KEY INFORMATION FOR DUAL ANTIPLATELET THERAPY ADHERENCE WITH REMINDER APP USAGE

We are asking you to choose whether or not to volunteer for a research study about whether antiplatelet medication reminders improve medication adherence following treatment of unruptured aneurysms. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if medication reminders decrease the risk of stroke and other types of thrombotic events following stent insertion. Your participation in this research will last about 6 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you participate, you will be randomized on a 1:1 basis to either the app group or the non-app using group. The study may not include a direct benefit to you even if you are selected for app group. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may feel uncomfortable sharing their healthcare and demographic information with members of the researcher staff. However, this information will be secure and not shared with anyone outside of the study. Participation is strictly voluntary and you may leave the study at any time or refuse to answer any question. You may report to the project administrators any event during the course of the study that causes them discomfort. It is important that you know that you will not be penalized nor will your care or benefits at Montefiore be at risk if you choose to withhold this information.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. David Altschul. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: (718) 920-7498.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research pilot study called **Dual Antiplatelet Therapy Adherence With Reminder App Usage.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits.

The researcher in charge of this project is called the "Principal Investigator." His name is Dr. David Altschul. You can reach Dr. Altschul at:
3316 Rochambeau Avenue
Bronx, NY 10467-2841
Phone:(718) 920-7498
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by **the Montefiore Medical Center Department of Neurosurgery**

Why is this study being done?

The purpose of the Dual Antiplatelet Therapy Adherence With Reminder App Usage study is to determine whether medication-reminders generated by an app are associated with increased adherence to antiplatelet therapy by stent-treated aneurysm participants compared to standard patient education.

Why am I being asked to participate?

You are being asked to voluntarily participate in this study. You are eligible to participate because you are a patient with an unruptured aneurysm that requires you to have stent-based treatment. The Retention study is expected to include about 68 subjects within the Montefiore Health System. You may not participate if you do not agree to the procedures detailed in this consent.

What will happen if I participate in the study?

If you accept to be part of the study, you will be one of approximately 68 participants enrolled at Montefiore Medical Center. You must be undergoing either flow-diverter device placement or stent-assisted coiling to qualify for this study. After consenting to the study, you will be randomized with 1:1 ratio into one of the 2 arms: the intervention arm (standard of care + medication compliance app) and the comparison arm (standard of care). Block randomization with the block size of 10 will be used to generate the randomization scheme.

This form describes the study and what you need to do for the duration of the study. If you are assigned to the intervention group, you will be asked to download an app onto your smartphone. The free app is called Endovascular Neurosurgery and is available on the Apple App Store. It was developed by Dr. Jonathan Nakhla and does not collect user data. The only data inputted into the app are your procedure date and the antiplatelet medications you have been prescribed. The app does not possess sensitive participant data. Both groups will receive the same standard of care. Once the app is installed, you may input your procedure type and the date of the procedure. You then will select the antiplatelet medications that have been prescribed and schedule a time to receive medication reminders. The medication(s) and time of usage will be selected following the shared-decision making process between the attending physician and you. These medication reminders may be turned off at any time on the app. Upon receiving a medication reminder, you only need to unlock your phone to end the reminder message.

If you are in the control group, you will not download the app and will simply receive the standard of care, including information on the risks of not taking your antiplatelet medications.

Regardless of which group you are in, you, will be asked to complete a survey of no longer than 5 minutes on standard demographic information that will allow researchers greater insight into the backgrounds of study participants. On the day of your procedure, you will be asked to answer questions from the Adherence Barriers Questionnaire [ABQ], regardless of which group you are in. This will take no longer than 5 minutes. You will answer these questions again at both follow-up appointments 2-4 weeks and 6 months post-procedure. The demographics survey and ABQ are a component outside of the standard of care.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the medication adherence app group or the control group. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to the medication adherence app group.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The NCT number is NCT05071027.

As part of this study we will review your medical records and put the information we collect in our research records.

How many people will take part in the research study?

You will be one of about 68 people who will be participating in this study at Montefiore Medical Center.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There may be added cost to you for participating in the study. You will be responsible for covering any cellular data usage costs associated with receiving medication reminders.

Your care and medications will be covered in the same manner they would normally be covered if you were not participating in this study.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

Certain information preliminary analysis of the utility of the app we learn from this study WILL be disclosed to you, AND to a representative from your clinical department.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study

team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

The app that will be utilized is not officially HIPAA compliant and there exists a small risk that app data and app communications will be misdirected.

New Findings
If we learn any significant findings during the study that might influence your decision to participate, we will contact you and explain them.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible community benefits of taking part in this study include the creation of an app that increases the antiplatelet adherence of neurosurgery patients, improving clinical outcomes.

What choices do I have other than participating in this study?

You can refuse to participate in the study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

Your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

_____

Participant cellular phone number

_____	_____	_____
Printed name of participant	Signature of participant	Date
_____	_____	_____
Printed name of the person conducting the consent process	Signature	Date