

COVID-19 RESEARCH RISK ASSESSMENT AND MANAGEMENT APPROACH (Version 2)

Prof Minrie Greeff

Emeritus Professor: Africa Unit for Transdisciplinary Health Research (AUPHeR)

North-West University

17 July 2020

1. Background of this document

South Africa went into a lockdown at midnight on the 26 March 2020 at an alert level 5, in response to the COVID-19 pandemic and has since moved down through the different alert levels, and will continue to do so. As a way of managing the COVID-19 pandemic, the SA government decided to follow a *risk-adjusted approach* based on specific criteria.

Criteria for the risk-adjusted approach:

- The level of the infection rate
- The rate of transmission
- Capacity of health facilities
- Extent of the public health intervention
- The economic and social impact of continued restrictions

Five alert levels have been identified:

- *Alert Level 5:* Drastic measures to contain the spread of the virus and save lives.
- *Alert Level 4:* Extreme precautions to limit community transmission and outbreaks while allowing some limited activity.
- *Alert Level 3:* Restrictions on many activities, including at work-places and socially, to address a high risk of transmission.
- *Alert Level 2:* Social distancing and restrictions on leisure and social activities to prevent a resurgence of the virus.
- *Alert Level 1:* Most normal activity resumes, with precautions and health guidelines, followed at all times.

To further manage the risks associated with the COVID-19 pandemic and its possible impact on the livelihoods of South Africans, the government has indicated that they might need to, from time to time, adjust the alert level of the country, based on the number of COVID-19 positive individuals. They have further indicated that it could even become necessary to have

different alert levels in different parts of the country e.g. only one town/city or province could be placed at a different alert level, if it was identified as being a hot spot and the health infrastructure would not be able to manage the numbers of admitted patients.

Scientists also predict that without an effective vaccine or treatment for COVID-19, the disease could be with us for at least the next two to three years. This has led to the coined phrase of us having to live with a “*new normal*”. Some go so far as to refer to this as a “*new world*”. This prediction has definite implications for all researchers, as they will not be able to continue with “*business as usual*”. They will also have to adjust in order to effectively and safely continue with research within this “*new normal*”.

2. Governmental ease in lockdown restrictions under alert level 3

On 17 June 2020, the president in an address to the nation on national television, indicated an ease in the lockdown restrictions, under alert level 3, which was mainly linked to an opening up of certain sectors of the economy.

Initially the following restrictions were stated as “*lockdown restrictions that will remain in place through every lockdown level*”:

- No gatherings of more than 10 people outside of a workplace will be permitted.
- Must wear a cloth face mask.
- Closure of the following businesses and events:
 - Conference and convention centres.
 - Sit-in restaurants and hotels.
 - Bars and shebeens.
 - Entertainment venues including cinemas, theatres, concerts.
 - Religious, cultural and social gatherings.

Early in June 2020, a change was indicated, allowing religious activities to continue but with very strict guidelines having to be followed e.g. not more than 50 individuals, social distancing, no singing, no refreshments to be served, etc. On 17 June 2020, during his address to the nation, he indicated that further sectors of the economy would be reopening. This was in order to find a solution to the dilemma of saving lives on the one hand and saving the economy on the other hand. Many negotiations facilitated this altered approach.

The sectors of the economy that would be opening were: Restaurants for sit-down meals; accredited and licensed accommodation (excluding home sharing accommodation like airBNBs); cinemas, theatres and casinos; and personal care services like hairdressers and beauty salons. Non-contact sports and contact sports (but only for practice purposes) would also be permitted. All this would be made possible only if *stringent safety prevention protocols*

are to be put into place and approved. Each mentioned sector had to identify the *specific risks as well as the measures to be put in place to manage these associated risks*.

He further indicated a move from the initial focus on *extreme measures to lessen community spread* to one on *personal responsibility* of each citizen. He stated that the latter would mean a *specific set of behaviours by the individual* linked to personal responsibility *to protect the collective*.

Required set of behaviours:

- Masked (not shared and washed on a daily basis).
- Regular hand washing.
- Social/physical distancing of at least 1.5m (seen as the most effective way).
- Not to touch face.
- Cleaning and sanitising of surfaces on a regular basis.

It is important to mention, however, that the restrictions on *social interaction* and *movement* would remain in place as originally intended under alert level 3.

Toolkit of the government to manage the pandemic (Prof S Karim):

In a follow up to the president's address to the nation, Prof Salim Karim specified what government would use as their "toolkit" to continue managing the COVID-19 pandemic.

- Social distancing.
- Lockdown (extreme form of social distancing).
- Hand hygiene practices – hand washing/sanitizing.
- Symptom screening.
- Cloth masks and cough etiquette.
- Appropriate use of Personal Protective Equipment (PPE).
- Testing isolation, quarantine and contact tracing.
- Frequent environmental cleaning.

3. Implications for researchers at Higher Education Institutions

During the various alert levels, Higher Education institutions (HEI) also have to adhere to the various regulations and directives provided for each specific sector, as well as those of other sectors that impact on the HE sector e.g. health, travel etc. This, per implication, then also indirectly refers to teaching-learning and research activities that have to be managed extremely carefully based on the various regulations and directives linked to each of the alert levels.

Each HEI then also has to create their own set of directives, based on their preparedness and capacity to manage the COVID-19 pandemic e.g. no research allowed under alert level 5 except research linked to COVID-19. Under alert level 4, HEIs remain closed and function on an online basis for teaching-learning and more specified research activities in laboratories are permitted, as well as online contact with human participants. Under alert level 3, most Higher Education Institutions (HEI), guided by the minister of Higher Education, decided to open their doors from the middle of June 2020, allowing an initial 33% return of staff and students which will then be followed by a phased in approach. The Department of Higher Education and Training (DHET) directive of 8 June altered this to mention a maximum of 33% students returning. This also allows for more research activities to resume but with strict restrictions on research, linked to the governmental regulations and directives of *social interaction and movement* that remain intact. As such no research can be undertaken that requires close contact of researchers with human participants (that is not linked to COVID-19 research), or that requires the researchers to enter communities for research purposes.

The pandemic has therefore hugely affected scholarship activities and placed a limitation on any research that necessitates face-to-face contact with any human participant (both qualitative and quantitative in nature). Researchers, therefore, have to adjust methodologies in order to adhere to the needed behavioural change expected of them as well as society. Some refer to a “post COVID society” that will need initiatives to salvage parts of or build a new society, which challenges researchers to think in a futuristic and innovative manner.

4. Research categorisation in the time of COVID-19

During the COVID-19 pandemic, research can be categorized broadly into two main categories i.e. COVID-19 related research (essential) and non-COVID 19 related studies (non-essential).

4.1 COVID-19 related research (essential)

- Research in clinical facilities with COVID-19 positive participants (life-saving interventions).
- Laboratory research linked to COVID-19 vaccine or treatment development.
- Clinical trial research linked to COVID-19.
- Psychosocial studies investigating the acute effects of COVID-19.

4.2 Non-COVID-19 related studies (non-essential)

- All the usual laboratory research related to animal or human studies.

- Online, telephone or email research with no direct close proximity, face-to-face contact with any human participants (qualitative or quantitative in nature).
- Close proximity contact with human participants in government facilities e.g. schools, facilities for the aged, prisons, health care facilities etc.
- Close proximity contact with human participants in HEI controlled facilities e.g. research units at universities, research units linked to health facilities etc.
- Close proximity contact with human participants in the community either in private homes or community facilities e.g. churches, community centres etc.
- Environmental research involving close proximity contact with human participants.
- Environmental research without any human contact.

The specific alert level during lockdown will have a direct impact on these various categories of research. ***See document: Implications of alert levels for researchers and postgraduate students during the COVID-19 pandemic (Greeff, 21 May 2020) for more guidance on the specific implications for research during each of the five alert levels.***

Due to 1) the impact the alert level will have on research; 2) the possible effect of COVID-19 itself on researchers or participants; as well as 3) the indirect effect on HEIs, researchers will have to follow a ***COVID-19 risk assessment and management approach*** when conducting any type of research. It will thus be necessary to in future include COVID-19 as part of the *risk-benefit analysis* of any research that is undertaken, and to include *precautionary measures aimed at mitigating the risks* linked to COVID-19 for both participants and researchers. In clinical and laboratory research special attentions should be given to the C19 Occupational Health and Safety Directive of 29 April, updated on 4 June 2020, as well as the Hazardous Biological Agents Regulations (2001). Researchers should also be aware that planned research could at any moment be negatively affected or put on hold by an increase in the alert level. All researchers should thus ensure that they are at all times accountable, responsible, current, and informed about all aspects of COVID-19, as well as the milieu in which the research is being undertaken, with an additional awareness of the *vulnerabilities* of both participants and researchers.

It is the responsibility of each researcher to be aware of:

- The present alert level and the accompanying governmental regulations and directives e.g. from the Department of Health, Department of Employment and Labour, etc.
- The information from health authorities about COVID-19.
- The institutional guidelines of what is permissible or not.

It is the responsibility of each researcher to ensure that they:

- Only conduct permissible research based on the alert level.
- Have the necessary approval, before data collection, from a REC for amendments to an existing proposal that had to be changed due to COVID-19 related implications.
- Have the necessary approval to *resume research* if research had to be halted.
- The usual ethical approval for all newly planned research.

5. Risks involved in conducting research during the COVID-19 pandemic

To be able to assess and manage the risks inherent in undertaking research during the COVID-19 global pandemic, it is necessary to be aware of all the possible risks to the:

- participant
- researcher
- HEI

The researcher must ensure that the risks to the participants and researchers are *justified* by the potential benefits to the participants, society and/or science.

Definition of a risk:

"The probability of harm occurring as a result of participation in research"

- Risk is about the *chance* of harm, rather than the harm itself.
- Risks need to be assessed for their *probability* and *magnitude*.

The principle of beneficence is grounded in the premises that:

- A person has the right to be protected from harm and discomfort.
- One should do good and above all do no harm.

It would be of the utmost importance to weigh the *benefit* of the research study against the *probability and magnitude of harm* before deciding to continue with either previously planned research or conducting a newly planned study. The researcher should thus ensure that the research is truly *justified, appropriate* and *needed* during the COVID-19 pandemic.

5.1 Risk to the participant

- Infected by a researcher or fellow research participant that might be asymptomatic/symptomatic during a visit to the HEI.
- Infected by a researcher that might be asymptomatic/symptomatic during a visit by the researcher to his/her home or community centre.

- Infected by handling objects contaminated by the virus.
- More severely affected by COVID-19 if over the age of 60 and having a comorbidity or an illness causing an immunocompromised health status.
- Carrying the virus from the research site into the home or community.
- Being fined or arrested for not adhering to appropriate lockdown alert level restrictions e.g. not wearing masks, travelling without appropriate permits etc.

5.2 Risk to the researcher

- Researcher/postgraduate student becoming infected due to contact with an asymptomatic/symptomatic person (fellow researcher or participant).
- Researcher/postgraduate student becoming infected by handling objects contaminated by the virus.
- Researcher/postgraduate student becoming infected by entering a high-risk COVID-19 area.
- Infecting co-researchers due to the aforementioned actions.
- Infecting own family members due to the aforementioned actions.
- More severely affected by COVID-19 if over the age of 60 and having a comorbidity or an illness causing an immunocompromised health status.
- Being fined or arrested for not adhering to appropriate lockdown alert level restrictions e.g. not wearing masks, travelling without appropriate permits etc.

5.3 Reputational damage to researchers and/or the university

- Participants infected by the researcher during the conduct of research blaming the university.
- The researcher carrying the virus into a private home or the community and the university being blamed for it.
- Researchers and postgraduate students becoming infected during research and blaming the university.
- Researchers not adhering to disaster and lockdown regulations e.g. visiting participants at their houses when social interaction is prohibited.

6. Precautionary measures

The previously discussed requirements for specific sectors in the economy, will also be applicable to researchers that will have identify the *specific risks related to their research*, as well as the *precautionary measures* to be put into place to manage these identified/associated risks. As for the other sectors, the precautionary measures should be based on *stringent*

prevention actions/protocols. The precautionary measures will, however, differ depending on the *nature* of the research, *where* the research is being conducted and the *people* involved in the research.

6.1 General remarks

- Researchers should adhere to the *restrictions on social interactions* and, as such, cannot conduct close proximity face-to-face research, collect biological samples or do anthropometric measurements with human participants when complete physical distancing is required (as prevented by a specific alert level). These activities are not permissible under alert levels 5, 4, and 3, and currently, there is no clear indication what will or will not be permissible under alert level 2 and 1.
- Researchers should adhere to the *travel restrictions* during specific alert levels e.g. crossing borders.
- Researchers should be aware of and adhere to the *restrictions or directives that the HEI* have in place at a given time.
- Researchers must ensure that the HEI's *liability coverage* is in place to cover them in a case made against them.

6.2 Health guidelines to follow during the COVID-19 pandemic

Researchers should at all times ensure that they follow the *health guidelines* as set out by the Department of Health and the WHO during the COVID-19 pandemic.

Health guidelines:

- Social distancing of at least 2 metres.
- Regular handwashing with soap or 80% alcohol-based sanitising hand rub.
- Wearing an appropriate mask when leaving home.
- Not to touch your face with unwashed hands.
- Covering your mouth and nose when you cough or sneeze, preferably into a tissue or your elbow.
- Sanitising all areas and surfaces.
- Avoid unnecessary public travelling and stay away from large groups of people.
- Refrain from smoking and other activities that weaken the lungs.
- Stay home if you feel unwell.
- Contact the appropriate health authorities, if you suspect you have COVID-19, to arrange for screening and testing and possible treatment.
- The use of appropriate PPE if you are a frontline worker.

6.3 COVID-19 researcher toolkit

Once researchers are allowed to undertake research involving activities in close proximity to participants, each researcher should ensure that they have a “*COVID-19 researcher toolkit*” when interacting with co-researchers and human participants.

- Own mask (might even need several if spending the whole day and having to touch your mask or remove it in between data collection with participants).
- A visor for the researcher and the participant might be essential when observation of facial expressions during research is essential.
- Masks for participants (even for others in the participants’ homes if research is community based).
- Thermometer.
- Alcohol based hand sanitiser.
- Sanitiser for surfaces e.g. chairs, table.
- A4 size plastic bag to put informed consent documents or paper questionnaires in (this will be left in the plastic bag for a minimum of three days).
- Availability of basic materials on COVID-19 (proper use of masks, proper hand washing, grounds for social distancing, reason for cough etiquette) to distribute to participants.
- Box of tissues.
- Bag for disposal of used masks, tissues or gloves.
- Disposable plastic covers for cloth covered chairs.

6.4 Specific precautionary measures

In order to assist researchers in developing effective risk mitigation strategies, several specific precautionary measures are presented under different headings depending on the *nature* of the research, *where* it is done and *who* will be involved. It is up to the researcher to select the applicable precautionary measures or to be innovative and add to the precautionary measures provided below.

6.4.1 Working with the research team

No matter what the nature of the research is, always train, prepare and evaluate the research team on:

- Knowing how to apply the *health guidelines* during the conduct of the research (see 6.2). Pay special attention to using well fitted masks, the right ways of putting it on, using it (not touching in between), and taking it off, the hygiene of masks (daily washing

and ironing), correct hand washing/sanitizing practices, and the correct use of gloves (if used).

- Always avoiding direct or close contact (closer than 2 meters) amongst researchers or researcher(s) and participant(s).
- Knowing how to recognise the symptoms of COVID-19 i.e.:
 - Fever.
 - Dry cough.
 - Sore throat.
 - Shortness of breath.
 - Redness of the eyes.
 - Loss of smell or taste.
- Knowing how COVID-19 spreads:
 - Between people who are in close proximity (within 2 meters) of a COVID-19 positive person when talking, coughing or sneezing and then inhaling the droplets.
 - Bodily contact (e.g. shaking hands) with a COVID-19 positive person contaminated with respiratory secretions and then touching their own mouth, nose, or eyes.
 - When airborne droplets are inhaled into the lungs.
 - When touching contaminated surfaces (e.g. doorknob) or objects (e.g. paper).
 - Handling contaminated samples (e.g. swabs) and then touching mouth, nose, or eyes.
 - Preliminary studies show the presence in blood (e.g. collection of biological samples).
- Special precautionary measures to take when working with vulnerable participants older than 60 and/or with a comorbidity or an immunocompromised health status:
 - Not to expose them to public transport.
 - Preferably see them at their homes.
 - If a home visit is not possible, see the participants individually and not in a group context.
- Know the correct PPE expected for the type of research to be undertaken if in clinical settings.
- Know how to safely handle samples that have been collected.
- Know how to safely handle paper e.g. informed consent documentation or questionnaires.

- Knowing how to support and refer a participant or team member if suspected of being COVID-19 positive:
 - Refer for testing.
 - Follow up to find out the final results.
 - Maintain contact with the person to support and follow up on progress.
- Knowing how to manage the rest of the participants or the research team if they were in contact with the suspected COVID-19 positive team member or participant:
 - Refer for testing.
 - Go into self-quarantine for 14 days.
 - Follow up to find out about the final results.
 - Maintain contact with the person to support and follow up on progress.
 - If symptoms get worse contact doctor/clinic.
 - Preliminarily suspend all further research activities until the venue has been sanitised.
- Knowing how to ensure a psycho-socially “safe space” for participants and team members e.g. caring, supporting, mentoring, counselling and consultation if needed.
- Knowing how to be more sensitive and manage vulnerability created by COVID-19 in participants and the research team.
- The availability of psycho-social care for the team.
- Knowing how to immediately report any unsafe or unhealthy situation to the project leader or study-supervisor.
- The need for constant intensive monitoring by the project leader/study-supervisor(s) during the physical part of data collection to ensure that the research team adheres to all the precautionary measures, is essential.

Screen the research team when in close proximity:

- Measure the temperature of team members (between 36°C and 37.5°C is normal).
- Do a screening test:
 - Do you have any of the following symptoms?
 - Do you have a cough?
 - Do you have a sore throat?
 - Do you have shortness of breath or any breathing problems?
 - Do you have difficulties with smelling or tasting?
 - In the past 14 days before these symptoms:
 - Where you in close contact with someone who is COVID-19 positive?
 - Have you travelled to or from another province?

- Have you travelled from another country?

Managing the team if they are busy with research for the whole day:

- If they are there for the whole day, regularly measure temperature (when they enter, during the day and when they leave).

What to do when data gathering has been completed:

- Place any paper documentation e.g. informed consent forms etc., in a plastic bag that can seal (leave untouched for three days if collected in highly contagious areas) and ensure that the outside of the plastic bag has been sanitized or if not possible wear gloves and clean before and after handling.
- Dispose of any potentially infected materials.
- Clean and disinfect area.
- Sanitize hands after leaving the facility.

What the researcher needs to do when he/she gets home:

- Leave shoes outside and first sanitize.
- Undress and place clothes in washing machine without shaking.
- Immediately have a bath/shower.
- Only greet the family after these procedures have been undertaken.

What a research team member should do if they feel sick:

- Stay at home.
- Report to the project leader that he/she will not be coming in.
- Know where to go for testing.
- Self-quarantine until test results are out.
- Notify project leader if they have tested positive for COVID-19.
- Stay in self-isolation for 14 days.
- If symptoms get worse contact doctor/clinic.
- Notify and clarify with project leader their intention of returning.

6.4.2 Keep in touch with your participants if you are prohibited from conducting research due to specific alert level regulations

- Make regular contact via telephone or Whatsapp.
- Keep them informed.

6.4.3 Working with the participant at research facilities

How to prepare to conduct research if in direct contact with participants:

- Prepare the venue:
 - Consider surroundings and if working indoors, ensure adequate natural ventilation (open windows, doors) and/or mechanical ventilations (fans, air-conditioning systems).
 - Sanitizing the area and surfaces.
 - Ensure enough facial masks are available.
 - Provide alcohol-based hand sanitizer.
 - Provide enough trash cans. Preference for closed-lid, hands free/touch free opening/closing types. Follow Occupational Health and Safety (OHS) guidelines for disposal of content.
 - Provide the correct PPE for the research team e.g. gloves if samples are being collected. Ensure sanitising/washing of hands after removal of gloves.
 - Provide soap, water and disposable towels.
 - Strict regular cleaning and disinfecting routine in place e.g. surfaces and high-touch surfaces.
 - Place chairs 2 metres apart.
 - Availability of basic materials and posters on walls about COVID-19 (masks, hand washing, social distancing, cough etiquette).
- Limit amount of participants per day (not more than three).
- Space meeting times far apart.
- Maintain 2 metre contact between researcher and participants or if possible making use of a physical barrier (Perspex screen) between the researcher and the participant.
- Limit use of focus groups and world café but if used:
 - Limit the number of participants to ensure you can have a 2 metre space between chairs.
 - Not more than four participants sitting at a big table and ensuring that a 2 metre distance is adhered to.
- Take temperature of self, research team and participant(s) before entering the premises (between 36°C and 37.5°C is normal).
- Screen self, research team and participants (as indicated previously).
- Sanitize hands before entering the premises.
- Ensure a psycho-social “safe space” (be caring, build trust and limit fear by telling them why you are doing specific things).

- If refreshments are provided ensure that it was sanitized e.g. fruit washed and in a plastic bag (person packing ensured of not being infected), drinks in disposable containers, no food preparation, no handling of refreshments e.g. pre-packed (person preparing ensured of not being not infected), no utensils, and not eating together which holds risks related to taking off masks.
- Provide water in disposable bottles and provide containers for disposal.
- Have plastic bag available to put paper documents in (leave untouched in bags for three days).

Protecting participants that have to use public transport (in addition to processes previously described):

- Self-screening before they come to the site.
- Guidance on minimum requirements e.g. wearing of mask, hand sanitising and open taxi windows.
- Sign indemnity during the informed consent process not to keep the university accountable if infected with COVID-19.

During contact with participants coming to the facility:

- Disinfect and clean surfaces before, between each participant and when they leave.
- Clean computer keyboards after use by each research team member.
- Clean and sanitize toilets and bathrooms after each use.
- Consider surroundings and if working indoors, ensure adequate natural ventilation (open windows, doors) and/or mechanical ventilations (fans, air-conditioning systems).
- If there for the whole day, regular temperature measurements (entry, during and when leave).
- Be ready to refer a participant if they are suspected of being COVID-19 positive and provide the necessary support.

How to handle a suspected COVID-19 positive participant:

- Follow standard operating procedure as set up by the Occupational Health and Safety committee of the university.
- Refer to the nearest test centre.
- Follow up on results.

6.4.4 Working with participants at their homes

Planning to conduct the home visit:

- Ensure that a research toolkit is available to the researcher (see 6.3).
- Make an appointment with the participant.

What to do when you enter the home of the participant:

- The researcher should wear a mask.
- Remain outside and respectfully and caringly explain how you will protect the participant and the researcher (masks, sanitizing of hand and surfaces).
- Researcher to sanitize own hands.
- Ensure that the participant and anybody else present have masks on and if not, provide masks.
- If visors/face shields are to be used by the researcher and participant, the researcher should provide a new one for each participant or thoroughly clean and sanitize before embarking on research for the day and placed in a new/clean plastic bag. The process should be explained to the participant to ensure they feel safe.
- On entry take the temperature of the participant and the researcher (if higher than 37.5 be ready to refer and do not continue with data gathering).
- Kindly request to sanitize the surface where you will be sitting e.g. table top and chair (sanitize hard surface chair or if cloth chair cover with a disposable plastic cover).

What to do when data gathering has been completed:

- Place any paper documentation e.g. signed informed consent forms, in a plastic bag that can seal (leave untouched for three days).
- Clean and disinfect the area.
- Sanitize hands after leaving the home.
- Dispose of any potentially infected materials as biological waste according to OHS guidelines.

What the researcher needs to do when he/she gets home:

- Leave shoes outside and first sanitize.
- Undress and place clothes in washing machine without shaking.
- Immediately have a bath/shower.
- Only greet the family after the aforementioned activities have been undertaken.

6.4.5 Working with participants in governmental facilities or NGOs

- Ensure that permission is obtained to enter the facility.

- Request to be informed of the standard operating procedure (SOP) to follow for COVID-19 and adhere to its prescriptions.
- The researcher should wear a mask.
- Ensure that the participant and anybody else present have masks on and if not, provide masks.
- The researcher to sanitize own hands and those of the participant(s).
- On entry take the temperature of the participants and the researchers (if higher than 37.5°C be ready to refer and do not continue with data gathering).
- If visors are to be used by the researcher and participant, sanitize the participant's visor in front of the participant to ensure they feel safe and accepted.
- Kindly request to sanitize the surface where you will be sitting e.g. chair and table top and explain why you are doing it.
- Place all paper documents in a plastic bag and leave sealed for 3 days.
- Sanitize hands when you leave the premises.

6.4.6 Working with participants in clinical facilities

- Ensure that permission is obtained to enter the clinical facility.
- Request to be informed of the SOP to follow for COVID-19 and adhere to its prescriptions.
- The researcher should wear required PPE and ensure that the participant wears a mask.
- Researcher to sanitize own hands.
- Place all paper documents in a plastic bag and leave sealed for 3 days.
- Sanitize hands when you leave the premises.

When collecting biological samples:

- Wear the required PPE (specifically a mask, face shield and gloves)
- Handle samples as possibly contaminated.
- Keep in a safe lock-up storage facility.

6.4.7 When working in laboratories

- Be well informed and adhere to the COVID-19 SOP of the institution, as well for the laboratory.
- Wear the required PPE.

7. How to include the risk assessment and management into the research

Once the risk assessment for a specific study has been conducted the researcher should:

- Describe the risks and precautionary measures in detail in the proposal
- If preferred, additionally develop a research specific SOP covering all the COVID-related aspects as discussed in this document.
- Clearly describe the risk mitigation strategies in the research ethics application form, as well as in the informed consent document.

Example: Risk assessment and management of face-to-face research conducted in close proximity with a participant in his/her own home

Note: Please use the document and not this sections for your research. This example only serves as an example of how to go about assessing and managing your research.

| Risk | Precautionary measures |
|--|--|
| Possible poor knowledge of the research team on COVID-19 management during research. | <p>Train, prepare and evaluate the research team on:</p> <ul style="list-style-type: none"> • Knowing how to apply <i>health guidelines</i> during the conduct of the research (see 6.2). Pay special attention to using well fitted masks, the right ways of putting on, using (not touching in between), and taking off of masks and gloves (if used), hygiene of masks (daily washing and ironing), as well as correct hand washing/sanitizing practices. • Always avoiding direct or close contact (closer than 2 metres) amongst researchers or researcher(s) and participant(s). • Knowing how to recognise the symptoms of COVID-19: <ul style="list-style-type: none"> ○ Fever. ○ Dry cough. ○ Sore throat. ○ Shortness of breath. ○ Redness of the eyes. ○ Loss of smell or taste. • Knowing how COVID-19 spreads: <ul style="list-style-type: none"> ○ Between people who are in close proximity (within 2 metres) of a positive infected person when talking, coughing or sneezing and then inhaling the droplets. ○ Bodily contact (e.g. shaking hands) with an infected person contaminated with respiratory secretions and then touching your own mouth, nose, or eyes. ○ When airborne droplets are inhaled into the lungs. ○ When touching contaminated surfaces (e.g. doorknob) or objects (e.g. paper). |

| | |
|--|--|
| | <ul style="list-style-type: none"> ○ Handling of contaminated samples (e.g. swabs) and then touching mouth, nose, or eyes. ○ Preliminary studies show the presence in blood (e.g. collection of biological samples). ● Special precautionary measures to take when working with vulnerable participants older than 60 and or immunocompromised: <ul style="list-style-type: none"> ○ Not exposing them to public transport. ○ Preferably see them at their homes. ○ If a home visit is not possible, see the participants individually and not in a group context. ● Know the correct PPE expected for the type of research. ● Know how to safely handle samples that were collected. ● Know how to safely handle paper e.g. informed consent documentation or questionnaires. ● Knowing how to support and refer a participant or team member if suspected of being COVID-19 positive: <ul style="list-style-type: none"> ○ Refer for testing. ○ Follow up to find out the final results. ○ Maintain contact with the person. ● Knowing how to manage the rest of the participants or the research team if they were in contact with the suspected COVID-19 positive team member or participant: <ul style="list-style-type: none"> ○ Refer for testing. ○ Go into self-quarantine until results are available. ○ Follow up to find out the final results. ○ Maintain contact with the person if symptoms get worse contact doctor/clinic. ○ Preliminary suspend all further research activities until the venue has been sanitised. ● Knowing how to ensure a psycho-social “safe space” for participants and team members e.g. caring, support, mentoring, counselling and consultation if needed. ● Knowing how to be more sensitive and manage vulnerability created by COVID-19 in participants and the research team. ● The availability of psycho-social care for the team. ● Knowing how to immediately report any unsafe or unhealthy situation to the project leader or study-supervisor. ● The need for constant intensive monitoring by the project leader/study-supervisor(s) during the physical part of data collection to ensure that the research team adheres to all the precautionary measures, is essential. |
|--|--|

Possibility of a researcher becoming infected with COVID-19 in the community.

Follow the health guidelines to follow during the COVID-19 pandemic:

Researchers should at all times ensure that they follow the *health guidelines* as set out by the WHO and the Department of Health during the COVID-19 pandemic:

- Social distancing of at least 2 metres.
- Regular handwashing with soap or 80% alcohol-based sanitising hand rub.
- Wearing an appropriate mask when leaving home.
- Not to touch your face with unwashed hands.
- Covering your mouth and nose when you cough or sneeze, preferably into a tissue or your elbow.
- Sanitising all areas and surfaces.
- Avoid unnecessary public travelling and stay away from large groups of people.
- Refrain from smoking and other activities that weaken the lungs.
- Stay home if you feel unwell.
- Contact the appropriate health authorities, if you suspect you have COVID-19, to arrange for screening testing and possible treatment.
- The use of PPE if a frontline worker.

Screen the research team when in close proximity:

- Measure the temperature (between 36°C and 37.5°C normal).
- Do a screening test:
 - Do you have any of the following symptoms?
 - Do you cough?
 - Do you have a sore throat?
 - Do you have shortness of breath or any breathing problems?
 - Do you have difficulties with smelling or tasting?
 - In the past 14 days before these symptoms:
 - Where you in close contact with someone that is COVID-19 positive?
 - Have you travelled to or from another province?
 - Have you travelled from another country?

What a research team member should do if they feel sick:

- Stay at home.
- Report to the project leader that he/she will not be coming in.
- Know where to go for testing.
- Self-quarantine.
- Notify project leader if tested COVID-19 positive.
- Stay in self-isolation for 14 days.

| | |
|--|---|
| | <ul style="list-style-type: none"> • If symptoms get worse contact doctor/clinic. • Notify and clarify with project leader intention of returning. |
| <p>Risk of either the researcher or participant becoming infected with COVID-19 during the home visit.</p> | <p>Essential COVID-19 researcher toolkit:</p> <p>Each researcher should ensure that they have a COVID-19 researcher toolkit when involving co-researchers and human participants.</p> <ul style="list-style-type: none"> • Own mask (might even need several if spending the whole day and having to touch your mask or remove it in between). • A visor for the researcher and the participant might be essential when observation of facial expressions during research is essential. • Masks for participants (even for others in their homes if research is community based). • Thermometer. • Alcohol based hand sanitiser. • Sanitiser for surfaces e.g. chairs, table. • A4 size plastic bag to put informed consent documents or paper questionnaires in (this will be left in the plastic bag for a minimum of three days). • Availability of basic materials on COVID-19 (masks, hand washing, social distancing, cough etiquette) to distribute to participants. • Box of tissues. • Bag for disposal of used masks and tissues. <p>Planning to conduct the home visit:</p> <ul style="list-style-type: none"> • Ensure that a research toolkit is available to the researcher. • Make an appointment. <p>What to do when you enter the home of the participant:</p> <ul style="list-style-type: none"> • The researcher should wear a mask. • Remain outside and respectfully and caringly explain how you will protect the participant and the researcher (masks, sanitizing of hand and surfaces). • Researcher to sanitize own hands. • Ensure that the participant's and anybody else present have masks on and if not, provide masks. • If visors are to be used by the researcher and participant, sanitize the participant's visor in front of the participant and explain process to ensure they feel safe and accepted. • On entry take the temperature (if higher than 37.5°C be ready to refer and do not continue with data gathering). • Kindly request to sanitize the surface where you will be sitting e.g. chair and table top. <p>What to do when data gathering has been completed:</p> |

| | |
|--|--|
| | <ul style="list-style-type: none"> • Place any paper documentation e.g. informed consent forms in a plastic bag that can seal (leave untouched for three days). • Clean and disinfect area. • Sanitize hands after leaving the home. • Dispose of any potentially infected materials. <p>Managing the team if they are busy with research for the whole day:</p> <ul style="list-style-type: none"> • If there for the whole day, regular temperature measures (when they enter, during the day and when they leave). <p>What the researcher needs to do when he/she gets home:</p> <ul style="list-style-type: none"> • Leave shoes outside and first sanitize. • Undress and place clothes in washing machine without shaking. • Immediately have a bath/shower. • Only greet your family after these procedures are completed. |
|--|--|

8. Other supportive Reading materials:

- Conducting qualitative research during a period of lockdown and social distancing (Greeff, 5 May 2020)
- Implications of alert levels for researchers and postgraduate students during the COVID-19 pandemic (Greeff, 21 May 2020)

Note: A special thank you to Prof Wayne Towers for help with the editing of the document.