Wake Forest®
School of Medicine

Department of Neurology

ANXIETY AND DEPRESSION IN EPILEPSY

Informed Consent for Research Heidi Munger Clary, MD, MPH, Principal Investigator

SUMMARY

You are invited to join research. This is *voluntary.*

This information can help you decide whether to join. Some key points:

- You may choose to join or not
  - If you join, you are free to leave any time.
- We are doing this research to compare two treatments for anxiety and/or depression with epilepsy. The treatments are:
  - medication prescribed here in the clinic and follow-up care, or
  - psychiatry referral.
- If you participate, you will answer questions and start one of the treatments today. We will also call you in 6 and 12 weeks.
- You will be randomly assigned to one of the two treatments.

- Risks: If you participate, there are some risks. We may learn more about your mood symptoms. The treatment may have side effects (similar to regular medical care).
- Benefits: The study treatments are standard treatments for anxiety and depression. Your symptoms may improve.
- Alternatives: Treatment for anxiety or depression outside the study

Take time to read this whole form. Ask us questions, and you can talk to others to help decide. Whether you join the study, your doctor will still care for you. You will not lose services, benefits, or rights if you choose not to join.

To join, you will sign this form. Before you sign, be sure you understand the study.

Dr. Heidi Munger Clary is in charge of the study. You can contact her at [redacted] **or** [redacted] if you want to stop taking part, or if you have questions or concerns about the study. If you have questions or concerns about your rights as a study participant, contact the Institutional Review Board (IRB) at [redacted].

INTRODUCTION

You are invited to this study because you have epilepsy and may have anxiety and/or depression. It is voluntary to join. Please take time to decide if you wish to join. Please ask any questions – we are happy to help!

WHY IS THIS STUDY BEING DONE?

To see how people with epilepsy do on one of two treatments for anxiety and/or depression. The study is assessing adherence to anxiety and depression medication prescribed by either an epileptologist or a mental health professional. The medications prescribed in this study, escitalopram and venlafaxine XR, are FDA approved for anxiety and depression.

HOW MANY PEOPLE WILL TAKE PART?

30 people here at Wake Forest Baptist Medical Center.

WHAT IS INVOLVED?

This study involves:

- **A set of questions** after your doctor visit today. We will ask questions about your medical history, medications, mood and quality of life. This will take less than 1 hour.
- **You will be assigned at random to one of two study groups** . This means you are put into a group by chance. It is like flipping a coin. You will have equal chance of being placed in any group. You will be assigned to one of these two common treatments for anxiety and/or depression:
    1. A prescription from your neurologist for a medication.
        - Lexapro (escitalopram) 10mg daily. We may change the dose or switch to Effexor XR (venlafaxine XR) 37.5mg daily.
    2. A psychiatry referral. Psychiatry referrals are a standard care for depression or anxiety.
- **We will call you in 6 weeks** to see how you are. We will mail you the questions. This will take 15 minutes.
- **We will call you in 12 weeks** to see how you are. We will mail you the questions. This should take 20 minutes. Also, another team member will call and ask about your medication or psychiatry appointment. This will take less than 10 minutes.

- **<u>Also, if you are prescribed medication today</u> – you will receive follow-up**

  medical care from your doctor's Nurse Practitioner (NP) or Physician Assistant (PA):
    - We will call you every two weeks. These **medication phone calls** are to see how

you are doing. This will be 2, 4, 8 and 10 weeks after today. These phone calls will be less than 15 minutes.

- **A clinic visit** in 6 weeks at . At this visit, we will ask questions about your mood and your medication. This will take about 30 minutes. The care at this visit will be provided using your medical insurance.

We will record important findings in your medical record.

In the future, researchers may need to know more about your health. The study team may give reports about your health. But, the researchers will NOT receive your name, address, phone number, or any other information about who you are unless you wish to be contacted for future studies.

____YES, you may contact me for future studies
____NO, do not contact me about future studies.

HOW LONG WILL I BE IN THE STUDY?

12 weeks. You can stop any time. If you want to stop, talk to the study staff first to learn about any potential risk.

WHAT ARE THE RISKS?

The medications and psychiatry referrals are common treatments. But, there is slight risk. Risks include:

- When you answer questions about your mood, we may find new symptoms
- When treatment is started for anxiety and/or depression, your symptoms might worsen. The risk is no higher than in usual medical care.
- If you receive the medication, there may be medication side effects. Few people have side effects. Common side effects of escitalopram are: trouble sleeping; ejaculation disorder; nausea; sweating; fatigue and sleepiness. Less common side effects are: dry mouth; dizziness; diarrhea; constipation; indigestion; stomach pain; flulike symptoms; low appetite; sexual problems; sinusitis and rhinitis. Common

side effects of venlafaxine XR are nausea; sleepiness; dry mouth; sweating; sexual problems; low appetite; and constipation. Less common side effects are low energy; high blood pressure; heart racing; blood vessel changes; constipation; diarrhea; vomiting; strange dreams; dizziness; trouble sleeping; nervousness; tingling; tremor; yawning and vision changes. Other, rare side effects may occur with both medications. Another risk is suicidal thoughts. This is most likely in the first few weeks after starting medication or with dose change. We can discuss side effects, change your dose or switch medication if needed.

- Since you are randomized to one of two standard of care treatments for anxiety and depression, researchers do not know which group will have a better outcome. You could be assigned to the group which performs either better or worse than the other group.
- There is a small risk that de-identified information might be re-identified or there could be a breach of confidentiality.
- During the study, you will be asked questions about your mood, thoughts, and actions. If we learn you or someone else is in danger, the study team is required to report this to the proper authorities.

You should discuss the risk of this study with the study staff.

A Data Safety and Monitoring Committee will review the data throughout the study.

Reproductive Risks

Due to uncertain risk of birth defects with the study medications, we encourage women of childbearing potential to use reliable birth control. Reliable birth control includes: not having sex; oral contraceptives; intrauterine device (IUD); Depo-Provera; tubal ligation; or vasectomy of the partner (with negative sperm counts) in a monogamous relationship (same partner). An acceptable, but less reliable, method is careful use of condoms and spermicide and/or a cervical cap or sponge. You should discuss this with your doctor if you have questions. If you are pregnant or breast feeding, you will not be enrolled.

ARE THERE BENEFITS?

If you agree to participate, there may or may not be benefit. Your anxiety or depression may improve. We hope the information from this study will help others in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to get treatment. Whether you join or not, your doctor will provide care. This may include standard treatments for anxiety or depression. These treatments may include medications; psychiatry referral; referral to your primary care doctor; relaxation training; or counseling/talk therapy.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The study team will keep your information confidential. We will keep your record safe. We may protect your information by coding research records, keeping records secure and allowing only authorized people to access records.

We will not share your identity and personal health information unless authorized by you, required by law or regulatory groups, or needed to protect safety for you or others.

LIMITS OF CONFIDENTIALITY

We may reveal your identity to someone outside the study if you are: 1) suicidal, or if test results require urgent medical attention; 2) homicidal; or
3) suspected of child or elder abuse on North Carolina law.

We may call your emergency contacts if you experience confusion or medical illness.

WHAT ABOUT MY HEALTH INFORMATION?

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the study team cannot be forced to share identifying information in research records, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from United States Government personnel for checking or evaluating federally funded projects. It also cannot be used for information needed to meet Food and Drug Administration (FDA) rules.

A Certificate of Confidentiality does not stop you or your family from sharing information about you or research involvement. If an insurer, employer, or other person gets your written consent for the researcher to share your information, then the researchers may not withhold that information.

In addition to the Certificate of Confidentiality, we will take other steps to keep your Protected Health Information (PHI) private. We will store research records in a cabinet in a locked office or on a secure computer.

In this research study, new information we collect from you and your medical records or other places about your health or actions is PHI. The information we will collect includes**:** demographics, medical history and questionnaires about your mood.

PHI collected from you during this study for treatment or diagnosis will be placed in your medical record. This information may be used to treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your PHI private. We will store records of your PHI in a cabinet in a locked office or on a secure computer.

Your PHI and information that identifies you ("your health information") may be given to others during and after the study. This may be to complete the study, to determine study results, to make sure the study is being done correctly, to provide required reports.

Some people, agencies and businesses may receive your health information. These include the research sponsor; representatives of the sponsor helping with research; the Institutional Review Board; Wake Forest University Health Sciences and North Carolina Baptist Hospital; staff from agencies such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Monitors, auditors, IRB or other agencies will be granted direct access to your medical record to check clinical trial records. These groups will not violate your confidentiality to the extent permitted by applicable laws. If required by law or court order, we might have to share your PHI with a judge, law enforcement, government agencies, or others. If your PHI is shared with any of these groups, it may no longer be protected by privacy rules.

Any Protected Health Information in the research records will be kept at least six years after the study finishes. Then any research information not already in your medical record will be destroyed or de- identified. Any research information entered into your medical record will be kept as long as the Medical Center keeps your medical record. You will not be able to get a copy of your PHI in the research records until the whole study is done.

You can tell Dr. Heidi Munger Clary you want to take away your permission to use and share your PHI at any time by sending a letter to:

Dr. Heidi Munger Clary
[redacted]

If you take away permission to use your Protected Health Information your study participation ends. We will stop collecting information about you, but records we already collected can still be used.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to take part in this study, your medical record at Wake Forest University Baptist Medical Center will show that you are enrolled in a clinical trial. Information about the research and any medications you receive may be in your medical record. This part of the medical record will only be available to people who have authorized access.

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

Information about your participation in the study will be in the NCBH medical record, along with any routine test results obtained at NCBH for this study.

WHAT ARE THE COSTS?

This study compares two common treatments for anxiety and depression. Because these are forms of standard medical care, the treatments will be provided using your medical insurance. Joining this study may lead to added cost to you or your insurance. If you decide not to join, other treatment may be provided using your medical insurance coverage, also with potential cost.

The study questionnaires will take some time.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card after the week 6 call and another $25 gift card after both week 12 calls.

WHO IS SPONSORING THIS STUDY?

This study is sponsored by the Wake Forest University Clinical and Translational Science Institute (CTSI). The CTSI is funded by the National Institutes of Health (NIH). The researchers do not hold a direct financial interest in the study treatment.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

If you suffer an injury or illness due to this study, Wake Forest University School of Medicine has limited research insurance for usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent of available coverage under this policy the reasonable costs of needed medical services will be paid, up to $25,000. Wake Forest University Baptist Medical Center holds the insurance policy. It provides up to $25,000 for each claim and a total limit of $250,000 for all claims in one year. The Wake Forest University School of Medicine, and North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay these medical services or provide any other payment for such injury or illness. More information is available from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may need your name, social security number, and date of birth to pay for your care. This is because the law requires the insurer to report any payments made to cover care under a government insurance plan to the Department of Health and Human Services.

You do not lose any legal rights as a research participant by signing this form. For more information on medical treatment for research injuries or to report a study related illness, adverse event, or injury, call **Dr. Heidi Munger Clary at [redacted].**

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part is voluntary. You may choose not to take part or you may leave the study any time. Refusing to take part or leaving the study will not cause any penalty or loss of benefits to which you are entitled. If you want to stop participating, we encourage you to talk to the study staff first. This is to discuss any potential health or safety risks. The investigators also have the right to stop your participation. This could be because:

- your study doctor feels it is in your best interest;
- your condition worsened;
- you may not be following study instructions;
- new information is available;
- or the study has stopped.

We will give you new information we find that would affect your willingness to continue participating.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study leader, **Heidi Munger Clary at** [redacted].

The Institutional Review Board (IRB) is a group that reviews this research to protect your rights. You can contact the Chairman of the IRB at [redacted]. Call if you have questions about your rights as a research participant, want more information, or would like to discuss problems or concerns about this study.

We will give you a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I allow use and sharing of my health information as described in this form. If I have not already received a copy of the Privacy Notice, I may request one. I have had a chance to ask questions about being in this study and receive answers. By signing this form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature:_____Date:_____Time:_____am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____Date:_____Time:_____am pm