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Author(s)	**MacDonald Bin &Tchoupe Eric**		
Function	**Laboratory Coordinators**		
Date and signature			

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1.0. GENERAL OVERVIEW

The purpose of the COVID-19 CCP Biobank is storing and managing ethically consented blood, swabs, serum, plasma, PBMC and other tissues, and matching longitudinal clinical data. This Biobank is a resource that may become available in the future to researchers throughout the Nation to support research investigating COVID-19, and its outcomes, in improving or creating diagnostic tests and identifying potential new treatments for the disease among other potential uses.

The samples collected from study participants will be stored in cryogenic vials that help preserve the tissue's proteins and genetic material almost indefinitely. The specimens, with matching clinical data, will be donated by consenting participants while enrolled in the COVID-19 CCP Project. Participants will have the option of consenting to the research team collecting a small additional sample of blood, swab, sputum, saliva and/or urine. These specimens will be processed and stored at the COVID-19 CCP Biobank, hosted by two potential sites: The biotechnology centre of the University of Yaoundé I, Cameroon and the **Centre for research on Filariasis and other Tropical Diseases** (CRFilMT). These samples will be stored under a unique code without the participants' personal identifiable information.

This Biobank will facilitate the development of new methods for screening, diagnosis and evaluation of COVID-19 which are likely to make a significant impact on patient care in the future. Researchers who are part of an ethically and scientifically approved research project will be able to apply to access samples from the COVID-19 CCP Biobank

1.0.1. Scope

The procedures within this document are for the practical guidance of all authorized personnel involved in the biological sample procurement and data collection of the COVID-19 CCP Project.

1.0.2. Responsibilities

The designated Biobank Staff will be responsible for all operations including compliance with current national and local regulations. They will also ensure the Biobank operates within budget and serve as a liaison to key users.

Personnel authorized and supervised by Laboratory Manager for biological sample procurement and processing, and data collection must familiarize themselves with these SOPs. Each person is responsible for ensuring that all procedures are performed as defined in the individual SOPs. The order for execution of the various procedures is indicated in the flow diagram in (2.0).

1.0.3 Safety

Safety plans are used to prevent or to minimize injuries to employees. Designated personnel will adhere to the Health and Safety guidelines of the host Laboratories/Institutions in the areas of biological, chemical, electrical, radiational, physical and fire safety. Staff shall undergo training (or induction) in possible hazards and precautionary measures e.g. staff members working with human research participants are encouraged to be vaccinated against hepatitis.

Personnel and visitors should wear appropriate personal protection wear (lab coats, long pants, covered shoes, masks) and eye protection as prescribed by national Health and Safety guidelines for this pathogen. Appropriate gloves are recommended in handling specimens.

1.0.4. Facilities and Equipment

Facilities including air conditioning, lighting, flooring, backup power, access, security systems, fire prevention systems and emergency preparedness are maintained by the host institutions/laboratories.

Equipment including liquid nitrogen freezers, mechanical freezers and refrigerators are maintained and will typically be monitored by the Biobank staff. Where dry ice is employed, there should be adequate ventilation to ensure sufficient air or oxygen levels exist. A temperature log of the freezers will be maintained and recorded at least 3 working days per week as per each laboratory's pertinent SOPs.

Operation of equipment by laboratory personnel will be strictly according to the operation manual specified by the manufacturer and the Standard Operating Procedures (SOP) specified by the Biobanking laboratory. All equipment is to be set up, used, maintained, calibrated, and serviced according to the manufacturer's instructions, the COVID-19 CCP Project SOPs, the Biobanking laboratory, and the preventative maintenance schedules of the host Institution.

1.2. TRAINING

Designated Biobanking laboratory staff and COVID-19 CCP Project staff will be properly trained to perform the tasks required for biobanking purposes. Training associated with safety and SOPs will be recorded in the training record.

1.0.6. Records Management

Records will be maintained securely and confidentially. Records associated with the Biobank include training documents, SOPs, equipment maintenance records, audit documents, informed consent documentation, collection and processing records, specimen storage location, sample distribution and quality control activities. Paper files containing confidential participant information are locked in records cabinets and access is limited to Biobanking laboratory staff and COVID-19 CCP Project team members. Electronic records are backed up daily on remote servers. All computer access is password protected and uses automatic timeout mechanisms (e.g. screensavers). Multi-level permission levels are determined by the Laboratory Manager.

Documents have unique titles, dates and version numbers i.e. version tracking. Dates have an unambiguous format where ***dd*** stands for day, ***mm*** for month and ***yy*** for year. SOPs would be reviewed annually.

Corrections in paper records are initialed and dated; changes in electronic records are noted and tracked with name, date and reason for change.

Records will be accessible for inspection by authorized regulatory or sponsor personnel. The Manager or delegate staff will oversee access of confidential participant information by regulatory agencies and other auditing groups.

1.3. DOCUMENT REVIEW

The Study Principal Investigator (PI) is responsible for overview of writing, for review and approval, and for maintenance of the master copies of all SOPs. The PI, or designee, will maintain a historical file of rewritten SOPs for audit purposes, and will ensure that all SOPs are reviewed annually, on the anniversary of their initial acceptance.

The author(s) of an SOP is (are) responsible for the preparation of clear and concise practice guidelines for the procedure, which comply with the requirements of the current scientific, technical, safety and regulatory standards. Detail should be sufficient to guide a trained operator to perform the procedure, ensuring uniformity in the conduct of the activity.

Authorized personnel performing the duties are required to inform the PI when alteration to a procedure is required, in order that a review of the SOP can be conducted and the procedure amended accordingly. SOP documents would be reviewed at 12 months after previous review to maintain contemporary content.

1.4. STUDY DATABASE

The database platform will be hosted and managed by REDCap.

1.5. IDENTIFIABLE AND DE-IDENTIFIED DATA

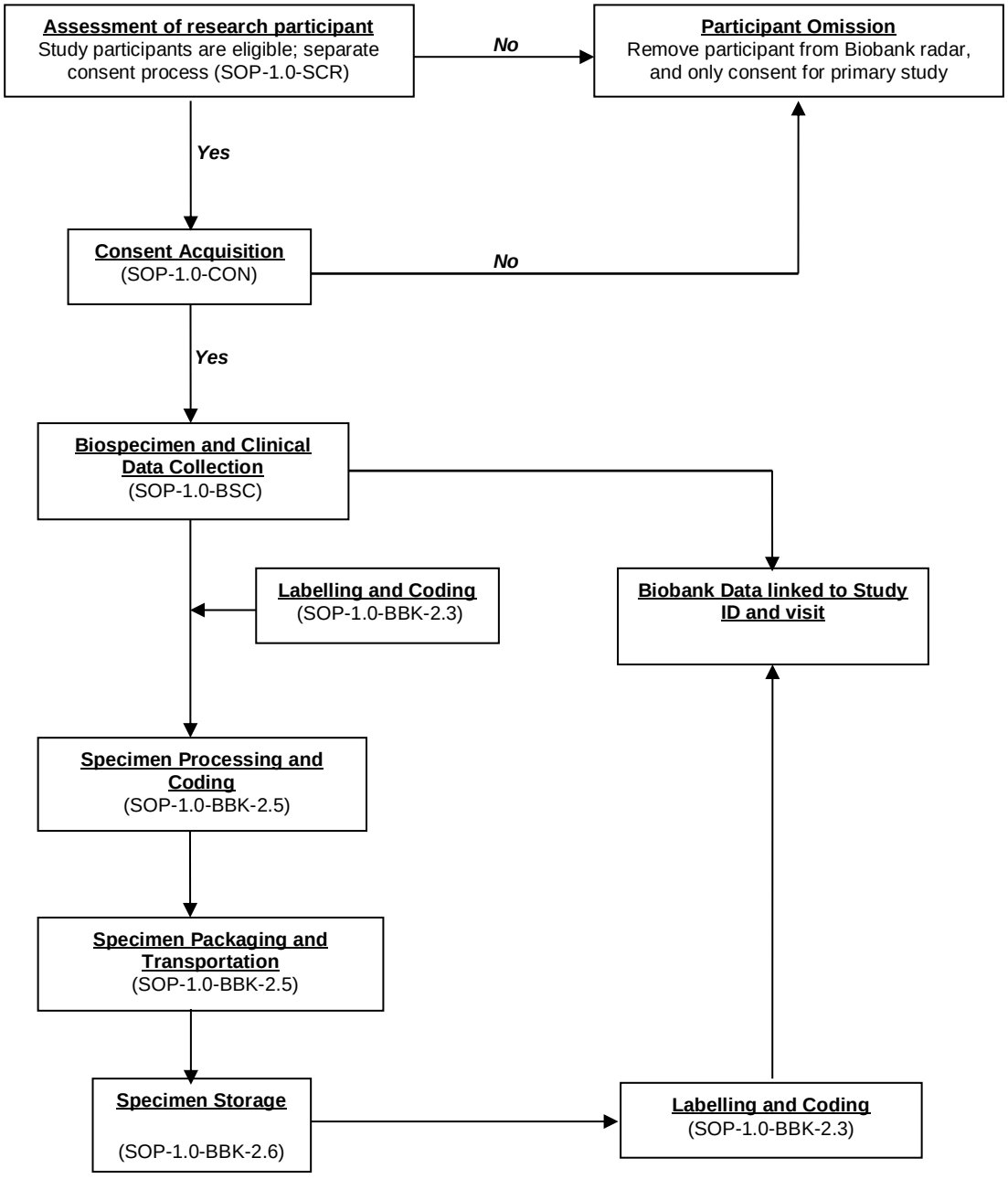
The Biobank samples will have identifiers removed and replaced by a code. Each sample will have a participant and sample ID; however, a link between the sample and the participant's identity will be retained. It will be possible to use the code to re-identify the person who donated the sample. The samples will therefore be referred to as re-identifiable (see below). A sample will only be re-identified in the instance a participant wishes to have their sample destroyed. Also, participants can indicate on the consent form if they wish to be contacted in future if a new finding is made from their sample that may have implications to their wellbeing or that of their family.

For the purpose of these SOPs, the following definitions are applied per

- individually identifiable data, where the identity of a special individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- re-identifiable data, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a special individual by, for example, using the code or linking different data sets;
- non-identifiable data, which have never been labeled with individual identifiers or from which identifiers have been permanently removed, and by means of which no special individual can be identified. A subset of non-identifiable data

2.0. STANDARD OPERATING PROCEDURES

Standard Operating Procedures (SOPs) include all the processes and procedures for the COVID-19 CCP Project Biobank. However, the different sites in Yaoundé and Douala may have some site-specific requirements. The SOPs described herein will follow a flowchart as shown below.



SOP 2.1. ALLOCATION OF PARTICIPANT AND SAMPLE ID NUMBERS

2.1.1. PURPOSE

To describe the participant and sample identification numbers for the Biobank.

2.1.2. RESPONSIBILITIES

- The CCP Project Data Manager (DM) is responsible for ensuring the sample identification numbers determined by the site can be accommodated in the database.
- It is the responsibility of the site to communicate the nature of the sample identifiers used for the Biobank to the Project DM via the Study database.
- Authorized personnel acting for the CCP Biobank must ensure that all procedures for allocation of participant and sample ID numbers are correctly followed.

2.1.3. PROCEDURES

- The participant ID is a combination of digits and letterspecifying the main site (Yaoundé or Douala), the health facility and a unique identifier automatically generated by the Database.
- The numeric parts of the Participant ID are automatically assigned by the database and the alphabetic part, from the participant initials and health facility.
- The ID numbers are unique to the participant sample and must never be reissued if a sample is withdrawn or distributed.

SOP 2.2. STORAGE OF PARTICIPANT INFORMATION

2.2.1. PURPOSE

To describe the procedures required to store participant information for the sites of the CCP Biobank. Participant information is that recorded for the CCP Study.

2.2.2. RESPONSIBILITIES

The on-site Coordinators will ensure that all security systems are in place to guarantee confidentiality of participant information.

Authorized personnel will ensure that all personal, clinical, pathological and demographic information obtained from the participant are securely stored to preserve the confidentiality of all gathered information. Information on biological sample type, storage location and storage coordinates will also be securely stored.

2.2.3. PROCEDURES

Hardcopy documents:

Paper records should be stored in a locked cupboard or filing cabinet [preferably fireproof] within a secure access area [preferably with a smoke detector and sprinkler system].

Note: Authorized persons should ensure that all CCP Biobank forms for the collection of clinical and pathological information required for entry into the database are retrieved from the participant, investigator and pathologist.

Database:

Both the computer and the database used to enter and store participant information must be accessible only with the knowledge of independent security passwords. This knowledge must be restricted to authorized personnel.

The authorized personnel will enter all relevant information from the hard copy documentation onto the database maintained for the site.

Where researchers outside the team are allowed access to the database for data analyses, they will be issued a lower level of access, and only be permitted to view de-identified information.

Regular back-up copies of the database for each site are the responsibility of the on-site Coordinators.

SOP 2.3: LABELING BIOSPECIMENS AND DOCUMENTATION

2.3.1. PURPOSE

This SOP describes the procedure for the labeling of biospecimen samples, sample storage boxes (where appropriate) and documentation of the CCP Biobank.

2.3.2. SCOPE

To ensure the format for labels is standardized across the Biobank sites; the actual procedure for printing labels within this SOP utilizing a Brady printer pertains.

2.3.3. RESPONSIBILITIES

Authorized personnel labeling biospecimen samples and other materials at the sites of the CCP Biobank must ensure that the appropriate label is used for each application, and that the Sample ID label numbers comply with the standard format.

2.3.3. EQUIPMENT AND MATERIALS

Equipment	Material
- Computer with installed Brady® Identilab software - Brady IP® 3000 Printer	- Brady IP Printer Ribbon - Brady Thermatab™ Markers THT-133-461 (Wrap around labels)

- Brady® IdentiLab™ Laboratory Labelling System software - Brady® Data cable with USB adapter - Printer Cleaning Kit for TLS2200™ Thermal Labelling System	

2.3.4. PROCEDURES

Choice of this label type is dictated by suitability for long-term storage in vapour phase of liquid nitrogen (LN), and resistance to numerous laboratory chemicals.

When labeling biospecimen samples avoid touching the adhesive area of the label whilst attaching to the container.

The minimum information on collection tubes is: participant ID, date of collection, time of collection, initials of collector.

Follow software instructions to print labels specifying the following items:

Item 1: Bar code / data matrix of Participant ID
Item 2: Participant ID (human readable format)
Item 3: Date of collection or processing of specimen (*DD-MM-YYYY*)
Item 4: Specimen Type e.g. PLASMA, SERUM), PBMC etc.
Item 5: Sample ID (human readable format)
Item 6. Biohazard symbol
Item 7: CCP Project Cameroon Biobank

If storage boxes are to be used, this will be done using the Brady® IdentiLab™ Laboratory Labeling System software, or equivalent.
Labels should be attached to the tubes prior to conducting sample processing. Contents should be visible.

SOP 2.4. COLLECTION OF WHOLE BLOOD SAMPLES

2.4.1. PURPOSE

To describe the procedures required for the collection of whole blood samples from participants for the CCP Biobank.

2.4.2. RESPONSIBILITIES

Authorized personnel must:

- ensure informed consent has been obtained prior to blood collection. Refer to CCP°SOP°1.0°CON
- collect or arrange collection of whole blood samples for the CCP Biobank
- ensure this SOP and relevant safety practices are followed
- ensure all samples are adequately de-identified
- ensure accurate records are kept and maintained on all samples processed

2.4.3. HEALTH AND SAFETY

Authorized personnel carrying out this procedure must maintain safe working practices and observe all relevant Health & Safety guidelines of their respective institutions pertaining to the collection, transportation and handling of human blood.

This includes the appropriate use of Personal Protective Equipment (PPE), disposal of waste, disinfection & clean-up of spills, and personal hygiene.

2.4.4. MATERIALS

- 2 x 9mL K_2/K_3 EDTA (di- or tri-potassium ethyldiamino-tetra-acetic acid) or ACD-A (Acid Citrate Dextrose) additive blood collection tubes.
- 1 x 8mL SST (Serum Separator Tube) gel separator/clot activator blood tube

- Blood collection set
- Transport container for human blood specimens (e.g. biospecimen bags).

2.4.5. PROCEDURES

- Blood should be transferred to the Biobank laboratory, preferably in a biospecimen bag, at ambient temperature (i.e. not on ice) as soon as possible.
- A record of the sample arriving in the lab shall be noted, including lot numbers and expiry dates of collection tubes.
- The tubes destined for the Biobank laboratory are to be inverted 6 times before being left to rest for at least 30 mins before spinning.
- Under normal circumstances blood should be processed immediately upon receipt in the laboratory.
- Where blood has to be stored overnight in the laboratory before processing, the tubes should be refrigerated (4°C) upon receipt in the laboratory.
- Irrespective of mode of collection, blood tubes should be adequately labeled with participant ID, date of collection and time of collection as minimum.

NB:The full procedure for blood collection is described in *CCP_SOP_BSC_V1.0*

SOP 2.5. PROCESSING WHOLE BLOOD TO BLOOD PRODUCTS

2.5.1. PURPOSE

To describe the procedures for the processing of participant blood samples into the following blood products:

- Plasma
- Serum
- Buffy coat cells

2.5.2. RESPONSIBILITIES

Authorized personnel processing whole blood samples must ensure that the procedures are followed correctly, and all documentation is completed.

2.5.3. HEALTH AND SAFETY

Personnel carrying out this procedure must maintain safe working practices and observe all relevant Health & Safety guidelines of their respective institutions pertaining to the collection, transportation and handling of human blood, according to universal precautions.

This includes the appropriate use of Personal Protective Equipment (PPE), Class II BioHazard Cabinets, and procedures for waste disposal, disinfection and spill clean-up, handling and transport of dry ice and liquid nitrogen, and personal hygiene.

2.5.4. EQUIPMENT AND MATERIALS

EQUIPMENT: PPE, Sterile plastic Pasteur pipettes, Calibrated P1000 and P200 pipettes, Sterile P1000 and P200 aerosol pipette tips, Cryovial racks, Centrifuge, Counter-balance tubes, Dewar flask

MATERIALS: Sterile cryovials, 1.8 ml, Blue cryovial cap inserts, Green cryovial cap inserts, Red cryovial cap inserts, eppendorf tubes, Ethanol or alcohol wipes, Liquid nitrogen, sterile syringe and needle

2.5.5. PROCEDURES

2.7.5.1. Processing of Plasma

- Plasma is harvested from K_2EDTA / K_3EDTA or ACD-A tubes only.
- Prepare labels and label storage cryovials according to **SOP 2.3: Labeling Biospecimens and Documentation.**
- Centrifuge each whole blood sample at 4000 rpm for 10 minutes. Ensure centrifuge rotor is balanced, and that the procedure follows that outlined in the respective manufacturer's instrumentation manual.
- The top and outside of the blood tube should be alcohol wiped before opening
- Using a calibrated / P1000 pipette with sterile aerosol tip or sterile disposable plastic Pasteur pipette, gently aspirate plasma without disturbing the Buffy coat layer, leaving a small amount of plasma above the Buffy coat layer for aliquotting directly into the cryovials. The aspirates from an individual participant can be combined in a separate tube.
- Retain blood tube for Buffy coat collection.
- Using a calibrated / P1000 pipette with sterile aerosol tip or sterile disposable plastic Pasteur pipette, dispense 500µl aliquots of plasma into labeled 1.8 ml cryovials, without wetting the rim. Up to 16 aliquots should be collected.
- Inset a red cryovial cap into each cryovial.
- Place each cryovial into liquid nitrogen to snap freeze (where appropriate).
- Transfer specimens into storage tray/box and store according to SOP 2.6. Storage of Biological Samples.

2.5.5.2 Processing of Buffy Coat Layer

- The Buffy coat, a thin, greyish-white layer of white blood cells (leukocytes) and platelets covers the top of the packed red cells, following centrifugation at 4000 rpm for 10 minutes.
- Buffy coat cells are harvested from K_2EDTA / K_3EDTA or ACD-A tubes, usually following harvest of the plasma fraction.

- Prepare and label storage cryovials according to SOP 2.5: Labeling Biospecimens and Documentation.
- Using a sterile 2ml syringe and 21G needle or sterile disposable plastic Pasteur pipette in a circular motion, gently aspirate the Buffy coat layer.
- Of necessity, passenger red blood cells will be included. The aspirates from an individual participant can be mixed, or kept separate according to individual site practice.
- Using a calibrated / P200 pipette with sterile aerosol tip or sterile disposable plastic Pasteur pipette, dispense Buffy coat cells in approximately 200µl aliquots into labeled 1.8mL cryovials, without wetting the rim. Up to 2 aliquots from each K_2EDTA / K_3EDTA or ACD-A tube should be collected.
- Inset a blue cryovial cap into each cryovial
- Place each cryovial into liquid nitrogen to snap freeze, where appropriate.
- Transfer specimens into storage tray/box and store according to **SOP 2.6:** Storage of Biological Samples

2.5.5.3. Processing of Serum

- Serum is harvested from SST tubes only. Ensure blood is clotted before proceeding.
- Prepare labels and label storage cryovials according to SOP 2.5:Labelling Biospecimens and Documentation.
- Centrifuge the SST tube at 4000 rpm for 10 minutes. Ensure centrifuge rotor is balanced, and that the procedure follows that outlined in the respective manufacturer's instrumentation manual.
- The top and outside of the blood tube should be alcohol wiped before opening.
- Using a calibrated pipette with sterile aerosol tip or sterile disposable plastic Pasteur pipette, gently aspirate serum avoiding contact with the gel layer.
- Pipette serum in 500µl aliquots into labeled 1.8 ml cryovials, (collect up to 8).
- Insert a green cryovial cap into each cryovial.
- Place each cryovial into liquid nitrogen to snap freeze, where appropriate.

- Transfer specimens into appropriate tray/box and store according to **SOP 2.6:** Storage of Biological Samples.
- Wipe down the Bench, tube racks and equipment with 70% ethanol.5.5 Completion of Forms for All Blood Products:
- Record all sample details into the CCP Study database.

SOP 2.6. COLLECTION AND PROCESSING OF SPUTUM

2.6.1. SCOPE

This SOP specifies the minimum requirements for the quality and quantity of biological specimens for culture and conditions for transportation of specimens to the laboratory and storage.

2.6.2. RESPONSIBILITIES

Authorized personnel processing sputum samples must ensure that the procedures are followed correctly, and all documentation is completed. This procedure should be undertaken only after approved training, supervised practice and competency assessment, and carried out in accordance with local policies and protocols.

2.6.3 EQUIPMENT AND MATERIALS

Universal container with a wide top; Apron; Non-sterile gloves; Facemask; Eye protection (if required); Appropriate documentation (according to local policy); Nebuliser (if required)

Wide-mouthed, unbreakable, leakproof, screw-capped containers; containers should have a volume capacity of 50 ml and made of translucent material in order to observe specimen volume and quality without opening the container.

2.6.4. DETAILED INSTRUCTIONS FOR THE PROCEDURE

2.6.4.1. Sputum Sample collection

- If good specimens are to be obtained, patients must be instructed in how to produce sputum. Specimens should be collected in a separate, ventilated room or preferably outdoors.
- Decontaminate hands and put on an apron, non-sterile gloves and a facemask if you are likely to come into contact with bodily fluids. This reduces the risk of contamination of the specimen and the risk of cross infection.
- Wear eye protection if you have concerns about splash injury.
- The patient's mouth should be rinsed with water before the sample is collected, to avoid contaminating the sample with food residue.
- It can also be helpful to remove dentures.
- Keeping both hands on hips, cough forcibly and collect sputum in the mouth; spit the sputum carefully into a wide-mouthed, unbreakable, leakproof container and close the lid tightly.
- Ask the patient to take several deep breaths – breathing in through the nose and exhaling though the mouth – to help loosen secretions.
- Ask the patient to force a deep cough to ensure a sample is obtained from the lower respiratory tract.
- Administer a prescribed sodium chloride 0.9% nebuliser to help to losen secretions if they are thick and difficult to expectorate.
- The patient should expectorate into the specimen pot and secure the lid to prevent contamination.

- Ensure the specimen is sputum rather than saliva, as samples contaminated with oropharyngeal secretions and saliva are difficult to interpret and can be misleading.
- Remove gloves, apron and facemask then decontaminate hands to reduce the risk of cross infection.
- Label the sample and complete microbiology forms.
- Send the sample to the laboratory as soon as possible (**WITHIN FOUR HOURS**).
- Document the procedure in the patient's notes
- Ideally, a sputum specimen should be 3–5ml in volume, although smaller quantities are acceptable if the quality is satisfactory.
- If specimens are to be cultured using a centrifugation method (see SOP Specimen processing for culture), sputa should preferably collected directly into 50-ml centrifuge tubes to avoid the need for their transfer from one container to another.
- Label each specimen with the unique identification number from the laboratory request form.
- Collect two or three specimens from each patient as need be

2.6.5. Transport conditions

- Sputa should be transported to the laboratory as soon as possible.
- If a delay of a few days cannot be avoided, keep specimens cool (refrigerated but *not frozen*).
- Up to a week in cold conditions will not significantly affect the positivity rate of smear microscopy; however, the additional growth of contaminants will result in an increased contamination rate on culture media.
- If the delay exceeds 3 days, an equal volume of cetyl pyridinium chloride (CPC; solution of 1% CPC in 2% sodium chloride) should therefore be added to sputum (see SOP preparation of reagents for culture).

- Sputum containing CPC can be kept for up to 7 days but must be kept at room temperature (>20 °C since CPC crystallizes at lower temperatures).
- The addition of CPC must be indicated on the accompanying documents (see form below) because CPC has to be removed before culturing.

2.6.6. Transport packaging

The basic packaging system for local surface transport of all specimens consists of three layers

- Primary receptacle – the specimen container – packaged with enough absorbent material to absorb all fluid in case of breakage.
- Secondary packaging – a second durable, watertight, leakproof packaging to enclose and protect the primary receptacle(s). Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material must be used to absorb all fluid in case of breakage.
- For cold transportation conditions, ice or dry ice shall be placed outside the secondary receptacle. Wet ice shall be placed in a leakproof container;
- Outer packaging – secondary packagings are placed in outer shipping packagings with suitable cushioning material. Outer packagings protect their contents from external influences, such as physical damage, during transit.
- For *surface transport* there is no maximum quantity per package.
- For *air transport*, no primary receptacle shall exceed 1 l for liquids or the outer packaging mass limit for solids.

2.6.7. Quality control

- Before specimens can be accepted in the laboratory, the accompanying request forms must be checked carefully for identity (sample and request form labelled with the same number).

- Specimens that cannot be identified exactly should not be processed.
- Specimens should be examined on receipt of the sample, to ensure that they correspond in type, quantity, quality and volume to the appropriate criteria. Any deviations must be documented and noted on the final report since they may affect the results.
- The transport conditions and duration must be checked. Delays in transportation and/or exposure of specimens to extremes of temperature without protective measures must be documented and noted in the report.

SOP 2.7. STORAGE OF BIOLOGICAL SAMPLES

2.7.1. PURPOSE

To describe the procedures for storage of biological samples after processing

2.8.2. RESPONSIBILITIES

Authorized personnel storing biological samples must ensure:

- storage procedures are carried out as directed
- all documentation is completed, and accurate records maintained on all samples.

2.7.3. HEALTH AND SAFETY

Personnel carrying out this procedure must maintain safe working practices and observe all relevant Health & Safety guidelines of their respective institutions pertaining to the collection, transportation and handling of human tissues, according to universal precautions.

This includes the appropriate use of Personal Protective Equipment (PPE), procedures for waste disposal, disinfection and spill clean-up, handling and transport of samples in dry ice, liquid nitrogen and at -80C, and personal hygiene.

2.7.4. EQUIPMENT AND MATERIALS

Ultracold -80C freezers, Liquid nitrogen storage tanks, Aluminum freezer racks, Block filing cabinets, Slide Filing cabinets, Storage boxes, with grid, Storage box identification labels, PPE.

2.7.5. PROCEDURES

- All samples and sample boxes must be labeled according to SOP 2.5: Labeling Biospecimens and Documentation before storage.
- Cryovials containing Plasma, Buffy coat cells, serum and sputum are stored in sample boxes or trays at -80C in an Ultracold freezer.

- When transferring samples to storage boxes/racks, place the cryovials sequentially in the next available slot beginning in the top left hand corner
- Transport the processed blood products in the cryobox immersed in liquid nitrogen to the –80°C freezer or liquid nitrogen tank in which they are to be stored.
- Complete the sample record forms.
- Lock the –80°C freezer or liquid nitrogen tank.
- Record all sample details in the CCP Study database.

SOP 2.8: TRANSFER TO SECONDARY STORAGE

2.8.1. PURPOSE

To describe the procedures for transfer of biological samples to secondary storage

2.8.2. SCOPE

These procedures pertain to the practice of transferring stored frozen samples to an alternate or secondary location, i.e. freezer to freezer or LN tank at the same location, or at a separate location at the same Institution, or a at a separate Institution. Under no circumstances will any samples be transferred or used from the biobank without explicit written authorization from the PI.

2.8.3. RESPONSIBILITIES

The PI is responsible for authorizing any transfer of material out of the biobank.

Authorized personnel storing biological samples must ensure:

- Preparation and storage procedures are carried out as directed
- All documentation is completed, and accurate records maintained on all samples.

2.8.4. HEALTH AND SAFETY

Personnel carrying out this procedure must maintain safe working practices and observe all relevant Health & Safety guidelines of their respective institutions pertaining to the collection, transportation and handling of human tissues, according to universal precautions.

This includes the appropriate use of Personal Protective Equipment (PPE), procedures for waste disposal, disinfection and spill clean-up, handling and transport of samples in dry ice, liquid nitrogen and at -80°C, and personal hygiene.

2.8.5. MATERIALS

Storage boxes/trays, with grid, Storage box ID labels, PPE, Outer packaging materials, Dry Ice, Techni-Ice or -80°C ice blocks, Biohazard Spill Clean Up Kit

2.8.6. PROCEDURES

2.8.6.1 Preparation of Stored Frozen Samples for Transfer to Secondary Storage

- **Notes**: All sample and sample boxes will have been previously labeled according to SOP 2.5. Labeling Biospecimens and Documentation before initial storage.
- The procedures for transferring cryovials containing plasma, Buffy coat cells or serum are identical.
- Pre-identify the samples for transfer to minimize the actual transfer procedure time.
- Label new storage boxes/trays for transfer to alternate site. The storage box ID number should bear the prefix ‘TF” to denote its transfer purpose.
- For each new storage box and subsequent movement of a storage box, complete form: Biological Sample Transfer Form, identifying in the table for each sample to be transferred, its original location and final destination.
- Remove original storage box from -80°C freezer to LN tank, and place onto Dry Ice, Techni-Ice or ice blocks at -80°C to maintain temperature as low as possible during sample transfer procedure.
- Carefully transfer designated samples into new transfer box/tray.
- Return the original storage boxes to designated location in -80°C freezer/LN tank.
- Lock the -80°C freezer / LN tank.
- Complete and sign LB Biological Specimen Transfer Form.
- Photocopy form, temporarily retain copy, original to be forwarded with consignment of sample for recipient signature

2.8.6.2. Transfer to Intact Boxes of Samples from -80°C to Liquid Nitrogen Storage

- Identify the storage boxes to be transferred to the liquid nitrogen storage facility.
- Place boxes in a suitable container of dry ice.
- Transfer to liquid nitrogen.
- Record new storage details on Biological Specimen Transfer Form.

2.8.6.3. Packaging of Sample for Shipment to Separate Institution

- Pre-arrange adequate dry ice to maintain frozen state during transport of samples to secondary storage.
- Package samples according to Institutional guidelines.
- Ship samples immediately after packaging.
- Upon receipt at secondary site, store samples at designated location
- Recipient to complete and sign front page of original Biological Specimen Transfer Form.
- Photocopy form, original to return to primary storage site, copy to be retained by secondary site.

2.8.6.4. Recording Transfer of Samples to Secondary Location

- Record all details in database

3.0. REFERENCES

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Appendix 1:

READ BY

NAME	DATE	SIGNATURE

4.0. AMENDMENTS

Version number	Date of amendment	Description of amendment