



Your Community Blood Bank

Corporate Office:
8167 Adams Drive
Hummelstown, PA 17036
(717) 566-6161 • 1-800-771-0059
Fax: (717) 566-7850
www.cbpb.org

PLEASE COMPLETE THE FORM IN INK

Blood Donor Parent/Guardian Consent Form

Please review the back side of the form for additional testing information

Your child has expressed an interest in donating blood. One blood donation can be separated into three components; your child has the potential to save three lives with a single donation. We hope you support and encourage your child's decision to donate blood. He or she is showing civic responsibility, maturity and a sense of community pride by donating.

Blood donation is a safe procedure using single use sterile supplies. Reactions such as lightheadedness, fainting, bruising or nerve injury occasionally occurs. Drinking plenty of fluids and eating well prior to donation can reduce donor reactions.

State law generally requires written consent by a parent or guardian for 16-year-olds to donate blood. In addition, if donating at a high school blood drive, some schools may require written consent for older students.* If you consent to your child's donating, please complete the consent form at the bottom of this page.

All blood donations are screened for certain blood borne diseases. These tests, on occasion, may be considered investigational. You and your child will be notified if the donation tests positive for these diseases. Your child may also be contacted for follow-up testing. Donors with a positive test may be placed on a deferral list and their blood cannot be used for treatment or care purposes. Positive test results and the donor's name are reported to health agencies as required by law. In some instances, such as when an insufficient amount of blood is collected, testing for infectious diseases may not be possible.

If you have questions regarding your child's decision, please call our Donor Advocate at 1-800-771-0059 ex. 3019.

* Persons 17 years of age or older (or certain emancipated minors) may donate without consent of parent or guardian (unless required by your high school).



Please fill out form below and return only the form portion during donation. Keep the top for your records.

Central Pennsylvania Blood Bank

Please use ink to complete this form.

Having read and understood this entire form, I give permission/consent for (Please Print) _____, my son/daughter or ward, to make a voluntary, uncompensated donation of blood to Central Pennsylvania Blood Bank.

Central Pennsylvania Blood Bank will notify my child and me of a positive test result(s) for certain blood borne diseases and my child may be contacted for follow-up testing. If tests are confirmed positive for HIV, hepatitis or syphilis (or other diseases as may be required by law or regulation), my child's name will be reported to the Department of Health.

This signed consent is valid for one (1) year or until child turns 17, unless earlier revoked by written notice from parent, guardian or child.

I verify that I am the undersigned donor's parent/guardian and that such donor lives with and is supported by me. In the event of an emergency, I may be contacted at the following telephone number: _____

Print Parent/Guardian Name: _____

Signature of Parent/Guardian: _____ Date: _____

Having read and understood this entire form, I give my permission/consent to Central Pennsylvania Blood Bank to release certain positive test results to my above-named parent/guardian.

Signature of Donor: _____ Date: _____

Donor's Date of Birth: _____

Version 03 (10/2016)

Important Reminder

The completed consent form must be presented at the time of donation to be accepted.

“Investigational testing” or “research testing” is testing that we do on the blood because it is required by our regulatory agencies, however, the test is still under evaluation for accuracy and effectiveness. If a donor’s blood tests positively with investigation testing, the donor will be notified and will be contacted to determine if he or she wishes to participate in additional testing that is available. Participation in this second phase of testing is not required.

Currently, we are using an investigational test to screen the blood for the Zika virus. Zika is a virus that is spread to humans primarily through the bite of an infected mosquito (*Aedes aegypti* and *Aedes albopictus*). Zika can also be spread through sexual contact from an infected man to a woman. Most people who become infected with Zika have no symptoms. It is very rare for Zika to cause death. However, if a pregnant woman should become infected with Zika virus, she can transmit the virus to her unborn child, which can result in severe birth defects. Because Zika can be transmitted by transfusion of blood products, our regulatory agencies are requiring that we test for the virus.

In keeping with the rules set down by the FDA, all blood used for transfusion must be tested for Zika virus. If you do not want your child’s blood to be tested, they should not donate and you should not sign the consent form. If you would like additional information on Zika, please refer to the Center for Disease Control’s website: www.cdc.gov/zika. You may also contact the Central Pennsylvania Blood Bank’s Donor Advocate at 1-800-771-0059 extension 3019.

RESEARCH PARTICIPANT INFORMATION SHEET

Protocol Title: A Prospective Study to Evaluate the Specificity of the **cobas®** Zika Test for use with the **cobas®** 6800/8800 System for Screening of Blood Donations for the Presence of Zika Virus RNA

Study #: cX8-ZIKA-412

Sponsor: Roche Molecular Systems, Inc.

Principal Investigator Name: **Scott W Hall MD, PhD**

Research Site Address(es):

Blood Bank of Delmarva
100 Hygeia Dr
Newark DE 19713

Daytime Telephone Number(s): 302-737-8405 Ext. 789
24-hour Contact Number(s): 302-545-2956

Additional contact information for your local blood donation center: Please refer either to the donation consent document that you signed at your local donation center or, if your donation consent was electronic, to your local donation center's website.

This donor center is doing a research study on a new test system used to detect Zika Virus. To participate, you must meet the following criteria:

- You must meet the standard donor eligibility criteria.
- If you are a minor (for example age 16-17 years), you may participate if you have obtained permission of a parent (or legal guardian), where required by law, to donate blood and you assent to donate blood.

If you donate, your test results will be used to evaluate the new test system. 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. Because of changes in blood screening regulations, your participation in this research study is necessary in order to donate today. Your alternative is to not donate today. If your test results show that you may have a Zika virus infection:

- This donation center will attempt to contact you only if your test results show that you may have a Zika virus infection and their significance will be explained. You will not be contacted if your results do not show that you may have Zika virus infection.
- You will be invited to participate in a voluntary follow-up study involving additional blood samples and you will be asked to sign an additional consent form.
- You should discuss these results with your primary care physician. You should discuss the potential

risk of sexual transmission of the Zika virus, and the potential harm to the fetus during pregnancy with either your physician or your donation center.

At any time, 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.

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. You will not be paid for your participation in this study. The risk of having your donation tested with the study test is not any greater than having your donation tested for other infectious diseases.

Your participation in this study is voluntary. If you decide not to participate after your donation is taken or not to donate today, there is no penalty to you. If you have questions about this study or would like to withdraw from further participation in this research study, call the Principal Investigator at the number(s) above.

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 Roche Molecular Systems, Inc.

If you have questions about your rights as a study participant call the Copernicus Group Independent Review Board (IRB) at 1-888-303-2224. An IRB is a group of people who review research independent of those sponsoring and doing the work. Please visit the Copernicus Group IRB website www.cgirb.com for more information about research studies and the role of a research study participant.