Djavad Mowafaghian CENTRE FOR BRAIN HEALTH

Vancouver CoastalHealth Research Institute

UBC

# PARTICIPANT INFORMATION and CONSENT FORM

## TITLE OF RESEARCH PROJECT:
## Djavad Mowafaghian Centre for Brain Health Biobank


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**Partners**:

- University of British Columbia (UBC)
- UBC Faculty of Medicine
- Vancouver Coastal Health
- Vancouver Coastal Health Research Institute

**Sponsor:** Borgland Family

## ACRONYMS

**CBH – Centre for Brain Health**

**DMCBH – Djavad Mowafaghian Centre for Brain Health**

**CREB – Clinical Research Ethics Board**

**VGH – Vancouver General Hospital**

**VCH – Vancouver Coastal Health**

## DEFINITIONS

Secure Database: database and the information it contains (Including your name and medical health information) is protected against threats to disclosure, using a wide variety of security measures. Also access to this database is limited to certain users who are DMCBH employees with a defined role in overseeing the biobank.

**Invitation:**

"This consent form may be signed by a substitute decision maker, and that all references to "you" refer to the participant."

**If you are a substitute decision-maker for someone who may take part in this study, permission from you and the agreement and the assent (agreement) of the potential research participant may be required. When we say "you" or "your" in this consent form, we mean the research participant; "we" means the doctors and other research staff.**

You are invited to participate in this research study because doctors and scientists at Djavad Mowafaghian Centre for Brain Health (DMCBH) would like to collect a blood, and/or pinprick blood drops, fecal, nasal/oral swab samples from patients and healthy individuals for research purposes. These samples can be used to better understand the causes of brain disorders, with the ultimate goal of improving diagnosis and treatment and preventing these diseases. The samples will be preserved, processed and stored in the DMCBH Biobank (also called 'Biobank') and used in the future for the purpose of brain health research.

In this study, you are being invited to donate biospecimens; (blood and/or pinprick blood drops, fecal, nasal/oral swab/wash samples) to be used for future research.

**Your participation is voluntary:**
Your participation in the DMCBH Biobank study is entirely voluntary. If you wish to participate, you will be asked to sign this form. If you do not wish to participate, you do not have to provide any reason for your decision and there will be no impact on your medical care.

Please take time to read this information carefully and to discuss it with your family, friends, and physician before you decide.

**Who is conducting the study?**
We are a group of doctors and scientists at the DMCBH located at the University of British Columbia in Vancouver, working together to identify underlying causes for brain related diseases to help optimize diagnosis and improve treatment.
The DMCBH Biobank is run by scientists under the direction of DMCBH Director, Dr.Lynn Raymond and Biobank Managing Director, Dr. Seti Boroomand.

We have received a generous donation from the Borgland Family to support this project.

**Background**
Human biological samples, such as blood, tissue, body fluids and DNA, and associated clinical and research data are key resources in identifying genetic and environmental factors underlying brain diseases and their outcomes. Insights derived from using human biospecimens are expected to assist with the development of new diagnostic, prognostic, and therapeutic tools. The main objective of the project is to establish a high quality human body fluid biobank which adheres to the highest international standards.

**Purpose of this study**
It is increasingly common for biobanks to invite participants to bank their data and samples for use in future research studies. Often the exact nature of these studies is not entirely known because new discoveries lead research in new and not always foreseen directions. For this reason, participants are asked to consider storing the data and samples into a databank and biorepository for future studies that are as yet undetermined.

The DMCBH Biobank collects biospecimens (e.g. blood, and/or pinprick blood drops, fecal, nasal/oral swab/wash samples) from volunteer participants who have given consent to participation. The samples will be given a specific code so the identity of the subject remains confidential. The coded samples will be processed and stored in a special way to preserve them for later use. The DMCBH Biobank also collects information about the participants such as age, diagnosis, date of diagnosis and treatments. This information is stored in a secure database on the hospital server. Scientists from UBC or other institutions can apply to the Biobank to request specific samples and data to use for their research. If the Biobank and the UBC Clinical Research Ethics Board (REB) approve the research, then coded (de-identified) samples will be given to the scientists to be used for research. If in the future, other researchers not involved in this study request your information, they may be given access only to the coded data but they will not know your identity. All future studies will also need to get proper research ethics approval to be allowed access to the database.

**Who can participate in this study?**
You may participate in the biobank if all the following apply:

- You are 18 years of age or older.

Further, patients who have highly contagious diseases (i.e., tuberculosis, hepatitis, HIV) and neurological transmissible diseases (i.e., Jacob-Creutzfeldt) will be excluded from the study. Additionally, patients with blood clotting disorders (hemophilia) may not be able to participate in having blood drawn from a vein.

Patients that do not read/understand English can give consent and participate with a translator present.

**What does the study involve?**
If you agree to take part in this study, you will be asked for:

1. A blood sample equivalent to a volume of up to approximately 5 teaspoons (about 25 ml), drawn from a vein in your arm. This blood sample will be obtained sometime after your first appointment at the DMCBH.
2. Pinprick blood drops equivalent to 5 blood drops drawn from fingertip. The fingertip will be punctured using a small lancet to collect the blood drops which will cover the circles on the blood spot card. This procedure will be done by a trained study team member.
3. Fecal sample for which participants will be instructed to collect the sample at home and will be provided with the proper material, including a mailing kit. They will be asked to describe their typical stool by referring to Bristol Stool Chart that is also provided with the collection kit.
4. An oral and/or nasal swab which will be collected at the study site by the research coordinator or a designated study team member. The oral cavity mucosa or nasal cavity

nostril will be sampled by rotating a small swab against the sides of the cavity for 5 seconds. The swab will then be placed in the labelled transport sleeve.

5. Permission to be contacted in the future to ask if you are interested in participating in other specific studies related to brain health research.
   If you choose to provide your permission to be contacted, one of the biobank study team members may be in touch with you to explain any new studies that you are eligible for. If you agree to participate, you will be scheduled to come into the clinic and will be provided a new consent form that you have the option to accept or decline.
6. Access to your Health Care Information: the investigators will collect associated health care information from available resources and this information will be de-identified (assigned a numerical code) and then stored in an electronic database. Health care information that is collected and stored includes, but is not limited to, your age, sex, ethnicity, diagnosis, present and past health history, medications, symptoms, test results such as x-rays and blood work, lifestyle, treatments and treatment response from records including the physician notes, prescriptions, and/or hospital records. Your personal health number will be collected in order to maintain information about your medical history, but never be shared with other groups. By signing this consent form, you agree that we may access your hospital records at Vancouver General or UBC Hospital. We may review and use that information for research purposes. Access to your health care information will be granted for as long as the DMCBH Biobank exists.

**What will happen to my samples?**

Biospecimens collected for this project will be sent to the Biobank and immediately processed and stored. The collected samples will be stored indefinitely in the Biobank at the DMCBH in Vancouver, BC under the supervision of the Biobank Directors until it is used for ethically approved research projects.

Your biospecimens will be divided and stored in multiple samples. In order to de-identify your samples a unique code or number will be assigned to them. This means that no information about you, such as your name, will be on your stored samples. However, the code on the sample with your name and Vancouver Coastal Health record number will be stored separately in the Biobank master list with highly secured methods. This sample and the associated information will be stored and used until the sample is used up for the research purposes described in this consent. The security measures to protect your privacy and the security of your donation have been considered and reviewed by the UBC Clinical Research Ethics Board (CREB), a research ethics committee that oversees the ethical conduct of this study to ensure that the DMCBH Biobank meets applicable standards that govern the operation of biobanks. If the samples are moved across national borders or given to a new set of researchers for other research than is described below, the new researchers must obtain the approval of the REB before new research is conducted.

In addition to UBC researchers at DMCBH the coded DNA samples or blood products and clinical information may also be shared and analysed by scientific collaborators, including industry collaborators, in other laboratories worldwide, solely for the purposes of research. Any outside analysis will be performed in a completely de-identified manner using numerical codes , mentioned previously and will follow all protocols outlined in this banking program. Some of the information obtained from future research could eventually be used in scientific publications or presentations using numerical codes to protect the identity of the participants. Knowledge

obtained or therapies developed from these research studies may eventually have commercial uses and may result in some financial gain for study investigators, UBC or an industry sponsor.

**What are the possible risks of harm and side effects of participating?**
Participation in research creates a risk to loss of privacy. We will strive to minimize this risk in the following ways: the information will be stored in an electronic database that is located on a secure hospital network and will not be accessible outside of the network or by mobile devices; users of the database will need approved user identities and passwords; access to your health care records will be limited to the DMCBH Director and Managing Director of the Biobank; and coded identification numbers will be used to identify all samples. No individual identities will be used in any reports or publications resulting from the DMCBH Biobank. However, despite these protective measures, there is a risk that the coded information about your donated samples may be linked back to the consent form and used to identify you.

Physical risks of blood draw: The amount of sample taken from you has been carefully considered and it is unlikely that there will be any harm to you. Drawing blood from a vein or fingertip involves little risk. You may feel a slight discomfort or pain. At the time of drawing blood from the vein you may even feel lightheaded for a few minutes. You might get a bruise on your arm after giving the blood, however the bruise should go away in a few days. There is also a slight possibility of infection at the puncture site.

**What are the benefits of participating in this study? Is there a direct benefit to me by participating in this study?**
There is no direct benefit to you for participating in this project. It is hoped that there will be a benefit to future patients and to society from using the information gained in this project to improve therapy and prognosis for patients with brain disease.

You will not receive any test results by participating in these studies. The information gained from these studies will be used only for research purposes and **will <u>not</u> be communicated to your physician**.
Since all genetic studies performed on your DNA in future research projects will be experimental, individual results will not be communicated to you or your family. Because all researchers will be working with de-identified samples, all study results, (including genetic status or unexpected findings involving other diseases), will never be returned to you or your physician.

**What happens if I decide to withdraw my consent to participate?**
You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information and/or samples collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data and/or samples will not be able to be withdrawn for example where the data and/or sample is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data and/or samples, please let the study manager know.

**Governance and accountability:**
The Director of the DMCBH and Biobank, are in charge of the DMCBH Biobank and are considered to be the stewards of the Biobank. All decisions related to the operation of the Biobank are made by the Director and the Biobank's Oversight Committee. The DMCBH Biobank Access Sub-Committee is ultimately responsible for deciding which samples to collect

and who gets access to the samples for research purposes. The DMCBH Biobank has standard operating procedures in place that cover all aspects of its activities.

**How will my samples and information be managed?**
De-identified biospeicmens and associated information are released for research studies only after approval from a formal review process by the DMCBH Biobank Access Sub-Committee and the research ethics board (REB). REBs review research studies to make sure that they follow standards of fairness in protecting the rights of participants. For approved studies, samples and associated information are released only as grouped data under a unique code (de-identified). The master list of codes will reside with the DMCBH Biobank in a secure database and ultimately links the biospecimens and data to the participant. Coded grouped samples and health information are de-identified, meaning a researcher (or anyone else) will be unlikely able to link it to participants.

**How long are the samples and related information kept?**
Samples and the associated information will be kept until the samples are used up by research studies or determined to be of poor quality.

**How will my participation in this study be kept confidential**?
We will take all necessary steps to ensure confidentiality. However, research records and health or other source records identifying you may be inspected in the presence of the Principle Investigator for this study (DMCBH Director) or his or her designate (Managing Director of the Biobank) and by representatives of the UBC Clinical Research Ethics Board for the purpose of monitoring the research. No information that discloses your identity will be released or published. No records which identify you will be allowed to leave the Biobank's offices.

You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity (for example your name or any other information that could identify you) as a participant in this study will be kept confidential. Information that contains your identity will remain only with the DMCBH Director and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available by request to your study physician.

Any study-related data or samples sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study related data and samples that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the DMCBH. By signing this consent form, you are consenting to the transfer of your de-identified information and samples to organizations located outside of Canada.

**What happens if something goes wrong?**

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan and/or by the Biobank.

**Will I receive any payments for participating?**
Samples and the associated information will be kept until the samples are used up by research studies or determined to be of poor quality.

**Who do I contact if I have questions about the study?**
If you have any questions or desire further information with respect to this project, you should contact the Biobank Managing Director Dr. Seti Boroomand (phone 604-822-0766) or email info.brainbiobank@ubc.ca.

**Who do I contact if I have any questions or concerns about my rights and/or experiences?**
If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598) and reference the current study number [H15-01193].

Before signing this consent form, please fill out the check boxes below.

| | |
|---|---|
| I am willing to donate the samples specified in the table below | ☐ |

| Yes | No | Biospecimen Type |
|---|---|---|
| | | Blood |
| | | Pinpick Blood Drop |
| | | Fecal |
| | | Nasal Swab |
| | | Oral Swab |

**Participant Consent: The Djavad Mowafaghian Centre for Brain Health Biobank**
My signature on this form means that:

- I have read and understood the participant information and consent form.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.

- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no direct benefit to me.
- I understand that all of the information collected will be kept confidential to the extent possible and they will only be used for scientific objectives
- I agree to the collection and storage of my biospecimen(s)
- I authorize access to my biospecimens as described in this consent form.
- I agree to the use of this sample(s) for brain health research
  ☐ Yes ☐ No (to all of the above)

- I authorize access to my Health record as described in this consent form, for purposes of scientific research
  ☐ Yes ☐ No

- I agree to be contacted in the future for information about my health and/or to give further samples
  ☐ Yes ☐ No

This consent form may be signed by a substitute decision maker.

- If a substitute decision maker is signing the consent form, the substitute decision-maker (legally authorized representative) and the Biobank Directors are satisfied that the information contained in this consent form was explained to the participant to the extent that he/she is able to understand it, that all questions have been answered, and that the participant assents to take part in the research.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

| | | |
|---|---|---|
| Participant's Signature or Mark | Printed Name | Date |
| Signature of Substitute Decision Maker | Printed Name | Date |
| Signature of Person Obtaining Consent | Printed Name & Study Role | Date |

f this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the participant assisted during the consent process in one of ways listed below?

☐ Yes ☐ No

If Yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant, and the person signing below attests that the project was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).

☐ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

| Signature of Person Assisting in the Consent Discussion | Printed Name | Date |
|---|---|---|