

Qualitative Recruitment Study



Procedure note:

- **Audio-recording Consultations**
- **Patient Interviews**

Introduction

Recruiting to clinical trials such as OPTIMA can be challenging. The Qualitative Recruitment Study (QRS) team can provide support on this front. We do this by investigating recruitment difficulties that arise in OPTIMA and offering tips, individual and group feedback and training to help overcome difficulties.

The quality of any training or feedback offered is very dependent on the data and evidence available to us. You can help by audio-recording consultations with patients (where OPTIMA is described), asking patients that you approach to join OPTIMA (both if they consent or decline) if they would be consider taking part in an interview, and taking part yourself in a short telephone (or face to face) interview with the QRS researchers. All information from consultations and interviews, including staff and patient names, will be anonymised.

This procedure note provides all the information you need to:

- obtain and register informed consent from patients for the audio-recordings
- make audio-recordings and transfer them to the QRS research team
- obtain consent from patients to pass on contact details so that QRS researchers can make contact about a possible patient interview

The Qualitative Recruitment Study is being run by researchers from the QuinteT team at the University of Bristol (UoB). In the first instance, please contact Carmel Conefrey if you have any questions.

Research Team

Dr Carmel Conefrey
(Lead contact)
0117 9287296

Dr Leila Rooshenas
0117 3314574

Nicola Farrar
(Patient Interviews)
0117 331 3307

carmel.conefrey@bristol.ac.uk

Leila.Rooshenas@bristol.ac.uk

nicola.farrar@bristol.ac.uk

Step-by-step guide to audio-recording for OPTIMA QRS

1. Seeking Staff One-off Consent



Circulate [Staff Information Sheet and Consent Form](#) to recruiting staff and request consent.

- Return completed consent forms to carmel.conefrey@bristol.ac.uk
- Place a copy in the OPTIMA local site file
- Give a copy to staff member

There are two different consent processes for audio-recording consultations:

- **One step consent** where the patient is sent the [QRS PIS](#) and [Consent form for Audio-recording](#) in advance of their first *in-person* oncology appointment
- **Two step consent** where the [QRS PIS](#) is not handed out in advance of the first appointment and where the appointment is carried out *remotely*.

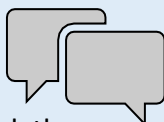
If you have an alternate patient pathway, please get in touch and we can discuss how to adapt the consent process it to fit with your local practices.

One Step Consent Process

1. Informing Patients

Where you provide the patient with the OPTIMA PIS in advance of an appointment with an oncologist, please also provide the [OPTIMA QRS PIS](#) and [QRS Consent form - Audio-recording of consultations](#)

2. Inviting Patient Questions



At the outset of the appointment, ask the patient if they have read and understood the [OPTIMA QRS PIS](#) and answer any questions the patient may have.

3. Obtaining patient consent



Ask if the patient consents to audio-recording.
If the patient says 'yes':

- Request written consent using [QRS Consent Form – Audio-recording of consultation](#)

Two Step Consent Process

1. Getting started



At the outset of the appointment, ask the patient if they are happy for their appointment to be recorded for research:

- If 'Yes', complete [Verbal Consent to Audio-recording](#).

2. Audio-recording



Where verbal consent is given, **start** audio-recording.

3. Informing Patients

At the end of the 1st appointment, hand out or send out the

- [OPTIMA QRS PIS](#)
- [QRS Consent Form – Audio-recording of consultations](#)

One Step Consent Process (continued)

4. Audio-recording



Where consent is given for audio-recordings:

- Record all appointments up until the patient makes a decision about participating or not, in the OPTIMA Study.

Warwick Clinical Trials Unit Randomising and Registering Service: Mon – Fri 09:00 – 17:00
Tel: 02476 150402 or Fax: 02476 151586

Any queries or for more information about audio-recording consultations please contact carmel.conefrey@bristol.ac.uk 0117 928 7296

Two Step Consent Process (continued)

4. Obtaining patient consent



At the start of the 2nd clinic appointment, ask the patient if they are happy to continue recording.

Where ongoing consent is given:

- Request written consent using the [Consent Form – Audio-recording of Consultations](#). If the appointment is remote, ask the patient to return the consent form by post or any locally approved method.
- Continue audio-recording appointments up until the patient makes a decision about trial participation.

Where patient does not give ongoing consent or where the patient does not return a completed consent form, **delete all** audio-recordings made.

5. Registering Patient Participation in Consultation Audio-recording



If patient **consents to OPTIMA**:

- register the audio-recordings on [Randomisation Form \(FORM #2\)](#) when randomising the patient with the Warwick Clinical Trials Unit

If patient **declines OPTIMA**:

- complete [QRS Patient Registration Form \(FORM #QRS\)](#) and register with the Warwick Clinical Trials Unit.

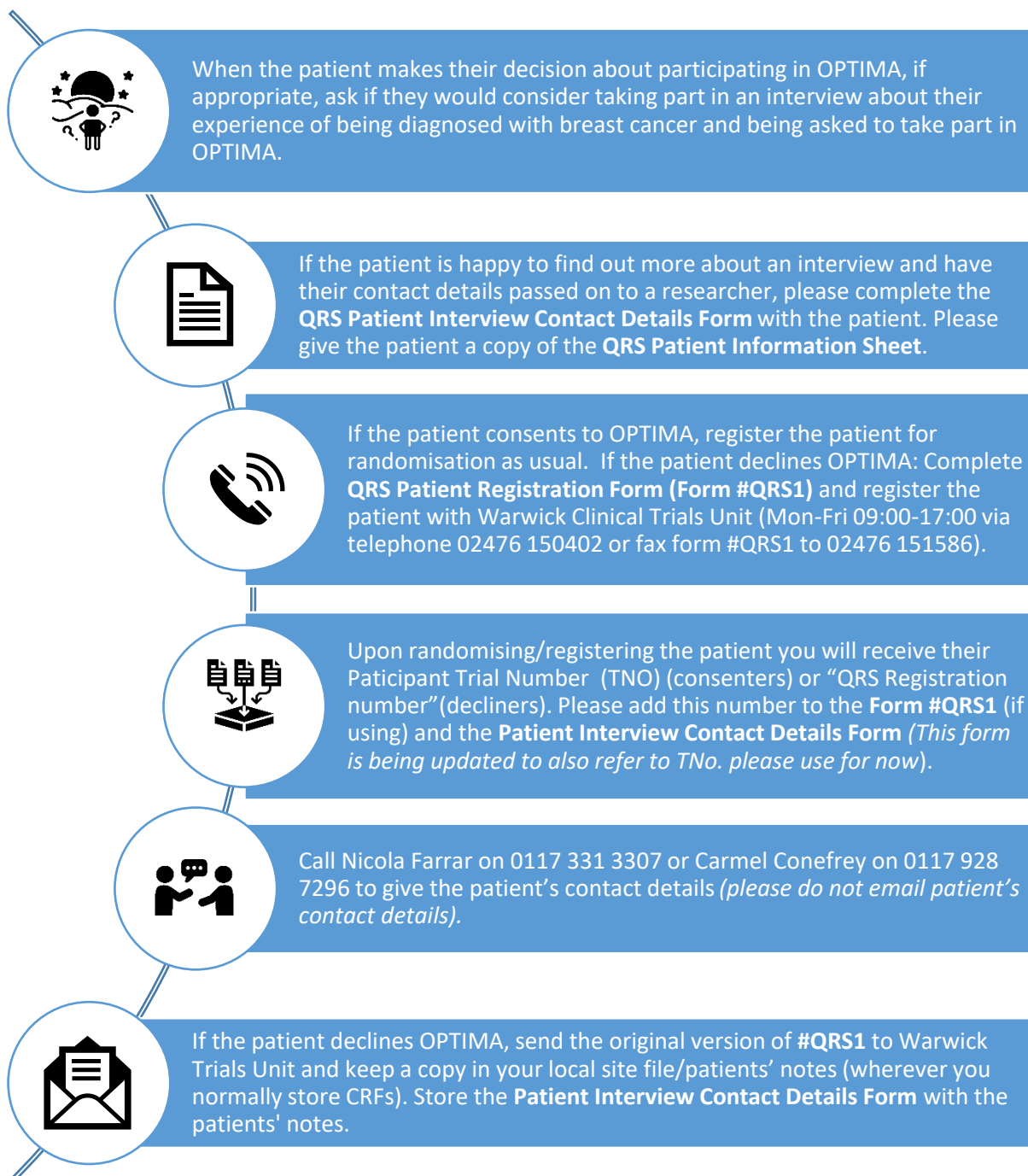
Periodically, a QuinteT researcher will send you a Special Delivery Envelope for you to return the audio-recorder. The researcher will download the files, recharge the battery and return it for ongoing use.

Patient Interviews

We would like to interview patients that have been approached to enter OPTIMA in order to explore patient decision making. We are seeking to interview patients who consent to OPTIMA and patients that decline. In particular, we would like to interview patients who have had their recruitment consultation audio-recorded. *Full details on the next page.*

Step-by-step guide to approaching patients about a potential interview

The OPTIMA qualitative team are keen to interview patients that have been approached to enter OPTIMA in order to explore patient decision making. We are seeking to interview both patients who consent to and decline OPTIMA. Learning about the patient perspective will significantly contribute to our goal of supporting recruitment and informed consent. Please consider asking any patient you approach for OPTIMA about an interview. We are particularly keen to interview patients who *have had their recruitment consultation audio-recorded*.



All documentation needed for this process is available at: <http://optimabreaststudy.com/optimasites/qualitative-recruitment-study.php>

The researcher conducting the interview will consent the patient for an interview.

Any queries or for more information about the interviews, please contact Nicola Farrar (nicola.farrar@bristol.ac.uk) or Carmel Conefrey (carmel.conefrey@bristol.ac.uk)

QRS Documents and Forms

QRS Document	What to do with the document
Staff Information Sheet and Consent Form	<p><i>Recruiting clinician/research nurse to complete and:</i></p> <p>a) return completed consent forms to carmel.conefrey@bristol.ac.uk</p> <p>b) place a copy in the OPTIMA local site file</p> <p>c) give a copy to staff member</p>
Verbal Consent to Audio-recording	<p><i>Recruiting clinician/research nurse to complete and:</i></p> <p>a) place a copy in local Optima site file</p> <p>b) add a copy to hospital notes</p>
Patient Information Sheet OPTIMA Qualitative Recruitment Study	<p><i>Recruiting clinician/research nurse: to:</i></p> <p>a) Provide potential OPTIMA patient with a copy</p>
Consent Form – Audio-recording of consultations	<p><i>Patient to complete and recruiting clinician/research nurse to:</i></p> <p>a) place original in OPTIMA Site File</p> <p>b) give a copy to the patient</p> <p>c) add a copy to hospital notes</p>
Patient Interview Contact Details Form	<p><i>Research nurse to complete with patient and:</i></p> <p>a) phone through patient's contact no. to Nicola Farrar or Carmel Conefrey (phone no. on front cover)</p> <p>b) place original in OPTIMA Site File</p> <p>c) give a copy to the patient</p> <p>d) add a copy to hospital notes</p>
QRS Patient Registration Form (Form #QRS)	<p><i>Research nurse to:</i></p> <p>a) Complete and register the patient with Warwick Clinical Trials Unit (Mon-Fri 09:00-17:00 via telephone 02476 150402 or fax form #QRS1 to 02476 151586.</p>

Accrual Points and the QRS

A site can gain a 1 accrual point per patient. This can be obtained from **one** of the following:

- Consenting a patient to OPTIMA
- Consenting a patient to OPTIMA and audio-recording the appointment
- Making an audio-recording and/or registering and passing on contact details for a potential patient interview

Optima Qualitative Research Study

OLYMPUS DS-3500 Audio-recorder – Quick Guide

- a) **TO TURN ON:** Turn on the recorder using the **Power/Hold** switch on the back of the device (slide and hold until the Olympus logo appears on screen). Enter password provided by Carmel Conefrey.
- b) **TO RECORD:** Press the red **REC** button on the right-hand side of the device. A red LED light indicator should appear on the front upper left-hand corner of device to indicate that recording is in process.
- **AT THE BEGINNING OF AN APPOINTMENT PLEASE DICTATE:**
 - Date of recording
 - Patient's Optima Screening Log ID
 - Staff Optima Study ID
 - Location of recording (eg. Breast Clinic at Barnet Hospital)
 - Who is accompanying the participant? (alone, partner, sibling, friend, etc.)
- c) **TO PAUSE:** Press the red **REC** button again
- d) **TO RESUME RECORDING:** Press the red **REC** button again
- e) **TO STOP:** Press the **STOP** button in right-hand side of the device.
- f) **TO TURN OFF:** use the **Power/Hold** switch on the back of the device (slide and hold until the Olympus logo leaves the screen). The recordings will be automatically saved.

Recording Telephone Conversations:

- If you have an **earpiece** – plug it into the jack on the left side of the audio-recorder labelled 'MIC' – this will enable you to record telephone conversations. *(Do not use the jack labelled 'EAR' as this will not record the patient on the other end of the phone.)*

If the patient is on loudspeaker, you can record using the audio-recorder as if the patient were in the room. Do not use the earpiece.

Optima Qualitative Research Investigation

Digital Audio-recording and Data Transfer

– Full Instructions: OLYMPUS DS-3500

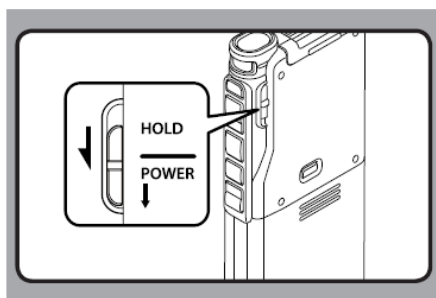
Your audio-recorder is set up and ready to use immediately.

Our intention is to make the audio-recording process as easy as possible. Should you have any queries, please do not hesitate to contact carmel.conefrey@bristol.ac.uk and 0117 3314564 and 01179287296.

GETTING STARTED

Turning on the power

While the recorder is turned off, slide the **POWER/HOLD** switch to the direction of the arrow.



• The power will be turned on.

To turn on:

Using the **Power/Hold** switch on the back of the device, slide and hold until the Olympus logo appears on screen.

Enter the numerical password onto the device (the password will be provided by Carmel Conefrey)

MAKING RECORDINGS:

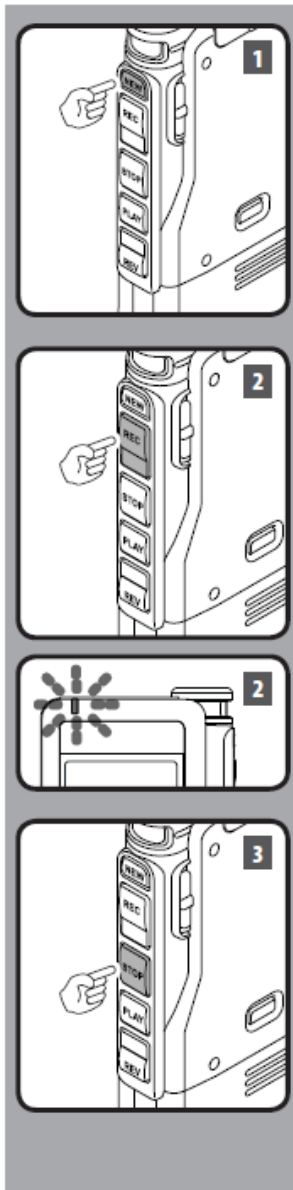
Once consent has been obtained, record each and every consultation using the audio-recorder provided.

Turn the recorder on, and at the start of the consultation please state:

- Date of recording
- Patient's Screening Log ID
- Staff ID(s)
- Location of recording (e.g. name of hospital/GP practice)
- Who is accompanying the patient (e.g. mother, daughter, friend, partner, e.t.c).
(if you forget, please provide these details at the end of the consultation)

To ensure anonymity, please avoid identifying anyone by name in the consultation.

Press the red **REC** button on the side of the device. A RED LED light indicator should appear on the front upper left-hand corner of device to indicate that recording is in process.

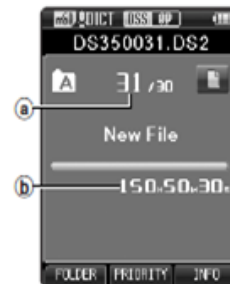


New recording

Create a new file to record in.

1 Press the **NEW** button to create a new file.

- It is possible to select the Work Type from the work type list uploaded using the ODMS software (see P.43).
- a New file number
b Remaining recording time



2 Press the **REC** button to start recording.

- The record indicator light turns on. Turn the microphone in the direction of the source to be recorded.



3 Press the **STOP** button to stop recording.

- If you want to append additional recordings to the same file, press the **REC** button again (This function will not be available if an MP3 file has been selected).



TO PAUSE: Press the red **REC** button again

TO RESUME RECORDING: Press the red **REC** button again

Please make a new recording for each patient. So ensure you press **STOP** at the end of the appointment and then press **NEW** for the next recording.

Please ensure the recording device is only used for the purposes of the Optima study, and that it is stored in a secure location when not in use.

TRANSFERRING RECORDINGS TO BRISTOL UNIVERSITY

All audio files should stay on the recorder and copies should not be created on local PCs. The files will be transferred by posting the audio-recorder to the QRS researcher at regular intervals. The QRS researcher will download the files and return the recorder.

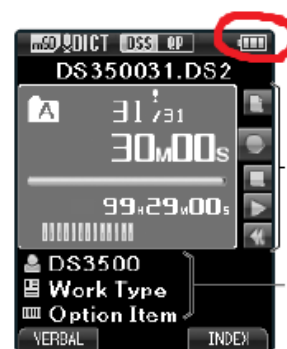
When returning the audio recorder, please enclose a completed OPTIMA Audio Recording Log and send by Special Delivery to:

Dr. Carmel Conefrey
OPTIMA Study
Research Associate for Quintet Programme
Population Health Sciences
Bristol Medical School
University of Bristol
Canyng Hall
39 Whatley Rd
Bristol
BS8 2PS

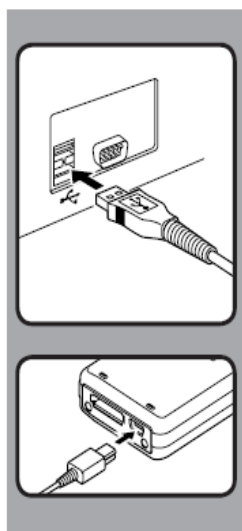
KEEPING YOUR AUDIO-RECORDER CHARGED AND READY TO USE

The recording device should be fully charged when you receive it.

To check the charge, look at the battery icon on the top left hand side. 3 bars indicate the battery is fully charged. If the battery is not charged, connect the USB port to the computer



fully



Connecting to your PC using the USB cable

- 1 Boot the PC.
- 2 Connect the USB cable to the USB port of the PC.
- 3 Connect the USB cable to the connecting terminal on the bottom of the recorder.

- [Remote (Composite)] is displayed on the recorder if the USB cable is connected.

After connecting the recorder to your PC, it will be powered through the USB cable.

When connected to a PC, the SD card and the microSD card will be recognized by the PC as separate removable disk drives.

Please **recharge** the recorder after each day of recording.

It will take approximately 2 ½ hours to fully recharge.

Contact carmel.conefrey@bristol.ac.uk and 0117 3314564 or 0117928729 for all queries.