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). 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. It is important to understand that you can still undergo HD testing without consenting to this DNA banking program.

Why should I contribute to the DNA Bank?

Further research is needed to develop more effective treatments for Huntington Disease (HD). 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 may be obtained and may ultimately contribute to significant improvements in the diagnosis and treatment of HD. Your plasma and blood cells may also be used for biochemical investigations relating to Huntington Disease 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.
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 form 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. In total, approximately 20 - 30 mL (2 tablespoons) 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 to be used for both HD genetic testing and for banking. After completion of the HD testing, a portion of your remaining DNA and remaining blood will be donated to the HD DNA and Tissue Bank located at the Centre for Molecular Medicine and Therapeutics (CMMT) at 950 West 28th Avenue in Vancouver for future HD research.

The results of your HD testing as well as other genetic, medical and family data from your clinic file will be stored in a secure HD Banking Database for the purposes of future HD research. This data may include your gender, date of birth, family history and, if applicable, age of HD onset as well as types of symptoms experienced and measures of disease progression. If you continue to be seen as a patient at the UBC HD Medical Clinic, your clinical data and contact information may be updated periodically in the database to ensure analysis 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. 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.

It is our hope that this DNA and clinical data bank 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 research. All HD 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, all samples will be coded with unique identifiers and all information related to your samples kept confidential. Banked samples will have all identifying information removed (e.g. name, date of birth), and only numerical codes will be used to identify all corresponding samples and research data sets. Only the DNA Bank Custodian and his designate will have access to the master database linking names of the subjects to the coded samples in the DNA Bank. Once these unique codes are assigned they will be used exclusively in future research projects conducted in this lab and by collaborators at other institutions. Paper records will be kept in locked cabinets at the HD BioBank in the CMMT. All computer files with identifiable information will be kept locked with restricted access passwords known solely by the Custodian and his designate.
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 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 subjects. 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 members, 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. Subjects 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. 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 with the placement of the intravenous needle, bruising at the site where blood was taken, 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 DNA Bank 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 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.

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

If you have any concerns about your rights as a research subject and/or your experiences while participating in this banking program, please contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598. Signing this consent form in no way limits your legal rights against the investigators or anyone else.

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 Coordinator at 604-875-3810. Your remaining DNA sample 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 Coordinator at 604-875-3999.
Huntington Disease BioBank at the University of British Columbia

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 have been told that I will receive a dated and signed copy of this form.
- If the subject is unable to legally give consent, the guardian should allow the subject to read the attached Assent Form, ask questions and decide for themselves before signing this consent on his/her behalf. If necessary, verbal assent is acceptable if he/she is unable to read it themselves.

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<tr>
<th>Subject’s name (printed)</th>
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<tr>
<td>Witness (printed)</td>
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<tr>
<td>Principal Investigator or Designate (printed)</td>
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OPTIONAL CONSENT FOR ADDITIONAL RESEARCH PROJECTS

**Question A:**
- [ ] YES
- [ ] NO

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.

**Question B:**
- [ ] YES
- [ ] NO

I consent to the use of my coded DNA, blood samples and clinical data in future unspecified research projects conducted at or in collaboration with the University of British Columbia with the approval of the respective Clinical Research Ethics Boards.