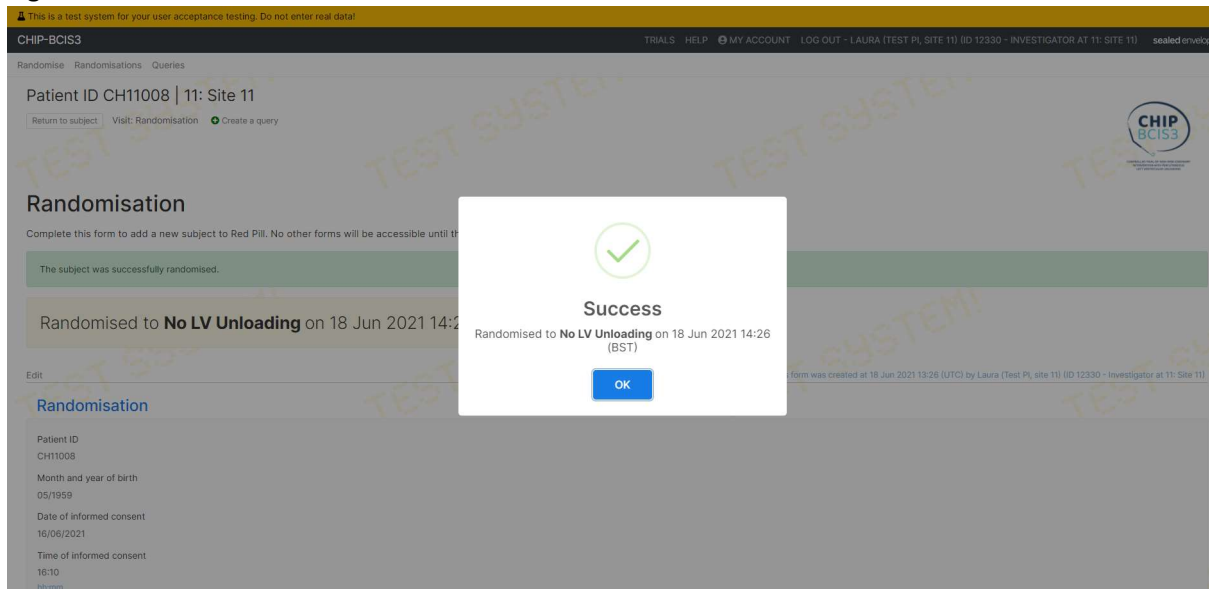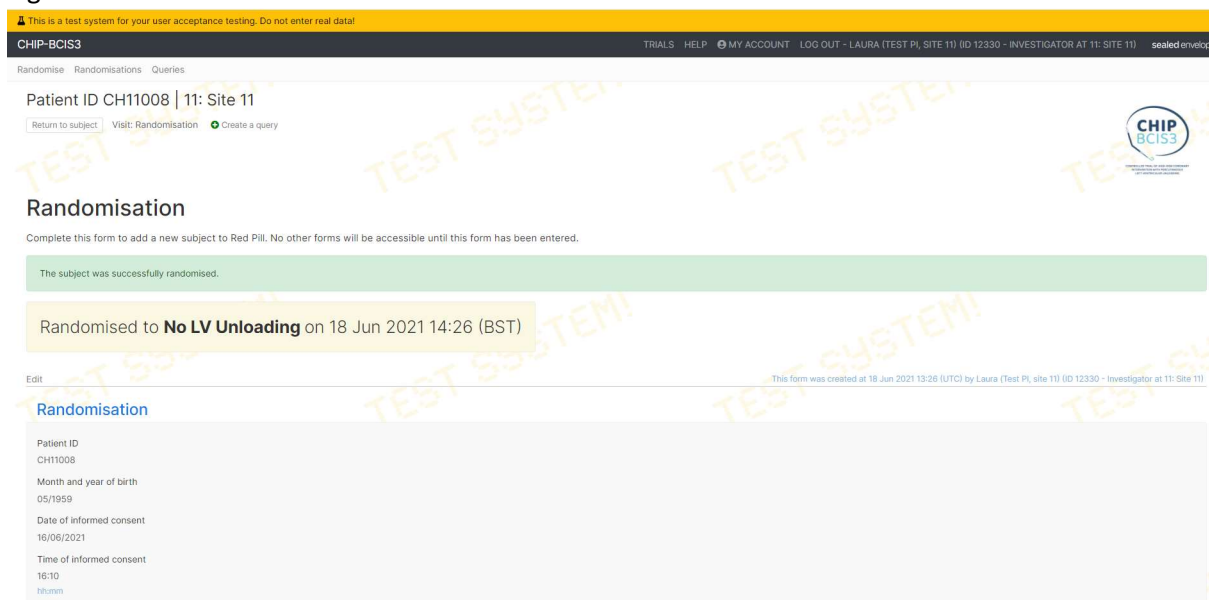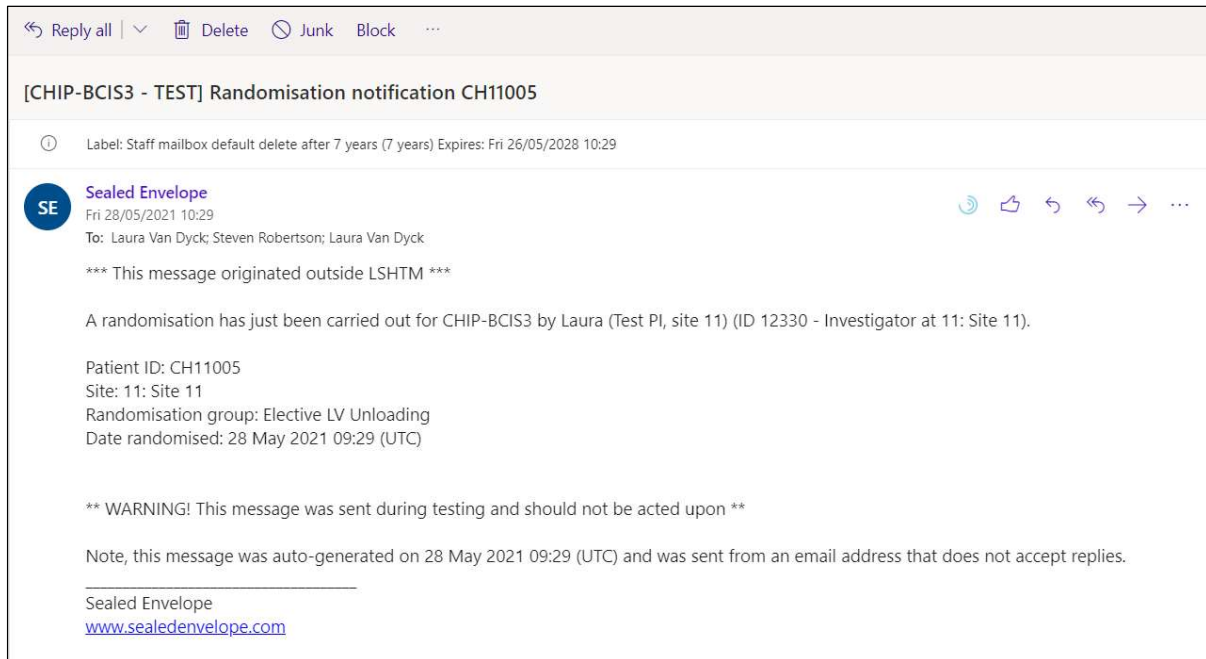
Figure 6a:

Figure 6b:

<u>Email confirmation</u>

The CHIP-BCIS3 CTU and all staff with 'Investigator' and 'Randomisation' accounts at the site will be sent an email containing the CHIP-BCIS3 patient ID number and treatment allocation (see Figure 7).

Figure 7:

Following randomisation, ensure that the treatment is carried out as per the randomisation allocation.

5.2 Patients randomised in error

Patients randomised in error should be a very rare occurrence, if all the correct procedures are carried out. However, if you suspect that a patient has been randomised in error please contact the CTU as soon as possible, who will advise on how to proceed.

Scenarios where a patient would be marked as 'Randomised in error' by the CTU:
1. A second randomisation of a patient (note: the first randomised allocation must be used in this scenario)
2. A patient randomised to the wrong trial
3. A patient randomised without the agreed consent procedures in place

6. Contacting the CHIP-BCIS3 CTU

If you require help with this instruction manual please contact the CHIP-BCIS3 CTU by emailing us at chip-bcis3@LSHTM.ac.uk

The CHIP-BCIS3 CTU is based at the London School of Hygiene and Tropical Medicine (LSHTM) which is part of the University of London.