

SOPHIST Laboratory Manual V7 18-06-2026

Trial Title	SOPHIST
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Associated Documents	

Abbreviations / terms used:

BNP	B-type natriuretic peptide
FBC	Full Blood Count
HbA1c	Glycated Haemoglobin
LFT	Liver Function Tests
NT-proBNP	N-terminal pro B-type natriuretic peptide
U&E	Urea and electrolytes

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1. Procedures

- Ensure all equipment used is within expiry date.
- Obtain blood samples as per local venepuncture Standard Operating Procedure.
- Dispose of all clinical equipment as per local policy.
- Deal with any needlestick injury or body fluid spillage as per local policies.

2. Equipment

2.1. Bloods

- Blood tubes as per visit (research blood tubes are provided).
- Venepuncture equipment (e.g. needles, tourniquet, cotton wool etc.).
- Collection set compatible with vacutainer tubes must be used.
- Centrifuge
- Pipettes
- Microtubes (provided)
- Sample labels (provided).
- Sample Logs (provided).
- Sample storage boxes (provided).
- Freezer (-65 to -80°C).






2.2. Urine






- Urine containers (research urine samples containers provided).
- Microtubes (provided)
- Urine pregnancy test kit, if required.
- Freezer (-65 to -80°C).

3. Sample ID

- Sample ID is made up of:
site number – participant number – visit number – sample number
e.g. sample ID 01-001-02-01 would be site 01 – participant 001- visit 02- sample number 01

4. Samples required

Visit	Local NHS Labs	Research bloods	Research bloods	Research Urine
		To be collected for participants that did NOT consent for additional samples for future research‡	To be collected for participants that have provided consent for additional samples for future research‡	
1 Screening	<p>Bloods:</p> <ul style="list-style-type: none"> FBC U&Es LFT Glucose HbA1c NT-proBNP/BNP (If not available within 12 months of screening) <p>Urine</p> <ul style="list-style-type: none"> Pregnancy test* 			
3 Baseline	<p>Bloods:</p> <ul style="list-style-type: none"> FBC U&Es LFT Glucose <p>Urine:</p> <ul style="list-style-type: none"> Albumin Creatinine Sodium Pregnancy test* 	 <p>Purple EDTA 4mL tube</p>	 <p>2 x 8.5mL Gold/SST tubes 1 x 3.5mL Gold/SST tube (Total SST= 20.5mL)</p>  <p>2 x 10mL Purple EDTA tubes (Total EDTA = 20mL)</p> <p>§ Genetic analysis:</p>  <p>1 x 4mL Purple EDTA tube</p>	<p>Urine universal container (Total = 20mL)</p> 
5	<p>Bloods:</p> <ul style="list-style-type: none"> FBC U&Es LFT Glucose <p>Urine:</p> <ul style="list-style-type: none"> Albumin Creatinine Sodium 			

<p>7</p>	<p>Bloods:</p> <ul style="list-style-type: none"> • FBC • U&Es • LFT • Glucose • HbA1c <p>Urine:</p> <ul style="list-style-type: none"> • Albumin • Creatinine • Sodium 	 <p>Purple EDTA 4mL tube</p>	 <p>2 x 8.5mL Gold/SST tubes 1 x 3.5mL Gold/SST tube (Total SST= 20.5mL)</p>  <p>2 x 10mL Purple EDTA tubes (Total EDTA = 20mL)</p> <p>§ Genetic analysis:</p>  <p>1 x 4mL Purple EDTA tube</p>	<p>Urine universal container (Total = 20mL)</p> 
<p>Unscheduled NHS bloods as clinically indicated</p>				

*To be carried out on women of childbearing potential

‡ The research blood and urine samples will be stored frozen and later shipped to Dundee for analysis for trial outcomes and future research.

§ Only to be collected if participant also consented for additional blood sample for future genetic analysis.

5. Research sample collection

Blood sample collection








Safety blood samples should always be drawn before research bloods but all samples should be taken at the same time with the SST tubes being collected before the EDTA tubes.

Urine sample collection




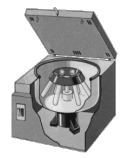














Ask patient to collect the sample in the middle of passing urine "mid-stream" in the white top universal container. Alternatively, a different clean container can be used in the toilet and the urine should be transferred to the 20mL universal container.





6. Research sample processing

For participants that did **NOT** consent for additional samples for future research

TUBES	INVERT TUBE	ALLOW TO STAND	CENTRIFUGE	TRANSFER	LABEL	FREEZE
<p>If the participant has not consented to additional blood samples for research</p>  <p>EDTA 4mL</p>	 <p>8-10 times</p>	 <p>Stand upright 30 mins</p>	 <p>1100 to 1300 xg for 15 mins</p>	 <p>Transfer 1 mL plasma per microtube</p>	 <p>As many microtubes as required for available plasma</p>	 <p>Store upright in <u>Plasma</u> box. Transfer to Freezer (-65 to -80°C) within 2 hours from venipuncture/ collection.</p>

For participants that have provided consent for additional samples for future research

TUBES	INVERT TUBE	ALLOW TO STAND	CENTRIFUGE	TRANSFER	LABEL	FREEZE
 <p>SST 2 x 8.5mL 1 x 3.5mL tubes Total = 20.5mL</p>	 <p>5 times</p>	 <p>Stand upright 30 mins</p>	 <p>1100 to 1300 xg for 15 mins</p>	 <p>Transfer 1 ml serum per microtube</p>	 <p>As many microtubes as required for available serum</p>	 <p>Store upright in <u>Serum</u> box. Transfer to freezer (-65 to -80°C) within 2 hours from venipuncture/ collection.</p>
 <p>EDTA 2 x 10mL tubes Total = 20mL</p>	 <p>8-10 times</p>	 <p>Stand upright 30 mins</p>	 <p>1100 to 1300 xg for 15 mins</p>	 <p>Transfer 1 mL plasma per microtube</p>	 <p>As many microtubes as required for available plasma</p>	 <p>Store upright in <u>Plasma</u> box. Transfer to freezer (-65 to -80°C) within 2 hours from venipuncture/ collection.</p>
 <p>EDTA 1 x 4mL tube Total = 4mL</p>	 <p>8-10 times</p>	N/A				 <p>Store upright in <u>Whole blood</u> box. Transfer to freezer (-65 to -80°C)</p>

				within 2 hours from venipuncture/ collection.
 <p>Urine 20mL Universal container.</p>	N/A	 <p>Transfer 2mL of urine per microtube</p>	 <p>5 microtubes</p>	 <p>Store upright in <u>Urine</u> box. Transfer to freezer (-65 to -80°C) within 2 hours from collection.</p>

7. Labelling research samples

- All trial samples should be labelled with the labels provided.

SOPHIST Whole Blood (EDTA)

Sample ID: ____-____-____-____

Date: ____-____-____

SOPHIST Serum 1 ml

Sample ID: ____-____-____-____

Date: ____-____-____

SOPHIST Plasma 1 ml

Sample ID: ____-____-____-____

Date: ____-____-____

SOPHIST Urine 2 ml

Sample ID: ____-____-____-____

Date: ____-____-____

- The appropriate sample label should be used for whole blood, serum or plasma blood sample or urine sample.
- All microtubes originating from the same vacutainer should be listed together on one row of the sample log.
- Ensure labels are attached **prior** to freezing. Ensure that the label is **firmly rubbed** on to the tube/microtube to prevent it coming off.
- Complete each label with full sample ID and date as below. Ensure label is completed **prior** to freezing and appropriate marker pen is used.
- Date to be filled in day/month/year i.e. 30-03-2024
- All samples should be logged on the appropriate SOPHIST Sample Log.

8. Storing research samples

- The research samples should be stored in the storage boxes provided as soon as possible but within 2 hours from venipuncture/collection.
- Research blood samples should be stored in separate boxes according to sample type.
- The storage boxes should be labelled with trial title, site number, sample type and box number.
- Storage location should be recorded on the SOPHIST Sample Log.

9. Shipping research samples from sites to University of Dundee

At the end of the trial the Trial Manager, Tayside Clinical Trials Unit, will organise a courier to transport frozen samples on dry ice to University of Dundee research labs.

- Collection will be arranged for Monday-Wednesday to arrive next day.
- All samples must be accompanied by:
 - Completed Sample Log (paper)
 - Completed Sample Shipment Manifest Document (paper)
 - The Sample Log (scanned copy) & Sample Shipment Manifest document (scanned copy) should be emailed to sophist-trial@dundee.ac.uk

Appendix 1 Obtaining Blood Samples When Monovette Tubes Are Used

This applies in sites where the NHS Labs use monovette blood collection tubes.

- The Research Samples MUST be collected in the tubes provided and therefore venepuncture should be carried out using a compatible blood collection system.

Visits 3 and 7

- A vacutainer blood collection system “Butterfly” can be used.
- A vacutainer needle and holder can be used



When NHS blood samples are also required and if your lab will only accept monovette tubes then these can be used with the vacutainer system.

- Pre-vacuum the monovette tube by pulling the plunger out.
- Attach to the vacutainer needle as below, fill tube and send to NHS Lab as local practice.

