



CONSENT FORM

Full Study title: A Randomised Controlled International Multicentre Study evaluating changes in Metabolic Syndrome in Smokers with type 2 Diabetes Mellitus after switching from Tobacco Cigarettes to Combustion-Free Nicotine Delivery Systems: DIASMOKE Study.

Study Acronym: DIASMOKE

Short Study Title: Metabolic Syndrome in Diabetic Smokers using Cigarettes & Combustion-Free Nicotine Delivery Systems

Name of PI: Dr Chong Lim

Patient Identification Number: _____

Please initial
each box

1. I confirm that I have read and understood the **Patient Information Sheet dated 23rd May 2020, UK Version 2.1**. I have had the opportunity to consider the information given concerning this study and to ask questions and have had these answered satisfactorily.
2. I confirm that I have been offered to join Trust smoking cessation programme which I have declined.
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason. My legal rights and medical care will not be affected by my decision.
4. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I agree that my data collected for the study will be recorded anonymously and forwarded to the company ECLAT srl for evaluation.
5. I agree to my personal data being stored for a period of 6-12 months after the end of the clinical investigation. After this my data will be deleted. However, my study related anonymised data can be used for analysis and publications for 5 years after the end of the study.
6. I agree to take part in this study and also agree that you inform my GP about my participation in this study.

_____ Name of participant	_____ Date	_____ Signature
_____ Name of person taking consent (If different from Researcher)	_____ Date	_____ Signature
_____ Researcher	_____ Date	_____ Signature

1 copy for patient; Original for researcher; 1 copy to be kept with hospital notes

DIASMOKE Study- IRAS Project ID: 280909, Consent Form Version 2.1, 23 May 2020