

Parent Consent Form

BLOOD DONOR ID NUMBER (BloodSource Staff Use Only)

Every day people like you need blood: students, teachers, family, and friends! The only source is generous volunteers like you! In fact, high school students donate over 18,000 lifesaving pints of blood with BloodSource each year!

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 your 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 may be able to give more with automated blood collection.

BLOOD DONOR QUALIFICATIONS

In general, volunteer blood donors must be 16 or older, weigh at least 110 pounds and be in good health.

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 donations 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%). 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.

- **Bring your signed parent consent form or turn it in ahead of time per school policy.** The signature block is below. Some schools may require parental consent for 17 and 18-year-old donors as well.
- **BRING A PICTURE I.D.** (driver’s license or student body card)
- You must pass the physical and health history examination given prior to donation. If you have any questions regarding your eligibility, please call 866.822.5663 to speak to one of our nurses.
- Eat a healthy meal before donating, even if you do not normally eat three meals a day.
- Drink 16 ounces of fluid 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, 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 is specially trained to respond to donor reactions. We will:

- Ask your student about their health, medication use, sexual behavior, travel and other risk factors for infectious disease during a private and confidential interview.
- Teach your student muscle tensing exercises to use during and after donation.
- Provide your student post-donation instructions.
- Provide refreshments & a snack.
- Tell your student to spend at least 15 minutes in our refreshment area.

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 Parent Consent form in order to donate.

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. BloodSource medical professionals are mandated by California law to report abuse and/or neglect involving anyone under the age of 18. 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 within research information document(s) available on our website. We are required to get parental consent for both 16- and 17-year old donors for this research.

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

Minor Donor’s Name (Please Print)

Signature of Parent/Guardian

Date

Parent/Guardian’s Name (Please Print)

On the day my student donates, I can be reached at the phone number listed above.

(PLEASE SIGN IN BLUE OR BLACK INK ONLY)

Donor’s Date of Birth:

Donor’s Age:



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: (602)343-7197

Additional Contacts: Sub-Principal Investigator: Dr. Jonathan Hughes at (916) 453-3726
Donor Counseling Service: Kathy Castillo at (916) 453-3726

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 a new test to detect the 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 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), and Hologic, Inc. 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 (916) 453-3726, Monday through Friday between the hours of 9:00 AM to 5:00 PM. 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.

BloodSource Medical Department: Dr. Jonathan Hughes
10536 Peter A McCuen Blvd
Mather CA 95655
(916) 453-3726

California Experimental Research Subject's Bill of Rights

Any person who is requested to consent to participate in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Learn the nature and purpose of the study (also called "experiment", "clinical trial" or "research")
2. Receive an explanation of the procedures to be followed in the medical study, and a description of any drug or device to be used.
3. Be informed of any related discomforts and risks that can reasonably to be expected from participating in the study.
4. Learn about any benefits you might expect from the study, if applicable.
5. Be told about any other procedures, drugs or services that might be helpful to you and the relative risks and benefits of these alternatives.
6. Be informed of the medical treatment, if any, available to you if you are injured because of the study.
7. Ask any questions about the study.
8. Stop the study at any time without any effect on your healthcare benefits or medical care, even if you stop the study.
9. Receive a copy of the signed and dated consent form when one is required.
10. Decide to consent or not to consent to a medical study without feeling forced to participate.

Hologic®
B10383-ZIKVPS-CSP-01