

sealed envelope™

Access

Sealed Envelope Ltd, 501 Clerkenwell Workshops, 27-31 Clerkenwell Close, London
EC1R 0AT, UK

<https://www.sealedenvelope.com>
contact@sealedenvelope.com

+44 (0)20 3488 5064

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Overview

Access allows users to login and access Sealed Envelope services such as [Red Pill and randomisation](#). 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 7.0, released Jul 2020.

Log in

Log in to Access via the [link](#) on Sealed Envelope's main website. User's 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, investigator or other account types 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 logout 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.

Staging environment

Test systems are separate from the live environment, and historically users accounts were independent of each other. This means a user may have two separate accounts — one for older test systems and one for live systems. For newer trials, however, users only have

Please log in

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

Email address:

Password:

[Log in](#)

[Forgot your password?](#)

Figure 1: log in screen

one account and can access both live and test (staging) environments from the same log in.

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.

Account suspension

Accounts can be suspended if too many failed log in attempts are made in a short space of time. An email will be sent to the account holder with details about the suspension. Suspensions last a maximum of one hour after which they are automatically lifted. Users can [reset their password](#) if they cannot remember it.

Clear ePRO login

If you have been testing [subject entered forms](#) you may find you cannot view the normal log in page. This is because a cookie has been set in your browser identifying you as a trial participant. To clear this cookie and go back to the log in page go to <https://www.sealedenvelope.com/access/subjectclear>. To avoid this issue we recommend you test ePRO forms in a different browser or using an incognito or private browser window.

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 (staging) or live (production). The environments are shown as different tabs and includes a tab to show trials in all environments. Trial panels have different colours and a *LIVE* or *TEST* badge in the top right corner. The environments are:

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

In each trial panel one or more buttons are provided to access the trial with a particular role. The role determines a user's privileges and the site data they have access to.

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

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

Multiple roles

User's can have more than one role in a trial, in which case several access buttons will be shown. Clicking a button will take the user to the trial application with the privileges and site determined by the role shown.

All Test **★ Live**

These are systems in multiple environments (test and live). Please be careful to pick the correct environment.

The screenshot displays three system cards on a trials summary page. At the top, there are tabs for 'All', 'Test', and '★ Live'. A grey banner below the tabs contains the text: 'These are systems in multiple environments (test and live). Please be careful to pick the correct environment.'

- JUMP (TEST):** A demonstration application to allow you to evaluate Red Pill. It lists two roles: 'Investigator at 1: Aberdeen' and 'Investigator at 4: Edinburgh is suspended'. Both roles have a notification toggle set to 'ON'.
- OACS-1 (LIVE):** Lists two roles: 'Monitor at 1: Foundling Hospital' and 'NCTU data entry'. Both roles have a notification toggle set to 'ON'.
- PREVENT (LIVE):** Lists '30 tech' and three roles: 'Users', 'Notification accounts', and 'Audit log'. It also lists an 'Administrator' role with a notification toggle set to 'ON'.

Figure 2: Trials summary page

Notifications

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.

Suspended roles

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

Viewing user accounts and roles

Viewing accounts for a trial

Administrators can view user accounts and roles for a specific trial from the *Users* link in the trial panel.

JUMP (STAGING)

[Settings](#) [Users](#) [Notification accounts](#) [Audit log](#)

This is a list of user accounts with access to JUMP (STAGING). Roles shown in italics are currently suspended.

Select a role to change it, suspend access or change notification settings. Note you cannot suspend an invited role (you must cancel the invitation). If you try to suspend multiple roles including your own, your administrator role will not be affected.

[Create a new user](#)

[Copy](#) [Excel](#) [CSV](#) [Select all](#) [Deselect all](#) [Suspend](#)

Name	↑↓ Email	↑↓ Role	↑↓
Clem Fandangos	fandangos@sealedenvelope.com	Archivist	
Clem Fandangos	fandangos@sealedenvelope.com	Statistician	
Jane Plough	j.plough@homeopathgland.org	Administrator INVITED	
Phoebe Wayfarer	pwayfarer@nhs.net	Investigator at Edinburgh	
Phoebe Wayfarer	pwayfarer@nhs.net	Investigator at Aberdeen	

Showing 1 to 5 of 5 entries

Figure 3: Viewing user accounts for a trial

Roles in italics are suspended. The list of user accounts and roles can be downloaded or copied using the *Copy*, *Excel* and *CSV* buttons. A row can be selected by clicking on it, or multiple rows can be selected using Shift-click or Ctrl-click (Cmd-click on Mac). When rows are selected the highlighted roles can be suspended or activated using the drop-down *Suspend* button.

Name	Email	Role
Clem Fandangos	fandangos@sealedenvelope.com	Archivist
Clem Fandangos	fandangos@sealedenvelope.com	Statistician
Jane Plough	j.plough@homeopathgland.org	Administrator INVITED
Phoebe Wayfarer	pwayfarer@nhs.net	Investigator at Edinburgh
Phoebe Wayfarer	pwayfarer@nhs.net	Investigator at Aberdeen

Showing 1 to 5 of 5 entries 2 rows selected

Figure 4: Suspending multiple roles

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 unique password reset link to the user's email address.

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

Viewing all users

Administrators can view user accounts across all trials that they administer by clicking the *Users* link in the navigation bar at the top of the screen.

Users with an outstanding invitation to a role in a trial are shown with an INVITED badge. An INACTIVE badge is shown for accounts that have not logged in for over 6 months. These should be regularly reviewed and the accounts suspended if access is no longer needed or appropriate. All roles in all trials for an account can be suspended from this list using the *Suspend* button.

User account for Clem Fandangos

This user cannot create designs

[Edit details](#)

Email: fandango@sealedenvelope.com

Last log in: Sun, 28 Jun 2020 12:34pm BST (15 minutes ago)

Last password change: Sat, 27 Jun 2020 6:49pm BST (about 18 hours ago)

[Reset password](#)

Add a new role for Clem Fandangos

Roles allow a user to access trials and designs with certain privileges and to have access to data at particular sites. A person can have multiple roles both within and across trials and designs. You can give Clem Fandangos access to a trial or design by adding a suitable role below.



Add role for trial:

Add role for design:

Current roles for Clem Fandangos

Roles shown below in italics are suspended. Select a role to change it, suspend access or change notification settings.

[CROWN Coronation \(LIVE\)](#)

[Administrator](#)

[DEMO \(STAGING\)](#)

[Investigator at Bath](#)

[JUMP \(STAGING\)](#)

[Statistician](#)

Figure 5: Viewing user account detail

Users

User accounts assigned to trials that you administer.

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. If you try to suspend multiple accounts including your own, your administrator role will not be affected.

<input type="button" value="Copy"/>	<input type="button" value="Excel"/>	<input type="button" value="CSV"/>	<input type="button" value="Select all"/>	<input type="button" value="Deselect all"/>	<input type="button" value="Suspend"/>	Search: <input type="text"/>
Name	Email address					
Andrea Amins	a.amin@foundling.nhs.uk					
Clem Fandangos	fandango@sealedenvelope.com					
Frank Kettle INVITED INACTIVE	f.kettle@doctors.org					
Iain Pearson INACTIVE	ipearson@foundling.nhs.uk					

Figure 6: Viewing all user accounts

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 Receives [email notifications](#) only - this account cannot log in to the system.

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. This role can only be assigned by Sealed Envelope on request.

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](#).

Viewing roles for a user

Clicking on a user's name shows all the user's current roles. Trials which are administered by the logged in user are clickable and show more detail on roles. Alternatively, clicking on a user's role in the trial specific user list shows all roles in the trial. New roles can be added from this page and existing roles edited

Andrea Amins

[Andrea Amins](#) (a.amin@foundling.nhs.uk) has 2 roles within this trial:

Administrator Edit role Created 21 Mar 2018 15:43 (today) Notifications are On	Archivist at all sites Edit role Created 11 Aug 2017 14:40 (222 days ago) Notifications are Off
---	--

[Assign new role](#)

Figure 7: Viewing roles in a trial

Creating accounts and roles

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. For roles that can be limited by site a site selection control is displayed.

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.

Invitations

Once the account is created an automatically generated email is sent to the email address with an invitation to log in and set-up the account. Invitations expire after 2 weeks and must be re-sent after this time. If the invitation was sent in error or is no longer required it can be deleted as long as the invitee has not already set up their account. Note that email notifications (such as for [randomisation](#) or [queries](#)) are not sent until the invitation has been accepted.

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

Demo 1 (blinded) (TEST)

 Users

 Notification accounts

 Audit log

New user

[Create administrator account](#)

[Create investigator account](#)

[Create monitor account](#)

[Create statistician account](#)

[Create unblinding account](#)

Figure 8: Creating a new user account

New user

Investigator role

Name:

Email address

Site

You can create and manage sites by [accessing the Demo 1 \(blinded\) trial](#) as an administrator

Send email notifications?

An invitation will be emailed to the user when you create the account.

This role will enable the user to:

- View subjects
- Randomise a subject
- View randomisation form
- View queries
- Add messages to queries
- Create queries
- Unblind the treatment for a randomised subject
- Assign a kit from the code list to a randomised subject
- Can be limited to subjects at one site

Figure 9: Screen shown when creating an investigator account

User account for Clem Fandango

 Clem Fandango [Edit details](#)

Email: fandango@hearingloss.org

Last log in: **(has not logged in yet)**

Last password change: **(never)**

Clem Fandango was invited to create an account on 5 Mar 2018 but has not yet logged in.

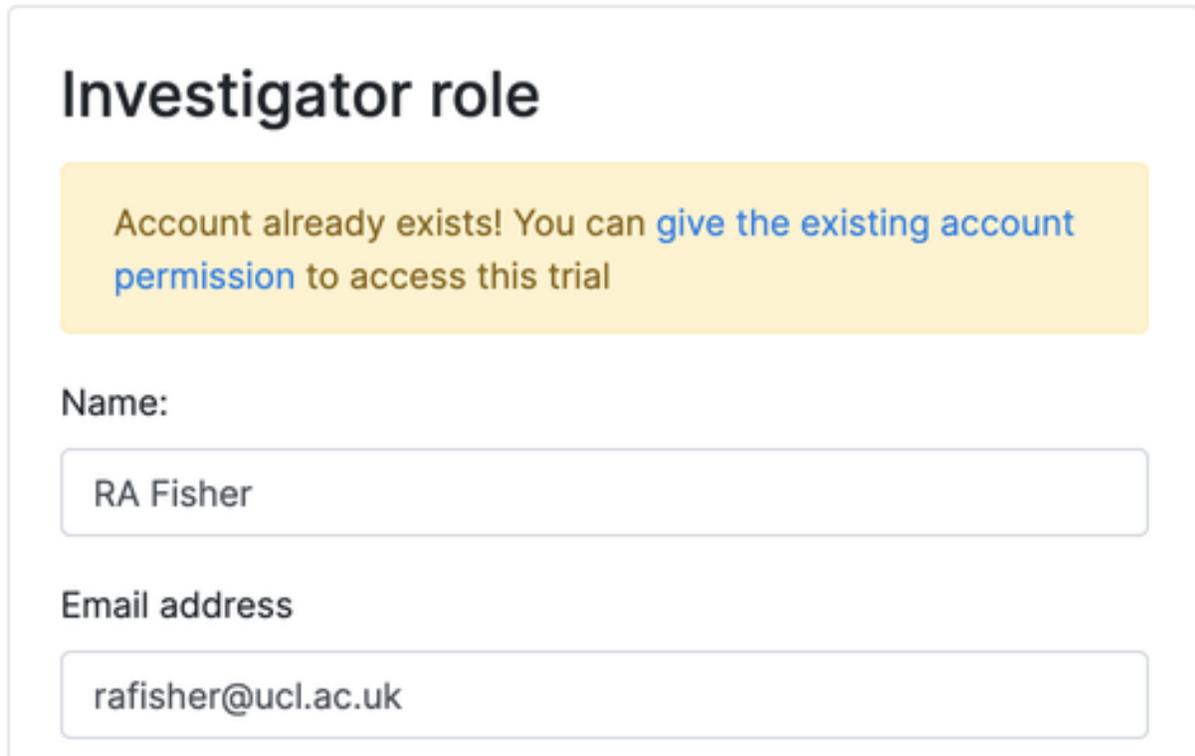
[Cancel invitation](#)

[Send another invitation](#)

Last invite was sent 10 Mar 2018

Figure 10: User account for invited user

link will be shown to allow the existing account to be associated with the new trial.



Investigator role

Account already exists! You can [give the existing account permission](#) to access this trial

Name:

RA Fisher

Email address

rafisher@ucl.ac.uk

Figure 11: Assign an existing user to a new trial

When an existing user logs in they will see any invitations they have for new roles or trials. The user can accept or decline the invitation.

Adding a role

Administrators can add a role to an existing account by first locating the user from the [users](#) page for a trial or the global users list. Links to add a new role are shown on the account details page.

The user will receive an email inviting them to link their existing account to the new trial or role. They can accept or decline this invitation.

Invitations

You accepted the invitation to DEMO (STAGING)

You have the following invitations:

JUMP (STAGING)

JUMP is a demonstration application to allow you to evaluate Red Pill

You have been invited with **statistician privileges**

You were invited on Sat, 27 Jun 2020 5:42pm UTC (7 minutes ago) by SE support 2

Figure 12: Invitation to new role

Assign new role to Clem Fandango

Clem Fandango (fandango@hearingloss.org)

Monitor role

Send email notifications?

Site

Dunedin

You can create and manage sites by [accessing the Demo 1 \(blinded\) trial](#) as an administrator

Assign

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

This role will allow Clem Fandango to:

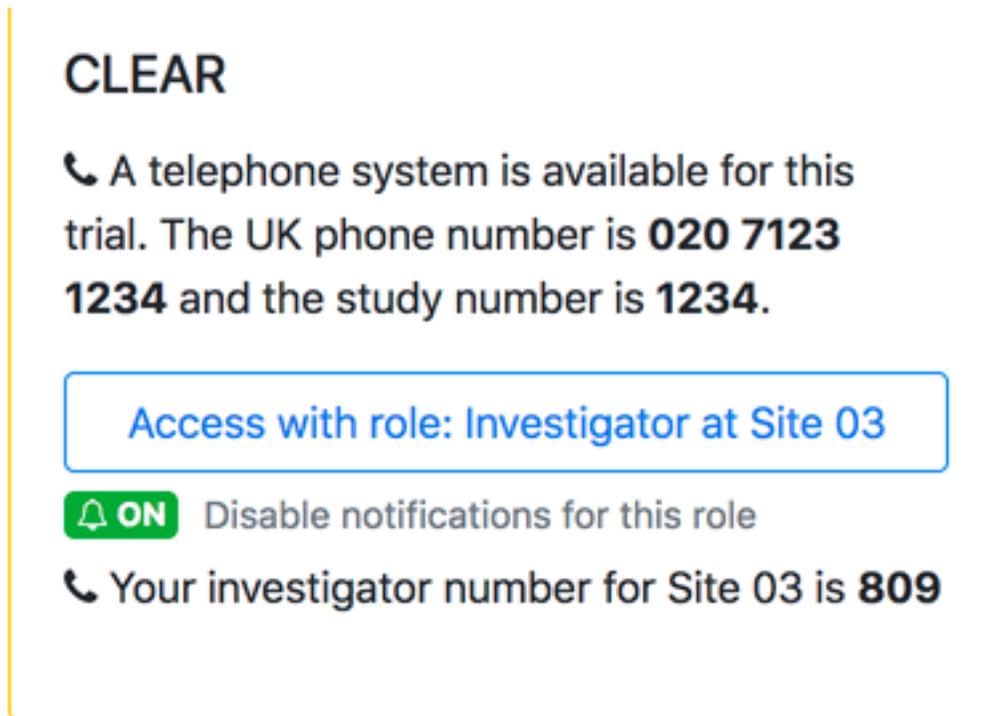
- View subjects
- View randomisation form
- View queries
- Add messages to queries
- Create queries
- Can be limited to subjects at one site

Figure 13: Assigning a role

Telephone randomisation

If a trial is making use of Sealed Envelope's telephone randomisation service, access to this service is granted 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](#).



CLEAR

📞 A telephone system is available for this trial. The UK phone number is **020 7123 1234** and the study number is **1234**.

Access with role: Investigator at Site 03

ON Disable notifications for this role

📞 Your investigator number for Site 03 is **809**

Figure 14: Showing investigator number for telephone randomisation

Editing accounts

Existing accounts may be edited by an administrator by clicking on the *Edit details* link when [viewing](#) an account. It is possible to change the account email address and name only. 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.

Editing roles

A role can be edited to change the site, status (active or suspended) and to enable or disable notifications. To edit a role find the user and view their roles, then click the *Edit role* link.

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 Jenny Jenns

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 15: Editing a user account

Update role for **Iain Pearsons**

Investigator at Helsingør

Iain Pearsons (ipearson@clinicalcentre.org)

Investigator role

Site

Helsingør

You can create and manage sites by [accessing the Demo 1 \(blinded\) trial](#) as an administrator

Status

Active

Suspended

Send email notifications?

Figure 16: Editing a role

Changing your own account details 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 name, email address, timezone, back-up email, mobile phone number or password. Administrators can update name and email address by [editing accounts](#) and can [reset passwords](#) for any user.

Self-service [password resets](#) are enabled by entering a back-up email address or mobile phone number to receive a security code.

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.

Timezone

The timezone setting applies to dates and times shown in the Access interface only. It does not affect dates and times in randomisation or Red Pill applications. These have their [own timezone settings](#) based on the site a subject was recruited at.

Recent log ins

Details of the five most recent log ins are displayed on the *My account* page. The date and time of each log in together with browser information and IP address are tabulated. The geographical location of each IP address is shown if available.

Update your details

Name:

Iain Pearsons

Email address

ipearson@foundling.nhs.uk

Timezone 

(GMT+00:00) UTC

Affects display of times in this Access interface only. Does not affect randomisation or Red Pill systems.

 Add a back-up email address or mobile phone number to allow you to reset your password if you forget it

Back-up email address

me@alternative.com

This email will only be used for account security purposes

Country

Mobile phone number

Choose...

7000 777777

This number will only be used for account security purposes

Confirm your current password to make changes to your account

current password

Update

Recent log ins

Thu, 14 Jun 2018 14:28:12 +0000 (9 minutes ago)

Wed, 21 Mar 2018 19:01:14 +0000 (3 months ago)

Tue, 20 Mar 2018 17:35:07 +0000 (3 months ago)

Tue, 20 Mar 2018 10:35:49 +0000 (3 months ago)

Tue, 13 Mar 2018 18:43:27 +0000 (3 months ago)

 Chrome 67.0.3396.79 on Mac 10.13.5

 Chrome 65.0.3325.162 on Mac 10.13.3

 Chrome 65.0.3325.162 on Mac 10.13.3

 Internet Explorer 11.0 on Windows 10

 Internet Explorer 11.0 on Windows 10

 London, England, United Kingdom, IP: 128.40.2

 London, England, United Kingdom, IP: 128.40.2

 London, England, United Kingdom, IP: 128.40.2

 Bromley, United Kingdom, IP: 82.16.30.167

 Bromley, United Kingdom, IP: 82.16.30.167

Change your password

You must change your password every 6 months. You last changed your password Wed, 30 Dec 2020 10:00:00 +0000 (over 2 years ago)

Confirm your current password

current password

Some password suggestions:

ic fake aw

awn false shad

foxy penny baxter

Suggest more passwords

Your new password

new password

Your new password must be at least 8 characters long

Confirm your new password

new password again

Change

You cannot submit this form with a weak password

Figure 17: Changing password

Password expiry

Passwords may expire after a number of 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. This setting is trial specific and if a user has roles in several trials, the most frequent password change interval will apply.

Forgotten passwords

If a user forgets their password they may be able to reset their own password. The user must have stored a back-up email or mobile phone number to do this, in order to receive a security code.

Self service reset

Users should click on the *Forgot your password?* link on the log in page and enter their email address. If the email address is for a valid account, an email will be sent with instructions. This will contain a unique password reset link that expires after 10 minutes. A security code will also be sent to the user's back-up email or mobile number which is needed on the password reset page.

Administrator reset

If the user has not stored a back-up email or mobile phone number, 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 an email to the account holder with a special link to reset their password. The link is valid for 2 hours. A security code is not required by the user to change their password.

Administrators are advised to verify the identity of users requesting a password reset in this way.

Requests for password resets made by investigators to Sealed Envelope will be referred to

Password reset

Security code

Check your back-up email or mobile to obtain this code

Some password suggestions:

grieve peer spade

inc skat moor

chore alder pedro

[Suggest more passwords](#)

Your new password

new password

Your new password must be at least 8 characters long

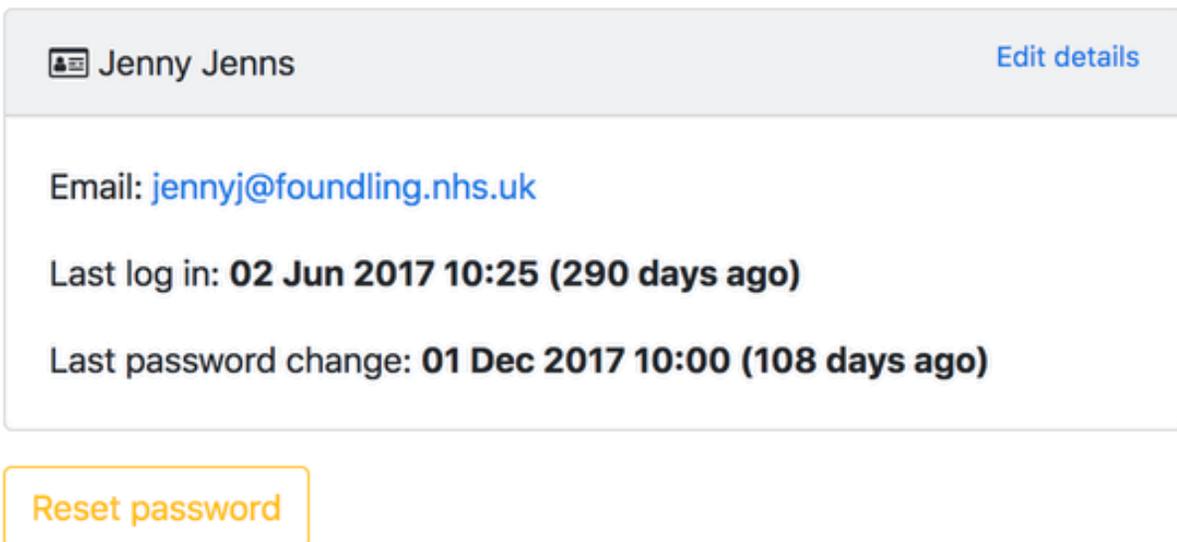
Confirm your new password

new password again

[Change](#)

the trial manager since Sealed Envelope has no way of authenticating the validity of such requests.

User account for Jenny Jenns



 Jenny Jenns [Edit details](#)

Email: jennyj@foundling.nhs.uk

Last log in: **02 Jun 2017 10:25 (290 days ago)**

Last password change: **01 Dec 2017 10:00 (108 days ago)**

[Reset password](#)

Figure 19: Viewing user account detail

Password change email

Once a user successfully changes their password, an email is sent to them informing them of the change. Unexpected password changes should be investigated without delay in case an account has been compromised. Contact Sealed Envelope for assistance if required.

Designs page

Designs are the blueprints for producing Red Pill and randomisation applications. If you have access to any designs you will see a Designs link in the top menu bar.

Each panel shows a different design along with options to add further users, view the audit trail, and edit the design. *LIVE* and *TEST* badges indicate whether the design has an associated live or test application. If so, these will be displayed on the [trials page](#).

Designs

Designs are like the blueprints for producing your trial applications. You can edit designs in the CRF builder, and allow other us

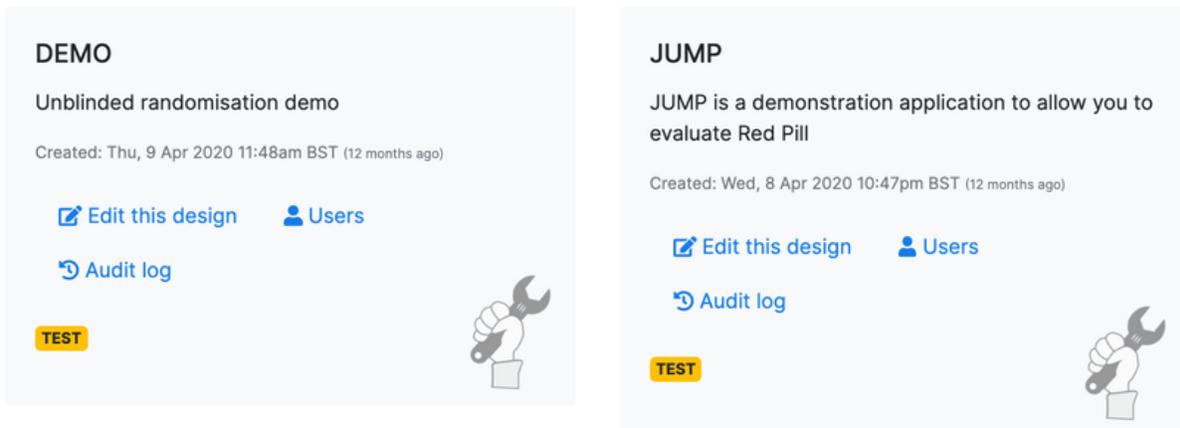


Figure 20: Designs page

The 'edit this design' link takes you to the [CRF builder](#). Depending on user permissions

you may see a 'Create a new design' button which allows you to add a new design in the CRF builder.

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. Entries can be searched, and sorted by clicking the header row.

Demo 1 (blinded) (TEST)

[Users](#) [Notification accounts](#) [Audit log](#)

This audit log shows all changes to user account data for Demo 1 (blinded) (TEST).

Search:

Timestamp	User	Action	Changes
2018-01-18T14:33:21Z	SE support (ID1, support2@sealedenvelope.com)	Updated role (ID 67) for user Iain Pearsons (ID 3, ipleason@clinicalcentre.org)	suspended changed from false to true
2018-01-21T22:13:25Z	Andrea Amins (ID2, a.amin@foundling.nhs.uk)	Updated user account for Iain Pearsons (ID 3, ipleason@clinicalcentre.org)	password changed, password_change changed from Fri, 21 Apr 2017 17:11:05 UTC +00:00 to Sun, 21 Jan 2018 22:13:25 UTC +00:00
2018-01-22T12:14:05Z	SE support (ID1, support2@sealedenvelope.com)	Updated user account for Andrea Amins (ID 2, a.amin@foundling.nhs.uk)	name changed from "Andrea Amin" to "Andrea Amins"

Figure 21: Audit log

Security

This page explains the various security features of the Access log in system and how you can help keep your account secure.

Recommendations

1. Choose a strong password that you do not use elsewhere.

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.

Tip: two or three word phrases are generally stronger than single word passwords especially if one or more of the words is not in the dictionary. Create non-dictionary words by adding digits or punctuation.

2. Use a password manager

A password manager helps you create and store secure passwords for all your online accounts. Many integrate with your web browser to make filling in password fields easy. Even if you are using a work PC on which you can't install password manager software, you can still use a mobile app on your phone to help you create and remember passwords. Popular password managers include [1Password](#), [LastPass](#) and [Dashlane](#).



Figure 22: Password managers

3. Add a backup-email or mobile phone number

By [adding a backup-email or mobile phone number](#) to your Sealed Envelope account you will be able to use the [self-service password reset](#) feature if you ever forget your password. If you don't, you will need to contact an administrator to reset your password instead.

4. Look out for account related emails

We will send you an email notification if any of the following occur:

- The reset password feature is used for your account email address. This will contain instructions on how to [reset your password](#).
- Your password is changed. Only you can change your password so if you receive this email unexpectedly you should report it to a trial administrator or Sealed Envelope for investigation.
- Your account details such as name or email address are changed. You can do this on the [My account](#) page or an administrator can make these changes for you. The notification will be sent to both your old and new email addresses (if applicable). If you are not sure why the changes have been made you should contact a trial administrator.
- Your account has been suspended because too many log in attempts have been made. If you receive this email unexpectedly it may be a sign that someone is trying to break into your account by guessing your password. If you think this may be the case please contact a trial administrator or Sealed Envelope for investigation.

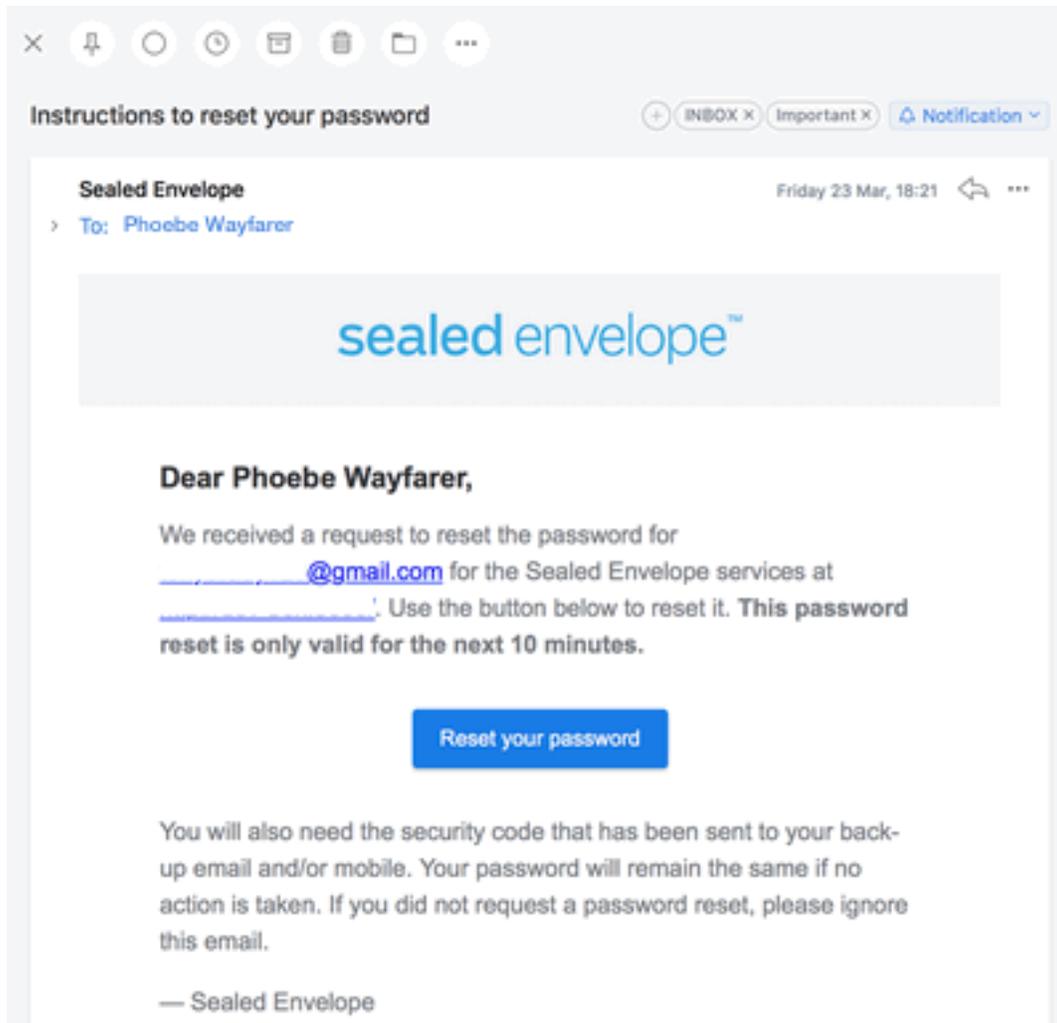


Figure 23: Reset password email

5. Check your recent log ins

You should check your recent log ins on the My account page regularly and report any suspicious activity from unknown locations or web browsers.

About enforced password resets

In the past it has been generally considered good practice to regularly change passwords and this has fed through to regulations (such as 21 CFR Part 11) and corporate policies. However, it is increasingly recognised that this practice might be counter productive and several influential bodies including [NIST](#) and the [UK Government](#) now advise against periodic enforced password changes.

Sealed Envelope support enforced password reset intervals at the trial level but by default this setting will be off. We recommend it is not used unless your trial has to comply with 21 CFR Part 11 or your own corporate policies. Trial administrators should contact Sealed Envelope if they require a password reset interval to be set.

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.

Notification accounts receive emails but cannot log in.

[Create a notification account](#)

Copy Excel CSV Search:

Name	↑↓	Email	↑↓	Site(s)	↑↓
Ray Purchase		notify@sealedenvelope.com		Foundling Hospital, Royal London	

Figure 24: List of notification accounts

Notification account

Notification accounts are only used to send out notifications. They cannot be used to log in to this trial.

Email address

Name

Limit to site(s). Notifications will be sent for all sites unless you select one or more sites below

- Foundling Hospital
- Royal London
- The University of Chicago Medicine

Figure 25: Creating a notification account

Archives

Users with the archivist role are able to download an archive containing all application data.

Archivist user accounts cannot be created by administrators and must be requested by contacting Sealed Envelope. The archivist role may be useful, for instance, by a statistician to download data required for interim analyses for Data Monitoring Committee meetings. It may also be used at the end of trial during close-out.

Archives may include **sensitive data such as randomisation lists and unblinded data**. For this reason the archivist role should not normally be assigned to any staff involved in the day to day running of the study. The fact an archive was downloaded is recorded in the [application audit trail](#).

Archive contents

Users with the archivist role will see a button to download the archive. The archive is a zip file containing:

- README.txt with a description of the archive contents and MD5 checksums for each file in the archive
- Complete [MySQL dump file](#) for the study database
- Comma separated value (CSV) files for all forms in the CRF and other datasets such as randomisation and code lists
- Stata files for all forms in the CRF and other datasets such as randomisation and code lists
- A data dictionary showing the structure of every form in the database. Additional information on each column shows the question as it appeared in the CRF or randomisation form.

CAP-IT

Efficacy, safety and impact on antimicrobial resistance of duration and dose of amoxicillin treatment for young children with Community-Acquired Pneumonia (CAP): A randomised controlled trial



 [Download an application archive](#)

Warning: archives contain sensitive data such as randomisation lists and unblinded data.

Figure 26: Download archive

- Copy of the final audit log. This text file contains a timestamped record of every action that created, updated or edited data. Each action is linked to the relevant user account.
- Log of user account actions. This text file contains a timestamped record of every action that created or updated a user account, role or notification account linked to the system and the user account that performed each action.

What's new

tba

Archivist accounts can now be created by an administrator like any other role. Please contact support to enable this for your trial.

Dec 2021 - version 7.2.0

Selecting all users now respects any search filters that are applied.

- [Validation certificate 7.2.0](#)

Sep 2021 - version 7.1.0

A bug affecting logins was fixed.

On log in users with an invitation are redirected to the invitations page. This is to try and help users unfamiliar with the system who frequently don't realise that they need to follow the link to accept an invitation before they can access a trial.

The email sent on password change has been updated to note that location information obtained by IP lookup is approximate.

- [Validation certificate 7.1.0](#)

Aug 2021 - version 7.0.5

A bug affecting trial listings was fixed.

A minor bug affecting the integration between the CRF builder and Access was fixed.

A bug resulting in notifications being delivered to extra recipients for a single customised system was fixed.

- [Validation certificate 7.0.5](#)

Oct 2020 - version 7.0.4

Inactive user accounts for decommissioned trials are now deleted. Invitations to create accounts that are not taken up within 6 months are automatically cancelled.

The option to have fax notifications was removed as it is no longer in use.

- [Validation certificate 7.0.4](#)

Sep 2020 - version 7.0.3

A minor update to speed up the user listing and relabel the staging environment as “test”.

- [Validation certificate 7.0.3](#)

Sep 2020 - version 7.0.1

A minor update to fix a couple of issues to do with trials hosted on remote hosts.

- [Validation certificate 7.0.1](#)

Jul 2020 - version 7.0.0

The screenshot shows a web interface for trial management. At the top, there are tabs for 'All', 'Test', and 'Live'. Below the tabs is a grey warning box: 'These are systems in multiple environments (test and live). Please be careful to pick the correct environment.' The main content area displays three trial cards:

- JUMP (TEST):** A demonstration application to allow you to evaluate Red Pill. Roles include 'Investigator at 1: Aberdeen' and 'Investigator at 4: Edinburgh is suspended'. A notification toggle is set to 'ON'.
- OACS-1 (LIVE):** Roles include 'Monitor at 1: Foundling Hospital' and 'NCTU data entry'. Notification toggles for both roles are set to 'ON'.
- PREVENT (LIVE):** 30 tech. Roles include 'Users', 'Notification accounts', 'Audit log', and 'Administrator'. A notification toggle for the Administrator role is set to 'ON'.

Figure 27: Trials summary page

Trials are now shown on different tabs by environment (all, live, staging). Only new trials

will appear in more than one environment. Existing trials still require the user to log in to the [live](#) or [staging](#) environment separately.

All roles associated with selected user accounts on the users page can be suspended or activated. A badge is shown next to inactive accounts (those that haven't logged in for more than 6 months). This makes it easier to suspend all access for staff that have left or are no longer involved in an organisation's trials.

Multiple selected roles for a trial can be suspended or activated at once. This is useful at the end of a trial to suspend access to all investigators for instance.

Notification accounts can be created for multiple sites. Previously it was only possible to receive notifications for all sites or one chosen site.

Users are now invited to new roles when they already have an account. They no longer have access or receive notification emails until they have accepted the invitation. They can also choose to decline invitations.

Tables showing user accounts and roles can now be downloaded as CSV or Excel files.

We no longer allow a duplicate role to be created for a user and we removed the site selection control from the statistician role as this was ignored by data downloads. We removed the general link to our website in password reset emails to avoid users getting confused about which link to click to reset their password.

- [Validation certificate 7.0.0](#)

Jul 2019 - version 6.3.1

Fixed an issue that could cause an error on the **My Account** page when the browser agent string was not recognised.

Validation certificates

We now produce a validation certificate for each release. This confirms the software was produced according to our SOPs and has passed all of our internal testing procedures.

- [Validation certificate 6.3.1](#)

March 2019 - version 6.3.0

Invitations

You accepted the invitation to DEMO (STAGING)

You have the following invitations:

JUMP (STAGING)

JUMP is a demonstration application to allow you to evaluate Red Pill

You have been invited with **statistician privileges**

You were invited on Sat, 27 Jun 2020 5:42pm UTC (7 minutes ago) by SE support 2

Figure 28: Invitation to new role

We changed the way we check for whether the user's browsers has cookies enabled. Cookies are required to be able to log in.

November 2018 - version 6.2.2

Fix for an intermittent problem with the password strength meter always showing the entered password was weak.

September 2018 - version 6.2.1

A minor update to help with testing subject entered forms.

July 2018 - version 6.2.0

The location information associated with your IP address has been updated to show a country flag and the name of your internet service provider (ISP). For those of you who work at large organisations the location shown is often related to the ISP rather than you.

Mobile numbers and security codes are now redacted when an administrator views the audit log.

June 2018 - version 6.1.0

A timezone setting has been added to user accounts so you can see times in the Access interface (such as times of your recent log ins) in your own timezone.

Some people were getting the test and live environments mixed up. A warning is now shown on the log in page for test systems to hopefully reduce confusion.

Some tweaks were made to the security code text messages for compatibility with North American mobile networks.

March 2018 - version 6.0.0

This update is all about **security**, making it easier for you to keep your account secure and recover from that common modern affliction – forgotten passwords.

You can now [recover your own password](#) using the *Forgot your password?* link on the [log in page](#), provided you have added a [back-up email or mobile phone number](#) to your account to receive security codes. If you haven't done this you can still ask an administrator to reset it for you.

We've added a help page on ways you can [keep your account secure](#). Check it out for some hopefully helpful advice.

Password reset

Enter your registered email address and we will send you instructions on how to reset your password

Email address:

me@example.com

Send instructions

Cancel

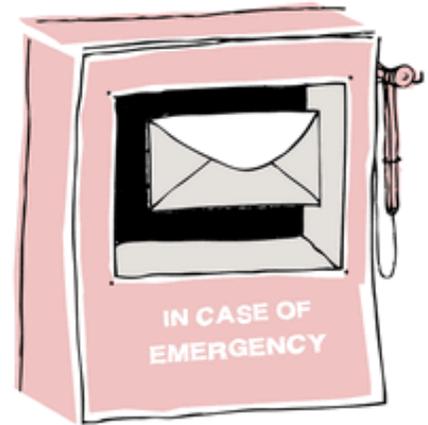


Figure 29: Forgot password screen

No more forced password changes (maybe)

Security guidance has finally caught up with common sense and heavy-weight bodies such as [NIST in the US](#) and the [UK Government](#) now advise against periodic enforced password changes. Why? Because making passwords expire means people tend to forget their new passwords, pick simple variations on their previous password, and are more likely to write them down on a sticky note.

Unfortunately some standards such as 21 CFR Part 11 contain requirements to enforce regular password changes, and so we have made this a trial level setting. We'll be asking customers whether they need to enforce regular password changes when we set up new trials. Customers can also ask us to turn off enforced changes for existing trials.

Watch over your account

We've added a [recent log ins](#) section to the *My account* page which shows where and when you logged in from. If you think something suspicious is going on, this is the first place to check. We also show you the last time you logged in when you log in.

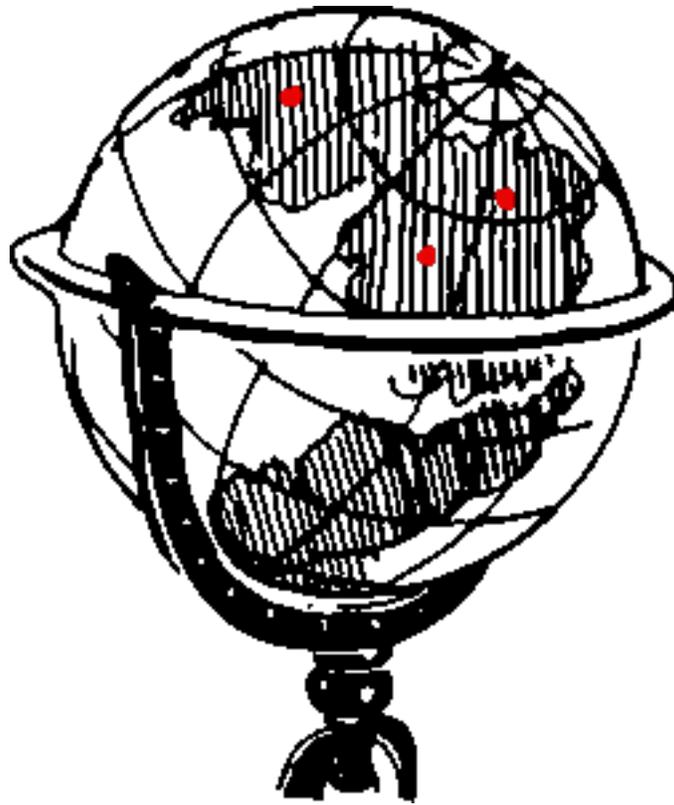


Figure 30: Globe

We now send you emails when things change concerning your account including:

- Changed account information
- Changed password
- Account suspension because of too many failed log in attempts

If you see any of these emails when you weren't expecting them, you should channel your inner Sherlock and investigate.

Other changes and bug fixes

- Older versions of Access are being retired and user accounts will be migrated to the latest version. We'll be in touch with customers affected by this change with more details.
- We've refreshed the way Access looks, and reduced the space each trial takes up on the [trials summary page](#)
- Search added to the trials summary page when there are more than 3 trials. Pagination added with 12 trials per page.
- User's can now change their own name (an administrator had to do it before)
- Deleted roles and notification accounts are now shown in the audit log
- The dictionary used to check for weak passwords has been interfrastically updated
- Invitation links are now sent to new users rather than passwords. Invitations expire after 2 weeks but can be renewed by administrators or cancelled.
- [Subject entered forms](#) invitation links now always take the user to a welcome screen with a button to start the survey (previously this screen was only shown if a memorable word was set). This prevents issues with email previews or virus checkers visiting links and inadvertently logging in as a subject.
- A subject who has logged out after entering forms is shown a finished message and no longer shown the usual user log in page if they try to visit a protected page
- Log in throttling should help prevent bad guys from trying automated password guessing to break into accounts
- We fixed an issue for users with longer timeout intervals for their trials. Access now also respects these longer timeout intervals so you can enjoy being logged in for longer.