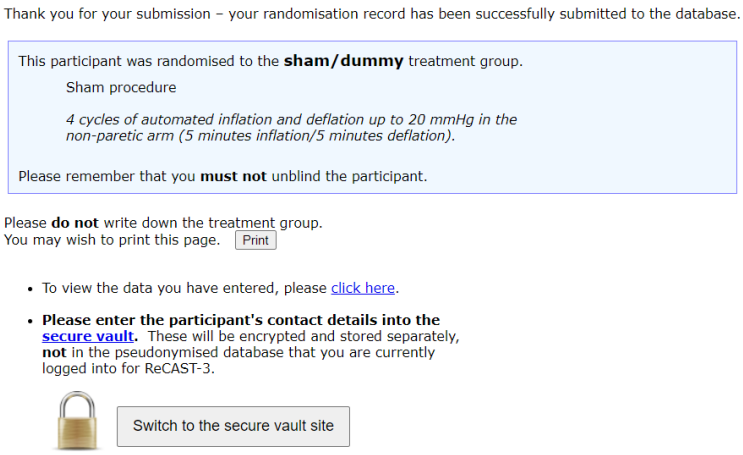
RECAST-3 – Working Practice Document
Title: Secure Vault Uploads - Site Process No. 005

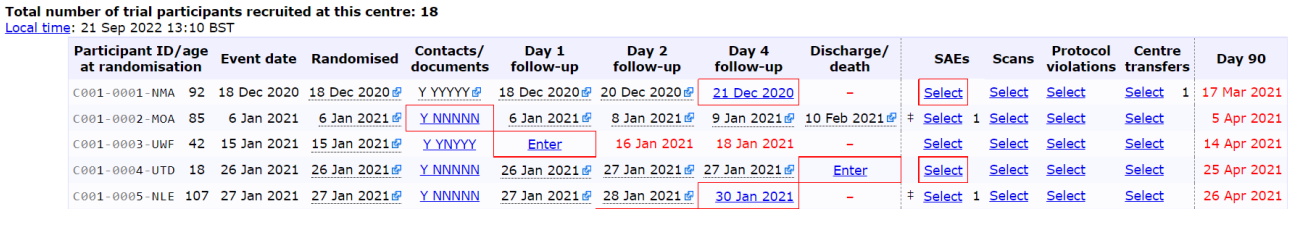
Introduction:
The purpose of this Working Practice Document (WPD) is to describe the procedure to be used by site investigators for the management of uploads to the secure vault.

Accessing the secure vault:
The secure vault is used for sites to upload the required anonymised and non-anonymised documentation relating to participants in the RECAST-3 trial.

On randomising a participant, the investigator will be prompted to access the secure vault in order to enter participant contact details for the day 90 follow-up (see screenshot below).



The secure vault can also be accessed at any time through the RECAST-3 database. Once the participant list is selected, a screen similar to the screenshot below will be shown.



Total number of trial participants recruited at this centre: 18
Local time: 21 Sep 2022 13:10 BST

Participant ID/age at randomisation	Event date	Randomised	Contacts/ documents	Day 1 follow-up	Day 2 follow-up	Day 4 follow-up	Discharge/ death	SAEs	Scans	Protocol violations	Centre transfers	Day 90
C001-0001-NMA 92	18 Dec 2020	18 Dec 2020	Y YYYYY	18 Dec 2020	20 Dec 2020	21 Dec 2020	–	Select	Select	Select	Select 1	17 Mar 2021
C001-0002-MOA 85	6 Jan 2021	6 Jan 2021	Y NNNNN	6 Jan 2021	8 Jan 2021	9 Jan 2021	10 Feb 2021	‡ Select 1	Select	Select	Select	5 Apr 2021
C001-0003-UWF 42	15 Jan 2021	15 Jan 2021	Y YNYYY	Enter	16 Jan 2021	18 Jan 2021	–	Select	Select	Select	Select	14 Apr 2021
C001-0004-UTD 18	26 Jan 2021	26 Jan 2021	Y NNNNN	26 Jan 2021	27 Jan 2021	27 Jan 2021	Enter	Select	Select	Select	Select	25 Apr 2021
C001-0005-NLE 107	27 Jan 2021	27 Jan 2021	Y NNNNN	27 Jan 2021	28 Jan 2021	30 Jan 2021	–	‡ Select 1	Select	Select	Select	26 Apr 2021

In the column titled “contacts/documents”, confirmation of the uploaded documents is indicated by the Y/N and relates to: follow-up contact details, consent form(s), dose accountability log, drug chart, baseline scan report and follow-up scan report. In this column, the investigator should select the link for the relevant participant and the next page will display a link to log into the secure vault.

Uploading to the secure vault:
The secure vault should be used to upload both anonymised and non-anonymised documents for participant’s enrolled into the RECAST-3 trial. Non-anonymised documents will be encrypted and stored separately.

As part of the ongoing monitoring throughout the duration of the trial, the following paperwork should be uploaded to the secure vault when a participant is recruited to the trial and will be reviewed by the coordinating centre:

- Consent forms
- Participants contact details (for follow-up)

The following documents must be uploaded anonymised, ensuring the participant's ID is evident:

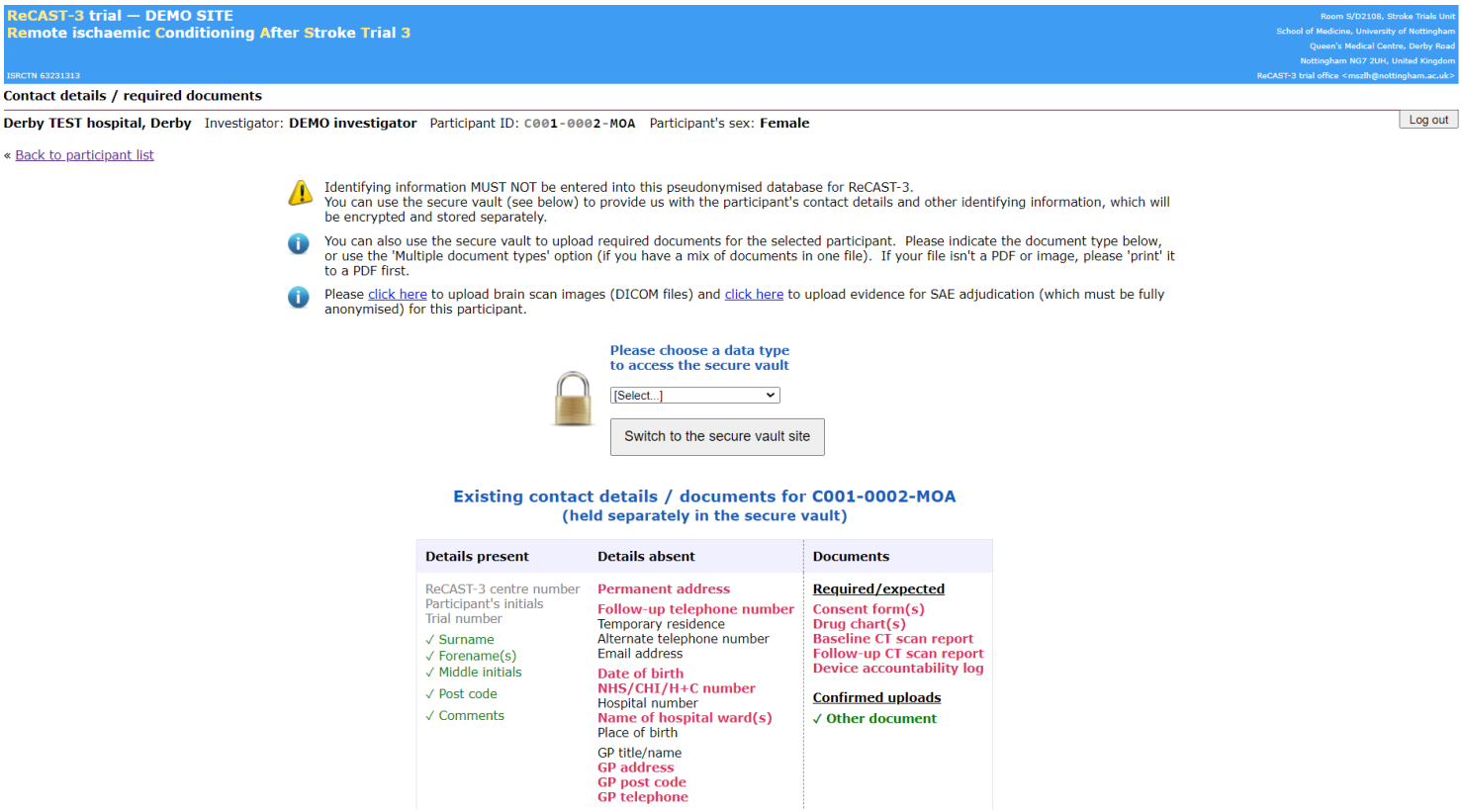
- Dose accountability logs
- Drug charts
- Any clinical neuroimaging reports for clinical brain scans performed during the 90-day follow up period
- Participant-specific file notes as required

Scan data should be uploaded via the RECAST-3 database as opposed to the secure vault. Please see WPD 004 - Uploading Images to the RECAST-3 Database for instructions on this process.

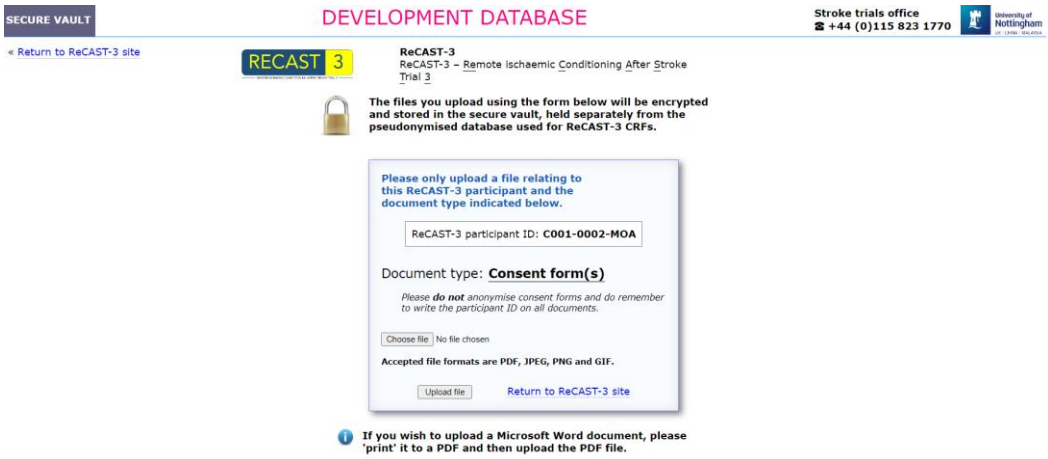
Please do not send any patient identifiable documentation to us via email or fax.

Upload Process:

1. On the participant list page, hovering over the YY/NNN will show what is still required to be uploaded for that particular participant. After clicking on the link, you will be presented with the screen below.



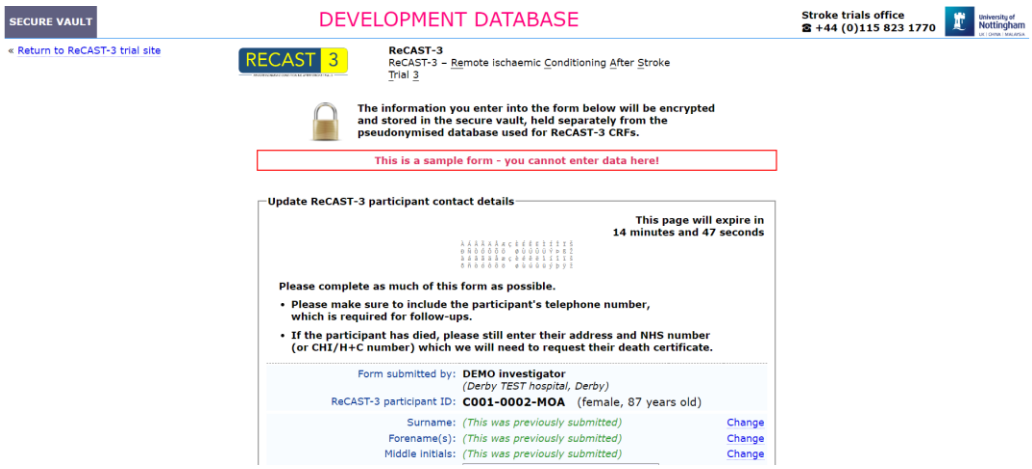
2. This page will show you in more detail what has been uploaded for that participant as well as which contact details have been completed:
   - Required/expected documents will remain red until uploaded.
   - Documents that have been uploaded by the site but are awaiting checks from the trial office will be blue.
   - Documents that have been uploaded by the site and checked by the trial office will be marked as green and ticked.
3. To upload a document, please select the document type (or use the 'multiple document types' option if you have a mix of documents in one file) from the drop-down box and click on the link to 'Switch to the secure vault site'.
4. The screen below will then be shown. Click 'choose file', select the file from your computer files and click 'upload file'.



5. From this page, you can also scroll down further to see the documents that you have already uploaded for that particular participant (see below) and whether they have been reviewed by the trial office yet.

Date/time received	Document type(s) / file type	File size	Investigators	
20 Jul 2021 15:34	**Device accountability log** (image/jpeg)	936 KB	ljhaywood_c1 **Awaiting review**	(428 days ago)
5 Aug 2021 09:54	**Follow-up CT scan report** (image/jpeg)	459 KB	ljhaywood_c1 **Awaiting review**	(413 days ago)
29 Sep 2021 17:02	**Consent form(s)** (image/jpeg)	425 KB	ljhaywood_c1 **Awaiting review**	(357 days ago)

6. Files must be uploaded in one of the following formats: PDF, JPEG, PNG, or GIF. If the document you are attempting to upload is currently in another format such as Word, you should go to your original document and select the 'print to PDF' option and save, this will convert the document to a PDF which you will then be able to upload.
7. On selecting the contact details, the screen below will be shown. You will be able to enter the participant's contact details straight into the database.



8. Once all required/expected documents have been uploaded and reviewed, the trial office will be able to lock the secure vault.

Required Documentation:

Please ensure that the documents listed below are uploaded to the secure vault within 7 days of completion.

Written Consent Form:

The consent form should meet the following requirements:

- Printed on local headed paper
- Correct version number and date of information sheet added
- Participant name and signature clearly visible
- Personal legal representative name and signature clearly visible (if applicable)
- Personal consultee or independent physician name and signature clearly visible (if applicable)
- Name and signature of authorised individual receiving consent clearly visible (code J on delegation log)
- If oral consent was initially obtained, the person who took this should sign the third line of the consent form
- If consent obtained via telemedicine, the participant (or consultee/legal representative) should sign the form as well as the witness, and should be signed by the individual taking consent on their return to the hospital
- Boxes have been **initialled** and not ticked
- Signatures are dated
- The consent form should be labelled with the participant ID

Dose Accountability Log:

- Sites should upload the dose accountability log detailing information regarding all 28 doses and pre- and post- hemodynamic readings.
- Each dose should be signed and dated to document the individual who delivered the dose. They should either be on the online delegation log as a research staff member or on the paper delegation log as a member of ward staff and assigned code O.
- There shouldn't be any patient identifiable information on the log. The participant ID must be present ie.C001/023/HUW (centre number/trial number/initials)

Drug Chart:

- Sites should upload the drug chart which should document that the participant received 28 doses in total across 14 (or the number of days the treatment was given) days. The timing of the initial dose should be within 6 hours of randomisation.
- The drug chart should not specify which group the participant was randomised to and should instead state 'RECAST-3 trial active/sham'.
- The drug chart must be anonymised and labelled with the participant ID.

Scan Reports:

- For sites taking part in the main trial, the scan reports for the baseline CT scan should be uploaded to the secure vault.
- The baseline scan should have been attended prior to randomisation (as some of the eligibility criteria is based on the results from neuroimaging at baseline).
- The scan reports must be anonymised and labelled with the participant ID.
- The corresponding imaging should be uploaded to the RECAST-3 database. For instructions regarding uploading scan data – please see WPD 004 Uploading Images to the RECAST-3 Database.

Contact details for 90-day follow-up:
The following information should be provided by sites:

1. Forename and Surname
2. Date of Birth
3. Permanent address
4. Follow-up telephone number
5. An alternative telephone number/address/email-address of a relative or carer
6. NHS/Hospital number
7. GP practice address and telephone number
8. Name of hospital ward(s)

File notes:

- Participant-specific file notes should be uploaded to the secure vault.
- Please use the RECAST-3 file note template which can be downloaded from the trial's documents page: https://stroke.nottingham.ac.uk/recast-3/docs/ (shortcut: http://recast-3.ac.uk/docs/)
- File notes must be anonymised, with the participant ID documented.
- Please provide a detailed description of what happened, what actions were taken and the impact on participant safety.
- Please ensure that the file note is signed and dated prior to upload.