Participant Identification Number				

NHS LOGO

INFORMED CONSENT FORM

Trial title: SOtagliflozin in Patients with Heart Failure Symptoms and Type 1 Diabetes - SOPHIST

A Trial of the Effect of Sotagliflozin for Treating Patients with Type 1 Diabetes and Heart Failure Symptoms

Chief Investigator: Dr Ify Mordi

Sponsors: University of Dundee and NHS Tayside

Please initial box

1. I confirm that I have read the Participant Information Sheet version..... dated…….. for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that taking part in this trial is voluntary, and that I am free to withdraw at any time without supplying a reason. This will not affect my medical care or legal rights. ☐
3. I agree that confidential information about me may be shared outside my clinical care team (or the research team) as needed to carry out this trial. ☐
4. I understand that relevant sections of my medical notes and data collected during the trial, may be looked at by individuals from University of Dundee, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I understand that the information collected about me will be used to support ethically approved future research, possibly including research with commercial organisations. Any information which identifies me will be removed before it is shared. ☐

1 copy for participant, 1 copy to be kept in medical records and 1 original for Investigator Site File.

6. I agree to the research team following up with me or my partner, should I/she become pregnant during the trial, until the birth of my/her baby. ☐

7. I agree that confidential information about me collected for this trial, including data from my Continuous Glucose Monitor (CGM) will be shared with the Juvenile Diabetes Research Foundation (JDRF) and Lexicon Pharmaceuticals as per the Clinical Research Agreement the Sponsor has with JDRF and Lexicon Pharmaceuticals. Any information which identifies me will be removed before it is shared. ☐

8. I agree to take part in video calls with the Research team.
Optional, please initial relevant option. YES ☐ NO ☐

9. I agree that additional blood and urine samples will be taken, stored and used to support ethically approved future research, possibly including research with commercial organisations. Any information which identifies me will be removed before it is shared. I agree to gift this blood and urine to the Sponsors.
Optional, please initial relevant option. YES ☐ NO ☐

10. I agree to having an additional blood sample taken which will be stored for future genetic analysis. Any information which identifies me will be removed before it is stored. I agree to gift this blood to the Sponsors.
Optional, please initial relevant option. YES ☐ NO ☐

11. I agree to my General Practitioner being involved in the trial, including any necessary exchange of information about me between my GP and the research team. ☐

12. I agree to be contacted by the Researcher and/or research team in the future should I be suitable for further projects and/or trials.
Optional, please initial relevant option. YES ☐ NO ☐

13. I voluntarily agree to take part in the above trial. ☐

Name of Participant (capitals)	Date	Signature
Name of Person taking consent (capitals)	Date	Signature

1 copy for participant, 1 copy to be kept in medical records and 1 original for Investigator Site File.