DISCOVERY
Determinants of Incident Stroke Cognitive Outcomes & Vascular Effects on Recovery

Subject Identification

Protocol Title: Determinants of Incident Stroke Cognitive Outcomes and Vascular Effects on Recovery (DISCOVERY)

Principal Investigator: Natalia Rost, MD, MPH; Steven Greenberg, MD, PhD

Site Principal Investigator: Kelly Sloane, MD

Description of Subject Population: Ischemic, hemorrhagic and aneurysmal subarachnoid hemorrage stroke patients without history of dementia

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get now or in the future.

IRB Protocol No: 2020P001099
IRB Expiration Date: 2/25/2027
Consent Form Valid Date: 2/27/2026
IRB Submission: CR6/AME92

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about what factors make people more or less likely to develop dementia (decline in memory, thinking, and other mental abilities that significantly affects daily functioning) after having a stroke.

How long will you take part in this research study?

If you decide to join this research study, it will take you up to 4 years to complete the study. During this time, we will ask you to make 2 study visits to The Hospital of the University of Pennsylvania, and complete approximately 4 phone calls with the research team.

What will happen if you take part in this research study?

If you decide to join this research study, you or a person who knows you well will complete a screening assessment to determine if you are eligible to take part in the study. If you are eligible, you will complete an initial visit and two in-person follow-up visits. You will also complete up to four annual phone calls. We will ask a person who knows you well, an informant, to answer some additional questions about your thinking and memory abilities throughout the study.

Why might you choose to take part in this study?

You will not directly benefit from taking part in this research study. In the future, other people who have a stroke may benefit from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include:

- Bruising or pain at the site of the blood draw
- Nervousness, discomfort or boredom during cognitive assessments

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are that you will have to return to the hospital for two in-person visits, and that it may take up to four years to complete the study.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Kelly Sloane, MD is the person in charge of this research study. You can call her at 215-349-5481 M-F 9-5. You can also call the study coordinator at 215-615-0561 M-F 9-5 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call the study coordinator at 215-615-0561.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

We are doing this research study to learn about what factors contribute to changes in thinking and memory abilities in patients who have had a stroke. The goal of this study is to help doctors identify patients at risk for dementia (decline in memory, thinking, and other mental abilities that significantly affects daily functioning) after their stroke so that future treatments may be developed to improve outcomes in stroke patients. For this study, a "stroke" is defined as either (1) an ischemic stroke (blood clot in the brain), (2) an intracerebral hemorrhage (bleeding in the brain), (3) or an aneurysmal subarachnoid hemorrhage (bleeding around the brain caused by an abnormal bulge in a blood vessel that bursts).

The National Institutes of Neurological Disorders and Stroke (NINDS) and the National Institute on Aging (NIA), branches of the National Institutes of Health (NIH), are paying for this research study to be done.

Who will take part in this research?

We are asking you to take part in this research study because you had a recent stroke and have no known history of dementia. About 8,000 people are expected to take part in this research study across about 30 hospitals. We expect that more than 200 subjects will be enrolled at The Hospital of the University of Pennsylvania.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

We will review your medical records throughout the duration of the study and collect brain scans that you had done during your stroke hospitalization. A notation that you are taking part in this research study may be made in your medical record.

We may ask you to choose a person who knows you well (an "informant") who can help to answer questions about you and your recovery throughout the study. You may also be asked to choose additional people who can help us get in touch with you if we can't reach you directly ("alternate contacts"). We may attempt to send you a letter, contact your doctor's office and/or

use other publicly available resources to locate you if we are unable to get in contact with you during the course of the study.

Screening Assessment

A member of the research team will ask you or your informant to answer some questions about any changes in your memory and ability to perform different activities before you had your stroke. This will take about 10 minutes to complete. The results of this assessment will be used to determine whether you are eligible to participate in the study. The researchers will tell you if you are eligible to participate in the study. If you are eligible, you will complete the following visits and activities:

Initial Visit

This visit will take about 1 hour. You will complete these study procedures while you're in the hospital, or if you have already been discharged the study coordinator will contact you to complete the remainder of the visit. At this visit, you will complete the following procedures:

Interview: We will ask you questions about your health, medication use, education and social history. We will also ask you questions about your independence, overall health and quality of life before your stroke and now.

Physical & Neurological Exam: We will perform a brief physical and neurological exam. During this exam, we may measure your blood pressure and heart rate, ask you some questions and have you do some thinking and physical tasks.

Cognitive Assessment: If you are able to do so, we will have you complete a cognitive (thinking) assessment. This will take about 30 minutes to complete and may be recorded. We will measure your ability to concentrate, solve problems, and remember things. Some people may not be able to do this because of their medical condition(s). If this is the case, a member of the research team may follow you in the hospital and/or by phone for up to six weeks after your stroke to see if you have recovered enough to complete the assessment.

Blood Draw: We will collect a blood sample of up to 25mL (less than 2 tablespoons). If it is possible to collect the blood during a clinical blood draw and avoid an additional needle stick, we will try to do so. If you are completing this visit over the telephone, we may collect this blood sample when you return for your first in-person follow-up visit.

We will look at markers in your blood and your genes (DNA). You inherit your genes from your parents, and some genes might make you more likely to get certain diseases. We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few

areas of your genetic code that are linked to a disease or condition. In whole genome analyses, all or most of your genes are looked at and used by researchers to study links to many diseases and conditions, including stroke and dementia.

Follow-Up Visits (3-6 months, 18 months)

You will be asked to return to The Hospital of the University of Pennsylvania for two in-person follow-up visits: one at 3-6 months, and a second at 18 months, after your stroke. If it is too difficult for you to come into the clinic for a follow-up visit, we will try to arrange a telephone or videoconference visit with you to collect some information. If you are in a medical facility, we may try to come to you to complete the visit in-person. These follow-up visits will take approximately 1 hour to complete. At these visits, you will complete the following procedures:

Interview: You will be asked about changes to your health and current medication use. We will also ask you questions about your social support, independence and emotional well-being.

Physical & Neurological Exam: We may perform a brief physical and neurological exam. During this exam, we may measure your blood pressure and heart rate, ask you some questions and have you do some thinking tasks and physical tasks.

Cognitive Assessments: If you are able to do so, you will complete a series of short assessments to measure your ability to concentrate, solve problems, or remember things. These assessments will take about 30 minutes to complete and may be recorded. Some people may not be able to do this because of their medical condition(s).

Follow-Up Phone Calls (annual)

An important part of this study is to see how your stroke may affect your thinking and memory. To assess this, you will have telephone interviews once a year for up to 4 years with research staff at the DISCOVERY Telephonic Assessment Center (TAC), located at the Mayo Clinic in Jacksonville, Florida. These interviews will last about 45 minutes to 1 hour and may be recorded. You will be asked about changes to your health, mood, memory and ability to complete daily tasks. You will also complete a series of short assessments to measure your ability to concentrate, solve problems, or remember things. The TAC may let us know if you have any changes to your health, symptoms of depression, or medical questions so that we can help to address those with you.

In addition, the TAC will attempt to contact your informant to ask them some questions about your ability to use your memory and perform activities since your stroke.

If you are unable to complete the in-person cognitive assessments during your baseline and/or in-person follow-up visit(s), the TAC may complete cognitive assessments with you over the telephone.

Your name, study ID and contact information, and your informant and alternate contacts' names and contact information will be entered into a separate database that researchers at the TAC are able to see so that they may contact you and your informant for your phone call visits.

Storage and Use of Your Samples and Health Information
Identifying information such as your name and hospital record number will be removed from your data, imaging and blood samples, and only a code number will be used to identify you. The key to the code connects your name to your clinical data, imaging and samples. This key is kept securely and only known to research staff. When your data, imaging and samples are shared with other institutions, they will be labeled with a code and researchers there will not know who you are when they receive them.

Coded blood samples collected for this study will be sent to a DISCOVERY Biorepository laboratory at the University of California, San Diego (UCSD) or the University of Southern California (USC) to be stored for the research. Coded blood samples will remain under the control of the DISCOVERY Biorepository for the duration of the study and may be directed to additional, affiliated laboratories as necessary. Data about your hospitalization and follow-up visits, including any images of your stroke (CT, MRI, etc.) collected during your hospital stay, will be entered into a database that is managed by researchers at Massachusetts General Hospital. Audio recordings and data from your cognitive assessments may be shared with researchers at institutions involved in this study who specialize in cognitive testing. Your coded samples and data will be sent to other institutions involved in this research study for analysis.

Your samples and data may be stored indefinitely. If you wish to remove your samples from the study, you must notify the research team in writing. Please refer to the section titled "Your Privacy Rights" for more information.

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other medical research of health and human disease. If you join this study, the researchers will remove all information that identifies you (for example your name, medical record number, and date of birth) and use these samples and data in other research. It won't be possible to link the information or samples

back to you. Information and/or samples may be shared with investigators at our hospitals, other universities and hospitals, for-profit commercial entities (companies), and not-for-profit organizations where they can be used for research. You will not be asked to provide additional informed consent for these uses.

Your samples, data and imaging cannot ever be sold for profit; however, it is possible that scientific knowledge gained using your samples, data and imaging could be used in the future to develop products, such as diagnostic tests, that could themselves be used for profit.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that collect and store samples and/or data from research studies. After your samples, data and imaging have been used for this study, these central banks may store your samples and the results from your research participation including imaging, genetic data and health information, and may share them with other researchers to do more studies.

We do not think that there will be further risks to your privacy and confidentiality by sharing your samples, whole genome information, data and imaging with these banks. However, we cannot predict how genetic information will be used in the future. The samples, imaging and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to these central banks. While there is a small chance that you could be identified using DNA, researchers must agree not to attempt to identify you, and the risk of identification, while real, is small. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease.

Will you get the results of this research study?

Researchers will look at your results from the cognitive assessments completed for the study on a regular basis to see if you are experiencing any changes in your thinking or memory abilities. If your results suggest that you may be experiencing problems with memory or thinking, we will send you a letter to let you know about this. It is important to remember that research results are not the same as clinical tests. However, if you are experiencing difficulty with memory and thinking abilities, follow-up testing with a doctor might be needed. You and your medical insurer may be responsible for the costs of these follow-up tests and any follow-up care,

including deductibles and co-payments. It is possible that you will never be contacted with individual research results. This does not mean that you don't have or won't develop an important health problem.

You and your doctor should not expect to get additional information about the results of the research study or the results of any other tests we perform for the study. The researchers involved in this study will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that the researchers involved in this study could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

You can choose to get a periodic newsletter that will tell you about the research we are doing. This newsletter will not announce your results or anyone else's, but it will tell you some information about what we are learning about stroke and dementia. We will also publish what we learn in medical journals. In the future, when research results are published, they may show that certain groups (for example, racial or ethnic groups, or men/women) have genes that are associated with increased risk of a disease. If this happens, you may learn that you are at increased risk of developing a disease or condition.

What are the risks and possible discomforts from being in this research study?

Loss of Confidentiality: The main risk of allowing us to use your samples and information for research is a potential loss of privacy. We protect your privacy by coding your samples, data and imaging.

Risks of Blood Draws: You may have a bruise (black-and-blue mark) or pain where we take the blood samples. There is also a small risk of feeling lightheaded, fainting, or infection.

Genetic Risks: Even without your name or identifiers, genetic information is unique to you, making it possible for someone to trace it back to you; however, the chances of this happening are very small. There is a risk that information about taking part in genetic research may influence insurance companies and/or employers regarding your health. There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information; however, GINA does not protect you against

discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination based on already known disease. If you do not disclose your participation in this research, you will reduce this risk.

Risks of Cognitive Assessments: Memory and thinking assessments are done by trained research staff and pose no major risks. You will be monitored closely and allowed to take breaks at any time. During the assessments, it is possible you will experience nervousness, discomfort or boredom. You will be permitted to stop at any time should you feel the need to do so. Results from these assessments will be used to answer research questions and are not meant to replace an exam with your doctor.

What are the possible benefits from being in this research study?

You will not benefit directly from taking part in this research study. However, it is possible that the cognitive assessments may provide some additional information about the way your brain is recovering after your stroke. We hope that other people who have a stroke in the future will benefit from what we learn in this study.

Can you still get medical care within University of Pennsylvania Health System (UPHS) if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within UPHS now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

We will cover your parking costs for each in-person study visit. We will also pay you after you complete certain follow-up visits for this study to help compensate you for your time and travel. The chart below outlines the amount that you will be paid for each visit:

VISIT	PAYMENT
In-Person Follow-Up Visits (3-6 & 18-Months)	$75.00 per visit
Annual Phone Follow-Up Visits (12-, 24-, 36- & 48-Months)	$50.00 per visit
Total Payment	**Up to $350.00 total**

We may provide coverage or reimbursement for additional travel-related expenses in some cases. The researchers will let you know if this applies to you.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

Greenphire ClinCard Reimbursement Program: Greenphire is a company working together with the University of Pennsylvania to manage your compensation. You will be issued a Greenphire ClinCard, which works like a debit card. When your participation is complete, funds will be approved and loaded onto your card. The funds will be available within 1 business day and can be used at your discretion. You will be issued one card for the duration of your participation. In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you from your study doctor, including your name, address and date of birth.

All information about you is stored in a secure fashion and is deleted from Greenphire's system once the study has been completed. Your information will not be shared with any third parties (including the study sponsor) and will be kept completely confidential.

By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up payments. You agree that the information you provide is used by Greenphire to perform reimbursement payments to you.

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is

required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services, including the blood draw, cognitive assessments, and exams that are done only for research. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires University of Pennsylvania Health System (UPHS) to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- UPHS researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within UPHS who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside UPHS, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside UPHS, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Subject Identification

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

_____

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

_____ _____ _____

Signature Date Time (optional)

Relationship to Subject:_____

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

I agree to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____ _____ _____

Adult Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, the subject was given the opportunity to ask questions, and the subject or authorized individual has given meaningful consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above

☐ Other means _____
(fill in above)

Witness	Date	Time (optional)

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