Document:	Informed Consent Document
Official Study Title:	Anticoagulation with Enhanced Gastrointestinal Safety (AEGIS): A pilot quality improvement trial to evaluate clinician- and patient-facing strategies to reduce upper gastrointestinal bleeding risk in patients on combination antithrombotic therapy
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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Anticoagulation with Enhanced Gastrointestinal Safety (AEGIS): A pilot quality improvement trial to evaluate clinician- and patient-facing strategies to reduce upper gastrointestinal bleeding risk in patients on combination antithrombotic therapy

Principal Investigator: Jacob E. Kurlander, MD, MS

GENERAL INFORMATION

We're doing a study to learn more about how patients who receive care from the Michigan Medicine anticoagulation clinic perceive a safety program that the clinic has recently adopted to reduce the risk of bleeding in patients who use warfarin (Coumadin®). To get information on how the program is working and how we can improve, we would like to interview 51 patients who receive care from the anticoagulation clinic and may have received information from the clinic as part of this safety program to better understand their perceptions and experiences. We expect the interview to take about 60 minutes to complete.

Participation in this research interview is entirely voluntary. Choosing not to participate in this study will not affect the medical care that you might receive at Michigan Medicine. You do not have to answer any interview questions that make you uncomfortable or that you do not want to answer. You can choose to skip any questions or end the interview at any time, and do not need to tell us why. If at any time you would like to end the interview or skip a question, please just let the interviewer know.

With your permission, we plan to record this interview. It will later be transcribed (i.e., written down word-for-word). However, we will remove any details from the transcript that could be used to identify you. After the interview has been transcribed, the recording will be destroyed. If for any reason you prefer that the interview not be recorded, you can still participate in this study and ask that the interviewer turn the recorder off and only take notes throughout the interview.

To keep your personal information confidential, we will label your interview with a code, rather than your name or any personal details that could be used to identify you. Although we will maintain a list of people who completed these interviews, no one outside of our study team will be able to identify who completed the interviews or who gave which answers. We plan to publish what we learn from these interviews, but we will not include any personal information that could be used to identify anyone who completed the interview.

While your participation in this interview may not benefit you directly, we hope that what we learn will help other patients in the future.

Your collected information may be shared with the National Institute for Diabetes, Digestive and Kidney Diseases (NIDDK). With appropriate permissions, your collected information may also be shared with other researchers and policymakers across the country and the world. This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

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 Institute for Diabetes, Digestive and Kidney Diseases 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 child abuse and neglect, or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

To thank you for taking the time to complete this interview, we will send you a $20 MasterCard gift card in the mail after the interview has been completed. The University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Jacob E. Kurlander, MD, MS Mailing Address: 2800 Plymouth Rd, Ann Arbor, MI 48109 Telephone: 734-647-9252 Email: jkurland@umich.edu	Study Coordinator: Danielle Helminski, MPH Mailing Address: 2800 Plymouth Rd, Ann Arbor, MI 48109 Telephone: 734-615-3952 Email: dhelmins@umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Sig-B

Consent/Assent to video/audio recording/photography solely for purposes of this research
This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____