The Ohio State University Consent to Participate in Research

Study Title:	**Olfactory Function Following Endoscopic Endonasal Skull Base Surgery: Clinical and Histological Outcomes**
Principal Investigator:	**Ricardo L. Carrau, MD**
Sponsor:	**OSU – Department of Neurological 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.

1. Why is this study being done?

You are being asked to take part in this study because you are at least 18 years old and have a skull base abnormality (i.e. tumor, inflammatory process, fracture, defect, etc.) requiring endoscopic endonasal surgery to remove the abnormality. This type of surgery has been proven over the last several years to be beneficial for patients with skull base abnormalities. However, this surgery can result in altering a person's sense of smell and/or olfactory function.

The purpose of this study is to compare your sense of smell before and after your surgery and use the information collected to validate approaches to surgery that will minimize side effects to the sense of smell function. Your doctor and/or research team will collect data using a smell identification test along with two questionnaires. In addition, demographic, medical history, treatment, outcome, and follow-up information will be collected from your medical chart. This information will allow the research team to evaluate sense of smell function in regards to endoscopic skull base surgery.

The surgery is considered a standard of care treatment and is FDA approved for the treatment of skull base abnormality removal.

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

Approximately 160 people will take part in this study at OSU.

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

As a part of the routine procedures for your endoscopic endonasal surgery, you will be asked to have a pre-surgery visit, and then follow-up visits after surgery at one, three, six, and 12 months. At the pre-surgery visit and the month six follow up, you will be asked to complete the University of Pennsylvania Smell Identification Test (UPSIT). This test will ask you to smell an odor and then identify that smell from a list of choices. This test will take approximately 10 minutes. If you participate in this study, we are asking you to repeat the UPSIT at your one, three, and twelve month follow-up visits. Your results will be correlated with the type of surgical approach you had along with any other factors from your surgery that may alter your sense of smell.

Prior to your surgery you will undergo the following standard of care procedures:

- A history and physical examination
- A head CT scan if clinically indicated by your doctor
- An MRI if clinically indicated by your doctor
- Women of childbearing potential will also undergo a serum pregnancy test prior to enrollment in the study to confirm that they are not pregnant.

As part of this research study, you will also be asked to answer two questionnaires: the ASK Nasal-12 and the Skull Base Inventory (SBI) before the surgery and at one, three, six and twelve months after the surgery. These questionnaires will allow you to answer questions and give input on your overall quality of life before and after the surgery. It will take approximately 10 – 15 minutes to complete these surveys at each time point. Please note that you may refuse to answer any question for which you are not comfortable.

If it is determined that you have experienced a loss of your sense of smell after surgery, you will be offered a standard of care nasal biopsy (removal of tissue) to try to determine the cause.

If you qualify and decide to participate in the study, your participation will last approximately 12 months and will include up to the following 6 visits to the doctor's office and hospital:

- **Visit #1**: Screening/ Enrollment (prior to surgery) (baseline UPSIT, ASK Nasal-12 and SBI completed)
- **Visit #2:** Surgery
- **Visit #3:** 1 month follow up visit (UPSIT, ASK Nasal-12 and SBI completed)
- **Visit #4:** 3 month follow up visit (UPSIT, ASK Nasal-12 and SBI completed)
- **Visit #5:** 6 month follow up visit (UPSIT, ASK Nasal-12 and SBI completed)
- **Visit #6:** 12 month follow up visit (UPSIT, ASK Nasal-12 and SBI completed)

You will be required to return to your doctor's office for these planned follow-up visits. However, if you are not able to complete the survey and/or UPSIT smell test during your follow-up visit (i.e. due to time constraints), the surveys and/or the UPSIT smell test and a self-addressed stamped envelope will be mailed to you. Additionally, if you are comfortable doing so, the researchers can email you the surveys to complete electronically.

Your doctor and/or research team will use the treatment, outcome, and follow-up data collected from your medical chart along with your UPSIT results and questionnaire responses to evaluate sense of smell function in regards to endoscopic skull base surgery.

4. How long will I be in the study?

You will be enrolled in the study for one-year (12 months). You will undergo endoscopic skull base surgery followed by 4 post surgery follow-up visits with your doctor. Data about you will be collected before, during and after your surgery. You will be required to complete follow-up visits at one month, three months, six months, and twelve months after surgery. Your participation in the study will be over after the 12 month follow-up visit.

5. Can I stop being in the study?

Taking part in this research study is voluntary. You may leave the study at any time. You may do so by sending a letter, calling, or e-mailing the study Principal Investigator, Dr. Ricardo Carrau:

Ricardo Carrau, MD
320 West 10th Ave.
Starling-Loving Hall, B221
Columbus, OH 43210
Phone #: 614-293-8074
E-mail address: Ricardo.Carrau@osumc.edu

If you decide to leave the study all of your information that has been collected to the point of withdrawal will be used.

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.

Your physician may take you out of the study, even without your agreement, if:

- It is not in your best medical interests to continue.
- You do not follow instructions.
- The study is terminated.

However, for your safety, if you leave the study early, your study doctor or his staff may or may not ask you to finish the study termination procedures.

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

This surgery is standard of care and will be performed regardless of your participation in this study. Standard of care is how most people with your disease or condition are surgically treated. You may have risks of surgery whether you take part in this study or not. The risks associated with the surgery will be described to you separately as this consent form pertains only to this research study.

You may have a number of x-rays and MRI scans that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These studies will not add to the risk of the research. However, if you have concerns about the overall radiation exposure or MRI safety issues, you should discuss them with your physician.

The only risk associated with this study is a breach (break) of confidentiality. Such a breach of confidentiality would only occur in the event of an error as all paper and computer based files will be kept in a secure location and only be accessible to personnel involved in the study. It may be inconvenient to take the time to complete the questions. Efforts will be made to keep personal information confidential, but the researchers cannot guarantee absolute confidentiality.

Other points to consider:
You may refuse to do any of the study tasks that you do not wish to.

You have the right to refuse to answer any question for any reason.

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

There will be no direct benefits to you during this study. However, the results from this study may help us learn more about treating patients with skull base abnormalities. Researchers hope to compare sense of smell before and after surgery to help validate approaches to surgery that will minimize side effects to the sense of smell function.

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

You may still be able to undergo endoscopic endonasal skull base surgery if you choose to not participate in this study because this treatment is considered standard of care. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

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

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.

Paper based files will be kept in a secure location in the OSU Department of Neurological Surgery research office and only accessible to personnel involved in the study. Within the research office, the research records are kept in a locked drawer or file cabinet. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. If the information obtained from this study is published in a medical journal, you will not be identified by name.

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).

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 records. 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

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

The UPSIT performed at the 1, 3, and 12 month post-surgery visits as well as the administration of the 2 surveys at all time points, are considered research procedures and will not be charged to you or your insurance company.

All other tests and procedures (i.e. pre-surgery pregnancy test, pre-surgery and 6 month post-surgery UPSIT, surgery, scans, and post-surgery follow-up visits), are considered part of your standard medical care (not part of the research.) All of these standard of care tests and procedures will be charged to you or your insurance company. You will be responsible for meeting any co-pay and deductible requirements by your insurance plan.

Participating in this research study may lead to additional costs to you. In some cases, it is possible that your insurance company will not pay for the standard of care procedures including the surgery as a result of your participation in the study.

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

You will not be paid for participating in this study.

12. 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 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.

13. 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.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Dr. Ricardo Carrau at 614-293-8074.**

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 Ms. Sandra Meadows in 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 **Dr. Ricardo Carrau at 614-293-8074.**

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 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