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APPROUVÉ PAR LE COMITÉ D'ÉTHIQUE

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Québec

INFORMATION AND CONSENT FORM

Project Title: PREvention of COVID-19 with Oral Vitamin D supplemental Therapy in Essential healthCare Teams (PROTECT)

Protocol Number: PROTECT 2020

- **Principal investigators at CHUSJ:** Dr. Francine M. Ducharme, MD, FRCPC, Paediatrician, Centre hospitalier universitaire Sainte-Justine (CHUSJ)
- **Principal investigator at the CHUM:** Dr. Cecile Tremblay, MD, FRCPC, Microbiologist/Infectiologist, Centre hospitalier universitaire de Montréal (CHUM)

Co-investigators:

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Co-investigators at the CHUM:

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Industrial Collaborators: Laboratoires Riva, Blainville, Quebec

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Multicenter identifier: MP-21-2021-3044

CHUM project number : 20.319

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS STUDY?

Today, we are inviting you to participate in this research study because you are a healthcare worker who is working in a high COVID-19 incidence area and in a setting with a high risk of contact with COVID-19 infected cases. Please read this information to help you decide if you want to participate in this research project. It is important that you understand this information. We encourage you to ask questions. Please take all the time you need to make your decision. You may also want to discuss this study with your family doctor, a family member or a close friend.

WHY IS THIS STUDY BEING DONE?

During the current COVID-19 pandemic, many healthcare workers are working in an environment which increases their probability of contracting this viral infection. Healthcare workers are more frequently infected than the rest of the population. Infected healthcare workers can infect their family, their patients, and their contacts. In addition to being withdrawn from work, they could have transmitted the disease to other colleagues, which further impedes our ability to deliver care to the population.

Vitamin D supplementation can decrease the risk of having the common cold, but it is not known if it could have an effect on the COVID-19 infection. Vitamin D is produced in our bodies from exposure to the sun and can be obtained from supplements and certain foods. However, many Canadians do not have an adequate intake of vitamin D throughout the year.

However, studies testing supplementation with other seemingly harmless vitamins, such as beta carotene and vitamin E, have shown unexpected important adverse reactions. Therefore, it is necessary to properly assess the benefits and the potential unexpected adverse reactions in the context of a clinical study.

This study will investigate whether a high-dose vitamin D supplementation could reduce the risk and severity of COVID-19 infection and work absence in healthcare workers.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We will be recruiting 2414 graduate healthcare workers, men and women, aged 18 to 69 years old, actively working and scheduled to continue working in a setting at high-risk of contact with people infected with COVID-19 and are working in high COVID incidence areas.

WHAT DOES THE STUDY INVOLVE?

If you agree to participate in this study, you will be assigned by chance to one of two groups. One group will receive one dose of 100,000 IU of vitamin D by mouth at the first visit and then take at home 1 pill of 10,000 IU of vitamin D once a week. The other group will receive a placebo dose at the first visit and then a placebo pill once a week. The vitamin D supplement is the active substance, meaning it could have an effect in the body. A placebo is an inactive substance, meaning it has no effect in the body. A placebo is used in clinical studies, such as this one, to ensure that observed changes are due to the active treatment and not to chance. You will have an equal chance of being assigned to each

group. The placebo and the vitamin D supplement look and taste exactly the same, so no one will know which treatment you are given, including the people involved in the study. In this informed consent form, we will use “Study supplement” to refer either to the vitamin D or the placebo.

This study should last 16 weeks and involves two visits. But prior to the first visit, we will conduct a screening/enrolment visit remotely by videoconferencing (or phone). If eligible and consenting, there will be a randomisation visit and an end-of-study visit, the latter two could be conducted in-person or remotely by videoconferencing, at your preference. Because of the pandemic, we wish to reduce the need and/or length of any in-person visit by doing as much as possible remotely.

Note that the study could finish earlier or be prolonged to 24 weeks, depending on the evolution of the pandemic. We ask that you don't change your usual diet or intake of vitamin supplements (if any) during the study.

Screening/Enrolment (pre-visit: about 45-60 minutes)

- ❖ We will review the eligibility questionnaire you have completed online, complete it with additional questions, explain the study in detail, and answer your questions.
- ❖ If eligible and consenting, you will be asked to sign the consent form, complete a few short study questionnaires and provide your contact information.
- ❖ We will ask you questions about your demographics (household, ethnicity), work-related activities and personal health (weight, height, skin color, smoking, medication, vitamins, supplements, health problems).
- ❖ To enable the creation of a medical and research pharmacy records, obtain information on COVID test, and ensure optimal contact with you throughout the study, we will ask personal information namely your RAMQ number, names (yours, your parents, your spouse), any drug allergy, your employee number (or practice number for physicians), your postal and email addresses, phone numbers and that of a next of kin and your preferred means to reach you.
- ❖ We could show you videos of key procedures (e.g. home blood collection) to help you chose your preferred type of randomisation visit.
- ❖ We will schedule the randomisation visit at a mutually convenient time and place given your choice of in-person or remote visit by videoconferencing. However, in case of a suspected prior COVID-19 infection, we would prefer you do an in-person visit to perform a rapid screening test for COVID-19 antibodies.

Randomisation visit (First visit: Week 0)

During the visit, which will last approximately an hour,

- ❖ If not already done, we will ask you to sign the consent forms, complete missing study questionnaires and your contact information.
- ❖ We will take a venous blood sample of about 15 mL (3 teaspoons) to measure the level of vitamin D, look for COVID-19 antibodies and to do an optional genetic analysis to examine a possible genetic predisposition to respond to vitamin D and to severity of COVID-19 symptoms.

- ❖ We would like to obtain a small drop of blood either from the venous puncture or via a finger-prick to look for COVID-19 antibodies in your blood using NADAL® COVID-19 IgG/IgM Rapid Test: if positive, you would not be eligible for this study. This test is not yet licensed for use in Canada and its use in this study is investigational. It has been selected for use prior to enrolment because it provides antibody results in 15 minutes. The results of this investigational test will be shared with you, acknowledging the risk of false positive or negative results. They will also be subsequently compared to the approved (Liaison IgG COVID-19) serology test.
- ❖ We will show you how a video on the TASSO home blood sampling kit at home for the last visit; if interested, we will show you how to use it, identify your sample, package it, and send it back to us (see below under First Remote visit). This device is not yet licensed for use in Canada and its use in this study is investigational. However, we have successfully pre-tested it and have validated the concordance between test results obtained with the TASSO and venous sampling.
- ❖ We will show you how to take a saliva sample by spitting into a tube. You will receive a pamphlet with instructions and could watch a video. You should not brush your teeth, eat, drink, smoke or chew gum for 30 minutes before spitting a small volume of saliva (2 mL). If you prefer to do an oro-nasopharyngeal sample, you would need to insert a swab (a small tube with a cotton tip) into the back of your mouth, then in one of your nostrils gently rotating the swab for about 5 seconds. We will ask you to take the saliva (or oro-nasopharyngeal) sample under our guidance. We will then show you how to identify it with our prepared labels, record the date and time, package it, and sent it back for analysis for COVID-19, and possibly other viruses and cells.
- ❖ You will be asked to take ten (10) pills of the Study supplement at this first visit only in front of the research personnel (in person or by videoconference). You will take home the bottle of Study supplement and be asked to take one (1) pill once a week until the end of the study.
- ❖ We will send you by text message or email as per your preference, a first reminder with a link to a questionnaire to confirm that you have received it and are able to complete and submit the brief questionnaire. The same approach will be used every week.
- ❖ We will give you all the other study materials including the saliva collection tube pre-printed labels, biohazard bags, insulated envelopes or boxes for shipment, prepaid courier waybills, and if you are interested in a **Remote end-of-study visit**, the TASSO home blood collection kit. It is possible that we ask you to use the NADAL® COVID-19 IgG/IgM Rapid Test at the last visit for validation purposes.

For participants choosing to have a **Remote First Visit**, in whom there is a suspicion that you may have had a prior undiagnosed COVID-19 infection in the past, we would prefer that you come for an in-person visit. Alternatively, we may send you first a finger-prick test kit to look for COVID-19 antibodies in your blood; if so, we would ask that you use it on your fingertip in front of us by videoconference. If positive, you would not be eligible for this study. If negative, the Study supplement and required materials would then be sent to the participant's home prior to the randomisation visit. We will ask you to take in front of us by videoconference, the Study supplement, the saliva sample, as well as the blood test and 2nd optional saliva sample (for genetic analysis).

- ❖ We will show you how to take a small sample (<1 mL) of capillary blood, using a blood collection kit specifically conceived for home collection, called TASSO-SST OnDemand. This device is not yet licensed for use in Canada and its use in this study is investigational. However, we have successfully pre-tested it and have validated the concordance between test results obtained with the TASSO and venous sampling. We will ask you to watch a short video and read the brochure explaining the procedure, then ask you to use it under our guidance. Briefly, you will need to warm the skin of your upper arm by rubbing it for about 45 seconds, disinfecting it, applying the little device on your arm, pressing on a button that will puncture a very small hole in the skin, then leave the device in place for about 5 minutes while blood flows slowly in a small tube. As only a small sample of blood can be obtained, it is very likely that we ask you to repeat this with a second kit. We will show you how to remove the small tube, close it with a small cap, identify the sample with our prepared labels, record the sampling date and time, package it, and prepare it to be sent for analysis for vitamin D and COVID-19 antibodies. We will ask your feedback on this type of blood collection method.
- ❖ If you wish to participate in the optional genetic analysis, we will ask you to collect 2 mL of saliva in another small tube (as the blood sample made by TASSO is not enough for this analysis), identify and date the sample with our prepared labels, and send it to us.

Between visits

- ❖ For the following weeks 0 to 16 (or later, should the study be extended up to 24 weeks) participants will take every week one (1) Study pill.
- ❖ You will receive a message via email or text message, according to your indicated preference, to remind you
 - Once a week to take the Study supplement
 - Once every two weeks to take the Study supplement, and fill out the brief electronic questionnaire (duration of 3-5 minutes) regarding your health and work status in the previous 2 weeks.
 - At any point in time if you have symptoms, to complete the daily symptoms diary (duration of 1-2 minutes) until 48 hours after the resolution of symptoms. If you have symptoms that should prompt testing for COVID-19, as listed on the cv19quebec.ca website, we will ask you to contact your health office for this purpose.
- ❖ If there is no response from you within a few days of sending the electronic questionnaire, we will contact you; if there is still no response from you within 7 days of us sending the electronic questionnaire, we will contact your next-of-kin indicated by you.

If you are infected during the study

If we obtain a positive COVID result from one of your saliva (or oro-nasopharyngeal) samples, you will be notified by a Study team member, by the preferred communication means you have indicated (phone, text message or email). As all positive results will be reported to the public health authorities you will be contacted as soon as possible by them for an assessment and instructions.

If you receive a positive COVID result from a test done outside this study (i.e., for clinical reasons), we ask that you inform us immediately and to indicate it in the follow-up questionnaire.

At the reception of a positive COVID test result,

- ❖ We will ask you to complete the daily diary of symptoms (duration of 1-2 minutes)
 - Until 48 hours after resolution of symptoms
 - Or if you remain asymptomatic, for a minimum of 14 days;
- ❖ If symptoms reappear, we will ask you to restart documenting them in the daily diary of symptoms
 - Until 48 hours after resolution of symptoms;
- ❖ If your symptoms continue beyond 14 days, we will ask you to complete the weekly diary of symptoms (duration of 1-2 minutes), once a week, until resolution of symptoms
- ❖ We will ask you to continue taking your weekly supplement and completing the follow-up questionnaire once every two weeks.

In case of an imminent vaccination against COVID-19

- ❖ If you expect to receive a vaccine against COVID-19 in the next few weeks, we will ask you to notify us immediately or via the questionnaire every two weeks.
 - We will rapidly organise a visit in person or remotely, before the scheduled date of the vaccination, to obtain a saliva sample to test for COVID-19 infection and a blood sample either in your vein (9 mL) or with the TASSO device at home to look for COVID-19 antibodies and level of vitamin D prior to the vaccination.
 - Just before, and about 1 month after, your second vaccine dose against COVID-19, we will ask you for another blood sample either in your vein (4.5 mL) or with the TASSO device at home to look for COVID-19 antibodies.
- ❖ We will ask you to continue
 - Once a week to take the Study supplement
 - Once every two weeks to fill out the brief electronic questionnaire (duration of 3-5 minutes) regarding your health and work status in the previous 2 weeks.
 - At any point in time if you have symptoms, to complete the daily symptoms diary (duration of 1-2 minutes) until 48 hours after the resolution of symptoms. If you have symptoms that should prompt testing for COVID-19, as listed on the cv19quebec.ca website, we will ask you to contact your health office for this purpose, whether you have been vaccinated or not.

End-of-study – Week 16 (or later if the study is prolonged)

At the end of the study, you will be invited to a last in-person or remote visit. This research visit will take approximately 30 minutes and involve the following:

- ❖ You will be asked to return the Study supplement bottle containing the unused pills.

- ❖ A venous (or capillary blood if done remotely) sample and, if you have not tested positive at COVID-19 before, a saliva (or oro-nasopharyngeal) sample will be collected.
- ❖ A rapid COVID-19 antibody test (NADAL®) may also be done on a blood drop (finger-prick or from the venous puncture) for validation purposes. If done remotely, this test may be done on blood sampled by finger-prick under our guidance by videoconference.
- ❖ You will complete the last few short study questionnaires and any missing information in the previous ones, if applicable.
- ❖ If conducted remotely, the samples, Study supplement bottle and unused material should also be shipped to the Coordinating Center.

Collecting information on COVID-19 tests made for clinical reasons

The results for a COVID-19 test performed for clinical reasons outside this study will be documented by you in the follow-up questionnaire (*faster means to inform us*) as well as in your institution's (Pandemic) or provincial database of COVID-19 cases, namely Trajectoire Santé publique (TSP) including all individuals who tested positive and all healthcare workers who tested positive under the supervision of the Ministère de la santé et des services sociaux (MSSS). If you are unable to answer the follow-up questionnaires, the information documented in these databases would ensure that we have complete information on the primary outcome of the study and thus allow us to determine accurately the impact of the intervention on the risk of infection with COVID-19.

Collecting information on healthcare services

The date, diagnosis, type of professional and of health care services which you have received during medical visits and hospitalisations will be obtained from the administrative databases of the Régie de l'assurance maladie du Québec (RAMQ) and Quebec hospital discharges (MED-ECHO). This will allow us to accurately determine the impact of the intervention on the severity of COVID-19 infection and other concomitant illnesses.

Collecting information of work absence

The number of days of work absence, overall, by type (i.e., holiday, illness, etc.), and specifically due to COVID-19, including absences due to an infection acquired at work or outside of work, preventive withdrawal due to pregnancy or other health conditions, awaiting test results/investigation, or other reason for quarantine will be collected from you via the follow-up questionnaire (*faster and most detailed means*), as well as from your institution's *Direction of Health Resources* or, if you are an attending physician, from the *Direction of professional services*. If you are unable to answer the follow-up questionnaires, the information documented in these databases would ensure that we accurately ascertain the impact of the intervention on work absences.

BIOBANK

For the purposes of this study, we will keep the biological samples collected (blood, saliva and/or oro-nasopharyngeal) in a biobank as well as the clinical and administrative data collected during the course of this study in order to complete the study's objectives, and to

conduct research on vitamin D, COVID-19 and its treatments and other related diseases. We would like to quantify specific cellular receptors which allow entry of COVID-19 into cells (for example, the angiotensin converting enzyme-ACE2) and inflammatory markers (such as the C-reactive protein). The collected samples will be kept in a biobank in the Research Center of CHU Sainte-Justine under the supervision of Dr Francine M. Ducharme. The samples will be kept as long as the research team can guarantee their proper management. Confidentiality of the identity of the samples will be guaranteed by assigning them a specific code. Your sample will not be identified by your name and cannot be used to identify you directly. After 5 years, the code key will be destroyed, and the samples will become completely anonymous. Your samples could possibly be shared with other researchers in other institutions. However, the access to data will only be allowed for approved projects by an independent research ethics board.

GENETIC ANALYSIS (optional)

Each person has their own set of unique genes or “genome”. Genetic research aims to determine if there are genetic predispositions which make you more susceptible to a COVID-19 infection, to respond to vitamin D, to modulate disease severity and the interaction of these factors.

If you accept to participate in the genetic analysis, these analyses will be done on a small part (4 mL) of the venous blood sample provided during the first visit. If you decide to participate remotely, we will ask you to provide a saliva sample in a small tube.

We would like to sequence your entire genome and conduct gene expression analyses. We would also like to share your genetic data as well as other collected clinical data during the PROTECT study with the Canadian database Hostseq COVID-19 for use for COVID-19 related research and other aspects of human health. This biobank will serve as a centralized resource in Canada for COVID-19 research and other health-related studies. The data in the HostSeq database are under the supervision of CGen, a national Canadian platform financed by the federal government for sequencing and genome analysis. The principal investigators of the PROTECT study as well as the administrators of the Hostseq biobank COVID-19 will share your genetic and clinical information with other Canadian and international researchers whom are approved by CGen (the sponsor). The data could also be used for commercial use. However, your data will not be shared with until after an examination by a data access committee. This committee will verify that the use of the proposed research is in line with the objectives of the database HostSeq and that the research team which requests access has already been granted the required approval in accordance in terms of research ethics requirements. Approved researchers will sign agreements. These agreements will control how the data will be used. Individual results of any research conducted using your samples or any individual incidental findings will not be shared with you, as the research conducted on your data will have no individual diagnostic or therapeutic significance to you.

WHAT ARE THE BENEFITS AND RISKS OF THIS STUDY?

Benefits:

You may not benefit directly from the study intervention if it is not efficacious or if you have been assigned in the placebo group. However, the screening may identify earlier an active or past COVID-19 infection that was not apparent. Your participation will help advance our knowledge on vitamin D and on the prevention of COVID-19 infection in healthcare workers and other individuals at risk of infection.

Each positive COVID-19 result from the saliva (or oro-nasopharyngeal) or blood sample will be shared with you according to your preferred way of communication: telephone, text message or email. All positive saliva (or oro-nasopharyngeal) results will also be shared by the Microbiology Laboratory of CHUM with the Public health authorities and will be added into your file at the CHUM and Dossier Santé Québec. No other research result will be provided to you. Research findings resulting from your participation to this study could potentially contribute to creating commercial products from which you would not be able to claim any financial benefit.

Risks:**• Related to study medication:**

The vitamin D dose used in this study has been shown to be safe in adults. This dose is approved by Health Canada for the purpose of this study only, but not for clinical use yet. It is unlikely that you will have any side effects because of the amount of vitamin D used in this study as when combining the first and weekly doses, the total remains below the maximum amount allowed.

However, we will ask you to notify us immediately if you have any of the following, as they could be signs of an acute excess intake of vitamin D: mainly, a marked increase in thirst or an increase in the volume and frequency of urination (with or without fatigue, loss of appetite, nausea or vomiting, headaches, drowsiness, cardiac arrhythmias, constipation, muscle or bone or chest pain, mouth dryness or a metallic taste).

Later signs and symptoms that may indicate a chronic excess intake of vitamin D are: a marked increase in thirst, an increase in the volume and frequency of urination including during the night, loss of appetite, weight loss, red eye or conjunctivitis, inflammation of the pancreas, light sensitivity, runny nose, itching, fever, reduced libido, kidney stones, increased concentration of some analytes in the blood (BUN, AST, ALT, cholesterol), or in urine (albumin), ectopic calcification, hypertension, cardiac arrhythmias and rarely, a psychosis.

It's possible that other currently unknown risks are associated with Vitamin D intake.

One of the reasons we collect a blood sample is to measure the concentration of vitamin D in the blood at the start and end of the study. this will allow us to see if the vitamin D blood level is linked to the number and severity of COVID-19 confirmed cases.

• Related to study procedures:

The salivary collection sample is painless. If done, an oro-nasopharyngeal swab may cause slight discomfort during collection that will subside after its removal. The side effects of having blood collected by venous puncture or TASSO can include bleeding, bruising, discomfort and pain at the sample site. It is possible that the NADAL COVID-19 IgG/IgM Test may give false positive or false negative results. In case of divergence of results, we will communicate to you the results of the approved IgG test when available.

• **Related to confidentiality:**

There is always a small risk that your data could one day be re-identified. The genetic information is unique to each person, just as your fingerprint. This means that theoretically, you could be identified using your genetic code; however, this is not easy to do. Considering the advances in technology, there could be new ways to link you to data that we have not foreseen today, despite the strict confidentiality measures in place. Possible re-identification or unintentional disclosure of your genetic and clinical research data could lead to a loss in confidentiality and a possible future discrimination against yourself or your biological parents. But all security measures will be put in place to protect your privacy.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

The Study supplements are provided free of charge by the manufacturer, Laboratoire RIVA.

WHAT ARE THE OTHER FINANCIAL ASPECTS?

For each completed visit (0 and 16 weeks), you will receive a \$25 check by mail to compensate for your time. The check may arrive at your home between 4 and 8 weeks after the visit.

HOW IS PRIVACY INSURED?

During your participation in this research study, the investigators responsible for this study as well as the members of their research team will collect, in a research file, the required personal information to answer the scientific objectives of this research project.

These information could include your demographic data (name, sex, date of birth, ethnic origin, weight and height), your past and present health status, your health-related habits, medication you take, your work absences, and the results of all tests, exams, and procedures which you will participate in. Your personal file will include your address, email, telephone numbers, RAMQ number, and employee or practice number be kept in a separate file with restricted access; this information is required to create a medical and pharmacy file at the CHUM and for communication purposes during the study.

The coded blood, saliva (and/or oro-nasopharyngeal) samples will be sent to the biobank located at the Research Center of CHU Sainte-Justine under the supervision of Dr Francine M. Ducharme. The coded results of completed analyses will be kept on a protected server with restricted access at DACIMA company during the study, and thereby transferred to a secure server with restricted access in the Research Center of CHU Sainte-Justine under the supervision of Dr Francine M. Ducharme. During the study, the personal information

used to arrange virtual and in-person study visit appointments will be kept on a protected server with restricted access at the company providing the appointment-making software. Following the conclusion of the study, this information of yours will be transferred to a secure server with restricted access in the Research Center of CHU Sainte-Justine under the supervision of Dr Francine M. Ducharme. The database of HostSeq will be kept on secure cloud servers (online) that are based in Canada and will be indefinitely kept or until they are not useful for research.

To ensure your privacy, a copy of the consent form as well as the results to the diagnostic tests required for conducting the research project, will be copied in the research and medical file of the CHUM. Therefore, each person or company which you authorize to consult your medical file, will have access to this information.

The research data will be kept for at least 25 years by the principle investigator. The data collected could be published or discussed during scientific meetings, but it would not be possible to identify you.

All collected information will remain confidential within the limits provided by law. You will only be identified by a code number. The key to the code linking your name to your research file will be kept by the investigator responsible for this research project.

To ensure your safety, a copy of the consent form as well as the results of the diagnostic tests required for research purposes will be placed in the research file and the medical file of the CHUM. Consequently, any person or company to whom you give access to your medical file will have access to this information.

Research data will be kept for at least 25 years by the investigator responsible for this research project. Research data may be published or be the subject of scientific discussion, but it will not be possible to identify you.

For the purposes of surveillance, control, safety and marketing of the Study drug, your research as well as your medical files could be consulted by a person mandated by a regulatory organization, in Canada or elsewhere, such as Health Canada, as well as sponsor representatives of the company manufacturing the vitamin D pills for this project (Laboratoire RIVA), the institution or research ethics committee. These people and organizations adhere to a strict confidentiality agreement.

You have the right to consult your research file to verify the collected data and to correct them, if needed. Moreover, access to certain information before the end of the study could mean your removal from this study in order to maintain the study's integrity.

IS YOUR PARTICIPATION VOLUNTARY?

Yes. Taking part in this study is voluntary. You may choose not to be in this study. You can decide to stop being in the study at any time, without needing to provide any reason, but simply informing the research team.

Your decision to refuse participation or to stop participating in the study at a later time, will have no effect on the quality of care or services to which you are entitled or on your relationship with the people that provide them.

The principal investigators of this study, the research ethics board, the funding agency or the sponsor could decide to end your participation in the study without your consent. This could happen if there are new information or findings that indicate your participation is no longer in the best of your interests, or if you have not been following the study instructions as explained, or if there are other administrative-related reasons to stop the project.

If you stop participating in the study or if you have been removed from it, the collected information and material already received will be kept (as well as the data pertaining to healthcare services and work absences will continue to be collected) and analysed to ensure the validity of this project, unless you specifically ask for them to be destroyed. If this is the case, these data and/or material will be removed from the biobank provided that the code key (linking between nominal data and the study code) is still available, that is, up to 5 years after the end of the study.

If you decide to drop out of the HostSeq database, your data will no longer be shared, and no new data will be collected. The data already in the HostSeq database will be destroyed once informed about this decision. However, it could be impossible to remove the results once they have been compiled with the results of other participants or if they have been published. Moreover, if certain data have been shared with other researchers, it could be possible not to be able to remove this part of the data. In such a case of unsuccessful withdrawal from the study, your identity will always be protected.

All new information acquired during the course of the study which could have an impact on your decision to continue participation will be shared with you rapidly, which is the reason why we would like to keep your personal information and have your approval to communicate with you after the end of the study (optional).

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions about the research project or if you have any problems that you believe are related to your participation in the project, you can call the researchers responsible for the project:

- Dr. Francine M. Ducharme at 514 345 4931, extension 4398
- Dr. Cecile Tremblay at 514 890-8000, extension 14645

If you would like information about your rights related to your participation in the research, you may contact the Ombudsman - complaints and quality services of the CHU Sainte-Justine at 514 345-4749, of the CHUM at 514 890-8484 or your CIUSSS/CIUSSS:

- CIUSSS de l'Est-de-l'Île-de-Montréal : 514 252-3510
- CIUSSS de l'Ouest-de-l'Île-de-Montréal : 514-989-1885, extension- 1010
- CIUSSS du Centre-Sud-de-l'Île-de-Montréal : 514 593-3600
- CISSS de la Montérégie-Est : 450-468-8447
- CISSS de la Montérégie-Centre : 450-466-5434

RESEARCH ETHICS COMMITTEE

The Research Ethics Board of CHU Sainte-Justine has approved this study and will continue to monitor it for all participating institutions of the Quebec Health and Social Services network.

LIABILITY

This research is not funded by a private industry. In case of side effects resulting from the study medication or from procedures required for this research project, you will receive all necessary medical care covered by the Quebec's provincial health insurance plan (RAMQ) or by your private drug insurance plan. You will be responsible for paying the portion of any costs not covered.

CONSENT FORM

Research project title: PRevention of COVID-19 with Oral Vitamin D supplemental Therapy in Essential healthCare Teams (PROTECT)

The nature and procedures of this research project were explained to me. I have read the information and consent forms and I kept a copy, or a copy has been provided to me. I was able to ask my questions and they were answered to my satisfaction. After consideration, I agree to participate in this research project.

I authorize the research team to consult the collected data about me in the COVID infection database (Pandemic) of my institution and/or the provincial TSP database, the medical and hospitalisation services database (RAMQ and MED-ECHO), and the workplace absenteeism database (Human Resources Directorate or Professional Services Directorate) to obtain information that is pertinent to this project.

By agreeing to participate in this study, you are not waiving any of my rights under the law. You are not releasing the investigators from their legal and professional liability.

Name of participant (Print)	Signature	Date
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1. I consent to the analysis of gene expression and the sequencing of the whole genome of my coded biological material (blood, saliva, and/or oro-nasopharyngeal). The whole genome sequence could be hosted in the Canadian HostSeq COVID-19 biobank and linked to a database containing the viral genome. This would serve to explore any genetic predisposition to COVID-19, the severity of the disease and response to vaccine.

Yes _____ (Initials) No _____ (Initials)

2. I consent to prolonging the access to my coded data on healthcare use, COVID-19 infections and work absenteeism for 12 months following the study end date, to explore the long-term impact of COVID-19 infection and vaccination.

Yes _____ (Initials) No _____ (Initials)

3. I consent to being contacted to update my personal information, obtain additional information about my health or to be invited to participate in new research.

Yes _____ (Initials) No _____ (Initials)

4. In case I receive a vaccine against COVID-19 during the study, I agree to do the blood samples before the first and second vaccine dose as well as 1 month after the 2nd vaccine dose, even if these samples were to be done after the end-of-study's visit planned at week 16 (or 24).

Yes _____ (Initials) No _____ (Initials)

Participant's signature: _____

I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions. I explained that participation in a research project is free and voluntary and could be stopped at any time they choose.

Name of person obtaining consent (Print)	Signature	Date
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(FOR THE CHUM PARTICIPANTS ONLY)

COMMITMENT OF THE PRINCIPAL INVESTIGATOR AT THE CHUM

I certify that this information and consent form was explained to the research participant, and that the questions the participant had were answered.

I undertake, together with the research team, to respect what was agreed upon in the information and consent form, and to give a signed and dated copy of this form to the research participant.}

Name (Print)	Signature of the principal investigator at the CHUM	Date
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