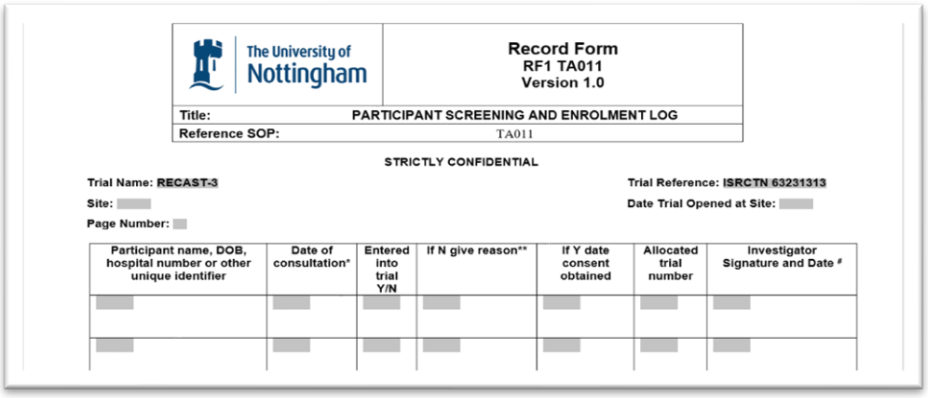
RECAST-3 Working Practice Document
Title: Screening and Enrolment Log, No. 001

Eligible patients

Please review any presenting stroke patients within 6 hours of onset for eligibility for the RECAST-3 trial. Patients who are eligible for the trial, should be recorded on RF1 Participant Screening and Enrolment Log (see below). This should include patients who are eligible for the trial, but are not recruited for another reason (i.e., lack of researcher capacity, out-of-hours, researcher not on delegation log).



The University of Nottingham

Record Form
RF1 TA011
Version 1.0

Title: PARTICIPANT SCREENING AND ENROLMENT LOG
Reference SOP: TA011

STRICTLY CONFIDENTIAL

Trial Name: RECAST-3
Trial Reference: ISRCTN 63231313
Site:
Date Trial Opened at Site:
Page Number:

Participant name, DOB, hospital number or other unique identifier	Date of consultation*	Entered into trial Y/N	If N give reason**	If Y date consent obtained	Allocated trial number	Investigator Signature and Date #

A copy of the log can be downloaded from the RECAST-3 documents page (https://stroke.nottingham.ac.uk/recast-3/docs/public.php) Alternatively, a master hard copy of the document is available in your investigator site file (ISF). Copies of the document can be downloaded or copied as required.

The screening logs will be requested by the trial coordinating centre on a monthly basis. The logs should be **anonymised** so that no patient-identifying information is visible and sent to recast-3@nottingham.ac.uk. Confirmation will be provided on receipt of the logs.

The information provided on the logs should correspond with the information that you upload to LPMS (local portfolio management system).

Completing the Screening and Enrolment Log

Ensure that the site details have been entered on the top of the log.

- **Entering patient details** – Please enter the unique identifier that your local site usually uses when completing screening/enrolment logs, i.e. hospital number, or name, etc**.**

  The original logs should be retained in the investigator site file (not anonymised) and copies sent to the coordinating centre **must be anonymised**.

- **Date of Consultation-** Date reviewed by team

- **Entered into the trial**- Yes or No
- **In No give reason-** For example lack of researcher capacity, out-of-hours, researcher not on delegation log).
- **If yes, date consent obtained-** Date of enrolment
- **Allocated trial number –** Which will be provided on recruitment to the trial
- **Investigator Signature and date-** To be completed for all entries

Ineligible patients

- For patients who are ineligible for the trial (i.e, they do not meet the inclusion criteria, **or** they fulfil one or more of the exclusion criteria), the cumulative totals must be recorded and sent across to the coordinating centre monthly.
- For example, 10 patients were ineligible because they had an NIHSS score of less than 3 or 12 patients were ineligible because they had a pre-morbid mRS of 4 or above.
- If there were multiple reasons for exclusion, the **main reason** should be provided. For example, if a patient's mRS score does not meet the inclusion criteria, and they presented out-of-hours, the mRS score would be recorded as the reason for exclusion. This is because if the presented within office hours, they would still be ineligible due to their mRS score.
- This information is essential as it is a sponsor requirement. It also helps the statistician to identify patient footfall, local patient population, barriers to recruitment, and the effectiveness of the protocol in capturing the required data.

If you have any questions please contact the RECAST-3 trial coordinating centre:

recast-3@nottingham.ac.uk or telephone **0115 823 1770.**