Laboratory samples

Blood and urine samples

- Blood and urine samples should be obtained as per Laboratory Manual.
- NHS samples:
  - Results should be reviewed by a doctor on the Delegation Log in a timely manner.
  - A copy of the results signed and dated by a delegated doctor must be filed in the participant's medical notes.
- Research samples:
  - Processed as per Laboratory Manual.
  - Stored at site and transferred to University of Dundee at end of trial.

Pregnancy Test

Visit 1 and 3

- Urine pregnancy test should be carried out on women of childbearing potential.
- Results should be signed and dated by a delegated doctor and filed in the participant's medical notes.

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) 

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‡	
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) 

*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.

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 container can be used in the toilet and the urine transferred to the 20mL universal container.

Research sample processing

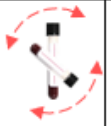
For participants that did **not** consent to additional samples for future research.

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.**

Research sample processing

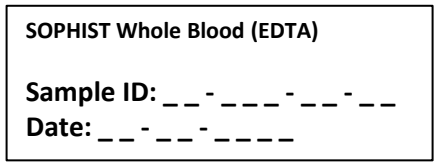
For participants that have provided consent for additional samples for future research.

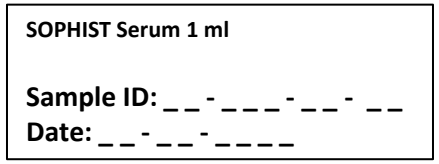
TUBES	INVERT TUBE	ALLOW TO STAND	CENTRIFUGE	TRANSFER	LABEL	FREEZE
 Urine 20mL Universal container.	N/A	 Transfer 2mL of urine per microtube			 5 microtubes	 Store upright in Urine box. Transfer to freezer (-65 to -80°C) **within 1 hour of collection.**

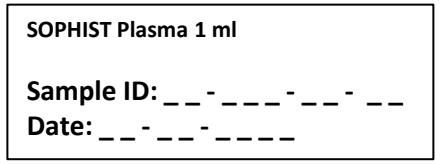
TUBES	INVERT TUBE	ALLOW TO STAND	CENTRIFUGE	TRANSFER	LABEL	FREEZE
 SST 2 x 8.5mL 1 x 3.5mL tubes Total = 20.5mL	 5 times	 Stand upright 30 mins	 1100 to 1300 xg for 15 mins	 Transfer **1 ml serum** per microtube	 **As many microtubes as required for available serum**	 Store upright in Serum box. Transfer 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.**

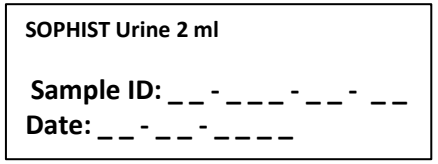
Labelling research samples

- All trial samples should be labelled with labels provided.
- 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 of collection. Ensure label is completed **prior** to freezing and appropriate marker pen is used.
- 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
- Date to be filled in day/month/year i.e. 30-03-2024
- All samples should be logged on the appropriate SOPHIST Sample Log.









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.

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 laboratories.

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