Memorial Sloan Kettering Cancer Center
IRB Number: 20-482 A(1)
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Participant Informed Consent for Clinical Research

Study title for participants: New Ways of Doing Magnetic Resonance Imaging in Children and Adults

Official study title for internet search on http://www.ClinicalTrials.gov:
New Image Techniques for Magnetic Resonance Imaging in Children and Adults

Lead Researcher: Gerald Behr, MD (212-639-6470)

If you are the parent or legal guardian of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to your child, if the participant is a minor, or to a person with a cognitive impairment for whom you are the Legally Authorized Representative (LAR).

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to take part in this research study because you receive care from the Department of Pediatrics at Memorial Sloan Kettering Cancer Center (MSK) and you have been scheduled for a routine magnetic resonance imaging (MRI) scan. An MRI uses a strong magnetic field and radio waves to make images of parts of the body. During an MRI, a person will lie on a movable table that will slide into a round opening in the MRI machine. Sometimes people have a hard time staying still during the procedure, and movement can cause problems with the results of the scan. Children often have a harder time staying still than adults.

We are doing this study to see how we can prevent problems caused by movement during the MRI scan. We will test different ways of doing the scan (techniques) to see if they are practical and can prevent problems related to motion. For example, we will look at changes in the timing of the magnetic field and the radio waves, and at changes in the way a computer is used to process the images. We will also look at how these new techniques compare with the techniques we usually use.

If you take part in this study, you will still have your scheduled routine MRI. We will make extra images using the new techniques during or immediately after this routine MRI. We will not use the results of the additional imaging to plan your treatment.

The Food and Drug Administration (FDA) has cleared (approved) the device used in this study. The experimental or investigational part of this study is using the device to test new techniques.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to magnetic resonance imaging for my condition?

People who are not in a study usually have their condition and/or treatment monitored with an MRI scan without having extra images taken for research purposes. You do not need to be in this study to have MRI scanning. Whether you take part in this study or not, you will still have your scheduled routine MRI.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will have extra images taken during or at the end of your scheduled routine MRI. You will remain lying on the table for about 5-10 minutes for these extra images. We will try the new MRI techniques while taking these extra images. Anesthesia, that had been used for your scheduled routine MRI, may be used for the additional time on the scanner to complete the research scan, if clinically recommended by your doctor.

Contrast material to improve the MRI image will only be injected into a vein in your arm if it is planned for your routine MRI.

Sometimes drugs (sedatives) are given to very young children during a routine MRI to limit movement while images are taken. Children who participate in this research study will only receive sedatives if this is planned for their routine MRI.

After you have the extra imaging, your participation in the study will end.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

Some of the most common side effects that the study doctors know about are:

- You may have a nervous reaction to the banging or clicking sounds made by the MRI machine
- You may feel claustrophobic, which is fear from being in a small space

There may be some risks that the study doctors do not yet know about.

Benefits

Because this study does not provide any form of treatment for your condition, you will not receive any health benefit from participating in the study. What we learn from the study may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- For women who are able to have children: You become pregnant while you are in the study
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

The purpose of this study is to test new ways of doing MRI scanning. In order to make an MRI image that is good enough for doctors to make a diagnosis or look for changes in the body, the patient must stay very still. Body movement (motion) during a scan, even from breathing or the beating of the heart, causes extra marks or blurring (artifacts) on the MRI images. Our aim with these new MRI techniques is to prevent problems caused by motion during the MRI procedure. We will look at whether these new techniques are practical and prevent problems related to motion. We will also see how the new techniques compare with standard techniques of MRI scanning. Examples of the new techniques include changes in the timing of the magnetic field the MRI machine creates and the radio waves the machine directs at the patient's body, and changes in the way a computer is used to process the images.

The FDA has cleared (approved) the device used in this study. The experimental or investigational part of this study is using the device to test new techniques.

About 20 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

All study participants will receive the same intervention: MRI scanning in addition to their scheduled routine MRI scan.

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. The screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

During the study:

You will have exams, tests, and procedures during the study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Additional MRI scanning during or immediately after your scheduled routine MRI scan. You will remain lying on the table for about 5-10 minutes for these extra images. Anesthesia, that had been used for your scheduled routine MRI, may be used for the additional time on the scanner as needed to complete the research scan, if clinically recommended by your doctor.
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After the additional MRI scanning, your participation in this study will be complete.

We will not use the results of the additional imaging to plan your treatment.

Will I receive the results of my research tests?

You will not receive the results of any tests done for research purposes during this study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss

There is also a risk that you could have side effects from the study approach. The study doctors do not know who will or will not have side effects.

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.

Possible side effects of additional MRI scanning:

MRI is a generally safe procedure that has no radiation risk. However, you could have the following side effects from MRI scanning:

- You may have a nervous reaction to the banging or clicking sounds made by the MRI machine
- You may feel claustrophobic
- Your body or a certain body part may feel hot

The MRI machine has a warning button, which you will hold in your hand. You can press the button if you want the scanning to stop. The study team will then take you out of the space inside the machine. For participants who receive sedation while being monitored by an anesthesiologist as part of their scheduled routine MRI, there is no added risk of remaining under sedation during the 5-10 minutes needed to take the research images.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointment
- Tell the study doctor about:
  - All medications and any supplements you are taking
  - Any side effects from these medications or supplements
  - Any doctor visits or hospital stays outside of this study
  - Whether you have been or are currently in another research study

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK). No conflicts of interest have been identified for either the institution or the investigators in this study.

What are the costs of taking part in this study?

You will not have to pay for the for tests and procedures done only for research purposes, including:

- Additional MRI scanning that occurs during or after your scheduled routine MRI scan
- Anesthesia that may be used for the additional MRI scanning

You and/or your health plan/insurance company will have to pay for all the other costs of treating your condition while you are in this study. These charges include the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

In the future, your information (data) may be de-identified, which means that your data will be assigned a unique code, and the list that links the code to your name will be stored separately from your data. Your de-identified information may be used for research that has not been described in this consent form, and it may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

New Ways of Doing Magnetic Resonance Imaging in Children and Adults

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Gerald Behr, MD and Jose Ricardo Otazo Torres, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study intervention.
- The sponsor's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working with the sponsor to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study intervention.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to your medical record at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

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Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent
I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement
I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant/LAR signature		**Date:**
Participant/LAR name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____
(The name of the witness must be documented in the EMR.)

Interpreter (if required)
Name of interpreter (if present): _____
ID number (if phone interpreter): _____
(The interpreter's name or ID number must be documented in the EMR.)

The participant/Legally Authorized Representative must be provided with a **signed copy** of this form.

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Participant Assent for Clinical Research

Assent is required for a minor age 7 to 17 and for a participant with mildly impaired decision-making capacity.

Consenting Professional Must Personally Sign and Date		
Consenting Professional's Statement I have explained the study to the participant in age-appropriate terms and he/she agreed to take part in the study. He/she should sign and date below in the participant section. I have given a copy of this form to the participant and his/her Legally Authorized Representative (LAR). ☐ Check the box if the participant verbally agreed to take part but declined to sign or is unable to sign.		
Signature of consenting professional obtaining assent		**Date:**
Consenting professional name (printed)		
Participant Should Personally Sign and Date		
Participant's Statement I have read this consent or it was explained to me. All my questions have been answered. I agree to be in this research study.		
Participant signature		**Date:**

This form must be accompanied by an IRB-approved consent form signed by a Legally Authorized Representative.