The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for a Study of:

Noninvasive modulation of motivational brain regions in healthy volunteers.
HRRC #20-623

Overview:

- You are invited to take part in a research study about decision-making by healthy volunteers.

- By doing this study, we hope to learn how precisely to engage brain regions involved in motivated behavior. The long-term goal is to design a method for brain rehabilitation for people who have impaired decision-making that is caused by neurological disorders such as traumatic brain injury (TBI).

- Your participation in this research will last about 11 to 14 hours, spread over 3 separate testing sessions on 3 different days.

- This study will primarily involve your:
    1. completing several computer tasks and questionnaires,
    2. receiving transcranial magnetic stimulation (TMS) (a non-invasive form of stimulation to temporarily affect your brain), and
    3. receiving magnetic resonance imaging (MRI) scans to take pictures of your brain.

Benefits and risks:

- By volunteering for this study, you will help science and medicine better understand how TBI impacts the brain and decision-making.

- One primary risk associated with MRI scans is the loud noises made by the scanner. We will provide noise-deadening headphones to reduce the sound levels.

- A second primary risk is the potential to become uncomfortable while you are in the enclosed space in the MRI device (that is, feeling claustrophobic). We will help you to be comfortable by talking to you before the scans begin and between each scan. You will also have a call-button that will tell us to turn off the scanner if you feel too uncomfortable.

- The primary risks associated with TMS are mild pain or headache caused by the contraction of your scalp muscles. This pain usually goes away quickly if you take over-the-counter pain medication such as acetaminophen or ibuprofen after you leave.

- The noise of the TMS magnet may also temporarily reduce your ability to hear -- so you will be given earplugs to wear during the procedure.

- There is a very small risk of your having a seizure with TMS, but this is very rare and has only been reported for certain types of individuals.

- For a complete description of the risks and benefits of this study, please see the Detailed Consent Information below.

- The study team is closely following guidelines from the State of New Mexico for minimizing COVID-19 exposure risk. We maintain physical distancing and face coverage, and participants and research staff are screened for COVID-19 symptoms or for having had recent close contact with anyone who has or recently has had COVID-19.

Declining to participate:

- If you decide to take part in this study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer to participate in this study. If you are a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grades. If you are an employee, if you decide not to take part in this study, your choice will have no effect on your employment status.

People to contact if you have questions:

- The person in charge of this study is Dr. Jeremy Hogeveen of the University of New Mexico, Department of Psychology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact him at: 505-277-7505, jhogeveen@unm.edu

- If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the UNM HSC Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Time (MT), Monday-Friday at 505-272-1129.

Detailed Consent Information
v. 3.24.2022

Purpose and General Information
You are being asked to participate in a research study that is being done by Dr. Jeremy Hogeveen, who is the Principal Investigator, and his research associates. This research is being done to evaluate how the human brain learns and makes decisions based on feedback, and how this learning and decision-making can be changed by stimulating certain brain circuits.

You are being asked to participate because you are a healthy, non-pregnant 18 to 55 year-old and you participated in a prior study (19-053). Approximately 42 healthy control participants will take part in this study at The University of New Mexico Health Sciences Center. This study is funded by the National Institute of General Medical Sciences (NIGMS).

This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This information is provided so you can make an informed choice about whether or not to participate in this study. Please read this consent form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

What will happen if I participate?
If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

- **CONSENT AND SCREENING PROCESS:** You will begin by going through the consent form with a member of the research team. You will then be asked to complete a short screening form that will determine if it is safe for you to have a magnetic resonance imaging (MRI) examination.

- **BEHAVIORAL AND PERSONALITY TESTING:** After you complete the consent and screening process, you will complete a series of questionnaires and button-pressing tasks on a computer or iPad. Some of these tests will assess your performance on tasks that measure your ability to do things like make decisions or remember words. Other tasks will involve asking for background information and reading statements about your personality and rating how much you agree with those statements. The consent, screening and testing process will take 1 to 2 hours to complete.

- **MRI SCAN:** After completing the behavioral and personality testing, you will go to the Mind Research Network (MRN) on the campus of UNM, and you will be placed in a long donut-shaped MRI magnet, which we will use to take pictures of your brain.
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  An MRI scanner acts like a large magnet, so it could move iron-containing objects in the room during the examination. Loose metal objects, like pocket knives or key chains, are not allowed in the MRI room, and you will be asked to remove your face mask and change into a clean hospital shirt and pants before the scanning begins to ensure that there is no metal in your clothing.

  During the MRI recording, you will hear loud rapping and knocking noises coming from the magnet, which we will play for you beforehand to get you used to them. We will also provide noise cancelling headphones during the scan so that the noises will not bother you.

It is important that you do not move while you are in the MRI scanner. Generally, you should not talk while an MRI scan is being taken, but you will be able to talk with the technician during breaks between scans. Also, in case of an emergency of any kind or if you feel too uncomfortable to continue, you will be given a call button that will tell members of the research team to turn off the scanner.

We will record your brain activity with the MRI while you perform behavioral tasks. We will also take high resolution pictures of the structure of your brain. Each MRI scan will take 1 to 2 hours to complete.

- After your scan is read, you will receive an e-mail letting you know you can download your MRI report from the Participant Portal Homepage. If we find an abnormality that requires follow-up, we may also mail a copy of the report to you, or contact you and your doctor (with your permission) by phone to help answer questions. Our Medical Director or the research team is always available to answer any questions you may have about your scan.

- **Transcranial Magnetic Stimulation** (**TMS):** During your second and third visits you will receive TMS. This is a form of non-invasive brain stimulation where a device is placed over your head and a magnetic pulse travels through the scalp and slightly changes the way the brain works for a short period of time. You will be seated in a comfortable chair and muscle electrodes will be applied to cleaned and prepared skin on your hands. The handheld TMS coil will be held on the top of your head to determine intensity thresholds and get baseline measurements. You may be asked to do a simple task with your hand for several minutes. Repetitive TMS (rTMS) may also be applied to your scalp. This involves a series of magnetic pulses with a short magnetic pulse every few seconds. rTMS is also a safe and common procedure designed to cause specific changes in your brain for a short period of time. You will hear a clicking sound (earplugs will be provided) and may feel a mild “flick”-like sensation on your scalp. Both single pulse TMS and low frequency repetitive TMS are extremely safe and will be used within the established safety guidelines for TMS. TMS devices have been approved by the Food and Drug Administration (FDA) for the treatment of depression and migraine. Each TMS may be active or inactive to account for the placebo effect. Following each TMS you will have another MRI scan that will take 1 to 2 hours.

- Participation in this study will take a total of 11 to 14 hours over three separate testing days. Each testing session must take place no less than 24 hours, and no more than two weeks apart from the previous session.

What are the possible risks or discomforts of being in this study?

- There are <u>no known long-term, adverse effects</u> from MRI or TMS. However, because the effect of MRI and TMS upon early development of the fetus is unknown, <u>females who are pregnant should not be studied</u>. If you answered “yes” to the question on the safety screening form that asks if there is a possibility of being pregnant, a urine pregnancy test will be provided for you. If you answered “no” to the question on the safety screening form that asks if there is a possibility of being pregnant, but would still like to take a test to be sure, a urine pregnancy test will be provided for you. The results of this test will be confidential and discussed with you alone. In the event of an unexpected positive

pregnancy test, your partners, family members, and parents may be told that you are not eligible for MR scanning or TMS, but the results of the pregnancy test will not be shared with anyone unless requested it be shared by you.

- Rarely, large tattoos can heat up during an MRI scan and cause skin irritation like a sunburn, so the MRI technologist will want to see any tattoos you have prior to the scan.

- If you have a piece of metal in your body, such as a pacemaker, nerve stimulator, or certain metal surgical implants, you will not be allowed into the MRI room and cannot have an MRI.

- Having an MRI may mean some added discomfort to you. In particular, you may be bothered by feelings of claustrophobia (that is, feeling very uncomfortable when in enclosed spaces) and by the loud banging noise during the study. Headphones will be provided for your safety and comfort. There is a speaker in the MRI scan room, as well as a window that allows the operator to view you during data collection. This allows the assistants to hear and see you at all times to ensure that you are comfortable and to allow them to respond if you are uncomfortable. You will be able to communicate with the study staff at all times and may ask to stop the study at any point if you become too uncomfortable.

- Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings – which is identifying something on imaging studies that may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your medical record unless you provide it to your physician. If the radiology report becomes part of your personal medical record, it may or may not have an effect on your getting health insurance or life insurance in the future.

- TMS is considered a safe procedure that has been used on tens of thousands of people to study the brain and to treat certain conditions. Most people do not find TMS painful, but some people experience discomfort or headache from contraction of the scalp muscles. Headaches usually go away quickly with over the counter pain medication such as aspirin or ibuprofen, but you may opt out of the procedure at any time if you find stimulation to be too uncomfortable. The TMS coil produces a clicking noise that may affect hearing, so earplugs are provided. The risk of TMS causing a seizure is considered very low and has occurred only rarely in individuals with epilepsy that is unable to be controlled with medication or in people who receive very high doses of stimulation. Risk factors that are screened for prior to every TMS session include sleep deprivation, a family or personal history of seizures, neurological disorders, multiple sclerosis, or stroke.

- There are risks of boredom, stress, emotional distress, inconvenience and loss of privacy and possible loss of confidentiality of your data associated with participating in a research study. The research team will do their best to keep you comfortable throughout your visit. We will remove all identifying information from your data so that it is handled as confidentially as possible. However, there is a small risk associated with participating in this research study that you could experience possible stress, emotional distress, and inconvenience. Please ask the investigator if you have any questions at all about the risks associated with the current study.

- In addition, there may also be side effects or risks to study participation that are unexpected and not known at this time.

- Participants who are found to have falsely represented any factors which should exclude them from the study, or who are unable to follow the study procedures for study session attendance may be withdrawn from the study.

- During the SARS-CoV-2 pandemic, the current study's procedures will be conducted in accordance with the guidelines provided by the State of New Mexico and UNM-HSC Office of Research for maintaining physical distancing and face coverage to reduce the spread and risk of infection. Despite these efforts, COVID-19 exposure is a potential risk that is associated with this study. Please note that individuals over 60 and with chronic conditions such as cancer, diabetes and lung disease have the highest rates of severe disease from COVID-19.

How will my information be kept confidential?
We will take measures to protect the security of all your personal information. Your name will not be used in any published reports about this project. Your data will be assigned a Unique Research Subject Identifier (URSI), and upon study termination it will not be possible for members of the research team to link your data back to your name or contact information. All behavioral and MRI data will be stored with your URSI and will be kept on password protected computers, and stored securely in restricted and protected databases according to MRN information security policies. Any paperwork that you complete will be kept for a maximum of 7 years after which it will be shredded by a member of the research team. Importantly, any data that is shared with external researchers will contain only a subject code and will not contain your name or contact information. Any MRI data that is shared with the research community will be 'skull-stripped' (i.e. the brain itself will be the only thing in the image) to obscure any potentially identifying facial features.

There may be times when we are required by law to share your information. You should understand that if the investigators learn about abuse of a child or elderly person or learn that you intend to harm yourself or someone else, we will report that information to the proper authorities.

Information from your participation in this study may be reviewed by the National Institute of General Medical Sciences (NIGMS), which is funding this study, federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC), which provides regulatory and ethical oversight of human research. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

Some of the information that this study will find out about you is considered sensitive because it has to do with your psychological well-being and mental health. To help us further protect the confidentiality of your data, a Certificate of Confidentiality (CoC) will be obtained from the Department of Health and Human Services (DHHS). With this certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings.

Disclosure will be necessary, however, upon request of DHHS or other federal agencies for audit or program evaluation purposes. You should understand that a CoC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the CoC to withhold this information. This means that you and your family must also actively protect your own privacy and the confidentiality of your data. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

A description of this clinical trial will be available on 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.

What are the benefits to being in this study?
In the course of this research, brain scans will be performed on you. These scans will be used solely for the purpose of gathering scientific information for this study. During the study, you will *not* be provided a medical diagnosis or treatment for any brain condition, or any other health problem. However, the radiologist may notice something in the scan of your brain that could lead to early intervention if a problem were found. There will be no additional benefit to you from participating in this research.

Information gained may help to better diagnose psychiatric problems in TBI patients using brain imaging, as well as help to inform treatments for mental health problems in brain-injured patients.

What other choices do I have if I don't participate?
Taking part in this study is voluntary so you can choose not to participate or to participate freely.

Will I be paid for taking part in this study?
In return for your time and the inconvenience of participating in this project, you will receive a $30 merchandise card for each hour of your time. You will receive no less than $30 for coming in on the day of the study, and your compensation will be rounded up to the nearest half hour if you are not able to complete the whole study. Compensation is considered taxable income. Amounts of $600 or more will be reported by UNM to the Internal Revenue Service (IRS).

What will happen if I am injured or become sick because I took part in this study?
If you are injured or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost.

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other health benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly or improperly in the study, please contact the Human Research Review Committee (HRRC) at the (505) 272-1129 for more information.

How will I know if you learn something new that may change my mind about participating?
You will be informed of any significant new findings that become available during the course of the study. This includes any changes in the risks or benefits resulting from participating in the research. You will also be informed about any new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time, and will be paid a minimum of $30 for your time. To protect the integrity of the research study, data collected up to the time of your withdrawal will remain in the database and managed according to the same standards of confidentiality. Alternatively, you may submit written notification detailed in this consent form that you intend to withdraw authorization for your data to be used in the current study.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation.

HIPAA Authorization for Use of Your Protected Health Information (PHI)
As part of this study, we will collect health information about you.
This information is "protected" under federal law because it is identifiable or "linked" to you.

Protected Health Information (PHI)
By signing this consent document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes: medical history, questionnaire and survey answers, neuropsychological testing and imaging scans. By signing this document, your permission to access and use your health information in this study will not expire, unless you revoke or cancel it. Otherwise, we will use your information as long as it is needed for the duration of the study.

In addition to researchers and staff at UNM and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this may include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your authorization for the use of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send your letter notifying them of your withdrawal to:

Jeremy Hogeveen
Logan Hall, MSC03 2220
1 University of New Mexico

Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use of your PHI, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Jeremy Hogeveen, PhD, or associates will be glad to answer them at (505)277-7505.

If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNMHSC and the community who provide independent oversight of safety and ethical issues related to research involving human participants.

What are my rights as a research participant?
If you have questions regarding your rights as a research participant, you may call the Human Research Protections Office (HRPO) at (505) 272-1129 or visit the HRPO website at https://hsc.unm.edu/research/hrpo/ .

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research participant.

We request your permission to store all of the data that was collected in this study in The Mind Research Network Data Sharing Repository for use in other, future research. The stored data will include information such as your age and gender, as well as assessment and imaging data that were collected about you during this study. It is possible that this information may remain linked to your name. It will be handled with the same care and confidentially as it is for the current study.

Research done with information from the data repository could lead to improved diagnostic and treatment interventions for illnesses and brain disorders. If published, results will be presented in summary form only and will not include your name or other identifying information. If MRN and/or the investigators develop intellectual property and/or commercialize products or services, directly or indirectly, based on the results of the research done with your data, there are no plans to provide you with any financial compensation.

You have my permission to store my data in the MRN Data Sharing Repository for future research. Please initial next to your choice below.

YES _____ Initials NO _____ Initials

We request your permission to contact you for participation in future studies at the Mind Research Network or the University of New Mexico. If you agree, your contact information may be shared with other scientists at MRN.

You have my permission to contact me about participation in future research studies. Please initial next to your choice below.

YES _____ Initials NO _____ Initials

I had an opportunity to ask questions, and all questions have been answered to my satisfaction.

By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to you.

_____	_____	_____
Name of Adult Participant (print)	Signature of Adult Participant	Date

RESEARCH TEAM MEMBER SIGNATURE

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

_____	_____	_____
Name of Research Team Member (print)	Signature of Research Team Member	Date