

Huntington Disease Biobank at the University of British Columbia

**DNA BANKING AND CLINICAL DATA COLLECTION CONSENT FORM**

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You are being invited to donate blood and DNA samples to the Huntington Disease Biobank because you, or a member of your family, may have inherited the DNA changes associated with Huntington Disease (HD) or an HD-like (phenocopy) disorder. Your decision to donate DNA to this bank is entirely voluntary and **you may refuse to participate or may withdraw at any time**. You do not have to provide any reasons for your decision. If you choose not to participate, it will in no way affect your current or future health care, or the health care of any of your family members.

***Why should I contribute to the DNA Bank?***

Further research is needed to develop more effective treatments for Huntington Disease (HD) and HD-like (phenocopy) disorders. The collection of DNA samples and medical information is important for this research. By making a donation of your blood and clinical information to the DNA bank, a better understanding of genetic factors which influence the clinical features of HD and HD phenocopy may be obtained and may ultimately contribute to significant improvements in the diagnosis and treatment of HD and related disorders. Your plasma and blood cells may also be used for biochemical investigations relating to HD including, but not limited to examinations of cholesterol, inflammatory response factors and proteins or enzymes in the body which may relate to disease onset or progression. Your blood cells may also be used to generate renewable cell lines called inducible pluripotent stem cells (iPSCs). These cell lines can be stored indefinitely as frozen clumps of cells which can be thawed, grown and divided to replenish themselves as needed. iPSCs are particularly important because,

although they would be derived from your blood, they can be grown into other cell types in a petri dish, such as muscle or nerve cells (neurons), allowing researchers to examine the effects of HD in different tissue types and in response to different treatments.

### ***What happens when I agree to donate my DNA to the Bank?***

Participation requires only the time it takes to read and sign this consent and approximately 15 minutes for the blood draw. If you choose to have your blood and DNA banked for HD research you will be asked to sign the last page of this form. Approximately 5 - 10 mL (1-2 teaspoons) of blood will be drawn from a vein in your arm. DNA (the genetic information contained in all the cells in your body) will be extracted from your blood and stored along with the remaining blood products (plasma and cells) at the HD Biobank located at the Centre for Molecular Medicine and Therapeutics (CMMT) at 950 West 28<sup>th</sup> Avenue in Vancouver for future HD research.

Your family and medical history will be recorded in a secure HD Biobank Database for the purposes of future HD research. This data may include your gender, date of birth, family history and, if applicable, age of onset of clinical symptoms as well as types of symptoms experienced and measures of disease progression. If you are a clinic patient at UBC, your clinical data and contact information may be updated periodically in the database to ensure analyses using the most accurate medical data. You may also be asked to donate additional small blood samples to the HD Biobank at future clinic visits if needed. You are under no obligation to do so and may decline at any time with no impact on your healthcare.

It is our hope that this Biobank of DNA, blood products and clinical data will serve as an essential resource for an ongoing program of HD research allowing us to explore new lines of investigation until a cure is found. With that in mind, all samples will be kept for an indefinite period of time, but used exclusively for this program of HD and HD phenocopy research. All HD related research proposals using banked samples will have to undergo ethical review by the Clinical Research Ethics Boards at the institutions conducting the research. Only studies receiving a certificate of ethical approval will be allowed to proceed.

### ***Will my information be kept confidential?***

After collection process is complete, you will be assigned a unique study number. This number will not include any personal information that could identify you (e.g., it will not include your PHN, SIN, or your initials, etc.). Only numbers will be used on any research-related information during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and coordinator. All samples will be coded with unique identifiers and all information related to your samples kept confidential. The list that matches your name to the unique study number that is used on your research-related information will not be released without your consent. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. Paper records will be kept in locked office cabinets at the HD Biobank in the CMMT. All computer files with identifiable information will be kept encrypted and locked with restricted access passwords known solely by the Custodian and the coordinator.

## ***Who can use my information and DNA?***

In addition to UBC researchers at the CMMT, the coded DNA samples or blood products and clinical information may also be shared and analyzed by scientific collaborators, including industry collaborators, in other laboratories worldwide, solely for the purposes of HD and HD phenocopy research. Any outside analysis will be performed in a completely de-identified manner using numerical codes 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.

Research records and medical records identifying you may be inspected in the presence of the Custodian or his designate by representatives of Health Canada and the UBC Research Ethics Boards for the purpose of monitoring the research. However, no records that identify you by name or initials will be allowed to leave the custodian's offices. **Your confidentiality will always be respected and no information about you will be given to third parties, including family, insurance companies or employers, without your express written permission.**

## ***What are the benefits and risks of participating?***

There are no known *direct* benefits to DNA Banking participants at this time. Participants donating samples will not receive any payment or remuneration for participating. 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 HD status or unexpected findings involving other diseases), will never be returned to the participant. However, your participation will increase our chances for successful research outcomes and the knowledge obtained through HD research could be of benefit to you in the future and to future generations.

The blood draw may cause minor discomfort or bruising at the site where the needle was placed, minimal bleeding and rarely infection. In addition to the risks of these physical harms, there are also possible non-physical risks associated with taking part in this study. Simply because participation requires that HD testing reports and clinical data be duplicated and stored in the Biobank files and database, there may be a potential, though small, risk of loss of privacy. Disclosure of genetic or tissue marker research data could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. Every precaution will be taken to protect the confidentiality of both computer and paper records.

## **Question A: Is it acceptable to have an HD researcher contact me directly?**

HD and HD phenocopy research is ongoing, and there may arise instances in the future when members of Dr. Michael Hayden's HD research team may want to contact you directly to discuss the possibility of participation in HD-related studies not provided for through the DNA

Bank and the clinical information originally gathered; (for example, you might be contacted to update family history information, collect other biological samples or complete a questionnaire about your experiences). **Please check “yes” to Question A if it is acceptable for UBC HD researchers to contact you directly in the future to discuss research possibilities.** You are under no obligation to participate in any future study. Ticking “yes” only indicates that you agree that someone from our HD research team may contact you.

*Question B: Is it acceptable for my coded clinical data and DNA to be used for other ethically approved (non-HD) medical research?*

By signing this form, you are consenting to have your DNA sample and clinical information used strictly for HD research. However, **if you are also willing to have your coded DNA sample used in other future unspecified medical research projects conducted through UBC** (e.g. to be used as a “normal” control sample in studies of other genetic diseases), **please check the “yes” box in response to Question B.**

If you allow unspecified non-HD research using your data and sample, UBC researchers or collaborators at other institutions or companies would only receive coded samples and data tables after providing evidence of ethical approval from their respective Research Ethics Board. The DNA bank custodian and coordinator will continue to be the only individuals with access to all names and other identifying information. Consenting for unspecified research is optional and if you agree you will **not** be re-contacted in the future to obtain consent for each additional research project, **nor** will you receive the results of any future tests. It is very unlikely that the research testing on your DNA will uncover findings that may affect your current or future health.

### ***What if I have concerns now or later?***

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this banking program, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at [RSIL@ors.ubc.ca](mailto:RSIL@ors.ubc.ca) or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number (H06-70467) when contacting the Complaint Line so the staff can better assist you.

**You are free to withdraw your consent from the DNA bank, Question A and/or Question B at any time.** If you change your mind and no longer wish to participate in HD DNA Banking, simply contact the Biobank Manager at 604-875-3811. Any remaining DNA sample, plasma or cell lines will be removed from the bank and destroyed; as well, your clinical and contact information in the database will be deleted. However, it may not always be possible to remove or delete research data results if they are no longer linked to you or have already been published in scientific articles.

**If you have any questions or desire further information about this banking program before or after your DNA donation, you can contact the HD Biobank Custodian or Manager at 604-875-3811.**



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**DNA BANKING AND CLINICAL DATA COLLECTION CONSENT STATEMENT**

- My signature on this form signifies that I have read and understood this consent form and that I freely give my consent to participate in this HD DNA and Clinical Data Banking program
- I have had sufficient time to consider the information provided, ask for advice, ask questions and I have received satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and will only be used for scientific objectives.
- I understand that my participation is voluntary and that I am completely free to refuse to donate my DNA, blood and clinical data or to withdraw it at any time.
- I agree that my DNA (material containing my genetic information which is extracted from my blood) and other blood products be studied in genetic and biochemical analyses relating to this program of HD research.
- I agree that my clinical records, biochemical and genetic data be entered into a secure password protected database for the purposes of this HD and HD phenocopy research program.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I have been told that I will receive a dated and signed copy of this form.

If the participant is unable to legally give consent, their parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in the research

_____	_____	_____
Participant's name (printed)	Signature of Participant or Legal Guardian	Date
_____	_____	_____
Principal Investigator or Designate (printed)	Signature	Date

**OPTIONAL CONSENT FOR ADDITIONAL RESEARCH PROJECTS**

**Question A:**

- YES      I consent to being contacted directly by members Dr. Hayden's team of HD researchers to discuss possible participation in future ethically approved HD related studies not provided for through the HD Biobank or my previously recorded clinical information.
- NO

**Question B:**

- YES      I consent to the use of my coded DNA, blood samples and clinical data in future unspecified non-HD research projects conducted at or in collaboration with University of British Columbia with the approval of the respective Clinical Research Ethics Boards.
- NO