UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

Refinement and Assessment of New MRI Technologies for Thoracic / Cardiovascular Exams

1.2 Company or agency sponsoring the study:

This study is conducted by the University of Michigan in conjunction with General Electric and Phillips Medical Systems

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Jadranka Nojkova Stojanovska MD	Department of Radiology	University of Michigan
Thomas L., Chenevert PhD	Department of Radiology	University of Michigan
Suzan Lowe, RT, R	Department of Radiology	University of Michigan
Paul Cronin MD	Department of Radiology	University of Michigan
Prachi Agarwal MD	Department of Radiology	University of Michigan
Maryam Ghadimi Mahani, MD	Department of Radiology	University of Michigan
Scott Swanson PhD	Department of Radiology	University of Michigan
Venkatesh Murthy MD	Department of Radiology	University of Michigan
Nicholas Burris MD	Department of Radiology	University of Michigan
Jimmy Lu MD	Department of Pediatrics	University of Michigan
Adam Dorfman MD	Department of Cardiology	University of Michigan
Yuxi Pang PhD	Department of Radiology	University of Michigan
Dariya Malyarenko PhD	Department of Radiology	University of Michigan
Frank Bogun MD	Department of Cardiology	University of Michigan
Aws Hamid MD	Department of Radiology	University of Michigan
Nicole Bhave MD	Department of Cardiology	University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

This study is being done to assess new Magnetic Resonance Imaging (MRI) technologies such as new hardware or software designed to improve MRI examinations of the chest. Software and hardware are always being improved, new machines replace old machines, software is updated and improved as well as devices used to help produce better MRI images.

Participating in this study will not change your standard MRI examination.

This study would allow the investigators of this study to give MRI data only from patient scans to MRI vendors such as General Electric and Philips. The information given provides the companies feedback on the performance of the new technology.

The results of this study would allow UM faculty to present and publish de-identified MRI data of these patient scans in reports regarding the performance of the new technology in radiology/MRI journals.

Some of the new technology to be used in this study will be FDA approved and some will not. But the FDA requires that all MRI machines be built to operate within safety limits regulated by the FDA.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

If you are a male or a non-pregnant female patient, age 18 years or older, presenting to MRI for a clinically-ordered chest MRI exam, you are eligible to participate in this study. If you are a female of child bearing potential you will be asked if you might be pregnant. Pregnancy screening, if necessary, is done routinely by ordering physicians prior to MRI scanning to confirm the patient is not pregnant.

People who cannot participate in this study are:

- Patients, who have electrically, magnetically or mechanically activated implants such as heart pacemaker, magnetic surgical clips, prostheses or implanted neurological stimulator.
- Pregnant patients or patients who are nursing
- A patient who is claustrophobic

3.2 How many people (subjects) are expected to take part in this study?

The Department of Radiology expects to recruit up to 1500 patients to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to participate in this study, you will be asked to read and sign this Informed Consent document. Your MRI exam will be done as your doctor ordered, but it will also include some new technology. This new technology will be used when there is strong evidence that its use will give us better MR images. Your study information along with your name and hospital registration number will be entered into a secure study database. This database will be kept in a password protected computer file and will not be part of your medical record. Additional time may be added to your time MRI scan by you taking part in this study. The investigators of the study will tell you how much time will be added to your clinical exam.

Examples of technologies that may be used are hardware (devices) and software (computer enhancements). Below are listed several technologies that may be used for this study. A check box is placed before each technology. The study doctor will tell you what specific technology we are asking you to participate in and will ask you to place a check in the appropriate box.

Hardware (devices):

☐ MRI coils- (a coil is a device that is placed on your body or over your head that will help provide clearer MRI images)

☐ Patient monitor devices, such as a heart monitor.

☐ Patient Positioning, support, or comfort devices, such as padding.

Software:

☐ Data collection pulse sequences (computer program that obtains the images)

☐ Data processing and analysis software (computer program that creates the images from the pulse sequences)

4.2 How much of my time will be needed to take part in this study?

The amount of additional scan time, if needed, will be explained to you as part of the informed consent process and depends on which new technology will be used along with your clinically ordered MRI. In most cases, being in the study will not add more time to your clinically ordered MRI exam.

4.3 When will my participation in the study be over?

Once the MRI is completed, your participation in this study is over.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

The known or expected risks associated with the new technologies will have no greater risks than those associated with standard clinical MRI scanning. The operating system and hardware of the MRI scanner have built-in safety features. These features will only allow the machine to operate its hardware within the safe limits defined by the Food and Drug Association (FDA). Non approved FDA technologies that may be studied are technologies not yet approved by the FDA but have been tested, are safe and are waiting to be approved by the FDA. Any changes to the scanner hardware/software to include the new MRI technologies (non FDA approved) in this study will be operated within the FDA-mandated safety guidelines.

- There is a minor risk of discomfort or anxiety from being in the confined space of the MRI scanner.
- The MRI scanner makes loud, vibrating noises. You will wear foam earplugs to reduce the loud noises made by the scanner and prevent any hearing damage.
- Some studies, like this one, 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. It may cause mild discomfort, but is not harmful to you. The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.
- Sometimes, subjects report a temporary, slight dizziness, light-headedness or nausea during or immediately after the scanning session. If you feel dizzy or light-headed, we will have you get up slowly from the scanner.

- Because the strong electromagnetic fields can move metal objects and cause heating, there is a risk that loose objects (jewelry, keys) outside your body could be accelerated by the magnetic field and strike you, causing you injury. There is also a risk that the magnetic fields could disturb a metal fragment in your body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your body to heat up, causing you harm. We keep the environment around the MRI scanner completely free of loose metal objects that could be moved by the magnetic field, and we will make sure that you have no metal on your body that could be affected by the MRI scanner. We will also ask you questions and have you complete an MRI screening form to make sure that you have no metal inside your body that would cause you harm during the MRI scan.
- There is the potential that a magnetic resonance image may reveal an abnormality that is already in your body, such as a cyst or tumor. Many such abnormalities are not clinically significant, but you may need or want to investigate them further. Such a finding might require additional studies, and maybe even treatment, which would not be paid for by the investigators, the sponsor, or the University of Michigan

The researchers will try to minimize these risks by:

As with any research study, there may be additional risks that are unknown or unexpected.

- You will complete a safety questionnaire in the Radiology Department prior to having each MRI performed.
- The MRI table is padded to make you as comfortable as possible without decreasing the ability to obtain adequate MRI screening.
- You will be offered earplugs to reduce the noise created by the MRI machine.
- Radiology personnel will be within seeing and hearing distance at all times and will be able to reassure you if you feel any anxiety. The research MRI can be discontinued at any time.
- All research records will be maintained in a locked room with limited access and or in a password protected computer program. Only those directly involved in this study will have access to the records.

There are no risks involved with evaluating new computer software.

You may feel inconvenienced by having been asked to read, and if willing, sign the Informed Consent document. In most instances, your time within the MRI machine will not be made much longer since typically the new technology only adds a few minutes to the standard 45-60 minute exam. Additional scan time, if any, will be explained to you prior to requesting signature on the Informed Consent document. There is a chance that your personal medical information could be seen by Radiology or other staff not involved in this study. The investigators of this study will keep all research records in a locked cabinet in a locked room or in a password protected computer program.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study.

You may not receive any personal benefits from being in this study. The information learned by the researchers of this study will add to their knowledge of MRI technology and my help future patients with diseases or injuries of the chest.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Your decision to participate in this study is voluntary and there are no penalties if you should choose not to participate. You will still have the standard clinically ordered MRI exam performed whether you participate in this study or not.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No. There will be no harm to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

There are no costs associated with your participation in this research. You or your insurance carrier will be responsible for the cost of the clinically ordered MRI scan but there will be no additional costs for the research portion.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

No, you will not be paid for taking part in this study.

8.3 Who could profit or financially benefit from the study results?

The company whose product is being studied: General Electric and Philips Medical Systems

The researchers conducting the study: Suzan Lowe's spouse is an employee of Philips and owns stock.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

Your name and your University registration number will be removed from all data sent to the sponsoring vendors of this study. All study logs and databases will be kept in a locked and secure area within the Department of Radiology by the Principal Investigator.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Any clinical information provided with the images to the MRI vendor will be limited to: patient age, sex, weight, and disease diagnosis.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. 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.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Jandranka Stojanovska
Mailing Address: 1500 E. Medical Center Drive TC B1 132H
Department of Radiology
Ann Arbor, MI 48109-5030
Telephone: 734-936-7411

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):_____

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____