

RECOVERY Trial: Antibody Therapies Arm

Blood sampling and transportation Standard Operating Procedure (SOP)

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1. Introduction

Patients who are eligible to be enrolled into the antibody therapy arm of the RECOVERY trial will be randomised to one of three groups on a 1:1:1 basis: no additional treatment (control), convalescent plasma (CP) or REGN-COV2 monoclonal antibodies (mAb), depending on suitability of the treatment for the participant and availability of the treatment at the site. For all participants enrolled into this arm, both the control and those who receive CP or mAb, a baseline serum sample must be obtained. The sample must be obtained after the participant has provided consent and prior to randomisation. The sample is then sent to a central laboratory in Oxford. This serum sample will be analysed to measure the levels of antibodies against SARS-CoV-2. Additionally, the presence of SARS-CoV-2 might also be tested.

This laboratory SOP includes information on sample collection, handling, labelling, storage, and transportation.

2. Equipment

- 1- Locally provided yellow (gel SST tubes preferred) or red top or equivalent tube for serum (preferably 6mL tube, but 5mL is also acceptable). Age-appropriate tubes for paediatrics.



- 2- Packaging kit for transport (provided by NHSBT). Keep the packaging kits away from the clinical area. Make sure you have enough kits at site. Contact NHSBT CTU team to request further supply as required (see contact details below).



The packaging kit includes:

- Secondary container,
- Outer box,
- Absorbent sachet,
- A tamper-proof mailing envelope with pre-paid return address attached,
- Label sticker to complete and attach to the serum tube,
- Sample Tracking Form to complete and enclose in the envelope along with the serum sample.

3. Sample collection and preparation for local lab transfer

Follow your hospital COVID-19 infection control and health and safety policies when collecting, handling and transferring blood samples from COVID-19 patients.

The following procedures will be performed on the ward by the research or designated ward team:

- Obtain informed consent from patient as per RECOVERY trial protocol prior to taking blood.
- Collect one 6mL or 5mL yellow or red top, or equivalent, tube for adults and older children; paediatric or neonatal counterparts for younger children and infants.
- Label the sample using your hospital's standard systems, including date and time, writing "RECOVERY" somewhere on the label or tube.
- Place the sample in a clear plastic specimen bag and write on it RECOVERY – Transfusion Lab, using a black marker pen or sticky label according to availability, and send to the local transfusion laboratory as soon as possible. If your laboratory requires a form, complete this including clear reference to RECOVERY.

4. Sample labeling

Follow your hospital COVID-19 infection control and health and safety policies when collecting, handling and transferring of blood samples from COVID-19 patients.

The following procedures will be performed by the designated local team (research and/or transfusion laboratory staff depending on local arrangements):

- Log into RECOVERY web system at <https://rct.npeu.ox.ac.uk/recovery/> (see Appendix 1)
- Using the label provided, label the tube clearly with the participant's study number, 7-digit ID number, and "RECOVERY" (details of the label – Appendix 2).
- Attach securely to the serum tube.
- Either remove the original sticker label from the sample tube that includes the participant's identifiable information, or obscure the details with a black marker pen.
- **Complete the Sample Tracking Form, provided in the packaging kit** (Appendix 3).
- **Complete the Local Sample Tracking Log - to be kept locally** – (Appendix 4).

5. Instructions for sample packaging and transportation to the central lab

The following procedures will be performed by the designated local team:

- Place the tubes in the absorbent white material, place in the secondary container, place in the outer box and then place in the tamper-proof mailing envelope.

- Insert the completed Sample Tracking Form into the tamper-proof mailing envelope.
- Seal the envelope.
- Please ensure the outside of the envelope is clearly labelled with the name and address of the person responsible at your site for sending the samples with a contact telephone number.
- The delivery address label is already attached to the envelope (as in Appendix 5).
- Take the envelope to the Post Room or post in the nearest Royal Mail Post Box.

6. Timing of sample delivery

- Samples should ideally be posted the same day as collection to obtain the best quality of information.
- Samples that are not sent on the same day must be sent as soon as possible as the quality will deteriorate.
- Samples collected on Fridays and weekends should be stored in the fridge and sent Monday morning to arrive on Tuesday.

7. Contacts

Central Laboratory team: contact@quod.org.uk

NHSBT CTU Trial Managers

Samaher Sweity – Samaher.sweity@nhsbt.nhs.uk - Mobile: 07392139747

Gillian Powter – Gillian.powter@nhsbt.nhs.uk - Mobile: 07590 353091

RECOVERY Trial team

Lucy Fletcher (Senior Trial Manager) – recoverytrial@ndph.ox.ac.uk - 0800 1385451

8. Appendices

Appendix 1: Accessing RECOVERY participant ID

1. Visit <https://rct.npeu.ox.ac.uk/recovery/>

2. Select site name from drop-down list

3. This will automatically enter correct Site Username. Enter password (which has been sent to your laboratory manager).

4. You will see a menu screen like this:

Latest 3 participants			
Study no	NHS number	Date randomised	Time since randomisation
1020304	6414368776	18/07/20 10:56	about a minute
1020297	8893745275	18/07/20 10:55	2 minutes
1020285	8392998820	18/07/20 10:54	3 minutes

Please select one of the following options:

1. **Enrol patient into study**
Enrol patient into study with random data
2. **View recent recruitment list**
3. **Enrol patient into second phase**
4. **Log out**

If the sample belongs to one of the last three people to be randomised, their NHS number (or CHI number in Scotland) will be visible in the “Latest 3 participants” table and their study number displayed next to it.

5. If other people have been randomised since, click on “2. View recent recruitment list”. **IMPORTANT: DO NOT SELECT “1. Enrol patient into study”.**

Centre 1					
Study no	NHS number	Main randomisation			
		Time randomised	Allocation	Part B	Print
1020304	6414368776	18/07/20 10:56	Azithromycin	Usual standard management	<input type="button" value="Print"/>
1020297	8893745275	18/07/20 10:55	Usual standard management	Convalescent plasma	<input type="button" value="Print"/>
1020285	8392998820	18/07/20 10:54	Usual standard management	Convalescent plasma	<input type="button" value="Print"/>

6. Find their NHS number (or CHI number in Scotland) and the study number is displayed next to it.

7. At the bottom of the page, click on “Home” and then “4. Log out”

If you cannot find the participant’s NHS or CHI number on this list, please contact your local RECOVERY Principal Investigator. Their details have been sent to your laboratory manager. Please store the sample safely until this is resolved. Please contact the RECOVERY trial team if further assistance is needed.

If you are asked to provide convalescent plasma for a participant, *and you have not received this baseline serum sample*, please ask the requester to send a sample as soon as possible.

Appendix 2: Template Sample Tube Label

This label will be included in the packaging kit

Recovery Trial Serum Sample						
Study number:						
1						
Date & Time collected:						

Appendix 3: Sample Tracking Form (this is provided in the packaging kit).

Sample Tracking Form

Please complete this form and send with samples.

Each sample should be labelled with the participant’s RECOVERY study number. Please do not include participant identifiable information.

Hospital Site: _____		Recovery Study Number: _____	
Sample type	Date Posted	Comments	
Serum tube x 1			
Name		LABORATORY USE ONLY	
Signature		Date received/processed:	
Date			

Appendix 4: Local Sample Tracking Log

Please keep this log on site

Hospital site.....

RECOVERY Study Number	Date and time Sample Received at local lab	Date Posted	Comments

Appendix 5: Template Sample Postage Address Label

This pre-paid return address will be included, attached to the envelope included in the sample packaging kit.

<p>RECOVERY Randomised Evaluation of COVID-19 Therapy</p> <p>COVID Oxford BioArchive (COBA)</p> <p>FAO: QUOD Team</p> <p>NHS Blood and Transplant</p> <p>John Radcliffe Hospital</p> <p>Oxford</p> <p>OX3 9BQ</p> <p>Immediate cold storage is required</p>
