EudraCT Number: 2014-000988-41

ROMANCE

UNIVERSITY OF LIVERPOOL

PATIENT CONSENT FORM (please read carefully)

ROMANCE

A randomised, controlled multi-centre trial of 26 weeks of subcutaneous Liraglutide (a GLP1 receptor agonist), with or without continuous positive airway pressure (CPAP), in patients with Type 2 Diabetes Mellitus (T2DM) and Obstructive Sleep Apnoea (OSA)

Name of Researcher:_____
(Principal Investigator)

Please initial each box

1. I confirm that I have read and understand the patient information sheet date: …… (Version: .....) describing the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of my medical notes and data collected during the study may be looked at by responsible individuals involved in this research or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to allow my General Practitioner and any other relevant medical practitioner to be informed of my involvement in the study. ☐
5. I agree for a copy of this completed consent form to be sent to the Liverpool Cancer Trial Unit (where it will be kept securely) to allow confirmation that my consent for the trial has been given. ☐
6. I understand that information held by the NHS and records maintained by the NHS Information Centre may be used to keep in touch with me and follow-up my health status**.** ☐

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7. I understand that, under the Data Protection Act, I can at any time ask for access to the information I provide and I can also request the destruction of that information if I wish. ☐
8. I understand that my data may be transferred outside the European Economic Area to countries which may have a lower level of data protection. ☐
9. I understand that the information that I provide will be processed and analysed as is required by this clinical study. ☐
10. I agree to the annonymised data collected from me being used in future ethically approved research. ☐
11. I agree to take part in the above study. ☐

POINTS 12, 13 AND 14 BELOW ARE OPTIONAL

12. I agree to take part in the optional ECHO tests which will require two additional visits to be scheduled on a Saturday/Sunday. ☐
13. I agree to donate the required samples of my blood as specified in the Participant Information Sheet. No genetic analysis will be performed on these samples. I understand that these projects may be conducted both within and outside the European Union and that some countries outside Europe may not have laws which protect my privacy to the same extent as the Data Protection Act in the UK or European Law. ☐
14. I give permission for additional adipose tissue samples to be provided for later biochemical analysis. No genetic analysis will be performed on these samples. I understand that these projects may be conducted both within and outside the European Union and that some countries outside Europe may not have laws which protect my privacy to the same extent as the Data Protection Act in the UK or European Law. ☐

Name of patient	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Researcher (Principal Investigator)	Date	Signature

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