

## SAMPLE KITS AND COURIER SHIPPING

### 1 Scope

- 1.1 This SOP is for preparing shipments to CIGMR and requesting sample collection kits for the REQUIRE study.

### 2 Purpose

- 2.1 To describe the procedure and records required for preparing shipments to CIGMR and requesting sample collection kits for the REQUIRE study.

### 3 Process Owner (Responsibility)

- 3.1 Operations Manager

### 4 Health and Safety

All employees should make themselves aware of any health and safety issues related to the use of blood and bodily fluids (RA\_G002<sup>1</sup>), and demonstrate adequate training has been received. Employees are responsible for ensuring the health and safety of themselves and others in the workplace. By virtue of the University and Manchester's statutes (specifically statutes XII and XIII), members of staff are obliged to comply with the statement and associated procedures and guidance, and disciplinary action is possible in cases where these are breached.

### 5 References/Related Documents

- RQ5 Blood Collection and Storage SOP

All related documents will be available under [www.REQUIRE.eu](http://www.REQUIRE.eu)

### 6 Materials

#### 6.1 Materials

Material	Supplier	Cat#
Shipping container	PHSE	N/A
Shipping Labels		
Dry ice or bubble wrap		
Plastic bags/patho pouches		

### 7 Method

#### 7.1 Requesting REQUIRE Sample Collection Kits

- 7.1.1 Sample collection kits and labels can be obtained by written request from the biobank at The Centre For Integrated Genomic Medicine (CIGMR), University of Manchester.

<sup>1</sup> Used for internal purposes of CIGMR.

Requests for sample collection packages and labels should be made using the documents entitled 'RQ10a Sample Kit Request Form'<sup>2</sup> or 'RQ10b Off Project Sample Kit Request Form'<sup>3</sup>.

**Note:** Should you require an additional copy of either of these forms, please contact CIGMR at the email addresses provided in 7.1.3.

7.1.2 Completed form(s) must be received at the biobank 4 weeks prior to when the sample collection packages are required.

**Note:** This lead-time allows the biobank sufficient time to build, validate and ship the collection packages to each site.

7.1.3 Completed request form(s) should be sent to all three of the following e-mail addresses (to ensure requests are dealt with when staff are away on holiday/on sick leave):

- [Genevieve.Pridham@manchester.ac.uk](mailto:Genevieve.Pridham@manchester.ac.uk) (Project Manager)
- [Kate.Dixon@manchester.ac.uk](mailto:Kate.Dixon@manchester.ac.uk)
- [samples-cigmrbiobank@manchester.ac.uk](mailto:samples-cigmrbiobank@manchester.ac.uk)

7.1.4 Sample labels and collection kits will be sent to one 'hub' site in each country; this site will then be responsible for distributing sample collection kits and labels to any 'sub-sites' within that country. The biobank endeavours to provide delivery of sample collection kits to the country hub site within 4 weeks of receipt of the written request for sample collection kits.

7.1.5 Please see below for a list of the country specific hub sites:

- Gent, Belgium
- Leuven, Belgium
- Montpellier, France
- Heidelberg, Germany
- Milan, Italy
- Santiago, Spain
- Manchester, UK
- Leicester, UK
- Mount Sinai, New York, USA

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<sup>2</sup> For internal purposes of CIGMR: FORM/SM/001/A

<sup>3</sup> For internal purposes of CIGMR: FORM/SM/001/B

## 7.2 Preparing EDTA Blood Samples for Shipment to CIGMR

7.2.1 Collecting sites should ensure that the number of EDTA bloods being prepared for shipment is of suitable size i.e. at least 50 bloods.

**Note:** Smaller batches of bloods are not cost effective to ship and should be held until higher numbers are obtained.

7.2.2 All bloods must be stored upright in a cryobox or other suitable container and be kept frozen at -80°C until the courier arrives for collection.

7.2.3 Ensure a REQUIRE Shipping Manifest sheet is completed and emailed to CIGMR that details all EDTA samples to be shipped (using the RQ8 Sample Tracking Log as template) and includes all box positions, subject IDs, blood volumes and any samples which are damaged.

7.2.4 When emailing the manifest, take the opportunity to arrange a suitable shipping date with the Project Manager at CIGMR, see 7.1.3 for the email address.

**Note:** Please take into account all UK bank holidays (<https://www.gov.uk/bank-holidays>) when booking collections. In addition, please do not book collections on a Friday as these may be delayed over the weekend and may thaw as a result.

## 7.3 Booking a Courier Shipment

7.3.1 In order to book a courier shipment, contact PHSE by email ([customerservices.uk@phse.com](mailto:customerservices.uk@phse.com)) with the preferred shipment date and contents.

7.3.2 The required notification windows, preferred pickup days and expected transit times for collections are shown below:

	Pick Up Notification	Preferred Pick Up Date	Expected Transit Time (subject to customs)
<b>UK</b>	24Hrs	Monday, Tuesday, Wednesday, Thursday	>24Hrs
<b>Europe</b>	48Hrs	Tuesday, Wednesday	>48Hrs
<b>USA</b>	48Hrs	Tuesday, Wednesday	>72Hrs

7.3.3 For all other queries and details regarding courier shipments with PHSE, please refer to the document provided by PHSE entitled: 'Standard Operating Procedure for: The University of Manchester; Project: REQUIRE Study' listed in the Appendix.

## 8 Document History

8.1 This is the 2nd version of this SOP: 'Standard Operating Procedure for: The University of Manchester; Project: REQUIRE Study' has been added as an appendix to this document.

## 9 Appendix

### Standard Operating Procedures for: University of Manchester Project: REQUIRE Study

#### Purpose of SOP Document

This Standard Operating Procedure (named SOP hereafter) describes the cargo information and document flow from the time the order is received by PHSE up to final delivery of the shipment at destination for the REQUIRE study. The SOP will also contain information regarding the actual handling and monitoring of shipments which shall be used to guarantee seamless shipment flows in all areas of transportation.

#### Field of Application

This SOP applies to all warehouse staff, transport, operators (internal and external) and management involved in the handling of the REQUIRE study.

#### Responsibility and Training

All staff at PHSE who deal with this process are responsible for adhering to these procedures. This includes observation and reporting to the UK Operations Director of any deviations. All parties involved with this SOP will have training before handling the consignments.

#### University of Manchester Contact Details

University of Manchester  
Centre for Integrated Genomic Medical Research (CIGMR)  
Stopford Building  
Oxford Road  
Manchester M13 9PT

**Genevieve Pridham**  
Project Manager and Senior Laboratory Technician  
Tel: +44 (0) 161 275 5598  
Email: Genevieve.Pridham@manchester.ac.uk

**Kate Dixon**  
Email: katherine.dixon@manchester.ac.uk

### PHSE Contact Details

PHSE London Heathrow will be the controlling office for this account.

PHSE UK Limited  
373 Hatton Road  
Feltham, Middlesex  
TW14 9QS  
Tel: 0203 725 4000  
Email: customerservices.uk@phse.com

<p>Karen Smith Customer Services Manager Tel: 0203 725 4002 Email: karen.smith@phse.com</p>	<p>Richard Cunningham Business Development Manager Tel: 0203 725 4004 Email: richard.cunningham@phse.com</p>
<p>Matthew O'Day Customer Services Tel: 0203 725 4003 Email: matthew.oday@phse.com</p>	<p>Paul Balkwell Operations Director Tel: 0203 725 4001 Email: paul.balkwell@phse.com</p>

### Site Contact Details

As per the attached REQUIRE Site information documents (TBC)

### Scope of Services

PHSE has been nominated for the collection of samples from the various study sites and delivery back to the Biobank at the University of Manchester.

There may also be additional shipments from the University of Manchester to worldwide destinations including the provision to the sites of sample collection packets.

### Commodity & Packaging Requirement

#### Sample Collections

Commodity: Biological Substance Cat B

Temperature: Frozen - minimum -20°C at all times

Packaging: Validated Thermo Control Packaging TP20 to TP40 (or equivalent) as approved by the University of Manchester

Temperature Monitor: Yes – Calibrated LogTag TRIL-8 Datalogger to be used for each Frozen shipment

#### Sample Collection Packets

Commodity: Empty Tubes, Labels & Bags

Temperature: Uncontrolled

Packaging: Various – Non Specific

Temperature Monitor: No

## Working Procedures

### Sample Collections – Inbound to UoM

1. University of Manchester or the collection site will notify PHSE via email (customerservices.uk@phse.com) of the collection request in accordance with the agreed lead time for collections.  
The collection details should include preferred collection date, time for collection during that day (Min 4 hour window), contact at site for handover of samples and size of Thermobox to be used.
2. PHSE will confirm receipt of the collection request within 30 minutes via email.
3. PHSE will arrange the collection and email the collection site (with cc the contacts at University of Manchester) the Waybill for the shipment as confirmation of booking.
4. The site should prepare the samples for collection at the confirmed time and also provide a Customs invoice (if required) to accompany the shipment. This should be printed on the sites letter headed paper and dated and signed. This Invoice should be given to the driver upon collection.
5. PHSE driver will provide the Thermobox, Pathopouch, Dry Ice and Datalogger for the shipment. Samples are to be packed in the Pathopouch before placing in the Dry Ice in accordance with IATA packing instruction 650.
6. The Datalogger will be started and placed in the Thermobox at least 1 hour before collection to ensure accurate temperature reporting upon collection. PHSE will ensure that the vehicle collecting the shipment will be dry, clean and odour free and will protect the consignment from the elements.
7. PHSE driver will request the collection site signs the PHSE Waybill upon collection with Signature, Name and time of collection. This package on board (POB) information will be sent as a tracking update to all relevant contacts for the shipment via email.
8. PHSE will notify all relevant contacts for the shipment the following status updates:  
Booked Flight  
Departed Flight  
Received from Flight  
Cleared Customs  
Out for Delivery
9. PHSE will deliver the consignment in the agreed transit time relating to the site location in good condition and the integrity of the samples will be intact. All consignments will be checked before delivery to the University of Manchester and Dry Ice replenished should this be necessary.
10. Upon delivery to the University of Manchester the driver will request a clear signature, printed name and time of delivery on the PHSE Waybill. The Datalogger will be removed at the time of delivery and the Datalogger report will be emailed to the contacts at the University of Manchester with 24hrs.
11. The Proof of Delivery information (POD) will be emailed to all relevant contacts for the shipment.
12. PHSE will notify the University of Manchester of any delays in transporting the shipment, and agreed corrective action can be taken if necessary.

### Sample Collection Packets – Outbound from UoM

1. University of Manchester will notify PHSE via email (customerservices.uk@phse.com) of the requirement to send sample collection packets to the sites for use in the REQUIRE study. The collection details should include preferred collection date, time for collection that day (min 4 hour window), Box requirement and destination.
2. PHSE will confirm receipt of the collection request within 30 minutes via email.
3. PHSE will arrange the collection and email the contacts at the University of Manchester the Waybill for the shipment as confirmation of booking.
4. University of Manchester should prepare the samples for collection at the confirmed time and also provide a Customs invoice (if required) to accompany the shipment. This should be printed on the University of Manchester's letter headed paper and dated and signed. This Invoice should be given to the driver upon collection.
5. PHSE driver will request the collection site signs the PHSE Waybill upon collection with Signature, Name and time of collection.
6. Upon delivery to the Consignee the driver will request a clear signature, printed name and time of delivery on the PHSE Waybill. This Proof of Delivery information (POD) will be emailed to the contacts at the University of Manchester as a final delivered status.
7. PHSE will notify the University of Manchester of any delays in transporting the shipment, and agreed corrective

action can be taken if necessary.

### Invoicing Procedures

Once the consignment has been delivered to the University of Manchester, an invoice for the shipment will be raised to the pick up site and sent via email to the billing email address given by the relevant sites on the REQUIRE site information document.

The invoice will be for the agreed amount and payable within the agreed 30 days.

### SOP Review

This SOP can be amended and information can be added when agreed by PHSE UK and the University of Manchester.

Approved By:  
University of Manchester & PHSE UK

Genevieve Pridham

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Project Manager and Senior Laboratory Technician  
University of Manchester

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Date

Richard Cunningham

\_\_\_\_\_  
Business Development Manager  
PHSE UK Ltd

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Date

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Operations Director  
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Date

### SOP Information

Owner: Richard Cunningham  
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