Participant name:	
Hospital ID:	
CHI/Date of Birth:	

SOPHIST - SOtagliflozin in Patients with Heart failure Symptoms and Type 1 Diabetes

Sponsor	University of Dundee-NHS Tayside
Chief Investigator	Dr Ify Mordi
IRAS number	1007807

Principal Investigator	
Contact number	
Contact email	

Visit 1 – Screening

Date of visit: | | Participant trial ID: | | | | | |

Please tick to indicate the following have been completed:

Participant has had the Participant Information Sheet for at least 24 hours	
Confirmed participant's identity	

Method used to confirm participant's identity ……

Record insulin daily basal and bolus doses (average of last 7 days)	
Urine pregnancy test, if women of childbearing potential	
Full blood count, urea & electrolytes, liver function tests, glucose and HbA1c	
NT-proBNP or BNP (local NHS labs) if not available within 12 months of screening	

Physical characteristics and vital signs

Height	cm	Weight	kg
Waist Circumference	cm	Hip Circumference	cm
Systolic/Diastolic BP	mmHg	Pulse	bpm

Physical examination

Please tick:

Normal	
Abnormal, not clinically significant	
Abnormal, clinically significant	

If abnormal document abnormality and any actions taken, if any:

Name of doctor making assessment:

SOPHIST

Participant name:	
Hospital ID:	
CHI/Date of Birth:	

NYHA Class	

ECG

Please tick:

Normal	
Abnormal, not clinically significant	
Abnormal, clinically significant	

If abnormal document abnormality and any actions taken, if any:

Name of doctor making assessment:

Echocardiogram, if one is not available within 24 months of screening.

Please tick:

Normal	
Abnormal, not clinically significant	
Abnormal, clinically significant	

If abnormal document abnormality and any actions taken, if any:

Name of doctor making assessment:

Contraception

Is the participant a woman of childbearing potential? yes ☐ no ☐

If female but not of childbearing potential, how has this been confirmed?

Post-menopausal ☐ Date of last period ☐

Permanent sterilisation ☐

If female and of childbearing potential:

Has the participant agreed to either abstain from sexual activity or use a form of a medically approved birth control method? ☐

If male with a female partner of childbearing potential:

Has the participant agreed to either abstain from sexual activity or use a form of a medically approved birth control method? ☐

The following must have source data documented in the medical notes. If not documented elsewhere these should be written in the notes.

Participant name:	
Hospital ID:	
CHI/Date of Birth:	

- Concomitant medications, file a copy of repeat prescription if available, **ensure this is accurate for what the participant is taking at the time of visit**, update if necessary
- Medical history
- Echocardiogram results if a cardiac imaging test is available within 24 months
- NT-proBNP or BNP results if available within 12 months of screening
- Any notable findings and actions taken

The following should be filed in the participant's medical notes:

- Front coloured card/sheet/sticker/alert to state they are a research participant
- Copy of the signed Informed Consent Form
- Copy of the Participant Information Sheet, version which the participant consented to
- Copy of GP letter informing GP of participation
- Copy of all test printouts signed and dated by doctor in delegation log including laboratory results, imaging reports and ECG printouts
- Pregnancy test results, if applicable, signed & dated by doctor on delegation log
- If the participant was withdrawn from the trial at this visit, document reason

Any further information of note:

The visit has been carried out as per protocol.

Signature:	
Name:	
Job title:	
Date:	