UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Community Based Treatment for Glaucoma- (ComBaT Glaucoma Program)

Company or agency sponsoring the study: Michigan Medicine Department of Ophthalmology

Principal Investigator: Angela Elam, M.D, Ophthalmology and Visual Sciences, U of M

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, this study requires you to travel to scheduled visits at the study site at the Historic King Solomon Baptist Church (HKSBC). This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying eye health disparities in a black community. It involves education and motivational interviewing in a community church to decrease barriers to care and provide a chance for early diagnosis and treatment to reduce vision loss from glaucoma. Glaucoma is an increased pressure in the eyeball that causes gradual vision loss. We can test for glaucoma with specialized cameras that take pictures of the eye. This study will provide glaucoma education and help scheduling follow-up care with an ophthalmologist. You will receive standard of care education/"ehealth" education. Ehealth education is viewing the education materials from a video on a tablet or computer.

Your vision screening related information will be collected for this research study by a University of Michigan ophthalmic technician/study coordinator. Your information will be collected from the secure University of Michigan health record to be read by a University of Michigan Ophthalmologist for evaluation and management. You will meet with the ophthalmic technician/study coordinator at this visit you will receive your diagnosis, education, and be scheduled with an ophthalmologist for a follow-up appointment within 3 months (if possible).

IRBMED informed consent template—4-11-2020

Instructions revised 4-11-2020

DO NOT CHANGE THIS FIELD—IRBMED USE ONLY

Your health-related information regarding medical records of a completed Ophthalmology appointment will be collected for this research study.

1.2 Risks of Being in the Study
There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include:

Disclosure of personal identifying information. (Likelihood: Rare)
The researchers will try to minimize these risks by using a study ID rather than your name on surveys and study data to reduce this risk.

1.3 Benefits of Being in the Study
This study may offer some benefit to you now or others in the future by:

- Information on diagnosis and education
- Assistance with scheduling an appointment with an ophthalmologist.

This study may benefit others in the future by allowing us to better understand how intervention and education can change the behavior of someone's willingness to see an eye care provider to prevent blindness and glaucoma progression.

You can decide not to be in this study. If you need eye care, the alternative to joining this study is to see a local ophthalmologist or request a referral to Ophthalmology from your primary care physician.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
With nearly 80 million people affected, glaucoma is a population health burden and the leading cause of blindness worldwide. An estimated 3 million adults in the United States have glaucoma and Black Americans are disproportionately affected. However, 50% of people with glaucoma do not know they have the disease and Black Americans are four times more likely than White Americans to remain undiagnosed.

The purpose of this research is to evaluate if intervention and education can change the behavior of someone's willingness to see an eye care provider to prevent blindness and glaucoma progression. We would like to see if we can improve access to eye care by having individuals meet with a study coordinator to discuss any barriers they may have for receiving eye care and set a plan to overcome those barriers.

Through the ComBaT Glaucoma program people will be provided education about glaucoma and given additional help/resources to treat glaucoma. As research has shown these individuals may have extra

barriers which may prevent them from obtaining appropriate care, we would like to see if adding additional resources improves their access to care.

To get information, we'd like 60 people to join the ComBaT Glaucoma program and receive sessions with a study coordinator that can help assess and address barriers you may have to receiving eye care. After receiving these sessions, if you see an eye care doctor, we would like to obtain your medical record information from the visits.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

- Adults age 40 and over
- Black or African American
- Participated in the screening examination portion of the study
- Diagnosis of glaucoma or glaucoma suspect
- Are willing to travel to study site, the Historic King Solomon Baptist Church.

3.2 How many people are expected to take part in this study?

We expect approximately 60 people to take participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Those who underwent the screening exam and were eligible for this study will be included in the following:

Education session:

A study team member will discuss glaucoma and create an action plan for you to follow-up with an Ophthalmologist. This session may be audio recorded and will take approximately up to an hour. Following the education, we will ask you to complete these surveys on an iPad or paper; 1) National Eye Institute Glaucoma Eye-Q test, 2) Satisfaction with Information Scale, 3) Clinician and Group Survey of the Consumer Assessment of Healthcare Providers and Systems (CG- CAHPS), 4) Health-Care Climate-eye care (HCCQ), 5) Confidence in question asking. These surveys include 38 questions that ask about your knowledge of glaucoma, satisfaction with the education program/provider and if you are comfortable asking your provider questions. These surveys will take about 10-15 to complete.

Phone follow-up sessions:

Phone/Video Call/In-person "Check In": We may contact you every 3 months, with a total of 4 calls. You will receive a follow-up phone or video call from a study team member to find out if you followed up with an Ophthalmologist, and discuss any barriers you may have experienced if you have not. The barriers will be addressed and a new action plan will be created. If you did see an Ophthalmologist within the 3 month time frame we will request the appointment date and time to confirm the

appointment from your ophthalmologist's office, if the appointment happened outside the University of Michigan. We will stop contacting you once you have been seen by an Ophthalmologist. We will also ask you to complete two questionnaires at each session. There will be one additional questionnaire/survey at the very last phone call session.

Access to medical records: By participating in this research project, you authorize the access of your clinic medical records to be shared with the researchers.

4.2 How much of my time will be needed to take part in this study?

- **Education Session with study coordinator:** In person visit at the church (HKSBC) will take approximately take between 30-60 minutes.
- **(4) Follow-up phone, in-person or video sessions:** Approximately take between 10-20 minutes each session.

4.3 When will my participation in the study be over?
Your participation will end after the completion of the final survey, which is up to 1 year.

4.4 What will happen with my information used in this study?
The study coordinator/ophthalmic technician will enter all data into both the UM electronic health record and a secure research database (REDCap). Data will be entered into the medical record as a 'no charge' research visit.

Additionally, your medical information will be combined with the other study participants and shared with the National Institute of Health. This data will contain no information that can identify you.

With appropriate permissions, your collected information will be stripped of all identifiers and then may also be shared with other researchers, here, around the world, and with companies. Your de-identified information may be used for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
There may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.
As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you from other studies. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
This study may offer some benefit to you now by:

- Providing information regarding diagnosis
- Free glaucoma education
- Assistance with scheduling an appointment with an eye care provider.

This study may benefit others in the future by allowing us to better understand how to structure eye care to people who live in communities with limited access to glaucoma care resources and providing ways to overcome barriers when needing to see an ophthalmologist for care.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
You can decide not to be in this study. Participating in this study is voluntary, and is meant to allow us to assist you in assessing barriers you may have to eye care. You do not need to be in this study to address these on your own. You can seek an ophthalmologist and eye care at your own discretion.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
If you leave the study before it is finished there will be no harm to you. You will no longer be entitled to the benefits of next level of services in the study as you would if you remained in the study. At any time you can decide to get care on your own.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for the ComBaT Glaucoma Program education. You and/or your insurance company will be responsible for any costs associated with follow-up care with an ophthalmologist. If you cannot afford follow up care with an ophthalmologist the study coordinator will put you in touch with financial counselors with UM Support to help you find affordable follow-up eye care. The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.
You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10.1 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

- You will receive a $50 gift card for completing the education session.
- You will also receive a $20 gift card for each 3-month follow-up session completed, which may be a total of 4.
- The total for completing all the ComBaT Glaucoma program tasks is up to $130.

8.3 Who could profit or financially benefit from the study results?
The researchers conducting the study: No
The University of Michigan: No

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

All information collected about you during the study will be placed into a research record. This research record will not include your name, but will have codes entered in it that will allow the information to be linked to you. We will keep your research record confidential and limit access to only members of the study team. You will not be identified in any reports on this study. When information is presented publicly or published, no information will identify individual patients.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:

  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- Future IRB-approved research studies
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Angela Elam, MD
Mailing Address: Kellogg Eye Center, 1000 Wall St, Ann Arbor, MI 48105
Telephone: 313-405-9555

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____Date of Signature (mm/dd/yy): _____

Sig-B

Consent to audio recording/eye photographs solely for purposes of this research

I agree to be audio recorded as a subject in this research study. I also agree that the recording may be used for the purpose of this research. I understand that I can stop the recording at any time and remain a participant in the study.

Print Legal Name: _____

Signature: _____Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____Date of Signature (mm/dd/yy): _____