

sealed envelope™

Access

Version 4

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Chapter 1

Overview

Access allows users to login and access Sealed Envelope services such as [randomisation](#) and [Red Pill](#). Users can update their account settings such as password and email address and turn email notifications on or off. Access also allows administrative staff at the trial coordinating centre to view, create and update user accounts, including resetting lost passwords.

Sealed Envelope will create the first administrator account when a system is initialised, usually for the trial manager. This account should then be used to create additional administrator and investigator accounts as needed.

This documentation applies to version 4, released on 15 Oct 2015.

Chapter 2

Log in

Log in to Access via the [trials page](#) on Sealed Envelope's main website. Users are requested to authenticate themselves before access is granted to the system by providing their registered email address and password. If a user does not have an account on the system, or provides an incorrect password, they will not be allowed access.

New users can request an account by asking an existing administrator user to create one for them. When a trial is first set-up by Sealed Envelope, an administrator account will be created, usually for the trial manager. The trial manager can then create new administrator or investigator accounts as required. If the user already has an account, it can be linked to the new trial.

When a user has logged in their name and unique user ID number is always shown at the top of every page in the navigation bar. Once a user has finished using the system it is good practice to log out. This is particularly important if the user is not using his or her own computer. To log out click on the 'Logout' link in the navigation bar at the top of the page.

Note that 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.

Please log in

To log in you must enter your registered email address and password.

Email address:

Password:

Log in

Figure 2.1: log in screen

Auto timeout

After a set period of inactivity (usually 20 minutes but may differ for some trials) the user is automatically logged out of the system.

Chapter 3

Trials summary page

After logging in, users are presented with a list of trials to which they have access. The trials may be in different environments: test, training or live. The environment is shown in the top right corner of the trial panel and is also reflected in the panel colour. The environments are:

- **Live** is the system for use in the trial
- **Test** is for user acceptance testing by the sponsor
- **Training** is for site training and demonstration purposes

In each trial panel a button is provided to access the trial with a particular role. The role determines a user's privileges and the site data they have access to. User's can have more than one role in a trial, in which case several access buttons will be shown. Each role can have notifications turned on or off. Notifications are emails sent when events such as randomisation, unblinding or query creation occur. If notifications are off, click the 'Enable notifications for this role' link to turn them on. If notifications are on, click the 'Disable notifications for this role' link to turn them off.

Users with an administrator role for a trial will see options to view [trial sites](#), [users](#), [notification accounts](#) and the [audit log](#). Users with other roles will not see these options.

Roles can be suspended, which prevents further access with the role and disables notifications.

Once a user has accessed a trial, the summary page can be returned to at any time by clicking on 'Home' in the navigation bar at the top of the page.

Trials

ERIC LIVE


Effect of Remote Ischaemic Conditioning on clinical outcomes in ST-segment elevation myocardial infarction patients undergoing Primary Percutaneous Coronary Intervention (ERIC-PPCI).

Access with role: Investigator at Lanark

[Disable notifications for this role](#)

Access with role: Monitor at Leeds

[Disable notifications for this role](#)



JUMP TEST


The Jelly U-15D coolant for Material changes to cell Pathways trial (JUMP). EudraCT 2014-123456-01.

[Sites](#) [Users](#) [Notifications](#)

[Audit log](#)

Access with role: Administrator

[Disable notifications for this role](#)



JUMP TRAINING

This system should be used for site training and demonstration purposes

Access with role: Randomisation at UCL

[Disable notifications for this role](#)

Figure 3.1: Trials summary page

SCORE **LIVE**

The SCORE trial - Support Classes on Rural Education. Cluster randomised trial.

Access with role Administrator is suspended.



The logo for Effective Intervention features a stylized graphic of three human figures in blue and black, with their arms raised, set against a white circular background. Below the graphic, the text "Effective Intervention" is written in a blue, sans-serif font, underlined.

Figure 3.2: User with a suspended role

Chapter 4

User accounts and roles

For a trial

User accounts and roles for a specific trial can be viewed by administrators with the 'Users' link in the trial panel.

Roles in italics are suspended. New accounts can be [created](#) using the 'Create a new user' button. Clicking on a name in the list shows details about that account including name, email address, date of last log in and password change. The user's password can be reset using the 'Reset password' button on this page. This sends a new password to the user's email address.

The name and email address can be updated by [editing](#) the user account.

All users

User accounts across all trials that a user administers can be viewed by clicking the 'Users' link in the navigation bar at the top of the screen.

Clicking on a user's name shows all the user's roles. Roles in trials which are administered by the logged in user are clickable and show more detail on roles.

Assigning a user to a new role will send them an email to inform them of their additional role.

A role can be edited to change the site, status (active or suspended) and to enable or disable notifications.

Help-Diabetes randomisation (LIVE)

[Sites](#)[User accounts](#)[Notification accounts](#)[Audit log](#)

This is a list of user accounts with access to Help-Diabetes randomisation (LIVE). Roles shown in italics are currently suspended. Select a role to change it, suspend access or change notification settings.

[Create a new user](#)

Search:

Name	Email	Role
Andrea Amin	andrea@leedsth.nhs.uk	<i>Investigator at Leeds</i>
Andrea Amin	andrea@leedsth.nhs.uk	Administrator
Iain Pearson	ipearson@ucl.ac.uk	Investigator at UCL
RA Fisher	rafisher@ucl.ac.uk	Statistician at all sites

Figure 4.1: Viewing user accounts for a trial

User account for **Iain Pearson**

Iain Pearson
ipearson@ucl.ac.uk
Last log in: 27 Nov 2014 16:34 (today)
Last password change: 14 Nov 2014 14:38 (13 days ago)

[Edit user details](#)

[Reset password](#)

Figure 4.2: Viewing user account detail

Edit account for **Iain Pearson**

Changing these details affects the user's name and email address across **all trials**.

Do not use this form to allocate this account to a new person. Only change the name or email address to correct mistakes or update the information for the person the account belongs to.

Name:

Email address

Figure 4.3: Editing a user account

Users

User accounts assigned to trials that you administer.

You are an administrator for:

- JUMP (TEST) - [create a new user](#)

Select a user's name to change their email address, reset their password, and to view and edit their roles on the trials you administer.

Search:

Name	▼ Email address	↕
Andrea Amin	admin@sealedenvelope.com	
Iain Pearson	inves@sealedenvelope.com	
Jenny Jenns	jennyj2@gmail.com	

Figure 4.4: Viewing all user accounts

JUMP (TEST)

 Sites

 User accounts

 Notification accounts

Iain Pearson

Iain Pearson (ipearson@ucl.ac.uk) has 2 roles within this trial:

<i>Investigator at UCL</i>	SUSPENDED
Created 14 Nov 2014 14:36 (13 days ago)	
Notifications are not sent to suspended accounts	
Edit this role	

Unblinding at all sites
Created 17 Nov 2014 18:49 (10 days ago)
Notifications are Off
Edit this role

[Assign new role](#)

Figure 4.5: Viewing roles in a trial

JUMP (TEST)

[Sites](#) [User accounts](#) [Notification accounts](#)

Jenny Jenns

[Assign unblinding role](#)

[Assign randomisation role](#)

[Assign investigator role](#)

[Assign administrator role](#)

Assign investigator role

Jenny Jenns (jennyj2@gmail.com)

Send email notifications?

Site

All sites ▾

Assign

The user will be notified when you assign them to this new role.

Figure 4.6: Assigning a role

Iain Pearson

Investigator at UCL

Site

Royal Albert Hospital

You can create and manage sites by [accessing the JUMP trial](#) as an administrator

Status

Active

Suspended

Send email notifications?

Update

Figure 4.7: Editing a role

Roles and privileges

Each trial has several roles with different privileges. The roles and privileges will vary by trial. However the following roles are normally available:

Superuser Has access to all trials and all features. Reserved for Sealed Envelope staff only.

Administrator Has access to selected trials, but usually all features within those trials. Intended for use by trial managers and other staff at the trial co-ordinating centre.

Investigator Has limited access to selected trials. Investigator accounts are linked to a particular trial site and only subject data or randomisations from that site may be viewed. Investigators have no access to administrative functions (such as reports, sites, user accounts and log sections).

Notification Used for notifications only - this account cannot log in to the system. May, optionally if enabled, be used to send notifications to fax recipients.

Some trials may have the following account types:

Statistician Read only access to subject data and ability to download for analysis.

Monitor Read only access to subject data and ability to create or respond to queries.

Archivist Download an archive containing all application data.

Warning archives may contain sensitive data such as randomisation lists and unblinded data. Think carefully about the risks before assigning this role to anyone involved in the day-to-day running of the study.

[Randomisation](#) systems may also have the following account types:

Randomisation Limited account that can only randomise and view previous randomisations for a particular site.

Unblinding Limited account that can only unblind treatment and view previous randomisations for a particular site.

The privileges available to each account type are fine tuned by the configuration for a particular trial - for instance investigators may or may not be allowed to unblind treatment. The actual privileges available are shown on the account creation screen.

Administrator account

Name:

Email address

Send email notifications?

[Create account](#)

A randomly generated password will be emailed to the user when you create the account.

An administrator has full access to all functions for a trial:

- View audit log
- View specification
- View reports
- View patients
- View patient schedule and overdue CRF forms
- Edit randomisation form
- Edit CRF forms
- Randomise a patient
- Add patients and CRF forms
- View randomisation form

Figure 4.8: Screen shown when creating an administrator account

Chapter 5

Creating accounts

New accounts

An existing administrator can create new accounts for a particular trial from the [users](#) page for a trial or the global users list. When creating a new account, a role must also be chosen.

To create an account the user's real name and email address must be supplied.

The account can be set to receive notifications or not. Notifications are emails sent out when events like randomisation or unblinding occurs. Administrators receive notifications for all such events in the trial. Accounts that are limited to a particular site only receive notifications related to that site. [Notification only](#) accounts can also be created. Once the account is created an automatically generated email is sent to the email address supplied containing the randomly generated password necessary to access the account. An example of the generated email is:

```
From: automated@sealedenvelope.com
Subject: Confidential: new account details
Date: 15 July 2015 11:10:17 BDT
To: joe@trialcentre.org
```

Dear Joe Bloggs,

An account with administrator privileges has been created for you to access JUMP.

You can access the system online at <https://www.sealedenvelope.com/access> using these details:

JUMP (TEST)

 Sites

 User accounts

New user

Create unblinding account

Create randomisation account

Create investigator account

Create administrator account

Figure 5.1: Creating a new user account

JUMP (TEST)

[Sites](#) [User accounts](#) [Notification accounts](#) [Audit log](#)

New user

[Create unblinding account](#)
[Create randomisation account](#)
[Create investigator account](#)
[Create administrator account](#)

Investigator account

Name:

Email address

Send email notifications?

Site

This account will enable the user to:

- View patients
- Randomise a patient
- View randomisation form
- View queries
- Add messages to queries
- Create queries
- Can be limited to patients at one site

A randomly generated password will be emailed to the user when you create the account.

Figure 5.2: Screen shown when creating an investigator account

Email: joe@trialcentre.org
Temporary password: 2TVuxGR7

After you have logged in you will be required to change your password. If you have any difficulties please contact Simon Admin (simon@trialcentre.org).

Note, this message was auto-generated on Tue 15 Jul 2014 11:10 Europe/London (GMT +0100) and was sent from an email address that does not accept replies.

Sealed Envelope
<http://www.sealedenvelope.com>

Existing accounts

Sometimes a user may already have an account on the system for a different trial. Attempting to create a new account for an existing email address will trigger an error. A link will be shown to allow the existing account to be associated with the new trial. The user will receive an email informing them that their existing account has been associated with the new trial.

Telephone randomisation

If your trial is making use of Sealed Envelope's telephone randomisation service, you can give access to this service by specifying an investigator number when creating the account. The investigator number must be a unique 3 digit number in the range 100-999.

When the user calls the telephone randomisation service they must enter the study number and investigator number to gain access to the system. These are shown to administrators and users with telephone access on the [trials summary page](#).

Investigator account

Account already exists! You can [assign the existing account](#) to this trial instead

Name:

Email address

Send email notifications?

Site

[Create account](#)

Figure 5.3: Assign an existing user to a new trial

Jenny Jenns

Role

Investigator

Site

UCL

Status

Active

Suspended

Send email notifications?

3 digit investigator number

376

Enter a number to allow access to the telephone system

Update

Figure 5.4: Assigning an investigator number for telephone randomisation

JUMP **TEST**

The Jelly U-15D coolant for Material changes to cell Pathways trial (JUMP). EudraCT 2014-123456-01.

Access with role: Investigator at UCL

[Disable notifications for this role](#)

📞 Randomisation by telephone is available for this trial. The UK phone number is **020 9999 9999** and the study number is **1234**. Your investigator number is **345**.

Figure 5.5: Showing investigator number for telephone randomisation

Chapter 6

Editing accounts

Existing accounts may be edited by an administrator by clicking on the 'Edit user details' link when [viewing](#) an account. It is possible to change the account email address and name only. Notification settings, site, role and status (active or suspended) are changed by [editing roles](#). The user's name should only be changed to correct spelling mistakes.

Existing user accounts should not be re-allocated to new users. User accounts that are no longer in use should be suspended and new accounts created for new users.

Deleting accounts

There is no facility for deleting accounts except notification accounts. This is to preserve the audit trail and history of who performed which actions. To remove the ability for an account to access a trial the account should be edited and the status set to **suspended**.

Edit account for **Iain Pearson**

Changing these details affects the user's name and email address across **all trials**.

Do not use this form to allocate this account to a new person. Only change the name or email address to correct mistakes or update the information for the person the account belongs to.

Name:

Email address

Update

Figure 6.1: Editing a user account

Chapter 7

Changing your own email address or password

The 'My account' link is shown in the navigation bar at the top of the page. This link directs the user to a page where they can edit their own email address or password. Administrators can manage these details for any user by [editing accounts](#) or [resetting passwords](#). The name on a user account can only be updated by an administrator.

To change a password it is necessary for the user to enter their existing password. New passwords must be at least 8 characters long and sufficiently complex to be labelled at least *Acceptable strength* by the password strength indicator. Some complex passwords are suggested above the new password box.

Passwords expire after 6 months, after which time a user is forced to change their password. Users with expired passwords have no access to the system except for the change password screen.

Update your email address

Email address

Change your password

Confirm your current password

Some password suggestions:

sheen nerve budd
gil boot newt
leery fool where

Your new password

Strong

Confirm your new password

Figure 7.1: Changing password

Chapter 8

Forgotten passwords

If a user forgets their password or log in details they should contact the trial manager or other holder of an administrator account. Administrators can reset a user's password on the user account details screen. This sends out a new password by email to the account holder. The new password applies to all trials that the user is associated with. Note that 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. Requests for password resets made by investigators to Sealed Envelope will be referred to the trial manager since Sealed Envelope has no way of authenticating the validity of such requests.

User account for **Iain Pearson**

Iain Pearson
ipearson@ucl.ac.uk
Last log in: 27 Nov 2014 16:34 (today)
Last password change: 14 Nov 2014 14:38 (13 days ago)

[Edit user details](#)

[Reset password](#)

Figure 8.1: Viewing user account detail

Chapter 9

Notification accounts

Notification accounts cannot be used to log in to the system but allow receipt of notifications for a trial. They can be created and edited in a similar way to standard user accounts. Notification accounts may also be deleted by clicking on the name in the list and using the delete button.

JUMP (TEST)

[Sites](#) [User accounts](#) [Notification accounts](#) [Audit log](#)

Notification accounts receive emails but cannot log in.

[Create a notification account](#)

Search:

Name	Email	Site
Adnan Syed	a.syed@nhs.net	UCL

Figure 9.1: List of notification accounts

Notification account details

Adnan Syed
a.syed@nhs.net
Limited to site UCL
Access granted to this trial 27 Nov 2014 16:24 (today)

[Edit notification account details](#)

Delete

Figure 9.2: Viewing a notification account

Chapter 10

Audit log

Changes to user account data are shown in the audit trail. Click on 'Audit log' in the navigation bar to view this file. Note that entries are in reverse order with more recent changes appearing at the top. An example is shown below.

Table 10.1: An example audit trail

Timestamp	User	Action	Changes
2014-08-18 15:27:57	J Bloggs (ID 6)	Updated assignment (ID 13)	site_id changed ...
2014-08-18 14:52:36	J Bloggs (ID 6)	Updated user account (ID 6)	password_change ...
2014-08-18 14:51:13	J Bloggs (ID 6)	Created assignment (ID 19)	role "Investiga- tor", ...

Timestamp	User	Action	Changes
2014-08-18 14:46:29	J Bloggs (ID 6)	Deleted notifica- tion account (ID 16)	name "St Marys", ...
2014-08-18 14:42:55	J Bloggs (ID 6)	Created notifica- tion account (ID 21)	name "P Brown", ...
2014-08-18 12:24:00	J Bloggs (ID 6)	Created user account (ID 7)	password_change ...