Welcome to...

optima
personalised treatment of breast cancer

WARWICK
CLINICAL TRIALS UNIT

'Lunch with OPTIMA'

The meeting will start at 12:30

- Please mute your microphone
- Please turn off your camera
- "Raise your hand" for attention **or** type any questions in the conversation window

UCL
University of BRISTOL
NIHR | National Institute for Health Research
WARWICK
CLINICAL TRIALS UNIT

optima
personalised treatment of breast cancer

WARWICK
CLINICAL TRIALS UNIT

Lunch with OPTIMA

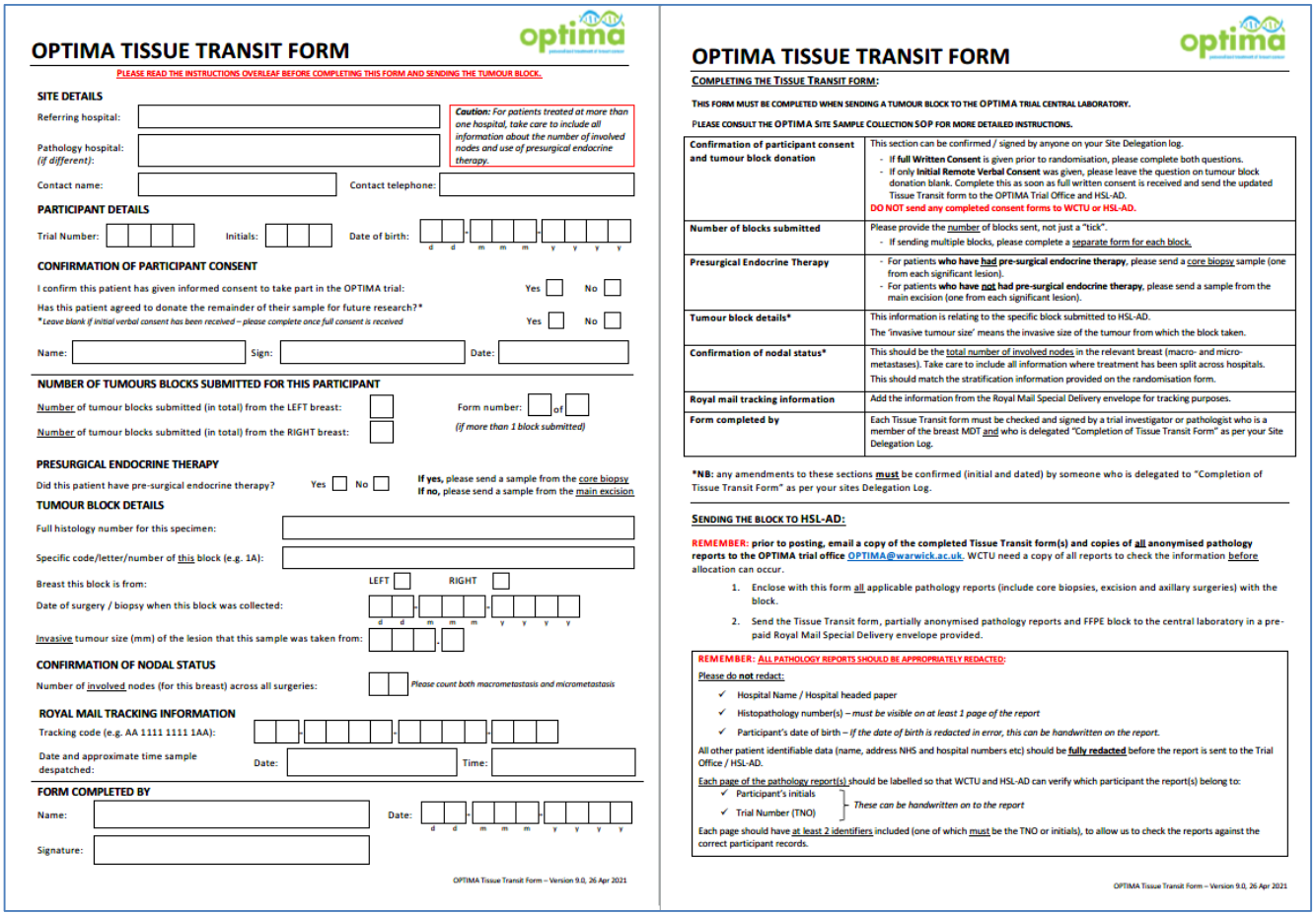
Tissue Transit form training

February 2024

OPTIMA Tissue Transit form v10.0

Page 1

Contains all the information the central lab needs for prosigna testing



OPTIMA TISSUE TRANSIT FORM

PLEASE READ THE INSTRUCTIONS OVERLEAF BEFORE COMPLETING THIS FORM AND SENDING THE TUMOUR BLOCK.

SITE DETAILS

Referring hospital:

Pathology hospital: *(if different)*:

Contact name: Contact telephone:

Caution: *For patients treated at more than one hospital, take care to include all information about the number of involved nodes and use of presurgical endocrine therapy.*

PARTICIPANT DETAILS

Trial Number: Initials: Date of birth: d d - m m - y y y y

CONFIRMATION OF PARTICIPANT CONSENT

I confirm this patient has given informed consent to take part in the OPTIMA trial: Yes ☐ No ☐

Has this patient agreed to donate the remainder of their sample for future research?*
**Leave blank if initial verbal consent has been received – please complete once full consent is received*
Yes ☐ No ☐

Name: Sign: Date:

NUMBER OF TUMOURS BLOCKS SUBMITTED FOR THIS PARTICIPANT

Number of tumour blocks submitted (in total) from the LEFT breast:

Number of tumour blocks submitted (in total) from the RIGHT breast:

Form number: of
(if more than 1 block submitted)

PRESURGICAL ENDOCRINE THERAPY

Did this patient have pre-surgical endocrine therapy? Yes ☐ No ☐

If yes, please send a sample from the core biopsy
If no, please send a sample from the main excision

TUMOUR BLOCK DETAILS

Full histology number for this specimen:

Specific code/letter/number of this block (e.g. 1A):

Breast this block is from: LEFT ☐ RIGHT ☐

Date of surgery / biopsy when this block was collected: d d - m m - y y y y

Invasive tumour size (mm) of the lesion that this sample was taken from: . ☐

CONFIRMATION OF NODAL STATUS

Number of involved nodes (for this breast) across all surgeries:
Please count both macrometastasis and micrometastasis

ROYAL MAIL TRACKING INFORMATION

Tracking code (e.g. AA 1111 1111 1AA):

Date and approximate time sample despatched: Date: Time:

FORM COMPLETED BY

Name: Date: d d - m m - y y y y

Signature:

OPTIMA Tissue Transit Form – Version 9.0, 26 Apr 2021

OPTIMA TISSUE TRANSIT FORM

COMPLETING THE TISSUE TRANSIT FORM:

THIS FORM MUST BE COMPLETED WHEN SENDING A TUMOUR BLOCK TO THE OPTIMA TRIAL CENTRAL LABORATORY.

PLEASE CONSULT THE OPTIMA SITE SAMPLE COLLECTION SOP FOR MORE DETAILED INSTRUCTIONS.

Confirmation of participant consent and tumour block donation	This section can be confirmed / signed by anyone on your Site Delegation log. - If **full Written Consent** is given prior to randomisation, please complete both questions. - If only **Initial Remote Verbal Consent** was given, please leave the question on tumour block donation blank. Complete this as soon as full written consent is received and send the updated Tissue Transit form to the OPTIMA Trial Office and HSL-AD. **DO NOT send any completed consent forms to WCTU or HSL-AD.**
Number of blocks submitted	Please provide the number of blocks sent, not just a "tick". - If sending multiple blocks, please complete a separate form for each block.
Presurgical Endocrine Therapy	- For patients **who have had pre-surgical endocrine therapy**, please send a core biopsy sample (one from each significant lesion). - For patients **who have not had pre-surgical endocrine therapy**, please send a sample from the main excision (one from each significant lesion).
Tumour block details*	This information is relating to the specific block submitted to HSL-AD. The 'invasive tumour size' means the invasive size of the tumour from which the block taken.
Confirmation of nodal status*	This should be the total number of involved nodes in the relevant breast (macro- and micro-metastases). Take care to include all information where treatment has been split across hospitals. This should match the stratification information provided on the randomisation form.
Royal mail tracking information	Add the information from the Royal Mail Special Delivery envelope for tracking purposes.
Form completed by	Each Tissue Transit form must be checked and signed by a trial investigator or pathologist who is a member of the breast MDT and who is delegated "Completion of Tissue Transit Form" as per your Site Delegation Log.

***NB:** any amendments to these sections **must** be confirmed (initial and dated) by someone who is delegated to "Completion of Tissue Transit Form" as per your sites Delegation Log.

SENDING THE BLOCK TO HSL-AD:

REMEMBER: prior to posting, email a copy of the completed Tissue Transit form(s) and copies of all anonymised pathology reports to the OPTIMA trial office OPTIMA@warwick.ac.uk. WCTU need a copy of all reports to check the information before allocation can occur.

1. Enclose with this form all applicable pathology reports (include core biopsies, excision and axillary surgeries) with the block.
2. Send the Tissue Transit form, partially anonymised pathology reports and FFPE block to the central laboratory in a pre-paid Royal Mail Special Delivery envelope provided.

REMEMBER: ALL PATHOLOGY REPORTS SHOULD BE APPROPRIATELY REDACTED:

Please do **not** redact:

- ✓ Hospital Name / Hospital headed paper
- ✓ Histopathology number(s) – *must be visible on at least 1 page of the report*
- ✓ Participant's date of birth – *If the date of birth is redacted in error, this can be handwritten on the report.*

All other patient identifiable data (name, address NHS and hospital numbers etc) should be **fully redacted** before the report is sent to the Trial Office / HSL-AD.

Each page of the pathology report(s) should be labelled so that WCTU and HSL-AD can verify which participant the report(s) belong to:

- ✓ Participant's initials
- ✓ Trial Number (TNO)

These can be handwritten on to the report

Each page should have at least 2 identifiers included (one of which must be the TNO or initials), to allow us to check the reports against the correct participant records.

OPTIMA Tissue Transit Form – Version 9.0, 26 Apr 2021

Page 2

Contains guidance on how to complete the Tissue Transit form

Section 1:

Site details and Patient Information

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PLEASE READ THE INSTRUCTIONS OVERLEAF BEFORE COMPLETING THIS FORM AND SENDING THE TUMOUR BLOCK.

SITE DETAILS

Referring hospital:

Pathology hospital: *(if different)*:

Caution: *For patients treated at more than one hospital, take care to include all information about the number of involved nodes and use of presurgical endocrine therapy.*

Contact name: Contact telephone:

PARTICIPANT DETAILS

Trial Number: Initials: Date of birth: d d - m m m - y y y y

CONFIRMATION OF PARTICIPANT CONSENT

I confirm this patient has given informed consent to take part in the OPTIMA trial: Yes No

Has this patient agreed to donate the remainder of their sample for future research?* Yes No

**Leave blank if initial verbal consent has been received – please complete once full consent is received*

Name: Sign: Date:

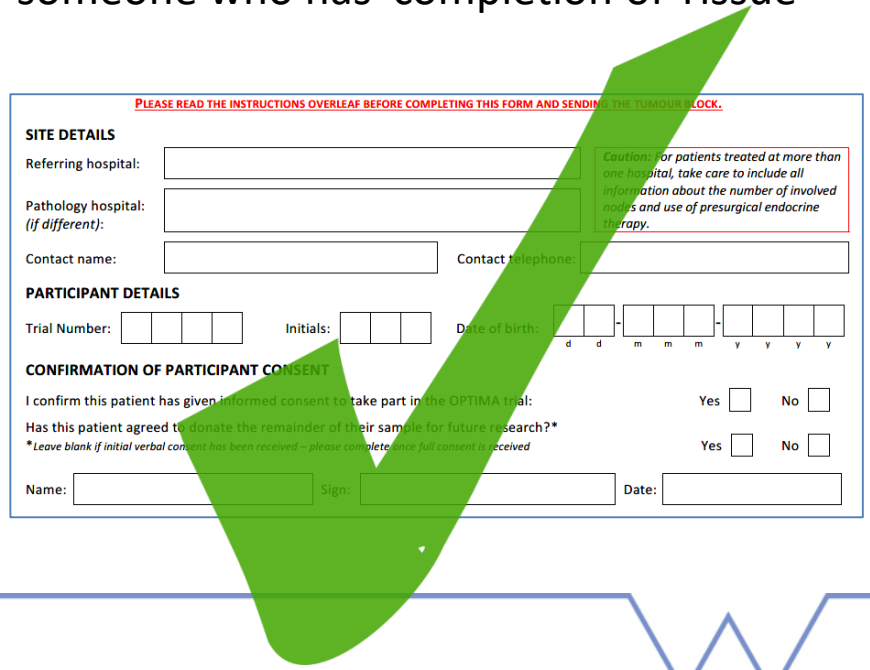
Section 1: Site details and Patient Information

- Referring Hospital: Should be the Site where the patient was randomised
- Pathology Hospital: Only needs to be completed if the sample has been sent to HSL-AD from a different Site (i.e. pathology dept. is in another hospital)
- Contact Name: This is the person we will contact if we need further guidance. Ordinarily, this would be the Main Site Contact.
- Patient Details: These are critical for checking the paperwork is for the correct patient.
- Confirmation of consent: This section is confirmation that a consent form has been received (either full written or initial verbal consent). It is not, itself, consent so does not need to be signed by someone who is permitted to take consent for OPTIMA.
- Confirmation of consent: If the patient has given initial verbal consent, the second consent statement can be left blank until full consent is received.

Section 1: Site details and Patient Information

It is not unusual for the Main Site Contact to complete this section of the form before passing over to Pathology to complete the rest of the information.

Changes to this section can be confirmed / corrected by anyone on your Sites Delegation log and do not need to be countersigned by someone who has 'completion of Tissue Transit form' delegated to them.



PLEASE READ THE INSTRUCTIONS OVERLEAF BEFORE COMPLETING THIS FORM AND SENDING THE TUMOUR BLOCK.

SITE DETAILS

Referring hospital:

Pathology hospital: *(if different)*:

Caution: For patients treated at more than one hospital, take care to include all information about the number of involved nodes and use of presurgical endocrine therapy.

Contact name:

Contact telephone:

PARTICIPANT DETAILS

Trial Number:

Initials:

Date of birth: d d - m m m - y y y y

CONFIRMATION OF PARTICIPANT CONSENT

I confirm this patient has given informed consent to take part in the OPTIMA trial: Yes No

Has this patient agreed to donate the remainder of their sample for future research?* Yes No

**Leave blank if initial verbal consent has been received – please complete once full consent is received*

Name: Sign: Date:

Section 2:

Tumour Sample details

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NUMBER OF TUMOURS BLOCKS SUBMITTED FOR THIS PARTICIPANT

Number of tumour blocks submitted (in total) from the LEFT breast: ☐

Number of tumour blocks submitted (in total) from the RIGHT breast: ☐

Form number: ☐ of ☐

(if more than 1 block submitted)

PRESURGICAL ENDOCRINE THERAPY

Did this patient have pre-surgical endocrine therapy? Yes ☐ No ☐

If yes, please send a sample from the core biopsy
If no, please send a sample from the main excision

TUMOUR BLOCK DETAILS

Full histology number for this specimen: ☐

Specific code/letter/number of this block (e.g. 1A): ☐

Breast this block is from: LEFT ☐ RIGHT ☐

Date of surgery / biopsy when this block was collected: ☐☐-☐☐☐-☐☐☐☐ (d d m m m y y y y)

Invasive tumour size (mm) of the lesion that this sample was taken from: ☐☐☐.☐

CONFIRMATION OF NODAL STATUS

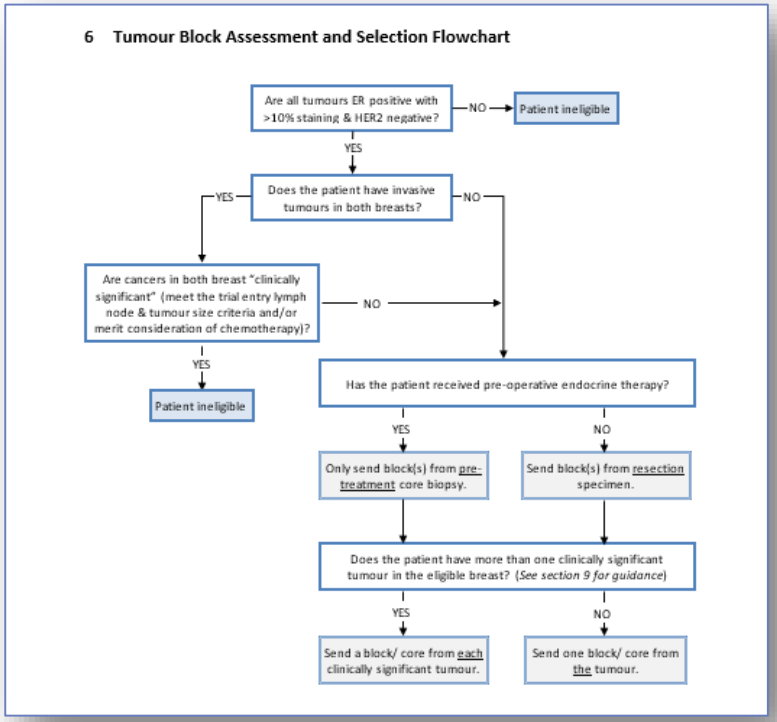
Number of involved nodes (for this breast) across all surgeries: ☐☐ *Please count both macrometastasis and micrometastasis*

Section 2: Tumour Sample details

To determine which samples should be sent to OPTIMA, you will need a pathologist or a Trial Investigator to review the reports and confirm.

There is an SOP which can help Sites identify which samples to send: OPTIMA Site Sample Collection SOP v8.0_2021-07-27

Section 6 of this document contains a flow chart.



Section 2: Tumour Sample details

- Number of tumour blocks submitted for this patient: You should confirm the number of samples sent, and complete the appropriate box depending on which breast the sample(s) are from.

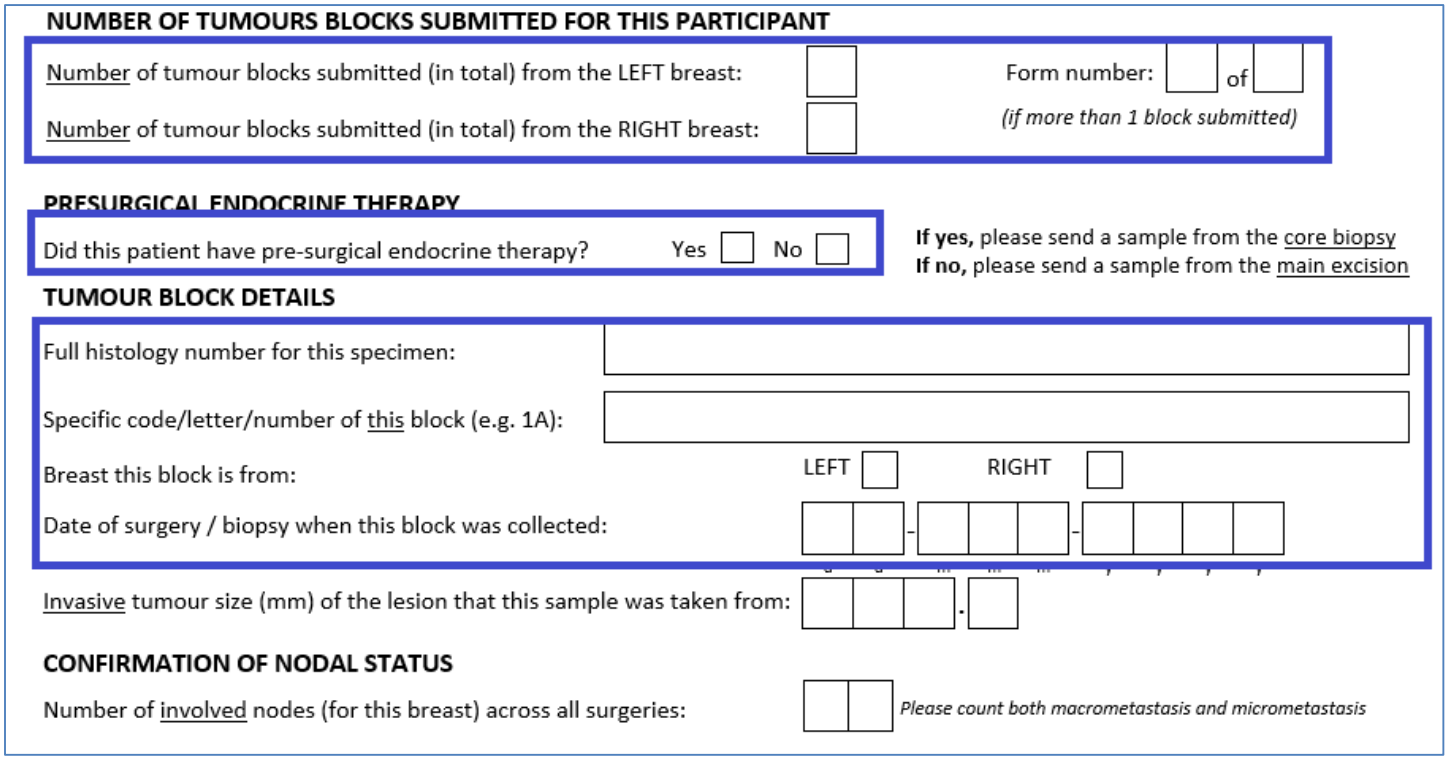
- Pre-surgical Endocrine therapy: This is a critical check. It enables us to ensure that the correct sample is sent to the lab so if you don't know, you need to find out.

- Tumour block details: The information within this section is used to confirm that the correct block has been sent to HSL-AD, as well as checking eligibility.
  - **The invasive tumour size is also critical as this figure is used for the prosigna assay.**

- Confirmation of Nodal Status: This should be the total number of involved nodes in the relevant breast.
  - **The number of involved nodes is also critical as this figure is used for the prosigna assay.**

Section 2: Tumour Sample details

Information required for eligibility checks / checking the sample is suitable:



NUMBER OF TUMOURS BLOCKS SUBMITTED FOR THIS PARTICIPANT

Number of tumour blocks submitted (in total) from the LEFT breast: ☐

Number of tumour blocks submitted (in total) from the RIGHT breast: ☐

Form number: ☐ of ☐

(if more than 1 block submitted)

PRESURGICAL ENDOCRINE THERAPY

Did this patient have pre-surgical endocrine therapy? Yes ☐ No ☐

If yes, please send a sample from the core biopsy
If no, please send a sample from the main excision

TUMOUR BLOCK DETAILS

Full histology number for this specimen:

Specific code/letter/number of this block (e.g. 1A):

Breast this block is from: LEFT ☐ RIGHT ☐

Date of surgery / biopsy when this block was collected: ☐☐-☐☐☐-☐☐☐☐

Invasive tumour size (mm) of the lesion that this sample was taken from: ☐☐☐.☐

CONFIRMATION OF NODAL STATUS

Number of involved nodes (for this breast) across all surgeries: ☐☐ *Please count both macrometastasis and micrometastasis*

Section 2: Tumour Sample details

Information required for the prosigna assay:

NUMBER OF TUMOURS BLOCKS SUBMITTED FOR THIS PARTICIPANT

Number of tumour blocks submitted (in total) from the LEFT breast: ☐

Number of tumour blocks submitted (in total) from the RIGHT breast: ☐

Form number: ☐ of ☐

(if more than 1 block submitted)

PRESURGICAL ENDOCRINE THERAPY

Did this patient have pre-surgical endocrine therapy? Yes ☐ No ☐

If yes, please send a sample from the core biopsy
If no, please send a sample from the main excision

TUMOUR BLOCK DETAILS

Full histology number for this specimen: ☐

Specific code/letter/number of this block (e.g. 1A): ☐

Breast this block is from: LEFT ☐ RIGHT ☐

Date of surgery / biopsy when this block was collected: ☐☐-☐☐☐-☐☐☐☐ (d d - m m m - y y y y)

Invasive tumour size (mm) of the lesion that this sample was taken from: ☐☐☐.☐

CONFIRMATION OF NODAL STATUS

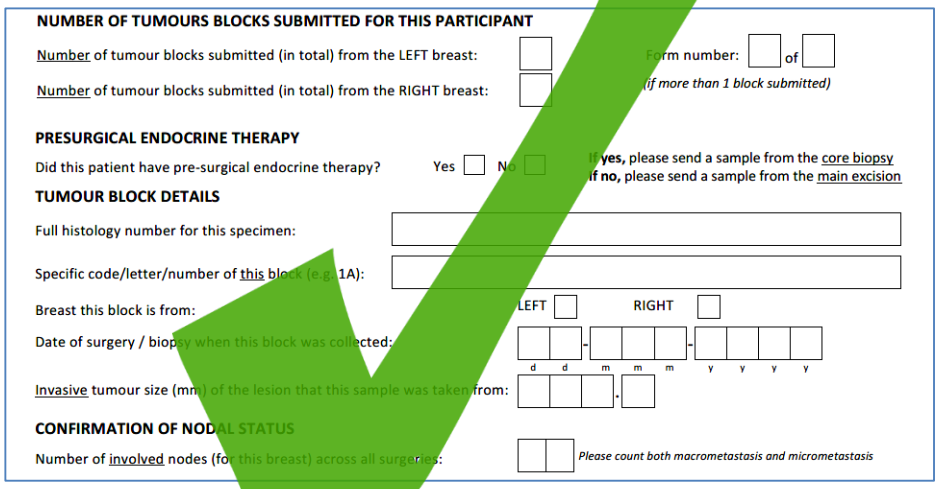
Number of involved nodes (for this breast) across all surgeries: ☐☐ *Please count both macrometastasis and micrometastasis*

Section 2: Tumour Sample details

It is not unusual for the Main Site Contact to complete some of this section of the form before passing over to Pathology however these data items are critical for the outcome of the prosigna test.

As long as an appropriately delegated individual checks and signs the form off, we are happy.

Changes to the 'tumour block details' section must be countersigned by someone who has 'completion of Tissue Transit form' delegated to them.



NUMBER OF TUMOURS BLOCKS SUBMITTED FOR THIS PARTICIPANT

Number of tumour blocks submitted (in total) from the LEFT breast:

Number of tumour blocks submitted (in total) from the RIGHT breast:

Form number: of *(if more than 1 block submitted)*

PRESURGICAL ENDOCRINE THERAPY

Did this patient have pre-surgical endocrine therapy? Yes No

If **yes,** please send a sample from the core biopsy
if no, please send a sample from the main excision

TUMOUR BLOCK DETAILS

Full histology number for this specimen:

Specific code/letter/number of this block (e.g. 1A):

Breast this block is from: LEFT RIGHT

Date of surgery / biopsy when this block was collected: d d m m m y y y y

Invasive tumour size (mm) of the lesion that this sample was taken from:

CONFIRMATION OF NODAL STATUS

Number of involved nodes (for this breast) across all surgeries: *Please count both macrometastasis and micrometastasis*

Section 3:

Sample tracking and Sign off

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ROYAL MAIL TRACKING INFORMATION

Tracking code (e.g. AA 1111 1111 1AA):	__ __ - __ __ __ __ - __ __ __ __ - __ __ __			
Date and approximate time sample despatched:	Date:		Time:	

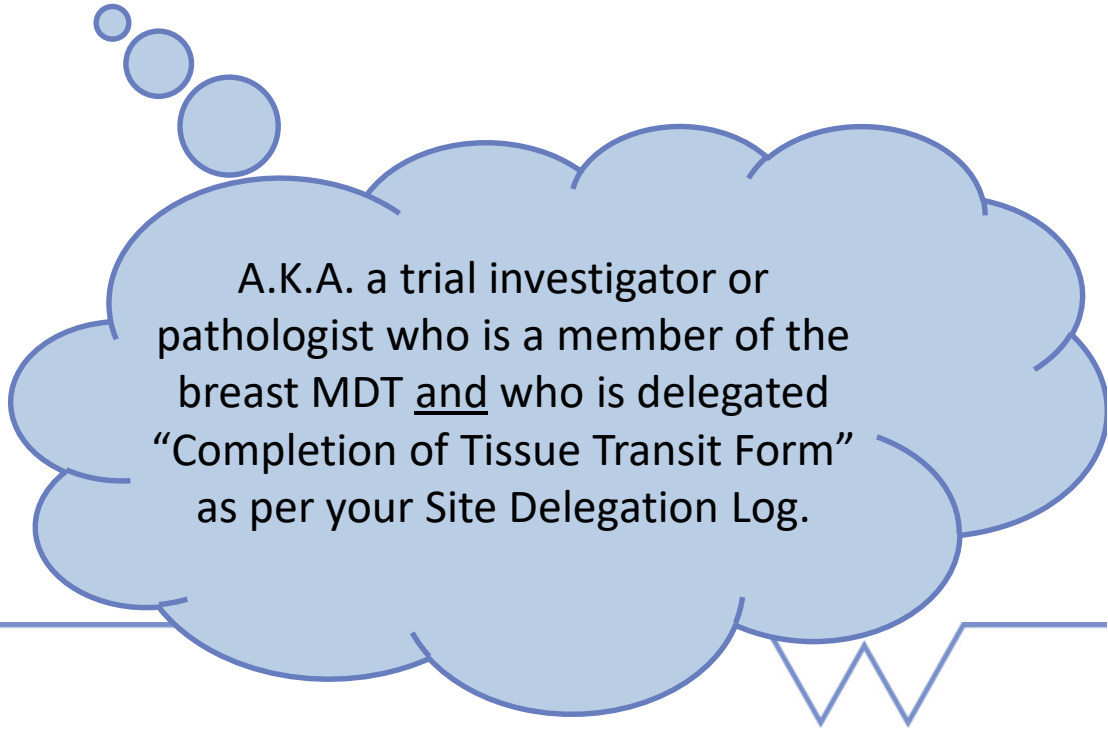
FORM COMPLETED BY

Name:		Date:	d d - m m m - y y y y
Signature:			

Section 3: Sample tracking and Sign off

- Royal Mail tracking information (UK only): All Tissue Transit Envelopes provided to Sites include Royal Mail tracking information. It is good practice to include this information on the Tissue Transit form as it allows us to track the package if it were to go missing.

- Form Completed by: Once the Tissue Transit form is complete, the whole form must be checked and signed by a suitably trained individual.



Page 2:

Completion Guidance

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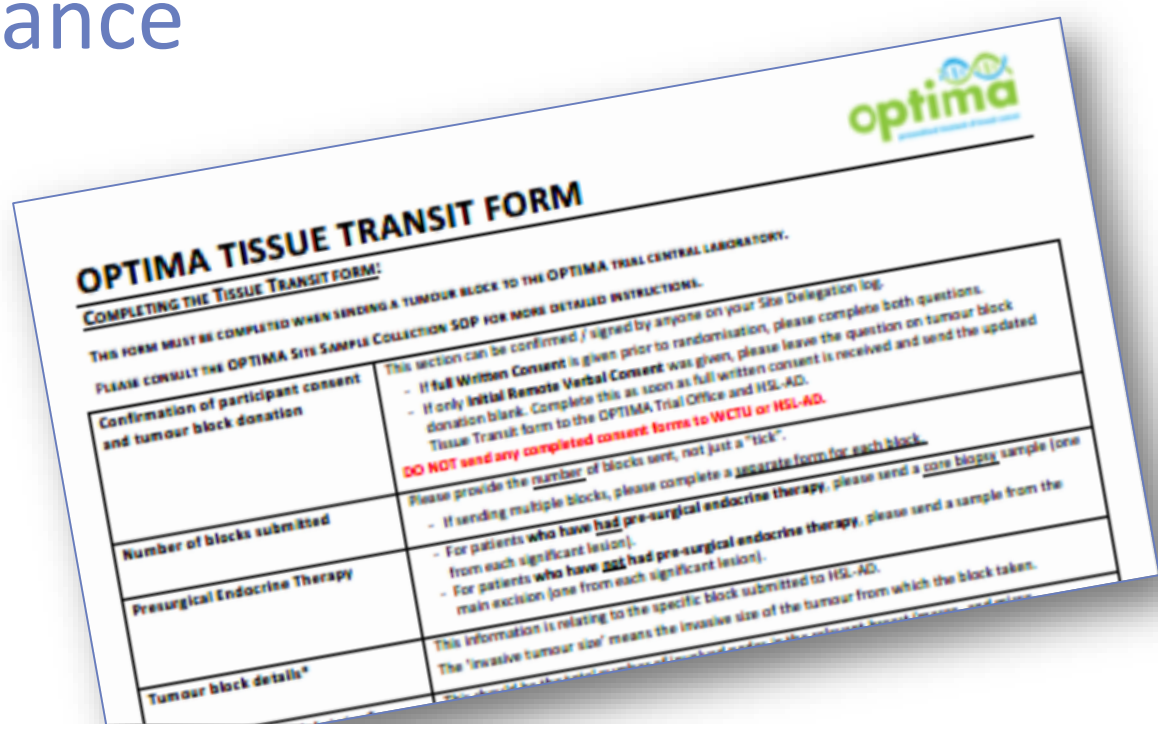

optima

OPTIMA TISSUE TRANSIT FORM

COMPLETING THE TISSUE TRANSIT FORM:

THIS FORM MUST BE COMPLETED WHEN SENDING A TUMOUR BLOCK TO THE OPTIMA TRIAL CENTRAL LABORATORY.

PLEASE CONSULT THE OPTIMA SITE SAMPLE COLLECTION SOP FOR MORE DETAILED INSTRUCTIONS.

Confirmation of participant consent and tumour block donation	This section can be confirmed / signed by anyone on your Site Delegation log. – If **full Written Consent** is given prior to randomisation, please complete both questions. – If only **Initial Remote Verbal Consent** was given, please leave the question on tumour block donation blank. Complete this as soon as full written consent is received and send the updated Tissue Transit form to the OPTIMA Trial Office and HSL-AD. **DO NOT send any completed consent forms to WCTU or HSL-AD.**
Number of blocks submitted	Please provide the number of blocks sent, not just a "tick". – If sending multiple blocks, please complete a separate form for each block.
Presurgical Endocrine Therapy	– For patients **who have had pre-surgical endocrine therapy**, please send a core biopsy sample (one from each significant lesion). – For patients **who have not had pre-surgical endocrine therapy**, please send a sample from the main excision (one from each significant lesion).
Tumour block details*	This information is relating to the specific block submitted to HSL-AD. The 'invasive tumour size' means the invasive size of the tumour from which the block taken.

Most Common Queries – Tissue Transit Form

Section of Paperwork:	Example:	Resolution:
Number of blocks submitted	The number of blocks sent has been ticked.	Please provide the number of blocks sent, not just a "tick". If sending multiple blocks, you should complete a separate form for each block.
Presurgical Endocrine Therapy	The incorrect sample has been received: i.e. • we have been sent an excision specimen when we require a core biopsy sample (due to the patient receiving pre-surgical endocrine therapy). • we have been sent a core biopsy sample when we require an excision specimen (due to the patient not having pre-surgical endocrine therapy).	Site will need to send the correct sample: • For patients who have had pre-surgical endocrine therapy, please send a core biopsy sample (one from each significant lesion). • For patients who have not had pre-surgical endocrine therapy, please send a sample from the main excision (one from each significant lesion).

Most Common Queries – Tissue Transit Form

Section of Paperwork:	Example:	Resolution:
Insufficient Samples Sent	The tumour block sent to the lab does not contain enough tumour	Site will need to send the correct sample: • Please refer to the sample selection SOP for information relating to the minimum accepted tumour cellularity for processing to occur.
	A node has been sent to the lab instead of a sample from the breast	Site will need to send the correct sample: • We cannot process a node.
	Only one sample sent when there is more than one tumour present	Site will need to send an additional sample: • We require a sample from each clinically significant tumour.

Most Common Queries – Tissue Transit Form

Section of Paperwork:	Example:	Resolution:
Tumour block details*	The whole tumour size has been written on the tissue transit form	We require the **invasive** tumour size to be confirmed on the Tissue Transit Form.
	The patient had residual tumour but this has not been included on the tissue transit form.	Please add all residual tumour found to the final/total invasive tumour size on the Tissue Transit Form. Take care to include all information where treatment has been split across hospitals.
Confirmation of nodal status*	The tissue transit form only considers the nodal status from one surgery, not all surgeries.	This should be the total number of involved nodes across all surgeries. Take care to include all information where treatment has been split across hospitals.
Form completed by	The Tissue Transit Form has been signed by someone who is not delegated to do so.	Each Tissue Transit form must be checked and signed by a trial investigator or pathologist who is a member of the breast MDT and who is delegated "Completion of Tissue Transit Form" as per your Site Delegation Log.

***NB:** any amendments to these sections **must** be confirmed (initial and dated) by someone who is delegated to "Completion of Tissue Transit Form" as per your sites Delegation Log.

General CRF completion:

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- All amendments should be crossed out with a single line and initialled and dated.

- Any amendments to the Tissue Transit form must be initialled and dated by an appropriate staff member, as per your Site Delegation log.

Good Clinical Practice 

Sending the sample for processing

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- The following slides are relevant to UK sample processing
- International Sites should refer to their local guidance documents/protocol annex

Sending the block to HSL-AD

Redacting the reports

- Please do **not** redact:
  - ✓ Hospital Name / Hospital headed paper
  - ✓ Histopathology number(s) – *must be visible on at least 1 page of the report*
  - ✓ Participant's date of birth – *If the date of birth is redacted in error, this can be handwritten on the report.*
- All other patient identifiable data (name, address NHS and hospital numbers etc) should be **fully redacted** before the report is sent to the Trial Office / HSL-AD.
- Each page of the pathology report(s) should be labelled so that WCTU and HSL-AD can verify which participant the report(s) belong to:
  - ✓ Participant's initials
  - ✓ Trial Number (TNO)

  } *These can be handwritten on to the report*
- Each page should have at least 2 identifiers included (one of which must be the TNO or initials), to allow us to check the reports against the correct participant records.

Most Common Queries – UK Specific

Section of Paperwork:	Example:	Resolution:
Lab	The tumour block has been sent to the lab with none / some of the pathology reports enclosed	Please ensure that copies of **all** pathology reports are posted to HSL-AD (alongside the tumour block) **and** emailed to WCTU. • The central lab and WCTU are not in the same location. • The lab need to check the information in preparation for processing, and WCTU need to check the paperwork in parallel. • We cannot allocate treatment until the paperwork has been checked and confirmed accurate, by both parties. **Please also ensure that we have copies of all relevant reports, for all surgeries/procedures.**
WCTU	The pathology reports and Tissue Transit Form have been sent to the lab via post, but have not been emailed to the CTU.	
Reports	Histology reports have been insufficiently redacted.	We will need to note this as a processor data breach as we are not permitted to receive any patient identifiable data.
	Consent form sent to the lab / WCTU	

OPTIMA team contacts

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WCTU Team

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Email: optima@warwick.ac.uk