Qualitative Recruitment Study (QRS) Patient Registration Form

Form #QRS1

Version 2.0—15 April 2019

Please complete this form for any patient who consents to participate in the Qualitative Recruitment Study (audio-recordings and/or interviews) but has not consented to be randomised into the OPTIMA study.
To register the patient, please contact Warwick Clinical Trials Unit
Mon-Fri 09:00-17:00 via telephone 02476 150402 or fax this form to 02476 151586.

QRS1.1 SITE DETAILS

Site:

Registering investigator:

QRS1.2 CALLER'S DETAILS

Name:

Telephone:

Fax:

QRS1.3 PARTICIPANT DETAILS

1. Participant initials: ☐☐☐

2. Gender: Female ☐ Male ☐

3. Age: ☐☐☐ Years

QRS1.4 CONSENT DETALS

1. Has the participant consented to have their consultations about the study audio-recorded?

☐ No, participant not approached

☐ No, participant declined

☐ Yes ⟶ If Yes, provide following details:

Date audio-recording consent form signed by participant: ☐☐ - ☐☐☐ - ☐☐☐☐ (d d - m m m - y y y y)

How many audio-recordings were made with the participant? ☐☐

2. Has the participant agreed for their contact details to be passed to an OPTIMA Qualitative Recruitment Study researcher for the purposes of being approached about taking part in an interview?

☐ No, participant not approached

☐ No, participant declined

☐ Yes

Form completed by

Printed name:

Signature:

Date signed: ☐☐ - ☐☐☐ - ☐☐☐☐ (d d - m m m - y y y y)

N.B. The individual named must be on the delegation log with the assigned responsibility to perform registration.

TO BE COMPLETED BY SITE AFTER QRS REGISTRATION

PARTICIPANT QRS REGISTRATION NUMBER: Q ☐☐☐☐

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Completion Guidelines for CRF 21 - QRS Patient Registration Form

Please complete this form only for any patient who consents to participate in the Qualitative Recruitment Study (audio-recordings and/or interviews) but has not consented to be randomised into the OPTIMA study.

If a patient consents to be randomised into the OPTIMA study AND to participate in the Qualitative Recruitment Study please do not complete this form but complete CRF 2 - Randomisation Form.

21.1. SITE DETAILS

Registering investigator

Audio recording:

If registering consent details for QRS audio-recording, the Randomising Investigator is the trial investigator who counter-signed the participant's consent form. This individual's name must be on the Site Signature and Delegation Log with the assigned responsibility to obtain informed consent.

Interviews:

If registering a patient in agreement for their contact details to be passed on to an OPTIMA QRS researcher, for the purposes of being approached about taking part in an interview, the study should be discussed by a consultant delegated to take consent for OPTIMA but this is not mandated.
If the QRS interviews were discussed with a staff member who is not a trial investigator, please document the "Registering Investigator" as the consultant responsible for the patients care, who is delegated to review / take informed consent for OPTIMA.

21.2. CALLER'S DETAILS

Caller's name

This will be the person the randomisation confirmation fax and email will be sent to and to whom queries regarding the randomisation will be directed. This individual's name must be on the Site Signature and Delegation Log with the assigned responsibility to perform registration.

21.3. PARTICIPANT DETAILS

Participant initials

Write the initials of the participant's first/given name, middle name and surname/family name. If no middle name place dash ("-") in middle box.

Form Completed by

The person completing this form **does not** need to be delegated to review / take informed consent, however, the person must be on the delegation log with the responsibility to perform registration.

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