Informed Consent Form

THE RECUT PLUS STUDY

Exploratory study of clonal evolution in cancer for patients undergoing transoral **R**obotic surgery for radiation **E**xposed residual/re**C**urrent tumours of the **U**pper aerodigestive **T**ract.

Version:	1.2
Date:	31st July 2020
Sponsor:	The Royal Marsden NHS foundation Trust Fulham Road, London SW3 6JJ
Research Ethics Committee:	Berkshire B Research
CCR number:	5263
IRAS number:	280262

Instructions:

This Informed Consent Form should be used in conjunction with the Participant Information Sheet [version 1.0]. Please ensure that there are 3 copies of this form:

1 copy for participant
1 copy for research study file
1 copy for participant's medical notes

1 CERTIFICATE OF CONSENT

1.1 Statement by the participant

Please place your initials in each box:

1. I have been invited to participate in **The RECUT Plus study**, investigating the impact of radiotherapy on cancers in the Head and Neck region. ☐
2. I have read the relevant Participant Information Sheet, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
4. I understand that relevant sections of my medical notes may be looked at by representatives from The Royal Marsden NHS Foundation Trust, and appropriate regulatory authorities, 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 RECUT Plus team will access my previously collected tumour biopsy samples. ☐
6. I understand my tissue samples will be shared with **The RECUT Plus Study** team, which will undergo molecular analysis, including DNA profiling. ☐
7. I understand that molecular analysis will be conducted on my tissue samples, but it is not the intention of this research to test for common inherited genetic conditions. As such, I will not be notified of the results of the genetic testing. ☐
8. I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers. ☐
9. OPTIONAL: I agree that my samples may be retained for use in future research projects, beyond the scope of the current project ☐
10. I agree to my General Practitioner being informed of my participation in the study and may be contacted in the future to establish my health status for up to 5 years. ☐
11. I agree to take part in the above study. ☐

Signature of Participant: _____ **Date:** _____

Print Name of Participant: _____ **Date I read the Participant Information Sheet:** _____

1.2 Statement by the researcher taking consent

I have accurately discussed the information in this document with the potential participant, and to the best of my ability made sure that the participant understands what the research will involve, their rights of refusal and that it will have no impact on their care if they chose not to participate.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. Copies of this consent form have been filed in accordance with the instructions above.

Print Name of Researcher taking consent: _____

Signature of Researcher taking consent: _____

Date: _____