TRUST LOGO
Local contact details

Study Code: E N

Site ID Code:

Participant identification number:

Randomised controlled trial evaluating effectiveness of neoadjuvant endocrine treatment in post-menopausal women

CONSENT FORM

If you agree, please initial box (in the electronic version of the form - individuals will select a Yes option instead of initials against each clause)

1. I confirm that I have read and understand the information sheet dated insert date (version number) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. 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.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from University of Oxford, from regulatory authorities [and from the NHS Trust(s)], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree for access to my electronic health records (medical notes kept on a computer) inclusive of nationally held health data (by the NHS, the General Register, eDRIS, NHS England/NHS Central Register, NHS Spine/ISD Scotland, the Health and Social Care Information Centre, the national registries and other cancer related datasets and databases for data collection), for purposes directly linked to this research study. I understand this information may be used to provide information about my health status and I will not need to be contacted again for this information to be collected. This will enable researchers to understand long term outcomes (20 years or more following study entry) and my health status for the study.	

5. To enable access to my information from these national electronic data sources, I agree that my NHS number (or equivalent number in the devolved nations e.g. Community Health Index (CHI) number in Scotland) and EndoNET Trial number can be collected and held by the University of Oxford and/or the central study office at the University of Oxford for the purposes of this study. This information can be shared with the managing organisations holding the data, so that they obtain my information within their records and send this information to the study team.		
6. I agree to donate tissue samples. I consider these samples a gift to the University of Oxford and I understand I will not gain any direct personal or financial benefit from them. I understand samples will be stored at other secure locations in compliance with the Human Tissue Authority.		
7. I understand and agree that my tumour samples may be used in research aimed at understanding genetic influences on disease and that the results of these investigations are unlikely to have any implications for me personally.		
8. I agree to my General Practitioner being informed of my participation in the study.		
9. I agree to take part in this study.		
Additional:		
10. I agree for my anonymised samples to be used in future research which has ethics approval that may be here or abroad. I understand this research may involve commercial organisations.	Yes	No
11. I agree to be contacted in the future about ethically approved research for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes	No

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

When completed: 1 for participant (e.g. emailed securely to participant); 1 for researcher site file (original); 1 to be kept in medical notes