RESEARCH SUBJECT CONSENT FORM

TITLE:	Open Label Study to Assess the ~32-Year Persistence of Hepatitis A Antibody among Participants in the Pivotal, Double-Blind, Placebo-Controlled Efficacy Study of VAQTA, (Study 023-001)
PROTOCOL NO.:	Study 023– Persistence WCG IRB Protocol #20233780
SPONSOR:	Best Healthcare Inc.
INVESTIGATOR:	Alan Werzberger, MD, FAAP Best Healthcare Inc. 22 Van Buren Drive Suite 102 Monroe, NY 10950 United States
STUDY-RELATED PHONE NUMBER(S):	845 783 2222 914-523-7131 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you do not take part, it will not be held against you.
- You can take part now and later drop out, and it will not be held against you
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
We expect that your taking part in this research will last 1 day to several months depending on whether you choose to be revaccinated.

Why is this research being done?
The purpose of this research is to determine whether persons vaccinated with hepatitis A vaccine approximately 32 years ago still have detectable antibody (a substance the body makes as part of an immune response). Those who do not have evidence of protection will be offered an additional investigational third dose of vaccine and tested to see if they then develop antibody.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, you will be asked to provide a blood specimen. If testing shows that you are no longer protected against hepatitis A, you will offered an additional dose of vaccine and asked to provide two more blood specimens. You are free to refuse the additional dose of vaccine.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include pain or bruising in your arm where the blood was drawn. This should go away within hours or days.

If you choose to be revaccinated, the most important risks or discomforts that you may expect include soreness or redness where the shot is given. You could also have a fever, headache, tiredness, or loss of appetite after vaccination. People sometimes faint after medical procedures. As with any medicine, there is a chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

Will being in this research benefit me?
The most important benefits that you may expect from taking part in this research include that you will be informed whether you still have detectable antibody to hepatitis A. If you do not, you will be offered an additional dose of vaccine. It is not expected that you will personally benefit from this research.

The information obtained in this study may be helpful in determining whether other adults need to obtain another dose of vaccine to be protected.

DETAILED RESEARCH CONSENT
You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?
- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.

- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you do not understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to determine whether persons vaccinated with hepatitis A vaccine approximately 32 years ago are still protected (have detectable antibody). Those who do not have evidence of protection will be offered an additional dose of vaccine and tested to see if they then have antibody.

About 300 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last for 1 day to several months depending on whether you choose to be revaccinated.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, you will be asked to provide a blood specimen (approximately 1 teaspoon) at a physician's office. Your blood will be tested by an outside laboratory to determine if you still have antibodies which tells whether you are still protected against hepatitis A. We will contact you once the testing is completed to inform you whether you still are protected against hepatitis A.

If testing shows that you are no longer protected against hepatitis A, you will be offered an additional dose of hepatitis A vaccine (VAQTA), a vaccine that has been licensed in the United States since 1996. The vaccine is licensed as a 2-dose vaccine. Administration of a 3rd (booster) dose is investigational, which means that it is not approved by the Food and Drug Administration (FDA). Earlier clinical studies in a small number of adults showed that a 3rd dose was well tolerated.

If you are female, choose to receive another dose of vaccine, and uncertain if you are pregnant, you will be offered an optional pregnancy test.

If you choose to be revaccinated, you will be asked to provide two additional blood specimens (approximately 1 teaspoon each) after vaccination. The first sample will be obtained 7-10 days after vaccination and the second sample will be obtained 30 days after vaccination. We will ask those who receive another dose of vaccine to complete a questionnaire documenting any reactions to the vaccine for 7 days after injection.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Promptly notify the investigator of any significant side effects from the blood draw or vaccination
- Immediately notify the investigator or seek medical attention by calling 9-1-1 if you have any signs of an allergic reaction (hives, swelling of the face and throat, difficultly breathing, a fast heartbeat, dizziness, or weakness.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include pain or bruising in your arm where the blood was drawn. This should go away within hours or days.

If you choose to be revaccinated, the most important risks or discomforts that you may expect from taking part in this research include soreness or redness where the shot is given. You could also have a fever, headache, tiredness, or loss of appetite after vaccination. People sometimes faint after medical procedures. As with any medicine, there is a chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

In addition to these risks, taking part in this research may harm you in unknown ways.

The safety of hepatitis A vaccination during pregnancy has not been determined; however, because hepatitis A vaccine is produced from inactivated hepatitis A virus (HAV), the theoretic risk to the developing fetus is expected to be low. The risk associated with vaccination should be weighed against the risk for hepatitis A in pregnant women who might be at high risk for exposure to HAV.

Will it cost me money to take part in this research?

It will not cost you any money to take part in this research.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include obtaining information on whether you still have protection against hepatitis A and being revaccinated if you are not protected.

The information obtained in this study may be helpful in determining whether other adults need to obtain another dose of vaccine to be protected.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research
- Your physician

Information from your previous participation in this study including previous levels of hepatitis A antibody will be shared with investigator and study staff.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Information about a Certificate of Confidentiality for this research:
Dr. Alan Werzberger and Best Healthcare Inc. have received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about you collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, you may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

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.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately at the number on the first page of this consent form. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- The research is canceled by the FDA or the sponsor
- You are unable to take the research vaccine
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can document your decision in the study records.

Will I be paid for taking part in this research?

For taking part in this research, you will be paid $25 for providing the first blood specimen and up to $75 more if you choose to be revaccinated and provide two additional blood specimens according to the protocol. Your compensation will be broken down as follows:

- $25 for the first blood sample
- $25 for each visit for those who choose to be revaccinated (revaccination visit + two visits for blood samples)
- Payments will be made at the end of the study. If you withdraw from the study; you will receive payment for the portion of the study you have completed.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date