Appendix 5: Consent statement

Purpose of study

You are being asked to take part in this research study, The Longitudinal Study of Ocular Complications of AIDS (LSOCA) because you have been diagnosed with AIDS, the condition caused by the human immunodeficiency virus (HIV). The purpose of the study is to learn how HIV infections and its treatments affect people's eyes and their sight. The study is being conducted at several clinics around the country. We plan to enroll approximately 2,800 patients and follow them for 4 years or longer. Your participation in the study is voluntary. If you decide not to take part in the study, it will not affect the quality of the medical care you receive at this institution.

Whether or not you decide to enroll in the study, you will continue to receive whatever treatments you and your doctor have chosen to treat your condition. This study does not pay for any medical treatments or any costs of your care. You will not receive drugs or treatment as part of LSOCA. If you want, you can take part in any other research study that you are eligible for, including other SOCA studies.

Procedures

If you enroll in the study, you will be asked to come to the clinic for study visits. The study visits will be every 6 months , and we will call you between the study visits to ask you a few questions about your eyes.

At all study visits, your eyes will be examined. We will test how well you can see by asking you to read letters on a chart. We will also test how well you can see things to the side. If you have or if you develop serious eye problems, we will take photographs of the inside of your eyes (fundus photographs). Fundus photographs will be taken at the Baseline visit and every five years thereafter for patients without serious eye problems. You will be asked questions about your medical history, any illness you have and any medications that you take. We will also ask you questions about how you are feeling and about the quality of your life.

Blood tests will be performed every study visit. One to three tablespoons of blood will be drawn from a vein, usually in your arm. This may cause some pain, bruising, swelling and the chance of infection. These blood tests are not being done to manage your treatment. Blood will be stored at a central facility for future analysis. Near the end of the study, the blood will be tested for things related to eye disease and HIV diseases (such as HIV viral load and CMV viral load).

Specimen Banking and Use

If you agree to participate in LSOCA, some of your blood will be stored and may be used for AIDS-related research in the future including possibly genetic tests related to HIV/AIDS. It is possible that the use of your blood may result in the development of new products or tests, some of which may have commercial value. You will not receive any payment or financial benefits from such products or tests.

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We regard the banking of blood as an essential part of LSOCA. Therefore, blood once collected cannot be withdrawn by you from the study. Study data and blood samples collected, including blood for banking, are considered the property of LSOCA. If you are uncomfortable with having a portion of your blood banked for future research, you might want to consider not enrolling in the study.

Your blood will be stored with an assigned patient number-code at the specimen bank such that you will not be identified by name from your blood specimen. We will not inform you or anyone else about the results of tests done with your banked blood. These tests are done for research purposes only and are not conducted to manage your care or treatment.

Risks and benefits

The risks involved in participating in this study are minimal. Before doing an eye exam and taking photographs, we need to put drops in your eyes to dilate your pupils. Afterwards, your vision may be blurred for about two hours, sometimes longer. You may need to have someone drive you home after a visit.

You may benefit by having regular eye exams. If we detect a problem with your eyes, we will let you know. By participating in the study, you will help us to better understand how HIV disease and its treatment affect vision.

Rights and responsibilities

All people who take part in part in this study have rights and responsibilities that include:

- The choice to enter the study is up to you.
- You can leave the study at any time. Leaving the study will not affect the care that you receive at this institution. If you decide to leave the study, we would still like to contact you to find out how you are doing, but you can choose not to be contacted if you so indicate.
- Clinic staff will be prepared to answer questions or discuss any concerns about the study you may have now or in the future.
- The success of the study depends on coming to the clinic for regularly scheduled follow up visits. If you enroll we expect you to:
- Come to clinic for the study visits, and possibly answer questions about your health over the telephone.
- Work with the clinic staff to complete the examinations and give information about your medical history and quality of life.
- Tell the clinic staff about any changes in your address or phone number.

If you do not think you will be able to do these things, you should not enroll in LSOCA.

Appendix 5: Consent statement

Privacy and confidentiality

We are collecting data for the purpose of this study. We will keep the data at the SOCA clinic and at the SOCA Coordinating Center in Baltimore, Maryland. We will keep your records confidential to the extent possible within the limits of the law. To make sure that your identity and the data we collect about you are confidential, we will do the following:

- We will not use your name or address on study records. A number and a letter-code will be used for identification.
- The personal identifying information that we need will be kept in a secure location apart from the study records.
- With your written permission, we may read your medical record or speak with your doctor to get information about your health and what medications you are taking.
- We will not publish or present any of the results of this study in such a way that you could be identified as participating in this study.

It is important for you to know that we have gotten a Certificate of Confidentiality from the Federal Government for this study, to make sure we can best protect your privacy. This certificate means that researchers cannot be forced to tell people who are not connected with the study about your participation. This includes courts and the police. However, if you request disclosure, the researchers will release information.

There are some limits to the researchers' ability to maintain your confidentiality. If we learn that keeping information private would immediately put you in danger, or put in danger someone else we know about, then we will have to tell the appropriate agencies to protect you or another person.

Other things to consider

Examinations and tests performed for the study which you would not normally have done for your clinical care will be performed at no charge to you. Neither this institution nor the Federal Government has insurance to cover any costs if you are injured or have any bad effects that are not the fault of the investigator taking part in this study.

Consent

Before you agree to enroll, be sure that you have answers for all your questions about the study. Dr. *(name of doctor)* and the clinic staff will answer questions you may have. They can be reached at *(phone number)*. Once you have enrolled, if you believe that you have been injured or harmed by being in the study or are not being treated fairly, you may contact the clinic or the institutional review board to discuss your concerns. The phone number is *(institution and phone number)*. The study is being coordinated by The Johns Hopkins University. You may also contact The Johns Hopkins University's Office for Research Subjects at (410) 955-3193.

Appendix 5: Consent statement

To be completed by the patient

The purpose of the study has been explained to me. I have had my questions answered. I understand that if I have questions later on, the clinic staff will answer them. If I sign below, it shows that I agree to participate in the study. *(Record date)*

_____ _____

_____ _____

To be completed by SOCA certified personnel *(witness the patient's signature, sign below and record date.)*

_____ _____

_____ _____

SOCA personnel signature *date*

Clinic ID code: ____ ____ ____ ____

Patient ID#: ____ ____ ____ ____

Patient name code: ____ ____ ____ ____ ____