



Understanding Your Participation & Informed Consent Form

Understanding Your Participation

For the purpose of this Consent, “the patient” will refer to the person diagnosed with the syndrome or tumor condition you are reporting. “You” will refer to the person entering the information. This may be the affected individual or a family member or guardian of the affected individual (the person legally responsible for the care and maintenance of the affected individual). “CGIP Database” refers to the Cancer in Our Genes International Patient Database, a division of the VHL Alliance.

WHAT IS THE CANCER IN OUR GENES INTERNATIONAL PATIENT DATABASE?

A patient database is a place where medical information, family history and other related information from patients is collected and stored for medical research.

The Cancer in Our Genes International Patient Database is collecting information about Von Hippel-Lindau (VHL), Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC), Birt-Hogg-Dubé (BHD), and other related conditions in hopes of finding a cure for these diseases. Learning about their similarities and differences will help scientists understand how these genes work in the cell, and how we might intervene and make a difference.

WHY IS HAVING A CANCER IN OUR GENES INTERNATIONAL PATIENT DATABASE IMPORTANT?

Von Hippel-Lindau (VHL) is a disease which causes tumors in multiple parts of the body. Since the discovery of the VHL gene in 1993, progress has been made in understanding the processes within the cell governed by the VHL gene. The series of processes (or pathways) controlled by VHL also include the genes for Birt-Hogg-Dubé (BHD) and Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC), two other genetic kidney cancer syndromes. Drugs to assist in management of these diseases are beginning to emerge and will need to go through clinical trials to evaluate their effectiveness. These diseases are rare, which makes it difficult to gather

Study Title: The Cancer in Our Genes International Patient Database

information and develop treatments. The CGIP Database will collect information from patients all over the world and could help researchers have a better understanding of VHL and associated diseases. The rarity of these diseases makes it difficult to conduct large clinical trials. To address these deficiencies, the VHL Alliance, in collaboration with the National Organization for Rare Disorders, is developing a patient database to collect detailed medical information on patients with VHL, BHD, and HLRCC, and related tumors, to help discover possible factors contributing to disease pathogenesis/progression, and to help evaluate efficacy of novel therapies.

WHAT IS THE PURPOSE OF THE CANCER IN OUR GENES INTERNATIONAL PATIENT DATABASE?

The purpose of the CGIP Database is to collect and store medical and other information from individuals with VHL, BHD, HLRCC, and related tumors. A patient database is a place where medical information, including family history and other related information is collected and stored for medical research. Information from the CGIP Database will be used to better understand these diseases and to develop new treatments. Studies may include those to better understand the natural history (progression) of these tumor conditions and/or environmental factors that may contribute to tumor development and progression. The database may also be used to contact patients about clinical trials, including those investigating new treatments, for which they may be eligible. Participation in a clinical trial will be based solely upon the voluntary consent of the patient.

To ensure that the rights and welfare of participants be protected, an independent ethics committee (Institutional Review Board), Chesapeake IRB, has approved the CGIP Database project.

WHAT KIND OF COMMITMENT DO YOU NEED TO MAKE TO PARTICIPATE IN THE CANCER IN OUR GENES INTERNATIONAL PATIENT DATABASE?

Participation in this database is voluntary. Participation in a clinical trial will be based solely upon the voluntary consent of the patient.

You have the right to know about the procedures, risks, and benefits of participating in the CGIP Database. To participate in this database, you will need to give your consent after reading this document, "Understanding your Participation." If you answer, "yes" to the statements affirming your participation and use of the information you are providing, you will have "consented." You will find these statements of consent at the end of the consent form. If you decide to participate, you can change your mind later and leave the database. Please take your time to make your decision and discuss it with your family, friends, and caregivers.

WHOSE DATA ARE YOU COLLECTING IN THE CGIP DATABASE?

The CGIP Database will include individuals who have a diagnosis of VHL, HLRCC, BHD, or other related conditions included in this project, including those who have passed away. The diagnosis must be confirmed by a physician, usually with a positive DNA diagnosis or a positive clinical diagnosis. Please discuss any questions with the CGIP Database Coordinator (see contact information at the end of this document).

WHO CAN GIVE CONSENT?

You are being asked to participate in this database because you are diagnosed with one of the member conditions. Patients over the age of 18 who understand the consent form (and who do not have a legal guardian) are eligible to join the CGIP Database on their own. Otherwise, the legal guardian or parent of the patient must give consent for the patient to join. When the patient turns 18 (and is able), consent for continued participation will be obtained directly from the patient if they do not have a legal guardian. Those minors who choose not to re-enroll as adults will have their records deleted from the CGIP Database.

WHAT ARE THE STEPS TO FILLING OUT THE CGIP DATABASE?

If you decide to participate in this CGIP Database, you will need to read “Understanding Your Participation & Informed Consent,” to complete the Consent form, and click on the box to confirm that you understand the risks and benefits of participation, and that you agree to participate in the database.

You will then be directed to the registration form, and will be asked to create a login username and password. After completing the registration form, you will be ready to continue to the database survey.

If more than one family member has VHL or another of the participating conditions, you can create a single family account. First register one individual with the diagnosis and answer the survey. Then you will be able to add other family members with the diagnosis to the same account.

You will be asked to provide medical information on the patient’s disease and diagnosis. You will be asked to update your database information at least once per year. The CGIP Database will send you a reminder each year. The CGIP Database may also ask you or your doctor to add medication information, or to fax or upload your test results, and any other relevant reports or testing results. Your CGIP Database account can be updated whenever there is a change in the patient’s health, change in medication, or new symptom. If the CGIP Database cannot contact you, your account may become inactive.

Study Title: The Cancer in Our Genes International Patient Database

The CGIP Database is also linked to the VHL biobank at National Disease Resource Interchange (NDRI) which is a place that stores tissue, blood or other samples from the patients. If you decide to donate your samples, you will need to provide separate consent for the biobank.

WHO WILL HAVE ACCESS TO THE MEDICAL AND OTHER RECORDS ON THE CGIP DATABASE?

The goal of the CGIP Database is to share detailed medical and other information with scientists and other researchers, while still protecting your privacy. All of the information you provide will be maintained in a safe (“secure”) computer, and any information that could identify you and your family members will not be shared without your approval. Your privacy will be protected by hiding the name, address and other “identifying” information from researchers. We call this information “de-identified” because all personal identifiers have been removed. Your personal information such as your name, address, or other information that identifies you or your family will be labeled with a code number, encrypted, stored in a secure place and protected with a password. Only authorized people who work in the CGIP Database will know the code and be able to identify you if needed. Your identifiable information will not be shared with anyone outside the CGIP Database (unless you give your permission to share it).

WHO WILL HAVE ACCESS TO THE DE-IDENTIFIED DATA?

Your de-identified information collected and compiled by the CGIP Database belongs to the VHL Alliance. The Cancer in Our Genes International Patient Database is the guardian of the information contained within the CGIP Database.

Your de-identified information may be shared with other databases authorized by the CGIP Database such as the Global Rare Disease Patient Registry and Data Repository (GRDR). We may combine our de-identified data with other databases in order to develop global knowledge of these diseases that may lead to new research studies, clinical trials, and clinical treatments.

Scientists, researchers, and clinicians approved by the CGIP Database will be allowed to see the de-identified information and may search the de-identified data for candidates for their studies. If a patient looks like a good match for a study and the researcher wants to contact you, he/she can do it only through the CGIP Database. The CGIP Database will then contact you, but the researcher will not contact you directly.

The CGIP Database has to follow rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study. It also tells you who might see or use your information.

Generally, only the CGIP Database Coordinator and CGIP Database curator(s) will know that you have given information and will see your information. However, there are a few exceptions that are listed in the next section.

WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?

The VHL Alliance will make every reasonable effort to assure that your personal information, in our possession, will be kept confidential. However, we cannot guarantee total privacy. Your personal information may be released if required by law. If information from the CGIP Database is published or presented at scientific meetings, your name and other personal information will **NOT** be used.

The VHL Alliance owns the CGIP Database data. This CGIP Database will be managed by The National Organization for Rare Disorders (NORD). NORD manages other rare disease registries that are part of the global rare disease research initiative. NORD does not have access to your personal information, only to the de-identified data.

NORD strictly follows the rules and standards provided by the United States Health Insurance Portability and Accountability Act (HIPAA).

In the event that the VHL Alliance ceases to exist (this is not likely), all attempts will be made to find another suitable entity to take ownership of the CGIP Database. You will be asked to give your consent to the transfer of your data (this includes identifiable and de-identified information). The data of those not consenting for such a transfer will be destroyed. If all attempts fail to fund a suitable entity, then all data collected by the CGIP Database will be destroyed, thus protecting your privacy. You will be contacted and informed of this action.

If you would like more detailed information regarding the security of the CGIP Database, please contact the CGIP Database coordinator at <mailto:registry@vhl.org>.

WHAT ARE THE RISKS OF PARTICIPATING IN THE CGIP DATABASE?

There is minimal risk in taking part in the CGIP Database. The CGIP Database includes questions that can be sensitive and you may feel uncomfortable answering. You do not have to share any information you do not want to.

There may be risks to your privacy. The CGIP Database will store study records and other information about you in a secure location and will grant access only to personnel authorized by the CGIP Database. However, just like other personal information kept by your health care providers, your banks, and others, even these safeguards cannot guarantee absolute protection of the data. If private information gets into the wrong hands, it can cause harm. Although rare, there are reported cases of breaches that have resulted in discrimination in insurance or employment. In the event there is a breach in the CGIP Database's computer system, all participants will be notified. Compliance with HIPAA rules and standards and an annual review of the CGIP Database by an Institutional Review Board (IRB) serve to minimize risks to the

Study Title: The Cancer in Our Genes International Patient Database

patient. If you would like more detailed information regarding the security of the CGIP Database, please contact the CGIP Database coordinator at <mailto:registry@vhl.org>.

WHAT ARE THE BENEFITS TO PARTICIPATING IN THE CGIP DATABASE?

Providing your information to the CGIP Database and participating in this CGIP Database is voluntary. Participation may not benefit you personally, medically or financially. However, your participation may help all those with VHL, HLRCC, BHD or other diseases by increasing the understanding of these and other diseases. Collected data may help speed up research by collecting information scientists can use. Researchers may learn whether and how treatments work. Medical professionals may be able to improve how they treat the disease. Participants may receive information about opportunities to participate in research, clinical trials, medical advances and other news from the CGIP Database. Participants will also have instant access to how other patients have responded to the CGIP Database questions.

WHAT ARE THE COSTS OF TAKING PART IN THIS CGIP DATABASE?

There is no charge for you to participate in this database. Neither you nor your insurance carrier will be charged for participating in the database.

DO YOU HAVE TO PARTICIPATE AND CAN YOU STOP PARTICIPATING IN THE CGIP DATABASE?

Participating in this database is your choice, is completely voluntary and will not affect your healthcare.

If you decide to participate in the database, you can decide to stop at any time. Simply contact the CGIP Database, and all of your data will be removed from the CGIP Database. De-identified data shared with the GRDR will also be removed. However, de-identified data cannot be retrieved from researchers that have already accessed it prior to your request for removal.

The VHL Alliance may withdraw you from the CGIP Database if circumstances arise which warrant doing so, even if you would like to continue.

We will tell you about new information or changes in the CGIP Database that may affect your willingness to continue in the study.

IF YOU HAVE GIVEN DATA OR INFORMATION TO DOCTORS, RESEARCHERS, CLINICS, OR HOSPITALS IN THE PAST, IS IT OKAY TO GIVE YOUR DATA TO THE CGIP DATABASE NOW?

Yes, it is. Your information may be used differently, for different purposes and by different researchers looking for different aspects of these diseases.

WILL YOU BE COMPENSATED FOR BEING IN THIS STUDY?

You will not be paid for taking part in this study. The CGIP Database maintains ownership of the de-identified data collected and compiled by the CGIP Database and is the guardian of the information contained within the CGIP Database. You will have no property ownership or interest in such data derived from the CGIP Database and no right or entitlement in any research or research product using or derived from the data. However on the CGIP Database site you will have access to statistics on how others with these conditions have responded to questions, and if you would like to, you will have access to view new studies of these diseases.

I WANT TO BE INVOLVED IN A CLINICAL TRIAL. IS THIS GUARANTEED?

Although one of the main goals of the CGIP Database is to make it easier for VHL, HLRCC, and BHD patients to participate in research, there is no guarantee that you will be eligible for a trial. Even if you are eligible for a trial based on the data you store in the CGIP Database, it is possible that you do not meet the trial requirements. In order to participate in any trial, you will need to discuss the trial with the research staff and fill out a separate informed consent form specific to the trial. Informing you about the existence of a trial does not imply that the VHL Alliance endorses it.

I DON'T WANT TO BE INVOLVED IN A CLINICAL TRIAL. SHOULD I STILL REGISTER?

Even if you do not want to take part in a clinical trial, your information may still be useful to researchers who are trying to learn more about patients with VHL, HLRCC, and BHD.

WHO SHOULD YOU CONTACT IF YOU HAVE ANY QUESTIONS?

If there are questions that you do not understand in the CGIP Database, please first go to the Glossary tab found at the top [%% not yet implemented] for more information. If you have further questions, simply type your question into the “Ask an Expert” tab found at the top of the page. [%% not yet implemented]

If you have any questions about the registration process, about participation in the CGIP Database or about reporting problems that result from your participation in the CGIP Database, please contact the CGIP Database coordinator at <mailto:registry@vhl.org>.

To inquire about your rights as a participant in the CGIP Database, you may also contact Chesapeake IRB at <mailto:dmarvel@irbinfo.com>. [%% not until we go live]

If you have further questions, please contact CGIP Database Coordinator at <mailto:registry@vhl.org>

Study Title: The Cancer in Our Genes International Patient Database

For additional information regarding the terms and conditions of this web site or the privacy policy please go to the documents “Terms and Conditions” and “Privacy Policy” which can be found at <http://vhl.org/vhl-research/cgip-database>

By clicking to agree to participate on the Informed Consent Form, you do not give away any legal rights or benefits to which you are otherwise entitled.

By clicking to agree to participate on the Informed Consent Form, 1) you have indicated that you understand your rights and want to take part in this CGIP database; 2) you have read and understand the information above; 3) you have had the opportunity to ask questions; 4) you have had time to consider fully whether you want to join the CGIP database; 5) you have consented to participate.

Informed Consent Form

For the purpose of this document “you” and “your” refers to the registrant, either the individual affected by VHL, HLRCC, or BHD, or the parent, guardian or family member providing the information on behalf of the affected individual (the person legally responsible for the care and maintenance of the affected individual). “The database” refers to the CGIP Database.

All of the following questions must be answered in order to participate in the CGIP Database.

1. Your information will be saved in the database using a code. The code is used so others don’t know who you are. The CGIP database has processes in place to protect your identity. The CGIP database may share your coded de-identified information with other registries or databases. This information may be used for research or to plan clinical trials. Do you give your permission for your information to be shared with other approved registries and databases?

☐ Yes

2. Your participation in the CGIP database is entirely voluntary. Should you change your mind and wish to withdraw your data from the CGIP database, you will be free to do so without having to provide any explanation. Do you understand this?

☐ Yes

3. The CGIP database has been fully explained to me. I understand “Understanding my Participation” and “Informed Consent Form.” I also know how to access this document in the

Study Title: The Cancer in Our Genes International Patient Database

future if I want to review it. I have had the opportunity to ask questions of the CGIP database Coordinator. All my questions have been answered to my satisfaction.

☐ Yes

4. Your information will be saved in the CGIP Database using a code. The CGIP database has processes in place to protect your identity. The CGIP Database may share your coded information with other registries or databases. This information may be used for research or to plan clinical trials. Do you give your permission for your information to be transferred to other registries or databases?

☐ Yes ☐ No

5. If researchers learn anything interesting about your condition, do you want to be contacted by the CGIP database with this information?

☐ Yes ☐ No

6. The CGIP database may get information about a clinical trial that you might be eligible for. Do you want to be contacted with this information?

(Please note that even if the coordinators of a clinical trial believe that you might be eligible for the trial, based on the data about you stored in the CGIP database, it is still possible that later on it will turn out that you do not meet the trial inclusion criteria after all. Please also be aware that if we inform you about the existence of a trial, this does not imply that we endorse it. In order to participate in any trial, you will need to fill out a separate informed consent form.)

☐ Yes ☐ No

7. It is important that The CGIP database information be up to date. We will contact you once a year to ask about changes in your medical condition. We may also send you electronic forms to fill out each year. Do you give us permission to contact you for this information?

☐ Yes

8. The participant is 18 years old or older

☐ Yes ☐ No

Study Title: The Cancer in Our Genes International Patient Database

If the participant is between the ages of 7 and 17 inclusive, he or she needs to read the Participation Assent Form available at <http://vhl.org/vhl-research/cgip-database> and needs to agree to participate in the CGIP Database.

9. I understand the risks and benefits of participation and I agree to participate in the CGIP database.

☐ Yes

Name of patient _____

Name of legal representative _____

Relationship to Patient _____

Contact email address _____ Date _____

A “Yes” response to the questions above means that you have given Cancer in Our Genes International Patient Database your consent.

Contact information: CGIP database Coordinator

E-mail: registry@vhl.org

Fax: 866-209-0288 or +1-858-712-8712

Paper mail: CGIP Database

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