Official Title:Newer Direct-Acting Anti-Viral Agents as Sole Therapy of Porphyria Cutanea Tarda in Subjects With Chronic Hepatitis C
IRB Approved Date: 12/16/21
NCT03118674

utmb Health

The University of Texas Medical Branch at Galveston
Research Consent Form

Protocol Title	Newer Direct-Acting Anti-Viral Agents as Sole Therapy ofPorphyria Cutanea Tarda in Subjects with Chronic Hepatitis C
IRB Number:	17-0081
Sponsors:	Icahn School of Medicine at Mt. Sinai Wake Forest School of Medicine Gilead Sciences National Institute of Diabetes and Digestive and Kidney Diseases/NIH/DHHS

Principal Investigator: Karl E. Anderson, MD
Address: [redacted]
Phone: [redacted] (during business hours)
[redacted] (after business hours)
Fax: [redacted]

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have been diagnosed with both Porphyria Cutanea Tarda (PCT) and Chronic Hepatitis C caused by an infection of the Hepatitis C virus (HCV).

STUDY SUMMARY:
The purpose of this study is to learn whether Harvoni, a simple oral treatment for the HCV infection, is effective as treatment for PCT. The duration of the study is two years. If you choose to participate, you will be asked to come to University of Texas Medical Branch (UTMB) every month for the first year of the study, and every 4 months during the second year of the study. At each visit, blood and urine samples will be collected for testing. Based on these results, Dr. Karl Anderson, the principal investigator of this study, will determine how long you will need to take Harvoni for (8. 12, or 24 weeks).

Risks or discomforts from this research could include pain upon needle insertion during the blood draw, fatigue or headaches from taking Harvoni, or your PCT symptoms not improving.

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There may not be direct benefits for you, however, possible benefits include successful treatment with Harvoni for your Hepatitis C, and/or resolution of your PCT symptoms.

Taking part in this research study is voluntary. You do not have to participate and you can stop at any time. Please take your time to read this entire form and ask questions before deciding if you want to take party in this research study.

What is the purpose of this research study?
The purpose of this study is to learn whether Harvoni, a simple oral treatment for chronic hepatitis C virus (HCV) infection, is effective as treatment for Porphyria Cutanea Tarda (PCT). Harvoni is approved by the FDA for treatment of hepatitis C, and is a combination of 90 mg of ledipasvir and 400 mg of sofosbuvir, which are two direct-acting antiviral agents. Harvoni is considered investigational in this study, meaning it is not approved for marketing by the FDA for use in treating PCT.

PCT is the most common form of porphyria in the USA and most other countries. It is due to an acquired deficiency of the enzyme uroporphyrinogen decarboxylase (UROD) in the liver. Susceptibility factors for PCT include heavy alcohol use, iron overload, HCV infection, human immunodeficiency virus (HIV) infection and estrogens. Genetic factors may include UROD mutations, which are found in about 20% of PCT patients and partially reduce UROD from birth, and HFE mutations, which predispose to iron overload. Most patients with PCT have at least several of these acquired and inherited susceptibility factors.

The current standard treatments for PCT is phlebotomy, which reduces the amount of iron in the body by removing a specific amount of blood at regular intervals (usually a pint every 2 weeks). A second standard treatment is a medication called hydroxychloroquine, which is given in small doses to remove porphyrins from the liver.

There have been reports of patients with PCT having their PCT symptoms resolve with HCV infection treatments. But treatment of HCV infection has been difficult and not always successful, so PCT has generally been treated first. With the recent development of better therapies for HCV infection such as Harvoni, with fewer side-effects and better success rates, it is important to look into whether these HCV therapies can also help resolve PCT symptoms.

This is a study to determine whether Harvoni (the study drug) is as effective a treatment for PCT as the current standard of care treatments, phlebotomy or hydroxychloroquine. You may qualify to take part in this research study because you have been diagnosed with PCT and HCV.
Funds for conducting this research are provided by Icahn School of Medicine at Mt. Sinai, Wake Forest School of Medicine, National Institute of Diabetes and Kidney Diseases/NIH/DHHS, and Gilead Sciences. Gilead is the manufacturer of the study drug and is providing Harvoni for the study at no cost.

How many people will take part in this study?
Your participation in this research study is expected to last for two years.
The number of people expected to take part in this research study at UTMB is about 20. The total number of people expected to take part in this research study at this and other sites is 49.

What procedures are involved as part of this research study?
If you agree to participate in this research study, the following information describes what may be involved. All clinically relevant results of this research will be communicated with you, in particular your response to treatment with Harvoni.

Baseline visit:
This first study visit will take place at our study center. To participate in this study, we will ask you to sign this consent form. This visit can take up to 2 hours to complete. You will be seen by a liver specialist at this visit.

We will ask you questions about your medical and family history, and give you a physical examination. We will ask you about any medicines that you are taking or that you have taken in the past. We will check your medical records for information that will help us determine if you are eligible for the study, such as laboratory tests and previous or ongoing treatment. We will take your blood pressure, temperature, pulse, height, weight and other body measurements. You will have to complete questionnaires about your PCT symptoms and we will also take pictures of your skin blisters and scars. If these pictures are of your face your eyes will be blacked out so you are not easily recognized.

A collection of samples will be obtained, including blood (about 2-4 tablespoons) and urine (about 1/4 cup) for testing. These lab tests are standard tests to diagnose HCV and PCT and monitor them during treatment. DNA analysis will look for a mutations (or change) in the UROD gene and the HFE (hemochromatosis) gene, unless already done and documented. UROD mutations are found in only about 20% of PCT patients, and HFE mutations are more common. You will also be tested for HIV antibodies if not already done within 4 months of screening.

A test to estimate liver fibrosis (scarring) or stiffness will be performed This may be a blood test called Fibrosure, or a scan such as Fibroscan that uses a non-invasive probe that estimates stiffness using sound waves. Delivering sound waves to the liver does not entail any significant risk.

Testing on these samples may include measurement of certain products, such as porphyrins, found in the blood and urine of people with porphyria, and DNA analysis to find the mutations (or changes) in genes known to play a role in PCT (the UROD and HFE genes).

PCT can be associated with some liver abnormalities which can resemble those due to other liver conditions. Therefore, tests will be done to rule out other liver diseases, including other types of hepatitis (such as hepatitis B) and diabetes, unless these were done before. A liver ultrasound and a liver biopsy are not required as part of this study, but may be recommended as part of your standard medical care and will not be covered by the study.

You will also be tested for other conditions that would not allow you to participate in this study, such as diseases affecting the kidneys or bone marrow. If you are female, a urine pregnancy test will also be performed during this visit.

As part of your treatment for PCT, you have been advised to avoid things that make PCT worse, such as drinking alcohol, smoking, and other recreational substances. You should also avoid sunlight exposure (direct sunlight, tanning beds, etc.) until your condition has been successfully treated.

Treatment and Follow-Up Visits:
The study drug will need to be taken daily for 8, or in most cases 12 or 24 weeks; your study doctor or the liver specialist will determine whether you should take it for 8, 12 or 24 weeks. For the first year you are in the study, including when you take the study medication, you will need to return to the study center every month for monitoring and some of the same procedures done during the baseline visit will be repeated.

If you stop before you complete Harvoni therapy or if you are still experiencing PCT symptoms or your porphyrin levels have not returned to normal after you complete Harvoni therapy, then standard PCT treatment would be offered. This care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. We would ask you to still participate in follow-up visits for this study if this happens.

After one year you will be asked to return every four months for another one year. This is to determine if PCT and its symptoms return. You will be seen by a liver specialist at some of these follow up visits. If you did not complete the study within the proposed two-year time period due to unforeseen circumstances, such as the COVID-19 pandemic, we may extend the study in order to complete the last visit (month 24) and collect important data needed to conclude the study.

After two years you will be asked to participate in the Longitudinal Study of the Porphyrias and to continue coming to the study center once a year for check-ups. This is to see if PCT returns after treatment with Harvoni, but without phlebotomy or hydroxychloroquine.

You will be given a unique code number which will be used to label all samples (blood and urine) and information from you. The information collected from you, including health and family history information, will be entered into a computer. This information will be linked to you, meaning that we will be able to find out whom the samples (blood and urine) and information came from. This may be important if the researchers need additional information or samples to help the research. Additionally, the information collected for this study will be stored by the NIH at the Data Management and Coordinating Center (DMCC) at the Cincinnati Children's Hospital Medical Center in Cincinnati, OH and also sent to a Federal data repository. The DMCC uses several layers of protection for the clinical data stored there. It meets all of the local and federal security requirements for research datacenters. Your information is stored using only your code number. No personal identifiers like your name, address or medical record number will be sent to the DMCC.

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The following table shows what will happen at each visit. The Baseline Visit is to determine whether or not you are eligible to participate in the study, inform you about all the study procedures and then give you the opportunity to sign this consent form. The study drug may be started then, or at a later visit, after eligibility and consenting are complete.

Procedures	**Base-line Visit***	**Start of Study Medi-cation**	**Follow-Up Visits (Months After Start of Study Medication)**													
			1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**16**	**20**	**24**
Consent	**X**																
Medical history	**X**																
Follow-up history			**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Physical exam	**X**				**X**			**X**			**X**			**X**	**X**	**X**	**X**
PCT symptom questionnaire & skin pictures	**X**		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Blood & urine collection	**X**		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Fibroscan or Fibrosure	**X**													**X**			**X**
Provide study medication		**X**	**X**	**X**	**X †**	**X †**	**X †**										

*Up to one month before you begin study medication.
†If additional medication is indicated for treatment for 24 weeks rather than 12 weeks.

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If you decide to take part in this research study you will be responsible for the following things:

- Reliably taking the study medication on a daily basis and reporting if and when study medication has not been taken
- Coming to your scheduled study visits on time
- Providing us with a urine and blood samples at each visit
- Providing accurate details about your medical history as well as medications you are taking.
- Reporting any illnesses or medical problems that occur during the time you are taking the study medication
- Completing questionnaires during the study visits
- It is advised that you stop drinking alcohol and smoking while taking part in this study. If you do not stop you will not be removed from the study but you must report how much you drink and smoke to the study team
- If you are female you must be taking an acceptable method of contraception to avoid pregnancy. For a list of these methods ask the study team. If you become pregnant while taking Harvoni the study drug will be stopped. We will not collect information on your pregnancy.
- You should not take rifampicin or St. John's wort while on Harvoni

It is possible your PCT symptoms might worsen if you participate in this study. If this happens, the study doctor will decide with you at what point you should stop HCV treatment and begin standard of care PCT treatment. Some of the information from your standard of care PCT treatments may still be entered into the study database.

What extra tests and procedures will I have if I take part in this study?

The following will be performed for research purposes and probably would not be given to you if you were being treated outside the study:

- Alcohol and Tobacco Questionnaires
- Porphyria Cutanea Tarda (PCT) questionnaire
- Photographs taken as part of your skin assessment
- Visits as frequently as monthly

The research study will pay for all of the above-mentioned tests and procedures.

What are the possible risks for choosing to participate in this research study?
The study involves potential risks and discomforts. These risks will not be very different from standard treatment with Harvoni. Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider.

1. **Risks of Study Procedures and Intervention**
   a) Blood draw: When the needle is inserted it can hurt. There is a small chance of fainting and/or bruising. Since the skin is broken, an infection at the puncture site can occur, although this is very rare. Occasionally some people become dizzy, lightheaded or feel faint. The amount of blood requested is within approved safety limits and will be modified for individuals who have a medical condition that limits their ability to provide the requested volume of blood.
   b) Side effects of Harvoni: the most frequent side effects have been fatigue, headaches, nausea, diarrhea, and insomnia. Any significant new findings that the investigators learn about during the course of the study which could increase your risk of participating or developing negative reactions will be told to you.

2. **Your symptoms may not improve.**
   There is a chance that your PCT symptoms will not improve with Harvoni, or improve more slowly than with standard treatment. The purpose of the study is to find out if Harvoni is an effective and equally rapid treatment for PCT when associated with hepatitis C, but this is not yet known. Although this is unlikely, your PCT symptoms may instead worsen while taking Harvoni. This includes blisters on sun exposed areas, fragile skin, increased hair growth, as well as darkening and thickening of the skin. Potential complications of having blisters include scarring and a small risk of blistered areas becoming infected. You will be instructed on how to care for any blisters.

3. **Risk of loss of Confidentiality**
   The potential for loss of private information always exists; however, there are procedures in place to minimize this risk. The PI and his delegates will do their best to keep your information confidential; however, there is a possibility that your data, including clinical and diagnostic information will be accidentally divulged to the wrong source; if that happens you might be discriminated against in obtaining life insurance, employment or

ability to adopt children. There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

4. **Risks to the Fetus**

If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. For that reason, pregnant and breast-feeding females cannot participate in the study. If you can become pregnant, a urine pregnancy test will be done, and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study. Medically-acceptable birth control (contraceptives) includes: (1) surgical sterilization (such as hysterectomy or "tubes tied"), (2) approved hormonal contraceptives (such as birth control pills, patch or ring; Depo-Provera, Implanon), (3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or (4) a intrauterine device (IUD). You need to let us know which of these options you are using and also inform us if you change to another option during the study. Some hormonal contraceptives may not be advisable for someone with porphyria cutanea tarda, so you also should discuss these options with the study physician. If you do become pregnant during this study, you must tell the researchers immediately.

5. **Psychological Stress**

There may be risks because of the HIV and hepatitis tests, which could cause mental and social harm. A positive test could have a bad influence on your being able to get insurance or be employed, and could make family relationships difficult. You will be referred for appropriate counseling and medical care for any such condition that is discovered.

6. **Other risks.** There may be additional and unforeseeable risks from participating in this study.

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What are the potential benefits for participating in this research study?
If you agree to take part in this study, there may not be direct benefits to you. We hope the information learned from this study will benefit others with PCT in the future. However, possible benefits may include:

- Possible successful treatment with Harvoni for your Hepatitis C
- Possible resolution of your PCT symptoms

Will I be reimbursed for participating in this research study?
You will be reimbursed for travel, time and inconvenience. Every time you complete a study visit, you will be reimbursed $75, plus round-trip mileage at $0.57.5 per mile up to $200, for each study visit. Even if you do not complete the entire study, you will still be reimbursed for each individual study visit that you complete. You will be issued a UTMB Clincard, which is a debit card that your funds are loaded onto following the completion of each study visit. You can decide not to be reimbursed if you wish. We will validate your parking ticket for each study visit.

You will not be reimbursed if your visit is not scheduled in advance, or if your visit is part of necessary medical treatment or hospital admission at UTMB. If the visit is for more than one porphyria research study, you will only be reimbursed for one study. If you travel together within the same vehicle for a study visit with one or more family members who are also participating in this or another porphyria study, only one participant will be reimbursed for the mileage.

When a study visit is completed, funds will be approved and loaded onto your Clincard. The funds will be available within 72 hours and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, you can contact customer service at [redacted]. We will collect some information about you, including name, address, telephone number, date of birth, email address, if applicable, and your social security number (if a US citizen) in order to issue the Clincard. All information is stored in a secure fashion and will be kept confidential.

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Is there an alternative treatment procedure?
Yes. You do not have to participate in this research to receive care for your medical problem. Instead of being in this study, you have the following options:

- Standard of care treatment for PCT and hepatitis C will still be available to you in the usual manner. If you do not participate in the study, this will not affect your medical care at UTMB.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page of this consent. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or becomes worse.
- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Specimens or data stored as part of the research study can be destroyed without your consent.

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Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study. The study drug and testing performed during this study will be provided at no cost to you.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately. Compensation for an injury resulting from your participation in this research is not available from the University of Texas Medical Branch at Galveston. You or your insurance company or health care plan, will be billed and you will be responsible for any charges. You will be responsible for paying any costs related to illnesses and medical events not associated with being in the study. There are no plans to provide other forms of compensation. However, you are not waiving any of your legal rights by participating in this study.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group. Clinically important information will be included in your hospital medical records.

The clinical information collected for this study will be stored at the Data Management and Coordinating Center (DMCC) at the Cincinnati Children's Hospital Medical Center in Cincinnati, OH and also sent to a Federal data repository. It meets all of the local and federal security requirements for research datacenters. Any photographs taken of you will be for research only and will be stored with other research information collected in a secure database that will not identify you by name. Also, your eyes will be blacked out on the photographs to help further in protecting your confidentiality and privacy. Your information is stored using only a coded number. No personal identifiers like your name, address or medical record number will be sent to the DMCC.

Certificate of Confidentiality:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or

biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the U.S. Department of Health and Human Services and/or the National Institutes of Health which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Even with the Certificate of Confidentiality, the investigators continue to have ethical obligations to report child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information private would immediately put you or someone else in danger, the investigators would release information to protect you or another person. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as reports of child abuse and neglect, or harm to self or others.

How will my privacy be protected?
We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical

records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your regular doctors who are not involved in the research, may also see or give out your information. We make this information available to your regular doctors and your medical records for your safety. If you think this study might affect your clinical care, please inform your study doctor.

As part of the study, the Principal Investigator, study team and others at UTMB may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project including members of the Rare Diseases Clinical Research Network and members of the Porphyrias Consortium.
- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers: Data Management and Coordinating Center (DMCC) at the Cincinnati Children's Hospital Medical Center..
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institutes of Health (NIH).
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

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

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

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We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Finally, please specifically authorize the use of your private health information relating to substance abuse, psychiatric information, or HIV/AIDS, if applicable, for the above-described purposes.

Initial_____

Whom can I contact with questions about this research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Dr. Karl Anderson at [redacted] or, if after normal office hours, at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your

rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

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.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have

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been answered to your satisfaction. You have been told whom to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Signature of Subject	Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject

Signature of Person Obtaining Consent	Date and Time Consent Obtained

Printed Name of Person Obtaining Consent

Name: UH#: