The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Head and Neck Cancer Patient Symptoms and Oncologic Outcomes as a Function of Head and Neck Volume Changes**
Principal Investigator:	**Roman Skoracki, Department of Plastic and Reconstructive Surgery, The James Cancer Hospital and Solove Research Institute**
Sponsor:	**Department of Plastic and Reconstructive Surgery**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study is being performed in order to take advantage of and apply new technology to the volume measurement of head and neck lymphedema—or swelling due to excess fluid production—which is a common side effect of surgical treatment for head and neck cancer. We hope to determine whether there exists a meaningful relationship between the amount of swelling and the patient's quality of life as well as his/her disease status. If such a relationship

exists, we may be able introduce a better method to measure swelling as a variable to improve the standard of care for patients with head and neck cancer.

If you choose to enroll for the entire duration of this study, you can expect to be a participant for about one year. You will have your facial volume scanned and be given a wellness questionnaire to fill out at each routinely scheduled appointment; once before your operation, and four more times after your operation, with the final appointment being about one year after your operation. You can expect each appointment to last an additional 30 minutes in order to accommodate the scans and questionnaire. There is minimal risk of harm or discomfort to you during this study, the greatest discomfort being the need to remain completely still for 1-2 minutes while the scan takes place. An iPad or iPhone with the scanning application will be used to take the scans.

If you participate in this study, you can expect to benefit by having an additional variable for the clinical team to use in their long-term treatment of your condition. If this variable (i.e. the amount of head and neck swelling) is found to have significance, the clinical team may be able to better treat your condition and improve your quality of life. In addition, you would help us establish head and neck swelling as an important way to improve the standard of care for future patients with head and neck cancer.

There is no penalty or loss of benefits if you choose not to participate in this study. In such a case, you will receive the standard treatment and care that you would receive if this study were not taking place.

1. Why is this study being done?

The availability of affordable and portable 3D technologies that can be used on tablets in physician clinics has brought the possibility of a volume measurement tool that will be able to measure volumes of various body parts. This tool will allow physicians to compare changes in head or neck volume to assess degree of lymphedema—or swelling due to excess fluid production—between patient visits. We hope to use this technology to measure changes in the amount of swelling in the head and neck region and correlate those measurements with clinical outcomes and patient self-reports of physical, social, and emotional well-being after receiving surgical treatment for their head and neck cancer. This would help us establish the use of tracking head and neck volume changes as a crucial part of patient care and follow up after surgery for head and neck cancer.

In order to take advantage of available 3D technology and develop this tool, we have partnered with Knockout Concepts / Mobile 3D Scanning Software, a Columbus-based company, specializing in 3D surface scanning and analysis software.

2. How many people will take part in this study?

A total of 100 participants will participate in this study. We will be recruiting an equal number of men and women across a range of age and body composition from 18-90+ years old.

3. What will happen if I take part in this study?

During the main part of the study...

If you meet the inclusion and exclusion criteria choose to take part in the study, then you will complete the following tasks:

1. Your weight will be recorded.
2. We will provide you with a gown and cover and ask you to remove enough clothing as to expose your head, neck and shoulders.
3. We will ask you to tie back any hair that is blocking our view of your neck and shoulders using hair ties or caps that we will provide you with.
4. We will ask you to be seated and look directly ahead. We will use the Knockout 3D scanner to take multiple videos from all angles that we use to form a 3D scan of your head, neck, and shoulders. Each scan takes between 90 seconds – 120 seconds.
5. We will take three good scans. We may have to repeat a scan if the software doesn't get enough views to fully cover the entire surface of your head, neck and shoulders.
6. After all scans have been taken, you will be able to dress and remove any hair band/caps you may have used in order to obtain the scan. Every scan will be uploaded to Knockout Concepts' HIPAA compliant and secure server.
7. You will be given a short, multiple choice questionnaire to complete that will ask you how you have been feeling in the past week. This questionnaire will be on the electronic tablet and will automatically upload to a HIPAA compliant and secure REDCap database.

After you complete the main part of the study

Once you have completed all scans and questionnaires for five visits (a total of 15 scans and 5 questionnaires), your participation in the study will be complete. Your scans and responses will be held on the server during the duration of the study, including data analyses, writing, and study publication.

4. How long will I be in the study?

This study will take place during five visits, each taking between 30 and 45 minutes. The first set of scans will occur during a pre-operative clinical visit, and the final four sets of scans will occur post-operatively at your standard 3, 6, 9, and 12-month interval follow-up appointments. Total additional time commitment for the study will be less than 2 hours. Your total involved participation in this study will last no more than a year if you choose to remain in the study for its entire duration.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Risks from participating in this study are minimal and include mild discomfort from sitting still for two minutes while the scan occurs. To minimize this risk, we will provide you with a

covering and perform the scans in a timely manner. The scanner uses infrared technology, therefore there will be no radiation exposure as in traditional x-ray or CT scans.

During this study you will have 15 total 3D scans of your head and neck region (three per visit). These scans are solely for the purpose of this research and you would not have these scan(s) if you decide not to participate in this research study. A 3D scan uses two cameras and infrared light in order to assess depth and create a 3D image of objects. You will not be subject to any radiation by participating in this study.

7. What benefits can I expect from being in the study?

There are no direct monetary or known health benefits to you for participating in this study. The technology developed through your participation could help in diagnosing debilitating and potentially life-threatening swelling in patients undergoing surgery to remove head and neck cancers. It could also establish the volume of head and neck swelling as a crucial variable in the long-term monitoring of disease status and patient wellbeing.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There is no cost to you for participation in this study. There may be out-of-pocket expenses such as parking and transportation fees. To minimize any such fees, we are performing the study at a site with free visitor parking.

10. Will I be paid for taking part in this study?

There is no payment for participation in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my de-identified information be used or shared for future research?

Your facial scans will be deleted at the conclusion of the study, but your de-identified volume measurements may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

The 3D scans of your head and neck region will be stored on Knockout Concepts' cloud-based server, which is compliant with HIPAA regulations. These scans will be uploaded as 3D images of your face, but they will then be stored as de-identified facial contour maps that will maintain the 3D structure of your head and neck while eliminating any defining facial features or characteristics. Upon conclusion of the study, they will be deleted. Your responses to the questionnaire will be coded and stored on the REDCap database, which is compliant with HIPAA regulations. Furthermore, your name will not be directly attached to your scans, weight, or demographic characteristics. Rather, we will assign you a study ID (number from 1-100) and these will be used to refer to your data directly.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;

- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results
- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;
- Others: Knockout Concepts, the company who makes the 3D scanner and the cloud-based HIPAA-compliant server that stores the scans, will have access to your scans, but not to any of your past or present medical records or any other identifying information.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact ***Roman Skoracki*** at **roman.skoracki@osumc.edu**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **Kathleen Ojala** at **kathleen.ojala@osumc.edu**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***Roman Skoracki*** at **roman.skoracki@osumc.edu**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time