Dartmouth College Brain Imaging Center

Department of Psychological and Brain Sciences
6207 Moore Hall
Hanover, New Hampshire 03755

Consent to Participate in Research

***Title of research study**: Individualized spatial topology in functional neuroimaging*

IRB Protocol Number: 31937

Investigator: Tor Wager

Purpose of the Study

The purpose of the study is gain a better understanding of how brain regions and systems work together to create cognitive and emotional states. Your participation in this study will not have any direct benefits to you, but will help advance the knowledge base of neuroscience research.

We invite you to take part in a research study because you are an adult aged 18-55 with no pain conditions, pieces of metal in your body, implants or devices, and are not pregnant.

Explanation of Procedures

This experiment will be conducted in the Brain Imaging Center located in Moore Hall, Dartmouth College, Hanover, New Hampshire. The time commitment for this research study is about 13 hours total and you will receive financial compensation and/or course credit at the conclusion of the study. This experiment will take place over four sessions. Before your first session, you will be asked to complete a series of online surveys, which will take roughly an hour. This series of online surveys will include questions about:

- Demographics
- Personality
- Alcohol Use
- Tobacco Use
- Illegal drug use
- Legal drug use
- Prior traumatic experiences
- Mental Health

Once you complete the online survey, your participation will include ~12.25 hours as follows:

- Session one: 3 Hours including a behavioral session prior to scanning. This session will include thermal heat (pain) stimulation.
- Session two: 2.75 Hours including a behavioral session prior to scanning.

- Session three: 3.5 Hours including a behavioral session prior to scanning and a post scan task. This session will include thermal heat (pain) stimulation.
- Session four: 3 Hours including a behavioral session prior to scanning. This session will include thermal heat (pain) stimulation.

Sessions one, three, and four will involve pain stimulation, more specifically, thermal heat stimulation. All painful stimuli will be delivered at a level tolerable to you, and you will always have control and have the opportunity to tell us to stop if you need to. All sessions are described in more detail below.

Session one:

When you first arrive for the experiment you will meet the research coordinator who will bring you to a behavioral testing room (outside the scanner) for you to be familiarized and trained on the type of tasks you will be performing in the scanner. First, you will be asked to fill out an MRI safety form as part of our facilities protocol.

Next, there will be a pain calibration task in which you will experience different levels of heat pain from a thermode (Medoc Ltd.) and make ratings on the intensity using a semicircular rating scale. The heat pain is similar to holding a cup of hot coffee. During this task, you can discontinue at any time if it becomes too uncomfortable.

As part of this study, you will have MRI scans. This is a special three-dimensional picture of the brain using magnetic waves. The magnetic field of the MR environment has the potential to cause burns or bodily injury if ferrous metal objects are implanted in the body or if personal articles containing ferrous material are brought into the environment. Prior to going into the MRI scanner, the study personnel and the MRI technologist on duty will ask you to change into scrubs and to remove all jewelry and metal objects from your pockets. You will be asked to complete a screening form to ensure it is safe for you to go into the MR environment. Because the effects of MRI on fetuses has not been determined, if you are female there are pregnancy tests available should you wish to take a pregnancy test before you go into the scanner.

When you go into the scanner, you will lie down on a padded table and will be placed into a long donut-shaped tube that is only slightly larger than your body. Your head and waist will be enclosed in the tube. If you are uncomfortable being in small or confined places, please tell the research team.

A specially designed coil will be placed around your head to provide better images (as is done with standard clinical examinations). As the MRI scan is performed, you will hear loud rapping and knocking noises that are normal for an MRI scan. We will give you headphones to block out some of the noise. You will still be able to hear the researchers and the MRI technician through an intercom and will be able to squeeze a ball to get their attention and stop the scan at any point. During the experiment it is very important for participants to remain as still a possible since the brain imaging technique is very sensitive to movement.

Afterwards, you will begin the experiment in which you will be doing a social pain task, which involves thermal heat. Then you will watch a series of videos and be asked to answer questions regarding the videos, all of which will become familiar to you prior to the scan. During this task, you can discontinue at any time.

Session two:
When you arrive first for your second visit the research coordinator will bring you to a behavioral testing room (outside the scanner) for you to be familiarized and trained on the type of tasks you will be performing in the scanner. You will be asked to sign the MRI safety form and then you will change into scrubs. The coordinator will then bring you to the MRI scanning room and follow the procedures for scanning that you underwent during your first visit. While in the scanner, you will be asked to complete two cognitive tasks. During the first task you will listen to audio narratives and answer questions regarding the nature of the narratives. The second task involves making judgments of faces. Next you will watch another series of videos and be asked questions regarding the videos.

Session three:
The next visit will involve a behavioral session prior to scanning. This behavioral session will involve signing the MRI safety form and familiarization of the task you will do while in the scanner. Next, you will prepare for the scan by changing into scrubs and the coordinator will bring you to the MRI scanning room. While in the scanner, you will complete the two cognitive tasks that you became familiar with during the behavioral session and watch another series of videos and be asked to answer questions regarding the videos. For the first cognitive task, you will complete a social pain task, which involves thermal heat.. During the second cognitive task you will be asked to make judgments about characteristics of short video clips. Following the scan you will be directed to a behavioral testing room where you will complete a task which is related to the first cognitive task in the scanner.

Session four:
When you arrive first for your last visit the research coordinator will bring you to a behavioral testing room (outside the scanner) for you to be familiarized and trained on the type of tasks you will be performing in the scanner. You will be asked to sign the MRI safety form again and then you will change into scrubs. The coordinator will then bring you to the MRI scanning room and follow the procedures for scanning that you underwent during your other visits. While in the scanner, you will repeat the social pain task. Next there will be a series of four cognitive tasks which include the following: (1) reading stories and answering questions, (2) viewing images and answering questions, (3) identification of a target, and (4) a memory task. Finally, you will watch another series of videos and be asked to answer questions regarding the videos.

Once you are done with the scanning portion of the session, you will be brought to a behavioral testing room where you will complete the second portion of the memory task. Next, you will be given a debriefing form regarding the study you participated in. You will be issued your payment and thanked for participation.

Information relevant to all MRI scanning sessions: While you are in the MRI scanner, we will collect a number of physiological autonomic measurements (e.g., heart rate, skin conductance, respiration). We will do so by using non-invasive sensors, which are not associated with any uncomfortable, harmful or painful sensations. The sensors will be placed, by the research coordinator and the MRI technician, on your feet and torso in order to record the physiological responses throughout the experiment.

You will not be charged for any of the experimental study procedures, including the MRI scan. If incidental findings from study result in the need for further evaluation/treatment, then you or

your insurance will be responsible for additional clinical evaluation/treatment that may be needed.

Incidental Findings

MRI is commonly used in medicine for the purpose of diagnosing abnormalities of the brain. The procedures that are to be used in this study are different from clinical MRI scanning. As researchers, we do not intend to make any medical diagnosis with the MRI as used in this research project, and we are not trained in medical diagnosis. The MRI may not be reviewed in a timely way. However, if in the course of this research study we observe an anomaly in one or more of the MRI images, we feel ethically obligated to inform you of the observation. We believe it is important to inform you of such observations, because we cannot rule out the possibility that an anomaly may require medical attention. In this event, all information collected as part of this study will be made available to you for further examination by a medical professional. You will be fully responsible for the costs associated with a radiological examination and any further examinations or treatments that may be required for medical purposes. If you prefer not to be informed of an image anomaly, you must choose not to participate in the study.

If you are a Dartmouth Student, depending on the results of the medical review, we will also contact Dick's House or your parents to continue follow up.

Risks and Discomforts

There are some potential risks if you take part in this study. These may include:

Thermal Pain

You will be exposed to experimental pain induced by applying heat to the outer calf/arm. This is likely to cause you some physical discomfort, though the pain will always be kept within limits that are tolerable to you. Additionally, because some people respond differently to thermal stimulation, there is a slight risk (less than 1%) of irritation and/or blistering to the stimulated skin site. Several factors, including dryness of skin, dehydration, and possibly skin pigmentation, may influence a person's response to thermal pain stimulation. Skin irritation and/or blistering could also result from a malfunction of the equipment used in this study. However, the probability of a machinery malfunction is extremely low, as thousands of individuals are safely tested each year on this equipment, and we carefully monitor the equipment regularly to ensure its proper functioning. Over 500 participants have undergone thermal stimulation in the Principal Investigator's lab over the past 4 years with no adverse events reported.

If at any point during the experiment, the thermode temperature becomes intolerable to you, manually remove the thermode from your arm immediately and alert the experimenter.

Should you experience any skin irritation or blistering at any point during the experiment or shortly after, please contact the experimenter immediately, in the event of a burn, run the affected skin site under cool water for several minutes, and seek medical attention if the site continues to burn. Safety guidelines for the design and administration of this study are strictly

followed in order to minimize any such risk. Stimulation will be administered with a widely used commercial product, and the risk to human subjects is rated as low.

Psychological Discomfort

The pre-session surveys online include questions regarding illegal activities as well as possible traumatic experiences. These questions may cause some psychological discomfort.

You will be exposed to pain, videos, and audio narratives which may cause psychological discomfort. However, as described above, the level of pain is calibrated to always be within your tolerable level. We do not expect the videos or audio content of this experiment to cause any lasting psychological discomfort. In addition, you may discontinue the experiment at any time should they wish.

MRI Scanning - Physical Risks and Discomforts

The risks of participation in the MRI scanning procedure are minimal. Special considerations are made for the following:

1. *Metal*: The MRI machine produces a constant, strong magnetic field (3 Tesla), so if you have metal implants and clips within your body they may be influenced by the magnetic field and shift in position. Thus, if you have such implants you must inform us and withdraw from the study. Metal earrings and necklaces also must be removed prior to the study. If you have shrapnel, surgical implants, or other pieces of metal in your body that cannot be removed, you may not be able to participate in studies involving the MRI scanner. In many cases, people having dental appliances in their mouths can participate but should notify the investigator to be certain.

2. *Women of child bearing potential*: The risks of an MRI scan to the unborn fetus are unknown. We strongly recommend pregnant women do not take part in this research study. By signing this form you are indicating to the best of your knowledge that you are not pregnant. If you are uncertain then the study can be rescheduled to a later date.

3. *Hearing*: Functional MRI scanning produces a loud (92 dB) high frequency tone that can cause hearing damage if appropriate hearing protection is not used. Adequate hearing protection in the form of foam ear-plugs will be provided and required.

4. *Claustrophobia*: The functional scanning coil fits closely around your head, so if you feel anxious in confined spaces, you may not want to participate. If you decide to participate, and then at a later time decide to discontinue, just let us know and we will stop the experiment.

Other important items you should know:

• **Voluntary Participation and Withdrawal:** Whether or not you take part in this research is your choice. You can leave the research at any time and it will not be held against you. You have the right to refuse to answer any question(s) or refuse to participate in any procedure for any reason. Refusing to participate in this study will not result in any penalty or loss of benefits to which you are otherwise entitled. If you choose to discontinue the study early, you will be compensated a prorated rate based upon the amount of time you participated in the

study, with no penalty for discontinuing. The experimental data collected up until the time you decide to withdraw will be destroyed if you choose to do so.

If you are a Dartmouth student or employee, taking part in this research is not part of your class work or duties. You can refuse to enroll, or withdraw after enrolling at any time, with no effect on your class standing, grades, or job at Dartmouth. You will not be offered or receive any special consideration if you take part in this research.

• **Number of people in this study:** We expect about 150 participants will be in this research study.
• **Funding:** • This project is funded by the National Institute of Health.

Confidentiality

All information you provide will be kept confidential except as required by law. Your name will not be used in any publication that may result from this study. The Office of the Committee for the Protection of Human Subjects may request access to this form to ensure procedures designed to protect research participants are being properly followed. The manufacturer of the MRI scanner (Siemens) may request the use of images acquired in this study, although they will not have access to the names of any subjects.

As with other data from the PI's studies, data will be stored on restricted access servers and/or in locked filing cabinets in a locked room, to which only the PIs and members of the research team have access. These procedures will minimize the risk of personal information being divulged to non-members of the research team. No identifying information will be linked to the data from the study except by a master list accessible only to the PI and research coordinator. Identifying information will be used by a single member of the research staff to verify your eligibility and confirm completion of online surveys and other study requirements. Once your eligibility is determined, the research staff will not access your individual survey responses. Additional members of the research staff will only examine your responses after your data has been deidentified and assigned an alphanumeric ID code.

Strict standards of confidentiality are maintained. MRI data will be electronically stored and analyzed using ID codes. If the data are published, you will remain anonymous in all publications. Data will be stored indefinitely and will not be shared with other investigators without explicit permission from the Dartmouth IRB.

We will discard any personally identifying information we collect from you as soon as we are able to, ensuring that any data we retain cannot be linked back to you. Subsequently, your data will be retained indefinitely in a de-identified form using a randomly assigned identification number, and will be stored on password-protected computers accessible only to the research team. All paper forms including will be kept in locked offices in locked filing cabinets. Electronic consent forms and completed questionnaires will be stored safely and only accessible to members of the research team.

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. This certification means that the researchers cannot be forced to tell people who are not connected with the study, such as the court system, about your participation in this study. But, if you request that we do so, we will release information that is unique to you.

Will my data be deidentified and used in the future for other purposes?
Your data may also be shared with other researchers around the world or with a publicly available data archive. In such cases, every reasonable effort will be made to remove identifiers from the data that would indicate any connection to you (e.g. the removal of your name, address, SSN, etc.).

There are three exceptions to this promise of confidentiality:

1. If we see or are told information that makes us reasonably suspect that a child or at-risk adult is being or has been abused, mistreated, or neglected, we will immediately report that information to the county department of social services or a local law enforcement agency.
2. If we learn of a serious threat of imminent physical violence against a person, we will report that information to the appropriate legal authorities and make reasonable and timely efforts to notify the potential victim.
3. This promise of confidentiality does not include information we may learn about future criminal conduct.

Your Right to Revoke Consent to Participate in this fMRI Study: At any time now or in the future you feel that your data should no longer be used for research purposes, you have the right to revoke the consent you gave in signing this document. Please communicate your desire to have your data removed from the investigator's database by contacting the investigator(s) or person(s) listed below. Keep in mind that if your anonymized brain image data have been shared with other researchers or placed in a centralized archive, then it may be impossible to have these copies deleted.

Payment for Participation

If you agree to take part in this research study, at the conclusion of the four sessions we will pay you $400 for your time and effort (including a completion bonus).

Alternatively, eligible Dartmouth students can receive 8 T-points (1 T-point/hour of scanning) plus $200 for their time and effort (including a completion bonus). If you earn the T-point maximum before finishing the study, we will still compensate you for your time ($25/hour of scanning).

If you decide to withdraw before completion of the experiment, you will be compensated at a prorated rate to the nearest half hour.

It is important to know that payment for participation is taxable income.

Questions

This research is being conducted by members of the Department of Psychological and Brain Sciences at Dartmouth College. For further information about this study, you may contact:

Investigator: Tor Wager

Phone Number: 603-646-2196
Email Address: Cognitive.and.Affective.Neuroscience.Lab.Studies@Dartmouth.edu
CPHS Number: #31937

Should you have any additional questions about your participation in a research study, you may call the office of the Committee for the Protection of Human Subjects at Dartmouth College at (603) 646-6482.

Signatures

I have read the above information about ***Individualized spatial topology in functional neuroimaging*** and have been given time to ask questions. I agree to take part in this study and I will be given a copy of this signed consent form.

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Signature of subject Date

_____

Printed name of subject

_____

Signature of person obtaining consent Date

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Printed name of person obtaining consent