MAPS-2 Working Practice Document

Activating REDCap and Bespoke System Accounts

To participate in the MAPS-2 trial at your respective site, all members of the trial team will require access to the <u>two</u> following database systems:

1) **REDCap** electronic data capture (EDC) –> the system used to general data entry: recording the daily clinical monitoring log, baseline data, day-14 follow-up SAEs.
2) **Bespoke System** -> the system used to randomise patients, upload documents (consent forms, daily clinical log, chest x-ray reports and patient's prescription), enter patient contact details (for 6-month follow-up), and access the electronic delegation log.

The purpose of this document is to explain *how* to activate your accounts in these systems, before you can access the databases.

<u>REDCap:</u>

1. Once Nottingham Stroke Trials Unit (NSTU) has had the confirmation of *who* exactly will be participating in MAPS-2 at your site, *we* will collate this information and send this to our REDCap database administrators, based within the University of Nottingham. Using the information we provide, they will send you **two** separate (automated emails). One email will contain a link to create ('reset') your REDCap password and thus activate your account, whilst the other contains a link to the REDCap login screen to access the MAPS-2 database. The emails will be from either:

    i)   **daniel.simpkins@nottingham.ac.uk, or**
    ii)   **br-cdss@nottingham.ac.uk**

    [1] If you are unable to locate the emails in your inbox, please search for this email addresses separately in your inbox. Remember to check your junk/spam folders if you are unable to find them. If you are still unable to find these emails, then please get in touch and we will have the REDCap team re-send your credentials (we will give you a warning in advance when you can expect to receive them!).

2. Once located, the emails should look like below.
    Email #1:

> [This message was automatically generated by REDCap]
>
> A REDCap account has been created for you in which your REDCap username is ▭ Click the link below to set your new password and log in.
>
> After logging in, please make sure to set up your password recovery question, which will allow you to use the 'Forgot your password?' link on the login page without the need to contact the REDCap Administrator. You will be prompted to set your recovery question on the My Projects page, but you can also set it on your 'My Profile' page under 'Login-related options'.
>
> Set your new REDCap password Also, please note that your REDCap user account has been given an expiration date (**18-01-2024 09:14 -- 1094 days from now**), which means that after that time you will no longer be able to access REDCap. You will, however, be given a warning prior to your account expiration in case you need to inquire about changing the expiration date (if applicable).

In this email, click the link in the last paragraph. This will take you a page where you will be asked to set up a recovery question, which will then allow you create a new REDCap password by selecting the 'Forgot your password?' link.

3. Once you have set up a recovery question, proceed to 'verify' your REDCap username. This should look like the below:

REDCap Password Recovery

You may use this page to reset your REDCap password. You must first provide your REDCap username, and once it is verified as an authentic REDCap account, you will then need to answer a security question that you have previously set for yourself. If you answer the security question correctly, an email will be sent to you containing a link allowing you to reset your password and then log in to your account.

Username: [   ]

[Verify username]

*If you try and 'verify' your username without setting up a recovery question then this process will not work, and the below error message will appear:

> ⓘ **CANNOT RESET PASSWORD FOR** ▭
>
> The username '▭ cannot be reset due to one of the following reasons: 1) It is not a valid REDCap username, 2) You have not yet set up a security question for your REDCap account, or 3) The password for this user is not able to be reset in REDCap because it can only be reset using an outside resource at your institution.
>
> If you are not sure what to do now or are not sure where or how to reset your password for this account, please contact your REDCap administrator.

Once done correctly, you should be able to reset your password.

4. Email #2 should look something like the below:

[This message was automatically generated by REDCap]

You have been given access to the REDCap project named   MAPS-2   Using your user name   XXXX   you may log in to the project using the link below.

https://cdss.nottingham.ac.uk/redcap/

After clicking the link at the bottom of the email, this should direct you to the below page, where you can log into REDCap using your username and password:

REDCap®

Log In

Please log in with your user name and password. If you are having trouble logging in, please contact Clinical Database Support Service (cdss@nottingham.ac.uk).

Username:	
Password:	

Log In   Forgot your password?

5. Select 'MAPS-2' from the My Projects tab:

My Projects	Organize	Collapse All			Filter projects by title	×	⬛
Project Title			Records	Fields	Instruments	Type	Status
BEET-Winter		🗋	82	430	22 forms 2 surveys	⬳	☑
FINE-ST		🗋	361	724	53 forms	⬳	☑
MAPS-2 Trial		🗋	6	399	10 forms 1 survey	⬳	☑

6. You should be directed to the REDCap homepage.

Bespoke System:

1. Access to the bespoke system can only be achieved once users have access to the REDCap database. Once REDCap accounts have been created (and activated), it is the responsibility of Nottingham Stroke Trials Unit to go into the bespoke system and complete the investigator accounts for each member of the trial team. The Investigator accounts look like the below:

To create the update the accounts for each member of the trial team, Nottingham Stroke Trials Unit will require a written signature for each investigator. This can be from the investigator's signed CV, signed training log, or signed SOP compliance form.

2. Once investigators' accounts have been updated by Nottingham STU, we will send you an automated email from the system. The email, like the REDCap automated email, will contain a link that you will need to click. An example email is shown below:
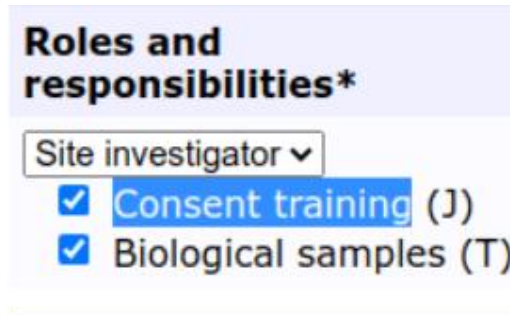
3. Click this link and it will take you to an account activation page, where you will be required to click your responsibilities in the trial. You will need to 'tick' whether you are trained to take informed from patients for clinical research, and also indicate whether you are trained to take biological samples (in MAPS-2, this refers to urine samples). This should resemble the below:

Roles and responsibilities*

Site investigator ⌄
☑ Consent training (J)
☑ Biological samples (T)

[1] Please ensure that you tick the correct responsibilities before activating your account. If the incorrect responsibilities are ticked, then you will need to be removed from the electronic delegation and then be re-added manually (which can be very time consuming!).

[2] Please also select the correct role from the drop-down menu. As of April 2022, there is now an option to select 'Site Administrator' from the drop-down (separate from PI & Site Investigator).

4. Confirm your selection. You should then appear on the electronic delegation log for your site, and your PI will receive an email notification, reminding them to authorise you. An example of the electronic delegation log is shown below:

Log ID	Investigator name/ID	Certificate/ date trained	Roles and responsibilities*	Delegation log status
-	XXX	*(Pending)*	**Site Investigator**	*(Not authorised)*

5. The Principal Investigator is required to authorise all members of the research team, including themselves, on the electronic delegation log. Instructions on how to do this is detailed in step 7 of this section. Once staff have been authorised, the bespoke system can be accessed. To access the bespoke system, log into REDCap and click into 'MAPS-2'. In the left column homepage, select 'supporting site':

Project Bookmarks   ⊟
↪ Add new participant
↪ Randomise
↪ Supporting site
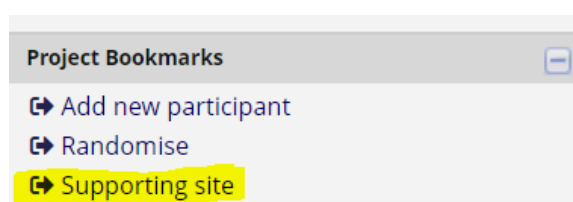
6. You should be directed to a page that resembles the below. Please note that you will not have the same accesses as Nottingham Stroke Trials Unit, which is why there appears to be more options:

- Participant list
- Data reports
- Site delegation log
- Central trial staff delegation log
- Printable forms
- Investigator account manager
- View your training certificate

7. **FOR PRINCIPAL INVESTIGATORS**. Once staff have activated their accounts, you are required to authorise them on the electronic delegation log. To do this, follow steps 5-6 and select 'Site delegation log'.

8. Your site delegation log should appear, with all staff listed as *Not Authorised*. This should resemble the below:

Log ID	Investigator name/ID	Certificate/ date trained	Roles and responsibilities*	Delegation log status
-	XXX	*(Pending)*	**Site Investigator**	*(Not authorised)*

9. Towards the right side of each investigator listed, a drop-down box should show, allowing the option to authorise them. The responsibility boxes they ticked, as shown in previous step 3, will also be displayed. It is important the PI checks these boxes to ensure these responsibilities are correct:

Roles and responsibilities*	Delegation log status	Action
Site investigator ˅ ☑ Consent training (J) ☑ Biological samples (T)	*(Not authorised)*	Authorise ˅

10. Once 'Authorise' has been selected and confirmed for each investigator, they will then show as *Authorised*:

Log ID	Investigator name/ID	Certificate/ date trained	Roles and responsibilities*	Delegation log status
1	Principal Investigator	N3X7K6 28 Feb 2022	**Principal investigator** ABCDEFGHIJKLMNOPQRSTUVWXY	31 Mar 2022 17:05 **Authorised**

11. To remove investigators from the delegation (i.e., if they have left their role), steps 5-6 should be followed. Locate the investigator that you wish to remove, scroll to the right side of their entry to the drop-down box. Select 'Role finished' for the investigator, and confirm. They will then be removed from the delegation log, and the date/time of removal will be logged by the system, as below:

| 2 | ███████ *Senior Research Practitioner* ███ | M7L9G6 9 Feb 2022 | **Site investigator** BFHIKLNOPQRSY | 18 Feb 2022 13:32 **Authorised** ███████████ 23 Feb 2022 12:39 **Role finished** ███████ |