This information sheet for informed consent explains the investigational study being performed for testing blood donors for evidence of infection to *Babesia microti* and other rarer types of Babesia that infect humans. Babesia are parasites that infect red blood cells and cause babesiosis in humans. The study involves testing your blood sample for the presence of Babesia ribosomal RNA (nucleic acid). This will be done using an investigational test. 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 Grifols Diagnostic Solutions, Inc. If you choose not to participate, however, we cannot accept you as a blood donor today at this site because this site is designated to have their collections tested. 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 ensure 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. The purpose of this study is to test the ability of a new investigational nucleic acid test called transcription-mediated amplification (TMA) to detect the *B. microti* parasite as well as other rarer types of Babesia (*Babesia divergens*, *Babesia duncani*, and *Babesia venatorum*) to investigate whether this new test will improve blood safety. 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. Your blood sample may be tested with the investigational screening tests for Babesia. If the investigational screening test is 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 positive 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 positive by the investigational screening test, 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 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 positive for Babesia by the investigational screening test, 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 and benefits of taking part in this study?
The risks of participating in the study are small. There is a small chance that the investigational screening test will give a false-positive result. Whether we believe that you are infected with Babesia or tested falsely positive, you will be deferred from future blood donation until the FDA allows donor reinstatement for false positivity or resolved infection.

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 test result, you may be asked to participate in follow-up studies. You will learn more about the follow-up study if you test positive.

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 be used to 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 the investigational test.

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. If you decide not to participate, you cannot donate blood at this location today; we will provide you alternate sites in which you may donate blood.

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 Grifols 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?**

- Portions of your donation sample may be saved and frozen indefinitely by the American Red Cross or Grifols for testing in the future for research related to blood safety. Each new test outside this protocol 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. Samples saved for testing in the future for research related to blood safety could be used for commercial profit that will not be shared with you.
- 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 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.