

qStudy EudraCT number: 2018-004662-33

Study Protocol number: C/39/2018

Centre Number: < Insert Centre Number>

Patient Study Identification Number: <Insert Patient Number>

CONSENT FORM – NOVEL Trial

Full title: Nonavalent HPV prophylactic vaccine after local conservative treatment for cervical intra-epithelial neoplasia: a randomised controlled trial (NOVEL)

Short title: NOVEL

Please initial each box:

1. I confirm that I have read and understand the participant information sheet dated version for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study sponsor, Imperial College London and its representatives, Imperial College Healthcare NHS Trust and its contractors, MSD Company Ltd., contracted companies conducting laboratory tests, regulatory authorities, or the NHS Trust/Health Board where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. If applicable, should I become pregnant during the trial, I give permission for the above individuals to have access to any of my medical notes and information collected about my pregnancy. This is optional, if you do not wish to take part in this please do not initial the box – this will not affect your participation in the study.	
5. I agree to my GP being informed of my participation in the study.	
6. I agree to donate the cytology, swabs and tissue sample(s) taken at diagnosis, local treatment and/or follow-up that may include use of my DNA. This research may involve international partners and my samples may be sent abroad. I understand that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected.	
7. I agree to donate vulva, anal and perianal samples taken at months 0, 6 and 24. I understand that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected. This is optional, if you do not wish to take part in this please do not initial the box – this will not affect your participation in the study.	
8. I agree to donate blood samples taken at months 0, 6 and 24 for research related to this study that may include use of my DNA. I understand that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected. This is optional, if you do not wish to take part in this please do not initial the box – this will not affect your participation in the study.	
9. I agree that any residual or additional swabs, smears, blood and tissue samples, as described in the participant information sheet may be used for further ethically approved research. This further research may involve international partners and my samples may be sent abroad. I understand that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected. This is optional, if you do not wish to take part in this please do not initial the box – this will not affect your participation in the study.	

10. I agree for my postcode to be accessed and used by the Clinical Trials Unit on behalf of the NHS Trust/Health Board where it is relevant to my taking part in this research, and shared with NHS Digital, in order to obtain my Index of Multiple Deprivation (IMD) for entry onto the study database. I understand that I am free to withdraw my approval for this at any time without giving a reason and without my medical treatment or legal rights being affected. This is optional, if you do not wish to take part in this please do not initial the box – this will not affect your participation in the study	
11. I give permission for my NHS number and/or date of birth to be sent to NHS Digital by the Clinical Trials Unit on behalf of the NHS Trust/Health Board where it is relevant to my taking part in this research in order to link my health records or health data about me, as described in the participant information sheet. I understand that NHS Digital will provide Imperial College or the collaborators with information about my hospital attendance, health status and death from the Office of National Statistics for up to 20 years. I give permission for this information to be obtained and securely stored by Imperial College or the collaborators to enable long-term follow up, as described in the participant information sheet. I understand that I am free to withdraw my approval for this at any time without giving a reason and without my medical treatment or legal rights being affected. This is optional, if you do not wish to take part in this please do not initial the box – this will not affect your participation in the study.	
12. I give permission to being contacted about participating in an interview study at my 6-month follow-up visit. I understand that this is voluntary, that I will be given more information about this and that I can change my mind about participating in an interview at any time.	
13. I understand that the information collected about me may be used for research purposes in the future and may be shared anonymously with other researchers.	
14. I agree to take part in the above study.	

Name of Patient (**BLOCK CAPITALS**)

Date

Signature

Name of Investigator (**BLOCK CAPITALS**) Date

Signature

When completed: Take 2 copies. Original to be kept in medical notes, 1 copy to be kept in investigator site file, and 1 copy to be given to the patient.