FOR CCI USE ONLY
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Administrator: Lily Moy (JG)

Consent Approval Date: 6/6/17

Protocol Number: 2012P-000005

Study Approval Expiration Date: 5/7/18

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
05/07/2018
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY
Main Study

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Study of Deferoxamine Mesylate in Intracerebral Hemorrhage
PRINCIPAL INVESTIGATOR: Magdy Selim, MD, PhD
PROTOCOL NUMBER: 2012P-000005

INTRODUCTION:
You (or the person that you represent) are invited to take part in a research study about brain hemorrhage because you have had a sudden brain hemorrhage.

Research studies include only people who choose to take part. Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you (or the person that you represent) do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study.

- Your participation is voluntary;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with your doctor or with Beth Israel Deaconess Medical Center.

Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS
This study is being conducted by Dr. Magdy Selim and is funded by National Institute of Neurological Disorders and Stroke (NINDS), a federal organization that conducts and supports research on brain and nervous system disorders. The funding agency in this study (NINDS) is paying Beth Israel Deaconess Medical Center, Dr. Magdy Selim, and his colleagues to perform this research. BIDMC or Dr. Selim and his colleagues have no additional interests in this research project or in the funding agency.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

WHY THIS STUDY IS BEING DONE

A brain hemorrhage occurs when a blood vessel in part of the brain bursts open. This causes blood to leak into the brain. This may lead to a hemorrhagic stroke – when the blood flow to a part of the brain stops. The blood in the brain also contains iron – this iron damages the brain.

The focus of this study is to evaluate the study drug, deferoxamine mesylate – or deferoxamine. This drug removes iron. We are studying whether removal of iron from the brain after a brain hemorrhage will reduce the effects of the brain hemorrhage.

The study drug has been tested with brain hemorrhage patients in two previous small human research studies. The results provided information about the safety of deferoxamine and the appropriate dose to be used in patients with brain hemorrhage. Please read the following section entitled "Possible Risks, Side Effects, and Discomforts" carefully. It summarizes the information that we have learned from these studies.

The main purpose of this study is to examine the effects of the study drug – deferoxamine – on brain hemorrhage. We will look specifically at a person's ability to function well and to think well after a brain hemorrhage. We are also conducting this study to learn more about the safety of the study drug.

The drug involved in this study, deferoxamine mesylate, is investigational. This means that the study drug is still being tested in research studies and is not approved by the Food and Drug Administration [FDA] for the way that it is being used in this study. This particular investigational agent, deferoxamine, has been approved by the FDA for use in other diseases to remove excess iron from the body. Deferoxamine combines with iron in the bloodstream. The combination of iron and deferoxamine is then removed from the body by the kidneys. We do not yet know if it is useful or safe as a treatment for brain hemorrhage.

WHO WILL PARTICIPATE IN THE STUDY

Approximately 24-30 people will take part in this study at Beth Israel Deaconess Medical Center. A total of 294 people will take part in this study at all study sites.

WHAT WILL HAPPEN DURING THE STUDY

If you (or the person that you represent) agree to be in this study, you will be asked to read and sign this consent form. Your participation in this study will last up to 6 months. After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. The screening procedures for this study are the same as routine care that is given to all patients with a brain hemorrhage. In other words, you would have these tests and procedures even if you were not in this study. The tests and procedures will take between 1 and 11/2 hours to complete.

   For this research study, the screening procedures include:

   - A thorough neurological examination including a check of your consciousness, the severity and extent of your disability, and assessment of your vision and hearing.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

- A physical examination. We will measure your blood pressure, heart rate, rate of breathing, temperature, and body weight.

- A review of your medical history and your use of medications. If you have a known hypersensitivity (allergic reaction) to Deferoxamine or its products, you should not participate in this study.

The study doctors will also review the standard care procedures and tests that you completed.

- The CAT scan (a special kind of brain x-ray) of your head. This scan will help us to see where your stroke occurred.
- Routine blood work that was drawn. This includes
  - the number of red, white and clotting cells in your blood, and clotting tests
  - electrolytes, such as sodium and potassium
  - tests to see how your kidney and liver are functioning

2. Randomization Procedures: You will be assigned to one of two study groups. We will use a process called "randomization" to decide which study group that you will be in. With randomization, you are selected to be in a study group "by chance". Getting a head or a tail when you flip a coin is a type of "by chance."

Participants in one of the two study groups will receive a placebo. We use placebo to help us to decide whether it is the study drug or something else that leads to the results we observe. The placebo in this study will be salt water with no study drug.

You will have a 1 in 2 chance of receiving the study drug (50-50). You will not be able to choose the study group to which you will be assigned.

This is a double blind study. This means that the study team will not know and you will not know whether you are receiving the study drug or the placebo. However, this information can be learned by your treating physicians in case of an emergency.

You will be randomly assigned to be in one of two study groups

- Participants in one study group will receive the Deferoxamine -- the study drug**.** The dose will be determined by your body weight (32 mg per kilogram per day). For example, a person who weighs 100 pounds (i.e. approximately, 45 kilograms) will receive a dose of around 1.4 grams each day. A person who weighs 180 pounds will receive a dose of around 2.6 grams each day. The maximum dose will be 6 grams per day.

- Participants in the other study group will receive the placebo – the salt water with no study drug.

In this consent form, the term "**study infusion**" will be used for participants in both the study drug and placebo groups.

Participants in both study groups will receive the same care as someone who has a brain hemorrhage

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

who is not participating in this study. This is called "standard care."

3. Research Procedures: If you qualify to take part in this research study, you will undergo the following research procedures. These procedures will occur while you are in the hospital**.** You will also be asked to come to the clinic and to have a study phone call after you leave the hospital for follow-up purposes.

   While you are in the **hospital**

   - We will take a blood sample. We will use the blood drawn for your routine clinical care if possible. If not, we will take a sample (about one teaspoon) and a needle stick may be required.

   - You will have an intravenous catheter – IV – in a vein in your arm. The IV catheter is a thin plastic tube. We will infuse – or "drip" – the study infusion through the vein into your bloodstream.

   - You will start the study infusion within 24 hours of the brain hemorrhage. You will receive the study drug by an intravenous infusion every day. This infusion will last for a few hours depending on your weight, and will be repeated daily for 3 consecutive days.

   - You will receive standard care treatment for brain hemorrhage. Standard care often includes physical and neurological exams, daily blood tests, a CAT scan or MRI (magnetic resonance imaging) of your head. Your standard care will be decided by your hospital doctors.

   However, for **the purpose of this research study,** you will have the following tests and procedures during the study infusion and afterward.

   - The study team will monitor you closely for any side effects that could be related to the study infusion.

   - We will measure your blood pressure, pulse and breathing rate every 4 hours (around the clock) until the study infusion is complete.

You will have daily exams by the study doctor while you are receiving the study infusion. The study doctor will check your condition and see whether there are side effects of the study infusion. These exams will include

- A physical examination. We will measure your blood pressure, heart rate, rate of breathing, and temperature.

- A thorough neurological examination including a check of your consciousness, the progress of your condition, and assessment of your vision and hearing

You will also have the above exams

- One day after the study infusion ends

AND

- On the 7th day of your hospitalization OR on the day you are discharged if it comes before the 7th day.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

On the day after the infusion ends (approximately day 4 of your hospitalization):

- You will have a CAT scan of your head. The purpose of this procedure is to see if there are any changes in the size of your brain hemorrhage or brain swelling
- You will give a blood sample of approximately 2 Tablespoons (30 milliliters) for testing:
  - the number of red, white and clotting cells in your blood, and clotting tests
  - electrolytes, such as sodium and potassium
  - tests to see how your kidney and liver are functioning
- We will ask you to provide a urine sample for analysis.

At the 7th day or discharge exam we will also complete a "checklist" of your thinking, memory and how you are functioning

Please note that some of the above tests (blood tests or CAT scan) may be repeated at other times during your hospitalization if your physicians decide that this is necessary to assure your safety and to follow up on some abnormal results.

4. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures. The follow-up procedures for this study include 2 in-person study visits and 2 study phone calls.

- The first in-person visit will occur one month after your brain hemorrhage. This may occur in the hospital or – if you are discharged from the hospital – in the clinic. This visit is expected to take 45 minutes. At this study visit, the study doctor will
  - conduct a physical examination. We will measure your blood pressure, heart rate, rate of breathing and temperature.
  - complete a thorough neurological examination including a check of your consciousness, the progress of your condition, and assessment of your vision and hearing

  - The study doctors will ask you about
    - any hospitalizations, medical procedures, or bad side effects you may have had since the brain hemorrhage
    - any medications you have taken
    - where you are living
    - anything important that has happened since your hospital discharge

- We will call by telephone approximately two months after your brain hemorrhage We will speak with you or a family member by telephone. This call should take approximately 10 to 15 minutes. We will ask questions about your quality of life, how you are functioning, and any hospitalizations, medical procedures, or bad side effects you may have had since your last follow-up visit.

- The second in-person visit will occur three months after your brain hemorrhage. The study doctor will
  - conduct a physical examination. We will measure your blood pressure, heart rate, rate of breathing, and temperature

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

- complete a thorough neurological examination including a check of your consciousness, the progress of your condition, and assessment of your vision and hearing

- The study doctors will ask you about
  - any hospitalizations, medical procedures, or bad side effects you may have had since the brain hemorrhage
  - any medications you have taken
  - where you are living
  - anything important that has happened since your hospital discharge

- We will complete a "checklist" of your thinking, memory, and how you are functioning

- We will call by telephone approximately six months after your brain hemorrhage. We will speak with you or a family member by telephone. This call should take approximately 10 to 15 minutes. We will ask questions about your quality of life and how you are functioning since your last follow-up visit. This is your final follow-up assessment for the study.

POSSIBLE RISKS, SIDE EFFECTS, AND DISCOMFORTS

RISKS OF THE RESEARCH STUDY

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose. It is important that you consider all of the options before you decide to participate in this research study.

A risk to taking part in this study is the likelihood that the study drug or the dose that you will receive may not be effective in helping to treat your disease. This means that you may spend time and experience side effects taking a drug that may not provide you with any health-related benefits.

Deferoxamine – the study drug
The study drug is approved for use in clinical practice but **not** for patients – like you -- with brain hemorrhage. Safety studies indicate that the study drug is relatively safe and well tolerated. The study team will monitor you carefully for any side effects that we think will be related to the drug.
There is no specific medication that can be given to counteract the study drug. If we are concerned that you are having a side effect from the study drug, we may stop the study infusion. We will treat your symptoms and support you as needed. For example, we will give you fluids if your blood pressure becomes low.

However, like all drugs, the study drug may have potential side effects. Some of the side effects may be **life-threatening**. The side effects you experience could include some, all, or none of the following -effects.

- Low blood pressure with shock. This is a serious but rare side effect. Shock is a body collapse when your blood flow to body organs is seriously reduced. We give the study infusion slowly to help prevent low blood pressure with shock.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

- An allergic reaction is possible. Signs and symptoms include a rash, hives, flushing, headache and fever. The most serious allergic reaction includes trouble breathing and shortness of breath.

- Intravenous injection of the study drug may cause local irritation, pain, burning, swelling, itching or redness at the injection site.

- You may experience changes in your
  - hearing, such as ringing in your ears or trouble hearing
  - vision, such as blurred vision, trouble seeing at night or trouble seeing colors. You may develop visual hallucinations or cataracts.

- You may develop nausea, abdominal pain, diarrhea or joint pain.

- You may develop changes in the amount of salts and minerals (electrolytes) in your body, such as sodium, potassium, phosphorus, calcium, or magnesium

- You may develop changes in your heart, blood and lungs, which could be life-threatening. This includes that your heart rate may become fast or slow. You may develop pneumonia or your breathing system may fail.

- You may have nervous system effects. You may have tingling or numbness in your hands or feet. You may become weak, and you may have a seizure.

- You may develop an infection from a bacteria or from a fungus ("mold").

We previously investigated the use of the study drug, deferoxamine, in patients with brain hemorrhage in two small studies. In the first study, we administered various doses of the drug by an intravenous infusion for 3 days and determined that a dose of 62 milligram per kilogram of body weight each day was reasonably well tolerated. We subsequently examined the use of this dose given for 5 days in 21 subjects with brain hemorrhage in the first part of this study. However, we noticed increased incidence of a condition called "acute respiratory distress syndrome" in the patients who received the study drug compared with placebo. Acute respiratory distress syndrome (ARDS) leads to a buildup of fluid in the lungs. The fluid buildup makes the lungs heavy and stiff, and decreases the lungs' ability to expand, which prevents enough oxygen from passing into the bloodstream. The level of oxygen in the blood can be dangerously low, resulting in failure of other organ systems, such as the liver or kidneys. This condition can be life-threatening and may ultimately result in death. In the first part of this study, the ARDS cases varied in severity from mild to severe; and resulted in death in two cases. To minimize the development of ARDS, we have revised the current research protocol to: decrease the dose of the study drug from 62 mg/kg/day to 32 mg/kg/day; shorten the duration of the study drug infusion from 5 to 3 days; implement more rigid safety monitoring to allow for rapid detection of ARDS and stop the study drug if ARDS develops; and exclude subjects who are at high risk of developing ARDS from participating in the study.

Since the use of deferoxamine in this study is investigational, it is possible that you may experience some other side effects that we cannot predict. It is also important to understand that your condition may or may not improve, or may worsen while participating in the study. Anyone diagnosed with a brain hemorrhage faces the possibility of

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

experiencing further strokes, increased bleeding into the brain, seizures or brain swelling; all of which can cause long-term disability, and even death.

CAT SCANS

This research study involves exposure to radiation from two CAT scans. The first scan is part of your routine clinical care and is the one that you already had to diagnose brain hemorrhage. The second scan is obtained following completion of the study drug infusion, on day 4. This radiation exposure is not necessary for your medical care and is for research purposes only. This is in addition to the radiation exposure that you will receive as part of standard care. Using the standard way of describing radiation exposure, from participating in this study you will receive a total of less than 5.2 mSv.

For comparison, the average person in the United States receives a radiation exposure of 3 mSv per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from this research study is about the same amount you would normally receive in one and three-quarter years from these natural sources.

One possible effect that could occur at these doses is a slight increase in the risk of cancer. Please be aware that the natural chance of a person getting a fatal cancer during his/her lifetime is about 1 out of 4 (or 25 percent). The increase in the chance of getting a fatal cancer, as a result of the radiation exposure received from this research study, is 0.03%. Therefore, the total risk of fatal cancer may be estimated to increase from 25 percent to 25.03%. This change in risk is small and cannot be measured directly. Compared with other everyday risks, such as flying in an airplane or driving a car, this increase is considered slight.

One concern some people may have about radiation exposure is the effect on fertility or on the possibility of causing harm to future children (i.e., genetic risk). The doses you will receive in the study are well below the known levels that affect fertility or cause genetic effects.

PREGNANCY

There are no adequate studies regarding the safety of deferoxamine in pregnant women. It is also not known whether the drug is excreted in human milk. Therefore, you will not be allowed to participate in this study if you are a woman and are pregnant or breast-feeding a baby. You must also have a negative pregnancy test before you can enroll, if you are a woman of child-bearing potential.

BLOOD SAMPLES

There are some minor risks and discomforts associated with obtaining blood drawing from a vein. These include: the possibility of pain or bruising at the site of the blood draw; occasional feelings of lightheadedness or fainting; and, rarely, infection at the site of the blood draw. Whenever possible, blood samples for this research study will be drawn at the same time as samples for other laboratory tests ordered by your treating physician. If not, an additional needle stick may be required.

INTRAVENOUS

As part of this study, you will receive the study infusion through a vein in your arm – intravenously. Intravenous is also called "IV." You may feel discomfort when the IV is placed. After that, administration of the study infusion should be painless. Please report any pain or burning during the infusion to your nurse or doctor.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

The most common side effects for the IV are irritation, pain, burning, swelling, itching or redness where your IV is located.

LOSS OF CONFIDENTIALITY
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

We will take every measure to protect your privacy and confidentiality. Any information will be coded by a study-specific identification number to protect your confidentiality. Study documentation will be kept and securely archived. Your identity will be kept confidential when the results of this study are published.

When telephoning, the study staff will ask if it is a convenient time and will call back if it is not.

PSYCHOLOGICAL STRESS:
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the interview. You may stop your participation in the study at any time.

POSSIBLE BENEFITS
It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS
Taking part in this study is voluntary. The only alternative to participation in this research study is not to participate.

Regardless of whether or not you decide to participate, you will receive the standard care treatment and supportive care for patients with brain hemorrhage

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY
Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. However, please be aware that there may be risks to leaving the study before it has been completed. Monitoring follow-up visits allow the investigators to determine any emergent side effects from the study drug and to facilitate appropriate treatment. If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with your doctor or with Beth Israel Deaconess Medical Center. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

INVESTIGATORS RIGHT TO STOP THE STUDY
The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

by the investigators. Beth Israel Deaconess Medical Center or the funding source (NINDS) may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for the study drug or placebo, additional head CAT scans, study visits, or blood tests that are part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

CO-PAYMENT/DEDUCTIBLE STATEMENT

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

PAYMENTS TO YOU:

You will not be compensated in any way for participation in this research study. However, you will be reimbursed (pay you back) for parking fees when you return for the clinic study visits.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section "Who to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work, such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

CONFIDENTIALITY

Information learned from your participation in this study and from your medical records may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical records may be used for research purposes and may be published; however, you will not be identified by name in such publications.

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.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting and sharing information about you with others. Please review this section carefully as it contains information about the federal privacy rules and the use of your information.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists such as past and present medical records, research records, diagnosis and treatment of mental health conditions, demographic information, and laboratory or other diagnostic tests, such as CAT scans, as well as any new information generated as part of this study through tests, phone calls, visits, questionnaires, study drug or placebo, and physical exams we may ask you to undergo. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with investigators listed on this consent form as well as the supporting research team [i.e. research assistants, statisticians, data managers, laboratory personnel, administrative assistants]. Your Protected Health Information may also be shared with the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center as it is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The funding source of this study [The NINDS] and their clinical research organizations
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions.
- Statisticians and other data monitors not affiliated with BIDMC [The Department of Public Health Sciences at the Medical University of South Carolina]
- Centralized data collectors [The Data Coordination Unit and the Department of Public Health Sciences at the Medical University of South Carolina]
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], and the Office for Human Research Protections [OHRP]
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study

Those who receive your Protected Health Information may make further disclosures to others. If they do, your information may no longer be covered by the federal privacy regulations.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. We also shall use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to

Magdy Selim, MD, PhD
330 Brookline Ave.
Dept. of Neurology
Boston, MA 02215

Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter.

REFUSAL TO SIGN
If you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI
If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

NOTICE OF PRIVACY PRACTICES
In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

WHOM TO CALL IF YOU HAVE QUESTIONS OR PROBLEMS
If you have any questions, concerns or complaints about this research or experience any problems, you should contact Magdy Selim, Md, PhD at [617] 632-8913.

You may contact the Human Subjects Protection Office at [617] 667-0469 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

ICF REVISION DATES:

12/30/2011	CCI Submission
11/26/2012	Amendment to add Shruti Sonni; Vasileios Lioutas; Megan Farinella as investigators
01/07/2013	The word "hemorrhage" was added to the end of the first sentence of the introduction
08/09/2013	Amendment to remove Shruti Sonni & Megan Farinella and to add Gioachinno Curiale & Violiza Inoa Acosta as investigators

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
05/07/2018
APPROVAL EXPIRATION DATE

10/21/2013	Added changes in slats & minerals to potential risks, and clarified that changes in the heart & lung could be life-threatening
05/20/2014	Revised ICF to reflect protocol changes (Protocol Version #IV/I); to decrease the dose & duration of study drug infusion; to expand on previous safety data regarding ARDS; to eliminate CAT scan on day 90; to add a follow up phone call after 6 months; and to add Erica Siwila-Sackman as an investigator
07/17/2014	Amendment to remove Gioacchino Curiale, Violiza Inoa Acosta, and Erica Siwila-Sackman and to add Lester Leung, Mark McAllister, and Caroline Feigert as investigators
10/9/2014	Clarification of study drug infusion rate and schedule.

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.
If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO) at [617]667-0469
I am aware that this is a research project and that unforeseen side effects may occur.
I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.
I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.
I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: STUDY OF DEFEROXAMINE MESYLATE IN INTRACEREBRAL HEMORRHAGE - MAIN CONSENT
PRINCIPAL INVESTIGATOR'S NAME: MAGDY SELIM, MD, PHD
PROTOCOL #: 2012P-000005

PRINT INVESTIGATOR'S/Co-Investigator's NAME

THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.
Signature of Interpreter: _____
Printed name of Interpreter: _____
Date: _____