Supplementary Material 3: Standard Operating Procedures

3.1 Safety in clinics and mobile clinics during the COVID-19 epidemic

**Document Details**

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| Document Author | Melanie van Eeden, Anne Derache | | | |
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| Author | Name: | Melanie van Eeden | Signature: |  |
| Author | Name: | Anne Derache | Signature: |  |
| Approved by | Name: | Kobus Herbst | Signature: |  |
|  | Position: | Principal Investigator | Approval date: |  |

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1. **Purpose**

The purpose of this SOP is to ensure optimal safety for Health Care Workers performing COVID-19 related tasks in clinics and mobile clinics.

1. **Definition of key terms**

In this document, the following words and abbreviations shall have the following meanings, unless the context clearly indicates otherwise:

| Term | Definition |
| --- | --- |
| COVID-19 | Coronavirus Disease 2019 |
| CRA | Clinical Research Assistant |
| Donning | Sequence for putting on PPE |
| Doffing | Sequence for taking off PPE |
| PPE | Personal Protective Equipment |
| PRN | Professional Research Nurse |

1. **Responsibilities and authority**

This SOP targets all staff members who are required to understand and follow these procedures.  
Line manager, with the support of the Occupational Health and Safety team, are responsible for training staff according to this SOP, and for ensuring that staff members follow the described procedures.

1. **Scope**

This SOP applies to all AHRI staff members who are involved with COVID-19 screening, testing or other direct interactions with study participants in a healthcare setting.

1. **Procedure**
   1. **Keep the environment clean**

**To prevent COVID-19 contamination and transmission, keep the environment in which you are working clean:**

1. Wash your hands as often as possible, always before AND after each participant encounter, and preferably every hour. If soap and water are not available (e.g. in mobile clinic), use hand sanitiser.
2. Open all doors and windows whenever possible to encourage natural ventilation, weather permitting.
3. Between each participant, wipe all furniture encountered by the participant (tables, seats, examination beds), study equipment (e.g. stethoscopes, oximeters, blood pressure cuffs) and shared surfaces (chairs, door handles, mobile clinic surfaces, cooler boxes), etc. **Note**: it is recommended to spray the wipe first, and then wipe the surfaces to avoid aerosol-generating situation.
4. Use safe work practices to protect yourself:
   1. Keep hands away from face
   2. Do not touch surfaces
   3. Change gloves when torn or contaminated and in between each participant seen
   4. Perform hand hygiene
5. When close contact with participant is inevitable (e.g. use of oximeter), ensure that:
   1. Participant wears a surgical mask
   2. Participant’s hands are clean
   3. Medical equipment used is cleaned before and after procedure
   4. **Minimum PPE required for all staff working with suspected or confirmed COVID-19 cases**

**If you are working with suspected or confirmed COVID-19 cases, at ALL times wear the following:**

1. Gloves
2. Gown
3. Surgical mask
4. Face shield or goggle

When **collecting swabs**, which is considered as an aerosol-generating procedure, please wear **a N95 mask** if available; alternatively use a surgical mask. You can also use a hair cover to protect your hair from potential droplets, and a plastic apron on top of the gown when available. When PPE supplies allow, do change your PPE between each participant: gloves, apron, and wipe the face shield.

* 1. **![A picture containing drawing

     Description automatically generated]()How to put on PPE = DONNING**

1. Gown

* Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
* Fasten at back of neck and around the waist
* If available, cover the gown with a plastic apron.

2. Mask

* ![A picture containing drawing

  Description automatically generated]()Tie hair back
* Secure ties or elastic bands behind the ears (for surgical masks) or at back of head (for N95 masks)
* If using surgical mask, make sure the blue side is facing outside
* Fit flexible band to nose bridge
* Fit snug to face and below chin
* Fit-check respirator by breathing in quickly, the mask should suck onto our face

3. Hair cap/net (when available)

* Put on the hair cap/net and make sure that all hair are wrapped in and covered
* Cover also the ears



4. Face shield or goggles

* Place shield over the face and /or eyes, and adjust to fit.

![A picture containing knife

Description automatically generated]()

5. Gloves

* Out on the gloves and cover wrist of isolation gown
  1. **How to remove PPE safely = DOFFING**

![A close up of a logo

Description automatically generated]()1. Gloves

* Outside of gloves are contaminated – do not touch!
* Using a gloved hand, grasp the pal area of the other gloved hand and peel off first glove
* Hold removed glove in gloved hand
* Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
* Discard gloves in a waste container
* If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitiser.

![A close up of a logo

Description automatically generated]()2. Face shield or goggles

* Outside of face shield of goggles are contaminated – do not touch!
* Remove face shield or goggles from the back by lifting head band or ear pieces
* Place in the face shield or goggles on a surface for disinfection
* Wipe the face shield or goggles with a surface disinfectant
* Wipe with disinfectant the surface where the face shield or goggles were placed
* If your hands get contaminated during face shield or goggles removal, immediately wash your hands or use an alcohol-based hand sanitiser.

A close up of a logo

Description automatically generated3. Gown and/or plastic apron

* Gown front and sleeves are contaminated – do not touch!
* Unfasten gown ties, taking care that sleeves don’t contact your body when reaching for ties
* Pull gown away from neck and shoulders, touching inside of gown only
* Turn gown inside out
* If reusing, place the gown on a hanger and spray with alcohol-based solution. If discarding at the end of the day, discard in a waste container.
* If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitiser.

4. Hair cap/net (if available)

* Front of the hair cap/net is contaminated – do not touch!
* Grasp the back of the hair cap/net and remove without touching the front.
* Discard in a waste container
* If your hands get contaminated during hair cap/net removal, immediately wash your hands or use an alcohol-based hand sanitiser.

![A close up of a device

Description automatically generated]()5. Mask

* Front of mask is contaminated – do not touch!
* Grasp elastic of the mask behind the ears, and removing without touching the front.
* Discard the mask in a waste container at the end of the day
* If taking a break or going for lunch, store mask and N95 as indicated in section 5.5 below.
* If your hands get contaminated during mask removal, immediately wash your hands or use an alcohol-based hand sanitiser.

![A close up of an object

Description automatically generated]()

6. WASH HANDS WITH SOAP AND WATER OF USE AN ALCOHOL-BASED HAND SANITISER IMMEDIATELY AFTER REMOVING ALL PPE.

* 1. **Can I re-use masks and N95 respirators?**

**When interacting with participants:**

**1/ wearing a face shield;**

**2/ maintaining physical distancing when possible (1-2m) and;**

**3/ asking the participant to wear a surgical mask and clean their hands**

**are really important to avoid the contamination of the mask.**

In these instances, it is possible to reuse the mask according to CDC guidelines. For example, you would keep it on while seeing several participants until you go for a break, store the mask according to the guidelines below and put it back on again (please note that the mask should only be reused once). Nonetheless the reuse of the mask can be considered in the following situations:

* For interactions with participant that do NOT include aerosol generating procedures (e.g. questionnaire, clinical assessment), the surgical mask can be used all day, and discarded at the end of the day. The reuse of the surgical mask (e.g. during lunch break), must be limited to twice; see below how to store it.
* Swab collection is not considered as an aerosol generating procedures, BUT additional precautions must be taken: the N95 or surgical mask is protected with the face shield; if no droplets are emitted during the swab collection (e.g. sneeze or cough), the mask can be used all day, and discarded at the end of the day. The reuse of the surgical mask (e.g. during lunch break), must be limited to twice; see below how to store it. If the individual sneezed or coughed, discard the mask and use a new one.

If reusing the mask:

1. Hang used masks and respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. To minimize potential cross-contamination, store respirators individually so that they do not touch each other and the person using the respirator is clearly identified.
2. Storage envelopes or paper bags should be disposed of daily
3. Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit)
4. Take care to remove the mask/respirator without touching the contaminated area; use straps or elastics to remove from container for re-use.
5. Avoid touching the inside of the mask/respirator. If inadvertent contact is made with the inside of the respirator, discard the mask/respirator and perform hand hygiene.
6. Use a pair of clean gloves when donning a used N95 respirator and performing a user seal check. Discard gloves after the N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.
   1. **What to do if the PPE is contaminated**

**If a participant sneeze or cough on you:**

1. **DO NOT PANIC!** You are protected from contamination with your PPE
2. Clean your gloves with hand sanitiser
3. Identify the areas that are potentially contaminated, and act accordingly:

If droplets on the face area:

1. Disinfect you gloved hands, then remove gloves and put on new pair of gloves

2. Wipe the outside area of the face shield with disinfectant; then remove the face shield;

3. Disinfect your gloved hands

4. Remove the hair net/cap (if applicable) as indicated above and discard in the bin;

5. Disinfect your gloved hands

5. Remove the PPE as indicated above, and discard in the bin.

6. Wipe your gloves with disinfectant and put on new PPE and your cleaned face shield.

If droplets on the torso area (remember, the apron and gowns are liquid proof):

1. Wipe the area with disinfectant immediately

2. If wearing a plastic apron on top of the gown, remove the apron as described above and replace with a new one (the gown is protected)

* 1. **General procedures for AHRI personnel**
  2. If a staff member displays symptoms suggestive of COVID-19, such as cough, fever, difficulty breathing and/or sore throat, s/he must stay at home (self-isolate) and inform his/her line manager telephonically or via email.
  3. If a staff member develops symptoms at work, s/he must put on a surgical mask, inform his/her manager and go home.
  4. Staff are encouraged to have lunch or tea in their own areas of work and not congregate.
  5. Personnel are advised to avoid touching their face, and no hugging, hand shaking or other physical contact is allowed.
  6. In their personal lives, personnel are encouraged to avoid busy places including restaurants, malls, etc. in order to implement social distancing.
  7. A personnel member must inform his/her manager s/he has been in contact with a confirmed COVID-19 case, this will be followed up by the Occupational Health and Safety team.
  8. Staff members may access the Employee Wellness Program or counselling for stress or anxiety experienced due to potential exposure to COVID-19 or when responding to family members/friends/colleagues who may be affected. ICAS toll free line 0800214 773.
  9. **Measure to ensure safe travels in AHRI vehicles**

1. AHRI vehicles will only be allowed to transport essential workers and those who have the necessary permits and identification on them. Always keep your permit and ID on you .
2. Vehicles must carry no more than 50% of that vehicle’s licensed capacity:

* Vehicles licensed for two people may only carry the driver (e.g. mobile clinic)
* Cars licensed for four people may only carry two, including the driver

1. Staff are encouraged to use their own vehicles to site, where possible. Travel can be reimbursed.
2. Staff to wash or sanitize their hands before entering the vehicle.
3. Doors of the vehicle should be opened using a paper towel, tissue or disinfectant.
4. When travelling in the vehicles, the windows must remain open.
5. After each use of the vehicle, the commonly touched areas of each vehicle should be sprayed with sanitizer and wiped with paper towel by the driver. Further options for cleaning the vehicles include:

* Bleach solutions which can be made using 5% pure bleach. Mix 990ml COLD water and 10ml bleach to make 0.05% solution.
* Household detergents can be used, following the manufacturer’s instructions for dilution.

1. Instructions for drivers when wiping down the vehicles:

* Have a biohazard bag for disposal ready
* Wear gloves when wiping down the vehicle.
* Use disposable paper towel.
* If possible clean hard surfaces with sanitizer or surface disinfectant.
* Avoid creating splashes and sprays.
* Pay special attention to areas that are touched frequently such as door handles.
* Dispose all waste and gloves into red biohazard bag and close the bag up.
* Following this, wash hands with soap and water for at least 20 seconds. Alcohol hand gel is ok if soap and running water is not available.

1. **Linked Documents**

* AHRI SOP HS-0019

1. **References**

* SAMRC - HPRU Screening and Response Procedures for COVID-19
* World Health Organization COVID-19 Risk Communication Package for Healthcare facilities
* COVID-19 Symptom monitoring tool V6
* APHL Risk Assessment Best practices
* NICD NDoH Guidelines for case-finding, diagnosis, management and public health response in South Africa
* CDC Coronavirus infection control recommendations

1. **Appendices**

NA

1. Document Change History

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3.2 **Referral pathways for participants suspected and confirmed Covid-19 cases**

**Document Details**

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| --- | --- | --- | --- | --- |
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| Author | Name: | Mark Siedner | Signature: |  |
| Author | Name: | Anne Derache | Signature: |  |
| Approved by | Name: | Thandeka Khoza | Signature: |  |
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1. **Purpose**

The purpose of this SOP is to provide clear referral pathways to support the management of suspected and confirmed COVID-19 cases detected as part of this study. These referral pathways were designed according to the NICD/DoH guidelines, and will be adapted as necessary to follow them as the epidemic evolves.

1. **Definition of key terms**

In this document, the following words and abbreviations shall have the following meanings, unless the context clearly indicates otherwise:

| Term | Definition |
| --- | --- |
| COVID-19 | Coronavirus Disease 2019 |
| COVID-19 suspect | Participant that presents with the clinical case definition of likely COVID19 as determined by the Department of Health |
| COVID-19 contact | Participant that has COVID-19 contact history without COVID19 symptoms. |
| COVID-19 case | Participant that has tested positive for SARS-CoV-2 infection |
| CRA | Clinical Research Assistant |
| DOH | Department of Health |
| LIMS | Laboratory Information Management System |
| NICD | National Institute for Communicable Diseases |
| NMC | Notifiable Medical Condition |
| PIP | Population Intervention Platform |
| PUI | Person Under Investigation |
| Respiratory distress | An acute or chronic condition marked by severely impaired pulmonary function, characterized by decreased oxygen, and shortness of breath. Respiratory distress is characteristic of severe COVID-19 disease. |
| SARS-CoV-2 | Severe Acute Respiratory Syndrome Coronavirus 2 |

1. **Responsibilities and authority**

This SOP targets all staff members who are required to understand and follow these procedures.  
The line manager is responsible for training staff according to this SOP, and for ensuring that staff members follow the described procedures.

1. **Scope**

This SOP applies to all study staff involved in referral pathways systems, from Research Data Management team that develops questionnaires and tools, to Clinical staff (i.e. CRA, professional nurse, clinician) that will engage with participants to refer them appropriately.

1. **Procedure**
   1. **Evolution of testing infrastructure**

Depending on the needs for testing coverage, the testing setup is currently planned as follows, with adjustments to be made as the epidemic unfolds and priorities are clarified. The testing platform could take the following forms, among others:

* Traveling mobile clinic site: a mobile clinic will travel to the vicinity of households where COVID-19 suspects have been identified during phone-based screening.
* Fixed mobile clinic site: a mobile clinic will be set up at a fixed location for the week, and household member(s) identified as COVID-19 suspects will be referred to it for testing after identification during phone-based screening.
* Clinic-based testing: participants identified as COVID-19 suspects as part of phone-based screening will be referred to the closest fixed-clinic (where AHRI staff will be embedded).
  1. **Household COVID-19 screening questionnaires initiated from the call centre**

PIP households will be called either as part of the routine demographic surveillance, or as part of intensive surveillance of a random sample of households as described in the study protocol. A Survey Solutions-based questionnaire for COVID-19 screening will be administered to conduct COVID-19 surveillance (refer to ‘COVID-19 Surveillance study’ folder on the shared drive). This survey will determine whether household member(s) meet the criteria of COVID-19 suspects according to the NICD criteria for a PUI (see Appendix 1).

* + 1. **Household member(s) identified as COVID-19 suspects**

Any household member(s) will be informed that they are eligible for SARS-CoV-2 testing; they will be referred for testing at the testing site. While awaiting for testing, they will be advised about:

* Good hygiene practices (following the most up-to-date advice from the DoH);
* Maintaining physical- and social-distancing;
* Self-isolation guidance; and
* Refraining from contact with people over 50 years old or with other health conditions.
  + 1. **Household member(s) identified as COVID contacts**

Any household member(s) deemed to be COVID contacts who do not meet criteria for testing will be informed that they are not eligible for SARS-CoV-2 testing. They will be advised about:

* Good hygiene practices (following the most up-to-date advice from the DoH);
* Maintaining physical- and social-distancing; and
* Self-monitoring for signs and COVID-19 related symptoms up to 14 days. If symptoms develop, they will be asked to call the NICD hotline (**0800 029 999** or **0800 111 132)** to inquire about COVID-19 testing and referral to care, and to also self-isolate in order to avoid COVID-19 transmission to other household members, particularly the most vulnerable (elderly and other comorbidities).
  + 1. **All household member(s) who are not deemed to be either COVID-19 suspects or contacts will receive health education about COVID-19 and hygiene practices**

The household member(s) will be informed that they are not eligible for SARS-CoV-2 testing. They will be advised about:

* Good hygiene practices (following the most up-to-date advice from the DoH); and
* Maintaining physical- and social-distancing.
  1. **COVID-19 screening questionnaire at the testing sites**

Household member(s) referred for testing will be re-screened for COVID-19 at the testing site. These procedures will be supported using REDCap questionnaires and decision support tools.

The procedures will depend on the nature of the participant and their questionnaire responses:

* + 1. **COVID-19 screening by the CRA**
* The CRA will first collect the participant’s contact information, and their demographic using the REDCap COVID-19 Clinical screening tool:
  + If the participant was referred from the Call Centre, the CRA will retrieve participant’s data by searching for and entering the BSID.
* Before proceeding with COVID-19 questionnaires, the CRA will complete the verbal informed consent process (see consenting SOP) and record it.
* The CRA will then proceed with temperature measurement using a non-contact infrared thermometer (if available), and record it on the REDCap Clinical screening tool. They will complete the COVID-19 symptoms and risk factors questionnaire (refer to ‘COVID-19 Surveillance study’ folder on the shared drive).
* At the end of the screening questionnaire, an algorithm will categorize the participant into one of the following:
* COVID-19 suspect: the CRA will complete the contact tracing questionnaire and refer the participant to the professional nurse for further clinical assessment and specimen collection (SOP PIP-CR-003 and PIP-LAB-001).
* Non COVID-19 suspects with symptoms that do not meet criteria for COVID-19: the CRA will refer the participant to the professional nurse for further clinical assessment.
* Non COVID-19 suspects without symptoms: the CRA will terminate the visit and provide the appropriate informational brochures for self-isolation (if the participant is a COVID-19 contact) and/or home hygiene (See Section 5.3.3)
  + 1. **Clinical assessment**

The clinical assessment is described in details in the SOP PIP-CR-003.

* + 1. **Discharge instructions**
* Non COVID-19 suspects will be discharged home and will receive a flyer describing good hygiene practices at home (Appendix 2)
* COVID-19 contacts will be discharged home and will receive a flyer describing good hygiene practices at home and DoH self-isolation guidelines, and will be asked to monitor symptoms appearance, and call the NICD hotline if it occurs.
* COVID-19 suspects that present no or moderate symptoms will be discharged home and will receive a flyer describing good hygiene practices at home, and DoH self-isolation guidelines (Appendix 3).
  1. **COVID-19 testing and results return**
     1. **COVID-19 negative participants**

After receipt of their results in the main COVID database, participants testing negative will be informed of their result by SMS. The SMS will also include hygiene practices for the home and information about self-isolation for those who were also contacts.

* + 1. **COVID-19 positive participants**

The AHRI clinician will call the participant to give them their test result, and will proceed with an assessment of their health condition:

1. COVID-19 positive participant with mild or no symptoms:

* If the participant feels well, the AHRI clinician will give guidance on self-isolation and good hygiene practices.
* The AHRI clinician will call every 3-4 days until symptoms have resolved using the REDCap phone call project.

1. COVID-19 positive participant with moderate or severe symptoms

* If the participant reports shortness of breath, weakness, or other concerning symptoms: the AHRI clinician will obtain a history from the patient or relative if participant unable to communicate.
* If a participant has worsening shortness of breath or other clinical signs concerning for worsening disease, they will be referred to the mobile clinic for a physical examination. If the participant is unwell, the professional nurse will phone the designated doctor at the reference hospital and will phone the Mounties EMS ambulance provider to arrange transfer of the confirmed COVID-19 participant.
  + 1. **DoH case notification**
* All positive and negative SARS-COV-2 testing results will be submitted to the DoH using their [NMC web portal](https://mstrweb.nicd.ac.za/Microstrategy/asp/Main.aspx?Server=NICDSANDMSTRI01&Project=NMC&Port=0&evt=2048001&src=Main.aspx.2048001&documentID=A55F346D40BC93092AED39B6D0759D0A&currentViewMedia=1&visMode=0&uid=WebRegister&pwd=Gue$tWeb@1) – the AHRI clinician will be the referent person for registering and submitting on the portal.
* After receipt of the testing result on the LIMS system, a result report will be generated with all relevant information to be captured on the NMC portal; the AHRI Clinician will be responsible for filling out the NMC form online for each tested participant, ideally as soon as the participant’s testing result is available.
  + 1. **NHLS / uMkhanyakude District notification**
* COVID-19 positive cases will be reported to the NHLS representative of KwaZulu-Natal; the following need to be submitted to [siyabonga.simelane@nhls.ac.za](mailto:siyabonga.simelane@nhls.ac.za), who will then share with the relevant people within the region:
* the NICD PUI form (Appendix 4) with all necessary details;
* the COVID-19 contact line list (Appendix 5); and
* the positive testing result.
  + 1. **Contact tracing**
* The NICD Contact line list will be established for each COVID-19 suspects during their visit to the testing site.
* If positive, the Contact line list will be updated by the AHRI Clinician when calling COVID-19 positive participants for giving the result back; the Contact line list will then be sent to the KZN NHLS as described in section 5.4.4.

**To prevent COVID-1contamina**

**you are working**

1. **Linked Documents**

* AHRI SOP HS-0019 – Safety in clinics and mobile clinics during the COVID-19 pandemic
* SOP PIP-LAB-001 – Naso- and oropharyngeal swab collection, storage and transport
* SOP PIP-CR-003 – COVID-19 suspects clinical assessment

1. **References**

NA

1. **Appendices**

* Appendix 1: NICD Criteria for PUI – *updated from April 2 2020*
* Appendix 2: Good hygiene practices and other information – KZN Provincial DoH – isiZulu version
* Appendix 3: Guidelines for self-isolation and contacts – DoH – isiZulu version
* Appendix 4: Person Under Investigation form for COVID-19 – NICD – v4.3 – 3Apr2020
* Appendix 5: COVID-19 Contact Line List – NICD – v4.3 – 3Apr2020

1. Document Change History

| Version | Review Date/  Date of change | Contributor | Change Details |
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3.3 **Naso- and oropharyngeal swab collection, storage, transport and quality control**

**Document Details**

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1. **Purpose**

The purpose of this SOP is to provide the PRN with the appropriate and safe procedures for collecting naso- and oropharyngeal swabs for SARS-CoV-2 testing. This SOP also describes procedures for storing and transporting specimens.

1. **Definition of key terms**

In this document, the following words and abbreviations shall have the following meanings, unless the context clearly indicates otherwise:

| Term | Definition |
| --- | --- |
| ACB | African Centre Building |
| COVID-19 | Coronavirus Disease 2019 |
| CRA | Clinical Research Assistant |
| DSID | Demographic Surveillance Identifier |
| LIMS | Laboratory Information Management System |
| PPE | Personal Protective Equipment |
| PRN | Professional Research Nurse |
| QC | Quality Control |
| SARS-CoV-2 | Severe Acute Respiratory Syndrome Coronavirus 2 |
| VTM | Virus Transport Medium |

1. **Responsibilities and authority**

This SOP targets all staff members who are required to understand and follow these procedures.  
The line manager is responsible for training staff according to this SOP, and for ensuring that staff members follow the described procedures.

1. **Scope**

The collection procedures apply to the PRN who performs the collection of specimens.   
The storage procedures apply to PRN and CRA who are responsible for the appropriate storage of the samples between collection and transport to the lab.  
The swab collection storage and transport procedures apply to the Somkhele laboratory staff.  
The transport procedures apply to AHRI staff members driving the ‘Specimen shuttle’ from Somkhele lab to Durban lab.

1. **Procedure**
   1. **General considerations**
      1. The collection of naso- and oropharyngeal swabs MUST take place in a clean environment.
      2. Appropriate PPE MUST be worn by the PRN i.e. gloves, gown, face shield, hair cap (if available) and N95 mask (if not available, use surgical mask).
      3. Gloved hands MUST be sanitised before and after handling the swab collection kits.
      4. After swab collection, contaminated specimen collection devices and gloves must be discarded in the biohazard waste bags/containers.
      5. The swab collection kits are collected from the Somkhele laboratory by the relevant PRN each morning prior to going out to site; they will be handed over in a cooler box with 2 to 3 ice bricks and must be retained in the cooler box and in a cool place (out of direct sun) during the day. Another cooler box with 3-4 ice bricks will be provided to store specimens collected during the day. This cooler box must also be kept out of direct sun and in a cool place throughout the day.
      6. After collecting the swabs, the PRN must scan the 2D barcode label on the 2ml tube with the tablet provided into REDCap, to ensure that the swabs are associated with the participant and that analytical results will be associated with the correct participant.
      7. Participants undergoing swab collection and testing must fulfil the criteria of PUI as per NICD/DoH guidelines (see Appendix 1); as these guidelines may evolve over time, the line manager will keep the PRN informed on these criteria.
      8. The PRN will maintain a specimen log that they will hand over to the Somkhele lab at the end of the day for QC purposes.
   2. **Swabs collection kit**

Each kit consists of a self-sealing transparent plastic bag that contains:

* + 1. Two swabs individually wrapped
    2. One 2ml orange-cap tube labelled with the 2D barcode, containing 2ml of VTM
    3. One tongue depressor (if available)
    4. One strip of parafilm

The swab collection kits are prepared in the AHRI Diagnostic Research Laboratory, Durban (as per the laboratory’s SOP) and distributed to the Somkhele laboratory for holding at refrigerated temperatures until use. The stock held at Somkhele will be replenished at a regular interval to ensure adequate supply to meet the demand.

The CRA or PRN will collect a cooler box prepared by the Somkhele laboratory staff (as per the laboratory’s SOP) each day sample collection is planned. The cooler box must be adequately marked to meet IATA Category B transportation regulations (UN3373). The cooler box will contain up to 1 kg of dry ice in a cryobox but direct contact with this should be avoided.

* 1. **Swabs collection procedure**

Before collecting the swabs, the PRN will discuss the procedure with the participant and explain that the process may cause some discomfort and may make them sneeze or cough; if this happens they should turn away and cough/sneeze into the tissues that will be provided .

* + 1. Nasopharyngeal swab

1. Enter the thin, flexible swab several centimetres with a slow steady motion along the floor of the nose (straight back, not up) until the posterior nasopharynx has been reached (distance from nostrils to external opening of ear).
2. Once resistance is met (the swab should pass into the pharynx relatively easily), rotate the swab several times (for 10 to 15 seconds) and withdraw the swab
3. Open the 2ml orange-cap tube, put the swab in the VTM, rotate several times and break it off at the break point of the swab (it will snap off with relative ease).
4. Replace the lid, close it and proceed to collect the oropharyngeal swab sampleA picture containing food

   Description automatically generated
   * 1. Oropharyngeal swab
5. Using the tongue depressor (if available), depress the participant’s tongue. Alternatively, ask them to stick their tongue out.
6. Quickly but gently rub the swab over the pillars of the fauces (area between uvula and in front of the tonsils).
7. Open the same 2ml orange-cap tube, put the swab in the same VTM that has the nasopharyngeal swab tip, rotate several times and break it off at the break point (it will snap off).
8. Replace the lid, close the tube tightly.
9. Wrap a strip of parafilm over the join of the tube and its cap to ensure that the VTM won’t leak.

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* + 1. Alternative procedures for swab collection in children

The collection of nasopharyngeal and oropharyngeal swabs might be difficult and/or challenging in young children; therefore the CDC has dressed up a list of alternative samples that are acceptable for SARS-CoV-2 testing. The collection of nasal mid-turbinate swabs, which is recommended in other settings for young children, would be the alternative specimen collected. The procedure is as follows

1. A drawing of a face

   Description automatically generatedTilt the child’s head back 70°.
2. While gently rotating the swab, insert swab less than 2 cm into nostril, until resistance is met at the turbinates.
3. Rotate the swab 2 or 3 times then hold the swab in place for 5 seconds to absorb the sample material.
4. Using the same swab, repeat in the other nostril.
5. Open the same 2ml orange-cap tube, put the swab in the VTM, rotate several times and break it off at the break point of the swab (it will snap off with relative ease).
6. Replace the lid, close the tube tightly.
7. Wrap a strip of parafilm over the join of the tube and its cap to ensure that the VTM won’t leak.
   * 1. Once the swabs have been collected, ask the participant to put their surgical mask back on.
   1. **Swab collection storage**
      1. Once the swabs have been collected, place the orange-cap tube containing both swabs into the zip-lock transparent plastic bag and ensure the bag is properly sealed.
      2. Wipe the plastic bag with disinfectant and place the plastic bag in the appropriate cooler box, containing cryoboxes with a separator (bubble wrapped foam/cardboard) to ensure that they are kept within 2-8°C.
      3. At the end of the day, the PRN or CRA will hand over the cooler box with the collected swabs and a tally sheet to the Somkhele laboratory (see Section 5.6. for more details).
      4. The Laboratory technician will remove the specimen packets from the cooler box straight into a Biosafety Cabinet according to the laboratory SOP for this procedure
      5. The specimen packets containing the tubes with swabs will be transferred to a larger plastic zip lock bag. This will be sprayed down with disinfectant and then transferred to a container in the refrigerator.
      6. Swabs will kept refrigerated at 2-8°C overnight.
   2. **Swab collection transport**

The swabs need to be transported to the Durban laboratory for testing and permanent storage.

* + 1. The laboratory staff in Somkhele will be responsible for preparing the specimens for shipment to the Durban laboratory each week day, and/or occasionally on a weekend. The large ziplock bag/s will be packed into a cooler box with ice bricks.
    2. The Laboratory staff must sign the driver’s log book and indicate the number of cooler boxes to be transported.
    3. The driver will comply to the measures to ensure safe travel in AHRI vehicles during the COVID-19 epidemic, described in the SOP AHRI-HS-0019 (see Appendix 2).
    4. The driver should leave ACB Somkhele by no later than 7:00am on scheduled days and any other required day, to ensure the specimens reach the Durban laboratory before 10:00am.
    5. On arrival in Durban, the driver needs to don a pair of gloves, off load all the cooler boxes, and deliver to the Receiving laboratory, Room 139, level 1, DDMRI building.
    6. A laboratory staff member in Durban will sign for the receipt of the cooler boxes.
    7. The driver should discard the gloves in the biohazard box and wash their hands.
    8. The laboratory staff should ensure that the cooler boxes are emptied, sprayed down with disinfectant and left for 5 minutes before wiping dry. The cooler boxes are then placed in the demarcated area in the DDMRI laboratory for collection by the driver prior to his return to ACB, Somkhele.
  1. **Sample submission and quality control**
     1. Mobile clinics will keep a tally sheet (Appendix 3) of participants they have seen for the day. This tally sheet will contain the participant’s DSID and a specimen bar code label.
     2. Each time the nurse collects a sample, they add the participant to the tally sheet and stick the specimen barcode next to it; alternatively, they can write it down.
     3. When returning to the ACB, the nurse will review the actual samples collected against the day’s tally sheet(s).
     4. The nurse then hands the sample in at the Somkhele lab, sign for it and leave a copy of the tally sheet with the lab.
     5. The original tally sheet needs to be stored in a central location for the person doing the QC.
     6. The next morning at 08:00 a designated QC person will generate and print a specimen log on their PC.
     7. They will compare the specimen log (representing the data captures in REDCap) with the tally sheet.
     8. Any discrepancies should be resolvable by doing an obvious data correction as they have the source (tally sheet) with them. They should run the specimen log again and confirm that there are no more issues.
     9. After all issues have been resolved, they will update the specimen log by marking “Yes’ next to each sample collected and save the document.
     10. Thereafter they will execute the loading of the data to LIMS, which will generate an email with the shipping log.
     11. The generation of the shipping log needs to happen before 09:00 so that the records are ine LIMS before the shuttle arrives.

1. **Linked Documents**

* SOP AHRI-HS-0019

1. **References**

* MRC Gambia – Collection of respiratory samples from PUI.
* NICD NDoH Guidelines for case-finding, diagnosis, management and public health response in South Africa
* CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) – updated April 14th 2020

<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

1. **Appendices**

* Appendix 1: NICD/DoH Criteria for PUI – update April 2nd 2020
* Appendix 2: Measures to ensure safe travel in AHRI vehicles – SOP AHRI-HS-0019

1. Document Change History

| Version | Review Date/  Date of change | Contributor | Change Details |
| --- | --- | --- | --- |
| 1 |  |  |  |
| 2 |  |  |  |