SIGNET

Randomisation number: R

NHS Blood and Transplant

SOURCE DATA FORM V2.0

8th January 2023

Site: ..... Site Code: Name of Specialist Nurse completing form: .....

Date of Organ Retrieval: 2 0 (D D M M Y Y Y Y)

6 Digit ODT Donor ID number:

ELIGIBILITY CHECKLIST

INCLUSION CRITERIA	YES	NO
Is the patient within a recruiting Intensive Care Unit?	☐	
Has the patient been confirmed dead using neurological criteria? *(both sets of neurological testing completed)*	☐	
Is consent/authorisation for organ donation in place?	☐	
Is study specific consent/authorisation, from the donor family, in place?	☐	

IF ANY "NO" BOX IS TICKED THEN THE PATIENT IS NOT ELIGIBLE FOR THIS TRIAL

EXCLUSION CRITERIA	YES	NO
Is the patient aged < 18		☐
Planned donation after cessation of circulation (DCD)		☐
Known donor allergic hypersensitivity to Simvastatin		☐

IF ANY "YES" BOX IS TICKED THEN THE PATIENT IS NOT ELIGIBLE FOR THIS TRIAL

Name of person confirming eligibility: .....

Date and time of eligibility confirmation:

2 0 (D D M M Y Y Y Y) 24 hour clock (H H : M M)

CONSENT/AUTHORISATION

Date of consent/authorisation for organ donation: 2 0 (D D M M Y Y Y Y)

Date of study specific consent/authorisation: 2 0 (D D M M Y Y Y Y)

Name of person taking study specific consent: .....

Has the study specific sticker been stuck to the organ donation consent/ authorisation form? YES ☐ NO ☐

Has consent/authorisation been taken via phone or video? YES ☐ NO ☐

RANDOMISATION

Name of person performing randomisation: .....

Was the donor previously receiving statin therapy at ICU admission? (If unknown, please select 'No') YES ☐ NO ☐

Date and time of randomisation:

2 0 (D D M M Y Y Y Y) 24 hour clock (H H : M M)

Randomisation number: R

Randomisation allocation:

☐ Protocolised Standard Care ONLY

☐ Simvastatin 80 mg administered by NG tube in addition to protocolised standard care

PTO

THE DONOR'S ALLOCATION SHOULD REMAIN BLINDED TO THE RETRIEVAL AND RECIPIENT TEAM, PLEASE DOCUMENT ON DONORPATH THAT THEY WERE RANDOMISED TO SIGNET, BUT NOT THEIR ALLOCATION

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INTERVENTION—Complete for Simvastatin arm only:

Has an ICU doctor reconfirmed that the patient meets all of the inclusion criteria and none of the exclusion criteria prior to prescribing 80mg Simvastatin? YES ☐ NO ☐

Name of ICU doctor reconfirming eligibility: .....

Has 80mg Simvastatin been prescribed? YES ☐ NO ☐

If Yes, Date and time of Simvastatin prescription :

D	D	M	M	Y	Y	Y	Y	24 hour clock H	H	: M	M
				2	0						

Name of prescriber: .....

Has 80mg Simvastatin been administered? YES ☐ NO ☐

If Yes, Date and time of Simvastatin administration:

D	D	M	M	Y	Y	Y	Y	24 hour clock H	H	: M	M
				2	0						

If No Simvastatin was prescribed/administered please specify why:

- ☐ Organ donation did not proceed → Complete End of Study section
- ☐ Study specific consent revoked → Complete Withdrawal section
- ☐ Other, please specify .....

WITHDRAWAL OF CONSENT

Has the patient been withdrawn from the study? YES ☐ NO ☐

If Yes, Date of withdrawal:

D	D	M	M	Y	Y	Y	Y
				2	0		

Reason for withdrawal:
- ☐ Study specific consent revoked
- ☐ Other, please specify .....

Does the patient representative agree for continued data collection? YES ☐ NO ☐

END OF STUDY—COMPLETE FOR ALL PATIENTS

Did the organ donation process proceed? YES ☐ NO ☐

If No, Reason:
- ☐ Organs/donation process unsuitable
- ☐ Consent revoked
- ☐ Other, please specify .....

Has the donor had any reportable Serious Adverse Events (see study manual for guidance)?

- ☐ Yes → Complete the SAE Form
- ☐ No

UNBLINDING

THE RETRIEVAL AND RECIPIENT TEAM SHOULD REMAIN BLINDED TO THE DONORS ALLOCATION UNLESS UNBLINDING WILL STOP HARM OR ALTER TREATMENT

Has there been a request to unblind the donor allocation? YES ☐ NO ☐

If Yes, Date of request:

D	D	M	M	Y	Y	Y	Y
				2	0		

Name of requestor: .....

Requestors team: .....

Reason for request to unblind:
- ☐ Recipient has known hypersensitivity to Simvastatin
- ☐ Recipient has had an anaphylactoid reaction
- ☐ Other, please specify .....

Was the donor allocation revealed? YES ☐ NO ☐