INFORMED CONSENT FOR CLINICAL RESEARCH

Study Title for Study Participants: Evaluation of functional Magnetic Resonance Imaging (fMRI) in Patients who Speak Two Languages Fluently

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Graph Theoretical Analysis of Pre-operative functional Magnetic Resonance Imaging (fMRI) Data in Bilingual Patients with Brain Tumors- *Volunteer Consent*

Introduction

You have been asked to participate in a research study. A clinical trial is a type of research study. Clinical trials include only people who choose to take part. This consent form gives you information about the clinical trial and what it would involve if you take part. Members of the study team will discuss this information with you.

Please take your time to make a decision about whether to take part. You may discuss your decision with your family and friends. If you have any questions, you should ask your study doctor or your health care team for more explanation.

This informed consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

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

If you decide not to take part in this study, you have other choices. For example:

- you may choose to take part in a different study, if one is available

Why is this study being done?

Functional magnetic resonance imaging (fMRI) is a non-invasive test used to detect changes in brain activity by taking picture of changes in blood flow. The imaging helps doctors better understand how the brain works. Task based fMRI (TB fMRI) prompts patients to perform different activities (e.g. word selection in a reading task), and is routinely performed on patients in preparation for a Neurological surgery (surgery that involves your nervous system, brain and/or spinal cord). The purpose is to locate areas of your brain that control speech and movement; these images will help make decisions about patient surgeries. However, there are gaps in knowledge specific to the language areas of the brain, especially for non-English patients and bilingual patients (those who are fluent in more than one language). This study proposes to evaluate if resting state fMRI (RS fMRI) that does not require any tasks, along with a novel way to analyze these images using "graphy theory," may provide more information. Graph theory is a new mathematical method to analyze the fMRI data. The overall goal is to determine if graph theory analysis on RS fMRI may reduce differences in health care treatment and outcomes for non-English speaking and bilingual patients. We hope that the results of this study will allow doctors to perform pre-operative fMRI in patients who do not speak English.

There will be about 60 people taking part in this study (30 patients and 30 volunteers).

What are the study groups?

All study participants will get the same intervention: TB fMRI, RS fMRI and an proficiency test (for bilinguals only), to measure language abilities.

Thirty volunteers will participate:

- 10 English only speakers
- 10 early bilinguals (volunteers who speak both English and were able to speak, listen, read and write in Spanish before the age of 10)
- 10 late bilinguals (volunteers who speak both English and became proficient in Spanish after the age of 10)

How long will I be in this study?

The required TB fMRI, RS fMRI and language tests will be performed on the same day, once done your participation is complete.

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

You will need to get a TB fMRI, RS fMRI and complete a language test as part of this study.

Before you begin the study:

- You may need to answer some questions to ensure you are eligible to participate.

During the study:

- **Task based fMRI (TB fMRI)**

  If you choose to take part in this study, the tasks required for you to complete the TB fMRI will be discussed before you go into the fMRI scanning room. You will then be taken into the scanning room and helped onto the MRI scanner table. The MRI machine is a large, donut-shaped magnet. It makes a loud tapping noise while the scan is in progress. When you have been made as comfortable as possible on the MRI table, your technologist will slide it into the magnetic part of the machine. You will be able to speak with your technologist and the clinician performing the fMRI exam during the entire scan. While you are lying in the fMRI scanner, the clinician will to ask to you to begin your selected task. You will be asked to perform a task for about 20 seconds and then you will rest. This will be repeated 5 to 6 times. It is important to lie still and breathe normally during the scan. The scan itself does not hurt, but lying on the table for a prolonged period of time may be uncomfortable. If you think this will be a problem for you, contact the study doctor and research staff before you come for the scan. When your scan is complete, the scanning table will be moved from the machine and you will be helped off the table. You may then leave the MRI suite.

- **Resting state fMRI (RS fMRI)**

  The same procedure as TB fMRI (described above) will be followed, except no tasks are required. The resting state fMRI will be done first before task based.

- **Language tests**

  If you speak both English and Spanish, you will complete two brief 4 item and 15 item language proficiency questionnaires, which together are expected to take about 17 minutes. This will allow study doctors to better understand your language abilities.

- **Timing**

  For the 10 English only volunteers: 2 task language tasks + 1 RS fMRI + 1 anatomical sequence, will be performed for a total of approximately 25 minutes.

  For the 10 early bilingual volunteers: 4 language tasks (2 English + 2 Spanish) + 1 RS fMRI + 1 anatomical sequence, will be performed for a total of approximately 39 minutes.

  For the 10 late bilingual volunteers: 4 language tasks (2 English + 2 Spanish) + 1 RS fMRI + 1 anatomical sequence, will be performed for a total of approximately 39 minutes.

- **Findings**

  Although the scan/ images you will have in this study is/ are being done for research purposes only, it is possible that the doctors may notice something that could be important to your health. If so, you will be contacted for an explanation of what was noticed. If you want, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

What possible 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 or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.

There are no additional known risks or side effects related to the RS fMRI scans. Participants who undergo standard MRI scans may experience the following side effects:

COMMON, SOME MAY BE SERIOUS In 100 people receiving **an MRI scan** more than 20 and up to 100 may note:
• The MRI scanner produces tapping sounds during the operation, which may reach very loud levels.

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving **an MRI scan** from 4 to 20 may feel:
• Feeling of being confined and closed-in. Please tell the technologist performing the scan if you feel uncomfortable and/ or claustrophobic. If you are unable to tolerate being in the scanner, the scan can be stopped immediately.

RARE, AND SERIOUS In 100 people receiving **an MRI scan** 3 or fewer may experience:
• That metallic objects inside the room could travel through the air toward the scanner and collide with you and the machine, due to the strong magnetic field used during scanning. To reduce this risk, all metal objects will be removed from the room and from everyone in the room following routine departmental procedure for all MRIs performed.

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

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

What possible benefits can I expect from taking part in this study?

This study is unlikely to directly help you. You may benefit from sharing your experience, and from knowing that this research may help others. This study may help doctors learn things that may help treatment planning prior to surgery and potentially outcomes for patients with gliomas (tumors that start in the brain or spine) in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the 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.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Memorial Sloan Kettering Cancer Center Institutional Review Board at 212-639-7592. For a non-physician whom you may call for concerns, complaints, input on research or for more information about the consent process, research patients' rights, or related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

What are the costs of taking part in this study?

The fMRI scans and language tests will be supplied at no charge while you take part in this study.

You will be given a $100 gift card, upon completion of the fMRI scans and language tests.

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

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

Who will see my protected health 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.

If your information from this study is used in any reports or publications, your name or 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.

Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.

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.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or 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).

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor Andrei Holodny, MD at (212) 639-3182.

RESEARCH AUTHORIZATION FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

EVALUATION OF FUNCTIONAL MAGNETIC RESONANCE IMAGING (FMRI) IN PATIENTS WHO SPEAK TWO LANGUAGES FLUENTLY

Federal law requires Memorial Sloan Kettering (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions ("protected health information"). 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 disclosing your protected health information for research purposes. This form helps make sure that you are informed of how your information will be used or disclosed in the future. Please read the information below carefully before signing 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?

- Existing medical records
- Your research records which includes new health information created from study-related tests, procedures, visits, and/or questionnaires
- HIV-related information. This includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV. (New York State requires us to obtain special consent)

2. Who will use or share protected health information about me?

- MSK will use and share your protected health information. Individuals and offices that deal with research oversight, quality assurance and/or billing will be able to use and share your protected health information. These include
    - The study's Principal Investigator and Co-Principal Investigator(s): *Andrei Holodny MD, Kyung Peck PhD, Nicole Brennan*
    - Your research team at MSK including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
    - Any health care personnel who provides services to you in connection with this study
    - The members and staff of the MSK's Institutional Review Board and Privacy Board
    - Staff of MSK's Office of Clinical Research which oversees clinical research and the Computing Resource Group who manage research databases
    - Members of the MSK's Data Safety Monitoring Board/Committee and Quality Assurance Committee

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

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or other countries, working with MSK to conduct the study, to monitor the study or to analyze the study information for this study or other research about the study fMRI scans and language tests
- 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. These include**:**
    - Office of Human Research Protection (OHRP)
    - Department of Health and Human Services,
    - Food and Drug Administration and other regulatory agencies responsible for oversight.
    - National Cancer Institute (NCI)/National Institute of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you

Some of these organizations who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

4. Why will protected information about me be used by or shared by MSK or others?

The main reasons may include the following:

- To conduct the study, to monitor your health status, to measure the effects of drugs/device/procedures being studied and determine the research results
- To ensure the research meets legal and institutional requirements
- It may be used to develop new tests, procedures and commercial products
- Your study information may be added to research databases so that it can design better research studies in the future, develop other therapies for patients or gain a better understanding of disease
- For MSK medical treatment, billing matters, or health care operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will protected health information about me 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 will be destroyed or no longer used. This is because the information used and *created* during the study may be analyzed for many years, and it is not possible to know when this will be complete.

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 the research study. If you do not sign, it will not affect your ongoing treatment or health care coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the Study Doctor listed above in the section: "Who can answer my questions about this study?" If you withdraw your permission, you will not be able to continue to participate in the research study.

- You have the right to request access to your protected health information that is used or shared during this research and that is related to the research or payment for the research, but you may access this information only after the study is completed. You can have access to your medical record at any time. To request this information, please contact the Study Doctor listed above in the section: "Who can answer my questions about this study?" 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 without your approval unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission of Human Rights at (212) 306-7500. These agencies are responsible for protecting your rights.

Memorial Sloan Kettering Cancer Center
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PARTICIPANT INFORMED CONSENT FOR CLINICAL RESEARCH

EVALUATION OF FUNCTIONAL MAGNETIC RESONANCE IMAGING (FMRI) IN PATIENTS WHO SPEAK TWO LANGUAGES FLUENTLY

Statement of professional obtaining consent

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

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter: I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).**

☐ **Other: I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.**

Name of Witness: _____

Signature of Witness: _____ **Date:** _____

(If witness is used for consent discussion, their name must be documented in the EMR.)

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form