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Staff Information Sheet

OPTIMA Qualitative Recruitment Study

Audio-recordings and Interviews

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

We are investigating how patients eligible for OPTIMA are invited to join the study and the opinion of researchers working on OPTIMA. We would like you to consider participating in our research. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. We will be happy to answer any questions. Take as much time as you need to decide.

Thank you for taking the time to read this information.

What is the purpose of this study?

This study aims to optimise the provision of clear and balanced information about patients' treatment options and the possibility of participation in OPTIMA. To do this, we want to examine what actually happens during treatment discussions with patients and to talk in detail with those members of staff involved. On the basis of what we find out we aim to develop strategies for optimising levels of informed consent and randomisation, and, if required, deliver customised training to individual recruiters as the study progresses. The goal is to enable recruiters to provide the best possible balanced information, whilst at the same time ensuring that recruitment is not coercive and participants are able to make an informed choice. We will document changes in recruitment rates as part of the evaluation of the impact of this study. Other important outcomes will be the extent to which patients and recruiters find the recruitment process acceptable. A main aim is to increase the satisfaction you gain from participation in the study as a recruiter.

Why have I been chosen?

You have been chosen because you are involved in conducting treatment discussions and recruitment appointments with patients eligible for OPTIMA at your centre or you are otherwise involved in running the study. The Principal Investigator for OPTIMA at your centre is interested in participating in this sub-study and has allowed us to provide you with this information sheet.

What do I have to do if I take part?

Taking part in this sub-study will involve the following:

(i) **[THIS ITEM (i) IS ONLY APPLICABLE IF YOU ARE A RECRUITER]** We will ask you to audio-record conversations you have with patients about participating in OPTIMA. These may include preliminary discussions about treatment options as well as the final recruitment appointment. We will provide you with equipment to record these discussions. You will also be asked to gain informed consent from patients for these recordings;

(ii) We may invite you to attend an interview to discuss your perspective on the OPTIMA study. This will be arranged for a time and place that is convenient to you and should last for about

one hour. In this interview we will be keen to obtain your views on the recruitment process, with a particular focus (as applicable) on appointments you have already conducted, the adequacy of the discussion, your satisfaction with the decision reached, the recruitment strategies you use, the acceptability of the study design, and why you feel recruitment may be proving difficult;

(iii) On the basis of qualitative analysis of the data collected, the OPTIMA team will provide feedback and training in order to support recruiters. You may be invited to attend individual and group training sessions. These will allow us to exchange ideas about how best to improve the recruitment process. All individual feedback sessions will be confidential; group-training sessions will focus on general issues (e.g. how best to talk to patients about randomisation) and your confidentiality will be maintained. Our aim is to be supportive, not critical – to collaborate with you to find effective recruitment strategies.

Do I have to take part?

It is entirely up to you to decide whether or not to take part in the audio-recordings and interviews sub-study. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are free to withdraw from the study at any time and without giving a reason. You are also free to refuse to answer any specific interview question, or to withdraw from an interview or training session without giving a reason.

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. Recorded data will be transferred to the University of Bristol to be used for research and training. All recordings will be labelled with your reference number (not with your name) to hide your identity. They will be stored in a locked cabinet and or a secure database that will be accessed by the University of Bristol team for the duration of the study and into the future so that they can be used for training, teaching and research purposes. Only the researchers employed on the OPTIMA study and the University of Bristol team and their associates conducting research in this area will have access to the recordings. All transcripts will also be anonymised so that you cannot be recognised from any of the recordings we collect from you. In addition, all individual feedback will be treated in confidence and any findings discussed in group training sessions will be anonymised so that your confidentiality is maintained.

We may wish to play parts of recordings or use quotes, for example as part of teaching or presentations at academic meetings. If we do use any of your data, 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 collected (interviews and audio-recordings) in our future research looking at common issues across studies. You will not be identified in any way whatsoever, in any report, presentation, or publication.

What are the possible disadvantages and risks of taking part?

There are no physical risks to taking part. If you agree to take part, there is a risk that you might feel that aspects of the training process are critical. This is not our intention. Our aim is to be supportive. If you do experience any difficulties with taking part, please feel free to discuss this with one of us so that we can try to resolve the matter. You remain free to withdraw from the study, or any aspect of it, if you wish.

What are the possible benefits of taking part?

If you take part, you will receive individual support in your role as recruiter and opportunities to discuss any difficulties you may be experiencing with the recruitment process. You may receive individually tailored feedback which will enable you to continue to improve your advanced communications skills. One of our

aims is to improve your job satisfaction. You will also be helping us to improve the ways in which medical research studies are run, both now and for the future.

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 will happen to the results of the research study?

After a thorough review by independent experts, a report of the study findings and academic papers will be published in respected journals. Findings may also be presented at academic conferences/workshops or used for training purposes. You will not be identified in any way whatsoever, in any report, publication, or presentation.

Who is organising and funding the research?

The OPTIMA study is being carried out by University College London (UCL). This sub-study, a part of the OPTIMA 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.

Who has reviewed the study?

The OPTIMA study protocol has been approved by a UK National Research Ethics Committee. This committee is responsible for making sure that research with patients is appropriate and that the participants' rights and welfare are protected. The Committee has also approved this sub-study. Every participating hospital will also have examined the details of the study before deciding to take part. (Integrated Research Application System 'IRAS' reference: 95626.)

What if I have other concerns?

If you want to talk to someone about this part of the OPTIMA study, please contact:
Dr Leila Rooshenas who is leading this research at the University of Bristol
Tel: 0117 3314574
Email: Leila.rooshneas@bristol.ac.uk

OR

Dr Carmel Conefrey, who is the lead researcher working on the OPTIMA QRS study
Tel: 0117 3314564
Email: Carmel.conefrey@bristol.ac.uk

Once again, many thanks for taking the time to read this information sheet. Should you decide to take part in the study, please complete the consent form overleaf.

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OPTIMA Qualitative Recruitment Study

Staff Consent Form – Audio-recordings and Interviews

Study Title:	**O**ptimal **P**ersonalised **T**reatment of early breast cancer us**i**ng **M**ulti-parameter **A**nalysis: Qualitative Recruitment Study
Study Number:	ISRCTN42400492 IRAS ref. 95626
Study Site:	

Participant statement and signature	Please **initial** boxes below if you agree
1. I have received and read a copy of the OPTIMA Qualitative Recruitment Study Staff Information Sheet version 4.0 dated 8 November 2018. I fully understand what is involved in taking part and have had an opportunity to ask questions, and all of my questions have been answered.	
2. I understand that my participation is entirely voluntary and that I am free to withdraw from the audio-recording study at any time without giving a reason.	
3. I agree to audio-record future consultations I have with patients eligible for OPTIMA if the patient gives consent.	
4. If approached, I agree to take part in an interview about my views on recruitment to the study.	
5. I agree to data from my audio-recorded appointments/interviews being transferred to and retained by the University of Bristol for training, teaching and research purposes, now and in the future. I understand that anonymised quotes from interview transcripts may be used in publications arising from this research.	
6. I understand that data collected for this study is covered by the Data Protection Act (2018) and all electronic data will be stored in a secure format. I understand that no information that allows me to be identified will be made public.	
7. I give my permission for the OPTIMA Trial Office to hold information about me including my identity which will be used exclusively for the purposes of my participation in the OPTIMA Qualitative Recruitment Study.	

Your signature confirms that you have had an opportunity to ask questions and that all of your questions have been answered. [You will be given a signed and dated copy of this consent form to take away with you]

Staff member name (print):	Signature:	Date signed:
_____	_____	_____

Investigator Statement and Signature.

To be completed by the person taking consent. Not required where the Researcher is a Principal Investigator or Co-Investigator

I have discussed this clinical research study with the participant. I believe that I have fully informed the participant of the nature of this study and the possible benefits and risks of taking part. I believe the participant has understood this explanation.

Name (print):	Signature:	Date signed:
_____	_____	_____

1 copy for staff participant; 1 for local site file; send 1 copy to QRS Researcher