RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	**Comparison of Ideal vs. Actual Weight Base Factor Dosing**
*****PROTOCOL NO.:**	(To be assigned later)
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 Providence Sacred Heart Children's 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 change in your gene can result in low levels of clotting factor, which can result in spontaneous or prolonged bleeding. The bleeding can be treated and prevented with clotting factor concentrate. Clotting

factor replacement is administered intravenously. Factor dosing is currently based on a patient's actual weight.

In overweight and obese patients, this dosing strategy may deliver too much clotting factor. This study will look a way to prevent delivering too much factor by using a patient's ideal body weight as a new dosing strategy to replace the dosing strategy of using a patient's actual body weight in overweight or obese patients.

This study will be conducted at four locations: Washington Center for Bleedings Disorders, Oregon Health & Science University, Seattle Children's Hospital, and Providence Sacred Heart Children's Hospital. Subjects will be recruited at these centers, and it is expected that sixteen patients will enroll. This study is a part of the Bleeding Disorder Collaborative for Care. The Bleeding Disorder Collaborative for Care is working to improve care to patients with bleeding disorders by developing evidence-based practices related to bleeding disorders.

ELIGIBILITY

In order to take part in this study, you must be a male, at least 12 years of age, and have hemophilia A. Your Body Mass Index, or BMI, must be classified as either overweight or obese for your age based on CDC definitions. You also must be willing and able to comply with the testing schedule.

PROCEDURE

We will measure factor levels immediately before, and at 4 or 5 time points after 2 different factor doses. All participants will undergo testing in the clinic twice: once for a dose of 50 U/kg (±20%) based on ideal body weight and once for a dose of 50 U/kg (±20%) based on actual body weight. The order of these two doses will be determined by chance. The procedure will be the same for both tests.

Participants will come to clinic for each factor dose, and at least two blood draws for each dose will be done in the clinic. The first draw occurs before the drug is administered, and it will measure the baseline level. The second draw will occur 30 ±10 minutes after the drug is taken, and it will measure the recovery level. Blood draws to measure half-life at the remaining time points may be drawn in other local labs. If the 30 ±10 minute recovery draw is missed at clinic, the participant can still be included with another attempt of the dose draw if the second dose/draw falls within the 2 month window.

**Post dose blood draws cannot be pulled from the port/IV that was used to administer factor. Sites may infuse factor through a peripheral line and obtain post blood draws through a port.

Blood draw time points:

Hemophilia A – regular half-life product

Baseline – 30 ± 10 minutes (recovery) – 5 to 7 hours – 20 to 26 hours – 44 to 50 hours

Hemophilia A – extended half-life factor

Baseline – 30 ± 10 minutes (recovery) – 5 to 7 hours – 20 to 26 hours – 44 to 50 hours – 69 to 75 hours – 93 to 99 hours

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 may not receive direct benefit from your participation in this research study. During the study, you will gain information about factor levels in your body based on different factor dosing strategies.

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. **Costs associated with dosing the ideal body weight strategy may be covered by the clinical trial.

***PAYMENT FOR PARTICIPATION

You will not receive any money for voluntarily providing a blood sample and providing your health information for this study.

(Was compensation considered? Mike R to add standard language on payments)

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 subject ID number. No identifiers will be used on specimens or during data generation or analysis. Your personal information will be kept using the subject 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: (insert site specific info here)

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