If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: The Effect of Temporal Muscle Suspension on the Risk of Temporal Hollowing: A Prospective Randomized Clinical Trial

Application No.: IRB00120812

Principal Investigator: Chad Gordon
601 N Caroline St. #157
Baltimore MD 21287
Phone: (443) 997-9466
Fax: (410) 614-1296

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

The purpose of this study is to compare 2 different surgical techniques for the approach to your neurosurgical (brain) procedure.
In order to approach the brain and the skull, the surgeon will often use an incision along the side of your head in a semi-lunar fashion. After incision of your skin, there is a large muscle called the Temporalis Muscle. This muscle on the side of your forehead is the next layer that needs to be retracted to moved in order to access the skull and eventually your brain beneath your skull. Often times the surgeon will either cut through the muscle, or keep the muscle as one piece to retract it from the skull.

Currently, doctors and surgeons do not know which approach (cutting through the muscle, or leaving it in one piece) results in a better outcome. A complication of this surgical approach is temporal hollowing. Temporal hollowing is when the muscle that is retracted for access to the brain shrinks and there is a flattening of that side of your head and face. This can occur around 6 months after your surgery. We are performing this study to see if one approach (cutting through the muscle or keeping the muscle as 1 piece) will lead to less temporal hollowing (flatness of the side of your head).

How many people will be in this study?
Thirty people who require temporal muscle suspension as part of their standard of care neurosurgical procedure will be enrolled into this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

A pre-operative CT scan will be performed as part of your routine care. If you agree to take part in the study, you will be randomly assigned (by chance, like the flip of a coin) into 1 of 2 surgical approach groups: Both of the surgery options are used in standard clinical care, which means you could still have either of these procedures whether you are in the study or not. You will not know the arm to which you have been assigned.

Traditional pterional approach with a muscle cuff left for TMS (Temporalis Muscle Suspension)
Traditional pterional approach with TMS performed with a bone plate. (Temporalis Muscle will be secured to a titanium plate)

Routine follow up will be performed at 1 week from surgery, 1 month, and 6 months from surgery where a routine post-operative CT scan will be performed. All other care and services will be as per routine. There will be no extra research procedures performed.

- Demographic data including age, gender, indication for surgery, length of surgical time, and complications will be recorded.
- Photographs of the side of your head will be taken If you agree to participate, the photos maybe used in a scientific journal. At no point will recognizable portions of your face be included in the photographs (eyes, nose,lips). All images will be deidentified so that no one can recognize your picture.

The study doctor can provide you with additional information if you have questions.

How long will you be in the study?

You will be in this study for 6 months.

4. What are the risks or discomforts of the study?

The procedure you are assigned to may have results that are not as good as the alternate procedure.There is the risk that information about you may become known to people outside the study. You will be assigned a confidential study number which will be linked to your medical record number. The linking database identifying patients with their alphanumeric code will be stored on a single computer that is password protected. The password will only be given to the co-investigators of the study.

There may be side effects and discomforts that are not yet known.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study.

If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You will still get the same neurosurgical procedure and reconstruction.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

11. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

12. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Chad Gordon at 410 997 9466. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, Dr. Chad Gordon at 410 997 9466 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Robin Yang at 410 997 9466 during regular office hours and 917 557 2401 after hours and on weekends.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your or data, and should researchers use them to create a new product or idea, you will not benefit financially

14. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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