Parental Information on Blood Donation

Your son or daughter has expressed interest in donating blood with BloodCenter of Wisconsin. In Wisconsin, a minor who is at least 16 years old may become a blood donor, if the minor’s parent agrees. After age 17, the consent of the minor’s parent is not required. A Consent to Blood Donation form for 16-year-old donors is required each time the minor donates. This form will provide you and your son or daughter with important information about blood donation.

We hope that you will support and encourage your son or daughter to become a blood donor. By becoming a blood donor, your son or daughter is showing great civic responsibility, maturity and a sense of community pride. Through blood donation, your son or daughter can positively impact the health of a patient.

The Donation Process. There are four steps to the donation process:

1. Registration – Each donor is required to present a picture ID with the donor’s date of birth and complete a list of health-related questions.

2. Medical Evaluation – The medical evaluation ensures safety for both the blood donor and recipients. In order to donate, an individual must be in good health, be at least 16-years-old, and weigh at least 110 pounds (see below for additional height and weight criteria). Each prospective donor will meet privately with a donor specialist who will check the donor’s blood pressure, temperature and pulse, and take a small drop of blood from the donor’s finger to test the donor’s blood count.

<table>
<thead>
<tr>
<th>MALES</th>
<th>4’ 10”</th>
<th>4’ 11”</th>
<th>5’ or taller</th>
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</thead>
<tbody>
<tr>
<td>You must weigh at least</td>
<td>120lbs.</td>
<td>115lbs.</td>
<td>110lbs.</td>
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<table>
<thead>
<tr>
<th>FEMALES</th>
<th>5’ 1”</th>
<th>5’ 2”</th>
<th>5’ 3”</th>
<th>5’ 4”</th>
<th>5’ 5”</th>
<th>5’ 6” or taller</th>
</tr>
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<tbody>
<tr>
<td>You must weigh at least</td>
<td>133lbs.</td>
<td>129lbs.</td>
<td>124lbs.</td>
<td>118lbs.</td>
<td>115lbs.</td>
<td>110lbs.</td>
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*Females: If you are shorter than 5’ 1”, you may still be eligible to donate blood. Call our Record Review Department at 414-937-6070 to ask about your eligibility.

3. Blood Collection and Testing – Blood is collected through a sterile needle inserted into the donor’s arm. The actual blood donation takes about 10 minutes. To ensure the safety of persons who may receive donated blood, all donated blood is tested for ABO blood typing, HIV (the virus that causes AIDS), hepatitis B and C, West Nile virus, syphilis, and other illnesses. All donor information is kept strictly confidential; however, if any of these screening tests are positive, BloodCenter will inform the donor and his or her parent/guardian. In some cases, the donor’s name may be entered in a registry of ineligible donors and we must inform certain government health agencies as required by law.

4. Refreshment and Relaxation – After the donation, donors are encouraged to spend time in the refreshment area. Snacks and drinks are provided to replenish fluids and energy levels. Also, it is important that the donor drinks plenty of fluids in the 24 hours after donation.

Potential Risks. There are some potential risks in donating blood, including: discomfort, swelling and bruising at the needle site; fainting and convulsions; injury to blood vessels or nerves; infection; and local blood clot. These risks are relatively uncommon.

Questions? If you have any questions or concerns about blood donation, please contact us at 414-937-6070 or visit our website at www.bcw.edu.

If you and your son or daughter want to proceed with blood donation, please read and sign and return the Consent to Blood Donation form with your child when they come to donate.
Are you donating blood today?
Would you be willing to take part in a research study?

BloodCenter of Wisconsin is adding a new test for *Babesia microti*, the parasite that causes Babesiosis, which may be spread by blood transfusion.

Babesiosis is caused by microscopic parasites that infect red blood cells and are spread by the same tick that transmits Lyme disease. Tickborne transmission in the US occurs mainly in parts of the Northeast and upper Midwest, including Minnesota and Wisconsin.

Many people who carry *Babesia* feel fine and have no symptoms. Others develop nonspecific flu-like symptoms, such as fever, chills, sweats, headache, body aches, loss of appetite, nausea, or fatigue.

Your blood will only be tested if your donation includes red blood cells. Donations limited to platelets or plasma will not be tested, as *Babesia* resides in red blood cells.

**Why is this study being done?**
- To evaluate an experimental laboratory test to detect exposure to the *Babesia* parasite.
- BloodCenter of Wisconsin is participating because the ticks that transmit the disease are common in our region.
- Area hospitals are starting to request *Babesia* tested blood products.
- Babesiosis can be a severe, life-threatening disease, particularly in people who have a weak immune system, have other serious health conditions, or are infants or elderly.

**What will happen if I take part in this research study?**
- Your blood will be tested for the antibody to *Babesia microti*.
- Blood samples collected today will be used in the study:

**What are the possible risks of taking part in Babesia testing?**
- Learning that your blood tested positive for Babesia exposure may cause you emotional distress and anxiety.
- If you have a positive screening test, BCW will contact you to discuss any necessary follow-up and you may be deferred from donating blood in the future (not allowed to donate blood) even if subsequent testing documents that it was a false positive test.
  - It is possible that this test may produce a false positive result for some donors. A false positive is like a false alarm on a home security or airport screening system.
  - When confirmatory tests are licensed, a reinstatement protocol for those who previously tested positive may be approved by the Food and Drug Administration (FDA), to allow you to once again be a blood donor.

**Are there any benefits for being in this study?**
- You may not benefit directly from taking part in this research study.
- Taking part in the study may help increase the safety of blood and blood products used for patients.
- However, in the unlikely event you found that your blood tested positive for Babesia, and it is confirmed, it may give you the chance to seek proper medical care.

Please read the following sheet for additional information on participating.

*Thank you for considering helping BloodCenter of Wisconsin and our research program!*
Use of Donor Information and Blood Samples in Research

This blood center performs research to help provide a safe and effective blood supply. Research studies are conducted to improve blood safety and contribute to advancing biomedical knowledge. Some research is conducted with other institutions, such as blood bank organizations, academic centers and biomedical companies.

Your participation in research studies is entirely voluntary.

What will happen if I agree to allow my blood to be used in research studies?
All research studies are evaluated and reviewed periodically by an independent committee that considers your rights as a research participant. Formal research studies are included in the clinical trial registry maintained by the National Institutes of Health for public access (www.ClinicalTrials.gov). Your participation will not require any additional procedures or time beyond the normal donation process. There will be no payments to you for your participation.

How might my blood or information be used in research?
A portion of your blood sample or information collected at the time of donation may be used to make research studies possible. Some examples of the types of research are:
- New methods for testing for infectious diseases.
- Studies relating to testing, storing, collecting, and processing blood.
- Studies of ways to recruit blood donors and evaluate donor eligibility.

What benefit will I receive for participating in a research study?
No benefit will be provided directly to you. However, use of blood donor data and samples for research provides for increased blood safety and understanding of health and disease.

Does my participation create any risk for me?
The risk of participating in these research studies is very small. There is a very low chance that your blood sample may give a result that means the blood that you donate will not be used for transfusion and there is a possibility that you may not be able to donate again. If this happens, additional testing may be available to help clarify the results and we will discuss these results and your eligibility to donate with you.

What else may happen due to my participation?
If your test results are positive or unexpected, you may be asked to participate in a follow-up study. Participation is voluntary and of no cost to you. Follow-up studies frequently involve completing a short questionnaire and providing additional samples for further testing. Information about follow-up studies will be provided to you before requesting your participation. Should you choose to participate, an additional informed consent process will be required.

What are my rights?
- You may refuse to participate by notifying blood collection staff that you do not want your donation to be used for research and that you will not be donating blood or blood components today. If you decide to withdraw after leaving the donation site, contact the blood center at 1-800-215-0061. However, test information collected before your withdrawal request may still be used after you are removed from the study.
- If you decide that you do not want your donation to be used for research, you will not be able to donate today. It is very important to include all blood donors and their donations in possible research studies to continue to provide a safe and effective blood supply.
- If you decide not to participate at this time, your decision will not change your future relationship with the blood center.

Whom should I contact if I have more questions?
For more information about research uses of your blood or information, call Natasha Leon at (414) 937-6412. If you have questions about your rights as a research participant, call the Western Institutional Review Board administrator at (360) 252-2500.

By signing your Blood Donation Record, you are giving consent to allow us to use a portion of your blood donation and information for research purposes.

You may keep this information sheet for future reference.
**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:** Julie Cruz MD

**Research Site Address(es):**
Indiana Blood Center
3450 N Meridian St
Indianapolis IN 46208

**Daytime Telephone Number(s):** 800-632-4722 Ext. 5101

**24-hour Contact Number(s):** 317-916-5279 9PM-7AM

**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/](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.

Rev. 31Oct2016