



Biological Samples Collection and Shipment to BioBank

Standard Operating Procedure

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PURPOSE

The purpose of this protocol is to describe procedures for collecting and transporting specimens from STRIVE Trial participants to the appropriate BioBank (contact details page 5).

Wales Neuroscience Research Tissue Bank will receive samples from STRIVE trial centres in Birmingham, Bristol, Liverpool, Manchester and Wales.

The KCL Infectious Diseases BioBank will receive samples from the rest of the STRIVE trial centres.

The samples will be obtained from paediatric and adult patient populations presenting with symptoms of transverse myelitis.

SCOPE

This protocol is written for research personnel at NHS sites participating in STRIVE Trial.

RESPONSIBILITIES

Practitioners taking blood and CSF samples should be GCP trained and their involvement should be clearly recorded on the delegation log. They should have sufficient experience and training to perform these activities safely and at minimum patient discomfort according to local research governance procedures.

SAMPLES REQUIRED

Samples listed in the table below should be collected on the same day if possible. Morning collection will be required in order to allow sufficient time for delivery to the appropriate BioBank.

Tissue to collect	Volume*	Collection Tube	Collected at Baseline (T0)	Collected at 6 months follow up (T3)
Serum	10 ml	SST, allow to sit at least 30 min at room temp.	✓	✓
Plasma	10 ml	EDTA, gently invert to mix 8-10 times	✓	✓
DNA	10 ml	EDTA, gently invert to mix 8-10 times	✓	
PBMC**	10 ml	EDTA or sodium heparin, gently invert to mix 8-10 times	✓	
RNA	10 ml	PAX tube	✓	
CSF	12 ml	Sterile polypropylene tube with lid	✓	

***NOTE:** These volumes may not be appropriate for **paediatric patients** but aim to collect as much as possible. **Minimum** volumes for each paediatric sample should be around **50% of the adult volumes**.

****NOTE:** PBMC samples to be collected from patients who have never been treated with steroids, immune-modulatory or immune-suppressive medication. If there is prior history of treatment with any of the drugs in these categories PBMC samples can be collected if sufficient time has lapsed since the treatment:

- IV pulse steroids: 30 days
- systemic oral steroids: 30 days

- immunomodulatory agent (glatiramer acetate or interferon b): 3 months
- immunosuppressive agent (azathioprine/ methotrexate): 6 months
- biologic therapy: do not collect blood for PBMC

METHOD FOR BLOOD EXTRACTION

1. Prior to blood extraction ensure informed consent from patient and/or guardian according to STRIVE study protocol was obtained.
2. Explain the procedure to participant giving time for any questions and ensure the patient is comfortable with the procedure.
3. Ensure all equipment is ready to hand in a tray next to the participant. Blood sampling tray should contain:
 - SST, EDTA, Sodium heparin and PAX collection tubes
 - Syringe with a green/blue needle or Vacutainer system with butterfly needle attachment
 - Cotton Swab/Gauze
 - Alcohol Swab
 - Tourniquet
 - Plastic gloves
4. Follow local procedures for safe blood extraction and ensure that collection tubes are full.
5. Label the tubes with: patient's **STRIVE PIN number, date and time blood sample was taken.**
6. Complete **STRIVE sample collection form** (see Appendix) which will be couriered to the BioBank with the samples at ambient temperature.
7. **Send to the BioBank as soon as possible to be delivered before 2 pm.**

METHOD FOR CSF EXTRACTION

1. Prior to CSF extraction ensure informed consent from patient and/or guardian according to STRIVE study protocol was obtained.
2. Explain the procedure to participant giving time for any questions and ensure the patient is comfortable with the procedure.
3. Ensure that lumbar puncture tray is complete and ready for use. Usually it will contain:
 - Povidone-iodine (10%) (Betadine®) and/or isopropyl alcohol (70%) with applicators or sterile pads
 - Fenestrated drape
 - Local anesthetic (lidocaine 1%, (10mg/mL) 1-2 mL)
 - Syringe with small needle (1-2 inch, ~23g) for use with local anaesthetic
 - 3.5 inch lumbar puncture needle (22 gauge atraumatic recommended)
 - Sterile polypropylene tubes with caps for CSF collection
4. Position patient appropriately for procedure and follow locally approved standards for safe extraction of CSF. It is recommended that location for extraction is between L3/L4 or L4/L5.
5. Label the tubes with: patient's **STRIVE PIN number, date and time blood sample was taken.**
6. Complete **STRIVE sample collection form** (see Appendix) which will be couriered to the BioBank with the samples.

7. Send to the BioBank as soon as possible to be delivered before 2 pm.

In some instances it may not be possible to collect blood and CSF samples on the same day so collect them on two consecutive mornings and deliver each sample to the BioBank as soon as possible on the day of collection.

BIOBOTTLE AND SHIPPING INSTRUCTIONS

1. Place *clearly labelled* blood and CSF tubes (patient study number, date and time of sample collection) inside a plastic bag first, then into the Biobottle. Aim to send all samples from a patient to the BioBank together.
2. Ensure the absorbent material is in the Biobottle.
3. Ensure the correct sample collection forms are placed with the matched blood and CSF samples.
4. Please ensure that all contents are inside the package before closing.
5. Please ensure the outside of the shipment box is clearly labelled with sender's details (the name and address of the person responsible at site for sending the samples with a contact telephone number) as well as the address of the BioBank to which the samples need to be couriered.
6. After taking a sample, the research nurse (or designated site person) at the STRIVE trial centre will call the specialist medical couriers (CitySprint Couriers Tel: 0845 020 3000) to arrange collection and delivery to the appropriate BioBank.
7. Upon booking the courier, a reference number will be provided by CitySprint.
8. **For deliveries to the KCL Infectious Diseases BioBank** the reference number will be communicated via email (biobank@kcl.ac.uk) by the site's designated person.

The courier will transport the sample to the Secretaries Office, Programme in Infection and Immunity, KCL, 2nd Floor Borough Wing, Guy's Hospital where the receiving individual will confirm receipt of the sample. The Secretaries' Office will ensure rapid sample transfer to BioBank staff who will then email the sender of the sample to confirm receipt of the sample.

9. **For deliveries to the Wales Neuroscience Research Tissue Bank** the reference number will be communicated via email (WNRTB@Cardiff.ac.uk) by the site's designated person. Additionally they can be phoned using telephone number 02920 743454.
10. In addition to the tracking number please quote '**STRIVE Trial**' when alerting the BioBanks that the samples have been collected from the site.
11. If the courier has not collected the samples within 90 minutes, the person who booked the courier should contact CitySprint to find out the status, quoting the reference number, and notify the appropriate BioBank of any delays.
12. If the BioBank staff have not confirmed receipt of the samples within two hours of collection from the trial centre by CitySprint, the courier will be contacted and the sample traced.

TIMING OF SAMPLE DELIVERY

After collection samples should be sent to the BioBank as soon as possible using CitySprint Couriers. Please ensure that the samples are **not sent** to the BioBank **after 2 pm**, Monday to Friday.

Once samples are safely secured inside the Biobox and ready for transfer to BioBank, please phone or email the contacts at the BioBank of their impending arrival so arrangements can be made to store the samples.

NOTE: For samples collected at **6 months follow up**, please contact the relevant BioBank well ahead of time and give them the date when the samples will be sent to them for processing.

PERSONNEL

Members of clinical staff trained to take blood and/or CSF, including doctors and nurses on the unit.

HEALTH AND SAFETY

1. Standard precautions are required. Always wear gloves when handling blood samples.
2. Refer to the risk assessment, hazard data sheets and the Departmental policy at your site for additional safety information.
3. Please take all reasonable efforts to notify the BioBank of any extraneous agents, or biologically active contaminants that the sender is aware of (for example, but not limited to, HIV, hepatitis B, tuberculosis and transmissible spongiform encephalopathies) which may have been or are present in the samples.

BIOBANKS' CONTACT DETAILS

Sample Delivery Address	Lab Co-ordinator	Telephone	Email	Trial Sites
The KCL Infectious Diseases BioBank Secretaries Office Programme of Infection and Immunity Second Floor Borough Wing Guy's Hospital Great Maze Pond London SE1 9RT	Christine Mant John Cason	020 7188 3069 020 7188 1180	Biobank@kcl.ac.uk john.cason@kcl.ac.uk	London Liverpool Oxford Southampton Newcastle Nottingham
Wales Neuroscience Research Tissue Bank For the attention of Dr Sam Loveless Welsh Neuroscience Research Tissue Bank, C/O Reception Desk Henry Wellcome Building Cardiff University Heath Park Campus Cardiff CF14 4XN	Samantha Loveless	029 2074 3454	LovelessS1@cardiff.ac.uk	Birmingham Bristol Manchester Wales

APPENDIX: STRIVE TRIAL SAMPLE COLLECTION FORM

Please ensure that this form is sent to the BioBank with patient’s samples but a copy should also be filed with patient’s study notes.

Please send the samples to the BioBank as soon as possible after collection.

STRIVE TRIAL SAMPLE COLLECTION FORM

Name of the hospital.....

STRIVE Patient ID:.....

DOB:.....

Gender: Male Female

Initials:.....

Date sample collected:.....

Time sample collected:.....

Patient did/did not (*please delete as appropriate*) receive steroid/immunomodulatory/suppressive treatments in the last 30 days/ 3 months/6 months.

Total Samples Collected:

TUBE	Quantity (ml)	Study time point	
		T0 (baseline)	T3 (6 M follow-up)
SST			
EDTA			
Sodium Heparin			
PAX tube			
Sterile polypropylene tube with lid			