DREXEL UNIVERSITY
Office of
Research &
Innovation

Research Subject Consent Form

Title:	*Investigating electroencephalographic predictors of default mode network anticorrelation*
Protocol Number.:	2208009389
Sponsor:	*National Institute of Mental Health*
Investigator:	*Aaron Kucyi* *Stratton Hall 341* *Philadelphia, PA, 19104* *United States* *aaron.kucyi@drexel.edu*
Daytime Phone Number:	*857-303-2563*

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will involve three visits to the Temple University Brain Research and Imaging Center. The visits will take place 1-2 weeks apart, the first lasting approximately 1 hour and the following two sessions lasting 2 hours each. All three visits will include about an hour of outside-of-scanner procedures . The latter two sessions will also include MRI scans which will last an additional 1 hour.

Why is this research being done?

The purpose of this research is to examine whether electroencephalography (EEG) can measure the same brain activity that functional magnetic resonance imaging (fMRI) measures. We will investigate whether a specific pattern of brain activity that is commonly measured with fMRI, involving the brain's default mode network, can also be predicted from EEG data. The purpose of this research is to determine whether EEG is just as good as fMRI at measuring the interplay between two brain networks, known as the default mode network and the dorsal attention network.

This study is funded by a grant from the National Institutes of Mental Health.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include performing cognitive tasks and undergoing MRI scans while wearing an EEG system. During the first session, you will fill out several surveys detailing demographic and mental health information. This session will also be dedicated to getting you acquainted with the equipment that we will be using and going over safety procedures. At the beginning of each of the two succeeding visits, prior to entering the MRI suite, you will complete a Subject MRI Safety Screening Form. Afterwards, you will undergo brief training for procedures to be performed in the MRI scanner and will be fitted with an EEG system that you will wear inside the MRI scanner. During the

training, you will perform cognitive tasks. You will press a button in response to visual displays that you will view on a laptop screen. You will later perform these tasks in the MRI scanner. This includes wearing a standard EEG cap on your head and having a small amount of electrode gel applied on 32 0.5-inch diameter circle areas your scalp. This is a required step to ensure EEG signal quality. You can wash away the gel with water.

During 1-hour MRI sessions, you will lie quietly on a table that will slide inside a large magnet. A large plastic cylinder (receiving antenna) with holes in it will surround your head and your head will be placed on a pillow.

You will undergo structural MRI followed by fMRI (measuring brain activity) including performance of three tasks:

- The Gradual-Onset Continuous Performance Task: You will view a stream of images (cities, mountains) and will respond with button presses to city scenes but withhold responses to mountain scenes.
- Resting state: You will view a central fixation cross and will let your mind wander.

- Experience sampling: You will be probed at random intervals while mind wandering about the content of your thoughts.

You will receive $175 at the end of the study (i.e., the end of session 3).

Could being in this research hurt me?

Behavioral Testing: The testing, as with any testing, may be an inconvenience and cause fatigue, but the tests are not known to cause undue distress or emotional stress. Although there is a possible risk of loss of confidentiality with the maintenance of databases, every effort will be made to minimize this risk through the use of password-protection and the separation of name and contact information from behavioral testing results as discussed above.

Magnetic Resonance Imaging

- The known risks associated with magnetic resonance imaging (MRI) are minimal. The greatest risk is a metallic object flying through the air toward the magnet and hitting you. To reduce this risk we require that all people involved with the study remove all metal from their clothing and all metal objects from their pockets. No metal objects are allowed to be brought into the magnet room at any time. In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the magnet.

- The radiowaves and magnetic fields, at the strengths used, are felt to be without harm. However, because of the magnetic fields people with cardiac pacemakers or a certain metallic implants cannot participate in the study. Since there is a risk of injury from flying objects in or near the magnet, it is important that all metallic objects be removed from your person prior to approaching the high field strength magnet, as these objects may be attracted to the magnet. In addition, such objects as watches and credit cards should also be removed as these could be

damaged (these items will be watched for you). Although there are no known risks of MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no direct benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women. Please take note that some subjects have experienced claustrophobia; you may discontinue the scan at anytime if you become uncomfortable. There are conservative Federal guidelines for radiowave exposure and our examinations fall within those guidelines. We feel these are safe levels. You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study.

- Also, the MRI unit makes loud noises during the examination. To protect your ears, you will be given foam earplugs that fit into your ears. You will also be given earphones to wear over the earplugs to block the noise, and minimize any possible discomfort.

EEG during MRI

With the use of simultaneous EEG during MRI, a risk is introduced of the equipment heating up in the MR environment, which could result in burns due to skin contact of hot electrodes. However, with responsible use of the MR-compatible EEG system that we will apply, such extreme incidents are highly unlikely. During EEG-fMRI, we will apply recommended MRI sequences that result in a conservative, safe level of specific absorption rate (i.e., the rate at which radiofrequency energy is absorbed per unit of tissue). There are no known risks for the EEG or fMRI procedures proposed in our research design. The setup of EEG involves application of a hypoallergenic gel between the skin and each electrode, which can sometimes be associated with subject discomfort. Participants with sensitive skin and/or skin allergies will be excluded from the study.

Pregnant Women

There is no known risk to a mother or fetus from fMRI; because the safety of the technique in pregnant women has not been fully studied, however, pregnant women are not permitted to participate in the study.

Incidental Findings

Although the purpose of this study is for research purposes only, there is a possibility that an MRI scan will show a possible brain abnormality. If we think we may have observed such an abnormality, we will seek the opinion of a professionally licensed neurologist or radiologist at no cost to you. In the event that the professional recommends clinical follow-up, we will inform you of the recommendation, make images from the scan session available to you, and provide a referral to a professional upon the subject's request. We are not responsible for any medical costs incurred after this point as a result of this potential anomaly.

Will being in this research benefit me?

It is not expected that you will personally benefit from this research. Possible benefits to others include generating scientific knowledge that is necessary for developing new therapies for mental illness.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to examine whether electroencephalography (EEG) can measure the same brain activity that functional magnetic resonance imaging (fMRI) measures. We will investigate whether a specific pattern of brain activity that is commonly measured with fMRI, involving the brain's default mode network, can also be predicted from EEG data. The purpose of this research is to determine whether EEG is just as good as fMRI at measuring the interplay between two brain networks, known as the default mode network and the dorsal attention network.

About 24 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will involve three visits to the Temple University Brain Research and Imaging Center. The visits will take place 1-2 weeks apart, the first lasting approximately 1 hour and the following two sessions lasting 2 hours each. All three visits will include about an hour of outside-of-scanner procedures. The latter two sessions will also include MRI scans which will last an additional 1 hour.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include performing cognitive tasks and undergoing MRI scans while wearing an EEG system. During the first session, you will fill out several surveys detailing demographic and mental health information. This session will also be dedicated to getting you acquainted with the equipment that we will be using and going over safety procedures. At the beginning of each of the two succeeding visits,

prior to entering the MRI suite, you will complete a Subject MRI Safety Screening Form. At the beginning of each visit, prior to entering the MRI suite, you will complete a Subject MRI Safety Screening Form. You will then undergo brief training for procedures to be performed in the MRI scanner and will be fitted with an EEG system that you will wear inside the MRI scanner. During the training, you will perform cognitive tasks. You will press a button in response to visual displays that you will view on a laptop screen. You will later perform these tasks in the MRI scanner. This includes wearing a standard EEG cap on your head and having a small amount of electrode gel applied on 32 0.5-inch diameter circle areas your scalp. This is a required step to ensure EEG signal quality. You can wash away the gel with water.
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You will undergo structural MRI followed by fMRI (measuring brain activity) including performance of three tasks:

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- Resting state: You will view a central fixation cross and will let your mind wander.
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- Experience sampling: You will be probed at random intervals while mind wandering about the content of your thoughts.

You will receive $175 at the end of the study (i.e., the end of session 3).

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Follow the investigator's or researcher's instructions.
- Tell the investigator or researcher right away if you have a complication or injury.

Could being in this research hurt me?

Behavioral Testing: The testing, as with any testing, may be an inconvenience and cause fatigue, but the tests are not known to cause undue distress or emotional stress. Although there is a possible risk of loss of confidentiality with the maintenance of databases, every effort will be made to minimize this risk through the use of password-protection and the separation of name and contact information from behavioral testing results as discussed above.

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- The radiowaves and magnetic fields, at the strengths used, are felt to be without harm. However, because of the magnetic fields people with cardiac pacemakers or a certain metallic implants cannot participate in the study. Since there is a risk of injury from flying objects in or near the magnet, it is important that all metallic objects be removed from your person prior to approaching the high field strength magnet, as these objects may be attracted to the magnet. In addition, such objects as watches and credit cards should also be removed as these could be damaged (these items will be watched for you). Although there are no known risks of MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no direct benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women. Please take note that some subjects have experienced claustrophobia; you may discontinue the scan at anytime if you become uncomfortable. There are conservative Federal guidelines for radiowave exposure and our examinations fall within those guidelines. We feel these are safe levels. You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study.

- Also, the MRI unit makes loud noises during the examination. To protect your ears, you will be given foam earplugs that fit into your ears. You will also be given earphones to wear over the earplugs to block the noise, and minimize any possible discomfort.

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Pregnant Women

There is no known risk to a mother or fetus from fMRI; because the safety of the technique in pregnant women has not been fully studied, however, pregnant women are not permitted to participate in the study.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

It is not expected that there will be any additional cost associated with your participation in this research.

Will being in this research benefit me?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include generating scientific knowledge that is necessary for developing new therapies for mental illness.

What happens to the information collected for this research?

Your private information will be shared with individuals and organizations (if applicable) that conduct or watch over this research, including:

- The research sponsor (National Institute of Mental Health)
- People who work with the research sponsor
- The Institutional Review Board (IRB) that reviewed this research
- Drexel University and its affiliates

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps protect your identifiable information and biological samples. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have

consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Mental Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (267) 359-2471 or HRPP@drexel.edu if:

You have questions, concerns, or complaints that are not being answered by the research team.
You are not getting answers from the research team.
You cannot reach the research team.
You want to talk to someone else about the research.
You have questions about your rights as a research subject.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- If all or part of the study is discontinued for any reason by the investigator, university authorities, or government agencies; or
- Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by the subject or other subjects in this study.
- You are unable to keep your scheduled appointments
- You become pregnant
- If we determine from MRI safety screening that it is unsafe for you to enter the MRI suite

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you agree to take part in the research now, you can stop at any time, and it will not be held against you. There are no consequences for not participating or continuing to participate.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $175. Your compensation will be broken down as follows:

- One payment at the end of the study (i.e., at the end of the third visit)
- If you complete only one visit, you will receive $35.
- If you complete two visits, but not the third, you will receive $105.

You will receive payment for your participation through a remote-payment electronic system at Drexel, which is administered by JPMorgan Chase Bank. This system allows us to compensate you for your participation in the study through a secure electronic payment system (ACH) that is used by most major banks. This system securely sends direct payments from an account associated with this study to your account, immediately upon study completion. The use of this system as a payment option allows for remote payment and helps us protect the privacy and safety of the participants and the research staff.

To use this form of payment, we will need to provide JPMorgan Chase Bank your participant number ID and your email and phone number. We will then send you an invitation to receive payment either as an email or a text message. Once you accept the invitation the funds will be disposed to your account by the next business day. Drexel University and the researcher team do not have any access to your account information and they are not directly involved in the disbursement of the funds.

If you cannot or do not want to receive a direct, electronic payment through this system, you have the option of receiving a check from Drexel University. This option takes several weeks to process, requires you to complete a federal W9 form, and requires you to disclose your name and social security number to Drexel's Accounts Payable department. You will also need to provide your name and address to JPMorgan Chase Bank, who will be sending this check to you.

Please note that if you make over $600 within one calendar year from participation in research studies including this one, Drexel will be required to issue a tax form to you. You will also be required to submit a completed W-9 form to Drexel's tax department.

What if this research has additional findings about me that were not related to the research questions?

Although the purpose of this study is for research purposes only, there is a possibility that an MRI scan will show a possible brain abnormality. If we think we may have observed such an abnormality, we will seek the opinion of a professionally licensed neurologist or radiologist at no cost to you. In the event that the professional recommends clinical follow-up, we will inform you

of the recommendation, make images from the scan session available to you, and provide a referral to a professional upon the subject's request. We are not responsible for any medical costs incurred after this point as a result of this potential anomaly.

Your signature documents your consent to take part in this research.

Printed Name and Signature of adult subject capable of consent	Date
Printed name and Signature of person obtaining consent	Date