

Parental Consent Form

Your child has expressed interest in donating blood, and students will be requested to donate blood. Because one blood donation can be separated into three components, your child has the potential to support three lives. We hope you will support and encourage your child's decision to donate. Blood donation is a safe procedure using single use, sterile supplies. Donors with no history of medical problems usually have no adverse reactions to donating blood. On occasion, there are donors who experience mild to moderate side effects, including pain, bruising, nerve injury, lightheadedness or fainting, which can occur during or shortly after donation. Rarely, fainting reactions can be delayed and occur after leaving the donation area or facility. Frequent red blood cell donation may also result in low iron levels or iron deficiency. Drinking plenty of fluids and eating well prior to donation may reduce these effects, so please encourage your child to eat a healthy breakfast and lunch and to drink extra water or fluids before they donate.

You may have questions regarding whether your child should donate. Donors must be at least 16 years of age on the date of the donation, weigh at least 110 pounds, and not have any symptoms of the cold or flu. There are other guidelines to be eligible to donate. **If you wish to discuss donor eligibility, please call the Medical Help Desk at 1-800-310-9556.**

Your child may be eligible to donate a double unit of packed red blood cells by an automated procedure where blood is collected and sent to a machine that keeps the red blood cells only and then returns platelets, plasma and normal saline to the donor. Donors who donate using the automated collection machine may experience significantly fewer side effects than donating whole blood.

Every donation is tested for HIV (the virus that causes AIDS), hepatitis B and C viruses, and other infectious diseases. If any test result disqualifies your child from future donation, we will communicate directly with your child and address any follow-up questions directly with them. We maintain the confidentiality of information that we obtain about our donors, and we will release a donor's confidential information to his or her parents only with the donor's consent.

This is a legal document required to allow your child to donate blood, please complete this form in ink and give it to your child who must present it when he or she registers to donate. 16 or 17 year olds may not donate without a signed Parent/Guardian Consent Form. In addition to this consent form, your child will need to bring documentation that includes full name, date of birth and a unique identifying number. For example, the last four digits of his/her social security number or other ID such as school ID, Drivers License, State ID, US Passport, birth certificate.

Your child will be asked to read and sign the following Donor Informed Written Consent prior to donating blood. For packed red cell donation, your child will also be asked to sign a separate consent.

DONOR INFORMED WRITTEN CONSENT

I am voluntarily donating my blood to the Blood Center for transfusion and other medical and scientific purposes including research studies. In doing so, I hereby give my informed consent to perform the procedures necessary to collect and test my blood. I understand that trained personnel will insert a needle into my arm to collect blood. I am aware that as a result of the procedure complications such as infection, nerve damage, muscle damage, hematomas and other forms of injury could occur. I am willing to undergo the risks involved in this procedure in order that I may donate my blood. I am aware that my blood will be tested for diseases that could be transmitted through a blood transfusion. I am aware that the test results will be recorded. If the results are positive or questionable and could present a risk to my health, I will be notified and my name will be placed on a permanent deferral list. My test results will be reported to health agencies as required by law. I understand that in some instances, such as when an insufficient sample is taken, testing for infectious disease is not possible. As a result, the unit of blood is discarded. I should not assume that my test results are negative, since testing cannot always be performed. I know or have been told that my blood will be tested for the presence of the Human Immunodeficiency Virus (HIV), the virus that causes AIDS. The tests have been explained to me, including their purposes, potential uses, limitations and the meaning of the results. I specifically consent to the performance of HIV-related testing. Information has been given to me about the prevention, exposure to and spread of HIV. I have also received information regarding the spread of HIV by the transfusion of blood and blood products. I verify that to my knowledge the use of my blood does not present a risk for the spread of any infectious disease, including AIDS. I have been given the opportunity to ask questions and all the questions that I have asked have been answered to my satisfaction. I have read the above statements.

(The bottom section of this form MUST be accurate and Completed in INK)

I understand that my son/daughter must bring this signed parental consent form and appropriate identification to the blood drive.

I HAVE LEGAL AUTHORITY AND I CONSENT TO MY CHILD'S BLOOD DONATION.

(Print in ink Parent/Guardian Name)

(Sign in ink Parent/Guardian name)

(Date)

16 or 17 YEAR-OLD DONOR INFORMATION:

Child's Full Legal Name: _____

Child's Date of Birth: _____

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: Dr. Mona Papari, (847) 260-2694

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 man, 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 a voluntary follow-up study involving additional blood samples. Should you choose to participate, an 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), 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 **1-800-310-9556**. 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.

Although you feel well and healthy at the time of your donation, please call us immediately at the phone number beside our donor center's name below if you develop any of the following symptoms within 14 days of your blood donation:

- Fever
- Rash
- Muscle or joint pain
- Eye pain or redness
- Headache

By notifying us as soon as possible after developing any of these symptoms you may prevent the blood you donated today from being transfused and possibly infecting a patient.

NOTE: If you recall being in an area where Zika is actively transmitted in the past 4 weeks, please call us. Although you are feeling well, you could be infected with Zika.

Medical Help Desk 1-800-310-9556