American Red Cross

Dear Parent or Guardian,

Your 16-year-old has expressed an interest in donating blood at an upcoming American Red Cross blood drive. The states of Arkansas, Illinois, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, Oklahoma, South Dakota, Tennessee, Texas and Wisconsin allow 16-year-olds to donate blood with written parental/guardian consent. We are asking for your support by completing the attached consent form.

Please read the attached information: "A Students Guide to Blood Donation" and additional information included on the back page of the Parental Consent for Blood Donation. If you have any questions about the information contained in these documents, please call 1-866-236-3276 to speak to a Red Cross representative.

We support each student's willingness to give blood and ask that you offer your encouragement too. Much like voting and driving a car, the opportunity to donate blood and save a life has become a rite of passage for thousands of high school students. Becoming a blood donor is a very personal decision, and we understand that parents and students may be somewhat apprehensive about taking this step. This is completely natural, so we want to provide you with some additional information about donating blood.

Blood donation is a safe procedure using single-use sterile needles and supplies. To ensure that your student has a positive experience, we recommend that they follow these guidelines:

- Get a good night's sleep before the blood drive.
- Eat well and drink plenty of fluids in the days leading up to the blood drive, especially the day of the drive.
- Drink at least 16 oz of caffeine free fluid (2 cups) 3-4 hours before the donation and after.
- Be honest and accurate about their weight (donors must weigh at least 110 lbs).

While the donation process is safe, reactions can occur. Most reactions are mild and can include fainting or small bruises. Our staff is fully trained to work with first-time and younger blood donors, and to respond to any reactions. We hope you will encourage your student to support our blood drive. Since one blood donation can be separated into three components, your student has the potential to save as many as three lives with a single donation.

Please note that the FDA requires that donors are asked specific questions about their health history. This information helps ensure the safety of the blood donor and the blood recipient. These questions are asked privately and are completely confidential.

You should be very proud of your son or daughter's decision to donate at the upcoming drive. *Please help support this act of generosity by completing the consent form prior to the drive.* If you are not currently a blood donor, please consider making an appointment for yourself. For more information call 1-800-RED CROSS (1-800-733-2767) or visit our website at redcrossblood.org.

Sincerely,

David C. Mair MD

David C. Mair, M.D., Chief Medical Officer

American Red Cross Biomedical Services
Washington, DC 20006

Form: Parental Consent for Blood Donation

Information
This form must be completed by a parent or legal guardian for blood donation by a minor when parental consent is required by state law or American Red Cross policy. Please call us at **1-800-RED-CROSS (1-800-733-2767) or visit www.redcrossblood.org** if you have questions or concerns about the blood donation process.

Parental Consent
I have read and understand

- The information on the back of this form
- "A Student's Guide to Blood Donation"
- Any research-related study sheets that were provided

In giving consent for your son, daughter, or ward to donate blood, you have **two options.**
Please complete Option 1 or Option 2 to indicate what type of donation you are consenting to.
(Please use medium-point black pen.)

OPTION 1: Whole Blood Donation Only

I hereby give permission for my son, daughter, or ward to make a whole blood donation to the American Red Cross.

Donor Name: (son, daughter, or ward) _____
Print Name

Parent/Guardian Name: _____
Print Name

Parent/Guardian Signature: _____
Signature *Today's Date (mm/dd/yyyy)*

Optional Parent/Guardian Phone Number: _____
Where you can be reached on day of donation

OPTION 2: Apheresis or Whole Blood Donation

I hereby give permission for my son, daughter, or ward to give blood by either apheresis or whole blood donation to the American Red Cross *(see back of form for details).*

Donor Name: (son, daughter, or ward) _____
Print Name

Parent/Guardian Name: _____
Print Name

Parent/Guardian Signature: _____
Signature *Today's Date (mm/dd/yyyy)*

Optional Parent/Guardian Phone Number: _____
Where you can be reached on day of donation

For American Red Cross Use Only WBN/DIN _____

Information for Parents
Please read the information below, which supplements the brochure called "A Student's Guide to Blood Donation."

Donor Screening
- We will ask your son, daughter, or ward questions about his or her health and medication use, sexual behavior, travel, and other risk factors for infectious diseases during a private and confidential interview.
- Every donation is tested for HIV (the virus that causes AIDS), hepatitis B and hepatitis C viruses, and other infectious diseases.
- If any test result or response to the questions suggests that your son or daughter is disqualified from donating blood in the future or may have an infectious disease, his or her name will be added to a confidential list of people who have similar test results or risk factors. When required, we report donor information, including test results, to health departments and regulatory agencies.
- The tests are very sensitive and detect most infections. But it is also possible that donors who are not infected will have falsely positive results. We are required to notify and disqualify donors even when subsequent test results indicate that the donor is not infected.
- We will communicate test results that disqualify your son or daughter from future donation directly with your son or daughter. We maintain the confidentiality of information we obtain about a donor and we will release a donor's confidential information to his or her parents only with the donor's consent.

Whole Blood Donation
- Each whole blood donation uses a new, sterile needle to collect about a pint of blood from a vein in the donor's arm.
- Most donors feel fine before and after donating blood, but some may have a lightheaded or dizzy feeling; an upset stomach; a black and blue mark, redness, or pain where the needle was; fainting or loss of consciousness and injury from related falls; or very rarely, nerve or artery damage.
- Young, first time, or low-weight donors are more likely to experience reactions than other donors.
- Blood donation removes iron and may cause or aggravate iron-deficiency anemia.

Apheresis (automated collection procedures, including two-unit (double) red cell collections)
- Apheresis is a type of blood donation in which we collect specific components of the donor's blood (platelets, plasma, or red cells). We place a needle in one or both of the donor's arms and use a machine to draw blood and separate it into different parts. One or several of the blood components are removed while the remainder and extra fluids are returned to the donor.
- Apheresis has the same risks as whole blood donation (see above). In addition, citrate is used during apheresis to prevent blood clotting. Citrate may cause chills, tingling sensations, feelings of anxiety, tremors, muscle cramping, numbness, nausea, vomiting, and/or convulsions. Donors may be given oral calcium supplements during the apheresis procedure to manage these symptoms. Very rarely, donors can experience allergic reactions (for example, skin rashes, hives, localized swelling, and/or flushing), air in the bloodstream, infection, or other complications.
- Repeated donation may result in iron depletion, anemia, fatigue, or changes in blood cell counts.

Research
- We may confidentially and anonymously use the information or leftover blood samples we collect from donors for medical research, such as research on ways to increase the safety of the blood supply.
- By giving your son or daughter permission to donate blood, you are also consenting to the use of the donation and donor information for this type of research.

A Student's Guide to Blood Donation

Why Should I Give Blood?
Because You Can Make a Difference!

Almost everyone during their life will know someone who needs a blood transfusion. They may be car accident or trauma victims, cancer or transplant patients, or people with sickle cell disease or other blood disorders. There is no substitute and still only one source of blood for transfusion – volunteer blood donors.

This guide will provide you with information about measures you can take before, during, and after donation for a good experience.

Learning more about blood donation and knowing what to expect should improve your donation experience.

What Happens During the Blood Donation Process?

1. Registration

- Remember to bring your photo ID and, if required, the signed parental consent form.
- Bring the names of medications that you are taking.
- Bring a list of the places you have traveled outside the US and Canada in the last 12 months.
- Read the educational materials about donating whole blood or apheresis.
- Ask Red Cross staff if you have questions.

2. Health History & Mini Physical

- You should feel healthy and well, and meet other criteria.
- We will take your temperature, check your blood count, and measure your blood pressure and pulse.
- We will ask you questions during a private and confidential interview. This protects your health and the safety of patients who receive blood transfusions.

3. Donation

- We will cleanse an area of your arm and insert a needle to draw whole blood.
- You can relax, listen to music, talk to other donors, or read while the blood is collected.
- After the collection, a staff member will remove the needle and place a bandage on your arm.

4. Refreshments

- You should spend 15 minutes or more enjoying refreshments in the recovery area.
- If you become dizzy or light-headed, stay in the recovery area and tell a staff member immediately.

American Red Cross

American Red Cross Biomedical Services
Process Owner: Senior Director, Blood Collections
Letter: A Student's Guide to Blood Donation

What Should I Do To Prepare?
Before Donation

Sleep: Get at least eight hours of sleep the night before your donation.

Eat: Eat a healthy breakfast or lunch - or both if your appointment is later in the day.

- Don't skip meals on the day of a donation.
- Make healthy food choices. Eat proteins (lean meat, cheese, and yogurt) or complex carbohydrates (bread, cereal, and fruit).
- Include iron-rich foods in your regular diet (red meat, fish, poultry, beans, iron-fortified cereals, and raisins).

Drink: Drink a few extra glasses of water or fluids in the days before you donate. Start the day with a bottle of water or a glass of orange juice.

If you drink water within 10-30 minutes before donation, you may be less likely to experience dizziness and light-headedness.

During Donation

Most people relax during donation and feel fine afterwards. Sometimes it helps to think about something else to distract your attention from the blood being drawn.

You may also be told to try a simple technique to tense and relax the muscles in your legs:

- Lift your legs (one at a time) off the donor bed.
- Hold for a few seconds, then repeat.
- Breathe normally.

If you practice this technique to tense and relax the muscles in your legs during the donation, you may be less likely to have a reaction.

Tell Red Cross staff immediately what you are experiencing and they will take care of you. There are ways to help prevent or limit discomfort with donation.

After Donation

Be sure to sit and relax in the refreshment area for 15 minutes or more and have a drink and a snack. Afterward, drink a few glasses of fluids to stay well-hydrated.

Most donors have uneventful donations and feel good about donating. Some people may experience light-headedness, dizziness, or an upset stomach that resolves soon after donation. Less commonly, a donor may faint after blood donation. If you feel faint, stop what you are doing and sit or lie down until you feel better.

Call the American Red Cross toll-free number provided to you after your donation if you have questions or concerns.

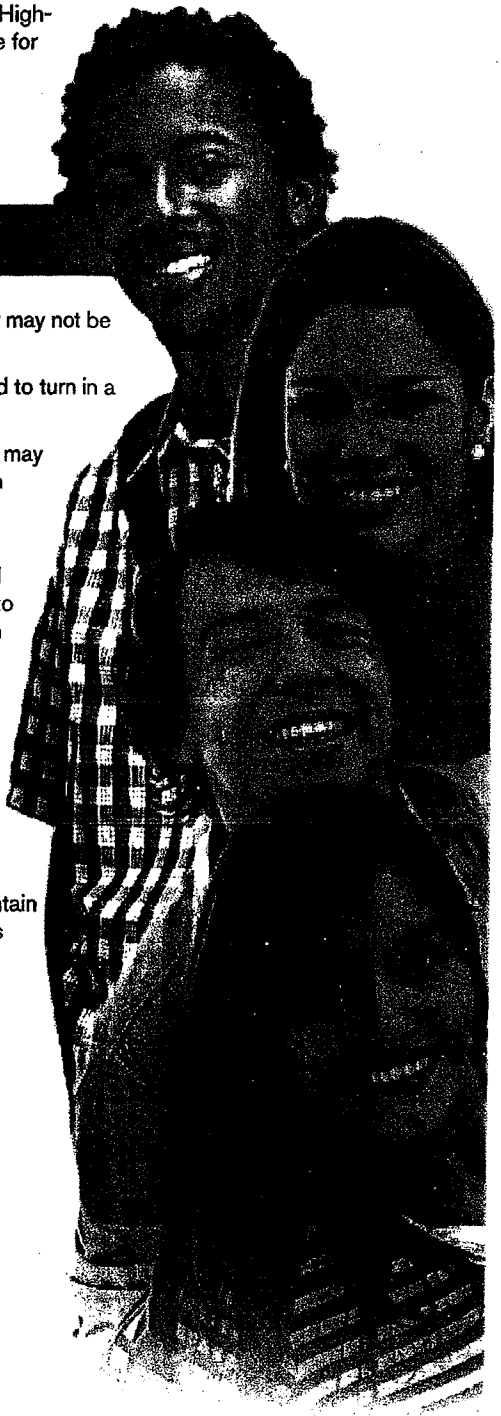
A Student's Guide to Blood Donation

Student Athletes

Student athletes should wait about 12 hours or more to resume strenuous exercise after blood donation, depending on how they feel. You temporarily lose fluid after donation which your body replaces within 24 hours or sooner if you drink extra fluids. As a precaution, do not donate blood on the same day of a competition or strenuous practice.

After a whole blood donation, your body replaces the red blood cells (the cells that deliver oxygen to muscles and tissues) within about 5 weeks, depending on nutrition and iron status. High-performance competitive athletes may notice a marginal decrease in exercise tolerance for about 1 week after a whole blood donation.

Plan ahead to best schedule your donation with sports and other activities.



Information for Parents

Parental permission is required for all 16-year-olds to donate blood. It may or may not be required for 17-year-olds depending on state laws and school requirements.

When we are required to obtain parental consent, your son or daughter will need to turn in a signed consent form to the donation site each time he or she plans to donate.

Most donors have uneventful donations and do fine afterwards. Some donors may become light-headed or dizzy during or after the donation or may faint or experience an injury requiring additional medical care. Young, first-time and/or low weight donors are more likely to experience reactions than other donors.

Every donation is tested for HIV (the virus that causes AIDS), hepatitis B and hepatitis C viruses, and other infectious diseases. If any test result or response to the questions suggests that your son or daughter is disqualified from donating blood in the future or may have an infectious disease, their name will be added to a confidential list of people who have similar test results or risk factors. When required, we report donor information, including test results to health departments and regulatory agencies.

The infectious disease tests are very sensitive and specific but **it is possible that donors who are not infected will have falsely positive results.** We are required to notify and disqualify donors even when subsequent test results indicate that the donor is not infected.

We will communicate test results directly with your son or daughter. We maintain the confidentiality of information we obtain about a donor, and we will release a donor's confidential information to his or her parents only with the donor's consent.

We may use information or residual blood samples we collect from donors confidentially and anonymously for medical research. Examples of this type of research include studies to increase the safety of the blood supply.

If you have questions about blood donation, please contact the American Red Cross.

American Red Cross

1-800-RED CROSS | redcross.org

American Red Cross Washington, DC 20006	**Babesia Investigational Study Donor Information for Informed Consent**	American Red Cross

This information sheet for informed consent explains the investigational study being performed for testing blood donors for evidence of infection to *Babesia microti,* a parasite that infects red blood cells and causes babesiosis in humans. The study involves testing your blood sample for the presence of *B. microti* DNA (nucleic acid) and for antibodies that you may have produced in response to an exposure to this parasite. This will be done using investigational tests. Before agreeing to participate, it is important that you read and understand the following explanation of the study. Your participation in this investigational study is completely voluntary. If you choose to participate, a small amount of blood from your donation today may be used in a study being conducted by the American Red Cross and Imugen, Inc. (Norwood, MA). If you choose not to participate, however, we cannot accept you as a blood donor today at this site. If you choose not to participate in the investigational study, there are other options for donation listed in "What alternative choices do I have?" below.

Why is this investigational study being done?

All blood establishments test blood samples to identify possible risks of infections, in order to assure the safety of the blood supply and the public's health. Blood establishments do this by using tests that the Food and Drug Administration (FDA) has approved for this purpose. Currently, there are no licensed tests for the detection of *Babesia* or its antibody, and researchers are trying to develop such tests.

The purpose of this study is to test the ability of a new investigational nucleic acid test called the polymerase chain reaction (PCR) to detect the *B. microti* parasite and a new investigational indirect immunofluorescent antibody assay (IFA) to detect *B. microti* antibody. Babesia infection in people is caused by a parasite that is carried by a deer tick. Babesia can be transmitted to people by a bite from a tick carrying the parasite or by exposure to *Babesia* parasite infected blood.

What will happen if I take part in this study?

- Your participation in this study will not involve any additional procedures or time beyond the normal blood donation process. No additional amount of blood will be taken from you today.
- The same sample that is used for routine blood donation testing may be tested with the investigational screening tests for *Babesia.* If the investigational screening test is reactive (positive), your sample may be tested by additional tests to determine if you are infected or had a previous exposure to *Babesia.* You will be notified if you test reactive with the investigational screening test; we will also notify you of the results of the additional tests that will be used.
- No medication or treatment will be given as part of this investigational study. No genetic testing of your sample will be done that is unrelated to determining if you are potentially infected with *Babesia.*
- If you test reactive or inconclusive (unable to determine) on either or both investigational screening tests, we will ask you to return and participate in a separate follow-up study so that we may better understand if you were actually infected or continue to be infected. The follow-up study would involve completing a short questionnaire and providing blood samples at different times. These samples would be used for testing that will help us better understand *Babesia* infection in humans.
- If you test reactive for *Babesia* by either or both investigational screening tests, you will be deferred as a blood donor. In subsequent testing, if you are shown to be not infected, we may be able to re-qualify you as a blood donor.

What alternative choices do I have?

You can choose not to participate in the study. If you choose not to participate in the study, you will not be able to donate today at this site. However, you may be able to donate at an alternate American Red Cross donation site and our staff can provide you with information on these alternate sites. You may also return here to donate blood after the investigational study has been completed.

What are the possible risks of taking part in this study?

The risks of participating in this study are small. There is a small chance that the investigational screening test will give a false-positive test result.

What are the benefits of taking part in this study?

By participating in this investigational study, you help protect the public health by supporting the development of new blood safety tests. In addition, there is the possibility that the investigational screening test will identify if you have an active infection.

What are the costs or payments for participation?
There will be no costs or payments to you for your participation in this study. If you have a positive or inconclusive test result and are asked to participate in follow-up studies, we will reimburse you if you participate. You will learn more about the follow-up study if you test positive or inconclusive.

Will my results be confidential?

- The American Red Cross and the test kit manufacturer will make every effort to keep confidential any information that we obtain in connection with this study that can identify you. Confidential information will not be disclosed without your written permission, unless required by law.
- Your study records and blood samples will be given a code number. You will not be listed by your full name in the study records. The blood samples will not have your name or address on them.
- Although the investigational study results may be published, donor names and other identifying information will not be revealed, except as required by law. Records are kept, as required by State and Federal laws. As of 2011, *Babesia*-infected individuals are required to be reported to the State public health laboratory. The FDA may need to review and copy donor records in order to verify study data; however, the FDA is committed to protection of the confidentiality of donor identity.
- As required by U.S. Law, the Department of Health in your state will be notified if you test positive by one or both of the investigational tests.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results of the entire study. You can search this web site at any time.

Is participation in the investigational study voluntary?
Your participation in the study is voluntary. You may decide not to participate at any time without loss of benefits to which you are entitled and without harm to your rights or future relationship with the American Red Cross.

Can I withdraw from the investigational study?
Yes. You are free to discontinue participation at any time without harm to your rights or future relationship with the American Red Cross by notifying the study Principal Investigator. If you begin donating and then decide that you do not want to participate, you must notify the blood collection staff before you leave the collection site and your donation will not be processed further. However, if you decide to withdraw from the study at a later time, the test information collected before your withdrawal may still be used or disclosed after your withdrawal. The Principal Investigator or Imugen may remove you from the study without your consent if it is discovered that you do not meet the study requirements, at the discretion of the Principal Investigator, or if the study is canceled.

Will my blood samples be stored?
Samples tested by Imugen using this protocol will be destroyed once testing is complete. However, other portions of your donation sample may be saved, frozen indefinitely by the American Red Cross for testing in the future for research related to blood safety.

- Each new test will be evaluated by a committee that will consider your rights as a research participant.
- Your sample will not be used for genetic testing or any other testing unrelated to blood safety without your consent.
- No personal identifiers will be available as part of your stored sample to the researchers doing the additional testing.
- You will be notified by phone or by letter about any abnormal test results that may impact your health.

Whom do I contact if I have any other questions or concerns about the study?
If you have any questions about your participation in this investigational study, or about the investigational study being conducted, or if you do not wish for your sample to be retained for future study, you may contact the study Principal Investigator: Dr. Susan Stramer at (866) 771-5534. If you have questions about your rights as an investigational study participant or if you feel that you have been injured because of the investigational use of your blood sample, contact the American Red Cross Institutional Review Board Administrator at (877) 738-0856.

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