[Print on Local Trust headed paper]

Patient Information Sheet

OPTIMA Qualitative Recruitment Study

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

Introduction

The Recruitment Study is an important aspect of the OPTIMA study and has been set up to understand how patients eligible for OPTIMA are invited to take part in the study. The Recruitment Study involves audio-recording consultations in which OPTIMA is discussed, and may include being interviewed by a researcher. You can take part in the Recruitment Study regardless of whether or not you agree to take part in the OPTIMA study. The overall aim of Recruitment Study is for us to improve how information about OPTIMA and other clinical studies is provided to future patients.

Before you decide whether to take part, 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 information leaflet explaining the main OPTIMA study.

What is the purpose of the Recruitment Study?

At present, we know little about how people make decisions about their treatment options and whether or not to take part in a research study. 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 about participation.

What do I have to do if I take part?

Taking part in the Recruitment Study will involve two things. Neither of these will happen without your permission, and you do not have to agree to both parts. You are free to opt in or out of either of them:

(i) 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. If you agree to this, we will ask you to sign a consent form.

(ii) After you have made a decision about whether or not to take part in the OPTIMA study, we may invite you to be interviewed at a location of your choice (or if you wish, over the telephone). If you agree, your interview with the researcher will be audio-recorded. The researcher will ask about your views on OPTIMA and how you came to your decision about whether or not to participate in the study. You will be asked to sign a consent form before the interview starts.

Why have I been chosen?

You have been chosen because you are eligible for the OPTIMA study. We would like to audio-record your consultations and possibly contact you for an interview regardless of whether or not you decide to take part in the main OPTIMA study.

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. If you do take part, you will be asked to sign a consent form for audio-recording your consultations, and a consent form for the interview. If you change your mind, you can withdraw at any time, without giving a reason.

Your care will not be affected in any way if you do not want your consultations recorded, or if you do not want to take part in an interview. You will still be able to join the main OPTIMA study. If you do agree to taking part in an interview and/or having your consultations recorded this does not commit you to join OPTIMA.

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 for the future. However, there will be no direct benefit to you.

Will my taking part in this study be kept confidential?

All personal information collected for OPTIMA is strictly confidential and is covered under the Data Protection Act 2018. No information that allows you to be identified will be made public. You will be given a reference number by the OPTIMA trials office at the Warwick Clinical Trials Unit, University of Warwick. All audio-recordings of your discussions with doctors/nurses working on OPTIMA will be labelled with your reference number (not with your name) to hide your identity. These audio-recordings will be transferred to the University of Bristol to be used for research and training. The researchers will make transcripts (i.e. a written record of the audio-recordings) which will also be anonymised so that you cannot be recognised from any of the information we collect from you. All recordings and transcripts will be stored in a locked cabinet and/or a secure database that will be accessed by the University of Bristol team and their associates conducting research in this area. Data will be stored for the duration of this study and into the future so that they can be used for training, teaching and research purposes.

We may wish to play parts of audio recordings or use quotes as part of teaching or presentations at academic and clinical meetings. If we do use any of your recordings, all the quotes will be anonymised so that you cannot be recognised from any of the information we present. We may also use the data from audio-recordings in our future research looking at common issues across studies. You will not be identified in any way whatsoever, in any report or publication.

What will happen to the results of this research study?

Our findings will help the doctors and nurses 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. Results may also be used for teaching and training purposes. You will not be identified in any way whatsoever, in any report, presentation, or publication.

Who is organising and funding the research?

This research 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 Qualitative Recruitment Study is organised in collaboration between UCL and The University of Bristol.

The study is funded by the National Institute for Health Research (NIHR) as part of the OPTIMA study (project number 10/34/501). Their Health Technology Assessment Programme is paying for it.

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 study has been approved by the South East Coast – Surrey Research Ethics Committee (Integrated Research Application System 'IRAS' reference: 95626). It has also been approved by patient representatives. Every participating hospital will also have examined the details of the study before deciding to take part.

What if something goes wrong?

If you wish to complain, or have any concerns about the way you have been approached or treated by the research team, both the National Health Service and the UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information about this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to the Chief Investigator (Dr Rob Stein, UCL Hospitals, 250 Euston Road, London NW1 2PG). The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

What happens when the research study stops?

Your health care is in no way dependent on your participation in the Recruitment Study. You will continue to receive the appropriate care whatever happens.

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:

Dr Carmel Conefrey
University of Bristol
Tel: 0117 3314564
Email: carmel.conefrey@bristol.ac.uk

OR

Dr Leila Rooshenas
University of Bristol
Tel: 0117 3314574
Email: leila.rooshenas@bristol.ac.uk

Thank you for taking time to read this Information Sheet.