

## MRI Research Study Consent Forms: Research Participation and Diagnostic Authorization

Investigators interested in conducting MRI research at NYUAD should be aware of the specific consent process and requirements for recruiting participants in such studies.

MRI research at NYUAD is reviewed by the Research Ethics Committee (REC) that follows Abu Dhabi's Department of Health (DOH) policy regarding human subjects research. In line with this, the REC believes that research relying on participant brain scans is ethically accountable in securing the possibility for these scans to be medically assessed (with a participant's consent). NYUAD has partnered with NMC, Abu Dhabi, in such a way that participants have the option to have their brain scans sent to the NMC radiology department for assessment. The NMC radiologist's report is sent back to the participant directly and privately, without NYUAD or the research team having a part in this diagnostic process. As a result of this the consent process for MRI research is twofold: investigators will need to obtain (1) consent for 'research participation' in order for a participant to take part in the research, as well as (2) consent for 'diagnostic authorization' if the participant wishes that their scans be sent to NMC. Diagnostic authorization is not a requirement for participation, participants can take part in research without electing to have their scans medically assessed.

Templates for both consent forms are provided below. Investigators are welcome to use Research Participation consent *verbatim* if this appropriate, but can also adapt the language around procedure to better fit their study. We ask that that the Diagnostic Authorization consent be used *verbatim*.

Please reach out to the IRB Office ([irbnyuad@nyu.edu](mailto:irbnyuad@nyu.edu); +971 2 628 4313) if you have any questions regarding your MRI research and the consent process.

## TEMPLATE: Research Participation Consent Form (MRI Research)

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[Principal Investigator Info]  
[Lab Info]

[Study Title]

PLEASE READ CAREFULLY BEFORE SIGNING

You have been invited to take part in a research study to learn more about optimizing Magnetic Resonance Imaging (MRI) sequences in the human brain. This study is directed by [PI, MRI physicist and technician].

You must be 18 years or older to participate in this study. If you are under the care of an epileptologist, you must have doctors consent in writing in order to participate.

Participation in this study will involve [participation in hrs/mins] of your time.

[Description of allowance payment and/or student credit, here is an example]: If you signed up to participate in this experiment in exchange for course credit, you will be compensated [credit] for taking part in this experiment. If you do not wish to receive course credit, you will receive a travel and subsistence allowance of [amount].

Not taking part in or withdrawing from this experiment will not affect your grades or academic standing in any way.

**Important Safety Note to all Participants: if you have any metallic objects or fragments inside your body, you are not allowed to take part of this study**

**Important Safety Note to Female Participants: you are not allowed to take part of this study if you are pregnant.**

### Procedure

If you agree to be in this study, images of your brain, called scans, will be taken using a Magnetic Resonance Imaging (MRI) scanner. The MRI scanner is a machine that enables us to acquire images of the brain by changing magnetic fields inside your body.

If you agree to take part in the study, you will be asked to do the following:

- Lie on a table that will slide inside the MRI scanner (so that your head and upper body are inside the magnet tube);
- Wear headphones or earplugs to limit the noise from the MRI and allow you to hear audio and instructions for the tasks you are being asked to do or questions from the investigator or the MRI operator;
- Have foam pads placed around your head to help you hold your head still during the MRI scan so that the scans will be clear;

- Lie still throughout your time in the MRI scanner;
- Allow a special video camera to track your eye movements and blinking during the scan (Note: video is for monitoring purposes only; no video will be recorded);
- [Description of the experimental task or activities the participant will be asked to perform].

Anatomical images (images that show us the structures in your brain) will be obtained during the first 10 minutes or the last 10 minutes of the scan. In addition, we will collect functional, diffusion, or perfusion scans. Functional and perfusion images are scans that show us how the brain works by illustrating what the brain is actively doing at a particular time. Diffusion scans show us how different parts of the brain are connected and do not require you to perform any tasks inside the scanner.

[For single/multiple sessions] Taking part in this study may involve a single MRI scanning session, or multiple MRI scanning sessions on different days. For multi-session scanning, each session will not be longer than 2 hours. In all sessions, it will involve 60 to 90 minutes for the MRI scans and additional 20 to 30 minutes for setting up the study and practicing the tasks outside of the scanner.

During your MRI scanning session, occasional breaks of a few minutes will be provided. You will remain in the MRI scanner during breaks, but you may close your eyes and rest. You may rest for as long as you need to be ready to continue the session.

### Potential Risks [Please use *verbatim*]

**Note: please read this section privately in the locker room. If you are willing to continue with your participation after reading this section, change your clothes into one of the scrubs available in the locker room and come outside where a member of our research team will assist you further. If you are not comfortable with proceeding, then feel free to inform the researcher and end your participation without any further explanation. Please note that even if the study has already started, you still have the right to withdraw at any time.**

There are no known significant risks or side effects associated with MRI scans. The magnetic fields, at the strengths used, are thought to be without harm and our MRI scanning procedures fall within USA's Food and Drug Administration (FDA) guidelines for radiofrequency electromagnetic field exposure created by the MRI. It is thought that these are safe levels and significantly less hazardous than a comparable x-ray computed tomography (CT) examination.

There is a risk if metal objects are near the MRI because they can be drawn into the MRI scanner and that could hurt someone in or near the machine. Metal objects might be in a body if a person has electrically, magnetically or mechanically activated implants (such as cardiac pacemakers), or clips on blood vessels in their brain, or other metallic objects in their body such as shrapnel, bullets, buckshot, or metal fragments.

To protect against this risk, you will be carefully screened for previous exposure to metallic fragments or to implanted devices. You will also be asked to place all metallic and magnetic objects in your possession (e.g. keys, jewelry, credit cards) in a locker outside the MRI room. Before entering the magnet, you will be asked to stand in front of a Ferromagnetic Detection system screener to ensure there is no remaining ferromagnetic materials left with you.

Some of the imaging software and hardware used to perform scans at the NYUAD Brain Imaging Center has not been approved by the FDA. This software has not been submitted to the FDA for evaluation, as it is intended for research use only and not for diagnostic purposes.

Although there are no known risks of an MRI scan to the unborn fetus, you **should not** take part in

the study if you are or might be pregnant. If you are a female, feel free to take a urine pregnancy test available for you in the locker. If you use one, please **do not** tell us about the result. As you can withdraw from the study at any time, if you find that you are pregnant, simply inform the researcher that you decline to continue without specifying the reason.

Some people have reported mild discomfort during MRI scans, such as:

- Claustrophobia (fear of enclosed spaces). You will be asked to lie on a table that slides into a horizontal cylinder only slightly wider than your body in all directions and your head will be secured to help you stay still. If you are uncomfortable or afraid from enclosed spaces, you should let the researcher in charge of the scan know.
- Mild back discomfort. If you have ever had back surgery or have a history of chronic backache, please notify the researcher in charge of the scan so that the padding on the MRI table can be enhanced.
- Reaction to noise levels. The MRI scanner makes loud knocking or beeping sounds during scans; earplugs and/or headphones will be provided to help reduce this noise. Let the operator know if the sound if noise is too loud.
- Peripheral nerve stimulation. Our scanning protocols are designed to minimize any stimulation of your peripheral nerves; however, because the magnet turns on and off during the scan, the possibility exists for peripheral nerve stimulation. If this happens, you may feel creeping or tingling sensations, typically along your arms or lower back. Although this is not a health risk, please inform the researcher if you experience any nerve stimulation.
- Dizziness and nausea. Dizziness and nausea may occur while you are in the MRI.
- Drying of eye contact lenses. This rarely occurs, but you should notify the investigator that you have contact lenses in your eyes, and you should either moisten your eyes before entering the scanner or remove your contacts (MRI safe prescription glasses are available if needed).
- Heating. It is possible that you may feel some warmth from the radio frequency coils, cables, and/or response monitoring devices. The MRI scanner is set so that this heating will be no more than one degree of body temperature.

You may notify the researchers at any time if you feel uncomfortable, no matter what the reason. Between each scan, you will be in contact with the research staff through a microphone mounted inside the MRI scanner. However, while the scanner is on, the speaker will be turned off and the research staff will not be able to hear you.

Nonetheless, in the case of an emergency, you will have a handheld squeeze ball device to let the operator know if you wish to immediately stop scanning and be removed from the magnet. The MRI scan can be stopped at any time at your request; when you squeeze the squeeze ball, the research staff will stop the scan. If you think that you have experienced a research-related injury or have any concerns about your participation in this experiment contact [PI name and contact details], or the NYUAD Institutional Review Board ([IRBnyuad@nyu.edu](mailto:IRBnyuad@nyu.edu); +971.2.628.4000).

- Check this box to indicate that you have read and understood the “Potential Risks” section above and still willing to proceed with the study. *If you are a female, checking this box indicates that you have understood the provision about pregnancy and are willing to continue.*

## Benefits

[Address benefits]

## Participation Allowance

You will receive a subsistence allowance of **xxx** per half hour the study.

[For varying allowances] Your allowance may be greater than **xxx** depending on decisions made during the experiment, including the speed and accuracy of your responses. Should you withdraw before the end of the study, subsistence allowance will be given (or research credit will be granted) based on the time that has passed (**example**). There will be no cost to you associated with participation in this study.

## Rights [Please use *verbatim*]

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Nonparticipation or withdrawal will not affect your grades, academic standing, or employment status.

Many forms of research involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all the care and precautions taken by the investigators, you might develop medical complications from participating in this study. If you should sustain any injury during the course of the research or experience any side effect from a study procedure, please contact [PI name and contact details]. If such complications arise, the researchers will assist you by referring you to appropriate medical practitioners, but this study does not provide financial assistance for additional medical or other costs. Also, NYUAD is not responsible for research and medical care either by NYUAD researchers or those at other institutions. You do not give up any rights to seek payment for personal injury by signing this form. If there is anything about the study or your participation that is unclear or that you do not understand, or if you have questions or wish to report a research-related problem, you may contact [PI name and contact details, MRI physicist contact details].

Per the Abu Dhabi Department of Health (DOH) policy, you may register a complaint or concern about this study at the following website: <https://www.haad.ae/haad/tabid/1560/Default.aspx>

For more information or questions about your rights as a research participant, you may contact the Institutional Review Board (IRB) at New York University Abu Dhabi, ([IRBnyuad@nyu.edu](mailto:IRBnyuad@nyu.edu); +971.2.628.4000).

## Confidentiality

Confidentiality of your research records will be strictly maintained. Your information (name, date of birth, etc.) will be stored in the investigator's file and will be identified by a code number. The code key connecting your name to specific information about you will be kept in a separate, secure location. All the MRI images of your body will be stripped out of your personal information and only linked to you with a unique subject identifier.

The results of this study may be published in a book, journal, conferences, or used for teaching purposes. However, your name or other identifiers that could identify you will not be used in any publication or teaching materials without your specific permission, which will be requested in writing.

The MRI images of your brain may be shared anonymously (that is, without any way of identifying who the scan is of) for teaching purposes, research (such as in academic databases), or displayed at scientific conferences or in publications.

Provided we get your consent, MRI images of your brain may also be shared with other researchers at NYUAD. Please check one of the following:

- By checking this box I indicate that *I am willing to allow* images of my brain, combined with information that could identify me (e.g., name, date of birth, subject ID), to be shared with other researchers at NYUAD.

Additionally, you have the option to be notified if images of your brain are shared by checking the box below:

- By checking this box, I indicate that I would like to be contacted if any MRI images of my brain are shared with other NYUAD researchers.

**OR**

- By checking this box I indicate that *I do not wish* to allow images of my brain, combined with information that could identify me (e.g., name), to be shared with other researchers at NYUAD. I understand that images of my brain may still be shared with other researchers in an anonymous manner (e.g., date of birth and subject ID number only).

### **Future Research [If applicable]**

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your participation in this study. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for another research study at NYUAD. It does not mean that you must join in any additional study.

By agreeing to be contacted about future studies, you authorize the principal investigator, **[PI name]**, and co-investigators to contact you about future research on brain function. At that time, you can decide whether or not you are interested in participating in a particular study. You will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project. Please check one of the boxes below:

- I agree to be contacted by a researcher affiliated with the NYUAD Center for Brain Imaging about research studies conducted at the NYUAD Center for Brain Imaging.

**OR**

I do not want to be contacted by a researcher affiliated with the NYUAD Center for Brain Imaging.

**Agreement to Participate**

YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, THAT YOU ARE 18 YEARS OF AGE OR OLDER, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

\_\_\_\_\_

Participant's Signature

\_\_\_\_\_

Date

\_\_\_\_\_

Participant's Printed Name

I certify that I have presented the above information to the participant and secured his or her consent.

\_\_\_\_\_

Experimenter's Signature

\_\_\_\_\_

Date

## TEMPLATE: Diagnostic Authorization Consent Form (MRI Research)

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[Principal Investigator Info]  
[Lab Info]

### Authorization to Release MRI Brain Scans for Proactive Medical Screening

On rare occasions, anatomical brain MRI scans may reveal potential brain abnormalities in research subjects. The investigators using the MRI facilities at NYUAD are neither radiologists nor medical doctors (M.D.) and cannot perform medical screening on your MRI brain scans. As a research subject volunteer, NYUAD is giving you the opportunity to have your brain scans reviewed – free of charge - by a radiologist licensed by the Health Authority of Abu Dhabi (HAAD). Therefore, if you wish to participate in the proactive medical screening program, you must give us your explicit permission by signing this Release Form. Then your MRI scans along with your personal information (which includes: copy of government-issued ID card, full name, date of birth, gender, screening form, consent form, and contact details) will be sent to the radiology department at NMC Hospital in Abu Dhabi to be screened by a licensed radiologist.

Please be aware that MRI scans performed at NYUAD are intended for research purposes and are not designed for medical screening. Hence a “negative” result does not imply that you are free of brain abnormalities or diseases. And conversely, a “positive” result does not necessarily imply you have a brain abnormality or disease. Finally, most often “positive” results are incidental, and do not require treatment, or pose any health risk.

In the unlikely event that the radiologist detects an abnormality in your scans, the Radiology Department at NMC will contact you to set up a formal appointment with a Neurologist (a doctor who specializes in the brain and nervous system) to discuss the findings, which may lead to more clinical tests at NMC Hospital. NYUAD and its researchers will not be made aware of or have access to your radiologist report at any stage. In all cases, it is your responsibility to follow-up on your radiology results. You can also obtain a copy of the report directly from NMC. Please note that NYUAD will cover only the initial cost of generating the radiologist report. You or your health insurance must cover all subsequent follow-ups. Please note that you are not obligated to pursue tests or treatments at NMC; you are free to consult with any other hospital or physician of your choice.

### Eligibility

Releasing your scans for proactive medical screening is voluntary. NYUAD will pay for obtaining the medical report to meet its ethical obligation toward research volunteers. However, you and your health insurance provider are responsible for any further costs. This release form is valid for 12 months and must be explicitly renewed by the volunteer. If you volunteer for multiple imaging sessions over multiple days, only the first set of anatomical images will be shared with NMC in a 12-months period.

Please check the appropriate box:

By checking this box I indicate that I authorize releasing images of my brain, combined with relevant personal information (e.g., copy of government-issued ID card, full name, date of birth, gender, screening form, consent form, and contact details), to be shared with a contracting radiology department for the



purposes of obtaining proactive medical diagnosis about my anatomical brain MRI scans.

**To select this option, you must:**

**a) Provide a valid Emirate ID or a Copy of Passport Identification Page with this consent form so that the hospital can create a file for you in their database.**

**b) Provide the hospital with your preferred delivery method for their report:  
email \_\_\_\_\_ and/or phone \_\_\_\_\_.**

By checking this box I indicate that I **do not** allow images of my brain to be sent for proactive medical screening. I understand that the imaging staff/researchers at NYUAD are not trained doctors and they cannot inform me about any potential brain abnormalities or diseases.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Printed Name