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Staff Information Sheet - Audio-recordings and Interviews

OPTIMA Qualitative Recruitment Study

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

We are inviting you to take part in the Qualitative Recruitment Study (QRS) which is integrated into the OPTIMA randomised controlled trial (RCT). The QRS aims to understand and address recruitment issues in OPTIMA as the trial progresses. This information sheet explains the purpose and conduct of the QRS to enable you to make an informed decision about participation. Please ask a member of the QRS team if there is anything that is unclear or if you would like more information. Our contact details shown at the end of this information sheet. Thank you for considering our request.

**What is the purpose of this study?**

The OPTIMA QRS aims to optimise the provision of clear and balanced information about patients’ treatment options and the possibility of participation in the OPTIMA RCT. To achieve this the QRS seeks to rapidly understand and address recruitment issues using multiple methods whilst the RCT is underway. We are asking if you will help with two of these. Specifically, we would like to audio-record appointments where OPTIMA is discussed with eligible patients, and interview professionals working on the RCT.

**Why have I been chosen?**

You have been chosen because of your involvement in OPTIMA. Your role may encompass identifying eligible patients, discussing treatments with patients, recruiting eligible patients, or you may have responsibility for oversight or conduct of OPTIMA at a site-level or study-wide level.

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

Taking part in the Recruitment Study will involve all or some of the following:

1. **Audio-recording recruitment discussions:** We will ask you to audio-record conversations you have with patients about participating in OPTIMA. These may include initial discussions about treatment options as well as any subsequent discussions and the patient’s decision about trial entry. We will provide you with an audio-recorder to do this.
2. **Being Interviewed:** We may invite you to attend one or more interviews with a qualitative researcher to discuss your views on the OPTIMA study. This will normally be a telephone interview, although we can do in-person interviews. We will arrange interviews at a time (and place) that is convenient to you. We will audio-record your interview if you consent, so that the researchers can listen to it again and make a transcript of the discussion.

You may be invited to attend individual and group recruitment feedback/training sessions, based on the QRS research findings. We usually do these by telephone, in-person or by video-link. This training will be supportive, with the aim of sharing good practice and jointly devising solutions to recruitment challenges.

**Do I have to take part?**

No. It is entirely up to you to decide whether to take part in the QRS. If you change your mind you can withdraw at any time and without giving a reason. If you do decide to take part, you will be asked to sign a consent form that includes separate clauses for audio-recording appointments and interviews. Audio-recording will only be carried out when patient consent is also obtained. Information for patients will be provided in a separate information sheet. Alternatively, for telephone interviews only, the researcher will read the consent form statements to you and ask if you accept/decline each statement. This consent discussion will be audio-recorded. 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.

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

There are no physical risks to taking part. If you audio-record recruitment discussions with potential OPTIMA participants, you may feel the presence of the recorder. Our experience is that recruiters report that they rapidly cease to be aware of it.

Interviews normally take between 30-45 minutes of your time. We will ensure this is arranged at your convenience. You may be asked to take part in more than one interview over the course of the OPTIMA study, although taking part in one interview does not obligate you to further interviews.

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

If you are involved in recruiting patients to OPTIMA, you may receive recruitment support delivered individually or as part of a group and will have opportunities to discuss any difficulties you may be experiencing with the recruitment process. You may receive individually tailored feedback from your consultations if you would like this, based on the analysis. Some people find that taking part in interview analysis can help them to reflect on and improve their practices.

**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.

**Who is organising and funding the research?**

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 coordinating the research. This Recruitment Study is organised in collaboration between UCL and The University of Bristol (UoB). 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 extremely unlikely that you will be harmed by taking part. However, if you do experience any difficulties with taking part in this research, please discuss this with the researcher named at the end of this information sheet so that we can try to resolve the matter. If you wish to complain to the Sponsor about your treatment, then the researcher will inform you about how to proceed.

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

All personal information collected for OPTIMA is strictly confidential and is subject to the UK Data Protection Act 2018 and GDPR. No information that allows you to be identified will be made public. All audio-recordings from your patient recruitment discussions and /or interviews will be labelled with a reference number only to hide your identity. We use secure technology for making recordings and for videoconferencing. Recordings will be transferred to the UoB when made at your site, and transcribed (i.e. a written record of the interviews produced) by a UoB employee or a UoB approved contracted transcribing service. These transcripts will be de-identified so that neither you nor other individuals can be recognised from these documents.

We need to collect some personal information about you, including your name, organisation and for interviews, your contact details. We do this so we can properly organise the data we collect, arrange interviews and provide recruiter feedback. All of this personal information together with personal identifying information contained in interviews we conduct with you and audio-recordings of your appointments, will be held on a secure database at the UoB which will only be accessed by authorised members of staff in the QuinteT team. Any paper copies of the transcripts will be stored securely in a locked filing cabinet at the UoB and destroyed at the end of the OPTIMA study.

UCL, as study sponsor, is the data controller for this study. You can access the UCL Data Privacy Notice which includes information about your legal rights and how to complain about our use of your personal information through the OPTIMA website at [optimabreaststudy.com/taking-part-in-optima/privacy](https://optimabreaststudy.com/taking-part-in-optima/privacy-statement.php).

**What will happen to my data?**

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

In addition, we are asking for your permission to make transcripts of your interviews and audio-recorded appointments “Controlled Access” data at the end of the OPTIMA study. 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. We will have no control over how these data are used if their application is approved. All data are de-identified before being made available.

Sharing access of research data and findings is considered good research practice and is a requirement of many funding bodies and scientific journals. Sharing data helps to maximise the impact of money invested into research studies and can encourage new avenues of research. We will request your permission for your data to be used in this specific way on the consent form.

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

The results of this study will be reported in scientific journals, including an end-of-study report for the funders. Summaries of the findings may be prepared for patients and members of the public and presented at scientific conferences and meetings. We may also play clips of recordings during presentations and teaching/training events. Any audio-recordings and quotes will be de-identified (e.g. through voice modification, avoiding use of names/places), so that neither you nor any other individuals can be recognised from the information presented. In the interest of making the best use of publicly funded research, we may use audio-recordings and transcripts from this study in our future research looking at identifying and addressing RCT recruitment issues. Quotes from recruitment discussions and interviews together with clips from audio-recordings included in these materials will be de-identified as described above.

**Who has reviewed the study?**

The OPTIMA study protocol which includes the OPTIMA Qualitative Recruitment Study has been reviewed and approved by the London - Surrey Research Ethics Committee (Integrated Research Application System ‘IRAS’ reference: 95626).

**Who do I contact if I want further information or have concerns?**

If you want to talk to someone about this part of the OPTIMA study, please contact:

|  |  |
| --- | --- |
| **Dr Carmel Conefrey**  University of Bristol  Tel: 01179287296  email: [carmel.conefrey@bristol.ac.uk](mailto:carmel.conefrey@bristol.ac.uk) | **Dr Leila Rooshenas**  University of Bristol  Tel: 0117 3314574  email: [leila.rooshenas@bristol.ac.uk](mailto:leila.rooshenas@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.**

[Print on Local Trust headed paper or University of Bristol headed paper depending on who is receiving the consent]



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Consent Form – Audio-recordings and Interviews of Staff

OPTIMA Qualitative Recruitment Study

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 5.1, dated 10 September 2020). 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. | | | |  | | |
| 1. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving a reason and without my legal rights being affected. I understand that withdrawal of data already used in reports and publications is not possible. | | | |  | | |
| 1. I agree to audio-record discussion I have with patients about OPTIMA (subject to the patient’s consent). | | | |  | | |
| 1. If approached, I agree to take part in audio-recorded interviews about recruitment to OPTIMA that will be carried out by a QRS researcher. | | | |  | | |
| 1. I agree to data from my audio-recorded appointments and/or interviews being transferred to and retained by the University of Bristol and their authorised representatives for transcription, training, teaching and research purposes. I understand that anonymised quotes from my consultation transcripts and/or interviews may be used in teaching and research activities. | | | |  | | |
| 1. I agree to data from my audio-recorded appointments and/or interviews being made “Controlled Access” after the study ends. I understand this means data will be stored indefinitely and may be used for purposes not related to this study, but that it will not be possible to identify me from these data. | | | |  | | |
| 1. I give my permission for the OPTIMA Trial Office and the University of Bristol to collect information about me for the purposes of my participation in audio-recordings. I understand that all information about me will be stored securely and will only be accessible by authorised personnel. | | | |  | | |
| 1. I agree to take part in the above study. | | | |  | | |
| [You will be given a copy of the completed consent form for your records.] | | | | | |
| Staff member name (print):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date signed:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

|  |  |  |
| --- | --- | --- |
| **Investigator Statement and Signature**  ***To be completed on site by the Principal Investigator or designee (for audio-recording and interview) or by the QRS Researcher (interview only) receiving consent.*** | | |
| 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:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Where completed by the QRS researcher** during a telephone or video interview, the researcher to read out statements and initial boxes where participant agrees. The QRS researcher should audio-record this consent process.

The completed form should be kept in the QRS researcher site file at the University of Bristol and a copy sent to the staff member.

**When completed at the recruiting site**, the Consent Form must be kept on site and should be stored in the OPTIMA site file and a copy given to the staff member and a copy sent to the QRS Researcher.