Return to Research Plan

University of Winnipeg, Department of Kinesiology and Applied Health

The following plan has been developed to comply with University of Winnipeg and Provincial Health Guidelines, in accordance with recommendations from key medical organizations (i.e., the Canadian Thoracic Society), and in consultation with principal investigators from other laboratories in Canada who conduct similar work (Dr. A. Willian Sheel, University of British Columbia; Dr. Jordan A. Guenette, University of British Columbia; Dr. Dennis Jensen, McGill University; Dr. Paolo B. Dominelli, University of Waterloo).

Principal Investigator:	Dr. Yannick Molgat-Seon
Building:	Duckworth Centre
Rooms:	1D11 and 3D16
Personnel Involved	

Faculty:Dr. Yannick Molgat-SeonUndergraduate Students:Mathieu Sawatzky and Sara Telles-Langdon

Required Resources

The proposed plan only affects the Duckworth Centre. All laboratory personnel will require access to room 1D11A and 1D11B. Additionally, Dr. Molgat-Seon will continue to have access to his office in room 3D16.

Overview

The current plan outlines the specific changes that will be made to current work practices in order to mitigate the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the context of the coronavirus disease 2019 (COVID-19) pandemic. In addition to standard work safe practices, COVID-19 screening will take place, training will be provided to laboratory personnel, work will be performed remotely whenever possible, and important adjustments will be made to the work place and to work processes. The requirement for use of personal protective equipment (PPE) will be bolstered and strict cleaning protocols will be put in place. The overarching aim is to provide a safe environment to conduct research involving human participants.

1. COVID-19 Vaccination

To protect the health and safety of our community, the University of Winnipeg has mandated that anyone seeking to access indoor campus spaces obtain an approved COVID-19 vaccination(s). Thus, all participants and research personnel need to have received at least 2 doses of a Health Canada-approved COVID-19 vaccine with supporting documentation prior to entering the laboratory for testing. Acceptable forms of supporting documentation include: i) government-issued photo identification, and ii) Manitoba Immunization QR Codes, Manitoba Immunization Cards, Manitoba Immunization Records, or proof from other jurisdictions. All screening will be performed by Dr. Yannick Molgat-Seon and personal health information will be kept confidential. Reasonable accommodation may be provided upon formal request, pending approval from the University of Winnipeg's Human Rights and Diversity Officer (s.belding@uwinnipeg.ca).

Further information can be found on the University of Winnipeg's website: <u>https://www.uwinnipeg.ca/institutional-analysis/docs/policies/vaccine-policy.pdf</u>

2. COVID-19 Screening

To minimize the risk of SARS-CoV-2 transmission, laboratory personnel and research participants must not come to campus when ill. Thus, prior to coming to the University of Winnipeg campus and entering the laboratory, laboratory personnel and research participants will need to use the province of Manitoba's COVID-19 self-assessment tool:

https://sharedhealthmb.ca/covid19/screening-tool/

- Laboratory personnel must use the province of Manitoba's COVID-19 self-assessment tool daily, prior to entering the laboratory. If they have symptoms of COVID-19 or feel ill, they will be required to stay home.
- Research participants must conduct self-assessment for using the province of Manitoba's COVID-19 self-assessment tool for 7 days prior to arrival to the laboratory. This will be completed with the assistance of laboratory personnel who will contact the participant by phone or by email to confirm that they have completed the self-assessment tool. If they have symptoms of COVID-19 or feel ill, they will be required to stay home and testing will be rescheduled or cancelled. Following their visit(s) to the laboratory, they will be asked to continue to monitor their symptoms and report directly to laboratory personnel should they become symptomatic.
- Prior to entering the laboratory testing days, all research personnel and the participant will undergo a COVID-19 rapid antigen test, which will be provided by the University of Winnipeg's Safety Office. If the participant or any of the research personnel test positive, testing will be rescheduled or cancelled. If the participant and all research personnel test negative, testing will proceed as planned and a confirmatory test will be performed on the research personnel 48 h later. If the confirmatory test on any of the research personnel is positive, the participant will be notified immediately. Rapid antigen testing will be performed according to Government of Canada Guidelines:

https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/use-rapid-antigen-detection-tests.html).

3. Training

Prior to returning to campus, Dr. Molgat-Seon will meet with students virtually to provide them with a detailed overview of how laboratory work will be conducted and the important changes that will be made regarding:

- COVID-19 vaccination requirements
- COVID-19 screening
- Remote work
- Workplace adjustments
- Work processes adjustments
- PPE

4. Remote Work

The aim will be to conduct the least amount of work possible in the laboratory. Thus, all work that can be conducted outside of the laboratory will be conducted off campus. This includes data analysis, paperwork, manuscript writing, laboratory meetings, presentation preparation, etc.

Remote work	Laboratory work
Meetings, data analysis, manuscript writing,	Preparation for participant testing
presentation preparation, etc.	Some preparation works needs to be done
	ahead of a scheduled testing session (e.g.,
All work not listed under Laboratory work	calibration, cleaning, etc.). The majority of the
will be done at home by all team members.	time, this will be done by a single individual in
	the room. When this is not possible, two
	laboratory personnel will be present, but will
	maintain physical distancing at all time and
	follow all sanitization procedures.
	Participant testing
	Specialized equipment is required for testing
	and cannot be done remotely. During testing,
	at least 2 members of the laboratory will be
	present to ensure safety.

5. Workplace Adjustments

The maximum number of individuals (including laboratory personnel and research participants) in room 1D11 at any one time will be reduced to no more than 3, which allows >12.5 m² of space per person. When laboratory personnel and/or research participants are in the laboratory, physical distancing guidelines (*i.e.*, ≥ 2 m between individuals) must be followed whenever possible. In order to achieve this in a relatively small space, non-essential equipment and furniture will be moved into room 1D11B to maximize the available space in 1D11A. At no time will two studies occur simultaneously and only one session of data collection will be allowed in a given day to ensure that there is adequate time to prepare the space for testing and subsequently clean the space following testing. The laboratory will also be divided into 4 quadrants to minimize the potential for close contact between individuals and to facilitate cleaning procedures. Accordingly, there will be designated areas for: i) participants to complete the study consent forms, questionnaires, and paper work, ii) for pulmonary function testing, iii) for exercise testing, and iv) for specialized procedures such as esophageal catheter placement. Each area will be outlined with coloured tape on the floor. All unused equipment will be stored in a separate room (1D11B). Finally, the room will be outfitted with a series of fans to promote ventilation and the available windows will be opened where possible.

Each week, the laboratory group will hold a virtual laboratory meeting, during which they will have a designated time to discuss COVID-19 related issues. Scheduling will be set ahead of time according the above guidelines and shared amongst laboratory members using a shared, online calendar.

6. Work Process Adjustments

Laboratory personnel will only be allowed within the hours of 9:00 AM to 4:00 PM. Preparation for testing and testing of participants must be performed by at least 2 laboratory personnel to ensure safety. Laboratory personnel will also be required to notify Dr. Molgat-Seon of the hours that they will be working in the laboratory on each day that they come to work. Unscheduled entrance to the laboratory will not be permitted without the approval of Dr. Molgat-Seon. All booking of laboratory time will be done on a shared, online calendar.

Research participants and laboratory staff will be asked not to bring any non-essential items to the laboratory; however, it will be necessary to bring some items to the laboratory (*e.g.*, keys, wallet, phone, etc.). The laboratory will have dedicated bins for each member of the laboratory personnel and for participants to use upon arrival to the laboratory. They will be asked to place all items in the bin and this will remain in a designated area. Only the individuals who placed the items in the bin will be allowed to handle the bin or its contents. The participant's bin will be disinfected once the participant has left the laboratory.

7. Personal Protective Equipment

Depending on the nature of the activities performed in the laboratory, laboratory personnel and research participants will need to wear a combination of the following PPE:

- Disposable, vinyl nitrile or latex <u>gloves</u> will be required for testing where there is human contact.
- <u>Face masks</u> must be worn at all times when on the University of Winnipeg Campus. This includes the laboratory space.
 - Where close contact with a study participant is required, the study participant must wear a <u>surgical mask</u> that will be provided to them upon arrival to the laboratory, and the researcher must wear an <u>KN95 or N95 respirator</u>.
 - Participants may remove their mask for as little time as possible during instrumentation, and during or after exercise.
- <u>Face shields</u> will be provided to laboratory personnel and must be wiped with a disinfectant before and after each use.
- Shared computers will have <u>plastic keyboard and mouse covers</u> and will be wiped with disinfectant before and after each use.
- <u>Gowns</u> will be provided to laboratory personnel and must be worn during testing of research participants. Gowns will be washed daily.
- Researchers are to wear <u>surgical masks</u> or <u>KN95/N95 respirators</u>, <u>face shields</u>, <u>gowns</u>, and <u>gloves</u> for studies that involve taking biological fluids (*e.g.*, spit, blood, other bodily fluids) and the participants are to wear surgical masks.

8. Cleaning Procedures

Thorough cleaning and disinfection is critical to mitigate the risk of SARS-CoV-2 transmission in a laboratory setting. Therefore, laboratory cleaning procedures will be modified as follows:

 Thorough work surface and equipment decontamination will be conducted before and after experiments are carried out (see Table 2). This applies to shared equipment such as workstations, but also to research equipment as high-use surfaces such as tables, chairs, and doorknobs (see Table 3). Laboratory personnel will be responsible for cleaning prior to and following testing and/or when they enter the laboratory space and before they leave. Details regarding the equipment of item, the disinfectant used, the active ingredients and their concentration, as well and the frequency of disinfection are provided in **Table 2** and **Table 3**.

ii) Laboratory personnel and research participants must maintain excellent personal hygiene while in the laboratory. Anyone entering the laboratory will be required to wash their hands immediately upon entering and exiting. Any contact with saliva from participant will result in gloves being immediately removed and hands washed. Hand hygiene stations will also be at both workstations and at the participant instrumentation area.

9. Human Participant Considerations

Research involving human participants increases the likelihood of spreading SARS-CoV-2; however, with rigorous safety protocols, safely performing research involving human participants is possible. The following section outlines the various aspect of Dr. Molgat-Seon's research program that involve human and how ensuring safety of the participants and laboratory personnel will be achieved.

Coming to the laboratory

Prior to any scheduling the Informed Consent Form will be sent to the participant and a phone call will be arranged if they are willing to participate. During this call, the laboratory personnel will explain the study, the COVID-19 safety protocols, and answer any questions the participant may have. If the participant is still willing to participate, provide them with instruction regarding how to come to the laboratory. As detailed above, we will be in contact with the participant for at least 7 days prior to the testing day to complete COVID-19 screening. If the participant passes the COVID-19 screening protocol, on the day of testing the participant will be asked to:

- i) Avoid brining no-essential items into the laboratory.
- ii) Wear a mask that conforms to Provincial Health Guidelines. If they do not have one, a disposable surgical mask will be provided.
- iii) Call, message, or email the laboratory personnel when they have arrived at the main entrance of Duckworth Centre. Laboratory personnel will then meet them outside the main doors and escort them into the laboratory, which >30 m straight ahead of the main doors.
- iv) Complete a log for contact tracing purposes.
- v) Wash their hands according to standard instructions upon entring the laboratory

The majority of the procedures conducted on human participants can be completed while maintaining physical distancing. A list of the task that will be conducted as part of upcoming research projects is listed in **Table 1**.

Task	Physical distancing requirements	Minimum Required PPE
 All task performed in the laboratory in the absence of a research participant Completing forms Explaining experimental procedures 	Distance of >2 m between individuals must be respected at all times	Surgical mask
• Pulmonary function testing	Distance of >2 m between individuals must be respected at all times	 Face shield KN95/N95 respirator Gloves Gown
 Esophageal balloon catheter placement Electrode placement Exercise testing 	Physical distancing is not always possible, but time in close proximity to participant will be minimized as much as possible	 Face shield KN95/N95 respirator Gloves Gown

Table 1. Laboratory tasks and the required PPE

Placing equipment on a participant

All equipment placed on a participant will disinfected before and after use (see **Table 2** and **Table 3**). For equipment that must be placed on the participant, instructions will be provided by laboratory personnel such that the participant can place the equipment on themselves while maintaining physical distancing (*e.g.*, placing a heart rate monitor, nose clips or a mouthpiece etc.). For some equipment, the laboratory personnel will need to place the device on the participant, during which time physical distancing will not be possible (*e.g.*, tightening a face mask, placing an electromyography electrode, inserting and esophageal balloon, etc.). In these situations

Procedures where physical distancing is not possible

Coming within 2 m will be minimized whenever possible. For example, the participant will be directed how to put on the equipment based on instruction provided by laboratory personnel, which can be done from a distance. However, certain procedures require that laboratory personnel come within 2 m of the participant (see **Table 1**). In these situations, time in close proximity will be minimized as much as possible. Anytime an investigator is within 2 m of the participants, they will also wear a face shield, a KN95/N95 respirator, gloves, and a gown. In every case possible, the participant and investigator will not directly face each other.

Pulmonary function testing

For all experiments, pulmonary function testing (PFT) will be performed on research participants. The breathing manoeuvres involved in PFT have the potential generate droplets and aerosols, typically when symptomatic individuals cough or sneeze. As such, Dr. Molgat-Seon's laboratory will follow the most recent guidelines concerning performing PFT during the COVID-19 pandemic, as outlined by the Canadian Thoracic Society (Stanojevic S *et al.*, 2020). Briefly, single use bacterial/viral inline filters that meet international standards of filtration performance (see Appendix) will be added to the breathing circuit of the PFT system. Participants will be asked to place the filter in the appropriate disposal bin following the completion of PFT. During PFT,

laboratory personnel will wear a face shield, a KN95/N95 respirator, gloves, and a gown (see **Table 1**).

Mouthpieces

After mouthpieces are cleaned, they will be stored in disinfected plastic containers ahead of the next participant. These will be opened by the participant and they will be the only ones handling the mouthpiece. We have sufficient number of full mouthpieces to be able to have several on hand prior to the arrival of a participant. As such, after cleaning, the mouthpiece will sit sealed for several days before used. To remove the mouthpiece after testing is completed, the participants will be asked to place the mouthpiece back into the same container and sealed. Hand sanitizer will be provided to the participant to sanitize their hands ahead of touching anything after mouthpiece removal. The plastic container and mouthpiece will then be sanitized after use (see **Table 2**).

Electromyography and electrocardiography electrodes

Proper placement of the electrodes is critical, as such placing electrodes on the participants will be done by laboratory personnel (see guidelines below concerning procedures where physical distancing is not possible). On testing is completed, all electrodes will be immediately discarded in waste bins; this will be done by the participant.

Esophageal catheters

On some occasions, an esophageal catheter will be used. This procedure will only be conducted by Dr. Molgat-Seon who trained an experienced in doing so. The procedure is safe but does increase infective risk due to the fact Dr. Molgat-Seon will need to be within 2 m of the subject. However, Dr. Molgat-Seon will wear a face shield, a KN95/N95 respirator, gloves, and a gown at all times during the procedure (see **Table 1**), which lasts approximately 5 minutes and will be performed in a designated area of the laboratory. Once the esophageal catheter is in place, the participants can complete exercise testing after which the catheter will be removed by Dr. Molgat-Seon, which takes approximately 30 s and the catheter will be immediately disposed of in a hazardous waste bin according to standard protocols.

<u>Exercise</u>

Most experiments will involve exercise, specifically cardiopulmonary exercise testing (CPET). Similar to pulmonary function testing, the risk of infective transmission during CPET resulting from forced expiration is increased. Thus, we will take every precaution to ensure that infective risk is minimized as much as possible, as outlined by the Canadian Thoracic Society in a recent position statement (Stanojevic S *et al.*, 2020). During exercise, laboratory personnel will wear a face shield, a KN95/N95 respirator, gloves, and a gown (see **Table 1**), won't be directly facing the participant, and the participant will always be wearing mouthpiece. The mouthpiece is connected to 2-way non-rebreathing valves that ensures that inspired and expired air flows through separate tubes. Single use bacterial/viral inline filters that meet international standards of filtration performance (see Appendix) will be added to the inspiratory and expiratory tubes. These filters are approved for CPET in a hospital setting an are currently being used in exercise physiology laboratories across Canada. Additionally, tubing will be raised above the level of the participant to mitigate the risk of droplets accumulating in the tubing and saturating the filter. Inspiratory and expiratory tubes will never be used interchangeably. Finally, during exercise, fans will be used but directed away from laboratory personnel.

10. Other Actions

Dr. Molgat-Seon confirms that in addition to the above protocols, the following actions will be completed prior to beginning research involving human participants:

- \boxtimes Occupancy limits will be posted on all laboratory entrances and exits.
- Hand hygiene stations will be installed for laboratory personnel and research participants to use.
- \boxtimes Hand hygiene procedures will be posted on all sinks and hand hygiene stations.
- \boxtimes Extraneous seating will be removed from the laboratory.
- All changes and protocols described in the current plan will be communicated to laboratory personnel.
- Disposable paper cups will be available for study participants as needed.
- Secure storage of participant information for contact tracing will be established.

References:

1. Stanojevic S *et al.*, Resumption of Pulmonary Function Testing during the Post-Peak Phase of the COVID-19 Pandemic: A Position Statement from the Canadian Thoracic Society and the Canadian Society of Respiratory Therapists. December 9th, 2020.

Equipment or Item	Disinfectant	Active Ingredient(s) and Concentration	Contact time*	Frequency of disinfection
 Exercise bike Computer workstation Calibration syringe Heart rate monitors Face shields 	<i>Lysol</i> wipes or <i>Saniblend</i> spray	<u>Lysol wipes</u> : Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride, 0.26% w/w <u>Saniblend spray</u> : n-Alkyl (5% C12, 60% C14, 30% C16, 5% C18) dimethyl benzyl ammonium chlorides 0.105% n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.105%	10 min Air dry	Before and after use
 Mouthpiece Tubing Devices in contact with participant saliva or expired gas Plastic containers for mouthpieces 	MetriCide-28+	Glutaraldehyde, 1.8%	Submerged for >12 min at 20 °C	After use
 Flow sensors Pressure transducers Gas analyzers 	CaviWipes†	Isopropanol, 17.2% Diisobutylphenoxyethoxyethyldimethylbenzyl ammonium chloride, 0.28%	3 min Air dry	Before and after use

Table 2. Equipment disinfection details

* Contact time refers to the amount of time that the disinfecting agent is required to be in wet contact with the surface/object to appropriately disinfect, based manufacturer's instructions.

+ Metricide is a commercially available disinfectant. It is commonly used in hospitals to clean endoscopy and bronchoscopy probes and other surgical type equipment that cannot be autoclaved or heat sterilized.

† CaviWipes are commercially available disinfectant wipes that are approved for use in hospitals. CaviWipes are specifically used for sensitive or delicate equipment since certain compounds in other disinfectant products are known to damage these items.

Equipment or Item	Disinfectant	Active Ingredient(s) and Concentration	Contact time*	Frequency of disinfection
 Doorknobs and handles Cupboard knobs and handles Faucets and tap handles Light switches Keyboards and mice Desks, tables, and chairs 	<i>Lysol</i> wipes or <i>Saniblend</i> spray	<u>Lysol wipes</u> : Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride, 0.26% w/w <u>Saniblend spray</u> : n-Alkyl (5% C12, 60% C14, 30% C16, 5% C18) dimethyl benzyl ammonium chlorides 0.105% n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.105%	10 min Air dry	9:00 AM and 2:00 PM every day when the laboratory is in use

Table 3. High-touch surface disinfection details

Cleaning product information:

Lysol Wipes https://www.lysol.com/products/disinfecting-wipes/lysol-disinfecting-wipes

Saniblend Spray

https://www.safeblend.com/en/products/saniblend-rtu-ready-to-use-2/

MetriCide-28+

https://www.metrex.com/en-us/products/high-level-disinfectants/metricide-28#bootstrap-fieldgroup-nav-item--sds-literature

Caviwipes

https://www.metrex.com/en-us/products/surface-disinfectants/caviwipes