



# **USER TRAINING GUIDE FOR USE WITH NWORDH COMPLETE LIST RANDOMISATION SYSTEM**



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All screen shots are taken from a mock trial, used for validation.

## 1 Before you start

Your username and password will have been emailed to you by the NWORDH IT team.

If you have not been issued with a username and password, please contact the trial manager. They will confirm that you are to perform randomisations and pass on your name, title, phone number and email address to the NWORDH IT team.

## 2 Logging In

Enter the URL [https://nworth.bangor.ac.uk/web\\_list\\_randomisation/](https://nworth.bangor.ac.uk/web_list_randomisation/) into the address bar in your browser.

You should see a page that looks like the one shown below:

The screenshot shows a web browser window with the address bar displaying <http://localhost/brando1/>. The browser window has a single tab titled "Logon". The page content features a large blue header with the text "NWORDH randomisation system" in a cursive font. Below this is a section titled "Logon" in bold black text. The login form includes a "Trial:" label next to a dropdown menu with the text "Select a Trial to logon" to its right. Below the dropdown are two input fields labeled "Username:" and "Password:". At the bottom of the form are two buttons: "Logon to Enter data" and "Logon to Test". A link "Forgot username / password" is located below the buttons. Four red callout boxes with lines pointing to specific elements provide instructions: "Click here to enter data" points to the "Logon to Enter data" button; "Important! Select your trial" points to the dropdown menu; "Fill in your login details" points to the "Username:" and "Password:" input fields; and "Click here to test the questionnaire" points to the "Logon to Test" button.

Select your trial and enter your username and password. Usernames and passwords are case-sensitive.

If you click the button "Logon to Enter data", you will be entering data: the database will be updated.

If you click the button “Logon to Test”, you will be using the system in the test mode. In this case you will be able to test the questionnaire, but the database will not be changed.

In case you have forgotten your login details, use the link “Forgot username / password” at the bottom of the login page. It will display the form shown below:

*NWORTH randomisation system*

## Forgot Password

Enter the email address you have been registered with in the system

Trial:  Select a Trial for the password

Email address:

Submit

Fill in the form and submit. Make sure to enter the email address you were registered in the system with originally. You will receive an email with your username and a new automatically generated password. After logging on using the emailed details you can change your password.

## 2.1 Enter data

After logging in you will see a form displaying the questionnaire for this trial:

**NWORTH randomisation system**

[View data](#) [Change Password](#) [Logoff](#)

### Questionnaire

**Trial: OQ\_Test**

Please fill in the form with the details of the participant and submit it.

<b>Participant ID</b>	<input type="text"/>	<i>Unique, 5 or 6 digits</i>
<b>Participant DOB</b>	<input type="text"/>	<i>DD MM YYYY</i>
<b>Participant Initials</b>	<input type="text"/>	<i>Required</i>
<b>Type of oq_test repair</b>	<input type="text"/>	<i>Select</i>
<b>Age</b>	<input type="text"/>	<i>Select</i>
<b>Consent</b>	<input type="text"/>	<i>Yes is required</i>
<b>Inclusion Criteria Met</b>	<input type="text"/>	<i>Yes is required</i>
<b>Gender</b>	<input type="text"/>	<i>Select</i>
<b>Centre</b>	<input type="text"/>	<i>Select</i>
<b>Bilateral repair</b>	<input type="text"/>	<i>Select</i>

*All the fields are required.*

On the left-hand side are the field captions. On the right-hand side are brief help texts, explaining the specific requirements for the corresponding data fields.

As displayed above the “Submit” button, all fields are required. The system does not accept incomplete data sets.

Fill in the questionnaire with the details of the participant and submit.

If you have logged on using the button “Logon to Test”, you will see the following screen:

The screenshot shows a web browser window with the URL <https://nworth.bangor.ac.uk/randomisation/randomise/questionnaire.jsp>. The page title is "Questionnaire". The main heading is "NWORTH randomisation system - Test", with "Test" circled in red. Below the heading are links for "View data", "Change Password", and "Logoff". A red arrow points from the text "Indicates 'test' mode" to the circled "Test". The form is titled "Questionnaire" and "Trial: OQ\_Test". It instructs the user to "Please fill in the form with the details of the participant and submit it." The form fields are:

<b>Participant ID</b>	<input type="text"/>	Unique, 5 or 6 digits
<b>Participant DOB</b>	<input type="text"/>	DD MM YYYY
<b>Participant Initials</b>	<input type="text"/>	Required
<b>Type of oq_test repair</b>	<input type="text"/>	Select
<b>Age</b>	<input type="text"/>	Select
<b>Consent</b>	<input type="text"/>	Yes is required
<b>Inclusion Criteria Met</b>	<input type="text"/>	Yes is required
<b>Gender</b>	<input type="text"/>	Select
<b>Centre</b>	<input type="text"/>	Select
<b>Bilateral repair</b>	<input type="text"/>	Select

All the fields are required.

In this instance you are using the randomisation system in test mode. The test mode is indicated on the top bar.

In test mode the database is not changed. The randomisations performed in it are not saved. Email notifications will not be sent.

The test mode serves to familiarise you with the questionnaire and the reactions of the randomisation system to your actions.

In test mode you can experiment with the system in a safe way.

## 2.2 After submitting the data

Below is an example of submitting an incomplete and inaccurate data set. In this case the system will go directly in the “Edit” mode, indicating the errors.

**NWORTH randomisation system - Test** [Logoff](#)

### Edit

**Trial: OQ\_Test**

Please edit the details of the Participant and submit the form.

<b>Participant ID</b>	<input type="text" value="12345"/>	<b>Unique, 5 or 6 digits</b>
<b>Participant DOB</b>	<input type="text" value="29 02 1927"/>	<b>DD MM YYYY</b>
<b>Participant Initials</b>	<input type="text" value="JR"/>	<b>Required</b>
<b>Type of oq_test repair</b>	<input type="text" value="TAPP"/>	<b>Select</b>
<b>Age</b>	<input type="text" value="65 and older"/>	<b>Select</b>
<b>Consent</b>	<input type="text" value="Yes"/>	<b>Yes is required</b>
<b>Inclusion Criteria Met</b>	<input type="text"/>	<b>Yes is required</b>
<b>Gender</b>	<input type="text" value="Male"/>	<b>Select</b>
<b>Centre</b>	<input type="text" value="Ysbyty Gwynedd"/>	<b>Select</b>
<b>Bilateral repair</b>	<input type="text" value="No"/>	<b>Select</b>

*All the fields are required.*

<https://nworth.bangor.ac.uk/randomisation/randomise/confirmData.jsp>

In the example above the “Participant ID” was not unique. In this case, there will be also an error if the ID contains symbols other than digits, or if it was shorter than 5 digits or if it were longer than 6 digits.

The system checks the dates for validity and correct format. In this case the format was correct, but the date was invalid.

The third error was because there was nothing selected for “Inclusion Criteria Met”.

**All fields must be completed.**



## 2.3 Data confirmation

After the data is corrected in the “Edit” mode and passes validation checks, the Confirm screen will be shown. An example of it is shown below:

**NWORTH randomisation system - Test** [Logoff](#)

### Confirm

**Trial: OQ\_Test**

Please Confirm the data or Edit to correct it. Confirmation will trigger the Randomisation process.

Captions	Entered values	Help text
Participant ID	123456	Unique, 5 or 6 digits
Participant DOB	28 02 1927	DD MM YYYY
Participant Initials	JR	Required
Type of oq_test repair	TAPP	Select
Age	65 and older	Select
Consent	Yes	Yes is required
Inclusion Criteria Met	Yes	Yes is required
Gender	Male	Select
Centre	Ysbyty Gwynedd	Select
Bilateral repair	No	Select

[Confirm](#) [Edit](#)

The system accepted the data, but it still could be wrong in a way the system cannot recognise.

Here is a final chance to check whether the entered values are correct and edit the data if they are not. After each edit, the system will require confirmation before saving the data.

If you click the button “Confirm”, this will trigger the saving data process.

When you are happy the data is correct, confirm to save it.



## 2.4 Viewing and editing data

In case an error is discovered after the data have been saved, but before it has been randomised, the data can be edited. Every centre can edit their own data entries if they are not already randomised. For editing randomised data a request to N Worth statisticians should be made.

**Data for randomisation**

Trial: OQ\_Test

Date	No	User	Status	Type	Group Id	Participant ID	Participant DOB	Participant Initials	Type of oq_test repair	Age	Conse
2013-08-12 10:44:34	<a href="#">0</a>	pepo	valid	normal		12345	12 11 1987	AB	516	518	521
2013-08-12 10:45:48	<a href="#">1</a>	pepo	valid	normal		12346	12 11 1987	AB	516	518	521
2013-08-12 10:46:43	<a href="#">2</a>	pepo	removed	normal		12347	12 12 1987	AB	516	518	521
2013-08-12 10:54:48	<a href="#">3</a>	pepo	valid	normal		12348	11 12 1987	OQ	517	518	521
2014-03-28 15:08:00	<a href="#">4</a>	pepo 2	valid	normal		12347	12 12 1987	ABC	516	518	521

The screen shows the data which was viewed via the link 'View data' from the Questionnaire page.

The data has not been randomised yet; the Group ID column is still empty. The column 'No' shows the line numbers and they are web links. Clicking on one will open the Edit page and the data from the corresponding row will be displayed for editing.

The editing process is the same as for entering data.

The picture above shows the result of editing line 2. The initials were changed and when the edit was confirmed, the source line (line 2) was marked as removed, and a new line with the result of the edit (line 4) was added to the data. In the field where the username of the person who made the change is stored, the original line number (source) is also stored.

## 2.5 Changing your Password

To change your password, click “Change password” at the top right of the page displaying the questionnaire. The link will display the following screen:

*NWORTH randomisation system*

### Change Password

The password should consist of at least 6 characters and use only letters and digits. It should contain at least one capital letter, one small letter and one digit, for example aXb2sd.

**All the fields are required**

**Current Password:**  Required

**New Password:**  Required

**New Password:**  Confirm

Enter your current password in the field titled “Current Password” and then enter your new password in the fields with caption “New Password”. If what you have entered in the field “Current Password” matches your current password and the entries in the fields “New Password” are identical, your password will be changed.

Note that the system will **not** send you any email notifications in connection to the change of the password. You should take care to remember your new password.

## 2.6 Downloading randomisations

When a statistician randomises a batch of participants, the system emails a specific link which allows this particular batch of randomisations to be downloaded. When this web link is used, it activates a logon page. After the logon comes a page with a warning about possible un-blinding and a link to the CSV file containing the randomised batch. Excel opens such files directly (by double-clicking on the file name).

Right-click the link to the CSV file, and from the drop-down menu, choose a save method. The options in the menu vary with the different browsers, but it is something like 'Save file as' or 'Save target as' or 'Save link as'. Activating the save option opens a dialogue box where you can select a directory in your local machine to save the file.

The link which the system sends after a randomisation can only be used to download the corresponding randomised batch. **It cannot be used for entering data.**

## 3 Trouble-shooting

If you experience any problems accessing the system or performing randomisations, please check this section of the guide.

### 3.1 Logon problems

- Make sure you have selected your trial correctly;
- Apply the right capitalisation in the username and password: the system is case sensitive and "mac15N" is different from "Mac15n".
- When using the "Forgot username / password" feature of the system, you will be identified by the email address and the trial. Make sure you select the right trial and the email address with which you have been registered as a user. An alias to that email address will not work.

If you are still having trouble, contact your trial manager. It may be that you have not been registered as a user in the system and the trial manager will send your details to the NWORTH IT team with a request to create you an account.

### 3.2 Problems entering data

- Check the mode you are using the randomisation system in. Test mode is indicated on the top bar of the pages – you cannot enter data, you can only look at the questionnaire.
- Check the dates in the questionnaire are the required formats. If the date is not in the required format, or it is not a valid date e.g. 36/11/1987, the system will not accept it.
- In fields where integer numbers are required, numbers containing a fraction part will be rejected.
- Where digits are required, only digits will be accepted.
- Participant IDs must be unique. When an ID is rejected, but it is otherwise correct in terms of format, length, value and character set, this is an indication that it is not unique.