RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	**Comparison of Ideal vs. Actual Weight Base Factor Dosing**
PROTOCOL NO.:	
SPONSOR:	Washington State Health Care Authority
INVESTIGATOR:	Rebecca Kruse-Jarres, MD, MPH
SITE(S):	Washington Center for Bleedings Disorders Oregon Health & Science University Seattle Children's Hospital Sacred Heart Hospital
SUB-INVESTIGATOR(S):	Michael Recht, MD, PhD Dana Matthews, MD Amanda Blair, MD Judy Felgenhauer, MD Donna Sullivan, PharmD, MS

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.

General Information about 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. This can result in spontaneous bleeding. The bleeding can be treated and prevented with clotting factor

concentrate. Clotting factor replacement is administered intravenously and is based on a patient's weight. The Bleeding Disorder Collaborative for Care was established to help determine whether factor replacement dosing should be bases on a patient's actual body weight or his/her ideal body weight. This study will be conducted at four locations: Washington Center for Bleedings Disorders, Oregon Health & Science University, Seattle Children's Hospital, and Sacred Heart Hospital. Subjects will be recruited at these centers, and it is expected that sixteen patients will enroll.

ELIGIBILITY

In order to take part in this study, you must be a male at least 12 years of age and have a FVIII diagnosis. Your Body Mass Index, or BMI, must be at least 25. You must be willing to comply with the testing schedule.

PROCEDURE

(need help with this section)

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

We do not think that there will be risks to your privacy and confidentiality by sharing your test results with the investigators.

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 study.

COSTS

Costs for routine medical care for your condition are not part of this study 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 study.

CONFIDENTIALITY

All of the information you provide will be confidential. Institutional, 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 using the study ID number. This information will be kept in a password protected computer with a security system.

COMPENSATION FOR INJURY

If you think you have an injury or illness related to having your blood drawn for this study, contact: (insert site specific info here)

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this research study 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 will receive from your doctors 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 samples at any time. Your sample and data will then be destroyed.

You can withdraw by sending written notice to:

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

Funding for this study comes from the general fund for Washington state, appropriation funding for fiscal years 2016 and 2017 as well as the Washington State Health Care Authority's administrative account.

QUESTIONS

Contact (insert MD at each site) at (insert phone #) for any of the following reasons:

- if you have any questions about this study 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, input or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB 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: *Verbal assent is required for subjects ages 12 through 14 years using the Assent section below.*
Verbal assent is required for subjects ages 15 through 17 years using the Assent section below

_____
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 12 - 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.