

Young Donor Consent Form

INFORMATION ABOUT DONATING BLOOD

Common Questions About Blood Donation

Q Is blood donation safe? Does it hurt?

A Not only is it safe, it is simple and it saves lives. Materials are new, sterile and discarded after each donation. At the time of the needle stick, you will feel a minor pinch at the site.

Q How long will it take?

A The entire process takes about an hour and includes sign in and donation screening; a mini- physical (blood pressure, pulse and finger prick to check blood count) and post-donation refreshments. The donation itself takes about 6-8 minutes.

Q Who can donate blood?

A Volunteer blood donors must be at least 15 years old, weigh 110 pounds and be in general good health. 15-, 16- and 17-year olds require this signed Young Donor Consent Form to donate.

Q Are there any limitations to eligibility?

A Here are a few common eligibility concerns answered:

- Acne treatments: Okay, if taking antibiotics for acne, but one-month wait after having taken Accutane (isotretinoin) or other medication containing this active ingredient.
- Allergies: Antihistamines and/or allergy injections are okay.
- Body and Ear piercing: Okay if performed in a jewelry store or doctor's office with sterile technique or by using new sterile earrings (or equipment). Otherwise, wait one year.

Blood Donation Defined

Whole-Blood Donation

When donating whole blood, the most common donation, all parts of the blood are collected simultaneously. The three major components are red cells, platelets and plasma. Blood is collected from the donor's arm vein and transferred into a bag specially designed to store blood.

Automated or "Apheresis" Blood Collection

(17-year-olds only)

While whole-blood donations collect all parts of the blood simultaneously, apheresis donations take only a specified component of blood – red cells, platelets and/or plasma – that are required to treat patients who are currently in need.



 **LifeStream**
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WWW.LSTREAM.ORG

Donors: Prepare To Be A Lifesaver!

1. If you are 15, 16 or 17 years old, please **bring this signed Young Donor Consent Form** when you donate.
2. **Bring a photo ID** with proof of age.
3. Eat up! Drink up! Get moving!
 - Eat up: Treat “blood donation day” as any other day. Don’t skip or add meals. Consume foods high in iron and Vitamin C, and salty snacks.
 - Drink up: Hydrate on donation day – water is best. Your blood will flow smoother and quicker, and you’ll be done faster!
 - Get moving: While lying down during your donation, flex your ankles and gently tense the muscles in your legs and glutes. These simple exercises will help keep your blood moving for a relaxing, rewarding donation.

NEW INFORMATION ABOUT IRON: Teenagers usually have lower iron levels than adults, and donating blood can make those levels even lower. There is no evidence that donating blood is harmful to young blood donors. However, in light of this information, you should consider iron supplements for your teenager. **Please talk to your healthcare provider**, and ask if your teen blood donor can take a multivitamin with iron or a low-dose iron supplement (18 mg of iron every day for 60 days after donation). For more information on iron and blood donation, please see www.LStream.org/iron-in-teens

PARENTS/GUARDIANS: On the day of donation we will help your child throughout the donation process. Our staff is specially trained to ensure a great experience, and every donation site is staffed with a Registered Nurse to handle potential reactions.

Some Potential Side Effects

The risks associated with blood donation include redness or bruising around the needle site (common); a sore arm; feeling dizzy, tired or weak; fainting (uncommon); irritation to arteries, nerves and tissues around the vein used for donation (more rare); temporary lower blood volume and blood counts. With automated or apheresis donations, other risks also include tingling or cold feeling; and possible allergic reactions.

Other Information

To protect patients, blood donations are tested for several types of hepatitis, HIV, syphilis, and other infections as required by law. If your child tests positive or false positive (positive test when the donor really doesn’t have the infection) he/she will be notified and results will be disclosed as required by law. In some cases, blood center staff may need to discuss test results with your child/donor. Per California law,

it is the donor’s decision whether his/her parents/guardians are to be included in that discussion.

To improve blood safety we may use your child’s donation history information and a sample of their blood, in a confidential manner, as described in the accompanying research information document. We are required to get parental consent for 15-, 16- and 17-year old donors for this research. For more information about this research or blood donation, go to www.LStream.org/zikaresearch.

Experimental Research Subject’s Bill of Rights

California law, under Health & Safety Code §24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

- 1 Be informed of the nature and purpose of the experiment.
- 2 Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- 3 Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- 4 Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- 5 Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- 6 Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- 7 Be given an opportunity to ask any questions concerning the experiment or procedures involved.
- 8 Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
- 9 Be given a copy of the signed and dated written consent form.
- 10 Be given the opportunity to decide to consent or not to consent to a medical experiment without intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject’s decision.

Please be sure that you and your child have read the information provided. Your child must bring this signed **Young Donor Consent Form** to their donation site in order to donate.

By signing below, I give my permission for my child to donate and for that donation to be tested as explained above.

MINOR DONOR’S NAME (PLEASE PRINT)

PARENT/GUARDIAN’S NAME (PLEASE PRINT)

SIGNATURE OF PARENT/GUARDIAN

DATE

PHONE NUMBER AT TIME OF BLOOD DRIVE

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, Ph.D.

Telephone: Donor Counseling Service/Medical Surveillance 800.879.4484 x655

Additional Contacts: D. Joe Chaffin, M.D. 323.203.7582

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.

The results of all testing on your donation during this study are confidential, except when reportable by

Zika Virus Research Information

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 800.879.4484 x655, Monday through Friday 8 am to 5 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.