Improving African American Glaucoma Patient Involvement in Visits and Outcomes

NCT number	NCT03657147
Document Date	10/22/2018

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study-Patients

IRB Study # 17-0688

Consent Form Version Date: 10/22/2018

Title of Study: Improving African American Glaucoma Patient Involvement in Visits and Outcomes

Principal Investigator: Betsy Sleath, Ph.D.
UNC-Chapel Hill Department: UNC Eshelman School of Pharmacy-Division of Pharmaceutical Outcomes and Policy

Co-Investigators: Delesha Carpenter, Ph.D. & Donald Budenz, MD

Funding Source and/or Sponsor: Agency for Healthcare Research and Quality (AHRQ)

Study Contact: Betsy Sleath, 919-962-0079

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The clinic is involved in a research project about services provided to African American patients with glaucoma. The goal of the project is to improve communication between providers and African-American patients about glaucoma.

How many people will take part in this study?
If you decide to be in this study, you will be one of approximately 380 African-American patients with glaucoma in this research study.

How long will your part in this study last?

Your participation in this study will last for approximately 12 months (one year). You will be interviewed today, in about six months from now, and about one year from now.

What will happen if you take part in the study?

During the course of this study, the following will occur today and about 6 months and 12 months from now at your follow-up glaucoma visits:

1. We will audio-tape record today's visit with your provider(s).
2. Half the patients will be shown a 11 minute video before their visit on the importance of being involved in their medical visits and will be given a one page sheet where they can check off questions they want to ask the provider. Half the patients will not receive anything before the visit. We will audio-tape record your visit. We will complete an interview with you in a private area of the clinic that should take about 15 to 20 minutes to complete immediately following your medical visit. The interview asks about your glaucoma, and your medical visit.
3. We will give you a large vial to put your glaucoma medications in. The top of the vial will record each time you open the vial to take your eye drops.
4. We will review your medical records to abstract information related to your glaucoma and use of glaucoma medications for the period of 12 months before and after you are enrolled in the study.

Are there any reasons you should not participate?

You should **not** participate in this study if:

- You are not African-American or Black.
- You are not age 18 or older.
- You are not able to speak and read English.
- You are not mentally competent to participate.
- You are not taking any glaucoma medications.
- You do not want to have the medical visit audio-recorded.
- You are blind.
- You report being more than 90% adherent to your glaucoma medications.

What are the possible risks or discomforts involved from being in this study?

This study might involve the following risks and/or discomforts to you: some people may feel uncomfortable having their physician visits audio-tape recorded. If at any time during your visit you would like to turn off the audio-tape recorder, please tell your provider. Also, some people may feel uncomfortable answering questions. You do not have to answer any questions that make you feel uncomfortable. In addition, there may be uncommon or previously unrecognized risks that might occur. You should report any problems to the researcher.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study. However, the findings of the study may help improve communication about glaucoma during medical visits.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
You will be assigned an identification number when you agree to participate in the study. All data collected in this study will be recorded under your identification number, not your name. A list which links provider and patients names to identification numbers will be kept in a locked filing cabinet that is separate from all study data. This list will be destroyed once all data is collected. No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-CH will take all steps allowable by law to protect the privacy of personal information.

The content and duration of the audio-tapes of the medical visits recorded during this study will be coded and summarized across all patients participating in the project. The audio-tape of your visit will be transcribed into text by a research staff member, and any information that could identify you and your provider will not be transcribed. The written transcript will only have an identification number on it, to protect your confidentiality. The audio-tape will be erased after it has been transcribed. Only the identification number on the transcript will be entered into the computer data set. No information in this project will identify you.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. Investigators also have the right to stop your participation at any time. This could be because you had an unexpected reaction or you failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will receive $25 for your participation today. You will receive another $25 after completing participation at each of the 6 month and 12 month follow-up visits.

Will it cost you anything to be in this study?
There will be no cost for being in the study.

Who is sponsoring this study?
This research is funded by the Agency for Healthcare Research and Quality (AHRQ). This means that the research team is being compensated by the sponsor for conducting the study. The researchers do not, however, hold a direct financial interest in the sponsor or in the outcome of this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Principal Investigator: Betsy Sleath, Ph.D.

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent