For Parents and Students: Minor Donor Permit and Information About Donating Blood

Every day people like you need blood: students, teachers, family, and friends! And when blood is needed, blood must be there. The only source is generous volunteers like you!

COMMON QUESTIONS ABOUT BLOOD DONATION

Q: Is blood donation safe? Does it hurt?

A: Donating blood is safe. All materials are used once, and then discarded. You cannot get any infectious disease by donating blood. Most people feel fine after they give. The actual needle stick (venipuncture) hurts no more than a pinch.

Q: How long will it take?

A: The entire process takes about 60 minutes, including the interview before and refreshment time after donation; automated donations take longer. For your safety, you must stay in the refreshment area at least 15 minutes following the donation.

Q: How much can I give?

A: Every donor is evaluated individually with safety in mind! When you donate whole blood, one unit, about a pint is collected. Depending on your gender, height, and weight, you can give up to 2 units in an automated blood collection. For example, one donor may be able to donate two units of Red Blood Cells (RBC); another may donate one unit of Platelets and one unit of Plasma.

BLOOD DONOR QUALIFICATIONS

In general, volunteer blood donors must be 16 or older and in good health.

Height/Weight Restrictions for Donors Age 16-22 Eligibility is Based on Estimated Total Blood Volume								
Males between 16 and 22: You must be at least 5' tall and weigh at least 110 pounds.								
Females between 16 and 22: If you weigh at least 110 but are shorter than 5'6", please refer to this chart*:								
Females who are:	**≥ 4'10"**	**≥ 4'11"**	**≥ 5'**	**≥ 5'1"**	**≥ 5'2"**	**≥ 5'3"**	**≥ 5'4"**	**≥ 5'5"**
Must weigh:	**≥ 146**	**≥ 142**	**≥ 138**	**≥ 133**	**≥ 129**	**≥ 124**	**≥ 120**	**≥ 115**
***Shorter people must weigh more to achieve a 3500 mL blood volume.								

Blood Donation: The Process

Whole Blood Donation

Blood is collected from an arm vein into a bag specially designed to store blood. Typically, each unit is separated into multiple components, usually RBCs and Plasma. Whole blood donation is the most common way to donate blood. We also use special machines for automated blood collection.

Automated Blood Collection Methods

With automated equipment, the blood center can collect the exact components that patients need. Blood is collected from an arm vein and passed through an apheresis instrument that separates the blood into its components. During donation, a small amount of anticoagulant (citrate) is added to the blood to prevent clotting. After the targeted component(s) is/are collected, the remainder of the blood is returned to the donor. The donor may receive saline solution to help replace fluid lost during the collection. The body naturally replaces the donated components: plasma within several hours, platelets within 24 hours, and red cells in about 56 days (112 days for 2-unit Red Blood Cell donation). The number of white blood cells lost is small.

Some Potential Side Effects

Serious complications are rare. However, as in any medical procedure, there are certain risks. Potential side effects of both whole blood and automated blood collection include fainting, dizziness, nausea, vomiting, bruising or redness in the area of the venipuncture, and iron deficiency in individuals making 3 or more donation a year. More serious reactions may include seizures and, rarely, nerve injury in the area of the venipuncture. While a small proportion of blood donors have adverse reactions (overall reaction rate of 1.43%), donors aged 16 to 22 do experience a higher prevalence of reactions (about 5%). To reduce the likelihood of a reaction, the blood center evaluates eligibility for younger donors based on weight and height to determine blood volume. The chart above indicates whether your blood volume is sufficient for you to donate. Please review it carefully. Other

possible complications include fatigue, decreased exercise tolerance for 3-5 days and, very rarely, allergic reaction, shortness of breath, chest pain, and decreased blood pressure.

In addition, during automated blood collections some common side effects that are easily resolved are due to the anticoagulant and include numbness and tingling sensations, muscle cramping, and chilliness. Less common complications include hemolysis and air embolism.

If you have any questions, please contact the blood center.

STUDENTS: Take these steps on the day of donation for a good blood donation experience.

- If you are 16 or 17, **bring this signed Minor Donor Permit** when you donate. The signature block is below.
- BRING ID containing name and one of the following: birth date, blood center donor number, or photo.
- You must pass the physical and health history examination given prior to donation. If you have any questions regarding your eligibility, please check with your Blood Drive Coordinator or the blood center.
- Eat a healthy meal before donating, even if you do not normally eat three meals a day.
- Drink 16 ounces of fluid 10-30 minutes before donating (soda, coffee, and tea don't count!).

PARENTS/GUARDIANS: Help your student have a good blood donation experience.

The Day Before Donation: Make sure your student eats a salty snack, like chips or pretzels, and has a meal that is higher in sodium, such as fast food, canned soup, pizza, etc. Physicians recommend this because donors lose about a gram of sodium during donation. Replacing some of that sodium ahead of time makes donors thirsty. Being well-hydrated helps donors maintain blood volume and can prevent dizziness or fainting.

The Day of Donation: Make sure your student has a light meal before donating, and encourage your student to carefully follow our directions.

Our staff are specially trained to respond to donor reactions. We will:

- Give your student reading material and instructions on how to have a safe, comfortable blood donation.
- Teach your student muscle tensing exercises to use during and after donation.
- Provide a sports drink or another beverage and a salty snack.
- Tell your student to spend at least 15 minutes in our refreshment area.

Our blood center participates in research to improve blood safety. We may use your donor history information and a sample of your blood, in a confidential manner, for blood safety research, as described in the accompanying research information document(s). We are required to get parental consent for both 16- and 17-year old donors for this research. For more information about this research or blood donation, go to http://unitedbloodservices.org/reading.aspx.

A sample from each blood donation will be tested for HIV (AIDS), HTLV, hepatitis, syphilis, and other infectious agents as required by regulations. These tests are performed to protect the patients who receive blood. Positive test results will be disclosed as authorized by law, and the donor will be notified. In some cases, blood center staff may need to discuss test results with the donor. Per California law, it is the donor's decision whether his/her parents are to be included in that discussion.

Please be sure that you and your student have read the information provided. If required by your state or school, your student must bring this signed Minor Donor Permit form in order to donate.

I give my permission for my student to donate and for that donation to be tested as explained above.

Parent/Guardian: Please complete all of the following using black or blue INK.

Student's Name: **(Print)** _____

Parent/Guardian Name: **(Print)** _____ **(Signature)** _____

Date of Approval: **(Month/Day/Year)** _____

Phone # where Parent/Guardian can be reached: _____

Zika Virus Research Information

Sponsor / Study Title:	Hologic, Inc. / Pre-pivotal Procleix® Zika Virus Assay Testing of Donations From Donors of Whole Blood and Blood Components
Protocol Number:	B10383-ZIKVPS-CSP-01
Principal Investigator:	Phillip Williamson, PhD
Telephone:	Donor Counseling Service 800-289-4923
Additional Contacts:	Ralph Vassallo, MD 800-289-4923

Please read this form carefully. Take time to ask the donor center staff as many questions about the use of your blood for research studies as you would like. The donor center staff can explain words or information that you do not understand. Reading this form and talking to the donor center staff may help you decide whether to donate or not.

You are being asked to participate in a research study to evaluate a new test for detection of a mosquito-borne agent known as Zika virus. Zika is a virus that rarely causes paralytic nervous system damage, but in pregnancy, can cause loss of the baby or serious birth defects. Most people do not get sick after infection. Only one in five people will have fever, rash, joint pain, and conjunctivitis (red eyes) lasting a few days to a week. Zika is usually transmitted by the bite of an infected mosquito. It can also be transmitted by sex with an infected person, from a pregnant mother to her baby and by blood transfusion.

This donor center is doing a research study to understand the effectiveness of new tests to detect Zika virus in donated blood and prevent patient exposure. Some of this research is conducted with other institutions, such as blood bank organizations, academic centers and biomedical companies. Any remainder of your donation may be stored up to 3 years after the completion of the study and used for further research related to the Zika virus.

Samples linked to your identifying information will be tested for ZIKA virus. If your test results suggest that you may be infected, this donation center will attempt to contact you to notify you and explain the significance of the results. The donation center will discuss the potential risk for sexual transmission of Zika Virus, and potential harm to the fetus during pregnancy. You will be notified in person, by phone, or by letter. If your test results suggest that you may be infected, you should discuss these results with your primary care physician. You may also visit the Centers for Disease Control and Prevention (CDC) website at http://www.cdc.gov/zika/ for additional information regarding Zika virus.

If the results suggest that you may have a Zika virus infection, you will be invited to participate in voluntary follow-up studies involving additional blood samples. Should you choose to participate, additional informed consent process will be required.

Your participation in this research study is entirely voluntary. You will not be paid for your participation in this study. Your participation will not require any additional procedures or time beyond the normal donation process. The risk of having your donation tested with the study test is not any greater than having your donation tested for other infectious diseases, although a positive result may alarm you. There is a very low chance that your blood sample may give a false positive result. If the test is positive, the blood that you donate will not be used for transfusion. There will be no costs or payments to you for your participation in this study. Although you may not receive a direct benefit from this study, the results may allow for better test systems to become available to protect the blood supply.

Zika Virus Research Information

The results of all testing on your donation during this study are confidential, except when reportable by law to public health authorities, and to authorized blood center personnel, the U.S. Food and Drug Administration (FDA), Hologic, Inc. and associated Zika studies. Your age, gender, general geographic location, and test results may be used to evaluate important information about Zika virus, but this information is combined with information about other donors and not identified with you.

You may refuse to participate by notifying the blood collection staff that you will not be donating blood or blood components today. If you decline testing we will be unable to use your whole blood or red blood cells, however, we will inform you whether you may donate plasma or platelets. If you decide not to participate at this time, your decision will not change your future relationship with the blood center and there is no penalty to you. If you decide not to participate after your donation is taken, call the Principal Investigator at the number(s) above.

An Independent Review Board (IRB) is a group of people who review research studies to protect the rights and welfare of research participants. If you have questions or complaints about your rights as a study participant contact the Chesapeake IRB:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00017603.

If you have scientific questions or questions about your participation in these studies, you may contact our Donor Counseling Service at **1-800-289-4923,** Monday through Friday 6:30 AM – 5:30 PM MST. **By signing your Blood Donation Record, you are giving consent to allow us to use a portion of your blood donation and associated information for research purposes related to Zika virus.**

Blood Centers of the Pacific:	(www.bloodcenters.org)	855-540-8064
Inland Northwest Blood Center:	(www.inbcsaves.org)	855-540-8064
Lifeblood:	(www.lifeblood.org)	855-540-8064
United Blood Services	(www.unitedbloodservices.org)	855-540-8064

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Use of Donor Information and Blood Samples in Research

This blood center performs research to help provide a safe and effective blood supply. Research studies are conducted to improve blood safety and contribute to advancing biomedical knowledge. Some research is conducted with other institutions, such as blood bank organizations, academic centers and biomedical companies.

Your participation in research studies is entirely voluntary.

What will happen if I agree to allow my blood to be used in research studies?
All research studies are evaluated and reviewed periodically by an independent committee that considers your rights as a research participant. Formal research studies are included in the clinical trial registry maintained by the National Institutes of Health for public access (www.ClinicalTrials.gov). Your participation will not require any additional procedures or time beyond the normal donation process. There will be no payments to you for your participation.

How might my blood or information be used in research?
A portion of your blood sample or information collected at the time of donation may be used to make research studies possible. Some examples of the types of research are:

- New methods for testing for infectious diseases.
- Studies relating to testing, storing, collecting, and processing blood.
- Studies of ways to recruit blood donors and evaluate donor eligibility.

Will my results and information be kept confidential if they are used for research purposes?

- Samples used by researchers will have your identifying information removed. Only authorized blood center personnel can link samples to your identifying information.
- Strict procedures are observed at all blood collection facilities to maintain your confidentiality. Identifying information will not be revealed to anyone unless required by law.

How might my sample be tested and will I be informed of results?

- Samples linked to your identifying information may be used for infectious disease testing to provide safe blood.
- You will be notified in person, by phone, or by letter, about any test results that may impact your health.

What will happen if my blood sample or information is stored for future research on blood safety?

- If your sample is stored for research purposes, only authorized blood center personnel can link it to your identifying information.
- Your identified sample and information will not be used for research unrelated to blood safety or advancing biomedical knowledge.

What benefit will I receive for participating in a research study?
No benefit will be provided directly to you. However, use of blood donor data and samples for research provides for increased blood safety and understanding of health and disease.

Does my participation create any risk for me?
The risk of participating in these research studies is very small. There is a very low chance that your blood sample may give a result that means the blood that you donate will not be used for transfusion and there is a possibility that you may not be able to donate again. If this happens, additional testing may be available to help clarify the results and we will discuss these results and your eligibility to donate with you.

What else may happen due to my participation?
If your test results are positive or unexpected, you may be asked to participate in a follow-up study. Participation is voluntary and of no cost to you. Follow-up studies frequently involve completing a short questionnaire and providing additional samples for further testing. Information about follow-up studies will be provided to you before requesting your participation. Should you choose to participate, an additional informed consent process will be required.

What are my rights?

- You may refuse to participate by notifying blood collection staff that you do not want your donation to be used for research and that you will not be donating blood or blood components today. If you decide to withdraw after leaving the donation site, contact the blood center at 800-289-4923 . However, test information collected before your withdrawal request may still be used after you are removed from the study.
- If you decide that you do not want your donation to be used for research, you will not be able to donate today. It is very important to include all blood donors and their donations in possible research studies to continue to provide a safe and effective blood supply.
- If you decide not to participate at this time, your decision will not change your future relationship with the blood center.

Whom should I contact if I have more questions?
For more information about research uses of your blood or information, call our Donor Counseling Service at 800-289-4923 . If you have questions about your rights as a research participant, call the Western Institutional Review Board administrator at (360) 252-2500).

By signing your Blood Donation Record , you are giving consent to allow us to use a portion of your blood donation and information for research purposes.

You may keep this information sheet for future reference.