optima
personalised treatment of breast cancer

LUNCH WITH OPTIMA
PROTOCOL V7 AND OTHER CHANGES

Rob Stein

Main Protocol v7 Changes

- Require >10% ER staining for trial eligibility
  - Patients with weakly ER-positive tumours are now ineligible
- Changes to allow more treatment flexibility, particularly for ovarian suppression
- Introduce remote consent procedure

Why require >10% ER staining for trial eligibility?

- International (US) guidelines have defined ER+ve as >1% of tumour cell staining since 2010.
- There has been concern in recent years that some tumours with 1-10% ER staining (& HER2-ve) behave like triple-negative BC.
- The US guidelines were revised in 2020 to add an "ER-low" (1-10% staining) ER+ve subcategory.
- Some ER-low tumours can have low (≤60) Prosigna scores.
  - This was not well documented when OPTIMA was designed.
- DMC advised excluding patients with ER-low tumours after a patient with a weakly ER+ve tumour had an early relapse on ET alone in 2019.
  - There are very few ER-low patients enrolled into OPTIMA.

ER testing in the UK

- There are several valid methods for testing ER-status.
- Allred (or Quick-Score) has been widely used in the UK since c.2000.
  - Allred & H-score (little-used) combine %staining & intensity
  - RCPath guidelines are being updated to %staining only

Add

% staining	0.1%-1%	>1%-10%	>10%-33%	>33%-67%	>67%-100%
score	1	2	3	4	5

Staining intensity	weak	moderate	strong
score	1	2	3

Allred score range = 0-8

Tumours with Allred score ≥3 are conventionally ER+ve; all have >1% staining

<u>All</u> tumours with Allred score ≥6 & <u>some</u> with score 4 or 5 have >10% staining

Allred score & eligibility for OPTIMA

- All patients with Allred score 6-8 tumours are eligible to join OPTIMA
- If you want to enter a patient with an Allred score 4-5 tumour, ask your pathologist for the %staining if not reported

Add

% staining	0.1%-1%	>1%-10%	>10%-33%	>33%-67%	>67%-100%
score	1	2	3	4	5

Staining intensity	weak	moderate	strong
score	1	2	3

Allred score range = 0-8

Tumours with Allred score ≥3 are conventionally ER+ve; all have >1% staining

All tumours with Allred score ≥6 & some with score 4 or 5 have >10% staining

Deferring Ovarian Suppression

- The old rule was all pre-menopausal patients were treated with OS.
  - This ensured that everybody received optimal endocrine therapy.
  - Menopause following chemo is common for women >40 who do not benefit.
- Non-use of OS is the commonest protocol non-compliance.
- Protocol v7 allows OS to be deferred for patients with amenorrhoea after chemotherapy.
  - Women who resume menses up to 2 years after trial entry should start treatment with OS (supported by evidence from the SOFT & ASTRRA trials).
  - There is no evidence of benefit for later initiation of OS.

3-monthly GnRH agonist for ovarian suppression

- Monthly goserelin (Zoladex®) is the commonly used GnRHa.
  - Triptorelin-monthly & leuprorelin-monthly have recently been licensed.
  - 3-monthly Zoladex is unlicensed as not reliable for breast cancer use.
- 3-monthly leuprorelin (Prostap®) was licensed for breast cancer use by MHRA in 2019; there is one generic, currently unlicensed.
- Prostap 3-monthly preparation is now allowed in OPTIMA.
- All current usage data is in combination with tam or as monotherapy.
  - MHRA advises monitoring E2 & FSH when combined with AI.
  - Applies also to monthly triptorelin & leuprorelin.
  - Sites are advised to check that E2 is postmenopausal after 3 months.

Other treatment changes

- Endocrine therapy started prior to trial entry:
  - Allow continuation to treatment allocation rather than stop at trial entry.
- Radiotherapy:
  - Add FAST-Forward 5-day hypofractionation schedule to approved list
  - Allow Intra-operative Radiotherapy use with proviso external beam RT is subsequently given
- Chemotherapy:
  - (F)EC has been replaced by EC & FEC as separate regimens.
  - Administrative change to allow clearer regime definition.

Remote consent for OPTIMA

Discussions about the trial and participation may be in person, by telephone or video consultation, or in any combination.

Patients must be provided with the PIS & given an opportunity to consider the trial and ask questions before consent is accepted.

1

Patient completes consent form remotely & returns to site

Consent form may be returned by:

- By post
- In person
- Scan/ photograph of full consent form sent electronically e.g. to approved email address

2

Consent form is countersigned by the investigator.

- Investigator who discussed trial should countersign form
- Investigator must be satisfied that consent is genuine

NB No requirement for same investigator & patient signature dates

3

Site completes randomisation form & contacts WCTU

- Proceed with tumour sample submission & allocated treatment

1

Initial remote verbal consent is allowed for convenience

- Used to avoid delays – e.g. postal return of signed consent form
- Limited scope: allows only randomisation & sample processing

2

Site processes remote verbal consent & contacts WCTU

- Investigator must formally document remote verbal consent
- Site completes randomisation form & contacts WCTU
- WCTU will record remote verbal consent only has been given
- Site proceeds with tumour sample submission

3

Site notifies WCTU once written consent form is completed

- Investigator who received verbal consent should countersign form (exception is allowed if unavailable)
- WCTU will release treatment allocation only when notified that full written consent has been completed

Randomisation and Sample processing can occur following either full *Written Consent*, or *Initial Remote Verbal Consent*.
Treatment Allocation requires completion of *Written Consent*.

Summary of Changes in Protocol v7

- Require >10% ER staining for trial eligibility
- Changes to allow more treatment flexibility
  - Allow initiation of ovarian suppression to be delayed for patients experiencing post-chemotherapy amenorrhoea.
  - Allow the use of licensed 3-monthly GnRH agonists for ovarian suppression in addition to monthly preparations.
  - Additional minor change to treatment – pre-allocation endocrine therapy, radiotherapy and chemotherapy
- Allow remote consent
- There is an explanation of all the changes in the SA#10 documents and a complete summary in Protocol appendix 2.

optima
personalised treatment of breast cancer

WARWICK
CLINICAL TRIALS UNIT

Data Management and Protocol changes in Substantial Amendment #10

Georgi Dotchin
OPTIMA Trial Manager, WCTU

Document updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

- OPTIMA Protocol V7.0
- OPTIMA PIS+CF V7.1
- OPTIMA Documentation Remote Consent V1.0

- OPTIMA Data Transparency Statement V2.0
- OPTIMA Patient Flyer V3.0
- OPTIMA Clinic poster V3.0

- Various QRS documents (Carmel will discuss further)

Document updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

- OPTIMA Protocol V7.0
- OPTIMA PIS+CF V7.1
- OPTIMA Documentation Remote Consent V1.0
- OPTIMA Data Transparency Statement V2.0
- OPTIMA Patient Flyer V3.0
- OPTIMA Clinic poster V3.0
- Various QRS documents (Carmel will discuss further)

Patients who are approached remotely and/or cannot provide full written consent immediately, will now be able to provide Remote Verbal Consent.

This will allow Sites to start the OPTIMA processes prior to receiving the signed consent form from the participant

Document updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

Documentation of Remote Verbal Consent for OPTIMA study

- Patients who are **unable to attend a clinic appointment in person** may give **remote verbal consent** to join OPTIMA **during a telephone or video consultation**.

- Remote verbal consent must be **received by a recruiter who is listed in the local delegation log** and who must document consent using the Documentation of Remote Verbal Consent form.

- A patient giving remote verbal consent **must be provided with the PIS** and afforded the **same opportunities to consider joining** the study and to ask questions as they would be when attending a consultation in person.

Document updates for implementation of protocol v7.0

Documentation of Remote Verbal Consent for OPTIMA study

- Participants giving remote consent may be entered into the trial and randomised by the OPTIMA Trial Office but **the Trial Office will not release details of treatment allocation until the randomising site has confirmed the receipt of written consent.**

- The patient may complete the written consent form remotely or in person.

- The **signed form**, or a scan or legible photograph of all sections of it, must be **returned to a named person at the recruiting site** using one of the following means:
  - by post
  - electronically (e.g. to an institutional email address)
  - in person

Document updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

- OPTIMA Protocol V7.0
- OPTIMA PIS+CF V7.1
- OPTIMA Documentation Remote Consent V1.0
- OPTIMA Data Transparency Statement V2.0
- OPTIMA Patient Flyer V3.0
- OPTIMA Clinic poster V3.0
- Various QRS documents (Carmel will discuss further)

The OPTIMA Trials Office do not require copies of either of these forms.

Sites should manage this process internally and complete the relevant CRFs to inform the Trials Office of which participants have consented in which way.

CRF updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

- CRF 1 – Eligibility Form
- CRF 2 – Randomisation Form
- CRF 2a – Confirmation of written consent

- Tissue Transit Form

CRF updates for implementation of protocol v7.0

- CRF 1 – Eligibility Form
- CRF 2 – Randomisation Form
- CRF 2a – Confirmation of written consent
- Tissue Transit Form

CRF updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

- CRF 1 – Eligibility Form
- CRF 2 – Randomisation Form
- CRF 2a – Confirmation of written consent
- Tissue Transit Form

For patients who provide full written consent immediately, **randomisation processes will remain the same.**
CRF 2a will not be required.

For patients who provide initial verbal consent, completion of CRF 2 will allow Sites to start the OPTIMA processes:

- Participant will be given a TNO
- Sample can be requested and sent to HSL-AD

CRF 2a must then be completed in order for WCTU to allocate the participants treatment outcome.

CRF updates for implementation of protocol v7.0

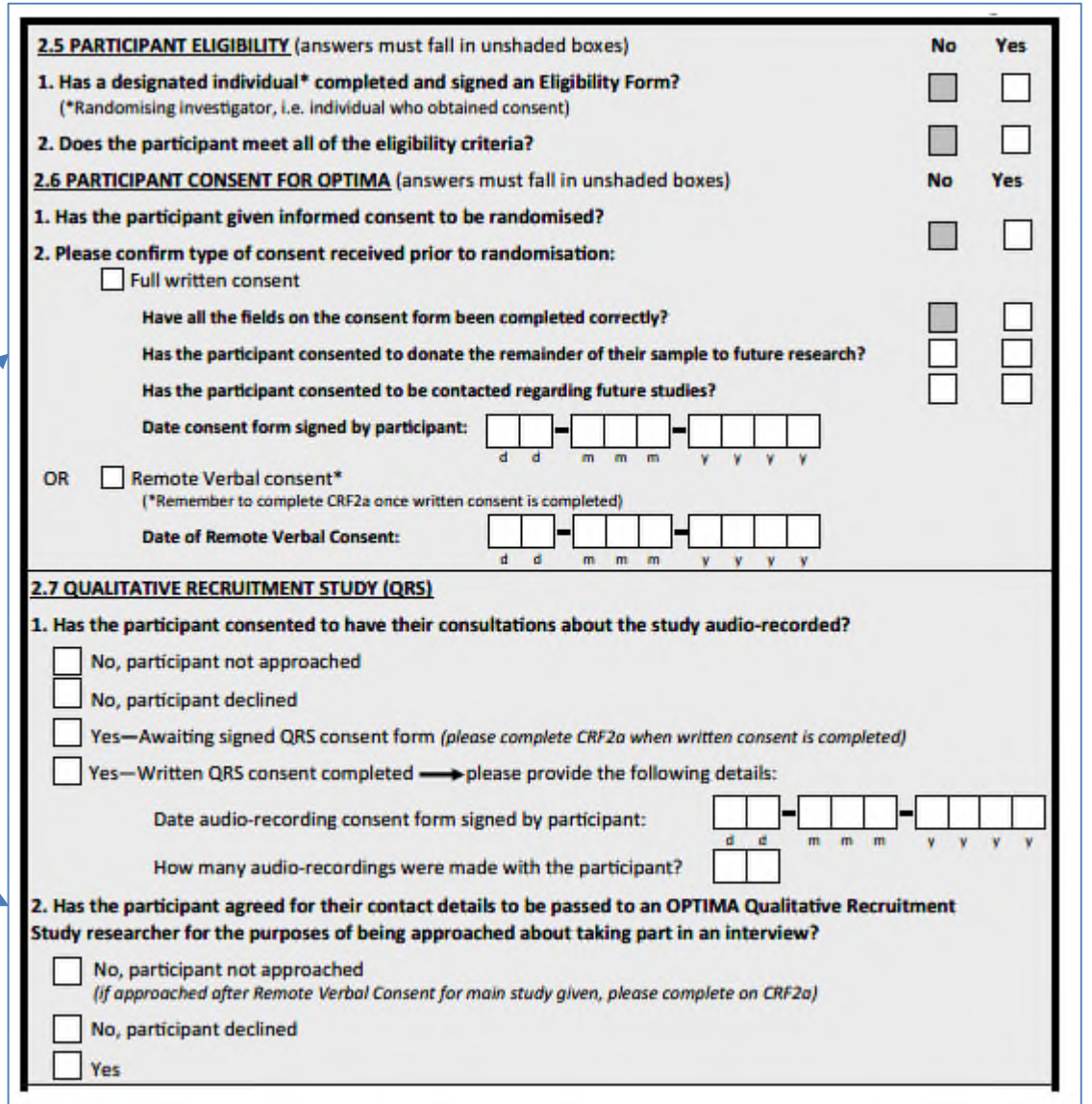
CRF 2 – Randomisation Form

- Page 1:

Chemotherapy regimens

- Page 2:

Consent section
QRS questions



2.5 PARTICIPANT ELIGIBILITY (answers must fall in unshaded boxes) — No / Yes

1. **Has a designated individual* completed and signed an Eligibility Form?**
   (*Randomising investigator, i.e. individual who obtained consent)
2. **Does the participant meet all of the eligibility criteria?**

2.6 PARTICIPANT CONSENT FOR OPTIMA (answers must fall in unshaded boxes) — No / Yes

1. **Has the participant given informed consent to be randomised?**
2. **Please confirm type of consent received prior to randomisation:**
   - ☐ Full written consent
     - **Have all the fields on the consent form been completed correctly?**
     - **Has the participant consented to donate the remainder of their sample to future research?**
     - **Has the participant consented to be contacted regarding future studies?**
     - **Date consent form signed by participant:** d d – m m m – y y y y

   OR ☐ Remote Verbal consent*
   (*Remember to complete CRF2a once written consent is completed)
   - **Date of Remote Verbal Consent:** d d – m m m – y y y y

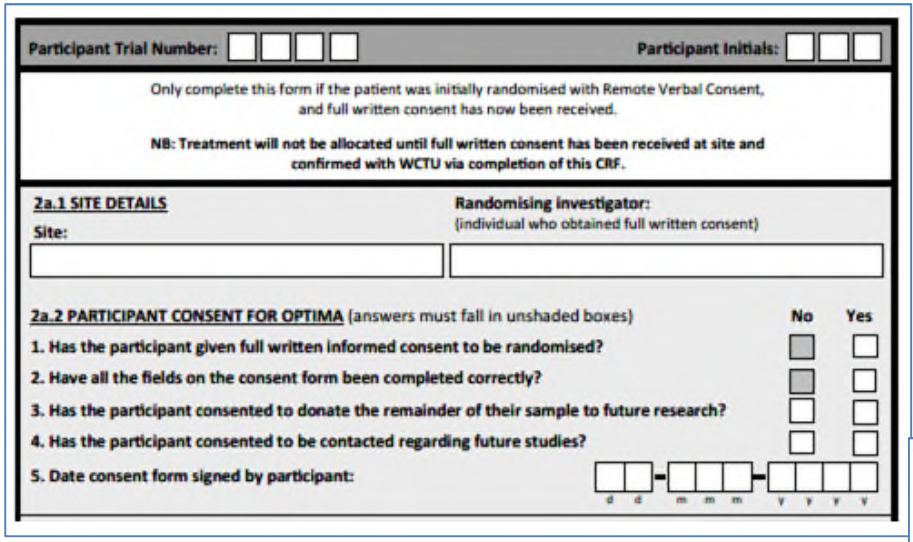
2.7 QUALITATIVE RECRUITMENT STUDY (QRS)

1. **Has the participant consented to have their consultations about the study audio-recorded?**
   - ☐ No, participant not approached
   - ☐ No, participant declined
   - ☐ Yes—Awaiting signed QRS consent form *(please complete CRF2a when written consent is completed)*
   - ☐ Yes—Written QRS consent completed ⟶ please provide the 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
     (if approached after Remote Verbal Consent for main study given, please complete on CRF2a)
   - ☐ No, participant declined
   - ☐ Yes

CRF updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

CRF 2a – Confirmation of written consent



Participant Trial Number: ☐☐☐☐ Participant Initials: ☐☐☐

Only complete this form if the patient was initially randomised with Remote Verbal Consent, and full written consent has now been received.

NB: Treatment will not be allocated until full written consent has been received at site and confirmed with WCTU via completion of this CRF.

2a.1 SITE DETAILS

Site:

Randomising investigator:
(individual who obtained full written consent)

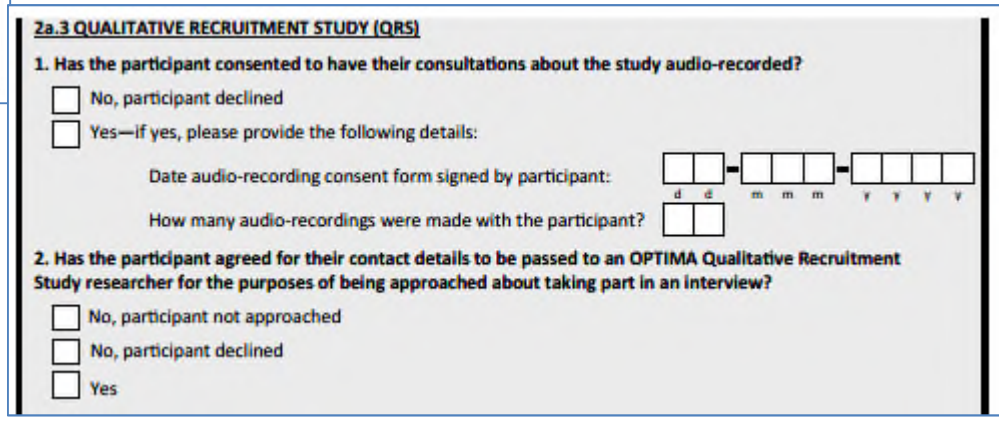
2a.2 PARTICIPANT CONSENT FOR OPTIMA (answers must fall in unshaded boxes)

	No	Yes
1. Has the participant given full written informed consent to be randomised?		☐
2. Have all the fields on the consent form been completed correctly?		☐
3. Has the participant consented to donate the remainder of their sample to future research?	☐	☐
4. Has the participant consented to be contacted regarding future studies?	☐	☐

5. Date consent form signed by participant: ☐☐-☐☐☐-☐☐☐☐ (d d - m m m - y y y y)

Consent section
QRS questions

(as per CRF 2)



2a.3 QUALITATIVE RECRUITMENT STUDY (QRS)

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

☐ No, participant declined

☐ Yes—if yes, please provide the 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

CRF updates for implementation of protocol v7.0

- CRF 1 – Eligibility Form
- CRF 2 – Randomisation Form
- CRF 2a – Confirmation of written consent
- Tissue Transit Form

CRF updates for implementation of protocol v7.0

WARWICK
CLINICAL TRIALS UNIT

- An updated ISF index and checklist will be sent to all Sites prior to the implementation date of **20th October 2020.**
- Any Sites who have already confirmed capacity and capability can implement **on receipt of this email.** Please do not implement before.
- All other Sites have until 20th October 2020, after which date the amendment will be implemented across all Sites.
- If you need more time to consider the amendment please contact us and we will assist with any queries you may have.

Other CRF updates to come…

CRF 3 – Baseline Details Form	Update to "Post-surgical endocrine therapy" questions
CRF 6 – Baseline Tumour Characteristics Form	Minor update to provide clarity
CRF 7 – Chemotherapy Form	Updated chemotherapy regimens
CRF 9 – Radiotherapy Form	Update to provide clarity and collect information on IORT
CRF 10 – Endocrine therapy Form	Update to collect Post-surgical endocrine therapy data and to facilitate delayed Ovarian suppression use
CRF 11 – Annual Follow up Form	Update to collected data on delayed Ovarian suppression
CRF 16 – Event Form	Minor layout changes
CRF 18 – Co-enrolment Form	Minor update to layout and
CRF 20 – Withdrawal Form	Update to collect data on patients who provide remote verbal consent but do not proceed to full consent

OPTIMA team contacts

WARWICK
CLINICAL TRIALS UNIT

Prof. Rob Stein

OPTIMA Chief Investigator

Email: r.stein@ucl.ac.uk

Carmel Conefrey

OPTIMA Qualitative Researcher

Tel: 0117 9287296

Email: carmel.conefrey@bristol.ac.uk

WCTU Team

Tel: 02476 151 057

Email: optima@warwick.ac.uk

optimabreaststudy.com

SA10 Changes to the Qualitative Recruitment Study

University of BRISTOL

Carmel Conefrey
Qualitative Recruitment Study Researcher

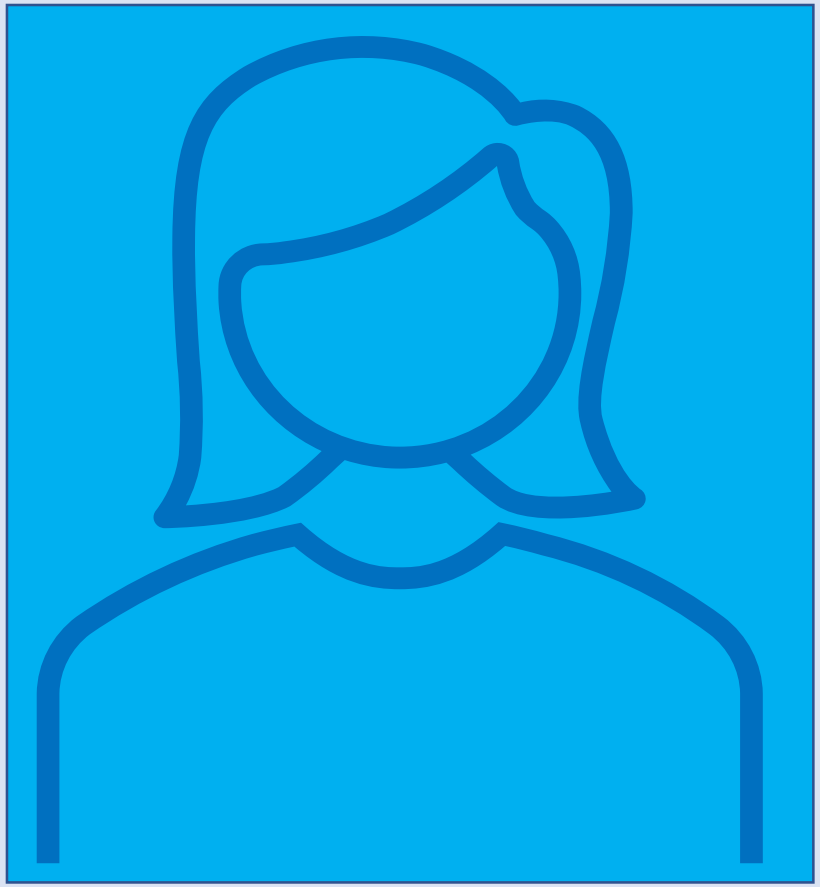
Audio-recording patient consultations

- Streamlined consent process when QRS PIS sent in advance.
- Changes mirror new consent processes in main study.
- Will send out new procedure note to audio-recording sites.

Get in touch to find out more about audio-recording:
Carmel.conefrey@bristol.ac.uk

Patient Interviews

Patients that join, patients that decline OPTIMA



Research nurse role

After the patient has made a decision about OPTIMA:

- Seek consent to pass on patient contact details to QRS researcher

- Register consent for patient details to be passed to the QRS researcher

QRS researcher role

- Contact the patient to provide more info & answer questions

- If willing, QRS researcher will:
  - Arrange interview date & time
  - Consent patient for the interview
  - Carry out interview over the phone, @ 40 minutes.

QRS Patient Interviews

	Interviews with Consenting Patients	
Scenarios	1. Patient **approached after agreed to join OPTIMA, i.e. at time of giving full written consent or Remote Verbal Consent to be randomised.**	
	1. Complete *Patient Interview Contact Details Form*.	
	3. Complete new question on the *Randomisation Form (2.7 (2))* to record patient consent for contact details to be passed to QRS researcher.	

[Print on Local Trust headed paper]

optima

Patient Interview Contact Details Form
OPTIMA Qualitative Recruitment Study

Part of the OPTIMA Qualitative Recruitment Study involves interviewing patients to explore their views on the OPTIMA Study and how patients arrived at their decision about whether or not to take part in the study

In completing this form, you are consenting for your contact details to be passed on to a Qualitative Recruitment Study researcher at the University of Bristol. The QRS researcher may approach you about setting up an interview to discuss the OPTIMA Study.

Title: (please circle) Mr / Mrs / Ms / Miss / Dr

First name:

Surname:

Telephone number:

Email address (optional):

Thank you.

The OPTIMA Trial Office will register completion of this form using non-personally identifiable information.

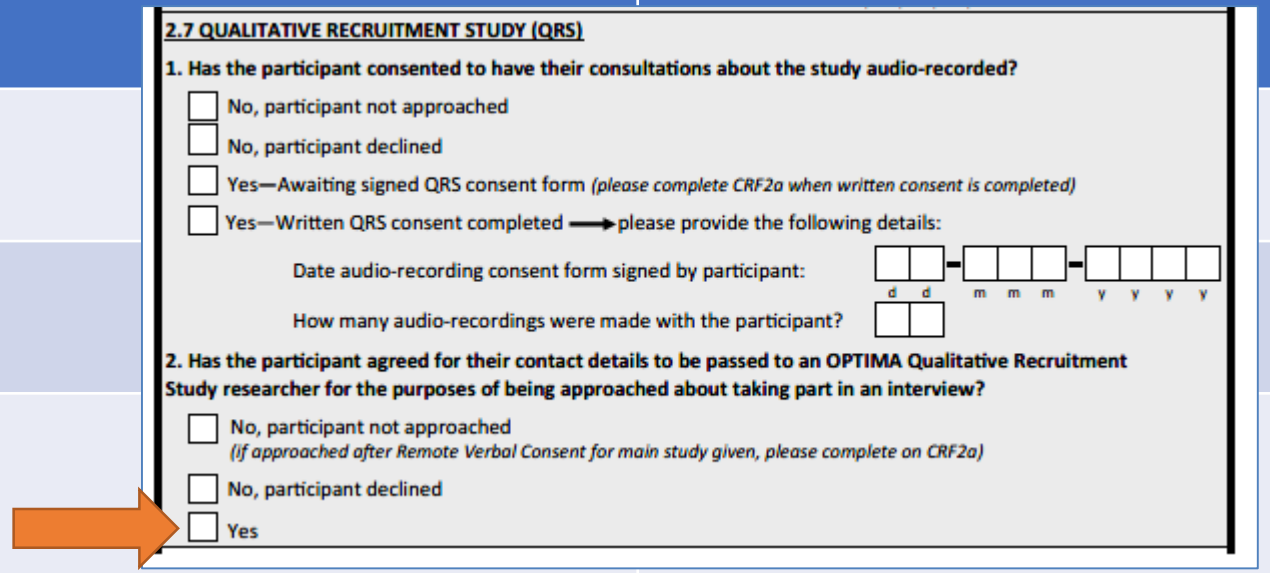
To be completed by hospital

If the patient consented to OPTIMA, please note **Participant trial number (TNO):**

If the patient declined OPTIMA, please note- **QRS Patient Registration number:** *[begins with a 'Q']*

QRS Patient Interviews

	Interviews with Consenting Patients		Patients that decline
Scenarios	1. Patient **approached after agreed to join OPTIMA, i.e. at time of giving full written consent or Remote Verbal Consent to be randomised.**		
	1. Complete *Patient Interview Contact Details Form*.		
QRS PIS	**2. Provide** PIS.		
	3. Complete new question on the *Randomisation Form* to record patient consent for contact details to be passed to QRS researcher.		



2.7 QUALITATIVE RECRUITMENT STUDY (QRS)

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

- ☐ No, participant not approached
- ☐ No, participant declined
- ☐ Yes—Awaiting signed QRS consent form *(please complete CRF2a when written consent is completed)*
- ☐ Yes—Written QRS consent completed → please provide the 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? ☐☐

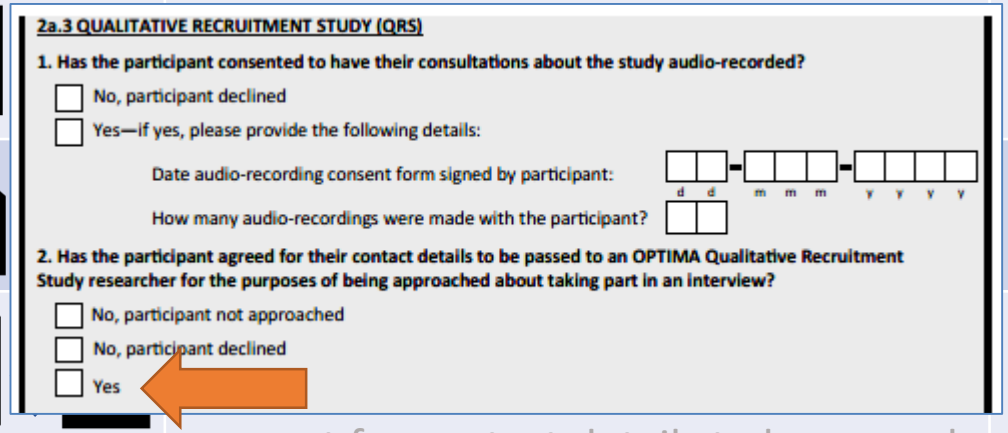
2. Has the participant agreed for their contact details to be passed to an OPTIMA Qualitative Recruitment Study researcher for the purposes of being approached about taking part in an interview?

- ☐ No, participant not approached
  (if approached after Remote Verbal Consent for main study given, please complete on CRF2a)
- ☐ No, participant declined
- ☐ Yes

QRS Patient Interviews

	Interviews with Consenting Patients		Patients that decline
Scenarios	1. Patient **approached after agreed to join OPTIMA, i.e. at time of giving full written consent or Remote Verbal Consent to be randomised.**		
	**1. Complete** *Patient Interview Contact Details Form*.		
 QRS PIS	**2. Provide** PIS.		
	**3. Complete new** question on the *Randomisation Form* to record patient consent for contact details to be passed to QRS researcher.		
	**4. Add** TNO to *Patient Interview Contact Details Form and* **contact** QRS researcher to pass on contact details.		

QRS Patient Interviews

Scenarios	Interviews with Consenting Patients		Patients that decline
	1. Patient **approached after agreed to join OPTIMA, i.e. at time of giving full written consent or Remote Verbal Consent to be randomised.**	2. Patient **approached after Remote Verbal Consent** for main study.	
		Process the same except for no. 3.	
	consent for contact details to be passed to QRS researcher.	3. **Record** consent on *CRF2a – Confirmation of Written Consent*.	
	4. Add TNO to *Patient Interview Contact Details Form and* **contact** QRS researcher to pass on contact details.		

2a.3 QUALITATIVE RECRUITMENT STUDY (QRS)

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

- ☐ No, participant declined
- ☐ Yes—if yes, please provide the 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

QRS Patient Interviews

Scenarios	Interviews with Consenting Patients		Patients that decline
	1. Patient **approached after agreed to join OPTIMA, i.e. at time of giving full written consent or Remote Verbal Consent to be randomised.**	2. Patient **approached after Remote Verbal Consent** for main study.	3. For patients that decline the study
	1. Complete *Pa… Details Form*.	…or no. 3.	**1. Complete** *Patient Interview Contact Details Form*.
QRS PIS	**2. Provide** PIS.		**2. Provide** PIS.
	3. Complete ne… *Randomisation* consent for con… to QRS research	*2a – …onsent.*	3. **Complete** QRS Patient Registration Form #QRS1 and register with Warwick CTU.
	4. Add TNO to *… Details Form an…* researcher to pass on contact details.		

optima

Qualitative Recruitment Study (QRS) Patient Registration Form

Form #QRS1

Version 1.0 — 21 Dec 2016

Page 1 of 1

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.

21.1 SITE DETAILS

Site: | Registering investigator: (individual who obtained consent)

21.2 CALLER'S DETAILS

Name: | Telephone: | Fax:

21.3 PARTICIPANT DETAILS

1. Participant initials: ☐☐☐
2. Gender: Female ☐ Male ☐
3. Age: ☐☐☐ Years

21.4 CONSENT DETALS

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

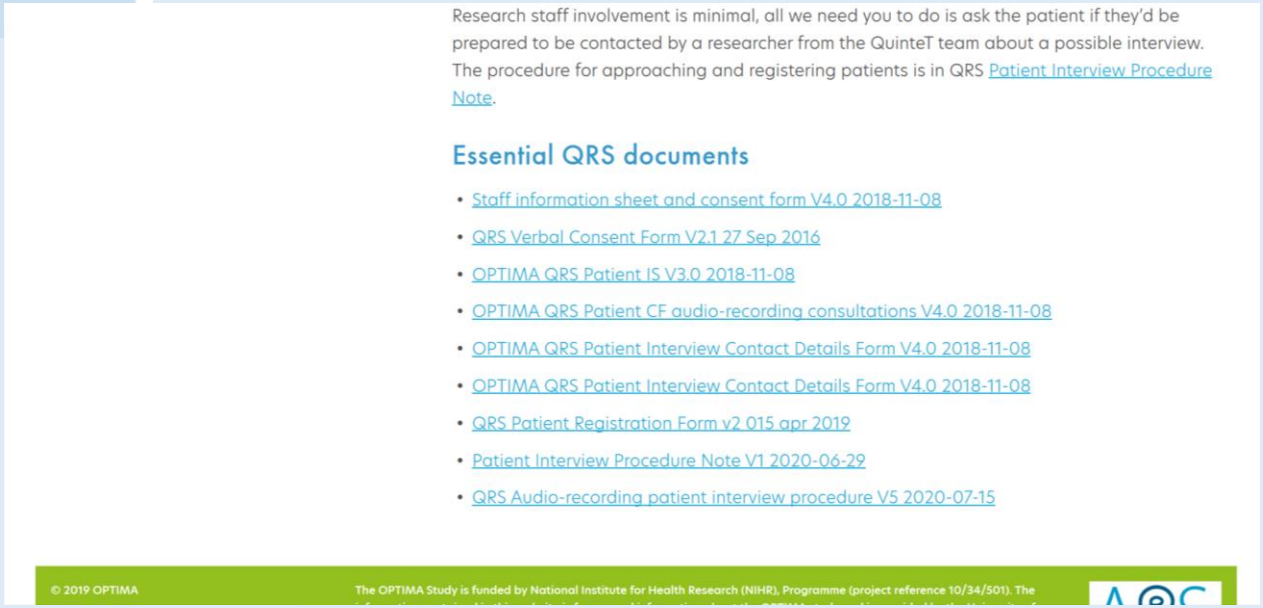
QRS Patient Interviews

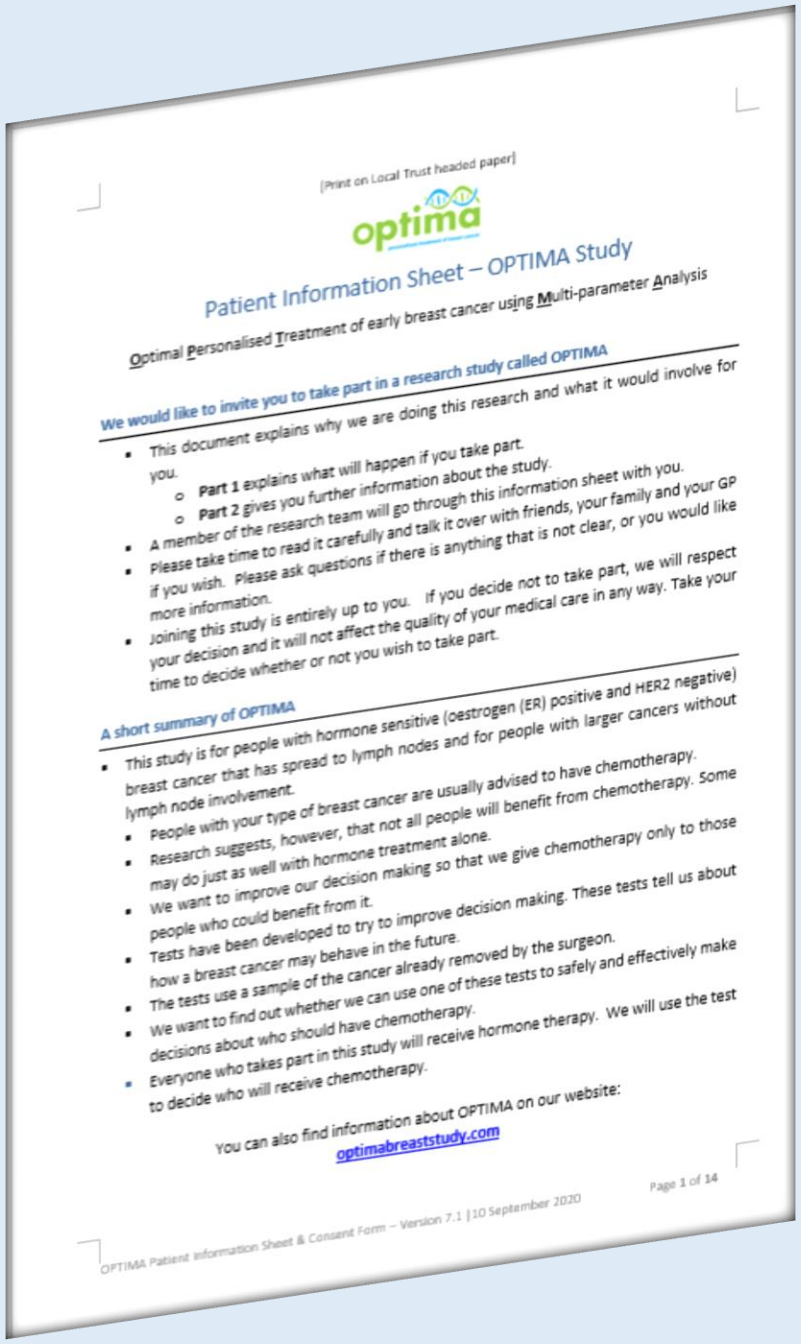
	Interviews with Consenting Patients		Patients that decline
Scenarios	1. Patient **approached after agreed to join OPTIMA, i.e. at time of giving full written consent or Remote Verbal Consent to be randomised.**	2. Patient **approached after Remote Verbal Consent** for main study.	3. For patients that decline the study
	**1. Complete** *Patient Interview Contact Details Form*.	Process the same except for no. 3.	**1. Complete** *Patient Interview Contact Details Form*.
 QRS PIS	**2. Provide** PIS.		**2. Provide** PIS.
	**3. Complete new** question on the *Randomisation Form* to record patient consent for contact details to be passed to QRS researcher.	3. **Record** consent on *CRF2a – Confirmation of Written Consent*.	3. **Complete** QRS Patient Registration Form #QRS1 and register with Warwick CTU.
	**4. Add** TNO to *Patient Interview Contact Details Form and* **contact** QRS researcher to pass on contact details.		**4. Add** the QRS Registration no. to *Patient Interview Contact Details Form* **contact** QRS researcher to pass on contact details.

For information about audio-recording and patient interviews & current forms:
optimabreaststudy.com

carmel.conefrey@bristol.ac.uk

nicola.farrar@bristol.ac.uk





[Print on Local Trust headed paper]

optima

Patient Information Sheet – OPTIMA Study

Optimal **P**ersonalised **T**reatment of early breast cancer usi**n**g **M**ulti-parameter **A**nalysis

We would like to invite you to take part in a research study called OPTIMA

- This document explains why we are doing this research and what it would involve for you.
  - **Part 1** explains what will happen if you take part.
  - **Part 2** gives you further information about the study.
- A member of the research team will go through this information sheet with you.
- Please take time to read it carefully and talk it over with friends, your family and your GP if you wish. Please ask questions if there is anything that is not clear, or you would like more information.
- Joining this study is entirely up to you. If you decide not to take part, we will respect your decision and it will not affect the quality of your medical care in any way. Take your time to decide whether or not you wish to take part.

A short summary of OPTIMA

- This study is for people with hormone sensitive (oestrogen (ER) positive and HER2 negative) breast cancer that has spread to lymph nodes and for people with larger cancers without lymph node involvement.
- People with your type of breast cancer are usually advised to have chemotherapy.
- Research suggests, however, that not all people will benefit from chemotherapy. Some may do just as well with hormone treatment alone.
- We want to improve our decision making so that we give chemotherapy only to those people who could benefit from it.
- Tests have been developed to try to improve decision making. These tests tell us about how a breast cancer may behave in the future.
- The tests use a sample of the cancer already removed by the surgeon.
- We want to find out whether we can use one of these tests to safely and effectively make decisions about who should have chemotherapy.
- Everyone who takes part in this study will receive hormone therapy. We will use the test to decide who will receive chemotherapy.

You can also find information about OPTIMA on our website:
optimabreaststudy.com

Patient Information Sheet

- More informing – where sent in advance
- With Independent Cancer Patient Voice