Cleveland Clinic
Consent to Participate in a Research Study

Study Title: A Single Center, Randomized, Open-Label, Two Arm Crossover Study of Subject Productivity Improvement and Satisfaction with Migraine Treatment Using Treximet™ vs Usual Triptan. "Does Treximet™ Improve Productivity and Patient Satisfaction Due to Sustained Response and Consistency of Response?"

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Daytime # for *med* questions: **216-444-8265**
After business hrs &wkends: **216-444-2200 and ask to page the Neurology Resident on-call.**

Sponsor: **Pernix Therapeutics**

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

You are being asked to participate in this research study because you suffer migraine headaches and have an active prescription for a triptan to treat your migraine headaches. The currently prescribed triptans are: sumatriptan (Imitrex), zolmitriptan (Zomig), rizatriptan (Maxalt), naratriptan (Amerge), almotriptan (Axert), frovatriptan (Frova) and eletriptan (Relpax).

Why Is This Study Being Done?

Researchers want to learn about your work productivity after treatment of a migraine headache with your usual migraine medication as compared to your work productivity after treatment with Treximet™. (Treximet™ is a combination drug containing sumatriptan succinate 85 mg and naproxen sodium 500 mg in one tablet.) Treximet™ is approved for sale in the United States by the U.S. Food and Drug Administration (FDA) for treatment of migraine headache.

The main purpose of this study is to compare the effectiveness of Treximet™ and your usual prescribed migraine medication in helping to stop your migraine so that your work is not slowed down and you may complete a full day's work.

During one part of this research, you will take Treximet™ for 3 workday migraine attacks. For the second part, you will take your usual prescribed medication for 3 workday migraine attacks. You will be randomized to decide which treatment, either Treximet™ or your usual triptan medication you will take for the first 3 migraine attacks. (Randomized means assigned to the treatment by chance or like flipping a coin to see which treatment you will use first.) You will use the other (Treximet™ or your usual medication) during the second part. You will not be able to take NSAIDs during your participation in this study.

How Many People Will Take Part In The Study?

About 60 female and male subjects over the age of 18 years will take part at Cleveland Clinic. This is the only site for this research study.

What Is Involved In The Study?

If you agree to take part in this study, you will first sign this informed consent form before any study-related procedures are performed.

The first visit of the study is a screening and enrollment visit when the study doctor will ask you questions and do some tests. You will be asked questions to determine if you have a history of migraine headaches and what medication you use to treat the migraine headaches. If the study doctor says you can be in the study and you want to be in the study, the study doctor or study staff will do some or all of the things listed below:

Screening and Enrollment Office Visit (#1):

- **Study Diary:** Give you a paper diary and tell you how to complete the questions each day for about one month. It is important that you record all information accurately in the study diary and that you do so each night before going to sleep.
- **Health and Medication Questions:** Ask you questions about your health and the medicines you take.
- **Physical Exam:** Give you a brief physical exam. You should ask your study doctor about what will be done during this exam.
- **Blood Pressure, Pulse:** Check your blood pressure by putting a band around your arm. This will squeeze your arm for about a minute. Check your pulse.
- **Urine Pregnancy Tests:** If you are female and able to have children, your urine will be tested at each office visit to see if you are pregnant. You will be told if the test result is positive. The result of the test must be negative in order to be in the study.
- **Randomization:** You will be assigned by chance (like flipping a coin) to one of 2 possible study groups. This will determine what medication you will use to treat your workday migraine headaches. You will either be randomized to the Treximet™ arm and be given a supply of 3 Treximet™ tablets to use during this part of the study or you will be randomized to treat your workday migraine headaches with your usual triptan dose.
- **WPAI:** You will be given 3 WPAI questionnaires to complete after you have treated each migraine headache attack. The WPAI will take about 2 minutes to complete.
- **CORS 1:** You will be given one CORS 1 questionnaire to complete after you have treated the 3rd migraine headache attack. The CORS 1 will take about 5 minutes to complete.
- **Migraine-ACT**: You will be given one Migraine-ACT questionnaire to complete after treating the 3rd migraine headache attack. The Migraine-ACT will take about 2 minutes to complete.
- **Knowledge Program**: You will complete questionnaires on a computer or tablet as you would normally do during a regular appointment

Office Visit 1 will last about 2 hours.

Visits 2, 3 and 4 (These are telephone call visits)

Telephone calls:

- After you treat each migraine, you will telephone the study coordinator who will review with you the research activities that occur after you have treated a migraine headache.
  - You will review your headache diary information for completeness
  - You will confirm your treatment dose for the migraine
  - If you are using Treximet™ for this part of the study, you will need to tell us how many tablets you have left. If needed, arrangements will be made to provide additional tablets for the remaining headaches to be treated.
  - You will be reminded to complete the post-headache questionnaire - the WPAI
  - After the 3rd migraine treatment you will be reminded to complete the post-headache CORS 1 and Migraine-Act questionnaires
  - You will have your Visit 5 scheduled

Visits 2, 3 and 4 will each take about 15 to 30 minutes.

Visit 5 (Office visit; occurs *no sooner* than 48 hours after the third migraine treatment)

- **Study Diary:** Collect the completed diary and give you a blank paper diary and remind you how to complete the questions each day for about one month. It is important that you record all information accurately in the study diary and that you do so each night before going to sleep.
- **Health and Medication Questions:** Update with you, questions about your health and the medicines you take.
- **Urine Pregnancy Tests:** If you are female and able to have children, your urine will be tested at each visit to see if you are pregnant. You will be told if the test results are positive. The results of the test must be negative in order to remain in the study.
- **Randomization:** You will be switched to the remaining study drug treatment arm. (If you were randomized to Treximet™ for the first workday migraine treatment arm, your second treatment arm will be your usual triptan treatment. If you were randomized to your usual triptan migraine treatment in the first arm, your second workday migraine treatment arm will be Treximet™.) If you used Treximet™ during Treatment Arm 1, at this visit, you will return the study drug containers and any unused study drug.
- **WPAI:** Your completed WPAI questionnaires will be collected and you will be given 3 blank WPAI questionnaires to complete after treating each migraine headache attack. The WPAI will take about 2 minutes to complete.
- **CORS 1 and CORS 2:** You will be have the completed CORS 1 collected and be given both of these questionnaires to complete after treating the 3rd workday migraine headache attack of this second treatment arm. The CORS1 and CORS2 will take about 8 minutes to complete.
- **Migraine-ACT**: You will have the completed Migraine-ACT questionnaire collected and you will be given one to complete after treating the 3rd migraine workday migraine headache attack in this second treatment arm. The Migraine-ACT will take about 2 minutes to complete.
- **Knowledge Program**: You will complete questionnaires on a computer or tablet as you would normally do during a regular appointment

Visit 5 will last about 2 hours.

Visits 6, 7 and 8 (These are Telephone call visits)

- Telephone call visits: After you treat each migraine, you will telephone the study coordinator who will review with you the research activities that occur after you have treated a migraine headache.
    - You will review your headache diary information for completeness
    - You will confirm your treatment dose for the migraine
    - If you are using Treximet™ for this treatment arm, you will need to confirm how many tablets remain, and if needed, arrangements will be made to provide additional tablets for the remaining headaches to be treated.
    - You will be reminded to complete the post-headache questionnaire - the WPAI
    - You will be reminded (after the 3rd migraine treatment) to complete the post-headache CORS 1, CORS 2, and Migraine-Act questionnaires

- You will have your Visit 9 scheduled

Visits 6, 7 and 8 will each take about 15 to 30 minutes.

Visit 9 (End of Study Office Visit)

- **Study Diary:** Collect and review the completed diaries.
- **Health and Medication Questions:** Update with you, questions about your health and the medicines you take.
- **Urine Pregnancy Tests:** If you are female and able to have children, your urine will be tested at each visit to see if you are pregnant. You will be told if the test result is positive. The result of the test must be negative at completion of the study.

In the event that you have a positive urine pregnancy test at any time during this research, a serum pregnancy test will be obtained. If that result is negative, the urine pregnancy tests will be considered a false positive result. If the serum pregnancy test is positive, you will be withdrawn from this research and will be medically followed until the pregnancy is completed and the health of the child is determined. You are not to become pregnant during this study.

- **Randomization/Study Drug:** You will return any remaining study drug and the study drug container (if you were provided Treximet™ to be taken to treat migraines during this Treatment Arm.)
- **WPAI:** Your completed 3 WPAI questionnaires will be collected.
- **CORS 1 and CORS 2:** Your completed CORS 1 and CORS 2 questionnaires will be collected.
- **Migraine-ACT**: You will have the completed Migraine-ACT questionnaire collected.
- **Knowledge Program**: You will complete questionnaires on a computer or tablet as you would normally do during a regular appointment

Visit 5 will last about 2 hours.

During final visit, the study doctor or study staff will ask you about all medications you are taking (both prescription and over-the-counter. You must tell the study doctor or study staff about any changes in the medications you have taken while you were in this study.

Treatments of Workday Migraine Attacks

When you treat a workday migraine, you will either be taking one tablet of Treximet™ or one dose of your usual prescribed triptan. The dose of your usual prescribed triptan will depend on which of the triptans you take. You will start with your usual triptan prescription dose (or Treximet™). If you have no relief at 2 hours, you may repeat that dose. Usual triptan starting doses (that may be repeated at 2 hours) inlcude:

Zomig at 2.5mg or 5mg tablet strength
Maxalt at 5mg or 10mg tablet strength
Imitrex at 25mg, 50mg or 100mg tablet strength
Amerge at 1mg or 2.5mg tablet strength
Axert at 6.25mg or 12.5mg tablet strength
Frova at 2.5mg tablet strength

or

Relpax at 20mg or 40mg tablet strength.

WHAT IF I still have pain from my migraine AFTER TAKING the medication?

When you are randomized to Treximet™, you may take an additional Treximet™ tablet (a rescue dose) 2 hours after the original dose. If you are taking your usual migraine medication you may take that medication again as a second (or rescue) dose at 2 hours after the original treatment. For a rescue medicine at 2 to 24 hours after the original treatment, you may NOT take a different triptan from the original dose treatment OR take a nonsteroidal antiinflammatory medicine (NSAID) as a rescue, while you participate in this research. The study doctor will discuss with you which rescue medications you may take in addition to the initial treatment of your migraine for any given attack.

You may also seek medical attention whenever necessary. Please alert the study coordinator or study doctor if you need to seek medical attention.

IS THERE ANYTHING I NEED TO DO WHILE I AM IN THE STUDY?

While you are in the study, you must:

· Follow the instructions you are given.
· Come to the study center for your visits with the study doctor.
· Tell the study doctor or study staff about any changes in your health.
· Tell the study doctor or study staff if you want to stop being in the study at any time.

How Long Will You Be In The Study?

Your participation will last about 3 months or until you have used both Treximet™ and your usual migraine medication for 3 migraine attacks. You will come to the study center a total of 3 times during the study for office visits. You will be required to call the clinic within 1-2 days after each migraine attack for which you have taken study drug (6 telephone calls).

2. RISKS AND DISCOMFORTS

What Are The Risks Of The Study?

All drugs may cause side effects in some people. Your participation in this study may involve risks that are currently unforeseeable or unknown. Known risks, side effects and/or discomforts to date are listed on the following 2 pages.

Possible Side Effects of Treximet™

Possible Frequent Risks Occurring in at least 1% [1/100] persons		
	Severe Symptoms (Potentially Life Threatening)	**Less Severe Symptoms (Not Potentially Life Threatening)**
Allergic reactions	X	
Diarrhea	X	
Nausea and/or vomiting	X	
Skin rashes or bruising	X	
Abdominal pain		X
Constipation		X
Dizziness		X
Drowsiness		X
Dry mouth		X
Fatigue (exhaustion)		X
Feeling light headed, unusually slow or fast heartbeats, or a feeling of irregular and/or forceful heartbeats		X
Heartburn		X
Itching		X
Malaise (no energy)		X
Nasal congestion		X
Pain/pressure sensations (in the chest, neck, throat or jaw)		X
Joint pain		X
Paresthesias (a sensation of prickling, tingling or creeping on the skin		X
Shortness of breath		X
Swelling in the hands or feet		X
Temperature sensation		X
Visual disturbances		X
Vertigo (feeling like the world is		X

spinning)		
Ringing in the ears		X
Possible Infrequent or Rare Risks - Occurring in less than 1%		
	Severe Symptoms (Potentially Life Threatening)	**Less Severe Symptoms (Not Potentially Life Threatening)**
Arrhythmia (irregular heartbeat)	X	
Jaundice (too much bile in the blood causing a yellow color to the skin, gums, eye, and other tissues)	X	
Myocardial Infarction (heart attack)	X	
Rectal bleeding (passage of bright red blood from the anus, often mixed with stool and/or blood clots)	X	
Seizures or fits	X	
Depression		X
Difficulty sleeping or concentrating		X
Flushing (redness of the face lasting for a short time)		X
Gastric ulcers (sore in the stomach that may produce pain and/or bleeding)	X	
Hair loss		X
Hearing difficulties		X
Loss of normal coloration in the fingers and toes		X
Mouth ulcers (sores in the mouth that may produce pain and/or bleeding)		X
Shaking or tremors		X
Uncontrolled movements		X

Some people may have a drug reaction called serotonin syndrome when they take sumatriptan, one of the ingredients in Treximet, or while taking an SSRI (selective serotonin reuptake inhibitors) or SNRI (serotonin-nor epinephrine reuptake inhibitor) with sumatripan. SSRI's may include but are not limited to Prozac®/fluoxetine, Paxil®/paroxetine, Zoloft®/sertraline, Celexa®/citalopram, Lexapro®/escitalopram medicine. SNRI's may include but are not limited to Effexor®/venlafaxine, Cymbalta®/duloxetine) medicine. Check with the study doctor, your doctor or pharmacist if you are unsure a medicine you are taking is an SSRI or SNRI.

Serotonin syndrome occurs when there is an excess of serotonin (a chemical that is believed to play an important role in the regulation of mood, sleep, vomiting, sexuality and appetite) in the central nervous system. Symptoms of serotonin syndrome may include confusion, hallucinations, fast heart beat, feeling faint, fever, muscle spasm, difficulty walking, sweating, and/or diarrhea. Notify the study doctor immediately if you have any of these symptoms after takingTreximet.

Please tell the study doctor or study staff right away if you have any of these side effects by:

- Calling the study doctor, Dr Jennifer Kriegler at 216/636-5549 during business hours (M-F, 8:30 am to 5:00 pm).
- After business hours and weekends: 216-444-2200 and ask to page the Neurology Resident on-call.

If you experience ANY SIGNIFICANT symptoms, you should:

- **call 911 for assistance, or**
- **Go to the nearest emergency room for help.**
- ***Do not* wait for a scheduled study phone call or study visit, please notify your doctor immediately when these symptoms occur.**

CARDIOVASCULAR RISKS

Sumatriptan, one of the active ingredients of TREXIMET™, may make your heart vessels temporarily constrict or narrow (also called coronary vasospasm). Sumatriptan is not recommended for people who have had heart attacks, or who have uncontrolled high blood pressure, chest pain (angina), or diseases of heart blood vessels. Increases in blood pressure have occurred in some people after taking sumatriptan.

The study doctor or study staff will make sure you are free of heart disease before taking the study drug if you have risk factors for heart disease such as high blood pressure, high cholesterol, obesity, diabetes, a strong family history of heart disease, or if you are a smoker.

Heart attacks, a life-threatening change in heartbeats, and death have occurred in people who have taken the type of study drug you will take during this study, but these side effects are uncommon. Some of these side effects happened in people who had no risk of heart disease and may have been due to blood vessels that supply the heart being narrowed (constricted) temporarily by the drug.

Chest, jaw, or neck pain, tightness, and pressure have been reported after taking sumatriptan but have rarely been associated with electrocardiogram (ECG) changes that suggest heart damage. If you have these symptoms after taking the study drug, tell the study doctor immediately.

Sumatriptan is not recommended for people with a history of, or signs or symptoms of, cerebrovascular disease (like strokes or blood clots in the brain), or peripheral vascular disease

(like Raynaud's Syndrome). You should tell the study doctor if you have a history of stroke, transient ischemic attacks (TIA's or mini-strokes), or Raynaud's Syndrome.

Recently released scientific information suggests that COX-2 selective NSAIDs (nonsteroidal anti-inflammatory drugs) may carry a risk of cardiovascular side effects. Naproxen is not a COX-2 selective NSAID, but the FDA has requested that manufacturers of naproxen warn patients and physicians regarding a potential for increased risk of serious cardiovascular events and serious gastrointestinal events with the use of naproxen and other non-selective NSAIDs. You should talk to the study doctor about this information.

ANAPHYLAXIS (Allergic Reaction) RISK

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction are:

- a rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

You should get medical help and notify the study doctor or study staff if you experience any of these or any other side effects during the study.

Unforeseeable risks:

There may be risks or side effects related to the study drug/device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

Incidental findings:

During the course of this study, you will undergo clinical tests. Although unlikely, it is possible that these tests may demonstrate incidental findings (which are information about your current health that we did not expect to find). If there are findings that are important to your health, your study doctor will review the findings with you. If these results indicate that you need further medical care, your study doctor will discuss this care with you and/or direct you to the appropriate department for further testing and/or care.

Pregnant women, fertile females/males:

You cannot be in this study if you are pregnant, planning to become pregnant, or nursing a baby.

It is not known whether Sumatriptan, or Naproxen cause harm to an unborn baby.

There may be unforeseen risks to an unborn child associated with your taking Treximet™. Therefore, if you are capable of giving birth to or fathering a child, you and your sexual partner should use adequate birth control measures while you are in the study. These measures may include abstinence, oral contraceptives (birth control pills), IUD, diaphragm, Norplant, approved hormone injections, condoms, or documentation of medical sterilization. If you are unwilling to do this, we ask that you not participate in this study.

Pregnancy tests will be performed on all women of child-bearing potential during Visit 1, Visit 5 and Visit 9. If you or your spouse becomes pregnant while taking part in this study you must notify the study doctor immediately and you will be withdrawn from the study. Your/your spouse's pregnancy will be followed until the outcome (i.e., birth or termination).

Questionnaire/Survey Research:

There are no physical risks associated with the study questionnaires. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed. Some of the questions we will ask you as part of this study questionnaire may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during completion of the study questionnaire.

3. BENEFITS

Are There Benefits To Taking Part In The Study?

Participation in this study may help to improve your condition, but it is also possible that your condition may worsen. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

4. ALTERNATIVES

What Other Options Are There?

You should continue to go to your regular doctor even if you join this study. You do not have to be in this study to get help for your migraine. The study doctor will talk to you about other things you can do for migraines. The study doctor will tell you more about the risks and benefits of participating in this study as compared to the risks and benefits of other treatments. You may take Treximet™ for you migraine, without being in this study.

Some other things you can take, if you decide not to be in the study or if the study doctor does not believe that you should be in the study, are:

- other triptans such as Imitrex®, Zomig®, and Maxalt®
- ergotamines such as Migranal® and DHE®45
- combination pain relievers such as Midrin® and the class of drugs called butalbitals
- drugs for nausea or vomiting such as Phenergan®
- NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen)

5. PRIVACY AND CONFIDENTIALITY

The medical and research information recorded about you for this research will be used within the Cleveland Clinic and/or disclosed outside the Cleveland Clinic. Tests and procedures done solely for this research study may be placed in your medical record to indicate your participation in this study. The information recorded about you as part of this research will be maintained in a confidential manner.

Upon completion of the study, you may have access to the research information if contained in the medical record. During the study, your access to research information about you will be limited. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study. This information will be available should an emergency arise that would require your treating physician to know this information to assist in treating you.

Federal regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the study doctor, the study staff, Cleveland Clinic monitors/auditors and IRB, the study Sponsor (Pernix Therapeutics) and its agents, the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), other governmental agencies from foreign countries. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. The Cleveland Clinic also may use and disclose this information for treatment and payment reasons. The Cleveland Clinic must comply with legal requirements that mandate disclosure in unusual situations. Once your personal health information is released it may be re-disclosed and no longer protected by federal privacy laws. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to Jennifer Kriegler, MD at The Cleveland Clinic, 9500 Euclid Avenue, Desk C-21, Cleveland, Ohio 44195. If you do so, your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of the research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. Even if you ask us to stop outside disclosures, information collected about you will be disclosed as required by state and federal law.

The Cleveland Clinic will not use or disclose the information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your medical records. If you choose not to sign this consent form, you will not be permitted to participate in this research study.

6. RESEARCH RELATED INJURIES

What Happens If An Injury Occurs?

In the event you are injured as a result of participation in this research, medical care is available to you and will be billed to your insurance company. The cost of such medical care that is not covered by your medical insurance shall be your responsibility. There are no plans to provide compensation for lost wages, direct or indirect losses. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at 216-444-2924.

7. COSTS

What Are The Costs?

There will be no costs to you for the study drug, or for the visits or procedures directly related to your participation in this study. If you decide to withdraw early from this study or the study is ended early you must return unused drug to Dr Jennifer Kriegler.

The Cleveland Clinic will not pay for the costs of procedures, tests, visits and hospitalizations in connection with this research.

You will be provided a study voucher which can be cashed at H-Cashier in the amount of $50 which is intended to defray your expense for travel and parking for study office visits. You will receive no other payment for taking part in this study.

There are no plans to provide financial compensation to you in the event the results from this research lead to the development of new products.

8. VOLUNTARY PARTICIPATION

What Are Your Rights As A Participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you want to stop being in the study, tell the study doctor or study staff and return all unused study medication and study materials including the e-diary. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study.

The study doctor or sponsor can withdraw you from the study at any time, even if you want to continue to be in the study. This could happen if:

- The study doctor believes it is in your best interest for you to stop being in the study.
- You don't follow directions about the study
- You become pregnant.
- It is discovered at a later date that you do not meet the study requirements.

Any information collected before you stop the study will be kept and used to determine the results of the study.

9. QUESTIONS

Whom Do You Call With Questions Or Problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Dr Jennifer Kriegler at 216-636-5549 during regular business hours (Monday through Friday 8:30 am – 5:00 pm). After business hours and weekends: 216-444-2200 and ask to page the Neurology Resident on-call who will contact the study doctor. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. SIGNATURE

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____

Printed name of person obtaining consent

_____

Signature of person obtaining consent

_____

Date