UNIVERSITÉ DE SHERBROOKE

Faculté de médecine et des sciences de la santé

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Cohorte dans le cadre des études médicales prédoctorales de l'Université de Sherbrooke

PROTOCOLE DE RECHERCHE
ANNEXE 4

CONSENT PROCESS

Name of the participant: _____

Participant was contacted by: _____

I certify that:

Consent to participate in the research project

- ☐ I explained the study and the participant seemed to understand it well.
- ☐ Consent was reviewed with the participant.
- ☐ I adequately answered all of the participant's questions.
- ☐ The participant has agreed to take part in the research project following a free and informed decision.

Consent to link with the medical record

- ☐ I explained the study and the participant seemed understand it well.
- ☐ Consent was reviewed with the participant.
- ☐ I adequately answered all of the participant's questions.
- ☐ The participant has agreed to link their medical record with the questionnaire.

Consent to follow up over the next few years

- ☐ I explained the study and the participant seemed to understand it well.
- ☐ Consent was reviewed with the participant.
- ☐ I adequately answered all of the participant's questions.
- ☐ The participant has agreed to be contacted again in the coming years.

_____
Interviewer's signature

_____
Date

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FREQUENTLY ASKED QUESTIONS

What are the objectives of the survey?

There are three mains objectives for the cohort as part of the undergraduate medical studies at the Université de Sherbrooke (CEMPUS):

1. To establish a cohort of participants recruited through public health surveys in Quebec and New Brunswick where third-year undergraduate medical students will contribute to both the collection and analysis of data.
2. To close the knowledge gap revealed by government population surveys in order to better understand the factors affecting the health of the targeted populations.
3. To carry out a prospective monitoring of the above-mentioned cohort.

In addition to contributing to the training of medical students, the specific purpose of the survey is to determine the magnitude of a variety of public health topics within the population and among subcategories (young adults, seniors, males/females, etc.). These topics include, among others, chronic diseases (e.g. hypertension, diabetes), protective behaviours (e.g. vaccination), or the verification of an issue regarding access to health services (e.g. family physician) according to personal income.

Is it obligatory to consent to participate in the survey?

No, your consent is free and voluntary.

Do I face any risks by participating in this survey?

The researchers will ensure that there is the lowest possible risk of tracking your profile and that no telephone contact (other than for the purposes of this yearly project) or email contact is possible from the collected data.

If you agree (consent) to provide your coordinates so that we can contact you again in the future for further information, please note that your coordinates will be kept in a separate databank which will be used to combine your survey data with the new data requested. Rest assured that any future requests will be accompanied by information explaining the specific objectives of the new research and to what extent it commits you.

Will my answers to the survey remain confidential?

Yes, at all times. Access to your data will be restricted solely to the researchers and their immediate collaborators who have received prior authorization to access the information contained in this databank. The researchers and their collaborators must uphold data confidentiality at all times. Under no circumstances will the survey data of a single individual used in this study be disseminated in scientific publications, either for health professionals or for the public. Also, data will be analyzed so that no participant can be identified.

Can I be contacted again by phone or email?

Your participation in this survey is anonymous and under no circumstances will researchers obtain the coordinates

where you can be reached. Only your answers to this survey will be transmitted to the researchers.

What does my participation entail?

To answer as best as you can the 15-18-minute questionnaire. Your participation is free and voluntary.

Rest assured that your answers will be used solely by researchers for the advancement of knowledge or for planning health services within the public network. It goes without saying that this excludes any company which might use the data for commercial purposes in the pursuit of profit.

At the very end of the survey, you will be asked whether you agree (consent) to combine your data regarding the use of health services with those of the questionnaire. It is possible that medical and administrative data might be useful to verify the utilization of services by respondents. Via a survey, it would be extremely onerous to monitor thousands of individuals to learn about their overall health characteristics and utilization of health services. The idea is to enable the integration of medical data obtained for administrative follow-ups in order to complete the information regarding service utilization because some specific information may be difficult to remember (e.g.: date), or unknown to the person (reason for the medical consultation from the perspective of the health care professional). Québec does not yet have an electronic patient record system which could be used to obtain information globally for a detailed profile of each individual. Such a profile is not complete given that it will not store individual perceptions about topics such as vaccination, sense of belonging to the community, as well as neighbourhood or municipal-based issues.

Researchers may investigate various types of health services whose data will likely come from one of the following databanks:

- Medical and hospital data through the CIRESS databank, property of the Centre hospitalier universitaire de Sherbrooke (CHUS), which contains data about hospitalizations and care provided within a hospital.

- Lots of medical and administrative data are the property of the ministère de la Santé et des Services sociaux du Québec. Some data are entrusted to a mandatary body, specifically the Régie de l'assurance maladie du Québec. Researchers may be interested in examining the utilization of services according to medical consultation, prescription drug data from the public prescription drug insurance plan, or even the services provided by health care professionals at a specific institution.

Can a researcher publish information concerning a single individual?

No. Researchers will publish aggregate results, meaning that any single individual's answers will never be presented as such. Only information about groups or categories can be published, which guarantees that any single participant cannot be identified or recognized through his response profile.

Where will the data be stored?

Once created, the databank shall be kept in the offices of the Faculté de médecine et des sciences de la santé de l'Université de Sherbrooke. It will be stored on a secure server and be protected by a password. The regulations governing the protection and conservation of information will also be enforced for this databank.

How long will the databank be kept?

The databank will exist as long as the Université de Sherbrooke offers a research program within its undergraduate medical studies. The data will be stored for a period of 25 years from when they were obtained. At the end of this deadline, the data will be destroyed.

Will participants be paid for their contribution to the research?

No. Participants will not be rewarded through monetary compensation, loyalty programs or gifts.

Will it be possible for me to remove my answers from the questionnaire once I have completed it or if I change my mind and no longer want my answers to be used in future research projects?

No data which can be used to identify you (e.g. name and coordinates) will be transmitted to the research teams responsible for data analysis. As a result, it will be impossible for the researchers to locate you in their database at a later date. You may request to withdraw your data from the databank at any time. Your data will be deleted and will no longer be used. However, in the event that they have already become anonymous, it will not be possible to request a withdrawal because, at this stage, it will not be possible to identify your data.

On the other hand, for a follow-up in time, you will have to provide coordinates so that we can eventually contact you. At any time, you will be able to withdraw from his project and ask that the information which concerns you be removed from the research databank.

Who is responsible for managing access to the databank?

Two people at the Faculté de médecine et des sciences de la santé will oversee access management and control: the lead principal investigator (Dr Paul Farand) and the survey coordinator (Fanny Lapointe). A databank management policy will be enforced by an internal management committee at the Faculté de médecine et des sciences de la santé. This process will make it possible to supervise access requests to data and certain results obtained within a university research framework. Also, any researcher affiliated with the Faculté de médecine et des sciences de la santé at the Université de Sherbrooke will have to submit his project for approval to the scientific committee and the research ethics committee of the institution before having access to the databank.

Which organization is funding the research?

The Université de Sherbrooke provides the necessary resources for the project.

Will researchers be able to earn money with the data gathered for this survey?

None of the data or study results may be sold. In fact, the databank was created solely for research purposes.

Will researchers be in conflict of interest if they use this databank for other research?

Any researcher working with databank information must disclose their financial interests in a company or whether their work is being funded by a company. The research ethics committee will determine whether there is in effect a conflict of interest based on the direction of the research. If there is a conflict of interest, the ethics committee may deny the researcher's access to the databank.

What can I do if I have additional questions?

You can email your questions to the following address: Paul.Farand@USherbrooke.ca mentioning "CEMPUS" in the subject line. Paul Farand will answer you as soon as possible. You can also dial 819-821-8000, extension 70324, and then ask your question(s) and leave us your phone number so that we can return your call. You can also refer to the website of the research project: *http://bit.ly/CEMPUS*

Which ethics committee examined this research project?

The research ethics board of the CHUS research center has studied this project, issued recommendations, and approved this survey to date, both as a research project and as a research databank.

If I wish to file a complaint regarding the project, whom can I address?

Research participants who wish to file a complaint may contact the service quality and complaints commissioner of the CIUSSS de l'Estrie – CHUS at 1-866-917-7903.

Who are the researchers implicated in the cohort as part of the undergraduate medical studies at the Université de Sherbrooke?

Principal investigator

Paul Farand *Responsable de la recherche pour le curriculum 2017, FMSS, Université de Sherbrooke*

Researchers

Alain Vanasse *Département de médecine de famille et de médecine d'urgence, FMSS, Université de Sherbrooke*
Félix Berrigan *Département de kinanthropologie, Faculté des sciences de l'activité physique, Université de Sherbrooke*
Marie-France Langlois *Service d'endocrinologie, Hôpital Fleurimont, CIUSSS de l'Estrie – CHUS*
Gina Bravo *Département des sciences de la santé communautaire, FMSS, Université de Sherbrooke*

Collaborators

Groupe de développement de la cohorte CEMPUS *Études médicales prédoctorales, FMSS, Université de Sherbrooke*
(Charlotte Verret, Celeste Tahershamsi, Émilie Pelchat,
Benoit Chartrand, Thomas Allard, Élodie Vertefeuille,
Frédérique Ouellet, Émilie Berthelot Coulmont)

Project coordinator

Fanny Lapointe *FMSS, Université de Sherbrooke*