MEDIC
REGIONAL BLOOD CENTER
1601 Ailor Avenue
Knoxville, TN 37921
865.524.3074

Parental/Guardian Consent for Young Blood Donors

THE FOLLOWING CONSENT MUST BE COMPLETED AND RETURNED TO THE BLOOD CENTER STAFF ON THE DATE OF THE BLOOD DRIVE ALONG WITH POSITIVE ID!

Please complete this form in black/blue ink and print the following information for the donor.

First Name: _____ Middle Initial: ____ Last Name: _____

Date of Birth: _____ Age: _____ Weight: _____ Social Security Last Four: _____

High School (if applicable): _____

Name of Parent/Guardian: _____ Relationship: _____

Address of Parent/Guardian: _____

_____

Contact Number (**where parent/guardian can be reached during the day**):_____

I certify that:

- **I have read and fully understand this consent (on the reverse).**
- **I have read the Zika Virus Research Information.**
- **I have asked and had answered any questions I have regarding the donation of blood.**
- **I give my permission for my 16/17 year-old son/daughter/ward to donate blood to MEDIC Regional Blood Center.**
- **I certify that my son/daughter meets the minimum weight criteria of 120 pounds for 16 year-old donors and 110 pounds for 17 year-old donors.**

Signatures:

Parent/Guardian Signature: _____ Date: _____

Young Donor Signature: _____ Date: _____

THIS COMPLETED CONSENT ALONG WITH POSITIVE ID MUST BE PRESENTED AT TIME OF CHECK IN!

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: For Immediate Assistance (Sub Principal Investigator): Dr. T. Watkins 865-524-3074

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 865-524-3074, Monday – Friday 9:00 AM to 4:00 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.**

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Parental/Guardian Consent for Young Blood Donors

Your son/daughter has been asked or has made the decision to give the gift of life by donating blood. We hope you encourage your child to participate in blood donation. He or she is showing great responsibility, maturity and a sense of community pride by becoming a blood donor.

In order to donate, your child must be at least 16-years-old and weigh 120 pounds or be 17-years-old and weigh 110 pounds and be in good general health.

On the day of donation, your child should eat a good meal and be well hydrated. Additionally, your child should have a good understanding of his/her health history prior to donation. Your child will be asked a series of questions that are personal in nature. They will be asked questions regarding any medications that they are currently taking and why they are taking them. There will be questions regarding intravenous drug use and travel outside the United States, along with other questions designed to increase the likelihood of a good donation experience for your child, and a safe blood product for the patients that will receive the blood. There will be questions regarding past sexual practices. Please keep in mind that all people do not define sex in the same way. To ensure that we maintain a safe blood supply, the Food & Drug Administration requires these questions be answered honestly.

Testing is done on each donation to detect various infectious agents that can be transmitted by transfusion, including HIV and hepatitis. If there are any abnormal laboratory results, the results will be released to your child, and will be shared with you if your child is 16-years-old or the test is investigational. (By signing below, a child consents to this disclosure.) However, if your child is at least 17-years-old, results will only be released to the donor, except for investigational test results. Otherwise, all health history information will be strictly confidential except as required by law.

Blood donors may give either whole blood or, they may donate red cells using a method called apheresis. In apheresis, the blood is drawn into a machine (the ALYX) that separates blood into components. With apheresis, possible side-effects may include: lightheadedness, tingling of hands & feet, numbness or tingling around the mouth, muscle discomfort, muscle twitching or spasm, sensation of coolness or chills, skin redness, hives, itching, dyspnea, dizziness, pallor, feeling of warmth and excessive tiredness. Although very rare, air embolism, blood clotting or hemolysis could occur.

Your child will be asked to read and sign the following donor consent on the day of donation:
I have reviewed and understand the information provided to me regarding the spread of the AIDS virus by blood or plasma. If I am potentially at risk for spreading the virus known to cause AIDS, I agree not to donate blood or plasma for transfusion to another person or for further manufacture. I understand that my blood may be used for transfusion, further manufacture, or research.

I understand that my blood will be tested for laboratory evidence of infectious agents capable of being spread through blood transfusion including, but not limited to, hepatitis, the AIDS virus, and other clinically important viruses. I understand my blood may be tested for other disease by additional tests thought to improve the safety of the nation's blood supply as they become available. If a test result is either positive or unclear, my blood will not be used and my name may be placed on a deferral list. State health authorities will be notified of certain positive test results. I understand that if I am determined to be ineligible to donate that my record will include this information. I understand there may be circumstances in which infectious disease tests will not be performed.

The blood donation process includes:
- screening (medical and social history; blood pressure, pulse, temperature and hemoglobin tests)
- cleansing of the arm and insertion of a sterile needle for one-time use
- collection of approximately one pint of blood
- refreshments, rest, and post-donation care instructions to help ensure your well-being

Though the blood donation process is generally safe and well tolerated, mild to severe adverse reactions may occur. These reactions could include dizziness, nausea and vomiting, bruising, hematoma, an allergic reaction, fatigue, loss of consciousness, nerve damage or arterial puncture. Loss of iron from the body will also occur. Iron is needed to make new blood cells to replace those lost from donation and other processes. Donating blood reduces iron stores in the body. In many people, this has no effect on their health. However, in some people, blood donation may remove enough iron that it may impact their iron stores. Symptoms of low iron levels may include fatigue, decreased exercise capacity, restless leg syndrome, and pica (craving to chew things such as chalk or ice). I understand I should speak with my health care provider if I have questions about my iron stores or questions about taking iron supplements.

MEDIC Blood Coverage **(donor and IRS dependents)** does not apply to pre-existing conditions diagnosed or treated within the 12 months prior to an application or donation for membership.

My signature certifies that (1) I have read the consent statement for whole blood or apheresis donors, (2) I understand the procedure of donating and the possibility of an adverse reaction, (3) the information I have given is true and accurate, (4) I am voluntarily granting MEDIC Blood Center permission to draw approximately 500 milliliters (approximately one pint) of my blood, (5) my questions have been answered, (6) I understand I have the right to stop the procedure at any time, and (7) if I have been told I am being deferred for any reason, this has been explained to me and I understand the reason for deferral.

If you have any question or concerns regarding the donation process, please call MEDIC at 865.525.3074 or visit our website at www.medicblood.org.