Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Optimizing Treatment for Human Papillomavirus-Associated Oropharyngeal Cancer in Older Adults

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to understand the priorities and preferences of patients with oropharyngeal cancer (OPC) in relation to aging and overall quality of life. If you participate in this study, you will be asked to determine your treatment priorities via 2 assessments: the Chicago HNC Priority Scale and the Standard Gamble, a brief set of standardized interactions with the study team to understand how you make tradeoffs between health and disability. You will attend one study visit remotely with a trained study coordinator via a video teleconference platform for 30 minutes. There are no physical risks to you joining the study. However, there is a possibility that you may feel uncomfortable or upset talking about your cancer treatment and the decisions surrounding it. Loss of confidentiality is also a risk of participation. Although, there is no direct benefit to you from participating in the study, it is hoped that the information gained from the study will improve treatment of future patients with OPC by informing treatment decision-making.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have/had human papillomavirus (HPV)-related OPC. The purpose of this study is to understand the priorities and preferences of patients with OPC in relation to aging and their overall quality of life. The study involves research. The study is sponsored by the Medical University of South Carolina and National Institute of Health/National Cancer Institute. The investigator in charge of this study is Evan Graboyes, MD, MPH, FACS. The study is being conducted at the Medical University of South Carolina. Approximately 150 people will take part in this study. A grant from the National Cancer Institute (NCI) will sponsor this study. Portions of Dr. Graboyes' and his research team's salaries will be paid by this grant.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. We will gather information about your background and cancer history from your state's cancer registry.
2. You will meet with the trained study coordinator via a video telemedicine platform. You will complete one questionnaire: the Chicago HNC Priority Scale. This questionnaire will ask you to rank 12 priorities of OPC treatment (such as being cured of cancer, having a normal amount of energy, etc.) in order of importance. You will also answer a brief set of standardized

questions called the Standard Gamble to assess how you make tradeoffs between health and disability. This meeting will take 30 minutes. It will not be video-recorded.

C. DURATION

Participation in the study will be conducted over a single, 30-minute video teleconference session.

D. RISKS AND DISCOMFORTS

There are no physical risks to you by joining this study.

1. Psychological Risks: Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

2. Confidentiality Risks: There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Measures will be put in place and every effort will be made to protect the confidentiality of your private information.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

~~Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.~~ A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

There will be no direct benefit to you from participating in this study. It is hoped that the information gathered from the participants will be used to improve preference-concordant shared decision-making and outcomes, particularly quality of life, among older adults with HPV-related OPC in the future.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50 for participation in this study. Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card, and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard after you have successfully completed the 30-minute teleconference visit with a study staff member. ~~at the beginning of the study~~. ~~Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above.~~
Details of the debit card system are explained on an additional sheet.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

Clinically relevant results, including individual research results, will not be disclosed to subjects.

~~L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION~~

~~As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.~~

~~The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.~~

~~Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:~~

- ~~The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;~~
- ~~Other institutions and investigators participating in the study;~~
- ~~Data Safety Monitoring Boards;~~
- ~~Accrediting agencies;~~
- ~~Clinical staff not involved in the study whom may become involved if it is relevant;~~
- ~~Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or~~
- ~~Health insurer or payer in order to secure payment for covered treatment;~~
- ~~Federal and state agencies and MUSC committees having authority over the study such as:~~

  - ~~The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.~~

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~~Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.~~

~~You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.~~

~~Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.~~

~~If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.~~

M. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the Medical University of South Carolina's Institutional Review Board for Human Research will have access to identifying information. All records in Medical University of South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University of South Carolina, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University of South Carolina and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact **Evan Graboyes, MD, MPH, FACS** at **(843) 792-0719.** I may contact Medical University of South Carolina's Hospital Medical Director at **843-792-5555** concerning medical treatment.
If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of South Carolina's Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at 843-792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form (either a paper or emailed version) for my own records. If you wish to participate, please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Signature of Participant Date

_____ _____
Name of Participant Date