Roche Babesia Investigational Study Donor Information for Informed Consent

This information sheet for informed consent explains the investigational study being performed for testing blood donors for evidence of infection with Babesia microti and other rarer types of Babesia that infect humans. Babesia is a parasite that infects red blood cells and causes babesiosis in humans. The study involves testing your blood sample for the presence of Babesia deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). This will be done using an investigational test. By participating in this investigational study, you help protect the public health by supporting the development of new blood safety tests and in return, learn more about your own health. 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 and of little risk to you. 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 Roche Molecular Systems, Inc. If you choose not to participate in the investigational study, there are other options for donation listed below in the “What alternative choices do I have?” section of this document.

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) approve for this purpose. The purpose of this study is to test the ability of a new investigational nucleic acid test called polymerase chain reaction (PCR) to detect the parasites that cause Babesia infection in people (B. microti, parasite as well as other rarer types of Babesia (Babesia divergens, Babesia duncani, and Babesia venatorum). Babesia infection in people is caused by these parasites that are carried by deer ticks. 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 time beyond the normal blood donation process, but will require the collection of an additional testing tube. 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 additional tests performed to confirm the result.
- No medication or treatment will be given as part of this investigational study. Your sample will not be used for human genetic testing or any other testing unrelated to blood safety without your consent.
- 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 indefinitely deferred from donating blood. If you are retested as part of the follow-up study, and shown to be not infected, we may be able to re-qualify you as a blood donor after a 2 year deferral period.
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 can come back to this site after the completion of the study, which is about 3 months, and donate then. If you choose not to participate in the study, but wish to donate today, tell the blood collections staff that you do not want to participate and we will not test your sample.

What are the possible risks 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 for two years from blood donation.

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. The investigational test to be evaluated in this study may have commercial value if it is licensed by the FDA. If licensed, you will not be compensated or benefit financially.

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. Study records may be shared with additional researchers/investigators for future research. If so, personal identifiers will be removed so study records cannot be identified with you.
- 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 unless you tell us in advance so that we will not test your sample.

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 Roche may remove you from the study without your consent if it is discovered that you do not meet the study requirements, or if the study is canceled.

American Red Cross Biomedical Services
BSL Attachment: Roche Babesia Investigational Study
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Legacy Doc No: 19-008-01 v-0.1
**Will my blood samples be stored?**
- If you agree, portions of your donation sample may be saved and frozen indefinitely by the American Red Cross or Roche for testing in the future for research related to blood safety.
- Your sample will not be used for human genetic testing or any other testing unrelated to blood safety without your consent.
- Your stored sample will be labeled with a code number and not your name. Only authorized American Red Cross staff will be able to link a code number, on your stored sample, to your identifying information. Your identifying information will not be available to external researchers. 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.
- Your sample, even if personal identifiers are removed, will not be distributed to other researchers outside of the American Red Cross or Roche.
- You will be notified by the American Red Cross, by phone or 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.