MRI Consent Form

You are being asked to undergo magnetic resonance imaging ('MRI") for a research study. This consent form explains the procedure, risks, and benefits of undergoing an MRI. Please read it carefully and take as much time as you need. If you have any question, please ask, regardless of whether you have them now or at a later time.

You are a volunteer. If you do join the study and change your mind about participating, you may quit at any time without fear of penalty or loss of benefits.

While you are in this study, the study team will keep you informed of any new information that could affect whether you want to stay in the study.

Please contact the Principal Investigator if you have any questions about this study. If you have any questions about your rights as a participant in this research study, please contact New York Institute of Technology's ("NYIT") Institutional Review Board ("IRB").

Title of Research: .

Principal Investigator:

Other Researchers:

Institutional Contact: Institutional Review Board
Office of Sponsored Programs and Research
New York Institute of Technology
Northern Boulevard, Old Westbury, NY 11568
Tel: 516-686-7488 or grants@nyit.edu

Contact in case of injury resulting from this study: Dr. Gabriel Gelves, (516) 686- 1300

A. What is magnetic resonance imaging?

Magnetic Resonance Imaging (MRI) is a noninvasive modality of imaging that allows three dimensional images of a patient's internal anatomy to be obtained. It works by using large magnets to induce a magnetic field and further change the directional axis of protons in water found in anatomical structures. Energy released from this directional change is used to formulate images that reflect the state of anatomical structures. This can be used to monitor and diagnose various medical conditions.

B. Procedure

If you agree to take part in the MRI aspect of this study, you will obtain an imaging study of your_____, which will take approximately _____minutes. If you so choose to partake in this aspect of the study, you will be required to do the following:

- Sign this consent form prior to partaking.
- Schedule a time to meet with study team members to obtain your images.
- Refrain from wearing metallic clothing, jewelry, or accessories on the days of your visit.
- Lie on your back on the MRI exam table, which will slide into the MRI machine.
- Wear protective headphones—throughout the entirety of the study—to minimize the discomfort of loud noises from the rotating magnets. These headphones will also allow you to talk to the person performing the examination.
- Lie as still as possible throughout the entirety of your scan.

Patients will be given a button at the beginning of the study that they can press if they choose or need to end the study at any time, for any reason.

C. Benefits

Obtaining an MRI of your _____will provide insight to the anatomical structures of your_____at no additional cost. **However, this is a research MRI and the images and reports generated will not be reflective of a comprehensive study.**

D. Potential Risks and Contraindications

As of today, there are no known significant side effects to obtaining an MRI. The efficacy and efficiency of NYIT's MRI machine has been thoroughly tested, and safety precautions have been thoroughly reviewed. However, **MRI scans are not recommended for the following individuals:**

<u>Patients with metallic implants and devices and/or retained metallic foreign bodies.</u>

- Metal objects can be drawn to the magnets of the MRI machine and can seriously harm the subject or anyone around them. Examples of metallic implants and devices include, but are not limited to, pacemakers, implants, or surgical clips. Examples of metallic foreign bodies may include retained metallic fragments, shrapnel, and bullets. If you have any questions as to whether you may have metallic implants or a metallic foreign body on your person, please contact your Principal Investigator prior to undergoing your MRI.

<u>Patients who are claustrophobic</u>

- MRIs require patients to lie as still as possible in a tight and enclosed space for an extended amount of time. The space is cylindrical and slightly wider than a human body. Please let us know if you are uncomfortable in enclosed spaces.

<u>Patients who are sensitive to loud noises</u>

- During MRIs, the large rotating magnets produce loud banging and/or beeping sounds. Protective headphones are provided to reduce discomfort; however, patients should still alert the research team if they feel uncomfortable at any time.

Multiple studies have found no increased risk of birth defects, developmental issues, or hearing problems for babies whose mothers had non-contrast MRI during pregnancies. Please reach out to your Principal Investigator if you are pregnant and have any concerns about participating prior to doing so.

If the participant is uncomfortable at any time during the scan and wishes to stop the study, they may do so without penalty. At the beginning of each scan, each participant will be given a button to press if they feel uncomfortable, and they may press it at any time to stop the scan. Patients will be able to contact and speak to research members in between scans through the headphones and microphone in the device.

E. Confidentiality

Each subject's name and date of birth will be collected and imputed into the NYITCOM MRI Machine. At the first presentation for imaging, they will be assigned a medical ID number which will be used for the rest of the study. Each patient's name and date of birth will remain in the system for the entirety of the study in case of incidental findings that patients need to be notified of. At the conclusion of the study, all images will be archived immediately and will be discarded.

F. Patient Rights

Your decision to take part in magnetic resonance imaging for this study is completely voluntary (of your free will). If you decide not to proceed, it will not affect the care or services you receive and will not result in any loss of benefits to which you are otherwise entitled. The subject may discontinue at any time without penalty.

If you want to obtain a copy of your images or report, please let the research team know and we will provide that to you. **Please keep in mind that this is a research MRI and the images and reports generated will not be reflective of a comprehensive study.**

Contact the NYIT Institutional Review Board at grants@nyit.edu or 516-686-7488 for further information regarding the research subject's rights. Contact Dr. Gabriel Gelves at ggelves@nyit.edu for additional information on the research study or research-related injury.

G. Incidental Findings

In the instance where an incidental finding is noted on a subject's MRI, the subject will be informed and given a copy of the imaging and report to be reviewed by their primary care physician.

H. Instructions for Imaging Days:

1) Please present to NYITCOM's Biomedical Research Innovation and Imaging Center (BRIIC) 15 minutes prior to your imaging time.
2) Wear loose and comfortable clothing.
3) Do NOT wear any metallic clothing, jewelry, or accessories. If you do, you may leave them in the changing/locker room of the BRIIC Building prior to your scan.
4) You may eat and drink normally on the day of your imaging.
5) You may take medications as normal on the day of your imaging.
6) You will be asked to change into a gown.
7) Please use the restroom before your scan

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or

identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Agreement to Participate in Research Study

☐ I have read this consent form OR

☐ It was read to me by:

Any questions I had were answered by:

I voluntarily agree to participate in the magnetic resonance imaging portion of this study.

☐ Yes

☐ No

I understand that I will be given a copy of this signed Consent Form.

Name of Participant (PRINT):

Signature: Date:

Signature of Person Obtaining Consent: Date:
(Investigator or IRB Approved Designee)