

**NCT02737930**

## **CONSENT FORM**

### **Fluoxetine for Visual Recovery after Ischemic Stroke (FLUORESC)**

**Principal Investigator:** Bogachan Sahin, MD, PhD

**Co-Principal Investigator:** Bradford Z. Mahon, PhD

**Co-Principal Investigator:** Zoe R. Williams, MD

**This consent form describes a research study. It explains what you may expect if you decide to take part. It contains important information to help you make your decision. Please read it carefully.**

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. Before you make a decision, you may discuss this consent form with your family, friends, and members of your health care team, including your primary care physician.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be affected in any way.
- There are risks associated with participation in any research study, and you should understand what these mean to you.

#### **Introduction**

You are being asked to take part in this study because you have had an ischemic stroke that affected your vision. An ischemic stroke is a condition where blood flow to part of your brain is cut off, usually because of a clot inside a blood vessel. This leads to tissue injury. In your case, the part of the brain that was damaged by the stroke played an important role in vision. As a result, your ability to see has been affected by your stroke.

This study is being conducted by Bogachan Sahin, MD, PhD and Zoe R. Williams, MD from the Departments of Neurology and Ophthalmology at the University of Rochester. This study is also being conducted at Carnegie Mellon University by Dr. Bradford Mahon of the Psychology Department at Carnegie Mellon University and the Department of Neurosurgery at the University of Rochester Medical Center.

### **Purpose of Study**

The purpose of this study is to determine if a medication called *fluoxetine* (also known by the brand name, Prozac®) can improve recovery from vision loss due to a stroke. Fluoxetine is a selective serotonin reuptake inhibitor (SSRI), a type of medication commonly used to treat depression. It has also been found to help with recovery of brain function after a stroke. In one recent clinical trial, stroke patients with severe weakness or paralysis affecting one side of the body were treated with fluoxetine for the first 3 months after their strokes. At the end of the 3-month treatment period, they had more strength on the side affected by the stroke compared to patients who had not taken fluoxetine. This study, the “Fluoxetine for Visual Recovery after Ischemic Stroke” (FLUORESCENCE) trial, is designed to see if fluoxetine can also help patients with vision loss due to a stroke.

Fluoxetine is not approved by the U.S. Food and Drug Administration (FDA) to help improve recovery after a stroke. Moreover, there are important differences between the parts of the brain involved in limb movement and those involved in vision. At this time, it is not known whether fluoxetine will help stroke patients with vision loss.

### **Description of Study Procedures**

THERE ARE A NUMBER OF POTENTIAL DRUG INTERACTIONS WITH THE STUDY DRUG. BEFORE YOU START TAKING ANY NEW PRESCRIPTION OR OVER-THE-COUNTER MEDICATIONS, OR ANY NEW HERBAL OR NUTRITIONAL SUPPLEMENTS, YOU MUST CHECK WITH YOUR PRIMARY CARE PHYSICIAN OR THE STUDY DOCTOR FIRST.

Please also note that you cannot be enrolled in another interventional study such as a clinical trial investigating a drug or device while you are participating in this study. If you know you are currently participating in another research study, or if you are considering enrolling in another study at any time, please contact a member of our study team.

Please see the Appendix at the end of this consent form and the Table on page 9 for a study timeline and a summary of all routine and study-related procedures.

### ***Before you begin the treatment part of the study...***

If you agree to take part in this study, your study doctor will check whether you meet all the required conditions to participate, including the results of any tests or procedures you have already had as part of your routine medical care in the hospital. The study team will also perform some additional tests, as indicated in **bold** in this section and all subsequent sections:

1. A complete physical examination and medical history, including any medications you are currently taking.

2. An assessment of your level of independence in your daily activities prior to your stroke, based on the modified Rankin Scale.
3. A magnetic resonance imaging (MRI) scan of your brain to confirm that you have had a stroke.
4. A psychological assessment called the **Patient Health Questionnaire-9 (PHQ-9)** to screen for depression.
5. **A urine pregnancy test.** If you are a woman of childbearing potential, we will obtain a urine sample to see if you are pregnant. Fluoxetine can adversely affect a fetus, so pregnant women may not participate in this study. If you are a woman of childbearing potential, you must use an acceptable method of birth control to avoid pregnancy while on the study drug. Acceptable methods of birth control include hormonal contraceptives, intrauterine device, abstinence, or spermicide and barrier.
6. A formal eye exam by a neuro-ophthalmologist (an eye doctor who specializes in nerve and brain problems that affect vision) and a vision test called automated Humphrey perimetry to determine how much of your vision has been affected by the stroke.
7. **Functional vision score.** This is an assessment of how your vision loss has affected your ability to perform your daily activities. It is calculated by the neuro-ophthalmologist using information already gathered as part of the formal eye exam. It does not require any additional testing.
8. A questionnaire called the **Visual Function Questionnaire-25** to determine if your vision affected your health-related quality of life in any way before your stroke.
9. An electrocardiogram (ECG) to make sure you do not have an abnormal heart rhythm.
10. Blood tests to measure your complete blood count and make sure your kidneys and liver are working well (**comprehensive metabolic panel**).

You will not be included in this study until all of these tests and procedures have been completed, and the study team has reviewed the results.

***During the treatment part of the study...***

If you are found eligible for this study after these tests and procedures are completed, you will be randomly assigned, or *randomized*, to one of the two groups described below. Randomization means that you are put into a group by chance, like tossing a coin. You will have an equal chance of being placed in one group or the other. This is a double-blind study, which means that neither you nor your study doctor will know which of the study groups you have been

assigned to. However, this information will be readily available in case of an emergency.

**Group A:** If you are assigned to this group, you will take a capsule containing 20 mg of fluoxetine by mouth every day for 90 days.

**Group B:** If you are assigned to this group, you will take a capsule containing an inactive substance (*placebo*, or sugar pill) by mouth every day for 90 days.

You will be started on fluoxetine or placebo during your hospital admission. (We will refer to them as the study drug from this point forward.) While you are taking the study drug, you will need to avoid certain medications that may have drug interactions with fluoxetine. A list of these medications will be provided to your primary care physician. If, in the opinion of your primary care physician or other treating doctors, you need to start taking one of these medications at any point during the 90-day treatment part of the study, the study drug will be stopped and you will be taken out of the study.

Several additional tests will be done to assess the function of your visual system before you leave the hospital, including:

1. **Neuropsychological assessment:** Participation in the study will involve approximately 5 ½ hours of neuropsychological testing spread over 4 sessions, as indicated in the Table on page 9. You will complete a neuropsychological examination lasting 45 minutes before your discharge from the hospital. This will be followed by sessions lasting 90 minutes each at 30 days, 90 days, and 6 months. These outpatient sessions will be conducted in Dr. Bradford Mahon's laboratory at the Rochester Center for Brain Imaging, where most fMRI studies will also take place (see below).

Neuropsychological testing will consist of picture naming tasks, face recognition tasks, and other simple tests of visual processing, such as indicating whether a particular visual target is displayed on a screen or not. Your eye position may be monitored using special cameras during certain tasks. Some tests may require you to indicate the location of an object or visual target on a screen with your finger. For these tests, finger position during the pointing motion will be tracked using a special camera system.

2. **Functional MRI (fMRI):** You will have a special MRI scan that looks at the activity of different parts of your brain while you perform certain visual tasks inside the MRI machine, such as viewing visual stimuli. You may be asked to participate in as much as 5 hours of fMRI testing, but any given session will only last 45 to 60 minutes, and sessions will take place over the span of 6 months as described in the Table on page 9. Sessions may take place at Strong Memorial Hospital, the University of Rochester Stroke

and Cerebrovascular Disorders Clinic, or the Rochester Center for Brain Imaging.

First you will be asked to fill out a safety screening form to assess whether it is safe for you to enter the MRI room. You will then be asked to remove any metal objects you may be carrying (e.g. wallets, watches, earrings, or piercings) and possibly to change into a gown that we will provide in case of large metal parts attached to your clothing, such as large zippers.

The MRI scanner is a large, tunnel-shaped machine. It produces a constant magnetic field that orients the water molecules in your body. Pulses of radio waves are then used to interact with the magnetic field and produce detailed pictures of the inside of the body.

You will first be asked to lie down on a table outside the MRI scanner. Your head will be kept still with padding so it cannot move; you should, however, feel comfortable at all times. Once you are comfortable, the table on which you are lying will be moved inside the MRI scanner. From this point forward, you will be asked to lie still when the MRI scanner is collecting images of your body. The MRI scanner does not collect images at all times. You will know when the MRI scanner is collecting images because you will hear the thumping noise from the electrical switching of the magnetic field and feel the associated vibrations. Please make sure to stay as still as possible during these times (no sneezing, scratching, stretching *etc.*). Between these periods of image collection, feel free to stretch or move as needed. You will be able to communicate with us at all times through a built-in intercom. You will also be holding an emergency rubber bulb that you can squeeze at any time to let us know you want to come out of the MRI scanner.

As part of this study, your fMRI data will be stored for future research. The data will be stored and shared only after all information that may identify you has been removed.

- 3. Optical coherence tomography (OCT):** This is a test to measure the thickness of your retina, the light-sensitive inner surface in the back of your eyeball where visual perception begins. It is a non-invasive test (a retinal scan) that uses light waves and takes about 30 seconds per eye. This test will be performed once at the beginning of the study and once at the end, as described in the Table on page 9. Testing will take place at the University of Rochester Medical Center Flaum Eye Institute.

Before your discharge from the hospital, you will be given a sufficient supply of the study drug to last you until the end of the study. In addition, an appointment for your next study visit will be made, and information about how to contact your study doctor will be provided. You will be asked for your contact information, including your email address and any alternate contacts, so that we can keep in touch with you throughout the study. You do not have to provide any alternate contacts if you do not wish to do so. You will also be asked to confirm the name

of your primary care physician so that he or she can be informed that you are participating in this study.

### **Study visits and phone calls:**

#### **1 week**

About one week after you start the study, the study coordinator will call you, or ask you in person, if you have been taking the study drug and **collect information about any new symptoms or side effects** you may be experiencing. The study coordinator will also collect information about your other medications.

#### **30 days**

You will return to the University of Rochester 30 days after starting the study. You will be asked to bring your bottle of the study drug with you so that we can confirm how many doses of the study drug you have taken since your discharge from the hospital.

Parts of this visit will be for your routine care as a stroke patient. Other parts will be for study purposes only, as indicated in **bold** below. At this 30-day follow-up visit:

1. You will be seen by your neurologist, who will review your medications and evaluate the progress of your recovery, the severity of your stroke symptoms, and your level of disability.
2. You will answer **a questionnaire about any new symptoms or side effects** you may be experiencing since starting the study;
3. You will have **a repeat psychological assessment (PHQ-9)** to screen for depression.
4. You will have your vision re-tested by **automated Humphrey perimetry**;
5. You will have a **repeat ECG**;
6. You will have **repeat laboratory tests**, and;
7. You will have a **repeat fMRI study** for us to understand if and how your brain is healing from the injury caused by the stroke. If this brain scan takes place at the Rochester Center for Brain Imaging, you will be asked to sign a separate consent form there immediately before the study.
8. You will have a **repeat neuropsychological evaluation** to assess your ability to perform certain tasks requiring different levels of visual processing.

#### **90 days**

You will return to the University of Rochester 90 days after starting the study. Once again, you will be asked to bring your bottle of the study drug with you so that we can confirm how many doses of the study drug you have taken since your discharge from the hospital.

Parts of this visit will be for your routine care as a stroke patient. Other parts will be for study purposes only, as indicated in **bold** below. At this 90-day follow-up visit:

1. You will be seen again by your neurologist, who will review your medications and evaluate the progress of your recovery, the severity of your stroke symptoms, and your level of disability.
2. You will answer **a questionnaire about any new symptoms or side effects** you may be experiencing since starting the study.
3. You will have **a repeat psychological assessment (PHQ-9)** to screen for depression.
4. You will have your vision re-tested by automated Humphrey perimetry;
5. You will have a **repeat fMRI study** for us to understand if and how your brain is healing from the injury caused by the stroke. If this brain scan takes place at the Rochester Center for Brain Imaging, you will be asked to sign a separate consent form there immediately before the study.
6. You will have a **repeat neuropsychological evaluation** to assess your ability to perform certain tasks requiring different levels of visual processing.

**At the 90-day study visit, we will remind you that the treatment part of the study is complete and you should stop taking the study drug.**

### **6 months**

You will return to the University of Rochester 6 months after starting the study. Parts of this visit will be for your routine care as a stroke patient. Other parts will be for study purposes only, as indicated in **bold** below. At this 6-month follow-up visit,

1. You will have your vision re-tested by automated Humphrey perimetry.
2. You will have **a repeat retinal scan (OCT)** to measure the thickness of your retina in each eye.
3. Your **functional vision score** will be calculated again to assess how your vision loss has affected your ability to perform your daily activities.
4. You will again answer the **Visual Function Questionnaire-25** for us to determine how your vision loss has affected your health-related quality of life.

5. You will answer **a questionnaire about any new symptoms or side effects** you may be experiencing since starting the study.
6. You will have **a repeat psychological assessment (PHQ-9)** to screen for depression.
7. You will have a **repeat fMRI study** for us to understand if and how your brain is healing from the injury caused by the stroke. If this brain scan takes place at the Rochester Center for Brain Imaging, you will be asked to sign a separate consent form there immediately before the study.
8. You will have a **repeat neuropsychological evaluation** to assess your ability to perform certain tasks requiring different levels of visual processing.

If you miss your follow-up visits, we will attempt to contact you by phone. If we are unable to reach you, we will ask your alternate contact and/or review your medical chart.

The following information about your participation in the study will be included in your electronic medical record.

- Documentation that you are in this study
- A copy of your signed consent form
- Results of your pregnancy test, if applicable
- Results of your 30-day blood tests
- Results of your 30-day ECG
- Results of any study-related visual exams

The fMRI studies are being done for research purposes only. The results of your fMRI studies will **not** be given to you or to your doctor, nor will they be included in your medical record.

**If at any time during the study you feel that you may be experiencing new symptoms or side effects, please contact the study team immediately or seek emergency medical care.**

### **Number of Subjects**

A total of 40 patients will be included in this study.

### **Duration of the Study**

The total length of your participation in this study is approximately 6 months. The amount of time needed to evaluate you and assign you to a treatment group during your hospital admission is about 2 ½ hours beyond what would normally be required for your care as a stroke patient. The telephone follow-up at day 7 will take about 15 minutes. The follow-up visits at 30 days and 90 days after your enrollment in the study will take about 2 hours of standard follow-up care, plus an



additional 3 or 4 hours to review any new symptoms or possible side effects, and perform additional laboratory and imaging tests. The final follow-up visit at 6 months will take 1 hour of standard follow-up care, plus 3 hours of additional testing. Therefore, a total of about 12 additional hours of participation will be needed from you if you decide to take part in the study.

### **Risks of Participation**

**1. Risks from the study drug:** All medications have possible side effects, including those that have been approved by the FDA. You may experience side effects while you are on the study drug. Everyone taking part in the study will be watched carefully for any side effects. Side effects may be mild or very serious. Many side effects will go away once you stop taking the study drug. However, in some cases, side effects can be serious and long-lasting, or may never go away. Known side effects of the study medication are listed below. The study drug may have side effects that no one knows about yet. The study team will let you know if they learn anything about the study drug during the study that might make you change your mind about participating. You should talk to your study doctor about any side effects you experience while you are taking part in the study.

**TABLE. Schedule of tests and procedures**

<b>Procedure</b>	<b>Baseline</b>	<b>1 week</b>	<b>30 days</b>	<b>90 days</b>	<b>6 months</b>
Physical examination & medical history	○				
MRI <sup>a</sup> scan of the brain	○				
Urine pregnancy test <sup>b</sup>	⊗				
Complete blood count	○		⊗		
Comprehensive metabolic panel	⊗		⊗		
Electrocardiogram (ECG)	○		⊗		
Modified Rankin Scale (mRS)	○		○	○	
Formal eye exam	○				
Automated Humphrey perimetry	○		⊗	○	○
Optical coherence tomography (OCT)	⊗				⊗
Functional vision score	⊗				⊗
Visual Function Questionnaire-25 (VFQ-25)	⊗				⊗
Neuropsychological testing	⊗		⊗	⊗	⊗
Functional MRI	⊗		⊗	⊗	⊗
Patient Health Questionnaire-9 (PHQ-9)	⊗		⊗	⊗	⊗
Adverse event questionnaire		⊗	⊗	⊗	⊗

<sup>a</sup> Magnetic resonance imaging

<sup>b</sup> For women of childbearing age only

○ Standard care

⊗ Study-related procedure

Patients who have a known allergic reaction to fluoxetine or other SSRIs may not participate in this study. The most common side effects of fluoxetine include abdominal pain, upset stomach, diarrhea, headache, irritability, and difficulty sleeping. Fluoxetine can also cause easy bruising and increase bleeding risk. In some people, it can cause drowsiness, dizziness, decreased sex drive, or impotence (decreased ability to have or maintain an erection). It can also cause liver abnormalities, heart rhythm irregularities, and hyponatremia (low sodium level in the blood). This is why we will monitor all patients in the study with repeat laboratory tests and ECG at 30 days. In rare cases, fluoxetine can cause dangerous side effects including anaphylactic shock (a severe life-threatening allergic reaction), seizures, acute angle-closure glaucoma (increased pressure in the eye), or serotonin syndrome or neuroleptic malignant syndrome (high blood pressure, rapid heart rate, fever, sweating, rigidity, muscle twitching, confusion, agitation, and hallucinations that can result from too much serotonin activity in the brain).

During the trial, you must immediately tell your study doctor about any abnormal or unexpected symptoms, and in particular about any irritability, hyperactivity, aggressive behavior, depression or suicidal thoughts, skin rash, difficulty breathing, chest pain, tremors, stomach ache, severe diarrhea, or jaundice (yellow discoloration of the skin).

If you are a woman of childbearing potential, you must not be pregnant or currently nursing a child, and you must use an acceptable method of birth control to avoid pregnancy while on the study drug. Acceptable methods of birth control include hormonal contraceptives, intrauterine device, abstinence, or spermicide and barrier. If you should become pregnant while on the study drug, you should notify your study doctor immediately.

You will be screened for depression during your enrollment in the study. If, at any point, you are diagnosed with depression, you will be referred to a health care provider for counseling and treatment. If you report any suicidal thoughts, you may be directed to the Emergency Department for further evaluation.

If you are hospitalized for any reason at another hospital, you must inform your study doctor as soon as possible.

## **2. Risks associated with MRI:**

- A. Metal: The MRI scanner produces a strong and constant magnetic field. There are no immediate risks associated with exposure to strong magnetic fields. However, if you have any metal in your body, the magnetic field may cause the metal in your body to heat up or shift position. You will be screened for the presence of metal in your body before each study session using a questionnaire. If you have a

cardiac pacemaker, implantable cardiac defibrillator, aneurysm clip, surgical wires, penile implant, metallic prosthesis, mechanical heart valve, cochlear implant, pump, shunt, or bullet or shrapnel fragments, or if you have a high risk of having metal fragments in your eyes as a result of working as a welder or metal worker, you will be excluded from the study.

- B. Claustrophobia: When you are inside the MRI machine, the scanner will surround your body and a close-fitting scanning coil will surround your head. If you feel anxious in confined spaces, you may not want to participate. If you decide to participate and feel claustrophobic later, you will be able to tell us through the intercom or squeeze the emergency rubber bulb in your hand, and we will stop the study and remove you from the scanner immediately.
- C. Inner ear damage: The MRI machine produces a loud tone that can cause injury to the inner ear if appropriate ear protection is not used. Earplugs or close-fitting silicone-padded headphones will be provided to protect your ears.
- D. Burns: In rare cases, contact with the MRI transmitting and receiving coil, contact with conductive materials such as wires, or skin-to-skin contact that forms conductive loops, may cause excessive heating and result in burns. The MRI operator will take steps, such as using foam pads when necessary, to minimize this risk. You should report any heating or burning sensation during the scan to the MRI operator immediately.
- E. Pregnancy: Exposure to strong magnetic fields may be harmful to a pregnant woman or unborn child. Although there are no established guidelines at this time about MRI during pregnancy, there is a possibility of an as-of-yet undiscovered pregnancy-related risk. You will not be included in the study if you are pregnant, or if you are unwilling or unable to use an acceptable method of birth control. Acceptable methods of birth control include hormonal contraceptives, intrauterine device, abstinence, or spermicide and barrier. If you should become pregnant during the study, you should notify your study doctor immediately.
- F. Long-term risks: The long-term health risks of MRI are unknown. Strong magnetic fields have been used in clinical practice and research for nearly 15 years, and so far no detrimental long-term effects have been identified, but this does not mean that we will not become aware of adverse long-term effects in the future. If new information about the risks of MRI becomes available during the course of the study, we will let you know.
- G. Acute ischemic stroke: Exposure to strong magnetic fields in the days and weeks immediately after a stroke may pose a slightly higher risk compared to magnetic field exposure months or years after a stroke. This risk is unlikely to be greater than minimal.

Nonetheless, in anticipation of any possible increase in risk during the study period, a neurologist familiar with your care will be on call during each fMRI session.

3. **Risks associated with blood draws:** These include pain or stinging when the needle is inserted and throbbing and/or bruising at the puncture site after the blood is drawn. To reduce the risk of bruising, you will be asked to hold pressure for several minutes at the puncture site after the the needle is removed. Rarely the vein may become inflamed after the blood is drawn. This is treated with a warm compress applied several times a day. Finally, there is a small risk of infection at the puncture site. This risk is minimal because your blood will be drawn by a trained health professional using proper sterile technique, including cleaning the puncture site with an alcohol swab before the needle gets inserted into your skin.
4. **Risks associated with questionnaire completion:** Common risks include possible boredom, mental fatigue, embarrassment at poor performance, frustration, or emotional discomfort when answering questions about one's health and well-being. You will be free to take breaks or stop completing the questionnaire at any time. As a result of responding to a health-related questionnaire, some people may rightly or wrongly conclude that they have a disease, disorder, or disturbance. Should you have such concerns, you will have a chance to discuss them with your study doctor.
5. **Risks associated with optical coherence tomography:** This is a noninvasive test that uses light waves to look inside the eye. It usually takes 30 seconds to perform. It does not involve radiation, ultrasound, radio waves, or magnetic fields. It has no known risks or harmful side effects other than possible boredom, fatigue, anxiety, or discomfort resulting from waiting and holding still while the test is being performed.
6. **Risks associated with automated Humphrey perimetry:** This is a noninvasive test that uses brief light signals to test your peripheral vision. It usually takes less than 10 minutes to perform. There are no known risks or harmful side effects other than possible boredom, fatigue, anxiety, or discomfort resulting from waiting while the test is being performed.
7. **Risks associated with neuropsychological testing:** This assessment consists of noninvasive tests that evaluate your ability to perform simple visual tasks requiring different levels of visual processing, such as naming objects, recognizing faces, and pointing at visual targets on a screen. It takes 45-90 minutes to complete. There are no known risks or harmful side effects other than possible boredom, mental fatigue, emotional discomfort as a result of being reminded of the visual impairment caused by your stroke; or

frustration, embarrassment, or anxiety due to real or perceived poor performance on the visual tasks in question.

8. **Confidentiality:** Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will assign you a study number instead of labeling the information we collect from you with your name or medical record number. All of the information we collect will be stored in a secure manner and only study team members will have access to it.

The study team may be notified if you receive other health care services at the University of Rochester Medical Center (URMC) or its Affiliates (e.g. visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study if it is included in your medical record:

- Staff at the University of Rochester Medical Center and its Affiliates (i.e. Strong Memorial Hospital, Highland Hospital, URMC primary care and specialist physician offices) who have a reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g. medical insurance companies, worker's compensation).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

### **Benefits of Participation**

You might not benefit from being in this study. If you are assigned to Group A, the recovery of your vision may be enhanced as a result of being on fluoxetine. If you are assigned to Group B, you may also benefit from the antidepressant effect of fluoxetine, as depression does occur in some stroke survivors.

### **New Study Findings**

If we discover anything that might make you change your mind about continuing in the study, we will let you know.

### **Alternatives to Participation**

You do not have to be in this study. If you choose not to participate in this study, you will still get the full care required by your condition. Currently there are no proven treatments to enhance visual recovery after a stroke. The standard of care for stroke patients with vision loss is occupational and cognitive rehabilitation, which will be offered to all patients whether they choose to participate in the study or not.

### **Costs**

Some of the tests and procedures you will receive during the course of this study are standard care (indicated in the Table on page 9 as blue squares). You and/or your insurance company will be responsible for paying for any tests, procedures, or exams that are done as part of your standard care. You are encouraged to discuss your coverage with your insurance provider.

The study drug and all study-related tests and procedures (indicated in the Table on page 9 as red circles), including all fMRI studies and retinal scans, all neuropsychological testing, the automated Humphrey perimetry study at 30 days, and the follow-up ECG and laboratory studies at 30 days, will be provided to you free of charge.

### **Payments**

Upon completing the study, you will receive a \$50 prepaid debit card for participating in this study.

### **Reimbursement for Travel Expenses**

You will be issued a pre-paid parking pass for your visits at 30 days, 90 days, and 6 months.

### **Circumstances for Dismissal**

You may be withdrawn from the study if the study team feels that staying in the study is harmful to your health. Additionally, you may be withdrawn from the study if you do not keep appointments for the study visits, or if you cannot complete study activities.

### **Compensation for Injury**

If you are directly injured by the drug that is being studied, or by the clinical procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research-related injury will be made on a case-by-case basis.

### **Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes**

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, you will only be identified by a study number (not by your name or initials) in the study records. Paper records will be kept in a locked file cabinet in a secure room, and computerized records will be kept on a secure server accessible only by authorized members of the study team.

Sometimes, however, researchers need to share information that may identify you to people that work for the University or to regulators. If this does happen, we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

At your request, information collected about you from your participation in this study may be given to your primary care doctor.

If you have never received a copy of the University of Rochester Medical Center and Affiliates Notice of Privacy Practices, please ask the study team for one.

*What information may be used and given to others?*

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Results of medical tests

*Who may use and give out information about you?*

- The study doctor and the study team
- University of Rochester Medical Center and its Affiliates
- Carnegie Mellon University

*Your information may be given to:*

- The Department of Health and Human Services
- The University of Rochester
- Carnegie Mellon University
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

*Why will this information be used and/or given to others?*

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

*What if I decide not to give permission to use and give out my health information?*

Then you will not be able to participate in this research study.

*May I review or copy my information?*

Yes, but only after the research is over.

*How long will this permission be valid?*

This permission will last indefinitely.

*May I cancel my permission to use and disclose information?*

Yes, you may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information, and you will not be able to stay in the study. Information that has already been gathered may need to be used and given to others for the validity of the study.

*May I withdraw from the study?*

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

*Is my health information protected after it has been given to others?*

No. There is a risk that your information will be given to others without your permission.

### **Contact Persons**

For more information concerning this research, or if you feel that your participation has resulted in any research-related injury, or emotional or physical discomfort, please contact **Bogachan Sahin, MD, PhD** by telephone at **(585) 275-2530**, or by email at **bogachan\_sahin@urmc.rochester.edu**.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd, CU 420315, Rochester, NY 14642; phone: (585) 276-0005 or (877) 449-4441 for any of the following reasons:

- You wish to talk to someone other than the research team about your rights as a research subject;
- You wish to voice concerns about the research;
- You wish to provide input concerning the research process;
- You are unable to reach the study team.

### **Voluntary Participation**

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.



**Signatures/Dates**

After reading and discussing the information in this consent form, you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

**Subject Consent**

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

\_\_\_\_\_  
Subject Name (Printed by Subject)

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

**Alternate Contacts**

Please place your initials in the “YES” box to the right if you agree to allow study team members to contact your alternate contacts to discuss your participation in this study and find out how you are doing if you are unreachable. Place your initials in the “NO” box if you do not wish to allow study team members to contact your alternate contacts.

YES	NO
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**Primary care physician**

Please place your initials in the “YES” box to the right if you agree to allow study team members to share information collected about you from your participation in this study with your primary care doctor.

<b>YES</b>	<b>NO</b>
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Place your initials in the “NO” box if you do not wish to allow study team members to share this information with your primary care doctor.

**Person Obtaining Consent**

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject’s satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

\_\_\_\_\_  
Name and Title (Print)

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

## APPENDIX

### Schedule of tests and procedures

<u>Procedure</u>	Baseline	1 week	30 days	90 days	6 months
Physical examination & medical history	○				
MRI <sup>a</sup> scan of the brain	○				
Urine pregnancy test <sup>b</sup>	⊗				
Complete blood count	○		⊗		
Comprehensive metabolic panel	⊗		⊗		
Electrocardiogram (ECG)	○		⊗		
Modified Rankin Scale (mRS)	○		○	○	
Formal eye exam	○				
Automated Humphrey perimetry	○		⊗	○	○
Optical coherence tomography (OCT)	⊗				⊗
Functional vision score	⊗				⊗
Visual Function Questionnaire-25 (VFQ-25)	⊗				⊗
Neuropsychological testing	⊗		⊗	⊗	⊗
Functional MRI	⊗		⊗	⊗	⊗
Patient Health Questionnaire-9 (PHQ-9)	⊗		⊗	⊗	⊗
Adverse event questionnaire		⊗	⊗	⊗	⊗

<sup>a</sup> Magnetic resonance imaging

<sup>b</sup> For women of childbearing age only procedure

○ Standard care

⊗ Study-related