

## Appendix 6: Assent statement

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The purpose of the Longitudinal Study of Ocular Complications of AIDS (LSOCA) is to help us learn how HIV infections and its treatments affect people's eyes and their sight. We will follow people with this condition for a period of several years.

If you agree to be in this study, you will continue to receive whatever treatments you and your doctor have chosen. You can take part in any other research study for which you are eligible. You will not receive any drugs or treatments as part of this study.

Participation in the study requires that you come to the clinic for study visits, and possibly answer questions about your health over the telephone. We will see you every 6 months. At each visit, your eyes will be examined. We will ask you to read letters on a chart. We also will test how well you can see to the side. If you have eye problems, we will take photographs of the inside of your eyes (pictures of your retina). If you do not have eye problems we will take photographs of the inside of your eye at Baseline and every five years. We will ask you questions about your medical history, illness that you have and medicines that you take. We will ask you questions about how you are feeling and about your activities you do in a day.

You will have blood drawn at every study visit. The amount of blood that will be drawn is about three tablespoons. We will take the blood from a vein, usually in your arm. This may cause some pain, bruising, swelling and the chance of infection.

You may choose not to be in this study. You also may leave the study at any time. 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. Also, if you decide not to be in this study, it will not affect your medical care. No one in the study will be upset with you. You should ask the doctors and nurses questions that you may have about the study. We would like you to talk this over with other people if you need to before giving your answer. If you want to, you can read more about this study in the Consent Statement for LSOCA. If you have any questions you can ask Dr. \_\_\_\_\_ at \_\_\_\_\_.

It is important for you to know that we have gotten a Certificate of Confidentiality from the Federal Government for this study. This certificate means that the people doing the study cannot be forced to tell people who are not connected with the study about your participation. This includes courts and the police. If you ask them to, the study doctor or nurse will give information about you to others.

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.

**Appendix 5: Consent statement**

If you agree to be in this study, please sign below.

<b>To be completed by the patient</b>	
The purpose of the study has been explained to me. My questions about it have been answered. If I sign below, it shows that I agree to be in the study.	
_____	_____
patient signature	date of signature

<b>To be completed by the parent/guardian</b> <i>(please sign below)</i>	
_____	_____
guardian/parent signature	date of signature

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

_____	_____
witness signature	date of signature

Clinic ID code:     \_\_\_\_\_

Patient ID#:        \_\_\_\_\_

Patient name code: \_\_\_\_\_

**A parent or guardian should review and sign a Consent Statement**