SOPHIST Laboratory Manual V4 16-12-24.docx

Trial Title	SOPHIST
CI	Dr Ify Mordi
Sponsor	University of Dundee and NHS Tayside
IRAS number	1007807
Author/Contact	Sophist-trial@dundee.ac.uk
Protocol Version	V4
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

Contents

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**	Bloods: • FBC • U&Es • LFT • Glucose • HbA1c • NT-proBNP/BNP (If not available within 12 months of screening) Urine • Pregnancy test*			
3 **Baseline**	Bloods: • FBC • U&Es • LFT • Glucose Urine: • Albumin • Creatinine • Sodium • Pregnancy test*	 Purple EDTA 4mL tube	 2 x 8.5mL Gold/SST tubes 1 x 3.5mL Gold/SST tube (Total SST= 20.5mL)  2 x 10mL Purple EDTA tubes (Total EDTA = 20mL) § Genetic analysis:  1 x 4mL Purple EDTA tube	Urine universal container (Total = 20mL) 
5	Bloods: • FBC • U&Es • LFT • Glucose Urine: • Albumin • Creatinine • Sodium			

7	Bloods: • FBC • U&Es • LFT • Glucose • HbA1c Urine: • Albumin • Creatinine • Sodium	 Purple EDTA 4mL tube	 2 x 8.5mL Gold/SST tubes 1 x 3.5mL Gold/SST tube (Total SST= 20.5mL)  2 x 10mL Purple EDTA tubes (Total EDTA = 20mL) § Genetic analysis:  1 x 4mL Purple EDTA tube	Urine universal container (Total = 20mL) 
Unscheduled **NHS bloods as clinically indicated**				

*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

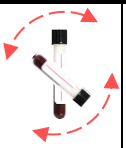
Ask patient to collect the sample in the middle of passing urine "mid-stream" in the sterile white top universal container. Alternatively, a different sterile container can be used in the toilet and the urine should be transferred to the sterile 20mL universal container.

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
If the participant has not consented to additional blood samples for research  EDTA 4mL	 8-10 times	 Stand upright 30 mins	 1100 to 1300 xg for 15 mins	 Transfer **1 mL plasma** per microtube	 **As many microtubes as required for available plasma**	 Store upright in Plasma box. Transfer to Freezer (-65 to -80°C) **within 1 hour of collection.**

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

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

 Urine 20mL Universal container.	N/A	 Transfer 2mL of urine per microtube	 5 microtubes	 Store upright in Urine box. Transfer to freezer (-65 to -80°C) **within 1 hour of collection.**

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 within 1 hour of 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

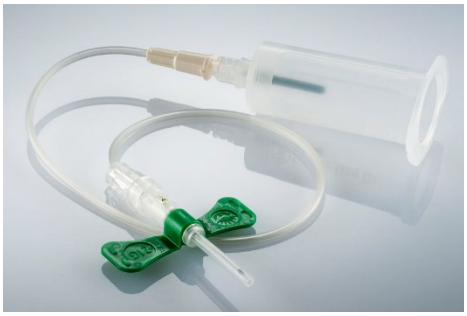
Appendix 1 Obtaining Blood Samples When Monovette Tubes Are Used

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.