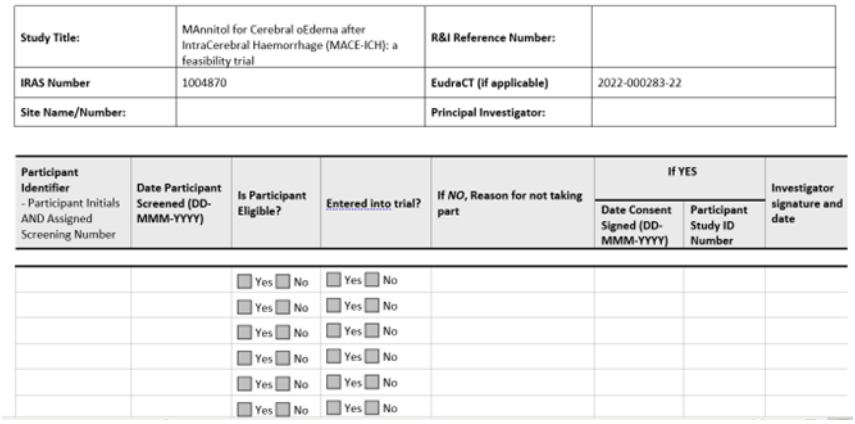
MACE-ICH – Working Practice Document

Title: Screening and Enrolment Logs, No. 005

Eligible patients

Please review any presenting patients with ICH stroke within 72 hours of onset for eligibility for the MACE-ICH trial. Patients who are eligible for the trial, should be recorded on TAFR01501 participant Screening 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).



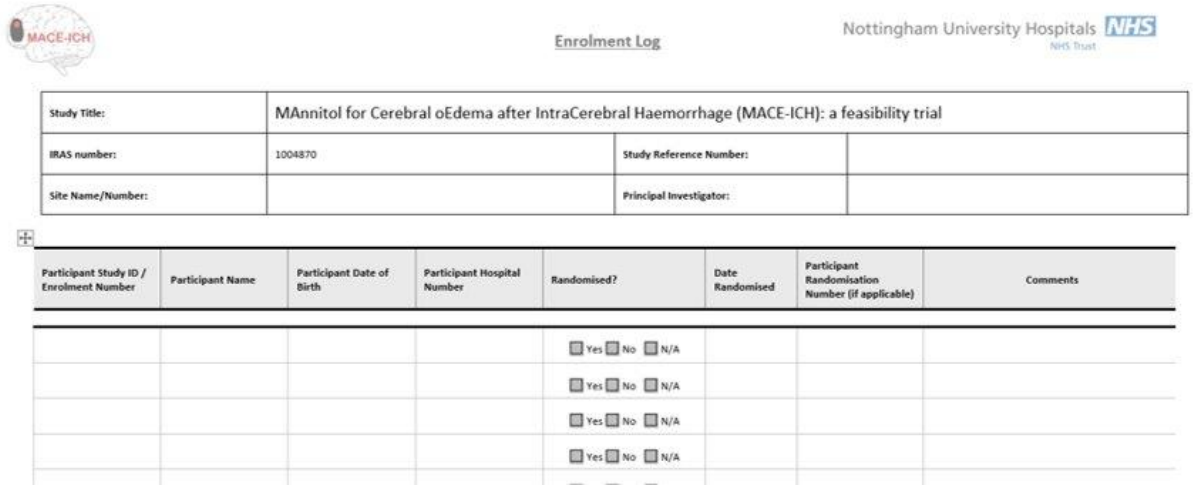
Study Title:	MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial	R&I Reference Number:	
IRAS Number	1004870	EudraCT (if applicable)	2022-000283-22
Site Name/Number:		Principal Investigator:	

Participant Identifier - Participant Initials AND Assigned Screening Number	Date Participant Screened (DD-MMM-YYYY)	Is Participant Eligible?	Entered into trial?	If *NO*, Reason for not taking part	If YES		Investigator signature and date
					Date Consent Signed (DD-MMM-YYYY)	Participant Study ID Number	
		☐ Yes ☐ No	☐ Yes ☐ No				
		☐ Yes ☐ No	☐ Yes ☐ No				
		☐ Yes ☐ No	☐ Yes ☐ No				
		☐ Yes ☐ No	☐ Yes ☐ No				
		☐ Yes ☐ No	☐ Yes ☐ No				
		☐ Yes ☐ No	☐ Yes ☐ No				

A copy of the log can be downloaded from the MACE-ICH documents page (https://stroke.nottingham.ac.uk/mace-ich/docs/).
The screening logs will be requested by the trial coordinating centre on a monthly basis. The logs should be **pseudonymised** so that no patient-identifying information is visible and sent to mace-ich@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 Enrolment Log

All participants enrolled in the trial need to be recorded on TAFR01502 Enrolment Log.



MACE-ICH Enrolment Log Nottingham University Hospitals NHS NHS Trust

Study Title:	MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial		
IRAS number:	1004870	Study Reference Number:	
Site Name/Number:		Principal Investigator:	

Participant Study ID / Enrolment Number	Participant Name	Participant Date of Birth	Participant Hospital Number	Randomised?	Date Randomised	Participant Randomisation Number (if applicable)	Comments
				☐ Yes ☐ No ☐ N/A			
				☐ Yes ☐ No ☐ N/A			
				☐ Yes ☐ No ☐ N/A			
				☐ Yes ☐ No ☐ N/A			

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Enrolment logs do not need to be sent to the coordinating centre unless requested (in which case the logs must be **pseudonymised** before sending). Enrolment logs will be reviewed during site monitoring visits.

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 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 eligibility criteria, and the patient presented out-of-hours, the mRS score would be recorded as the reason for exclusion. This is because if they had presented within office hours, they would still be ineligible due to their mRS score.
- This information is essential to address the feasibility outcomes and it 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 MACE-ICH trial coordinating centre:
mace-ich@nottingham.ac.uk or telephone 0115 823 1770.