Patient Verbal Consent

Title: ***Testing a medication risk communication and surveillance strategy: The EMC2 Trial***

Investigator: ***Michael Wolf, PhD, MPH***

Supported by: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Introduction: My name is _____. I am a research assistant working on behalf of _____ (site) and Northwestern University, inviting you to participate in a research study.

This is why the research is being done

We are doing a research study to evaluate different ways to give patients information on medications that might have important safety messages. We are also testing different ways to follow up with patients to see how they are doing once they have been taking the medicine for a while.

Here is why you are being asked to take part in this research study

We are inviting you to participate because you were recently prescribed one or more of the medicines that we are studying.

If you say that "Yes, you want to be in this research," here is what will happen

If you choose to participate, you will be assigned to one of two groups, based on the clinic you visited to get your prescription. If you are in the usual care group, you will receive the current standard of care. If you are in the intervention group, you will receive text or phone prompts to call into an automated phone system, which will ask questions about how your medicine is working for you. That call will take about 5 minutes. If you respond to the system that you are having any issues with your medicine, it will send a note to the clinic through your electronic medical record. The clinic staff would then follow up with you if they thought it was necessary.

Regardless of the group you are assigned to, we will ask you to complete up to three phone interviews, each lasting 15 to 20 minutes. During these interviews, we will ask you questions about the medicine you were just prescribed, your response to treatment, how you understand health information, and some general information about you. We would try to schedule the first interview in the next few days, if possible. Based on your answers, you may be eligible to complete two more interviews at 1 and 3 months after the first. .

This is what you should know about being in a research study

- Whether or not you choose to take part is up to you.
- If you decide not to participate, it will not be held against you or affect your right to any present or future medical treatment. You will not be penalized or lose any benefits to which you are entitled.
- If you do choose to participate, it's ok to change your mind later. You are free to leave the study at any time, for any reason. We will keep all data collected until the time you change your mind.
- You can ask all the questions you want before you decide.

Here is how being in this research could be bad for you

Your participation in this study does not involve any physical or emotional risk to you beyond that of everyday life. You may skip any questions that make you feel uncomfortable.

This is what will happen to the information collected for this research

Efforts will be made to limit the use and disclosure of your personal information. We cannot promise complete secrecy, but your privacy and the protection of your PHI, or protected health information, is very important to us. The PHI for this study includes your name, phone number, address, birth date, the name of your clinic and doctor, the name of the medicine you were prescribed and the date it was

prescribed on. To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). The following persons or groups may use and/or disclose your PHI for this study:

- The Principal Investigator and the research staff
- Boston Medical Center (BMC): The automated phone system is managed by our research partners at BMC. If you are in the intervention group, we would be sending them your name, phone number, birth date, the name of your clinic and doctor, the name of the medicine you were prescribed, and the date it was prescribed on so that they could set the call up. The data would be encrypted before sending; the only people who would see it would be the Northwestern study personnel and the programmer at BMC. Your information would be deleted once the automated call was completed.
- The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity, the US Office for Human Research Protections, and the US Food and Drug Administration may be given direct access to the information you provide as part of their work to oversee the research. By consenting, you are authorizing this access. We may publish the results of this research, but will keep your name and other identifying information confidential.

After the study is finished, a dataset that includes your responses but that cannot identify you will be kept indefinitely for future analyses. Only authorized research personnel will have access to these data.

You may revoke your authorization at any time by calling the Principal Investigator, Dr. Wolf, or by writing to: Dr. Michael Wolf, MPH, PhD, Professor, Division of General Internal Medicine and Geriatrics. 750 N Lake Shore Drive, 10th Floor, Chicago, IL 60611.

Here is who you can talk to

If you have questions or problems related to this study, you can call Dr. Michael Wolf, who is the person in charge of this research, at 312-503-5592. You can also call the Project Manager, Laurie Hedlund, at 312-503-5537. If you cannot reach them or if you have questions about your rights as a research subject, you can call the Institutional Review Board (IRB) office of Northwestern University at (312) 503-9338 or irb@northwestern.edu.

Here is some other information that is useful for you to know

If you agree to take part in this research study, you will be paid $40 for completing all study interviews. Depending upon the medication you were prescribed, you may be asked to do one longer interview for $40 dollars or two or three shorter interviews, paid $20 after the first and $20 after the last interview.

Consent: Do you wish to participate? (Record participant's response): Yes No

_____
Subject's Record ID

_____ _____ _____
Name (printed) of person obtaining consent *Signature* *Date*

IRB number: STU00201638