





Lunch with OPTIMA

Tissue Transit form training

OPTIMA Tissue Transit form v9.0



Page 1

Contains all the information the central lab needs for prosigna testing

OPTIMA TISSUE TRANSIT FORM	OPTIMA TISSUE	TRANSIT FORM Optima
PLEASE READ THE INSTRUCTIONS OVERLEAF BEFORE COMPLETING THIS FORM AND SENDING THE TUMOUR BLOCK.	COMPLETING THE TISSUE TRANSIT FO	ORM:
SITE DETAILS	THIS FORM MUST BE COMPLETED WHEN SEN	IDING A TUMOUR BLOCK TO THE OPTIMA TRIAL CENTRAL LABORATORY.
Referring hospital: Caution: For patients treated at more than one hospital, take care to include all	PLEASE CONSULT THE OPTIM A SITE SAMP	LE COLLECTION SOP FOR MORE DETAILED INSTRUCTIONS.
Pathology hospital: information about the number of involved nodes and use of presurgical endocrine	Confirmation of participant consent	This section can be confirmed / signed by anyone on your Site Delegation log.
(if different):	and tumour block donation	 If full Written Consent is given prior to randomisation, please complete both questions.
Contact name: Contact telephone:		 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
PARTICIPANT DETAILS		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 <u>number</u> of blocks sent, not just a "tick".
Trial Number: Date of birth: d d m m m y y y y		If sending multiple blocks, please complete a <u>separate form for each block.</u>
CONFIRMATION OF PARTICIPANT CONSENT	Presurgical Endocrine Therapy	 For patients who have <u>had</u> pre-surgical endocrine therapy, please send a <u>core biopsy</u> sample (one from each significant lesion).
I confirm this patient has given informed consent to take part in the OPTIMA trial:		- For patients who have not had pre-surgical endocrine therapy, please send a sample from the
Has this patient agreed to donate the remainder of their sample for future research?*	Tumour block details*	main excision (one from each significant lesion). This information is relating to the specific block submitted to HSL-AD.
Leave blank if initial verbal consent has been received – please complete once full consent is received Yes No	Tumour block details	The 'invasive tumour size' means the invasive size of the tumour from which the block taken.
Name: Sign: Date:	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.
NUMBER OF TUMOURS BLOCKS SUBMITTED FOR THIS PARTICIPANT	Royal mail tracking information	Add the information from the Royal Mail Special Delivery envelope for tracking purposes.
Number of tumour blocks submitted (in total) from the LEFT breast:	Form completed by	Each Tissue Transit form must be checked and signed by a trial investigator or pathologist who is a
Number of tumour blocks submitted (in total) from the RIGHT breast: (if more than 1 block submitted)	Portit Completed by	member of the breast MDT <u>and</u> who is delegated "Completion of Tissue Transit Form" as per your Site Delegation Log.
PRESURGICAL ENDOCRINE THERAPY	*NB: any amendments to these secti	ons must be confirmed (initial and dated) by someone who is delegated to "Completion of
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	Tissue Transit Form" as per your site:	
TUMOUR BLOCK DETAILS	SENDING THE BLOCK TO HSL-AD:	
Full histology number for this specimen:		
Specific code/letter/number of this block (e.g. 1A):		a copy of the completed Tissue Transit form(s) and copies of <u>all</u> anonymised pathology <u>PTIMA@warwick.ac.uk</u> , WCTU need a copy of all reports to check the information <u>before</u>
Breast this block is from:		Il applicable pathology reports (include core biopsies, excision and axillary surgeries) with the
Date of surgery / biopsy when this block was collected:	block.	
d d m m m y y y y		form, partially anonymised pathology reports and FFPE block to the central laboratory in a pre- Delivery envelope provided.
Invasive tumour size (mm) of the lesion that this sample was taken from:		
CONFIRMATION OF NODAL STATUS	REMEMBER: <u>ALL PATHOLOGY REPORTS</u> Please do not redact:	SHOULD BE APPROPRIATELY REDACTED:
Number of <u>involved</u> nodes (for this breast) across all surgeries:	✓ Hospital Name / Hospital hea	ded paper
ROYAL MAIL TRACKING INFORMATION	✓ Histopathology number(s) – n	nust be visible on at least 1 page of the report
Tracking code (e.g. AA 1111 1111 1AA):	 ✓ Participant's date of birth – If 	the date of birth is redacted in error, this can be handwritten on the report.
Date and approximate time sample Date:	All other patient identifiable data (nam Office / HSL-AD.	e, address NHS and hospital numbers etc) should be <u>fully redacted</u> before the report is sent to the Trial
despatched:		ould be labelled so that WCTU and HSL-AD can verify which participant the report(s) belong to:
FORM COMPLETED BY	 ✓ Participant's initials 	hese can be handwritten an to the report
Name: Date:	✓ Trial Number (TNO)	
d d m m m y y y y	Each page should have at least 2 identification correct participant records.	iers included (one of which must be the TNO or initials), to allow us to check the reports against the
Signature:		
OPTIMA Tissue Transit Form - Version 9.0, 26 Apr 2021		OPTIMA Tissue Transit Form – Version 9.0, 26 Apr 2021



Page 2

Contains guidance on how to complete the Tissue Transit form

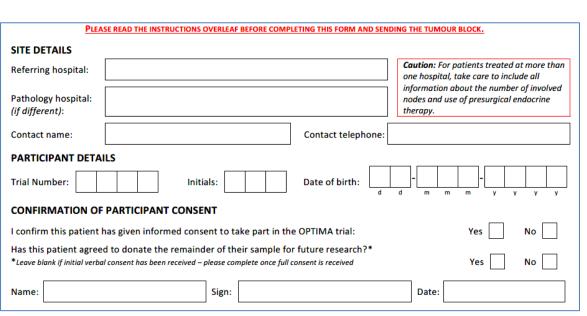


WARWICK

CLINICAL TRIALS UNIT

Section 1:

Site details and Patient Information



Section 1: Site details and Patient Information

- Referring Hospital: Should be the Site where the patient was <u>randomised</u>
- 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 <u>do not</u> need to be countersigned by someone who has 'completion of Tissue Transit form' delegated to them.

PLEAS	E READ THE INSTRUCTIONS OVERLEAF BEFORE COMPLETING THIS FORM AND SENDING THE TUMOUR BLOCK.
SITE DETAILS	
Referring hospital:	Caution: for patients treated at more than one hospital, take care to include all
Pathology hospital: (if different):	infomfation about the number of involved nodes and use of presurgical endocrine therapy.
Contact name:	Contact telephone:
PARTICIPANT DETAIL	s
Trial Number:	Initials: Date of birth:
CONFIRMATION OF	PARTICIPANT CONSENT
I confirm this patient ha	as given informed consent to take part in the OPTIMA trial:
	to donate the remainder of their sample for future research?* consent has been received – please complete once full consent as general. Yes No
Name:	Sign: Date:

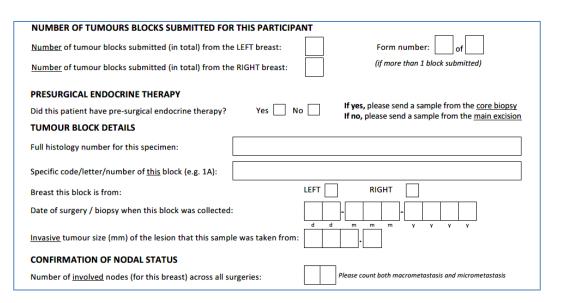


WARWICK

CLINICAL TRIALS UNIT

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.

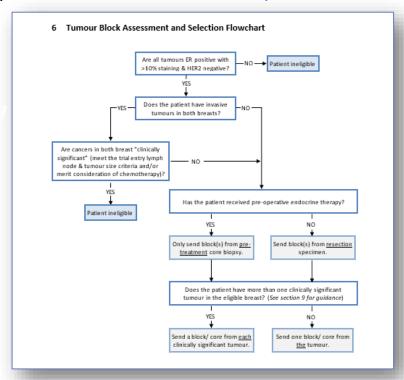
There is an SOP which can help Sites identify which samples to send: OPTIMA Site Sample Collection

SOP v8.0_2021-07-27

Section 6 of this document contains a flow chart.



If unsure, ask the WCTU team and we can advise.



- Number of tumour blocks submitted for this patient: You should confirm the <u>number</u> of samples sent, and complete the appropriate box depending on which breast the sample(s) are from.
- Pre-surgical Endocrine therapy: This is a <u>critical</u> 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 <u>invasive tumour size</u> 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 <u>number of involved nodes</u> is also critical as this figure is used for the prosigna assay.

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: Form number: of		
Number of tumour blocks submitted (in total) from the RIGHT breast: (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:		
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 <u>involved</u> nodes (for this breast) across all surgeries: Please count both macrometastasis and micrometastasis		

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: (if more than 1 block submitted)
PRESURGICAL ENDOCRINE THERAPY Did this patient have pre-surgical endocrine therapy? TUMOUR BLOCK DETAILS Yes No If yes, please send a sample from the core biopsy If no, please send a sample from the main excision
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

It is not unusual for the Main Site Contact to complete <u>some of</u> this section of the form before passing over to Pathology <u>however</u> 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 this section <u>may</u> need to be countersigned by someone who has 'completion of Tissue Transit form' delegated to them.

NUMBER OF TUMOURS BLOCKS SUBMITTED FOR THIS PARTICIPAN	т
Number of tumour blocks submitted (in total) from the LEFT breast:	Form number: of
Number of tumour blocks submitted (in total) from the RIGHT breast:	(if more than 1 block submitted)
PRESURGICAL ENDOCRINE THERAPY	
Did this patient have pre-surgical endocrine therapy?	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:	EFT 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 <u>involved</u> nodes (for this breast) across all surgenes:	Please count both macrometastasis and micrometastasis



Section 3: Sample tracking and Sign off



ROYAL MAIL TRACKING INFORMATION

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

Date and approximate time sample despatched:

FORM COMPLETED BY

Name:

Date:

Date

Section 3: Sample tracking and Sign off

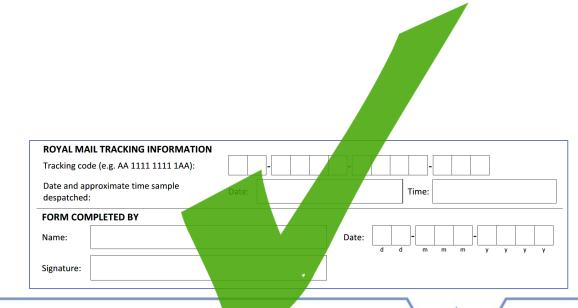
- Royal Mail tracking information: All Tissue Transit Envelopes provided to Sites include Royal Mail tracking information. It is good practice to include this information on the Tissue Transit form as it allows us to track the package if it were to go missing.
- Form Completed by: Once the Tissue Transit form is complete, the whole form must be checked and signed by a suitable trained individual.

A.K.A. a trial investigator or pathologist who is a member of the breast MDT <u>and</u> who is delegated "Completion of Tissue Transit Form" as per your Site Delegation Log.

Section 3: Sample tracking and Sign off

The whole Tissue Transit form must be signed off by a trial investigator or pathologist who is a member of the breast MDT <u>and</u> who is delegated "Completion of Tissue Transit Form" as per your Site Delegation Log.

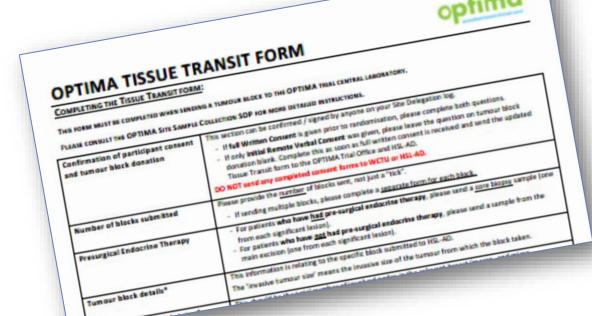
If your PI wants to delegate this task to someone else, they must confirm that the person is suitably trained and competent to do so.



Page 2: Completion Guidance



CLINICAL TRIALS UNIT



Completing the Tissue Transit form

Confirmation of participant	This section can be confirmed / signed by anyone on your Site
consent and tumour block	Delegation log.
donation	- 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	Please provide the <u>number</u> of blocks sent, not just a "tick".
submitted	- If sending multiple blocks, please complete a <u>separate form for each</u> <u>block.</u>
Presurgical Endocrine Therapy	 For patients who have <u>had</u> pre-surgical endocrine therapy, please send a <u>core biopsy</u> sample (one from each significant lesion). For patients who have <u>not</u> had pre-surgical endocrine therapy, please send a sample from the main excision (one from each significant lesion).

Completing the Tissue Transit form

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	This should be the total number of involved nodes in the relevant breast
status*	(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.
Royai maii tracking	Add the information from the Royal Mail Special Delivery envelope for
information	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 <u>must</u> be confirmed (initial and dated) by someone who is delegated to "Completion of Tissue Transit Form" as per your sites Delegation Log.

Completing the Tissue Transit form

Section 2: Tumour Sample details

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: (if more than 1 block submitted)
PRESURGICAL ENDOCRINE THERAPY If yes, please send a sample from the core biopsy
Did this patient have pre-surgical endocrine therapy? Yes No If no, please send a sample from the este 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:

*NB: any amendments to these sections <u>must</u> 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

- 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 <u>before</u> allocation can occur.
 - 1. Enclose with this form <u>all</u> 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.

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.

General CRF completion:



- 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



Most common queries:



- We need copies of <u>all</u> pathology reports.
- We need the <u>invasive</u> tumour size (not whole tumour size).
- For patients who have had pre-surgical endocrine therapy, you <u>must</u> send us a pre-treatment core biopsy.
- Insufficient samples sent...
 - only one sample when we need more
 - Core bx when we need an excision specimen
 - Not enough tumour tissue in the block
 - Samples from lymph nodes

OPTIMA team contacts

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