IRAS number: 95626

Optimal **P**ersonalised **T**reatment of early breast cancer us**i**ng **M**ulti-parameter **A**nalysis

Data Transparency Statement

Version 4.0 – 1 September 2021

This leaflet explains how your data is used in the OPTIMA study. It contains more detail than the Patient Information Sheet. This applies in particular if you joined OPTIMA before March 2019. If you joined OPTIMA from outside the UK, most of this information also applies to you.

UCL (University College London) is the sponsor for this study. UCL will be using information from you and your medical records to undertake the OPTIMA research and will act as the data controller for the study. UCL is legally responsible for looking after your information and using it properly. The Warwick Clinical Trials Unit at University of Warwick and other organisations described in this leaflet will store and process your information on behalf of UCL.

The OPTIMA study is paid for with taxpayer's money. This means that the information used for the research is in the public interest.

Your rights to access, change or move your information are limited. This is because we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how UCL uses your information from their general privacy notice. This includes information on how to complain if you feel your information has been misused. There is a link to this on the OPTIMA website at optimabreaststudy.com/taking-part-in-optima/privacy.

Your hospital will collect information from you and from your medical records for this research study in accordance with our instructions.

Processing your information

Your hospital will use your name, hospital and NHS numbers, and date of birth to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the Warwick Clinical Trials Unit, UCL and regulatory

organisations may visit your hospital and look at your medical and research records to check the accuracy of the research study.

Your hospital will pass information collected from you and your medical records to the Warwick Clinical Trials Unit. They will refer to you only by your trial number and initials when they do this. Staff at the Warwick Clinical Trials Unit who analyse the trial information will not know your name or contact details.

Your hospital will also pass your initials, NHS/ CHI/ HSC number, date of birth and pathology identifiers to the Warwick Clinical Trials Unit.

In the future we will contact the Health and Social Care Information Centre (HSCIC), Office of National Statistics (ONS) and other relevant public bodies about you. These organisations collect long-term health information about all NHS patients. The Warwick Clinical Trials Unit will use your NHS/ CHI/ HSC number and your date of birth to do this.

Your hospital will send your date of birth and pathology information to our Laboratory. These are used as extra identifiers to make sure the Laboratory receives the correct tumour sample as a mistake could affect your safety. The Laboratory will retain this information together with the results of the tests they perform. The Laboratory will then send your tumour samples, together with your identifiers for storage at our Tissue Bank. Laboratory and Tissue Bank staff do not have access to your name, NHS/ CHI/ HSC number and contact details.

We need to know whether the results of the study are influenced by your ethnicity and your gender when we come to analyse the results. Your hospital will provide this information to the Warwick Clinical Trials Unit when you join the study.

Up to early 2019, we stored local hospital numbers for everybody who joined OPTIMA. We no-longer need this so we have removed the ability of staff at the Warwick Clinical Trials Unit to access this information.

If you have agreed to audio-recording your consultations for the OPTIMA Qualitative Research Study, the recordings will be sent to the University of Bristol. The University of Bristol will keep the recordings in secure electronic format on behalf of UCL. The researchers who analyse the recordings will not know your identity. If you have also consented to be interviewed, your hospital will pass your name and telephone number or other contact details to the University of Bristol when this is needed. Your details will be stored in a locked filing cupboard for up to three months after your interview, after which they will be destroyed..

All identifiable information about you that is collected for the OPTIMA trial on behalf of UCL is stored securely. Information will be kept for 10 years after the study has finished, which we expect will be in early 2033.