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

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APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
05/07/2018
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY
Blood Repository Sub-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. You are invited to take part in this study because you have had a sudden brain hemorrhage.

This consent is for a sub-study of a main study about the study drug, deferoxamine, to be used with persons who have had a sudden brain hemorrhage. You are invited to take part in this blood repository research study. A repository means that something is stored. In this study, the repository will be storage of blood samples that will be used in future genetic testing.

You can choose not to participate in this blood repository study and <u>still participate</u> in the main research study.

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.

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

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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.

WHY THIS STUDY IS BEING DONE

The purpose of this study is to create a repository of participants' blood for research purposes. The future research in this study will be on participants' DNA, RNA and blood proteins.

This genetic material (DNA [deoxyribonucleic acid] and RNA [ribonucleic acid]) is contained in cells organized in large structures called chromosomes. Genetic materials provide an "instruction book" for making proteins that make a person unique. This "uniqueness" includes a person's diseases or other problems. Genetic materials also guide the body's biological reactions. The word "genes" refers to some sections of DNA and RNA.

In this study, we will create a "blood repository" from persons who have had a sudden brain hemorrhage. If you choose to participate in this study, we will be storing your blood in order to study your DNA, RNA, and blood proteins in future studies. We hope to learn about

- the genetics of brain hemorrhage
- how to better diagnose brain hemorrhage
- how to develop successful treatments for brain hemorrhage
- how different people react to medications – both whether the medications work and the medications' side effects for brain hemorrhage.

Since we do not know the exact questions that will be studied at a later date, we cannot tell you exactly what tests will be done on your blood or what that might mean to you. Your samples will be only used to learn more about brain hemorrhage, treatment and complications of brain hemorrhage,

The researchers may use some of your stored blood to make a cell line in a laboratory. This means that we will be able to obtain more of your DNA, RNA, and blood proteins for genetic testing without your participation. You will not be notified at the time that the cell line research begins. We will not obtain your consent for this additional research.

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WHO WILL PARTICIPATE IN THE STUDY

Approximately 24 to 30 people will take part in this study at Beth Israel Deaconess Medical Center. Approximately 294 people will take part in this study across all study sites.

WHAT WILL HAPPEN DURING THE STUDY

If you agree to be a part of this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

1. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures.

   - We will collect blood samples that are up to 2 tablespoons (or 30 milliliters) . These samples are above and beyond the samples you will give in the main study.

   - The samples will be collected at two times: (1) before you receive the study infusion and (2) after you finish all of the study infusions

   Materials

   - We will "de-identify" your samples so that information about you is not connected with your sample. We will label your blood sample with a "code" number to protect your privacy. We will create a master list that links your personal health information (your name, date of birth and medical record number) to the code number.

   - An electronic copy of this master list will be saved on a password-protected computer in a locked office. We will not keep any hard copies of the master list. Only the researchers at BIDMC listed on this consent form will have access to this electronic master list via the computer network.

   - At first, the blood sample will be stored in a very low-temperature locked freezer at Beth Israel Deaconess Medical Center. The freezer will only be used for this specific study. The researchers who analyze this blood will not know that the blood is yours.

   - We do not know where we will examine your genetic materials. We think the examination will be at the Broad Institute in Cambridge, Massachusetts. Your blood samples will be sent without any accompanying clinical information. To do the examination, your genetic materials will be "removed" from the blood cells and studied. The researchers who do these examinations will not see any personal information that identifies you.

RESEARCH DATA – STORAGE AND DISCLOSURE

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We intend for the researchers at the Broad Institute to isolate the genetic materials -- DNA, RNA and proteins -- from your blood sample. Your blood will not be used for any other laboratory work. Your genetic materials will be stored indefinitely – forever. We do not know the location of the storage area.

The safety of your blood sample is important. The laboratories we intend to use are secure facilities, where only employees with ID badges can enter. The de-identified genetic material from your blood will be stored in locked freezers only accessible to the research staff at those locations. These samples will never be destroyed. You may withdraw your blood sample and ask that your sample be destroyed at any time before we process your genetic material. This is likely to take place within 8-to-12 months after your signing of this consent form. You cannot withdraw your sample from this repository after your genetic materials have been isolated.

If you decide you would like to prevent your blood from being stored in this repository, please send a written request to withdraw your blood sample. This request should be submitted to

Magdy Selim, MD, PhD
Beth Israel Deaconess Medical Center
Department of Neurology
330 Brookline Avenue
Boston, MA 02215.

The investigators at BIDMC will receive the results of your genetic testing. However the researchers will not know that it is your genetic material.

We will take all measures necessary to protect your confidentiality at all times. In the event of future second or third party use of the samples, all codes will be removed so that there will be no method by which the sample can be tracked back to you and identifying information.

No genetic results will ever be released to you, your family, employers, insurance companies, or other doctors; and no information will ever be published or released in any way that will identify you.

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.

The greatest risk of identification of genetic information is to your privacy and potential loss of confidentiality. In particular, inadvertent accidental disclosure of collected blood and genetic samples

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could result in possible identification of genetic information about you. This could potentially lead to discrimination by employers or insurance providers. If your participation becomes known, it could create a problem or hardship for you depending upon the type of information that is disclosed.

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.

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. There is a risk that someone in the future could link your genetic or medical information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance; however there are laws against this kind of misuse. We believe the chance these things will happen is very small, but we cannot guarantee that your identity will never become known. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them.

Every effort will be made to protect the confidentiality of your identifiable information. To protect the confidentiality of identifiable information, we will not place any record of your participation in this sub-study in your medical record.

The results of genetic analysis performed for purposes of this research study will not appear in your medical records. Furthermore, master list that connects your name to your sample will be kept in a separate locked location on a password-protected network, only accessible to the principal investigator and his designees.

POSSIBLE BENEFITS

There is no direct benefit to you from being 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 blood bank repository sub-study is voluntary. The only alternative to participation in this research study is not to participate.

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. If you decide not to participate in the study or decide to leave the study early, your decision will not affect your

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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.

You may withdraw this consent or request that your blood sample and material obtained from your blood sample be destroyed and discontinue your participation in the study at any time before we process your genetic material. This is likely to occur within 8-to-12 months of your participation in this study. In such a case, you should notify your study doctor [Magdy Selim, MD, PhD (617) 632-8913] or his designee that you want to withdraw your consent or have your blood samples destroyed and discontinue your participation in this genetic research. The investigator will then notify involved parties to destroy your blood samples and all the material obtained from your blood sample that they still have, and request a written confirmation that the samples have been destroyed. At this point, any and all remaining samples will be destroyed. However, the investigators shall be entitled to retain and use any research results (data) that they obtain before you withdrew your consent.

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 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 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 sub-study.

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

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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 the main clinical trial and this sub-study 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.

There is a possibility that information that identifies you will be given to the Beth Israel Deaconess Medical Center oversight officials or to officials of the Department of Health and Human Services. This information may be used for audits or evaluations, or to be sure that research work is being done correctly. However, these officials are also obliged to protect your privacy and confidentiality.

Following strict confidentiality procedures can minimize risks associated with the inadvertent disclosure of genetic research data. Multiple steps have been taken to ensure that your blood sample(s), genetic material and protein obtained from your blood sample(s), and any data generated from the material obtained from your blood sample(s), are handled in a secure manner. Your name and social security number, phone number, address (or any other information uniquely identifying you) will not be written on or associated with the sample(s) you donate. The Investigator is the only person who knows your personal information (name, phone number and address). Other parties will only have a coded Patient Identification Number. This genetic research is not intended to provide you with clinical information.

Your coded genetic and health information may be put in a controlled access database such as U.S. National Institutes of Health (NIH) genomic database called dbGAP and used for future research. Your name and other information that could identify you will not be included in the database. The database will store your coded genetic and health information and give them to other qualified and approved researchers to do more studies. We will not know what types of health-related research will be done with the data that are sent to the database. We do not think that there will be further risks to your privacy and confidentiality by sharing your coded genetic and health information with this database. However, we cannot predict how genetic information will be used in the future.

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By signing this Informed Consent Form, you are acknowledging and agreeing that you will not be told about your individual genomic research results. It is possible, however, that members of regulatory authorities, such as the United States Food and Drug Administration (FDA), or other persons required by law, may have access to the foregoing information and your individual genomic research results. Although results from this research may be published, or otherwise disclosed to outside parties, those results will not identify you in any way. Any contact made with you regarding this research will be through the Investigator.

USE OF YOUR TISSUE AND DATA FOR COMMERCIAL DEVELOPMENT

As part of this research program, samples of your tissue and information about your medical history may be provided to other researchers and/or outside collaborators without identifying you by name. They may use your tissue and information in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from any such work that may be performed. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your tissue may be used for commercial purposes. You also understand and agree that tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. Beth Israel Medical Deaconess Medical Center has no program to compensate you in the event product testing or commercial development takes place.

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.

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, 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

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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 Epidemiology at the Medical University of South Carolina]
- Centralized data collectors [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

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.

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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
08/09/2013 Amendment to remove Shruti Sonni & Megan Farinella, and to add Gioacchino Curiale & Violiza Inoa Acosta as investigators
05/20/2014 Amendment to revise the number of subjects participating across all sites from 324 to 294; and to add Erica Siwila-Sackman as an investigator

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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

10/09/2014 Amendment to correct the amount of blood drawn and the name change for the Data Coordination Center at MUSC.

07/05/2015 Amendment to remove Lester Leung and Mark McAllister, and to add Joseph Tarsia and Luciana Catanese as investigators

07/27/2015 Risks and loss of confidentiality sections revised to add language regarding the deposition of data into the NIH dbGAP

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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

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

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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: _____