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

International Data Transparency Statement

Version 1.0 – 28 February 2022

This leaflet explains how your data is used in the OPTIMA study if you live outside of the UK.

Your legal rights

Your hospital will send some personal information about you to the OPTIMA Trial Office in the UK when you join the study. This information is protected by the European Union General Data Protection Regulation (GDPR). GDPR gives extra protection to sensitive personal information, called Special Category data. This includes health information and some other data such as ethnicity. GDPR is part of UK law and is included in the UK Data Protection Act (2018).

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.

UK taxpayers fund the OPTIMA study. This means that legally it is in the public interest to use personal information for this research.

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 (in English only). You will also be able to find the most up-to date version of this leaflet at the same address.

Processing your information

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

Your hospital will use your personal identifiers to make sure that information required by the study is recorded to ensure your care, and to oversee the quality of the study. Personal identifiers used by your hospital will include your name, date of birth, hospital number and any other healthcare numbers used in your country.

The Warwick Clinical Trials Unit, UCL and regulatory organisations may check the accuracy of the information collected by your hospital for the research study. To do this, individuals from these organisations or their representatives will visit your hospital and look at your medical and research records to check the information is correct. Your personal identifiers will not be recorded during an inspection.

Your hospital will pass information collected from you and your medical records to the Warwick Clinical Trials Unit in the UK. 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 send some personal information to our Laboratory. This is usually your date of birth and pathology information. This information is 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. The identifiers used by the Laboratory will also be stored by the Warwick Clinical Trials Unit even if the Laboratory is not in the UK. The exact arrangements differ between countries and are stated in your Patient Information Sheet.

Some countries collect long-term health information about all patients. If that is the case in your country, we may contact the relevant public body about your health in the future. We will need to collect a health care identifier such as national number to do this. This will be stored by the Warwick Clinical Trials Unit. Your Patient Information Sheet will contain more detail when this applies in your country.

We need to know whether the results of the study are influenced by your age (date of birth), 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.

All identifiable information about you that is collected for the OPTIMA trial on behalf of UCL is stored securely. We expect the study to finish in around 2035 and will keep study information for 10 years after it has finished.