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School of Medicine

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Informed Consent

Department of *Neurology*

Anxiety and depression in epilepsy: assessing outcomes using the electronic medical record (EMR)

Informed Consent Form to Participate in Research

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SUMMARY

You are invited to participate in a research study. The purpose of this research is to find out how people with epilepsy and possible symptoms of anxiety or depression are doing for 6 months after a regular epilepsy clinic visit. You are invited to be in this study because questionnaires from your epilepsy clinic visit suggest you might have symptoms of anxiety or depression. Your participation in this research will involve answering a few questions twice over the next 6 months, either over the phone or in mywakehealth.

Participation in this study will involve less than 10 minutes of questions today, then either two phone calls to answer questions, or two sets of questionnaires sent to you in mywakehealth. The results of these questionnaires will be placed into your medical record. If you decide to participate, you will be randomly assigned (like a "flip of a coin") to either telephone follow up calls, or to mywakehealth questionnaires. The phone calls or mywakehealth questions will occur in 3 months and again about 6 months from now and will take less than 15 minutes to complete.

All research studies involve some risks: in this study the main risk is your time and effort spent answering questions. We do not expect for you to benefit from participation in this study, but we aim to use the results to improve care for people with epilepsy.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to; your alternative choice is not to participate. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. You may choose to stop participating at any time.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Heidi M. Munger Clary, MD MPH. If you have questions, suggestions, or concerns regarding this study, her contact information is: [redacted] or [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

How Many People Will Take Part in the Study?

30 people may agree to take part in this study.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. In this study the main risk is your time and effort spent answering questions. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about *depression and anxiety symptoms.* If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities. Further, we may contact your emergency contacts if you seem to be experiencing any significant risk of harming yourself or if significant health concerns arise in our communication with you.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Are the Costs?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or

biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Advancing Translational Sciences which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.
The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid *$45* if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid *$15* for each complete study visit (initial telephone visit and the 3-month and 6 month questionnaires done by telephone or mywakehealth depending upon the group to which you are assigned).

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This is unlikely but could be because of any worsening of your condition that would prevent you from continuing participation in the research. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.