

Informed Consent Form For Follow-up Specimens

TITLE: Alinity s Anti-HCV II – Clinical Evaluation Protocol

PROTOCOL NO.: T3M3-02-19H04-01
IRB Protocol #20204503

SPONSOR: Abbott Laboratories

INVESTIGATOR:
Name
Address
City, State ZIP
Country

**STUDY-RELATED
PHONE NUMBER(S):** Name
(24 Hour Phone Number)

In this consent form, “you” generally refers to the subject. If you are a parent or guardian, please remember that “you” refers to the study subject.

Introduction

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This document describes the purpose, procedures, benefits, and risks of the study.

The study is being conducted for and funded by Abbott Laboratories. Approximately 15,000 individuals from several blood collection centers across the United States may be participating in the study associated with this follow-up blood draw.

Why is this research being done?

The purpose of this part of the study is to obtain an additional blood sample that may help interpret and better understand the investigational (research) test results of your previous specimen. The sample is to be used by Abbott to evaluate a new version under development of a blood test currently approved by the US Food and Drug Administration (FDA) to detect Hepatitis C antibody in donor blood. The new test (Alinity s Anti-HCV II) is investigational, meaning it has not been approved by the FDA for detection of Hepatitis C antibody.

The potential implications for donation include notification and counseling; and may result in temporary or permanent deferral from donating blood/plasma in the future.

State law requires that the results of positive tests for hepatitis be reported to a local health agency.

What will happen if I take part in this study?

Your participation in this part of the study involves collection of a blood specimen.

If you choose to participate, no more than 20 mL - 60 mL (about 1.5 – 4.5 tablespoons) of blood will be collected by routine venipuncture. Your participation will require approximately 30 minutes of your time. No medication or treatment will be given as part of this research study.

What alternative choices do I have?

This study is for research purposes only. The only alternative is to not participate in this study.

What are the possible risks involved with this study?

Drawing blood may cause pain, bruising, lightheadedness, and, on rare occasions, infection at the site of the blood draw. The study poses no special risk to pregnant women or to an unborn fetus. There is a small risk of loss of confidentiality.

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

This study is for research purposes only. You will not directly benefit from your participation in this study. Information from this study will be used to help others in the future by providing a better understanding of blood screening tests for Hepatitis C.

What are the costs or payments for participating in this study?

There will be no costs to you for your participation in this study. You will not be paid for your participation in the study.

Data We Collect From You:

Your personal health information including data resulting from your participation in this research will be collected during the course of this study. Your personal health information includes results of any blood testing done by the donor facility or Abbott Laboratories.

How Your Data Will Appear:

Your identity and contact details will not be disclosed unless required by law. Rather, your identity and contact details will be replaced by a code, such as a number.

Why We Collect This Data:

Your personal health information will be used for clinical research and also for seeking approval from regulatory authorities to market the studied Alinity s Anti-HCV II assay. It may also be used in study reports or for scientific presentations, but in a way that will not identify you by name. Your personal health information will be kept as confidential as possible and, unless required by law, will not be made publicly available. After this study has been completed, it is possible that your coded health information will be used for future research.

Who Will See Your Data:

The only people with access to your personal health information in identifiable form will be the investigator, personnel helping investigator conduct the study at the facility, sponsor representatives who are checking that the study is conducted properly, and regulatory authorities where required by law.

By signing this document, you are allowing the investigator and personnel at the facility to permit Abbott to have access to your personal health information for the purpose of collecting data, verifying the data is correct, and checking that the study is conducted properly.

In order to complete the research, Abbott, the investigator and personnel at the facility, the ethics committee(s) and domestic and foreign regulatory authorities responsible for overseeing research studies (including the FDA, U.S. Department of Health and Human Services (HHS), and/or equivalent government agencies in other countries) will have access to your coded health information.

Additionally, your personal health information may no longer be protected by HIPAA (Health Insurance Portability and Accountability Act) once it is disclosed to Abbott by the investigator. However, Abbott will take reasonable measures to keep your personal health information confidential. Unless withdrawn, your HIPAA authorization has no expiration date (except in the states of Washington, Indiana, or California, where it expires 50 years from the time you sign this form), since information collected for research purposes continues to be analyzed for many years.

Taking Back Your Permission to Use or Disclose Your Personal Health Information:

To take back your permission to use or disclose your personal health information you must write to the investigator using the mailing information provided to you on page 1 of this document. If you do this, you will no longer be allowed to be in this study. Any information that has already been collected at the time you take back your permission will be kept and, where the law allows, your personal health information will continue to be used by the investigator or Abbott or other parties involved with the study.

Rights to Your Data:

You may have the right to access, correct and make a copy of your clinical study records as allowed by applicable privacy laws. You may ask to see your records by requesting such records from the investigator or the facility(ies) where the study is being conducted. However, to ensure the valid results of the study, you agree that you may not be able to review or make a copy of some of your records related to the study until after the study has been completed.

When you, or your parent or legal guardian, sign this document, you agree to the access, collection, processing and transfer of your personal health information as described in this informed consent document. If you do not sign this document, you may not participate in the research study.

Trial Registration

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. You can search this Web site at any time.

What if I become injured participating in this study?

If during the course of the study any injury occurs to you as a direct result of your participation in this study, Abbott agrees to pay all reasonable medical expenses necessary to treat such injury, provided: (i) you have followed the directions of the investigators; and (ii) to the extent you are not otherwise reimbursed by medical insurance. Contact the study staff at the number listed on the first page of this document to find out where to go to obtain treatment.

Is my participation in the study voluntary?

Your participation in the study is voluntary. You may decide not to participate or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Can I withdraw from the study at any time?

You may choose not to participate, or to withdraw from the study at any time without any penalty or loss of benefits to which you are entitled. However, information collected prior to your withdrawal may still be used or disclosed after your withdrawal.

The investigator or Abbott may remove you from the study without your consent for any of the following reasons: (i) if it appears to be medically harmful to you, (ii) if it is discovered that you do not meet the study requirements, at the discretion of the investigator, or (iii) if the study is canceled.

Whom do I contact if I have questions or concerns about the study?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the investigator using the contact information provided to you on page 1 of this document,

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

CONSENT

- All children are required to assent
- Determination: If assent is obtained, have the person obtaining assent document assent on the consent form

I have read and understand this consent form. All my questions regarding participation in this research study have been answered. I, or my parent/guardian, will receive a copy of the consent form that was used during the consent process to keep for future reference. I do not give up any of my legal rights as a research subject by signing this form.

I voluntarily agree to participate in this study.

Printed Name of Subject

Subject ID

Signature of Subject

Date

Printed Name of Individual Conducting Consent Procedure

Signature of Individual Conducting Consent Procedure

Date

Assent for ages 16 and 17:

Printed Name of Subject

Subject ID

Signature of Subject for Assent

Date

Age (years)

Statement of Parent or Guardian:

My child appears to understand the research to the best of his or her ability and has agreed to participate.

Signature of Parent or Guardian

Date

ASSENT SECTION:

Statement of person conducting assent discussion:

- I have explained all aspects of the research to the subject to the best of his or her ability to understand.
- I have answered all the questions of the subject relating to this research.
- The subject agrees to be in the research.
- I believe the subject's decision to enroll is voluntary.
- The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Signature of Individual Conducting Assent Discussion

Date