

CENTRE FOR STUDIES ON HUMAN STRESS (CSHS)



POLICIES RELATED TO THE STRESS HORMONES BIOBANK: CENTRE FOR STUDIES ON HUMAN STRESS

Document prepared by Sonia J. Lupien, Ph.D. Director, Centre for Studies on Human Stress Translated from French by Nathalie Wan, M.Sc., Centre Coordinator **Stress Hormones Biobank**

Management and Responsibilities

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Biobank Objectives

The objective of the Stress Hormones Biobank is to enable researchers to conserve samples of saliva and/or blood they have obtained from their research on human stress, in a biobank. In general, studies on human stress focus on different biological markers (such as hormones, metabolic compounds and immune markers) that are activated when a person is stressed. According to various studies, these biomarkers are measured in saliva samples, and sometimes in blood samples. These saliva and/or blood samples are analyzed for hormones and biological markers that respond to stress. When samples of saliva or blood are analyzed, there remains a certain amount of saliva and/or blood that is not used to measure biological markers of stress. The purpose of the Stress Hormones Biobank is to allow researchers interested in conserving unused portions of saliva and/or blood from their participants in a biobank, which can be analyzed in future studies on stress and/or mental illness.

Subject to the approval of the ethics committee of each university and/or research centre affiliated with the researcher using the biobank services, the conservation of biological material permits the reuse of material in future research projects in the area of stress and/or mental health.

Biobanking Terms

Once the ethics committee of the university and/or the research center to which the principal investigator is affiliated with approves the signing of the consent forms for each study, the participants are invited to participate in the biobank. Participants interested in participating in the biobank will receive a biobank consent form specific to the biobank material related to the study. This form is accepted by the research ethics committee, for each researcher involved.

It is important to understand that the consent form specific to the biobank does <u>not</u> replace the consent form related to the participation in the study at hand. Therefore, when a researcher wishes to store and preserve biological samples in the biobank, the researcher must have the participant sign the following : 1) a consent form for the study 2) a consent form for the biobank. A participant may choose to consent to participate in a study without providing consent to have his/her samples stored in a biobank. This is why two consent forms are required in studies wanting to conserve biospecimens.

An example of a biobank consent form is available to researchers interested to use the biobank services, on the website <u>www.humanstress.ca</u> under the tab 'Salivary Analysis Laboratory' in the section 'Data Conservation'. Biological samples cannot be stored at the biobank of the Centre for Studies on Human Stress, if a proof of acceptance by the ethics committee for the conservation of biospecimens is not provided to the Centre for Studies on Human Stress.

Participants should take the time necessary to read and sign the biobank form. Deciding not to participate in the biobank does not prevent anyone from participating in scientific studies.

Biobank Location

The biobank of the Centre for Studies on Human Stress is located at the Louis-H. Lafontaine Hospital, Unit 226, Pavilion Riel, 7331, rue Hochelaga, Montreal, Quebec, H1N 3V2.

Biobank Participant Profile

Individuals who contribute to the biobank are children, adults and the elderly, who were recruited to participate in various research projects by researchers participating in the Stress Hormones Biobank. Individuals participating in the studies receive a 'biobank consent form' that is specific to the type of

samples obtained in the study in which the person participates. An example of a consent form for biobanking is available on the website *www.humanstress.ca* under the tab 'Salivary Analysis Laboratory'.

Biobank Contents

The biobank contains samples of saliva and blood that constitute the biological material related to studies on human stress. The biobank will conserve the unused portions of the saliva and/or blood samples from a research study participating in biobanking. In fact, when we measure stress hormone concentrations in a saliva or blood sample, there is always a small amount of unused saliva or blood remaining. These are the samples that are stored in the biobank for future analysis, after approval from the research ethics committee of the researcher responsible for the blood and saliva samples.

Methods used in the conservation of biological materials

Samples of saliva and/or blood will be frozen and stored in freezers at the Centre for Studies on Human Stress at Louis-H. Lafontaine Hospital. The biobank has several -20 and -80 degree Celsius freezers. Each freezer is equipped with an independent alarm system to alert technicians in case of breakage. In the event of a freezer failure, samples are immediately transferred to a spare freezer that is available at all times.

The Stress Hormones Biobank is financed by the costs acquired from storage and conservation of researchers wishing to use this service. These costs are available on the website : <u>*mnm.humanstress.ca*</u> under the tab '*Salivary Analysis Laboratory*'.

Biological material will be kept in the biobank in either a denominalized or anonymalized format, depending on the participant's request. The consent forms for the database and the biological material should, therefore, clearly indicate the differences between these 2 formats in order for the participant to be able to make an informed decision regarding the conservation of his/her biological material in the Stress Hormones Biobank at the Centre for Studies on Human Stress.

Researcher access to the biobank

The principal investigator using the Stress Hormones Biobank, and other members of his/her research team are the only people given access to use biospecimens from their study for subsequent research of the same nature. Research projects for which the biological material is to be used must have received prior approval from the ethics committee of the university or the research institute in which the researcher is affiliated with.

Benefits associated with the biobank

Participants do not receive any personal benefits from participating in the Stress Hormones Biobank. However, the biobank will advance the understanding of the mechanisms underlying the development of mental disorders related to chronic stress in humans. Furthermore, the samples could be used at a later date, thanks to the development of new scientific techniques that would analyze new stress markers in human saliva. We would then have better indicators of stress.

Risks and disadvantages associated with the biobank

There are no major risks associated with the biobank other than those related to a breach of confidentiality. As such, the Centre for Studies on Human Stress has implemented strict measures to protect the participants in this regard. All the freezer rooms are locked and only the personnel in charge of the salivary analysis laboratory have the key to access the freezers. In addition, no personal information is indicated on the samples of biospecimen that are conserved as they are all defined with a denomialized code ensuring strict confidentiality.

Participant Rights

By agreeing to participate in this biobank, participants have not waived any of their rights nor released the researchers and institutions accountable for their civil and professional responsibilities.

Biobank Policy

The biobank's policy is reviewed by the same committee and at regular intervals, to strictly meet medical, ethical and legislative standards. If the Director of the Centre for Studies on Human Stress must leave and/or resign from her position, she will be responsible to select a successor to manage the Stress Hormones Biobank. Prior agreements should be made on the use and what is to become of the data and biological material, following the guidelines in this document.

Contacts

For more information on the databank and biobank of the Centre for Studies on Human Stress, and for researchers interested in using the Stress Homornes Biobank services, please contact: Ms. Nathalie Wan, head coordinator of the Centre for Studies on Human Stress, at (514) 251-4015, ext. 3252.

Paper copies of this policy are also available.