



ICONIC: Improving outcomes
through collaboration in osteosarcoma

LABORATORY MANUAL

For the collection, processing, storage and shipping of samples
FOR ALL ICONIC PATIENTS ONLY

Version 8, 09 January 2026



Cancer
Trials
Centre



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VERSION	DATE	SUMMARY OF MAIN CHANGES	AUTHOR
1	25/10/2019	n/a	Krystyna Reczko
2	19/11/2019	Clarification on collection of blood samples on a Friday/Bank Holiday	Sharon Forsyth
3	13/11/2020	Addition of blood collection for CTCs at Newcastle Clarification of timepoint for Germline DNA sample	Krystyna Reczko
4	15/04/2021	<ul style="list-style-type: none"> Integration of surgery and chemotherapy lab manuals into single lab manual for all ICONIC sites. Clarification on collection of ctDNA samples for all patients Addition of blood collection for CTCs at Sheffield New clarification on collection of blood samples on a Friday 	Krystyna Reczko
5	20/05/2022	<ul style="list-style-type: none"> ctDNA follow up timepoint frequency clarified in section 2.5 Sheffield lab address and email contact for shipping CTC samples updated RNOH lab address updated Cryolabel details & examples updated 	Kate Sparksman
6	20/06/2024	<ul style="list-style-type: none"> Details of PBMC added Sample & Labs flowchart added Shipping sections for each sample type updated to advise that lab contacts are also in appendix 2 of the manual. Safebox packing instructions (appendix 1) updated for new cardboard safeboxes Reminders that patients must be registered before any samples are collected. Reminder that Sheffield Lab is only accepting relapse CTC samples for patients already on their substudy. No other samples should be taken. 	Krystyna Reczko
7	13/05/2025	<ul style="list-style-type: none"> Change ctDNA/Germline lab address from RNOH to GCLP Updated TIGI lab contacts Removal of fax contact numbers 	Krystyna Reczko
8	05/01/2026	<ul style="list-style-type: none"> Changed TIGI Lab references to GCLP references for PBMC samples Updated mail safebox details Removed appendix 1 safebox packing instructions and referred readers to instructions included with new safeboxes 	Krystyna Reczko

1 GLOSSARY

Acronym	Meaning
AB	Archival Biopsy
AS	Archival Surgery
AP	Doxorubicin, cisplatin chemotherapy
ccfDNA	Circulating cell free DNA
C2D21 MAP or C3 AP	MAP Cycle 2 Day 21 or AP Cycle 3
ctDNA	Circulating tumour DNA
CTCs	Circulating Tumour Cells
ECMC GCLP	Experimental Cancer Centre Good Clinical Laboratory Practice Facility
EoT	End of Treatment
FFBx	Fresh Frozen Biopsy
FFPE	Formalin-fixed paraffin-embedded
FUP	Follow Up
ISF	Investigator Site File
MAP	Methotrexate, doxorubicin, cisplatin chemotherapy
Mtx	Methotrexate
NBx	New Biopsy
OT	On Treatment
PBMC	Peripheral blood mononuclear cells
PreT	Pretreatment
SoC	Standard of Care
TM	Trial Manager
UCL CI	University College London Cancer Institute
UCL CTC	CR UK & UCL Cancer Trials Centre
UCLH	University College London Hospital

2 INTRODUCTION

This laboratory manual covers the collection, processing, storage and transportation of blood and tissue samples for the ICONIC study.

2.1 Site staff delegation of duties and training

To preserve patient sample integrity, samples must be collected, handled, processed and stored following the instructions in this manual and the current approved version of the study protocol. Designated staff must receive adequate training and be delegated authority to carry out these tasks (duty **O**) in the ICONIC Site Staff Delegation Log.

2.2 Sample audit trail and documentation

A complete audit trail must be maintained for all samples and it should be possible to locate any sample at any time.

For each sample, complete the relevant processing or shipping form which can be found in the laboratory section of the Investigator Site File (ISF). Electronic versions of these forms are also provided.

The sample processing or shipping forms and sample logs must be available for review during onsite monitoring visits, and at other times as requested by UCL CTC.

2.3 Temperature tolerances

The following are acceptable temperature ranges for conditions specified in this laboratory manual, unless otherwise stated:

Temperature tolerances

Storage condition specified	Temperature range (°C)
Ambient or room temperature	15 - 30
Fridge	02 - 08
Freezer or -80	-70 or colder

2.4 Contact Details

All ICONIC queries should be directed to the ICONIC Trial Manager.

Contact: **ICONIC Trial Manager**
Address: *To April 02 2026:*
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London
W1T 4TJ

From April 03 2026:
Cancer Research UK & UCL Cancer Trials Centre
Third Floor, Maple House
149 Tottenham Court Road
London
W1T 7NF

Email: ctc.iconic@ucl.ac.uk
Telephone: 020 7679 9878

Email is the preferred method of communication.

2.5 Summary of Sample Collection

SAMPLE	REQUIRED FROM:	SAMPLE TIMEPOINTS	PROCESSING	SHIPPING TIMELINE	SHIP TO
Archival FFPE tumour tissue	All patients	<ul style="list-style-type: none"> Biopsy/Surgery Preregistration 	None	On request from UCL CTC	RNOH, Stanmore
FFPE tumour tissue	All patients	<ul style="list-style-type: none"> Routine surgery post registration 			
Stored frozen tissue	All patients (collected as per SoC)	<ul style="list-style-type: none"> Baseline Surgical resection 	Freezing (per local practice)	On request from UCL CTC (courier provided)	RNOH, Stanmore
New relapse/ mets tumour biopsy	Patients with SoC local recurrence or mets resection or consenting Patients with resection of local recurrence or mets if not SoC.	Relapse resection of local recurrence or metastases	FFPE	On request from UCL CTC	RNOH, Stanmore
			Freezing (per local practice)	On request (courier provided)	
Blood for CTCs	Neoadjuvant chemotherapy patients only. <ul style="list-style-type: none"> ALL samples must be collected 	<ul style="list-style-type: none"> Baseline* (n.b. if patient has started chemotherapy prior to study entry NO CTC samples are collected) C2D21 MAP or C3 AP** Relapse 	None	On day of collection	Newcastle University: all eligible pts.
					Sheffield University: Relapse samples for Sheffield CTC patients ONLY ***
Blood for ctDNA, methylation profiles, future research	All patients (optional)	<ul style="list-style-type: none"> Baseline* (n.b. if patient has started chemotherapy prior to study entry ctDNA sample may still be collected) C2D21 MAP or C3 AP End of treatment Follow up - no more than 6 monthly Relapse/mets 	None	On day of collection	ECMC GCLP Lab, UCL Cancer Institute
Blood for germline DNA	All patients	<ul style="list-style-type: none"> Baseline* (n.b. if sample is missed at baseline the sample may still be collected at a later visit) 	None	On day of collection	ECMC GCLP Lab, UCL Cancer Institute
Blood for PBMC (from 20 UCLH Patients only)	20 UCLH Neoadjuvant chemotherapy patients	<ul style="list-style-type: none"> Baseline* On Treatment End of treatment**** Relapse/mets 	None	Take to The ECMC GCLP Lab on day of collection	ECMC GCLP Lab, UCL Cancer Institute





* For Newcastle Lab only. The patient's registration must be confirmed by UCL CTC before baseline samples can be collected

** n.b. only for Newcastle Lab and only if baseline collected

*** **Relapse only, for pts whose other samples have been collected**

**** End of treatment: after surgery for neoadjuvant and surgery only patients, after end of adjuvant chemotherapy for patients receiving adjuvant chemotherapy.

3 EQUIPMENT

Resource	Use	Picture
PAXgene ccfDNA tubes (10 mL)	Germline DNA & ctDNA blood samples - For UCL GCLP lab	
Streck tubes (10 mL)	CTC blood samples - For Newcastle & Sheffield labs	
Vacurette LH Lithium Heparin tubes (9mL)	PMBC blood samples – For The GCLP Lab	
Safe Boxes – 1st Class or Special Delivery	All blood samples – For all labs. Usually sent to sites with lab (GCLP, Newcastle & Sheffield) address labels on, but may be provided without these labels	

Consumables and shipping provided by UCL CTC

The following consumables will be provided to Sites by UCL CTC:

- ccfDNA PAXgene tubes (10 mL) (*ctDNA and Germline samples*)
- Streck tubes (10 mL) (*CTC samples*)
- Vacuette LH Lithium Heparin tubes (green top, 9 mL) (*UCLH PBMC samples*)
- Mail Safeboxes
- Sample labels
- Sample shipping forms
- Freezer boxes (on request)
- 2 mL Cryovials (on request)

Shipping

- For samples to be shipped on dry ice, UCL CTC will arrange and pay for the courier.
- The courier will provide dry ice and packaging required for shipment.

4 ARCHIVAL FFPE TUMOUR TISSUE SAMPLES

For the timing of sample collection please refer to [section 2.5](#) and protocol section 10.1.

Archival FFPE tissue blocks from previous surgery/biopsy and other samples from routine surgery taking place after registration will be collected.

n.b.: it is expected the site storing these samples would be responsible for submitting to the central laboratory (regardless of which site registered the patient). The collection of samples will be coordinated centrally by UCL CTC.

4.1 Equipment required

None.

4.2 Processing procedure

- Sites should obtain at least one and ideally two formalin fixed paraffin embedded (FFPE) tumour tissue block(s).
- Review the pathology report and select blocks as follows:
 - Biopsy cores: Choose cores that have the highest tumour tissue content.
 - Surgical resection tissue: Choose blocks containing the most tumour tissue.
- At least one block must be sent – two is preferable

Archival Biopsy cores

Labels will be provided with the following preprinted:

- Sample: **FFPE AB**
- Timepoint: **PreT**

Add the following information (in bold) using non water soluble ink:

- Pt ID (patient study ID): **ICO-XXX**
- Pt Initials (Patient Initials): **XXX**
- Date (date of sample collection): **DD/MM/YYYY**
- Block Number: **1** or **2**
- Example label below:

Pt ID: ICO-001	ICONIC	Sample: FFPE AB Timepoint: PreT
Pt Initials: HP		
Date: 01/01/2000		
Block No: 1		

Archival Surgery Resection tissue

Labels will be provided with the following preprinted:

- Sample: **FFPE AS**

Add the following information (in bold) using non water soluble ink:

- Pt ID (patient study ID): **ICO-XXX**
- Pt Initials (Patient Initials): **XXX**
- Date (date of sample collection): **DD/MM/YYYY**
- Block Number: **1** or **2**
- Timepoint:
 - **PreT** – Pre Treatment

- **OT** – On Treatment
- Example label below:

Pt ID: ICO-001 Pt Initials: HP Date: 01/01/2000 Block No: 1	ICONIC	Sample: FFPE AS Timepoint: OT
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- Complete sections 1 & 2 of the *Archival FFPE Sample Shipping form*. Ensure the decalcification questions are completed.
- Store until requested by UCL CTC.

4.3 Shipping

- Post tumour blocks in a padded envelope.
- Take a copy of the *Archival FFPE Sample Shipping Form* to keep.
- Send the original form with the tissue blocks.
- At the time of posting, email a scanned copy of the form to UCL CTC at ctc.iconic@ucl.ac.uk, and copy in the RNOH lab at roh.biobank@nhs.net

Post to:

RNOH Biobank Team
 Histopathology Department
 UCL Institute of Orthopaedics
 Royal National Orthopaedic Hospital
 Brockley Hill
 Stanmore
 Middlesex
 HA7 4LP

On receipt RNOH will complete section 3 of the *Archival FFPE Sample Shipping Form* and return to UCL CTC on ctc.iconic@ucl.ac.uk. Any discrepancies or inconsistencies will be raised with the Site by UCL CTC.

4.4 Return of FFPE samples

All FFPE samples will be stored at RNOH.

Sites may request return of routine samples if required for clinical purposes but must return the samples to RNOH after this.

5 STORED FROZEN TUMOUR FROM PRIMARY RESECTION

For the timing of sample collection please refer to [section 2.5](#) and protocol section 10.2.

During the Study, information will be captured about routine collection and storage of frozen tumour specimens.

- Fresh/frozen tumour specimens should be shipped on request from UCL CTC.
- At the end of the Study all routine fresh/frozen tumour specimens will be returned to site.

n.b.: it is expected the site storing these samples would be responsible for submitting to the central laboratory (regardless of which site registered the patient). The collection of samples will be coordinated centrally by UCL CTC.

5.1 Processing procedure

- One or two cores should be frozen according to local practice
- At least one block must be sent – two is preferable

Archival Biopsy cores

Labels will be provided with the following preprinted:

- Sample: **FFBx**
- Timepoints: PreT **PreTreatment**

Add the following information (in bold) using non water soluble ink:

- Pt ID (patient study ID): **ICO-XXX**
- Pt Initials (Patient Initials): **XXX**
- Date (date of sample collection): **DD/MM/YYYY**
- Block Number: **1** or **2**
- Example label below:

Pt ID: ICO-001	ICONIC	Sample: FFBx Timepoint: PreT
Pt Initials: HP		
Date: 01/01/2000		
Block No: 1		

Complete the *New Biopsy Frozen Tissue sample form* and file in ISF.

- Store until requested by UCL CTC.
- UCL CTC will arrange and pay for the courier. The courier will provide dry ice and packaging required for shipment.

5.2 Shipping

Shipping of these stored samples is not required until the end of the study.

UCL CTC will arrange for the samples to be collected by courier. The courier will provide the dry ice and packaging required for shipment.

On the day of shipping:

- Complete sections 1 and 2 of the *Dry Ice Shipping form* for the samples to be shipped

-
- Take a copy of the form to keep
 - Send the original form with the samples (but NOT in with the dry ice)
 - Email a scanned copy of the form to UCL CTC at ctc.iconic@ucl.ac.uk, and copy in the RNOH lab contacts (see [Appendix 2](#): lab contacts email addresses) at the time of posting.
 - Record details of shipping on the sample inventory log
 - Check the shipping container is addressed correctly (this will be provided by UCL CTC to courier at time of booking):

RNOH Biobank Team
Histopathology Department
UCL Institute of Orthopaedics
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
Middlesex
HA7 4LP

On receipt RNOH will complete section 3 of the *Dry Ice Shipping form* and return to UCL CTC at ctc.iconic@ucl.ac.uk. Any discrepancies or inconsistencies will be raised by UCL CTC with the Site.

6 NEW RELAPSE/METS BIOPSIES AS SoC OR FOR RESEARCH PURPOSES

For the timing of sample collection please refer to [section 2.5](#) and protocol section 10.3.

At relapse/resection of local recurrence/metastases a new biopsy may be collected for the ICONIC Study either as SoC or **if not collected routinely as part of SoC**, with the patient's consent as a trial specific procedure.

Collection of this biopsy for research purposes (rather than as SoC) is optional for all patients.

If possible two cores should be obtained:

- One core should be frozen according to local practice
- One core should be formalin fixed paraffin embedded

If it is not possible to obtain two cores, then one is acceptable. The preference for this would be frozen, but if not possible FFPE is permitted.

6.1 Fresh frozen samples

6.1.1 Equipment required

ITEM	SUPPLIED BY UCL CTC?
Cryovials	On request
Freezer storage box	On request
Freezer storage space (-70°C or below)	No
Labels for samples	Yes
Non water soluble ink pen	No
Fresh Frozen Biopsy Sample Form	Yes

6.1.2 Processing procedure

The sample should be frozen according to local practice. Cryovials can be provided by UCL CTC if required.

Labels will be provided with the following preprinted:

- Sample: **FFBx**
- Timepoint: **Relapse**

Add the following information (in bold) using non water soluble ink:

- Pt ID (patient study ID): **ICO-XXX**
- Pt Initials (Patient Initials): **XXX**
- Date (date of sample collection): **DD/MM/YYYY**
- Example label below:

Pt ID: ICO-001	ICONIC	Sample: FFBx Timepoint: Relapse
Pt Initials: HP		
Date:		
01/01/2001		

Complete the *New Biopsy Frozen Tissue Sample Form*.

Store at -70°C or colder. Freezer boxes are available from UCL CTC on request.

6.1.3 Shipping

Refer to [section 4.1](#) for details on shipping of these samples.

6.2 FFPE sample

6.2.1 Equipment required

None.

6.2.2 Processing procedure

Process sample to FFPE.

Labels will be provided with the following preprinted:

- Sample: **NBx**
- Timepoint: **Relapse**

Add the following information (in bold) using non water soluble ink:

- Pt ID (patient study ID): **ICO-XXX**
- Pt Initials (Patient Initials): **XXX**
- Date (date of sample collection): **DD/MM/YYYY**
- Example label below:

Pt ID: ICO-001 Pt Initials: HP Date: 01/01/2001	ICONIC	Sample: NBx Timepoint: Relapse
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- Complete sections 1 & 2 of the *New Biopsy FFPE Sample Shipping form*. **Ensure the decalcification questions are answered.**
- Store until requested by UCL CTC.

6.2.3 Shipping

- Post tumour blocks in a padded envelope.
- Take a copy of the *New Biopsy FFPE Sample Shipping Form* to keep.
- Send the original form with the tissue blocks.
- Email a scanned copy of the form to UCL CTC at ctc.iconic@ucl.ac.uk, and copy in the RNOH lab contacts (see [Appendix 2](#): the lab contacts email addresses) at the time of posting.

Post to:

RNOH Biobank Team
Histopathology Department
UCL Institute of Orthopaedics
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
Middlesex
HA7 4LP

On receipt RNOH will complete section 3 of the *New Biopsy FFPE Sample Shipping Form* and return to UCL CTC at ctc.iconic@ucl.ac.uk. Any discrepancies or inconsistencies will be raised by UCL CTC with the Site.

7 WHOLE BLOOD FOR CIRCULATING TUMOUR CELLS (CTCs)

Blood samples for CTCs will be obtained from patients receiving neoadjuvant chemotherapy. Sheffield are only accepting CTCs for relapse patients for whom they already have samples. For the timing of sample collection please refer to [section 2.5](#) and protocol section 10.4.

Where possible these should be collected at the same time as routine bloods.

n.b.: Any UCLH patient donating blood for PBMC analysis is EXCLUDED from the CTC blood collections.

n.b.: Sheffield are no longer collecting CTC blood samples for patients coming on the trial, they are only collecting RELAPSE samples for patients who have previously had CTC samples collected.

n.b.: All 3 timepoints are required for Newcastle CTC blood collection. If the baseline (pretreatment) sample cannot be collected, do NOT take further samples.

n.b.: Samples must not be collected until UCL CTC has confirmed the patient's registration on the study.

7.1 Equipment required

ITEM	SUPPLIED BY UCL CTC?
10 mL Streck tubes	Yes
Mail Safeboxes	Yes
Labels for samples	Yes
Non water soluble ink pen	No

7.2 Processing procedure

- Label 1 x 10 mL Streck tubes using labels supplied. The following will be preprinted:
 - Sample: **CTC**
 - Timepoint:
 - PreT** - Pre Treatment
 - OT** - On Treatment
 - Relapse (label 2 x 10 mL Streck tubes if Sheffield have received previous samples for this patient).**
- Add the following information (in bold) using non water soluble ink:
 - Pt ID (patient trial ID): **ICO-XXX**
 - Pt Initials (patient initials): **XXX**
 - Date (date of sample collection): **DD/MM/YYYY**
 - Time (time of collection): **HH:MM** (in 24 hour format)
 - Example label below:

Pt ID: ICO-001	ICONIC	Sample: CTC Timepoint: PreT
Pt Initials: HP		
Date: 01/01/2000		
Time: 14:30		

- Collect blood into 1 or 2 x 10 mL Streck tubes as appropriate (fill tubes) – avoid backflow by ensuring the patient's arm is in the downward position and that the tube contents do not touch the stopper or end of the needle during collection.
- If collecting at the same time as routine bloods Streck tubes should be drawn after EDTA tubes and before fluoride oxalate (glycolytic inhibitor) tubes.
- Record time and date of collection.
- Immediately mix the sample by gently inverting 10 times
- No further processing of this sample is required
- Complete sections 1, 2 & 3 of the CTC Sample Shipping Form.
- Send sample **on day of collection** in a Mail Safebox.
- Safeboxes must be taken directly to your Hospital's post room or posted in a Post Box (do not use internal mail). Ensure the sample is sent before the last post on the day of collection.
- If this sample has been collected but cannot be shipped according to the timeline specified, **contact the ICONIC Trial Manager (ctc.iconic@ucl.ac.uk) immediately.**

7.3 Shipping

- One sample is to be sent to Newcastle University and if this is a Relapse sample for a patient whose samples are already at Sheffield, one sample to Sheffield University.
- On the day of sample collection/posting:
 - Take copies of *CTC Sample Shipping Form* to keep.
 - Send the original forms with the blood samples.
 - Email a scanned copy of the form to UCL CTC at ctc.iconic@ucl.ac.uk, and copy in the Newcastle contacts and Sheffield lab if appropriate (see [Appendix 2](#): lab contacts email addresses) at the time of posting.
- Check the Safeboxes are addressed correctly:

<p>Mr Kenneth Rankin – ICONIC Study Northern Institute for Cancer Research Paul O’Gorman Building Framlington Place Newcastle University Newcastle upon Tyne NE2 4HH</p>	<p>FOR RELAPSE SAMPLES ONLY:</p> <p><i>Lab Manager – ICONIC Study Cancer Clinical Trials Centre Weston Park Hospital Whitham Road Sheffield S10 2SJ</i></p>
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On receipt the labs will complete section 4 of their *CTC Sample Shipping form* and scan copy to UCL CTC. Any discrepancies or inconsistencies will be raised by UCL CTC with the Site.

8 WHOLE BLOOD FOR ctDNA, METHYLATION PROFILES AND FUTURE RESEARCH

- **These samples are now to be sent to the UCL ECMC GCLP Lab only.**

Collection of these blood samples is **optional** for all patients.

n.b.: Samples must not be collected until the CTC has confirmed the patient's registration on the study.

n.b.: if patient has started chemotherapy prior to study entry this baseline sample may still be collected.

For the timing of sample collection please refer to [section 2.5](#) and protocol section 10.5. Where possible these should be collected at the same time as routine bloods.

8.1 Equipment required

REQUIRED ITEM	SUPPLIED BY UCL CTC?
10 mL BD Vacutainer® PAXgene ccfDNA blood collection tubes	Yes
Mail Safeboxes	Yes
Labels for samples	Yes
Non water soluble ink pen	No

8.2 Processing procedure

- **Samples must not be refrigerated**
- Ensure tubes are stored at room temperature
- Label 2 x 10 mL PAXgene tubes using labels supplied. The following will be preprinted:
 - Sample: **ctDNA**
 - Timepoint:
 - **PreT** – Pre Treatment
 - **OT** – On Treatment
 - **EoT** – End of Treatment
 - **FUP ___m** - Follow up ___m (number of months from end of treatment, e.g. 6m, 12m etc.)
 - **Relapse**
- Add the following information (in bold) using non water soluble ink:
 - Pt ID (patient trial ID): **ICO-XXX**
 - Pt Initials (patient initials): **XXX**
 - Date (date of sample collection): **DD/MM/YYYY**
 - Time (time of collection): **HH:MM** (in 24 hour format)
 - Tube (Tube number): **1 or 2** (label tubes sequentially)
 - Timepoint (for Follow up only)
 - **FUP xxm** (number of months from **end of treatment**)
 - Example label below:

Pt ID: ICO-001	ICONIC	Sample: ctDNA Timepoint: FUP-Q&M
Pt Initials: HP		
Date: 01/01/2000		
Time: 14:30		
Tube No: 1		

- Collect blood into 2 x 10 mL PAXgene tubes (fill each tube, if this is not possible ensure at least 5ml are supplied in each tube)
- Record time and date of collection
- Immediately mix the samples by gently inverting 10 times and store upright
- No further processing of these samples is required
- Complete sections 1 & 2 of the *ctDNA Sample Shipping Form*
- Send samples **on day of collection** in Mail Safeboxes. See manufacturer's instructions for Safebox packing.
- Safeboxes must be taken directly to your Hospital's post room or posted in a Post Box (do not use internal mail). Ensure the samples are sent before the last post on the day of collection.
- **Samples must not be refrigerated**
- If this sample has been collected but cannot be shipped according to the timeline specified, **contact the ICONIC Trial Manager immediately**

8.3 Shipping

- On the day of sample collection/posting:
 - Take a copy of the *ctDNA Sample Shipping Form* to keep.
 - Send the original form with the blood samples.
 - Email a scanned copy of the form to UCL CTC at ctc.iconic@ucl.ac.uk and copy in the GCLP lab contacts (see [appendix 2](#): lab contacts email addresses) at the time of posting.
- Check the Safebox is addressed correctly:

ICONIC Trial
 UCL ECMC GCLP Facility
 UCL Cancer Institute
 Paul O'Gorman Building
 University College London
 72 Huntley Street
 London
 WC1E 6DD

On receipt GCLP Lab will complete section 3 of the *ctDNA Sample Shipping Form* and return to UCL CTC at ctc.iconic@ucl.ac.uk. Any discrepancies or inconsistencies will be raised by UCL CTC with the Site.

9 WHOLE BLOOD FOR GERMLINE DNA

- **These samples are now to be sent to the UCL ECMC GCLP Lab only.**

For the timing of sample collection please refer to [section 2.5](#) and protocol section 10.6. Where possible this should be collected at the same time as routine bloods.

This sample is to be collected for ALL patients.

n.b.: Samples must not be collected until UCL CTC has confirmed the patient's registration on the study.

n.b.: This sample should be collected at baseline. If this is not possible it may be collected at any timepoint post registration.

9.1 Equipment required

REQUIRED ITEM	SUPPLIED BY UCL CTC?
10 mL BD Vacutainer® PAXgene ccfDNA blood collection tube	Yes
Mail Safeboxes	Yes
Labels for samples	Yes
Non water soluble ink pen	No

9.2 Processing procedure

- **Samples must not be refrigerated**
- Ensure tubes are stored at room temperature
- Label 1 x 10 mL PAXgene tube using labels supplied. The following will be preprinted:
 - Sample: **Germline**
- Add the following information (in bold) using non water soluble ink:
 - Pt ID (patient trial ID): **ICO-XXX**
 - Pt Initials (patient initials): **XXX**
 - Date (date of sample collection): **DD/MM/YYYY**
 - Time (time of collection): **HH:MM** (in 24 hour format)
 - Timepoint:
 - **PreT** – Pre Treatment
 - **OT** – On Treatment
 - **EoT**- End of Treatment
 - **FUP__m** - Follow up __m (number of months from end of treatment, e.g. 6m, 12m etc.)
 - **Relapse**
- *Example label below:*

Pt ID: ICO-001	ICONIC	Sample: Germline Timepoint: PreT
Pt Initials: HP		
Date: 01/01/2000		
Time: 14:30		

- Collect blood into one 10 mL PAXgene tube (fill the tube, if this is not possible ensure at least 5ml are supplied in the tube)
- Record time and date of collection
- Immediately mix the sample by gently inverting 10 times and store upright
- No further processing of this sample is required
- Complete sections 1 & 2 of the *Germline DNA Sample Shipping Form*
- Send sample **on day of collection** in a Mail Safebox.
- Safeboxes must be taken directly to your Hospital's post room or posted in a Post Box (do not use internal mail). Ensure the samples are sent before the last post on the day of collection.
- **Samples must not be refrigerated**
- If this sample has been collected but cannot be shipped according to the timeline specified, **contact the ICONIC Trial Manager immediately**

9.3 Shipping

- On the day of sample collection/posting:
 - Take a copy of the *Germline DNA Sample Shipping Form* to keep.
 - Send the original form with the blood samples.
 - Email a scanned copy of the form to UCL CTC at ctc.iconic@ucl.ac.uk, and copy in the GCLP lab contacts (see [Appendix 2](#): lab contacts mail addresses) at the time of posting.
- Check the Safebox is addressed correctly:

ICONIC Trial
 UCL ECMC GCLP Facility
 UCL Cancer Institute
 Paul O'Gorman Building
 University College London
 72 Huntley Street
 London
 WC1E 6DD

On receipt GCLP Lab will complete section 3 of the *Germline DNA Sample Shipping Form* and return to UCL CTC at ctc.iconic@ucl.ac.uk. Any discrepancies or inconsistencies will be raised by UCL CTC with the Site.

10 WHOLE BLOOD FOR PBMC SAMPLES (UCLH ONLY)

For the timing of sample collection please refer to [section 2.5](#) and protocol section 10.6. Where possible this should be collected at the same time as routine bloods.

- **These samples are now to be taken to the UCL ECMC GCLP Lab only.**

n.b.: Samples must not be collected until the CTC has confirmed the patient's registration on the study.

n.b.: This sample is to be collected for up to 20 UCLH patients ONLY

n.b.: Any UCLH patient donating blood for PBMC analysis is EXCLUDED from the CTC blood collections.

10.1 Equipment required

REQUIRED ITEM	SUPPLIED BY UCL CTC?
Vacurette LH Lithium Heparin tubes (green top, 9 mL)	Yes
Labels for samples	Yes
Non water soluble ink pen	No

10.2 Processing procedure

- Ensure tubes are stored at room temperature
- Label **2** x 9 mL Vacurette LH Lithium Heparin tubes using labels supplied. The following will be preprinted:
 - Sample: **PBMC xx**
- Add the following information (in bold) using non water soluble ink:
 - Pt ID (patient trial ID): **ICO-XXX**
 - Pt Initials (patient initials): **XXX**
 - Date (date of sample collection): **DD/MM/YYYY**
 - Time (time of collection): **HH:MM** (in 24 hour format)
 - Timepoints:
 - **PreT** – Pre Treatment
 - **OT** – On Treatment
 - **EoT**- End of Treatment
 - **Relapse/mets**
- *Example label below:*

Pt ID: ICO-001	ICONIC	Sample: PBMC Timepoint: PreT
Pt Initials: HP		
Date: 01/01/2000		
Time: 14:30		

-
- Collect blood into **2 x 9 mL** Vacurette LH Lithium Heparin tubes (fill the tube, if this is not possible ensure at least 5ml are supplied in the tube)
 - Record time and date of collection
 - Immediately mix the sample by gently inverting 10 times and store upright
 - No further processing of this sample is required
 - Complete sections 1 & 2 of the *PBMC Sample Shipping Form*
 - **Samples must not be refrigerated or stored in a hot place.**
 - **If the sample has been collected but cannot be taken to the Lab on the same day, contact the ICONIC Trial Manager (on ctc.iconic@ucl.ac.uk) immediately.**

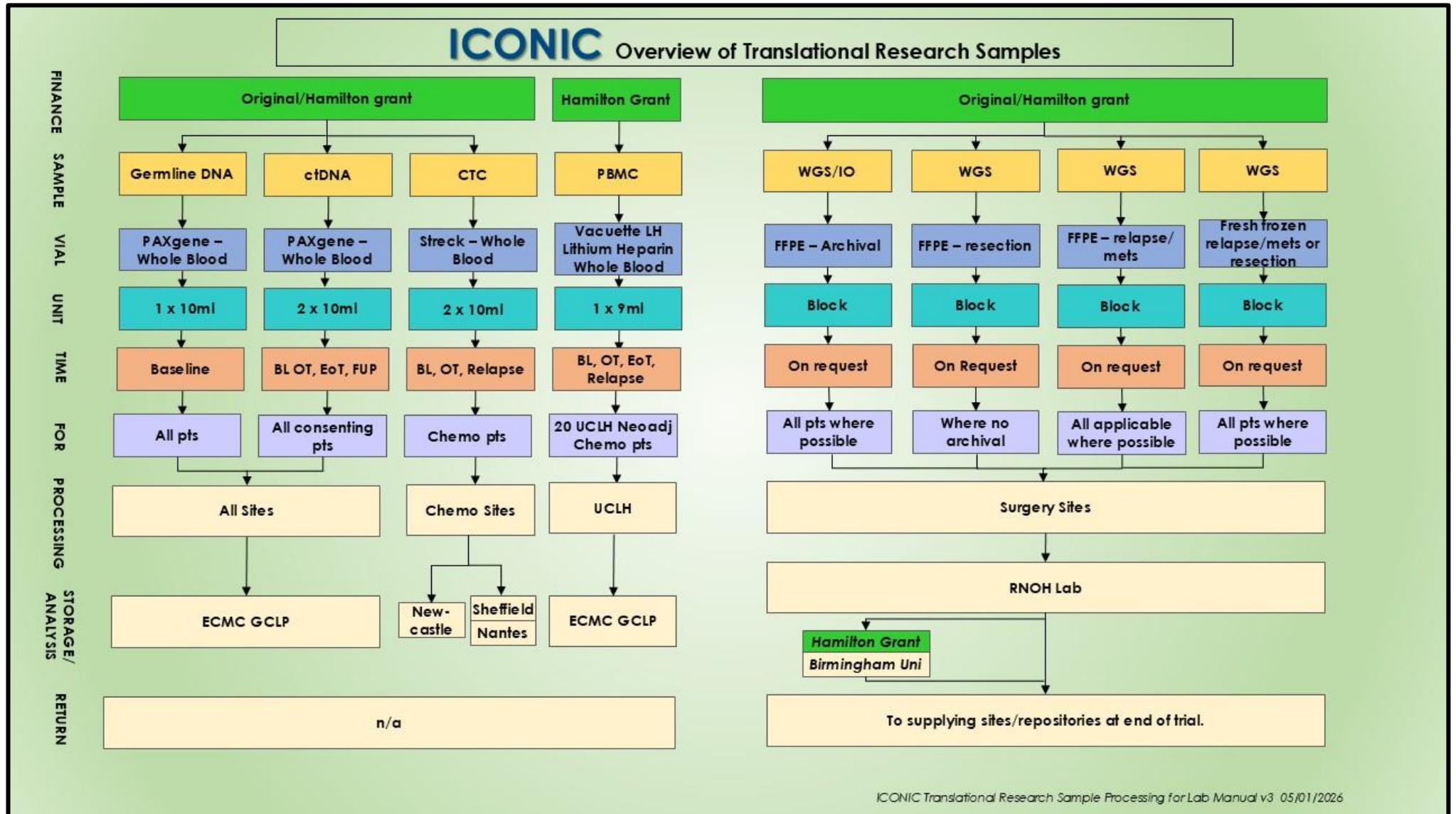
10.3 Delivery

- On the day of sample collection/delivery:
 - Take a copy of the *PBMC Sample Shipping Form* to keep.
 - Send the original form with the blood samples.
 - Email a scanned copy of the form to UCL CTC at ctc.iconic@ucl.ac.uk, and copy in the ECMC GCLP lab contacts (see [Appendix 2](#) ICONIC Lab Contacts for the lab contacts email addresses) at the time of delivery.
 - Package in a sealed plastic bag
 - Take the samples **on day of collection** to the ECMC GCLP Lab, UCL Cancer Institute. Do NOT use internal mail.

ICONIC Trial
UCL ECMC GCLP Facility
UCL Cancer Institute
Paul O'Gorman Building
University College London
72 Huntley Street
London
WC1E 6DD

On receipt the ECMC GCLP Lab will complete section 3 of the *PBMC Sample Shipping Form* and return to UCL CTC at ctc.iconic@ucl.ac.uk. Any discrepancies or inconsistencies will be raised by UCL CTC with the Site.

APPENDIX 1: OVERVIEW OF TRANSLATIONAL RESEARCH SAMPLES



APPENDIX 2: CONTACTS FOR ALL LAB SAMPLES

	Sample	Lab Manual	Contact Address	Contact email
1	All FFPE samples	Sections 4, 6	RNOH Biobank Team Histopathology Department UCL Institute of Orthopaedics Royal National Orthopaedic Hospital Brockley Hill Stanmore Middlesex HA7 4LP	rnoh.biobank@nhs.net
2	Frozen Tumour	Sections 5, 6	RNOH Biobank Team Histopathology Department UCL Institute of Orthopaedics Royal National Orthopaedic Hospital Brockley Hill Stanmore Middlesex HA7 4LP	rnoh.biobank@nhs.net
3	CTC bloods Newcastle	Section 7	Mr Kenneth Rankin – ICONIC Study Northern Institute for Cancer Research Paul O’Gorman Building Framlington Place Newcastle University Newcastle upon Tyne NE2 4HH	Andrea.Atkinson@newcastle.ac.uk
4	CTC bloods Relapse only Sheffield	Section 7	Lab Manager – ICONIC Study Cancer Clinical Trials Centre Weston Park Hospital Whitham Road Sheffield S10 2SJ	sth.cctc-ctateam@nhs.net
5	ctDNA, methylation profiles and future research	Section 8	ICONIC Trial UCL ECMC GCLP Facility UCL Cancer Institute Paul O’Gorman Building University College London 72 Huntley Street London WC1E 6DD	Victoria Spanswick v.spanswick@ucl.ac.uk (Study Manager, main contact) And CI.GCLP@ucl.ac.uk Please use both emails as the latter goes to all staff
6	Germline DNA bloods	Section 9	ICONIC Trial UCL ECMC GCLP Facility UCL Cancer Institute Paul O’Gorman Building University College London 72 Huntley Street London WC1E 6DD	Victoria Spanswick v.spanswick@ucl.ac.uk (Study Manager, main contact) And CI.GCLP@ucl.ac.uk Please use both emails as the latter goes to all staff
7	PBMC bloods	Section 10	ICONIC Trial UCL ECMC GCLP Facility UCL Cancer Institute Paul O’Gorman Building University College London 72 Huntley Street London WC1E 6DD	Victoria Spanswick v.spanswick@ucl.ac.uk (Study Manager, main contact) And CI.GCLP@ucl.ac.uk Please use both emails as the latter goes to all staff