RUTGERS
Robert Wood Johnson
Medical School

# CONSENT TO TAKE PART IN A RESEARCH STUDY

**TITLE OF STUDY:** A Comparison of the Efficacy of 5% Lidocaine Anesthetic to Provide SPGB Vs. Elavil for the Treatment of Transform Migraine
**Principal Investigator:** William Grubb, MD, DDS

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor, William Grubb, MD, DDS, or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Sponsor of the Study: Department of Anesthesiology, Rutgers-Robert Wood Johnson Medical School.

## Why is this study being done?

This study is being done to see which therapy, Sphenopalantine Ganglion Block (SPGB) or Elavil, is better at treating migraine pain in adult subjects with transformed migraines (chronic migraines). A SPGB is a technique in which a small applicator is inserted into the nose to numb the area that is involved with causing the migraine pain. We will use 5% lidocaine (common numbing agent) with this technique. The other group in the study will receive a commonly used medication, Elavil (prescription medication taken by mouth).

## Why have you been asked to take part in this study?

You are being asked to participate in this study because you have been diagnosed with transformed migraines (chronic migraines). You are an adult referred from a neurologist or other health care provider to the Pain Service at Rutgers-Robert Wood Johnson Medical School.

**Who may take part in this study? And who may not?**
You may participate in this study if you have been diagnosed with transformed migraines. Also, you are between the ages of 18 and 90, and are currently requiring treatment for the migraines, and are not being treated with Elavil. You can participate in this study if your background medications including any pain medication such as Mortin, Excedrin, Aspirin, or Fioricet or narcotic medications such as Percocet, Fiorinal, or other prescribed by your doctor has been stable for the past 3 months. You can participate in this study if you have not been responding to traditional medical treatments such as triptans (Imitrex, Amerge, Relpax), anticonvulsants (Depakote, Lamictal, Klonopin), and/or beta-blockers such as inderal, or catapres.

You may not participate in this study if you are less than 18 years of age or older than 90 years of age. Also, you may not participate in this study if you are currently being treated with lidocaine (patch or injection) for pain, if you have untreated heart failure, are pregnant (see below), or if you are unwilling to follow study procedures and participate in the follow up.
If you are a female between the ages of 18-50, you will have to accept a urine pregnancy test prior to each intervention
If you become pregnant during the course of the research, you will be withdrawn from the study
You will be requested to take steps to avoid pregnancy during the course of the study
You may also not participate in this study if you have an allergy to either lidocaine or Elavil or if you have a medical history of hypersensitivity to local anesthetics, including lidocaine

**How long will the study take and how many subjects will participate?**

We plan to enroll 26 subjects at Rutgers-Robert Wood Johnson Medical School. Your individual participation will consist of 4 weeks of active study visits to the Pain Clinic at Rutgers-Robert Wood Johnson Medical School. Then the individual will participate in a safety visit 2-4 weeks after the active treatment period at week 6.

**What will you be asked to do if you take part in this research study?**

You will be randomized to one of 2 treatment groups (assigned by a flip of a coin to one of 2 treatment groups). You will be asked to complete headache questionnaires throughout the study. If you are randomized into the SPGB group, you will have blood pressure, heart rate, and pulse oximetry (measures the % of oxygen in your blood) readings during the SPGB procedure, and you will be asked to complete an additional questionnaire approximately 20 minutes after the procedure is completed. Lidocaine, which is the medication that we will be using for the SPGB, is standard treatment for pain. SPG with lidocaine gel will be administered weekly for 4 weeks.

If you are randomized into the Elavil group you will receive a prescription from Dr. Grubb for 10 mg of Elavil by mouth for the first week followed by 20 mg by mouth for the remaining 3 weeks of the study which will total 30 days of treatment. You will obtain a prescription at your pharmacy for the Elavil. Elavil is a standard of care medication for the treatment of migraines.

**What are the risks and/or discomforts you might experience if you take part in this study?**

You may experience minor local discomfort during the SPGB procedure, bitter taste in the back of your throat, difficulty talking while the procedure is taking place, difficulty eating and drinking for a few minutes to up to 2 hours after the SPGB. You may also notice bloody drainage from the nose after the procedure, most notably on the applicator used to apply the lidocaine. There are no known psychological/emotional, social, legal and economic risks of harm from the SPGB.
Some minor risks associated with Elavil are nausea, drowsiness, constipation, and dry mouth. Because Elavil has potential adverse effects to unborn babies, pregnant women will not be included in this study.

A minor risk is the possible loss of anonymity from participation in this study. However, the Principal Investigator and his research team have built in protections to avoid and limit this from occurring.

**Are there any benefits for you if you choose to take part in this research study?**

The benefits of taking part in this study may be:
Either of the treatments could help your headache pain, but there may be no direct benefit

**What are your alternatives if you don't want to take part in this study?**

Your alternative is not to take part in this study, and to ask your doctor to provide either of the therapies available in the study

**How will you know if new information is learned that may affect whether you are willing to stay in this research study?**

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or after your follow-up is completed, you will be contacted.

**Will there be any cost to you to take part in this study?**

You will not incur extra costs for participating in this study.

**Will you be paid to take part in this study?**

You will not be paid for your participation in this research study.

**How will information about you be kept private or confidential?**

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

All measurements will be recorded on a case report form. All data will be kept in locked file cabinets in Dr. Grubb's office at the Clinical Academic Building Suite 3100, with limited access to study personnel. Your study files will be coded with your initials and a unique study number. All information will be kept confidential, the link to PHI (Personal Health Information) will be stored separate from the study files, and will be destroyed after the completion of the study.

A description of this clinical trial will be available on 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 website at any time.

**What will happen if you are injured during this study?**

Subjects in this study will be exposed to certain risks of personal injury, which include: slight discomfort during the SPGB procedure and some blood drainage from nose that may be seen on the applicator. In addition, it is possible that during the course of this study, new adverse effects of lidocaine and Elavil that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

**What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?**

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time and seek treatment for your migraines' by Dr. Grubb and his team. You will still be treated for your migraine headaches by the doctor you have an appointment with regardless if you decide to participate in this clinical study, this is considered standard of care treatment.
If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:

Dr. William Grubb, MD, DDS
Rutgers-Robert Wood Johnson Medical School
Clinical Academic Building Suite 3100,
New Brunswick, NJ 08901

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

**Who can you call if you have any questions?**

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

William Grubb, MD, DDS
Dept. of Anesthesiology, Rutgers-Robert Wood Johnson Medical School
732-235-7827

If you have any questions about your rights as a research subject, you can call:

IRB Director
(732)-235-9806 New Brunswick/Piscataway

**What are your rights if you decide to take part in this research study?**

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

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## AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization (permission). If you sign this consent form, it will provide that authorization. The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization and informed consent form as required or allowed by law. Because we are committed to protecting your health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form about what information we will collect about you, how we will use it, when or if it will be shared with others, and the measures we will take to protect your privacy and the confidentiality of your personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

**What is the purpose of this research study and how will my health information be utilized in the study?**

The purpose of this study is to determine if SPGB is superior to Elavil in the treatment of migraine headaches in subjects diagnosed with transformed migraines (chronic migraines). We will be using the headache questionnaires that you complete to analyze the study question. We do plan to publish or share our results to others in a peer-reviewed journal or at national and international conferences. These are places where specialists discuss the care and treatment of your condition in order to help improve the care you receive. These are generally professional meeting that doctors and medical professionals attend to improve the care in their daily practices. All clinical trials may be monitored by the FDA (Food and Drug Administration) without notice.

**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and receive any research-related products. However, signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke my authorization or withdraw my information later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your data (and to discontinue any other participation in the study) at any time.

If you wish to revoke your authorization for the research use or disclosure of your data in this study, you may do so in writing by contacting:

William Grubb, MD, DDS
Rutgers-Robert Wood Johnson Medical School
Clinical Academic Building Suite 3100,
New Brunswick, NJ 08901
732-235-7827

**What personal information will be used or disclosed?**

Your health information related to this study, may be used (disclosed) in connection with this research study, including, but not limited to, age, and sex. All medical information collected from or about you in connection with study such as the questionnaires you complete, your medical history and medical records you share with us, including any emergency treatment you may seek during your participation or during the follow-up in this study, may be shared with the agencies listed below who work to ensure your rights as a study subject. These agencies also ensure that the study doctors and his team follow all regulations to ensure your well-being, privacy and your overall health and legal rights.

**Who may use or disclose the information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Rutgers University-Institutional Review Board
- The Research Team in the Department of Anesthesiology
- Rutgers-Robert Wood Johnson University Hospital
- FDA
- The Office for Human Research Protections in the U.S. Department of Health and Human Services

**Who may receive/use the information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Rutgers University-Institutional Review Board
- The Research Team in the Department of Anesthesiology
- Rutgers-Robert Wood Johnson University Hospital
- FDA
- The Office for Human Research Protections in the U.S. Department of Health and Human Services.

**When will my authorization expire?**

Your authorization for the use and /or disclosure of your health information will expire: "There is not a set date at which your authorization will expire. 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."

**Will access to my research study record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

## AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

**Signature of Investigator/Individual Obtaining Consent:**

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____