PATH for PWS™
Paving the way for Advances in Treatments & Health for PWS

Blood Sample Collection Informed Consent Form

Sponsors' Information:	Zafgen, Inc. 175 Portland St, 4th Floor Boston, MA 02114 USA Phone: +1 (617) 622-4003 Foundation for Prader-Willi Research (FPWR) 340 S Lemon Ave, Suite 3620 Walnut, CA 91789 USA Phone: +1 (888) 322-5487
Protocol Title:	Blood Sample Collection for the Non-Interventional, Observational, Natural History Study of Serious Medical Events in Prader-Willi Syndrome
Branded Title:	Blood Sample Collection for the PATH for PWS Study: Paving the way for Advances in Treatments & Health for PWS
Protocol Number:	ZAF-PWS-001
Protocol Version:	Version 1.0
Protocol Date:	11 June 2018
Principal Investigator:	Theresa Strong, PhD Director of Research Programs Foundation for Prader-Willi Research
Sub-Investigators:	Shawn McCandless, MD Section Head, Genetics and Metabolism University of Colorado Jennifer Miller, MD Associate Professor Department of Pediatrics University of Florida
Site(s) of Investigation:	There are no sites of investigation as all information will be collected using a web interface.
Study Staff Contact:	Global PWS Registry 5455 Wilshire Blvd, Suite 2020 Los Angeles, CA 90036 info@pwsregistry.org phone: +1 (888) 322-5487 ext 702
Emergency Contact:	In the case of an emergency, study participants are to call their local emergency number.

THE INFORMED CONSENT PROCESS

Because the study participant has agreed to participate in the PATH for PWS Study, he/she is also being asked to provide a blood sample for analysis of D-dimer concentration if he/she lives in the United States. Providing a blood sample is optional. You can choose that the study participant not provide a blood sample and still remain in the PATH for PWS Study.

Before you decide if the study participant should agree to provide a blood sample, you need to understand the purpose, the possible risks and benefits, and what would be expected of you and the study participant. This process is called Informed Consent.

If you have additional questions after reading this consent, please contact the study staff using the information listed on page 1 of this consent form and ask as many questions about the blood sample collection as you would like. If there are any words or information that you do not understand, the study staff will explain them to you.

If you agree that the study participant should provide a blood sample, you must sign this consent form before doing so.

PURPOSE OF THE BLOOD COLLECTION

D-dimer is a protein in the blood that is present when a blood clot is forming or has formed. Some researchers noticed that D-dimer levels are usually higher in patients with PWS than individuals without PWS, but don't have enough information to know this for certain. Additionally, if D-dimer levels are generally elevated in individuals with PWS, it is unknown whether this represents an increased incidence of blot clots. The purpose of this research study is to learn more about D-dimer levels in individuals with PWS to help researchers know more about their risk of forming blood clots and how to interpret the results in future studies.

DESCRIPTION OF THE PROCEDURES INVOLVED

All study participants who are participating in the PATH for PWS Study, live in the United States, and agree to provide a blood sample may do so at a nearby laboratory that the Sponsors have selected. A list of participating laboratory locations where the blood sample can be collected may be viewed by clicking the link below.

https://www.labcorp.com/labs-and-appointments#

Study participants will be asked to provide the blood sample as soon as possible after enrollment. The total volume of blood to be collected for the sample will be 5 mL (1 teaspoon) or less.

When the laboratory has completed the analysis of the blood sample, the study staff will inform you of the study participant's D-dimer results. If the study participant's D-dimer result is abnormal, the study staff may also ask you additional questions about the study participant's health and request that the study participant undergo additional testing. You may also be advised to see a physician.

POSSIBLE RISKS OF PROVIDING A BLOOD SAMPLE

There are risks associated with routine blood collection, such as discomfort, bruising, minor infection, or bleeding during the procedure. If this happens, it can easily be treated.

POTENTIAL BENEFITS FROM PROVIDING A BLOOD SAMPLE

There is no direct benefit to the study participant from providing the blood sample. D-dimer levels measured using the blood sample will be used to help researchers determine if D-dimer will make a good marker for assessing blood clotting risk in patients with PWS in future studies.

VOLUNTARY PARTICIPATION AND HOW TO REVOKE YOUR AUTHORIZATION

Providing a blood sample is voluntary. The study participant can still participate in the PATH for PWS Study and not provide a blood sample. Refusing to provide a blood sample will involve no penalty or loss of benefits to which you/the study participant are otherwise entitled (such as health care outside the study, the payment for health care, and health care benefits).

If the study participant does provide a blood sample, you will be unable to revoke your authorization regarding the use of the study participant's test result. The information collected before you changed your mind may still be used to complete the research that has already started.

STOPPING THE STUDY UNEXPECTEDLY

This study may be stopped unexpectedly for a variety of reasons before the blood sample is collected, including decisions made in the commercial interests of the Sponsors or by local regulatory/health authorities.

In addition, the study doctor or the Sponsors can stop your participation at any time without your consent for any reason including:

- If it is discovered that you do not meet the study requirements
- For administrative reasons including if sufficient number of participants have been enrolled

The study staff will notify you if the study is stopped and inform you if blood collection from the study participant is still possible if a blood sample hasn't already been provided.

ALTERNATIVES TO PROVIDING A BLOOD SAMPLE

Your alternative is not to allow the study participant to provide a blood sample.

CONFIDENTIALITY AND USE, DISCLOSURE OF PERSONAL HEALTH INFORMATION

If you agree to allow the study participant to provide a blood sample, the study staff will share limited information about the study participant (eg, name, address, date of birth, and gender) along with the blood sample and results with a third-party vendor who will authorize the

physician's order for the lab test and with the laboratory who is analyzing the blood sample. Except as set forth in this consent, the results from the analysis of the blood sample will be de-identified before being shared beyond the study staff. De-identified means that all the personal identifiers have been removed, including the study participant's name, address, and all other information that identifies the study participant or the study participant's family.

When the results of this research are published or discussed in conferences, unless your specific consent is obtained, any personal information that could identify you or the study participant will be removed or coded to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your or the study participant's personal data.

Representatives from the National Institutes of Health, United States Food and Drug Administration, National Organization of Rare Disorders (NORD), Hummingbird Institutional Review Board (IRB), or other authorized parties may inspect study records during auditing procedures to be sure that this study is being protected according to regulations and policies. Information that is disclosed pursuant to this authorization may be redisclosed by the recipient, in which case the information may no longer be covered by the federal privacy protection regulations.

Your authorization for use of the study participant personal health information for this specific study does not expire.

You may withdraw your permission for the use and disclosure of any of the study participant's personal information for research, but you must do so in writing to the study staff using the address or email listed on page 1. Even if you withdraw your permission, the study staff may still use the study participant's personal information that was already collected if that information is necessary to complete the study.

You will be given a copy of this consent/authorization form describing the study participant's confidentiality and privacy rights for this study.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE BLOOD SAMPLE COLLECTION

You should contact the study staff using the contact information listed on page 1 with any questions or concerns. You can refer to the PATH for PWS Study consent form for additional information about Hummingbird, the IRB that reviewed this study.

COSTS OF PROVIDING A BLOOD SAMPLE

There will be no cost to you for the study participant to provide a blood sample.

COMPENSATION FOR PROVIDING A BLOOD SAMPLE

For your time and effort related to arranging and transporting the study participant to the laboratory to provide a blood sample, you will receive a $100 e-gift card (to Amazon.com) after the study participant's blood sample has been collected. If you have any questions regarding

your compensation for participation, please contact the study staff number using the information listed on page 1 of the main consent form.

YOUR ROLE IN PROVIDING A BLOOD SAMPLE

If the study participant agrees to provide a blood sample, you will need to arrange to transport the study participant to one of the laboratories on the list so they can take a blood sample to analyze D-dimer levels.

If the study participant's D-dimer result is abnormal, the study staff may also ask you additional questions about the study participant's health and request that the study participant undergo additional testing. You may also be advised to see a physician.

STATEMENT OF THE PERSON SIGNING THE CONSENT

I have read and understand the information provided above describing the blood sample collection. If appropriate, I have discussed this with the study participant to the extent compatible with his/her understanding. My questions have been satisfactorily answered and I have signed this form as indication of my desire to allow the study participant to provide a blood sample. I understand that I will receive an electronic copy of this consent/authorization form.

I authorize the release of the study participant's information to the parties identified in this consent, including the sponsors, the Food and Drug Administration (or other Regulatory Agencies) and Hummingbird IRB. By signing this consent form, I have not given up any of the legal rights which I or the study participant would otherwise have as a participant in a research study.

If appropriate, select the category that best describes the study participant's legally authorized representative who signed above, select all that apply:

- ☐ Court-appointed guardian
- ☐ Durable power of attorney
- ☐ Health care proxy
- ☐ Family member / next of kin (describe relationship below):

Relationship to Study Participant: _____

CHECK all that apply (Yes or No)

You must select "yes" for all of the statements below to participate in this study.

- The study participant lives in the United States. Yes _____ No _____
- I give permission on behalf of the study participant to provide a blood sample for the purposes described above. Yes _____ No _____

- I consent to being contacted by the study staff to receive instructions, reminders, and results regarding the blood sample collection. Yes _____ No ____
- I consent to receiving medical information about the study participant, including lab results via email. Yes _____ No ____
- I agree to arrange transportation for the study participant to one of the laboratories selected for the study for a blood sample collection. A link to the list of laboratory locations available on page 2. Yes _____ No ____