

INFORMATION AND CONSENT FORM FOR THE STRESS HORMONES BIOBANK

Introduction

The biobank was established as part of the research project entitled, (*title of research project*). This project is led by (*name of principal investigator*) in collaboration with (*name(s) of collaborator(s)*). The aim of the project is to (*explain aim(s) of research project*). You have been asked to participate in this study. We now wish to obtain your permission to retain any unused portion of saliva and/or blood samples (*select biospecimen according to your study*) that you agree to provide, in the Stress Hormones Biobank. Conservation of biological material in the biobank would permit us, subject to the approval by the ethics committee of (*name of the university and/or research centre of which the researcher is affiliated with*), to reuse them in future research projects in the field of stress, (*if you want to broaden the scope of future use, you can add the sentence 'and/or mental illness'*).

We ask that you take the time to read and understand this form. We invite you to ask any questions that you may have, to the principal researcher, biobank manager, or members of the team.

General profile of the biobank

■ *Researchers who established the biobank:*

Principal researcher responsible for the biobank:	Sonia J. Lupien, Ph.D. Centre for Studies on Human Stress 7331 rue Hochelaga, Montreal, Quebec, H1N 3V2
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- *Biobank location:* The Stress Hormones Biobank is located at the Centre for Studies on Human Stress, Louis-H. Lafontaine Hospital, (Unit 226, Pavilion Riel, 7331 rue Hochelaga, Montreal, Quebec, H1N 3V2).
- *Financing and Management:* This biobank is financed by the costs acquired from storage and conservation of researchers using the services of the Stress Hormones Biobank.
- *Profile of biobank participants:* Individuals who contribute to the biobank are all individuals who have been recruited to participate in research projects on stress and/or mental health in humans.
- *Biobank contents:* The biobank contains samples of saliva and/or blood (*select biospecimen according to your study*). The biobank stores remains of saliva and/or blood samples (*select biospecimen according to your study*) as provided as part of the research study. In essence, when we measure the levels of stress hormones in a saliva sample, there is still a bit of saliva that remains unused.
- *Arrangements made for storing biological material:* Samples of saliva and/or blood (*select biospecimen according to your study*) are frozen and stored at the Centre for Studies on Human Stress laboratory at Louis-H. Lafontaine Hospital. The costs associated with the freezing procedures are supported by the research project. The data and the samples will be conserved for a minimum of '*X years, not exceeding X years*' (*to be determined in collaboration with your research ethics committee*). The biological material will be kept in the biobank, in the format

specified by the participants. There are two forms of conservation: denominalized (coded) or anonymized.

- **Denominalized format:** In the denominalized format, a code replaces the participant's name. Therefore, when analyzing the results of the study, the name never appears in the database. The denominalized format ensures data confidentiality, while allowing the research team to track information about a participant, if important information needs to be communicated, or if the law requires us to waive confidentiality.
- **Anonymized format:** In the anonymized format, no code is associated with the participant's name. The names are permanently erased from the database. Therefore, if you wish to choose this format, we will not be able to provide you with any of your results, as we will not have access to your personal folder.

At the end of this form, you will have the opportunity to choose the format in which you would like us to conserve your biological material. You can only choose one of the two formats mentioned above.

- **Researcher's access to the biobank:** The biobank data will be accessible, free of charge, to researchers of the present research project. As for the samples of saliva and/or blood (*select biospecimen according to your study*), the principal investigator and other members of his/her research team are the only people who can use them for subsequent research of the same nature. Research projects for which biological data will be used must receive prior approval by a research ethics committee. Scientists managing the biobank at the Centre for Studies on Human Stress will not have access to any data from the analyses of saliva and/or blood (*select biospecimen according to your study*) of the present study.
 - **Purpose for which the biological material will be used:** The biological material will strictly be used for research on human stress and/or mental health (*to be determined according to your choice*). You have the choice of indicating the types of research projects for which you authorize the use of your biological material. It is possible for you to consent to both categories of research.

Nature of biobank participation

The participation to this biobank is confined to the consent of transferring the saliva and/or blood residuals (*select biospecimen according to your study*) that were collected for the research project that you have accepted to participate in.

Advantages associated with the bank

Participants will not gain any personal advantages by participating in the biobank. However, the biobank will advance the understanding of the mechanisms underlying the development of mental disorders associated with chronic stress in humans. The samples can be used at a later date when science has developed new techniques for measuring stress markers in human saliva. We would then have better indicators of stress.

Risks and inconveniences associated with the biobank

There are no major risks associated with the biobank other than those related to a breach of confidentiality. This is why we have put in place strict measures in this regard.

Respect for privacy and confidentiality protection

The biobank will hold only personal information necessary for its activities. Strict measures to protect confidentiality are implemented. Biological material will be stored and used in an anonymized or denominalized format, depending on the preference the participant indicates.

Disclosure of personal information

Depending on the type of future research, it is possible for researchers to make a discovery that could benefit participants. We will be able to notify participants and send this new information to the participant's doctor, with the participant's consent. Participants will have the opportunity, at the end of this form, to indicate whether he/she wishes to be informed of such a discovery. However, participants must understand that feedback is only possible if the denominalized format is chosen.

Compensation

Participants do not receive any compensation in return for their participation in the biobank.

Freedom of participation and withdrawal

Participating in the biobank is entirely voluntary. Participants can, therefore, refuse to participate. Participants may also withdraw at any time, upon verbal notice and without giving reasons. In such cases, all files containing the participant's saliva and/or blood samples (*select biospecimen according to your study*) will be destroyed, unless they have been anonymized.

Refusal to participate in the biobank and the decision to withdraw will not, in any way, affect the quality of care and services that participants are entitled to.

Rights of the participant

By agreeing to participate in this bank, participants do not waive any rights nor release the researchers and their institutions of their civil or professional responsibilities.

Contact

For more information about the biobank or to inform us of your decision to withdraw, please contact (*name of the coordinator in charge of the study*), from Monday to Friday, between 9AM and 5PM, at (*phone number*).

For questions about rights of the participant, or to make a complaint or comment, please contact the Local Commissioner of Quality Services at (*name of institution*), by phone at (*phone number*), or by writing to the following address: (*mailing address*).

Consent of participant

I declare that I have read the contents of this information and consent form. I acknowledge that I have been explained the nature of the biobank. I have asked all my questions and they have been answered to my satisfaction. I acknowledge that I was given time to make a decision. I know I am free to participate in the biobank, just as I am free to withdraw at any time, by verbal notice and without prejudice, unless the samples are anonymized. I understand that if I agree to participate in the biobank, only biological materials to be transferred will be those collected under the project: (*Title of research project*).

Yes **No** I consent for my saliva and/or blood samples (*select biospecimen according to your study*) to be transferred and stored in the biobank, within the following limits:

Yes **No** For any research involving human stress or other stress related disorders (if you answered 'Yes', check one of the formats of authorized conservation):

in a denominalized format * in an anonymized format **

Yes **No** For any research involving mental illness (if you answered 'Yes', check one of the formats of authorized conservation):

in a denominalized format * in an anonymized format **

* Note 1: Denominalized format: Information is coded in a way that only a research team member can access your information.

** Note 2: Anonymized format: No one can access your personal information (name, address etc.)

Yes **No** I would like to be notified of any discovery that might be useful to my doctor

I hereby agree to participate in the biobank under the conditions specified. I understand that I will be given a copy of this form duly signed and dated.

Name of participant

Signature

Date

Telephone number of participant

Signature and commitment of the biobank manager

I certify that I have explained the terms of the current information and consent form to the participant. I have responded to all the questions that have been asked, having clearly indicated that the participant remains free to terminate his/her participation and, at any time without prejudice. I agree to give the participant a copy of this form duly signed and dated.

Name of biobank manager

Signature

Date