Insert HTC name
Insert Sponsor Protocol Number
Insert WIRB Protocol Number

The language in this consent form may differ from consent forms used at other HTCs due to regional differences in regulatory requirements. Participants will need to carefully read, ask questions, and then sign the consent form approved for use at the local HTC they are at.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: My Life Our Future: A Hemophilia Genotyping Initiative Data and Sample Research Repository

PROTOCOL NO.: [insert here]

SPONSOR: Biogen Idec Hemophilia

INVESTIGATOR: [insert here]

SITE(S): [insert here]

STUDY-RELATED PHONE NUMBER(S): **[**insert here**]**

SUB-INVESTIGATOR(S): [insert here]

STUDY COORDINATORS: **[**insert here**]**

SUMMARY

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about why we are doing the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent". We will give you a copy of this form for your records.

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research (study) subject. If you are a parent, legal guardian or legally authorized representative, as you read this consent form remember that "you" means the research (study) subject.

THE *MY LIFE OUR FUTURE PROJECT* AND THIS STUDY

Special proteins in your blood help you to make a clot and stop bleeding when you are cut or hurt. These proteins are called clotting factors. Hemophilia happens when there is a change or mutation in a gene (small piece of your DNA) that makes a clotting factor. A laboratory can do genotyping, which is also called genetic testing. The lab looks at your DNA to see what change in your genes (known as a genetic mutation) is causing your hemophilia.

My Life Our Future is a national project which studies hemophilia. The partners who set up this project are the Puget Sound Blood Center (PSBC), the American Thrombosis and Hemostasis Network (ATHN), the National Hemophilia Foundation (NHF), and Biogen Idec Hemophilia (BIH). The *My Life Our Future* project has two parts you can choose from:

Part 1. Hemophilia Genotyping: You are eligible if you are a patient with hemophilia, or a family member, who lives in the United States. One purpose of this study is to provide genotype testing done at no cost to you. We expect about 5000 subjects with hemophilia A and B to take part. They are seen at about 130 Hemophilia Treatment Centers (HTCs). This genotyping test is done the same as if your doctor had ordered it through a HTC or hospital lab. You or your insurance carrier will not be billed for the test. Neither you nor your insurance company will be charged for voluntarily providing a sample for genotyping.

If you only want the genotyping test and are not interested in learning more about the second part of this project, a research repository, you may stop here.

Part 2. Data and Sample Research Repository. Another purpose of this project is to build a Research Repository. A repository is like a bank. Blood or tissue samples and health information from many participants will go into this bank. They can be taken out and used by researchers both now, and in the future. Researchers can use the repository to better understand hemophilia A and B, and other medical conditions. We will put your blood samples, health information, and genotype information (data) into the repository. Neither you nor your insurance company will be charged for voluntarily providing a sample for the repository. We expect to enroll about [insert number here] subjects from [insert HTC here] in this repository.

PROCEDURES

For the hemophilia genotyping, the lab needs about 1 teaspoon of blood for the test. After the lab is done with the genotyping test, there may be some blood samples or DNA leftover and not used up. If you participate in the repository, you agree to donate your leftover blood samples, DNA, and DNA information (code) from your factor VIII (8) and factor IX (9) gene sequence to the repository. The leftover blood samples, DNA and DNA code will be used for future research on hemophilia and other medical conditions. You can also choose to have up to 16ml or about 3 ½ teaspoons of blood drawn for future research on hemophilia and other medical conditions. For children who weigh less than 12 pounds, we will ask for a smaller amount of blood (less than ½ teaspoon per kilogram). All blood samples will be sent to the PSBC lab.

When you join the repository, your HTC will share your health information as part of the ATHN dataset. Your name and personal information will not go on this data. Instead, you are given a unique code, called your MLOF ID, to protect your personal information. The ATHN dataset

may have information about your clotting factor level, bleeding history, if you have or have had a factor inhibitor, general things about you (age, race, sex), and other medical conditions you have had.

The repository team at PSBC will keep a master list that links your MLOF ID and your Study ID. To protect your confidentiality, this link will be stored electronically on a secure server. Your blood and DNA samples will be stored in locked freezers in a secured building at PSBC. Your health information will be stored on the secure ATHN server.

Researchers need to apply to get permission to use the repository, and get health information from the ATHN dataset. They are from HTCs, universities, the federal government, drug companies, and health companies. Researchers are treated the same, and will use the same application and approval process. Researchers at the partners in the *My Life Our Future* project will not be treated differently, and will not have special access to samples or data.

The ATHN Research Review Committee will look at applications from researchers who want to study samples or data. This committee includes researchers, HTC medical providers, and at least one person with hemophilia or a family member of a person with hemophilia. They make sure that the research is scientifically valid, that subject rights and welfare are protected, and that any risks are minimized. Committee members are approved by the ATHN Board of Directors, and the *My Life Our Future* Steering Committee. The Steering Committee has one person from each of the four partners (ATHN, NHF, PSBC and BIH) as members.

There is no limit on the length of time we will use your health information in the ATHN dataset, and store your samples and information in the repository. We may keep using them for research indefinitely unless you decide to withdraw from the project.

Researchers may study all or most of your genetic information in studies called whole genome studies. Researchers may also use new methods as they are developed. Your genetic and health information could be placed into one or more restricted scientific databases. Only researchers who apply and are approved can use restricted databases. One such restricted data base is funded by the National Institutes of Health and is called dbGaP. This stands for DataBase for Genotype (genes) And Phenotype (things observed or measured by examination or laboratory tests). Your hemophilia genotype and clinical information about your hemophilia may be given to a database of hemophilia mutations. An example is the CDC Hemophilia A Mutation Project (CHAMP).

Your HTC will get the results of your hemophilia genotype, and they will share this with you. We will not give you the specific research test results performed on your repository samples. We will share what we learn from research through this project, in medical publications and presentations. The NHF will tell the hemophilia community about the advances in hemophilia research that may come from this project. None of these publications or presentations will include information that could identify you in any way.

We may want to contact you in the future. One reason is that your stored samples may be used up, or decrease in quality over time. We would need fresh samples to replace them. We would contact you through your HTC. They are the only ones who have the key between your personal

information and your MLOF ID number. You can decide whether or not you want to be contacted in the future. You can change your mind any time.

I agree that my HTC may contact me about this Repository in the future.

☐ Yes ☐ No Initials _____ Date _____

RISKS AND DISCOMFORTS

Physical Risks
When you give a blood sample, you might feel a little pain from the needle stick. You might feel light-headed or faint. Later, you might have a bruise, and there is a small risk of infection.

Privacy Risks
Because your DNA is unique to you, it is possible that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

We do not think that there will be further risks to your privacy and confidentiality by sharing your whole genome analysis with public or restricted databases. However, we cannot predict how genetic information will be used in the future. In the future, someone could develop ways to link your genetic or medical information in a database back to you. It is possible that you could be identified from the sample if someone already has genetic information from you to match to information in a study.

There is a risk that someone could get access to the data we have stored about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. The Genetic Information Nondiscrimination Act of 2008 (GINA) says that group and individual health insurers may not use your genetic information to determine whether you are eligible for insurance, how much you have to pay, nor can they request or require that you take a genetic test. We cannot guarantee that this will fully protect you. Your privacy and the confidentiality of your data are very important to us; we will make every effort to protect them. As with any research project, there may be additional risks that are unknown or unexpected.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
You will receive no direct benefit from your participation in this research repository. Patients in the future may benefit from studies using the repository data and samples.

COSTS
Costs for routine medical care for your condition are not part of this research repository and will be charged to you or your insurance carrier.

PAYMENT FOR PARTICIPATION
You will not receive any money for voluntarily providing a blood sample and providing your health information for this repository.

ALTERNATIVE TREATMENT
Your participation is **voluntary**. This is not a treatment study. The alternative is not to participate.

CONFIDENTIALITY
All of the information you provide will be confidential. PSBC, government, or university staff sometimes reviews studies such as this one to make sure they are being done safely and legally. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure.

Your data will be assigned a study ID number. No identifiers will be used on specimens or during data generation or analysis. Your personal information will be kept in the database using a study code. This information will be kept in a password protected computer with a security system.

To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation for projects funded by the federal government or for information that must be given in order to meet the requirements of the Federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily providing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent, in incidents such as child abuse, and intent to harm yourself or others. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

COMPENSATION FOR INJURY
If you think you have an injury or illness related to having your blood drawn for this repository, contact [insert here] right away. They will treat you or refer you for treatment. Biogen Idec Hemophilia (BIH) will reimburse for treatment of injury or illness resulting from a blood

collection for this Repository. BIH will not pay for the normal progress of your disease, or any injury or complication due to the medical condition you already have. BIH will not pay for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this research repository is **voluntary**. You may decide not to participate or you may decide to leave the study at any time. Your decision will not result in any change in the medical care you receive from your HTC and will result in no penalty or loss of benefits to which you are entitled.

You may withdraw or cancel your permission for researchers to use your data and repository samples at any time. Your sample and data that are in the research repository will then be destroyed. However, any samples and health information already given to researchers will not be able to be returned for destruction.

You can withdraw by sending written notice to [insert here] Your HTC will inform us by using your MLOF ID number.

The study doctor or the sponsor may also stop your participation in the study without your consent at any time for any reason. Reasons include:

- It is in your best interest.
- You do not consent to continue in the study after being told of changes in the research that may affect you.

SOURCE OF FUNDING FOR THE STUDY
Biogen Idec Hemophilia (BIH) is funding this repository. BIH will provide financial support for the Repository for at least 3 years. After that time financial support may come from BIH or another source. If funding is not available, PSBC may destroy the samples and all identifying information.

QUESTIONS
Contact [insert here] for any of the following reasons:

- if you have any questions about this repository or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

[insert IRB here]

[insert here] will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact [insert here] if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

CONSENT
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study. By signing this consent form, I have not given up any of my legal rights.

Consent and Assent Instructions:

Consent: *Subjects 18 years and older must sign on the subject line below Consent is provided by the Legally Authorized Representative for adult subjects unable to consent*
For subjects under 18, consent is provided by the parent or guardian

Assent: *Is not required for subjects 6 years and younger*
Verbal assent is required for subjects ages 7 through 14 years using the Assent section below and the Child Information Sheet (Ages 7 - 14).
Verbal assent is required for subjects ages 15 through 17 years using the Assent section below and the Adolescent Information Sheet (Ages 15 - 17).

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____ _____
Signature of Subject (18 years and older) Date

_____ _____
Signature of Legally Authorized Representative, Parent or Guardian (when applicable) Date

_____
Authority of Subject's Legally Authorized Representative or Relationship to Subject

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

ASSENT SECTION For Subjects Ages 7 - 17:
Statement of Person Conducting Assent Discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject's decision to enroll is voluntary.
5. The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

_____ _____
Signature of Person Conducting Assent Discussion Date

Statement of Parent or Guardian:

My child appears to understand the research to the best of his or her ability and has agreed to participate.

_____ _____
Signature of Parent or Guardian Date

ASSENT SIGNATURES, For Adult Subjects with a Legally Authorized Representative:

For adult subjects who have a legally authorized representative, I confirm that:

☐ I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.

OR

☐ The subject is not able to assent due to lack of mental capacity**.**

_____ _____
Signature of Person Conducting Assent Discussion Date

---------- Use this witness section only if applicable ----------

If this consent form is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Signature of Impartial Witness	Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.