

COVER PAGE

Abbott Laboratories Official Title of the Study: Abbott Laboratories Alinity s Blood Screening Assays
– Clinical Evaluation Protocol

NCT Number: NCT03285295

Type of Document: Informed Consent Form: Information Sheet for Local IRB

Date of Document: November 17, 2017

Possible Use of Donor Information and Blood Samples in Medical Research

The American Red Cross Blood Services' mission is to provide a safe and effective blood supply. As part of this mission, the American Red Cross may conduct research. Some research is conducted with other institutions, such as academic centers and biomedical companies. Rarely is research conducted using donor blood and information, however; this information sheet is provided to inform you of the possibility.

How might your blood or information be used in medical research?

A portion of your blood or information collected at the time of donation may be used to make research studies possible. Some examples of the types of research are

- Studies relating to testing, storing, collecting, and processing blood
- Studies of new methods to test blood for infectious diseases
- Studies of ways to recruit blood donors and evaluate donor eligibility

How is your confidentiality protected when your blood or information is used in research?

- Samples used by researchers are coded. Only authorized Red Cross personnel can link coded samples to a donor's identifying information.
- Your identifying information is not reported outside the Red Cross unless required by law.
- An independent committee [the Institutional Review Board (IRB)] approves all American Red Cross research using donor samples or information. The IRB is government regulated and is established to protect your rights and welfare.

How might your sample be tested and will you be informed of results?

- Samples linked to your identifying information may be used for infectious disease testing to provide a safe blood supply.
- You will be notified in person, by phone, or by letter, about any test results that are identified to you and that may impact your health.
- If your test results are unexpected, Red Cross staff may contact you by phone or letter and ask you to participate in a voluntary follow-up study.

What will happen if your sample or information is stored?

- Your sample may be stored for future research on blood safety.
- Your identified sample and information will not be used for research unrelated to blood safety without your consent.
- If your sample is stored, only authorized Red Cross personnel can link it to your identifying information.

What are your rights?

- 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 blood donors and their donations in possible research studies to continue to provide a safe and effective blood supply.
- Participation in research is voluntary. You may withdraw at any time 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 after leaving the donation site that you do not want your sample or information to be stored for research, contact the Scientific Support Office at (866) 771-5534. However, test information collected before your withdrawal may still be used after your withdrawal.

How to obtain more information

For more information about research uses of your blood or if you have questions about your rights as a research participant, call the American Red Cross Institutional Review Board administrator at (877) 738-0856.



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