Date: 09-05-2019

Project Title: Ocular Hypertension Treatment Study 20-Year Follow-up

Consent Form

http://www.clinicaltrials.gov/ct/show/NCT00000125

Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Ocular Hypertension Treatment Study: 20 Year Follow-up

Principal Investigator: Anjali Bhorade, MD

Research Team Contact: Eve Adcock, Coordinator, 314-286-2946

If you are the legally authorized representative of a person who is being invited to participate in this study, the word "you" in this document refers to the person you represent. As the legally authorized representative, you will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have any questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions, you understand the study and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you were a participant in the Ocular Hypertension Treatment Study (OHTS).

The purpose of the OHTS 20-year follow-up study is to determine how many people have developed glaucoma, how many have mild versus severe glaucoma and how many people have functional limitations because of glaucoma. We will also develop a 20-year prediction model of who is at high or low risk for developing glaucoma or for progressing rapidly.

WHAT WILL HAPPEN DURING THIS STUDY?

If you are returning to Washington University for study visits, you will be asked to complete one to three study visits. During these visits you will receive a complete eye examination. All tests and measures are standard for individuals with ocular hypertension or glaucoma. No procedures or tests are experimental. The OHTS eye examination includes visual acuity, contrast sensitivity, visual fields and optic disc photography and optical coherence tomography (OCT scans). Measures of general health to be performed include blood pressure, height and weight. If you are

FOR IRB USE ONLY
IRB ID #: 201507107
APPROVAL DATE: 02/06/19
RELEASED DATE: 02/06/19
EXPIRATION DATE: N/A

unable or unwilling to complete a visit at the Washington University clinic, you will be given the option of completing a telephone interview or an in-home visit.

All participants, regardless of whether you return to Washington University for an examination, complete a telephone interview, or complete your visit at home, will complete a survey about your general quality of life, vision and ability to function. You are free to skip any questions that you would prefer not to answer.

Your visual fields, optic disc photographs, optical coherence tomography and will be reviewed by a team of nationally recognized experts in the field who are masked as to your identity.

We will ask you to release data related to your diagnosis of ocular hypertension or glaucoma from your last OHTS visit to date, specifically visual fields and OCT scans. This data will help us to understand if and when glaucoma damage might have occurred.

WILL YOU SAVE MY RESEARCH DATA TO USE IN FUTURE RESEARCH STUDIES?

As part of this study, we are obtaining survey and medical record data from you, and exam data from some participants. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding ocular hypertension and glaucoma, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your data will be stored without your name or any other kind of link that would enable us to identify which data are yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored and used for future research as described above.

_____ **Yes** _____ **No**
Initials **Initials**

FOR IRB USE ONLY
IRB ID #: 201507107
APPROVAL DATE: 02/06/19
RELEASED DATE: 02/06/19
EXPIRATION DATE: N/A

My data may be shared with <u>other researchers and used by these researchers</u> for the future research as described above.

_____ **Yes** _____ **No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 31 people will take part in this study conducted by investigators at Washington University. Approximately 1,327 participants in the Ocular Hypertension Treatment Study nation-wide will take part in this study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, and you are coming to Washington University for an exam, you will be asked to complete one to three visits over an approximately six-month period at dates and times convenient for you. The first visit will take approximately four to six hours. You are welcome to take breaks during the examination to avoid getting tired. The study will cover the cost of lunch for you and a companion at each visit. If a second or third visit is needed, it should take approximately two hours. If you are not returning to Washington University for an exam, completing the surveys will take 30-60 minutes.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The risk of participation in OHTS 20-year follow-up examinations is minimal. All tests and measures are standard for individuals with ocular hypertension or glaucoma. No procedures or tests are experimental. No action is taken to initiate, terminate or change your current treatment.

There is a small chance you could develop a corneal abrasion or a subconjunctival hemorrhage from clinical examination. OHTS includes routine clinical tests performed by highly skilled certified clinicians and certified study technicians and interpreted by experienced specialists. Thus, the rate of adverse events should be lower than would occur with standard care.

The eye drop placed in your eyes may sting or burn for a few seconds or minutes. Your vision may be blurry after your eyes are dilated and you may be sensitive to bright lights. We will provide you with sunglasses if you need them.

Some questions about your health and vision may bother or embarrass you. You may skip any question that you prefer not to answer.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure,

and we think the risk of accidental disclosure is very small. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. It is possible that our examination will provide information about your eyes that is important for you to know. However, we hope that, in the future, other people might benefit from this study because we will learn about how many people develop open angle glaucoma over a 20-year period, the functional limitations associated with the disease, and the progression of the disease.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor. If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) and address in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you, which will take approximately 2 weeks. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will receive a $50 check for each of up to 3 completed visits. The study will cover the cost of transportation for each visit if needed and a $25 voucher for lunch for you and a companion at each visit. The study will also pay airfare and hotel costs for participants who are visiting St. Louis from out of town.

Participants completing phone surveys will receive a $50 check for their time.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health is funding this research study. This means that Washington University is receiving payments from the National Institutes of Health to do this study. No one

FOR IRB USE ONLY
IRB ID #: 201507107
APPROVAL DATE: 02/06/19
RELEASED DATE: 02/06/19
EXPIRATION DATE: N/A

on the research team will receive a direct payment or increase in salary from the National Institutes of Health for doing this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- National Institutes of Health
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, all research data are identified only by study code. Research data are stored in locked cabinets in locked offices with restricted access at Washington University. Electronic files containing research data are encrypted and transmitted to secure databases behind firewalls accessible only by password. The confidentiality of all study related records will be maintained in accordance with State and Federal Laws and Health Insurance Portability Act regulations. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

FOR IRB USE ONLY
IRB ID #: 201507107
APPROVAL DATE: 02/06/19
RELEASED DATE: 02/06/19
EXPIRATION DATE: N/A

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.

FOR IRB USE ONLY
IRB ID #: 201507107
APPROVAL DATE: 02/06/19
RELEASED DATE: 02/06/19
EXPIRATION DATE: N/A

- Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
- You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. You may also choose to only complete a portion of the study visit tests and measures. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Anjali Bhorade, MD, OHTS Clinical Center Investigator at 314-362-3973 or Eve Adcock, Coordinator at 314-286-2946. If you experience a research-related injury, please contact: Anjali Bhorade, MD, OHTS Clinical Center Investigator at 314-362-3973 or Eve Adcock, Coordinator at 314-286-2946.

If you have questions, concerns or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

FOR IRB USE ONLY
IRB ID #: 201507107
APPROVAL DATE: 02/06/19
RELEASED DATE: 02/06/19
EXPIRATION DATE: N/A

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

FOR IRB USE ONLY
IRB ID #: 201507107
APPROVAL DATE: 02/06/19
RELEASED DATE: 02/06/19
EXPIRATION DATE: N/A

Legally Authorized Representative's Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____
(Participant's name – printed)

_____ _____
(Signature of Legally Authorized Representative) (Date)

_____ _____
(Name of Legally Authorized Representative - printed)(Relationship to Participant – printed)

Who should sign as the Legally Authorized Representative (LAR)?
If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

(1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
(2) Adult child;
(3) Parent;
(4) Brother or sister;
(5) Relative by blood or marriage.

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)