

Title	Hygiene, sanitation, disinfection, protection and prevention procedure - COVID-19 virus
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Version History

DATE	VERSION	PAGE #	DESCRIPTIONS OF THE CHANGES
21APR2020	00	3	Original version
28APR2020	01	3	Add-ons
04MAY2020	02	3	Add-ons
08MAY2020	03	4	Add-ons and modifications
15MAY2020	04	4	Add-ons and modifications
29MAY2020	05	4	Modifications
12JUN2020	06	4	Add-ons and modifications
29JUN2020	07	4	Add-ons and modifications
11SEP2020	08	4	Add-ons and modifications
22SEP2020	09	4	Add-ons and modifications
25SEP2020	10	5	Add-ons and modifications
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26FEB2021	13	7	Add-ons and modifications
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Approval of the procedure

NAME	TITLE	SIGNATURE	DATE
Véronique Provencher	Sherbrooke Site Manager	By email	15JUN2021
Stacey Keet	Executive Director	By email	15JUN2021

Hygiene, sanitation, disinfection, protection and prevention procedure - COVID-19 virus

Procedure in yellow zone

These measures are intended to minimize the risk of spreading the COVID-19 virus within Diex Recherche Sherbrooke's facilities, among its employees and collaborators and among research participants.

These measures have been discussed with health professionals (physicians) before being implemented in order to ensure their effectiveness and relevance, considering the intended purpose mentioned in the above paragraph.

These measures are consistent with government recommendations to wear masks in the workplace and for inter-regional travel.

Procedures for entering the premises for employees and collaborators

- A bottle of Purell is placed at the employee entrance: all employees must disinfect their hands upon arrival.
- A box of procedure masks is at the entrance: all employees must wear a clean mask when moving around the office and when the 2m distance is not possible.
- The employee must complete the screening form before circulating on the site.
- Afterwards, all employees must wash their hands for 20 seconds in the employee room.
- All collaborators must disinfect their hands upon arrival with Purell and complete the screening form.
- All employees and collaborators must wash their hands for 20 seconds every hour.
- All employees and collaborators must disinfect their hands each time they enter the employee area (i.e. outside the clinic area).
- ~~— Permission to use Diex's bathroom for all employees to reduce the risk of contamination in the building's public bathroom.~~
- Avoid using the door behind the reception area; please prioritize the door on the clinic side.
- **From now on, we will use the bathroom in the IMMEX corridor. The DIEX bathroom is reserved exclusively for the participants.**

Entrance procedures for research participants and external visitors

- The participant's health status is validated during the appointment confirmation call, which is made the day before the appointment using the screening form.

Depending on the answers obtained during the call, the appointment is rescheduled or not, after discussion with the nurse, the clinical research coordinator, the site manager and/or the study physician.

During the appointment:

- All participants must disinfect their hands with Purell upon arrival and departure.
- All participants are given a procedure mask upon arrival. They then disinfect their hands with Purell.
- A staff member completes the screening form with the participant.

Depending on the responses to the screening form, the appointment may or may not be cancelled or additional security measures are put in place, after discussion with the nurse, the clinical research coordinator, the site manager and/or the study physician.

We are currently limiting access to our Diex Research sites due to the pandemic. Access will be managed on an individual basis and with the approval of the security committee. We will respect the governmental policies in effect in the different administrative regions.

- ~~○ The presence of a monitor in a site will be permitted only if one of the following cases is encountered:~~
 - ~~▪ Essential presence at the site (company obligation to continue the study/close out visit)~~
 - ~~▪ Medication check at the site~~
 - ~~▪ Verification of the regulatory box (if not in Realtime)~~
 - ~~▪ Verification of document sources (if not in CRIO)~~
- The presence of a monitor at the site is accepted, but controlled. Indeed, we can only welcome a limited number of monitors at a time in our facilities in order to respect the regulations in force.

Process for requesting ~~an exception~~: **a visit from an instructor**:

If a monitor contacts you for a monitoring visit to the site, confirm ~~if any of the above criteria is met with your DM~~. If so, transfer the exception request to with the consultant, clinic operation **if we can accommodate him/her**.

Site visit acceptance condition (this information will be requested by the Clinical Operations Advisor before the site visit is confirmed)

- No travel outside of Quebec in the last 14 days
- Compliance with government recommendations including, but not limited to:
 - Follow-up on recommendations for inter-regional travel
 - Wear a procedure mask ~~at all times~~ **when moving or when the 2m distance cannot be respected**.
 - Hand washing
 - Distancing (since distancing within the monitor rooms is impossible, all communication with the study staff and physician will be done by telephone).
- Limitation of access to the selected monitoring room, the door must be closed at all times.
- Provide a precise list of what will need to be checked during the visit.
- No contact with the subjects (therefore minimal travel to the site and if a site visit is requested, it will be made outside of the patient's attendance hours)

Information for Research coordinators or staff

- All requested documents should be prepared if possible before the monitor's visit and placed in the monitoring room.
- The distance must be respected so if it is not possible to be 2 m apart in the monitoring room any discussion must be done by phone. (No discussion with the door open is allowed to avoid the contact of a patient with the monitor).

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- After the monitor's visit, the room must be left closed with all the revised elements (except for medication which must return to the proper temperature) until at least ~~12~~ 6 hours after the visit. Once the ~~12~~ 6 hours is over, a disinfection of the room must take place.
- During a monitoring visit, hand disinfection with Purell is required. A procedure mask must be worn at all times. It can be removed in the room when the door is closed and must be put back on as soon as someone knocks on the door to enter.
- No personal visits are authorized on Diex's premises.
- Reduction in the number of chairs in the waiting room.

Procedures during participants visits

- For patients with young children: it would be preferable to postpone the appointment in order to be able to come alone to the site. In case of force majeure, and if the child is able to wear the procedure mask, we can tolerate the presence of the child during the appointment. Children who are not able to wear the mask safely should not come to the site.
- The staff member will greet the participant by walking through the clinic door, not the reception door.
- The employee having contact with a research participant must wear a procedure mask at all times during the appointment.
- The employee who has contact with a research participant ~~must~~ can wear eye protection ~~at all times~~ during the appointment from among the following choices (this measure is optional):
 - o A protective clip added to his or her glasses, if the employee wears glasses;
 - o A visor;
 - o A pair of protective glasses.
- The employee must change his mask every 4 hours or if it is soiled.
- Upon the participant's departure, the entire environment of the rooms used is disinfected with disinfectant wipes.
- Each time the patient goes to the toilet, a complete disinfection is done by the nursing staff.
- The device and its environment used for taking biometric tests is disinfected immediately after use.
- When the scale is used, it is disinfected afterwards and the environment touched by the patient as well: walls, shelf, etc.
- Electronic tablets and journals are disinfected after each use.
- Any material handed in by the participant (medication box, electronic journal) must be handled with disposable gloves and must be disinfected with a disinfectant wipe.
- After the patient has left the site, the door handle of the site must be disinfected.
- During spirometry, the wearing of PPE is preferred: The procedure mask, visor, gloves and gown must be worn throughout the procedure. The visor must be disinfected between each participant; the mask, gloves and gown must be changed between each participant. The room should be closed for 6 hours following the examination and then cleaned.

Disinfection of the device is done according to the instructions in the NIOX Vero and MasterScope user manual using Oxivir or equivalent (Masterscope: <https://www.ert.com/wp-content/uploads/2020/03/RESP-COVID19-CleaningInstructions.pdf>, NIOX: <https://www.niox.com/en-de/coronavirus-faq/>, Oxivir: <https://vto.qc.ca/produit/oxivir-plus-desinfectant-concentre/>)

Procedures for collecting and processing biological samples

- The equipment needed for blood collection is stripped to the bare bones in the collection room, all nonessential blood collection equipment has been stored in the cabinets.
- After **blood** samples are taken by the nurse, they are immediately given to designated personnel of the laboratory.
- The entire collection room is disinfected as soon as the participant leaves.
- For **urine** samples, the container is retrieved when the participant leaves the bathroom and given immediately to the designated personnel of the laboratory.
- Laboratory work surfaces are disinfected after each sample treatment.
- Centrifuges, refrigerators and freezers are disinfected in the late morning and at the end of the day.

Hygiene, sanitation and disinfection procedures for the premises

- All surfaces must be disinfected regularly. If the surface is dirty, first clean it with a cleaning agent and then disinfect it with a disinfectant. If the surface is clean, it can be directly disinfected.
- Patient rooms are disinfected with disinfectant wipes at the end of each patient visit: room door handle, telephone, chair, desk and any other equipment present in the room.
- The monitor rooms are disinfected with disinfectant wipes on the handle, desk, chair and any other material present after each visit of monitors in the monitor rooms, after the 6-hour time limit.
- After each use (~~employees and patients~~ **only, employees going to the one outside DIX**) of the bathroom, a disinfectant wipe is passed on the toilet handle, faucet, counter, door handle and light.
- The frequency of surface cleaning by the external cleaning company is increased to 3 times a week.
- All deliveries must be handled with disposable gloves. All boxes and envelopes must be disinfected with a disinfectant wipe before being transported to the other side of the reception area. All personal material belonging to the employee (handbag, lunch box) must be cleaned with a damp cloth and soap when the employee arrives at the office.
- Preventive procedures to reduce the risk of spreading and to detect contamination in a preventive manner Teleworking is mandatory for all employees who have the possibility to do so.

Decrease in the number of chairs in the employees' room in order to respect the social distancing rule of 2 meters.

- Teleworking is ~~mandatory~~ **recommended** for all employees who have the opportunity.
- Meeting by prioritized teleconference or with a minimum distance of 2 meters between participants wearing masks.
- Ask employees to eat in their respective offices, if applicable, if the 2-meter social distancing rule cannot be met in the employee room.
- Prioritized teleconference meeting, or with a minimum distance of 2 meters between participants with the wearing of a mask.
- Use of Skype or telephone as a means of communication rather than in-person meetings.
- All employees, on-site or teleworking, must take their body temperature every morning (detailed procedures attached).
- Employees must take their temperature during the day in case of URTI symptoms.
- All people must keep a distance of 2 meters at all times.

- When moving around the clinic, a mask must be worn at all times. ~~People who are alone, in a closed office, can take it off. However, they must put it back on as soon as someone enters and disinfect their hands with Purell afterwards. The mask, worn continuously, must be changed every 4 hours, or as soon as it is soiled.~~ When it is removed, for example for a break, it must be placed on a tissue or paper towel and the persons must wash their hands before and after removal. The tissue or paper towel is discarded after use. **When you are sitting at your desk, and 2m away from everyone, the mask can be removed.**
- Respect at all times the posted travel regulations, if applicable, in order to control social distancing.
- Make sure to minimize the use and especially the transport of paper: do not give paper requests for external procedures to the research participants, fax the requests, etc.
- If a participant brings paper documents, these documents are handled with gloves and placed in a quarantine box for 72 hours before being filed, along with any other material that cannot be disinfected.
- Receptions in Diex's offices are equipped with Plexiglas.
- Whenever possible, foot-opening door systems will be installed as soon as possible.
- All employees disinfect/wash their hands when they move out of the office and upon their return, i.e. after putting on their mask and before removing their mask.
- In areas where objects are shared by employees but where employees do not continuously wear masks (ex. dining room), employees must disinfect shared objects before touching them.

Isolation Procedures

Any person who is awaiting a result from a COVID-19 test must go into temporary isolation until the result is received and may return to Diex's premises upon receiving a negative result (unless otherwise directed by Health Canada), or as directed by Health Canada if the test is positive.

If an employee remains with someone who has been tested for COVID-19 and for whom the employee is awaiting the result, the employee must go into seclusion until confirmation of a negative test is received from the individual.

In the event of a positive test result, the procedures to be taken will then be dictated by Public Health.

Updating procedures

A COVID-19 Safety Committee has been set up. It is made up of the site managers, the Clinical Operations Advisor, the Executive Director and Dr. Ginette Girard. The Committee meets as needed to assess the situation, validate whether the procedures in place are still adequate in light of the changing situation, evaluate whether the procedures are being applied and followed by employees, and implement new procedures if necessary. The minutes of these meetings are appended to the COVID-19 safety procedures binder.