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UCLA Blood & Platelet Center

Parent/Guardian Consent Form for Blood Donation

Our goal is to provide donors with a positive donation experience and patients with safe blood. In order to accomplish this goal, please read the blood donor information on our website (www.gotblood.ucla.edu) as well as the following information to help prepare your child for their blood donation. Please feel free to contact the UCLA Blood & Platelet Center at (310) 825-0888 ext. 2 if you have any questions.

Important Information about Donating

Donating blood is a safe and simple process that uses single-use sterile supplies. Nevertheless, on rare occasions, temporary medical complications may be associated with donating blood, including bruising, dizziness, fainting, nausea and even more rarely, infection and nerve injury. Drinking plenty of fluids and eating well can help reduce reactions. It is important for donors to follow the post-donation instructions provided by the UCLA Blood & Platelet Center staff in order to help manage or avoid developing complications after the donation is completed.

- I have read and understand the information provided about donating blood. I am aware that my child (listed below) plans to make a voluntary donation.
- My child is at least 16 years old.
- I understand that my child will answer confidential questions regarding his or her health history.
- I understand that all donated blood will undergo laboratory testing for viral agents and diseases, including HIV, Syphilis, Hepatitis B virus, Hepatitis C virus, and other infectious agents as required by applicable laws or regulations. These tests are performed to protect the patients who receive blood. Testing for other infectious agents may involve the use of investigational tests.
- Abnormal (positive) test results will be disclosed 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/guardians are to be included in that discussion.
- I understand that donated blood is intended for patient use; any blood that cannot be used for patients (for example, due to positive test results) may be used for other purposes.

Please complete in blue or black non-erasable ink. Do not use white out.

To be completed by parent/guardian:

I am aware that my child plans to make a voluntary blood donation. By signing below, I am giving my consent for him/her to donate blood. My consent applies to this one donation.

Parent/Guardian Printed Name	Parent/Guardian Signature	Date

Parent/Guardian Phone Number *(On the day my child donates, I can be reached at this phone number.)*

To be completed by minor (donor):

By signing below, I understand that I will be notified of test results that are important to my health or which may affect my eligibility to donate blood, including the results of testing for HIV (the AIDS virus). I understand that a new Parent/Guardian Consent form is required for each time I donate until my 18th birthday. I understand that the UCLA Blood & Platelet Center may contact my parent or guardian to confirm his/her permission for me to donate blood.

Donor Printed Name	Birthdate	Donor Signature	Date

Present this signed consent form at the time of donation.

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:	(602) 343-7197
Additional Contacts:	Sub Principal Investigator, Dawn Ward, M. D. (310) 794-4969 Donor Center Counseling (310) 267-2686

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 (310) 267-2686, Monday through Friday 8:00 AM to 6:00 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.**