SIGNET

NHS Blood and Transplant

SAE Form

Randomisation Number

R | | | | |

Site: .....

Site code | | |

SERIOUS ADVERSE EVENT (SAE) FORM

RECORD EVENTS FROM THE POINT OF RANDOMISATION TO ORGAN RETRIEVAL

Type of report: *(Please tick one box only)*

Initial ☐ Follow up 1 ☐ Follow up 2 ☐

1. SAE Name: .....

2. Date and time of SAE onset: | | | | | 2 | 0 | | | (D D M M Y Y Y Y) 24 hour clock | | | | (H H : M M)

3. Is the event expected?

☐ Expected ☐ Not Expected

4. Principal Investigator's (PI) assessment of causal relationship to study procedures (please select **one**):

☐ Unrelated ☐ Probably

☐ Unlikely ☐ Definitely

☐ Possible

5. Did this event result in the loss of the capacity to donate one or more organs as a result of study procedures, in the opinion of the PI? YES ☐ NO ☐

5 a) If Yes, please specify as applicable:

	Donated	Loss of Capacity to donate	Not Donated (reasons unrelated to SIGNET)
Liver	☐	☐	☐
Heart	☐	☐	☐
Kidneys	☐	☐	☐
Lungs	☐	☐	☐
Pancreas	☐	☐	☐

6. Is this an anaphylactoid reaction to Simvastatin? YES ☐ NO ☐

7. Date and time of SAE resolution: | | | | | 2 | 0 | | | (D D M M Y Y Y Y) 24 hour clock | | | | (H H : M M)

Email SAEs report within 24 hours to Serious_Adverse_Events@nhsbt.nhs.uk

Principal Investigator (PI) Name (print) | PI Signature | Date of Form Completion: | | | | 2 | 0 | | | (D D M)

SIGNET

NHS Blood and Transplant

SAE Narrative Form

Randomisation Number

R				

Site: .....

Site code:

SERIOUS ADVERSE EVENT (SAE) NARRATIVE FORM

Type of report: *(Please tick one box only)*

Initial ☐ Follow up 1 ☐ Follow up 2 ☐

1. Serious Adverse Event Name : .....

2. Date and time of SAE onset:

				2	0		
D	D	M	M	Y	Y	Y	Y

24 hour clock

H	H	M	M

3. Describe SAE: (*including manifestation and progression of event. Continue on a separate sheet if necessary)*

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4. Treatment / Tests given:

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5. Outcome: .....

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Completed SAE Narrative Form must be sent to the NHSBT CTU within 5 working days of identification of the event.

Principal Investigator (PI) Name (print)

PI Signature:

Date of Form Completion:

				2	0		
D	D	M	M	Y	Y	Y	Y