IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Jan 13, 2020

INFORMED CONSENT TO PARTICIPATE IN AN EARLY FEASIBILITY STUDY

TITLE:	Comparison of outputs from the STrategically Acquired Gradient Echo (STAGE) Protocol to conventional 1.5 T and 3.0 T MR images
PROTOCOL NO.:	CP-STAGE-001 WIRB® Protocol #20193130
SPONSOR:	SpinTech, Inc.
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

INTRODUCTION

In this consent form, "you" always refers to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

You have been invited to join an Early Feasibility Study to evaluate the quality of the magnetic resonance (MR) imaging outputs from the Strategically Acquired Gradient Echo protocol and module (aka STAGE). The device is investigational and not approved by the Food and Drug Administration (FDA) for your medical condition.

This study is sponsored by SpinTech, Inc. Before you decide if you want to be involved in the study, it is important that you read and understand this information. Be sure to ask questions about anything that is unclear. Your Physician (also called study physician in this consent form) will answer your questions about the study, the device or any of the information being presented.

No study-related tests or procedures will be done before you sign this consent form.

PURPOSE AND BACKGROUND

The reason we are doing this research study is to evaluate the original MR images collected from the STAGE imaging protocol as well as post-processed images from the STAGE module, to see if the data can be used as a helpful addition to imaging in clinical diagnoses. This type of research study is called an "early feasibility study". Early feasibility studies typically evaluate innovative devices or innovative uses of approved devices. These studies enroll a small number of patients and provide initial information on the basic safety and performance of the study device when used in neuroimaging diseases and condition such as Multiple Sclerosis,

Traumatic Brain Injury, Parkinson's Disease, Dementia, aging and others. Since, this is an early feasibility study, some risks are unknown, and there is no guarantee that the device will help you or improve your condition.

STAGE is a medical grade processing computer which will process MR imaging collected from an MRI protocol which can rapidly collect images. There are several purposes for this protocol: to collect images rapidly on most manufacturers and field strengths, to standardize the data making longitudinal and inter-site scans comparable, and to provide a comprehensive number of image outputs for other clinical diagnosis. This protocol is designed to collect or generate the most number of MR images in the least amount of time, which has implications on patient burden and helps the issue with long MRI scan times which can be uncomfortable and costly.

This study is taking place in approximately 5 hospitals and up to 100 patients will be enrolled.

PRIOR INFORMATION AVAILABLE ON THE DEVICE

STAGE is composed of a medical grade computer manufactured by Onyx Healthcare: *Onyx High Performance Medical Grade Fanless Box PC (model: MEDPC-9200)*. The system is has been tested for safety and certified to federal and international standards.

WHO CAN PARTICIPATE IN THE STUDY

To find out if you meet all the requirements for this early feasibility study, your Physician will ask you questions and check your medical records. Before you decide to be in the study, be sure you understand all the information given and ask your Physician any questions you may have about your participation in this study.

If you decide to participate in this study, you can sign this form which will allow your Physician to perform additional study-related tests to see if you are a good candidate for this study. Please understand that your consent is required in order for your Physician to evaluate you further as a potential candidate for the study. You will not be actually enrolled into the study until your Physician will confirm you meet all of the following inclusion criteria and none of the following exclusion criteria.

INCLUSION/EXCLUSION CRITERIA:

Subject Inclusion Criteria

- Subjects 6-80 years of age, inclusive.
- Literate in English
- No contraindications to MR*
- Not claustrophobic

  * ACR Guidance Document on MR Safe Practices 2013 J Magn Reson Imaging 2013 Mar;37(3):501-530

Subject Exclusion Criteria

- Subject has diffuse white matter disease or leukoaraiosis.
- Participants, or Subject's parent or guardian unable to read and sign an informed

consent.
- Women who are pregnant or breast-feeding.
- Those with major surgery within the past eight weeks or scheduled surgery within 30 days.
- Chronic back pain or inability to lie still for 5 minutes or more.
- History of drug or alcohol abuse.
- Individuals who exceed 28 BMI or 320 lbs.
- Individual whose girth exceeds the magnetic bore.
- Direct employee or student of the PI.
- Participants belong to a vulnerable group.
  * ACR Guidance Document on MR Safe Practices 2013 J Magn Reson Imaging 2013 Mar;37(3):501-530

Eligibility Criteria
All subjects who meet all inclusion and do not meet any exclusion criteria are eligible to participate in the study. Subjects who are eligible will not be compensated for this study.

All subjects who meet the inclusion and do not meet the exclusion criteria are eligible to participate in the study.

STUDY PROCEDURE

Once your Physician determines you are good candidate for this study, your Physician will conduct study-related assessments to determine if you are eligible for the study. These assessments include:

- ☐ physical examinations
- ☐ medical and surgical history

GENERAL STUDY PROCEDURES

You will undergo a brain MRI scan using the STAGE Protocol* either at 3 Tesla or 1.5 Tesla field strength. An oral sedative might be prescribed to help you remain still in the scanner.

Since a primary aim of STAGE is to reduce acquisition times while generating a wealth of contrasts from the dataset, additional conventional MR images will be acquired. Your time in the MR machine will be kept under 40 minutes.

For the post- processing (you will not need to be present for this step), the images will be sent to the STAGE module (processing usit) to generate a variety of images and contrasts.

No follow-up tests are needed for this study. Your participation in the study will end after the images are collected.

RISKS AND DISCOMFORTS

Participation in this study poses a risk for breach of confidentiality. Records will be stored in a safe,

lockable storage unit.

MRI may be uncomfortable for some subjects. MRI does not involve the use of radiation; it does however involve the use of a strong magnetic field. Prior to starting the scan each subject will be asked if they have any metal implanted in their body. The presence of implanted metal will influence the scans. Some subjects who have claustrophobia (fear of small closed places) are concerned about being in the scanner, and if at any point during the scan this concerns you, the scanning will be stopped. Some studies, like the MRI, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds and is not harmful to the subject. The MRI machine is operated within federal guidelines so the potential for inducing PNS is low. There is the potential that a magnetic resonance image may reveal an abnormality, such as a cyst or tumor. Many such abnormalities are not clinically significant, but subjects may want to investigate them further. Such a finding may require notifying the subject's primary Physician.

The STAGE module will use a Medical Grade computer by Onyx Healthcare, Inc. and may have electrical or power issues.

The risks of oral sedation include upset stomach, drowsiness, and dizziness.

RISK MITIGATION STRATEGIES:

The Sponsor has done the following things to reduce the risks to subjects.

- The MRI scanners as well as the Onyx Medical Grade PC involved in this study are already FDA-approved.

- Your Study Doctor and any responsible clinical research Site personnel have been trained to follow the research study Protocol. This training includes the design and proper use of the Study Device.

- Every research Site must get approval to conduct this study from an Institutional Review Board (IRB). This group of people reviews the study Protocol and the informed consent to monitor whether the research study is ethical and your safety and welfare rights are protected.

- Prospective data will include imaging as well as questionnaire/survey with the neuroradiologist to evaluate the performance of the STAGE module and its outputs. The study will not consist of retrospective data (for example getting information in your medical records).

- To minimize the breach of confidentiality risk, we will not use your name or hospital number to identify you on any study records. Instead a unique study number will be assigned to each subject. Only this number will be used on study documents that relate to you. We will keep the list of subject names and corresponding unique study number in a secure, locked location. At the end of the project, this list will be destroyed.

- To minimize discomfort during the MRI, pads and blankets will be used to position each subject so you are as comfortable as possible during the scan. You may wear foam

earplugs or hearing-protective headphones to reduce hearing the loud noises made by the scanner. You will be able to talk to us throughout the study, and can let us know right away if you want to stop the study and get out of the scanner.

ALTERNATIVES TO JOINING THE STUDY

This is not a treatment study, your alternative is to not participate.

POSSIBLE BENEFITS IF YOU JOIN THIS STUDY

To the individual: There are no benefits for the research subject.

To society: If the device is successful, scan times could be reduced, helping to mitigate patient discomfort within the scanner.

The STAGE protocol may be an efficient way to collect this many contrasts, and therefore hospitals and imaging centers can increase the number of scans they do. Standardization would also be achieved between manufacturers and field strengths, which allow for ease in longitudinal assessment, and repeat scans. Further, standardized data may be helpful as input for better lesion detection, or to discern any abnormalities based on MR signal.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary. If you wish to participate in this early feasibility study, you will be asked to sign this form. Please take time to read this information carefully and to discuss it with your family, friends, and Physician before you decide.

You have the right to refuse to participate in this study. If you decide to participate, you can change your mind and choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services you may receive from this clinic or hospital. Your decision not to participate or to withdraw from the study will not lead to any penalties or loss of benefits you are otherwise entitled to.

If you decide to stop taking part in this study, you must tell your study Physician. You do not need to specify the reason for your withdrawal. Your study Physician will discuss with you whether any testing or follow-up may need to be done for your safety.

Your Physician or the sponsor can remove you from the study at any time without your approval. Any patient who is withdrawn from the study for any reason may not re-enter the study at any time.

CONFIDENTIALITY OF STUDY RECORDS AND MEDICAL RECORDS

Information collected for this study is confidential. Access to your personal medical information will be limited to the purposes of collection and processing information necessary for the completion of this study.

Your privacy is important. You will only be identified in the study by a code. This number is not derived from any of your personal information. Should results of this study be published (in a medical journal), you will not be identified through your name or other personal information. Data collected and reported to the sponsor for this study are the property of the sponsor. Your study records are just like hospital records. They may be subpoenaed by court order or may be inspected by federal regulatory authorities, including the Food and Drug Administration. Your information may also be reviewed by the Institutional Review Board (IRB).

MRI DICOM data will be collected in a de-identified manner in which Patient code will be used to ID the subject.

STUDY RELATED INJURY

If physical injury happens to you because of your involvement in this early feasibility study, medical treatment will be available, if appropriate, at the hospital. There are no plans to pay you for any study injury. Contact your Physician if you experience a study related injury.

RIGHTS AND COMPENSATION

You will not be paid to participate in this study. By signing this form, you do not give up any of your legal rights and you do not release the study Physician or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study. You will not be charged for any study procedures. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be billed to your medical plan. If your medical plan does not cover the costs, the treatment will be paid by the study sponsor SpinTech, Inc.

WHO YOU SHOULD CONTACT IF YOU HAVE QUESTIONS

If you have any questions, concerns, or complaints about taking part in this study, or if you think you may have been injured because of your participation in the study, call the study monitor, Sean Sethi at (248) 712-6789 or at sean@spintechimaging.com, [Name] at [Phone Number] (24 hours). If you have any questions, concerns or complaints about the study or your rights as a study patient, you can call the IRB at (360) 252-2500 or (800) 562-4789. You should also inform your study Physician if you have been injured or hospitalized for any reason during the study.

A description of this clinical trial will be available on http://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.

PATIENT'S STATEMENT

I have been given a chance to ask questions about this study. These questions have been answered to my satisfaction. If I have any more questions about taking part in this study, I may contact [Name] at [Phone Number] (24 hours).

PI name PI Phone number

I understand that my participation in this early feasibility study is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be otherwise entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study. If I have any questions about my rights as a patient in this study I may contact:

[PI Name]
PI Name

[PI Address]
PI Address

[PI Phone Number]
PI Phone number

Institutional Review Board (IRB)
(800) 562-4789
help@wirb.com

By signing this consent form, I have not waived any of my legal rights or released the parties involved in this study from liability for negligence.

I have read and understand the above information. I agree to participate in this study. I have been given a copy of this form for my own records.

Consent/Assent Instructions:

- Both parents are required to consent unless the second parent is deceased, unknown, incompetent, or not reasonably available, or the parent providing consent has sole legal responsibility for the care and custody of the child).
- All children are required to assent.
- If assent is obtained, have the child sign an [assent form/assent section below] unless the investigator determines the child is NOT capable of signing.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____ _____
Signature of Subject (18 years and older) Date

_____ _____
Signature of Parent or Guardian (when applicable) Date

_____
Authority of Subject's Parent or Guardian Relationship to Subject

_____ _____
Signature of Parent or Guardian (when applicable) Date

_____
Authority of Subject's Parent or Guardian Relationship to Subject

_____ _____
Signature of Person Obtaining Informed Consent Date

ASSENT SECTION For Subjects Ages 6-17:

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something. Dr. [PI's name] and some other doctors are doing a study a device which can image inside the body. After we tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

We are trying to make the imaging you will be undergoing much faster. Magnetic resonance imaging scanners can be uncomfortable, not just for children but also adults and we are testing new technology to achieve this goal.

What will happen to you if you are in this study?

Only if you agree:

1. We will image you in an MRI scanner for up to 40 minutes with headphones. In this period, the scanner will take pictures of your brain. Prior to this time, you may be given a sedative to remain still. You will be in contact with the technician so if you are uncomfortable, you can take a break, or stop the scan.

Will this study hurt?

The scanner will generate loud noises which the headphones will muffle so they are not as loud. Some patients experience discomfort. Other risks include patient burns and objects flying into the scanner but these are rare events.

Will you get better if you are in this study?

No, this study won't make you feel better or get well. But the doctors and researchers may obtain new information about the device we are studying.

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?

No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you.

If you don't want to be in this study, just tell us.

If you want to be in this study, just tell us.

The doctor will give you a copy of this form to keep.

Statement of person conducting assent discussion:

I have explained all aspects of the research to the subject to the best of his or her ability to understand.

I have answered all the questions of the subject relating to this research.

The subject agrees to be in the research.

I believe the subject's decision to enroll is voluntary.

The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

_____ _____
Signature of Subject providing Assent Date

_____ _____
Signature of Person Conducting Assent Discussion Date

Name of Investigator	Signature of Investigator	Date

HIPAA & PROTECTED HEALTH INFORMATION (PHI)

What information will be collected about you?

The study will collect information regarding the scans and your past and present medical conditions.

Who may use and disclose information about you?

The people who may use your Private Health Information include the clinician, [insert Physician name] and his/her staff; the STAGE (IRB: CP-STAGE-001) Institutional Review Board and its staff; legal counsel; audit and compliance staff; and other people who need to see the information to help the study or make sure it is being done correctly. These people may disclose your Private Health Information to staff of the entities listed in the next section.

Who may see your health information?

Your Private Health Information may be disclosed to people associated with the following entities:

- ☐ Governmental agencies that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration
- ☐ Other institutions that are participating in the study. The sponsor of the study and organizations that the sponsor may contract with for the study. The name of the sponsor is SpinTech, Inc.

Why will your information be used and disclosed?

Your information may be used to meet the reporting requirements of governmental agencies and to ensure the study was done properly.

Can you decide not to authorize the use and disclosure of your Private Health Information?

Yes. You do not have to authorize the use or disclosure of your Private Health Information. However, if you do not sign this authorization, then you cannot participate in the study.

Can you revoke your authorization?

Yes. You may revoke your authorization to allow your Private Health Information to be used or disclosed at any time by sending a written notice to the principal investigator, [Name].

If you revoke your authorization, you will be withdrawn from the study, and no health information about you will be gathered after that date. However, information gathered before that date may be used or disclosed if it is needed for the study analysis.

Is your health information protected after it has been disclosed to others?

If your health information is disclosed to someone who is not required to follow the Privacy Rule, then that information may no longer be protected, and it may be used or disclosed without your permission.

The Sponsor of the study, SpinTech, Inc., the Investigator and all involved third parties have agreed to be bound by the provisions of the Privacy Rule of the Health Insurance Portability and Accountability Act.

Can you see your health information?

Yes. You may see and copy your information after the study ends.

Does your authorization have an expiration date?

Your authorization to use and disclose health information will [continue until the end of the study and any necessary data analysis follow-up activities for

the study OR expire on [date]]. However, the information and data that are collected during your authorization period is effective can continue to be used and disclosed after your authorization has expired.

Signature

By signing below, I authorize the use and disclosure of my personal health information as described above for this study.

Name of Researcher	Signature	Date
Name of Participant	Signature	Date

If subject is 6-17 years of age:

Name of Parent or Guardian	Signature	Date
Name of Parent or Guardian	Signature	Date

Please sign both copies, keep one and return one to the researcher.