*[Print on Local Trust headed paper]*



Patient Information Sheet

OPTIMA Qualitative Recruitment Study

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

**Introduction**

The Recruitment Study is an important part of the OPTIMA study which looks at how doctors and nurses explain clinical research studies to patients. The Recruitment Study involves;

* audio-recording your consultations in which OPTIMA is discussed, and/or
* taking part in an interview with a researcher after you have decided whether or not to join the main OPTIMA study.

If you have already told your healthcare team whether or not you want to take part in OPTIMA when you receive this information sheet, the interview part alone will apply to you.

You can take part in the Recruitment Study **regardless of whether or not you decide to take part in the main OPTIMA study**. The overall goal of the Recruitment Study is to improve how health care professionals give information about OPTIMA and other clinical studies to future patients.

Before you decide whether to take part in the Recruitment Study, it is important for you to understand what is involved. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. This information leaflet is just about the Recruitment Study. You will be given another leaflet explaining the main OPTIMA study.

**What is the purpose of the Recruitment Study?**

We want to learn more about how doctors and nurses can support patients in making informed decisions about participating in clinical studies like OPTIMA. One way to improve our knowledge is to audio-record the conversations you have with hospital staff about your treatment options and possible participation in the OPTIMA study. Interviewing you after you have made your decision about whether or not to take part in OPTIMA will also help us to understand your views on the study, and how you came to your decision.

**What do I have to do if I take part?**

Taking in part in the Recruitment study will involve two optional things:

1. **Audio-recording your consultations with health care professionals** - We will ask your permission to audio-record all the consultations where the OPTIMA study and your treatment options are discussed, until you have chosen whether or not to take part in the OPTIMA study.
2. **An interview with a researcher** - After you have made a decision about whether or not to take part in the OPTIMA study, we may invite you to take part in an interview. We usually do this by telephone. The researcher is interested in how you came to your decision. Please be assured that whilst interested in your decision, the researcher will not question it or try to get you to change it. If you agree, your interview with the researcher will be audio-recorded.

You may wish to take part in both, one or none of the above.

**Why have I been invited to take part in the Recruitment Study?**

You have been invited to take part in the Recruitment Study because you are eligible to join the main OPTIMA study.

**Do I have to take part?**

No. It is up to you to decide whether or not you wish to take part in the Recruitment Study. Your care will not be affected in any way if you do not want your consultations recorded, or if you do not want to be interviewed. Your decision about audio-recording and the interview are independent of any decision you make or have made about joining the main OPTIMA study. Agreeing to have your consultations recorded does not commit you to join OPTIMA.

If you change your mind, you can withdraw at any time, without giving a reason.

**What are the possible disadvantages and risks of taking part?**

There are no physical risks to taking part.

**What are the possible benefits of taking part?**

If you take part in this research, you will be helping us to improve how people like you are informed about their treatment options, both now and in the future. However, there will be no direct benefit to you.

**What if I change my mind?**

You are free to withdraw from any aspect of this Recruitment study at any point. Your medical or legal rights will not be affected in any way. We will destroy recordings and transcripts of your data if you request this. However, because the researchers analyse the data as they go along, we will not be able to destroy reports or materials we have already produced that include your anonymised data.

**What happens when the Recruitment Study stops?**

Your ongoing health care is in no way dependent on your participation in the Recruitment Study. You will continue to receive appropriate care when the Recruitment Study comes to an end.

**Who is organising and funding the Recruitment Study?**

The OPTIMA study is run by University College London (UCL). UCL is Sponsor for the research. The Warwick Clinical Trials Unit is supporting UCL in the coordination of the research. This Recruitment Study is organised in collaboration between UCL and The University of Bristol. OPTIMA and the Recruitment Study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (project reference 10/34/501). NIHR would like you to know that any views expressed here are not necessarily those of the NIHR or the Department of Health and Social Care.

**What if something goes wrong?**

It is very unlikely that you will be harmed by taking part in this type of research study. However, if you wish to complain, or have any concerns about the way you have been approached or treated by the research team, both the NHS and the UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information about this.

If you suspect that the harm is the result of the Sponsor’s (University College London) or the hospital's lack of care then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to the Chief Investigator (Professor Rob Stein, UCL Hospitals, 250 Euston Road, London NW1 2PG). You also have the right to take independent legal action and you should consult a lawyer if you wish to do this.

**Will my taking part in this study be kept confidential?**

All personal information we collect for OPTIMA is strictly confidential and is subject to the UK Data Protection Act 2018 and GDPR. You will be given a reference number by the OPTIMA Trial Office at the Warwick Clinical Trials Unit, University of Warwick. All audio-recordings of your discussions with health care professionals about OPTIMA and any audio-recorded interviews will be labelled with your reference number and not with your name, to hide your identity. We use secure technology for making and transferring recordings. Recordings will be transcribed (i.e. a written record of the interviews produced) by a University of Bristol employee or a University of Bristol approved contracted transcribing service. These transcripts will be de-identified so that neither you nor other individuals can be recognised from these documents.

Information about you, including interviews we conduct with you and audio-recordings of your appointments, will be held on a secure database at the University of Bristol which will only be accessed by authorised members of staff.

If you agree to be contacted about a potential interview, we will ask your research nurse for your name, telephone number and e-mail address (optional). We will store your contact information securely at the University of Bristol and destroy it once we have completed your interview.

There is more information about how we process your information and about your legal rights in the OPTIMA Data Transparency Statement (version 2.0, 27 July 2020). You can find this on the privacy page of our website at [optimabreaststudy.com/taking-part-in-optima/privacy](https://optimabreaststudy.com/taking-part-in-optima/privacy). UCL, as the OPTIMA study sponsor, has overall legal responsibility for information we collect. You can also find a link to the UCL privacy notice on the OPTIMA website privacy page.

**What will happen to the results of this research study?**

Our findings will help health care professionals who work on the OPTIMA study by showing them how to improve the way they provide information about treatment for breast cancer and the OPTIMA study. The findings will be included in our study report and may be published in medical journals and presented at clinical and academic meetings to help inform doctors and nurses how best to discuss treatment options in randomised studies. We may also play clips of recordings during presentations and teaching/training events. Any audio-recordings and quotes will be de-identified (including through voice modification and avoiding use of names/places), so that neither you nor any other individuals can be recognised. In the interest of making the best use of public-funded research, we may use audio-recordings and transcripts of interviews and recorded appointments from this study in our future research looking at common issues across clinical studies.

**What will happen to my data?**

We will hold electronic recordings and transcripts of your data on University of Bristol encrypted drives for a maximum of 10 years after the study ends.

In addition, we are asking for your permission to make any transcripts of your recordings “Controlled Access” data. This means that transcripts will be stored in a secure online database indefinitely. This database can be accessed by approved researchers who are interested in conducting their own analyses of the data. These researchers will need to submit an application to do this, which will be assessed by an independent committee at the University of Bristol. We will have no control over how these data are used by other researchers if their application is approved. All data will be de-identified before being made available.

Sharing access of research data is considered good practice and is a requirement of many funding bodies and scientific journals. Sharing data helps to maximise the impact of money invested into studies and can encourage new avenues of research. You will be asked if you are happy for your data to be used in this way on the consent form.

**Who has reviewed this study?**

All research in the NHS is reviewed by an independent group of people, called a UK National Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. The Recruitment Study has been reviewed and approved by the London - Surrey Research Ethics Committee (Integrated Research Application System ‘IRAS’ reference: 95626) as part of its approval of the OPTIMA study. Patient representatives from Independent Cancer Patients’ Voice and from other groups have been involved in the study’s development from the start and have approved it. You can find out more about ICPV at [independentcancerpatientsvoice.org.uk](http://www.independentcancerpatientsvoice.org.uk/). Every participating hospital will also have examined the details of the study before deciding to take part.

**What if I have other concerns?**

You will have some time to think about this study and make your decision. If at any time you wish to discuss this with anybody in addition to your local team, please contact:

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**Thank you for taking time to read this Information Sheet.**

