Target engagement for intranasal oxytocin in Autism Spectrum Disorders, an fMRI dose response study.

Informed Consent Form Date: October 16, 2017

NCT Number: NCT03033784

Emory University
Consent to be a Research Subject / HIPAA Authorization
ASD

Title: Target engagement for intranasal oxytocin in Autism Spectrum Disorders, an fMRI dose response study.

Principal Investigator: Elissar Andari, PhD

Sponsor: Larry J. Young, PhD

Introduction

You are being asked to be in a medical research study. This form tells you everything you need to think about before deciding if you want to be a part of the research study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the study.** The decision to join or not join the study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff as they explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form to keep. Take your time to think about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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 the purpose of this study?

The purpose of this study is to look at behavioral and brain responses to social interactions. We are also studying emotional and social characteristics, genetic and immune factors, and the levels of chemicals and hormones. This will help us to understand individual differences in Autism Spectrum Disorder (ASD).
The main goal of the study is to look at the effects of intranasal oxytocin on the brain in ASD. Oxytocin is a hormone that exists naturally in our body and our brain. It affects a wide range of social behaviors and emotions. We will also study how the effects of oxytocin treatment can be changed by the above factors.

You will participate in five visits: the first visit is pre-clinical and then 4 clinical visits. During the first visit, you will complete a health assessment, personality tests, questionnaires, computerized tests and practice sessions. At the 4 clinical visits we will collect images of your brain and you will receive one of these four solutions intranasally on each clinical visit (using a nose spray):

- Dose 1 of oxytocin (8IU)
- Dose 2 of oxytocin (24IU)
- Dose 3 of oxytocin (48IU)
- Placebo (a solution without oxytocin).

Each participant will receive all these 4 solutions over the course of the study in a random order. Neither you nor the study team will know which solution you will receive during the clinical visits.
You will also have a pre-clinical visit (first visit).

We ask you to volunteer because you are on the Autism Spectrum and you are a male between the ages of 18 and 45. The time needed for you to complete this study is about 3.5 to 4 hours per visit. Almost 50 adults with ASD will participate in this portion of the study at Emory University.

What will I be asked to do?

All the study visits will take place on main Emory Campus at the Emory Hospital.
The first pre-clinical visit includes:

- Review of inclusion and exclusion criteria and MRI screening.
- A nurse or study physician will perform a basic health, history and physical assessment and review medical eligibility. Given that this health assessment is done at the CRN unit of the Emory hospital, the CRN nurses will also do basic nursing assessments for their records.
- Complete a general form that is related to family history.
- Provide saliva by spitting in 3 test tubes. DNA will be taken for genetic analysis. Your genetic information will be kept strictly confidential. We will store the saliva sample for this study and for future studies conducted by Dr. Andari. Your DNA will not be placed in a repository. The results of the genetic tests will not be made available to you or to your referring health care providers.
- Complete several questionnaires and forms. You can take some questionnaires or forms to complete at home if you would like. You can bring them back during the following visits.
- Complete behavioral tasks on the computer screen.
- Complete several practice sessions and quizzes on the tasks that will be conducted during the four clinical visits.
- Conduct a short clinical interview with the experimenter. You will be asked to wear a sensor. This sensor detects your heart rate, skin temperature, skin conductance and movement. The experimenter will also wear this sensor. The clinical interview will be video-taped and will be analyzed by the study staff.
- Walk to BITC and explore the MRI scanner. This includes:
    - lying down inside the scanner
    - resting for few minutes and looking at a fixation cross
    - looking at pictures on the screen and pressing a key when participant sees a blue fixation cross
    - detecting a color in a ball game
    - answering questions,
    - using the response box
    - listening to the noise of the MRI scan.

The MRI scanner uses a strong magnet and radiowaves (not x-rays) take a picture of your brain. We will ask you to enter a large room where a powerful magnet is located. We will tell you to remove all jewelry and metal objects. You will enter into a small tunnel about 6 feet long and 25 inches across. We will ask you to lie still during the scan.
Snacks will be provided.

The different tasks do not need to be performed in a particular order. Even the health assessment can be performed after the tasks described above given that this assessment should just be performed before your inclusion in the subsequent clinical visit. This health assessment is not a requirement for your inclusion in this first pre-clinical visit.

Four clinical visits:
You will meet at the Emory University Hospital.

The health assessment that was performed during the first visit (brief history and physical assessment) might be reviewed by the nurse or study physician one more time at some point during one of these 4 clinical visits (in case if the original health assessment expires (more than 30 days)).

During your first clinical visit:

- We will review the screening forms.
- You will complete computer practice sessions and training.
- You will be asked to complete quizzes to assess whether you understand the game. If you answer a question incorrectly, a research assistant will explain why the answer was wrong and make sure that you understand before continuing. You will then complete practice rounds of three tasks.
- You will complete some simple questionnaires.
- The nurses will measure your body temperature, heart rate, and blood pressure. They will also measure your weight and height. If your blood pressure was higher than 140/90 or your heart rate higher than 100, the nurses will ask you to rest for 5 minutes and then take the measurement again. If the measurements stay high, we will continue collecting vital signs for a total of 6 times in both limbs before contacting a physician to ask for advice.
- You will have a small sample of blood (~10 ml) drawn from your arm. We will use it to measure hormones, chemicals, genetic and epigenetic markers, and immune factors. Your blood will be stored for future studies that are related to Dr. Andari. Your DNA and blood will not be placed in a repository. The results of the genetic tests will not be made available to you or to your referring health care providers.
- You will receive one of the 4 solutions intranasally (as a nose spray): oxytocin dose 1 (8IU), dose 2 (24IU), dose 3 (48IU) or placebo. The nurse will instruct you to clear the nose before spray administration. The nurse will instruct you to sit with the head upright and little tilting to the back. During administration, you can close one nostril within one finger while the nurse is administering the spray in the other nostril. The nasal applicator will be placed in one nostril. You will be asked to breathe in deeply through the nose while blocking the opposing nostril, and the lever will be pressed until you feel a spray in the nostril. The nurse will repeat these steps for the other nostril. You will receive a total of 12 sprays. This process is not painful, and tissues will be provided if needed. Neither you nor the study team knows which of the four solutions you will receive.
- You will have another small sample of blood (~10 ml) drawn from your arm 5 minutes after spray intake. We will use it to measure hormones, chemicals, genetic and epigenetic markers, and immune factors. Your blood will be stored for future studies that are related to Dr. Andari.
- We will measure body temperature, heart rate, and blood pressure. If your temperature changes by more than 2 degrees, or if your heart rate or blood pressure changes above or below normal, we will take more measurements after a pause. If these measures stay abnormal after 6 consecutive times, we will notify the physician and ask for advice. We do not expect these changes with oxytocin or placebo inhalation, and side effects are expected to be minimal. In case of emergency, the Emory University Hospital Emergency Room is immediately available. In previous studies that used these solutions, no subjects withdrew because of side effects.
- We will ask you if you experience any adverse effects because of the nasal spray. If so, we will consult with the physician on call. We will ask you whether you think you took placebo or oxytocin.
- We will escort you the MRI Center in Emory University Hospital from the CRN unit.
- The MRI scanner uses a strong magnet and radiowaves to take a picture of your brain. We will ask you to enter a large room where a powerful magnet is located. We will tell you to remove all jewelry and metal objects. You will enter into a small tunnel about 6 feet long and 25 inches across. We will ask you to lie still during the scan. You will wear a sensor inside the scanner to measure your physical state.
- After a few minutes of localizer scans, we will conduct functional Magnetic Resonance Imaging (fMRI) brain scans.
    - First, you will be asked to rest for 8 minutes and to look at a cross symbol in front of you without thinking of anything specific and without sleeping.

  - Second, you will perform 2 sessions of a face task. You will be asked to press a key when you see a blue cross. You will see faces separated by red or blue crosses.
  - Third, you will play several sessions of a social ball-tossing game. You will play with other players who are connected with you by internet. You will play several games with several groups of people. You will play with 2 players at a time for several rounds. These players gain money based on how well you perform. You will receive a feedback from the computer about your performance after each trial. You will also briefly see the partner's face via a camera. They might communicate their approval or disapproval. You will also play several games with the computer for training purposes.
    We will ask you questions about your feelings towards the other players. We will ask you about the emotional states of the other players.
- We will take a structural magnetic resonance image scan to make detailed images of your brain.
- We will remove you from the scanner.
- We will take you to another room next the MRI scanner to rest. We will offer you some snacks. We will ask you to complete:
  - Questionnaires
  - Behavioral tasks on the computer screen
  - A clinical interview. We will ask you to wear a sensor.

The total time inside the scanner will be one hour.
All four clinical visits are similar.
At the end of the 5th visit, we will debrief you about this study and the previous study (IRB00064623).

Who owns my study information and samples?
If you join this study, you will donate your samples and study information. You will not receive any extra compensation if your samples or information are used to make a new product. If you withdraw from the study, the data and samples we collected may still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the hormone or procedures that are not known at this time.
You should not proceed with this study if you have the following medical conditions:
- Recent seizures (with the past 5 years)
- Brain damage or head trauma (can be included at discretion of PI and sponsor)
- Alcoholism or substance abuse
- Severe medical problems
- Severe mental retardation
- Cardiovascular disease
- Current and frequent untreated asthma
- Current and frequent untreated migraines
- Pacemakers, cochlear implants, surgical clips or metal fragments

You will be asked to refrain from use of caffeinated drinks or tobacco for at least 12 hours prior the blood pressure and heart rate measurement during clinical visits.

DNA: We recognize the sensitive nature of genetic information and the need for strict confidentiality for data that may eventually be available to the scientific community. Your DNA will be collected from saliva and blood samples you provide. A breach in confidentiality, resulting in accidental disclosure of genetic information to outside parties, can negatively impact your insurability, employability, or your reproductive plans. It could have a negative impact on family relationships and/or could result in paternity suits or stigmatization. To reduce the risk of accidental disclosure of information to outside parties, all information obtained from you will be kept strictly confidential. No individual genetic results will be given to you or your relatives. DNA used in this study will be assigned an ID number with no identifying information. The link to your identifying information will be available only to E. Andari and limited research staff.

Intranasal oxytocin and placebo administration:
Although oxytocin is not FDA approved for this indication, it is FDA approved and medically used for labor induction and labor support in case of difficult parturition. We also have permission from the FDA to use this Investigational New Drug (IND) in the study. Intranasal doses result in very low levels of the neuropeptide, as compared to intravenous administration. Therefore, the type of drug administration used in this study is expected to have minimal side effects.
The most common risks and discomforts expected in this study are:
None
The less common risks and discomforts expected in this study are:

- Headaches
- Tachycardia, bradycardia
- Nausea, vomiting

Rare but possible risks include:

- Irregularities of the pulse (arrhythmia, very rare hypertension)
- Skin rashes
- Runny nose
- Tiredness
- Sore throat
- Shakiness
- Sweating
- Coughing
- Allergic reactions to oxytocin leading to shortage of breath, blood pressure decreases or circulatory collapses

The effect of the study drug on sperm is not known. To protect against possible side effects, you should not get a sexual partner pregnant for the duration of the study. You and the study doctor should agree on a method of birth control to use throughout the study.

This particular treatment may involve risks to you which are currently unforeseeable.

Blood Draw:
The needle for the blood draw may cause brief pain or discomfort. In rare cases, bruising may occur. In rare cases, you may feel light-headed or faint.

MRI:
Magnetic Resonance Imaging uses magnetism and radio waves to take pictures. It has been in use for more than 20 years and millions of people have had the procedure without injury. Therefore, MRI is considered safe. However, no one can guarantee that there are no long-term adverse health effects. The only known risks are to individuals with cardiac pacemakers and certain types of metallic implants. If you have either of these, you cannot participate in this study because of the effect the magnetic field could have on the pacemaker or metallic implant. Be sure to tell us if you know or think you have a pacemaker or metallic implant, such as an aneurysm clip. All the equipment and MRI methods used in this study are standard methods approved by the U.S. Food and Drug Administration.
You may become tired from lying down in the scanner. You may become uncomfortable from lying in one position for a long period of time. If you become too cold, you may ask for a blanket. Some individuals have mild anxiety or claustrophobia while lying in the scanner. If this happens, you may ask to leave the scanner at any time. The MRI machine makes loud metallic popping sounds while it is taking pictures that may irritate you. We do provide ear plugs to help lessen this loud noise, but it does not completely alleviate it. You can ask to stop the MRI scan at any time.
Although we are trained to identify adverse effects of the study, we are not trained to find medical problems with your brain on the MRI scans we collect. The MRI and other images taken in this study are not the right

type to show medical problems. Your MRI scan will not be reviewed by a physician to look for abnormalities. You understand that if you are not told that there is an abnormality or referred to a specialist, this does not mean that an abnormality does not exist. If you have any concerns about your health, you should discuss this with your physician. The investigators and Emory University are not responsible if they do not find an existing medical problem or unusual condition in your scan.
However, the investigator may see something on a scan that seems unusual. If this happens, a medical doctor will be asked if more tests should be done. If so, the principal investigator will call and tell you. You will need to tell your own doctor about the call. If you have no doctor or health care provider, we will help you find one. You and your doctor will decide if you should have another examination or treatment. The investigators, the consulting medical doctor, and Emory University are not responsible for, nor will they pay for, any examination or treatment that you decide to have based on something we might see in your scan. The scans done in this study are not for a medical exam. If something unusual is found, it might keep you from getting health or life insurance. If you need to talk to someone about your concerns about an unusual finding, you be referred to a counselor but at your own expense.
You will be provided with a copy of the MRI anatomy scan.
We will arrange for emergency care if you are injured by this research. However, Emory University has not set aside funds to pay for this care if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Andari at 404-712 9661.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Given the absence of common risks associated with intranasal oxytocin, an adverse event will only be considered related to the study if it occurs during one of the 5 visits at Emory. Any adverse event occurring before your arrival to Emory, after you leave Emory, or in between visits, will not be considered related to this study.

Will I benefit directly from the study?
This study is not designed to benefit you directly. This study will help us learn more about the role of the hormone oxytocin in social functioning and brain function in Autism. The study results may help others in the future. The results of the study may help us to understand more precisely how oxytocin works.

Will I be compensated for my time and effort?
You will receive a compensation of $200 for 5 research visits ($40 for each). This compensation includes the parking fees that you might need to use while visiting us at Emory.

If you are injured by or get sick from intranasal oxytocin or the study procedures, we will arrange for medical care. We will arrange for emergency care if you are injured by this research. However, Emory University has not set aside funds to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Elissar Andari at 404-712 9661.

What are my other options?
You might not be able to participate in other research studies while you are actively enrolled in this clinical trial. In order to better study oxytocin's effects on the brain and behavior, we prefer that you do not participate in other clinical trials that involve drugs, hormones or neuroimaging while you are actively involved in this study.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results. Your private

information will be stored on a secure server of Emory University that is protected and/or in a locked cabinet with a key.
Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information
Your samples, genetic data and health information (without personal identifiable information) will be stored and shared with other researchers. The samples will be stored in the CRN (Clinical Research Network) unit at Emory Hospital, within the ACTSI (Atlanta Clinical and Translational Science Institute) facility. The samples and information will be available for any research question to understand what causes certain diseases. It can be available to develop new scientific methods, or the study of where different groups of people may have come from.

Medical Record
If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include:

- Behavioral and clinical diagnosis data
- Anatomy and neuroimaging data
- Physiological data
- Effects of oxytocin or placebo on brain function and behavior
- Family information
- Medication that you are currently taking
- Data on hormones, chemicals, genetic and epigenetic markers, and immune factors

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury
If you get ill or injured from being in this study, Emory will help you get medical treatment. Emory and the sponsor have not set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. “Negligence” is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Elissar Andari at *redacted*. You should also let any health care provider who treats you know that you are in a research study.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury” as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study
You have the right to leave the study at any time.
The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you object to any changes in the study plan.

Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

Giving state public health officials information about certain infectious diseases.
Giving law officials information about abuse of a child, elderly person or disabled person.
Giving out information to prevent harm to you or others.
Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications
- Medical and history information about your family
- All information that is collected about you and your family members during the research visits
- Video-taped interview
- Results of exams, procedures and tests
- Laboratory test results, including DNA analysis and other.

Purposes for Which Your PHI will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards

(IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will share your PHI with other collaborators (without names) and researchers to help research on autism. We will share the above information with National Data Base for Autism Research. We may share it also with the Research Domain Criteria data base to help make progress in autism research.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and share your PHI to conduct the study and give you study related treatment.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Larry J. Young is the Sponsor of the study. The Sponsor may use and share your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program
    - Offices involved in study administration and billing
    - Emory IRB
    - Food and Drug Administration
    - Emory Research and Healthcare Compliance Offices
    - Emory Office for Clinical Research
    - Government agencies that regulate the research including:
        - Public health agencies
        - Research monitors and reviewer
        - Accreditation agencies

- Sometimes a Principal Investigator moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Study/Storage of Data/Specimens for Future Research conducted by the principal investigator:

PHI that will be Used/Disclosed for Optional Study:
The PHI that we will use and/or share for the storage and future use includes:

- General information about you and your family

- Specimens, including saliva and blood
- Data on hormones, chemicals, genetic and epigenetic markers, and immune factors
- Physiological data
- Behavioral and clinical data
- Anatomical and functional brain data
- All the results of exams, procedures and tests conducted during the study
- All laboratory results
- Video-taped interview
- Your contact information for future research studies

Purposes for which you're PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct of the future studies that will help better research on autism.

Authorization for This Use of PHI is required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional storage and future use of data. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:
The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional research study/storage of PHI for future research. The PI might also share your information with trusted collaborators (without sharing names) in the future for conducting novel collaborative research projects.

Of note, this optional use of PHI for future studies is only possible if the PI is aware of it.

Expiration of Your Authorization
Your PHI will be used until all potential analysis and that future research studies that includes this data directed by E. Andari finish.

Revoking Your Authorization
If you sign this form, at any time later you may take back your permission to use your information. If you want to do this, you must contact Dr. Andari at the following mailing address: *redacted*

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.
To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you can receive the general results that are published. We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Elissar Andari at *redacted*:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- If you have questions about your rights as a research participant
- If you have questions, concerns or complaints about the research
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

Agree to provide saliva samples for genetic and other analysis related to this study
___ Yes ___ No
Agree to provide blood samples for genetic and other analysis related to this study
___ Yes ___ No
Use of all data collected in this study for future studies that will be led by Dr. E. Andari
___ Yes ___ No
Contact in the future for participating in future studies that are related to Dr. E. Andari
___ Yes ___ No
Approval to be contacted by phone if there is something unusual in the MRI scan
___ Yes ___ No

Even if I have a legal guardian or a legal representative, I confirm that I am an adult and understood all the details of this consent form ___ Initials (N/A, in case if you do not have any legal representative).

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the form to keep.

_____
Name of Subject

_____ _____
Signature of Subject (18 or older and able to consent) **Date Time**

_____
Name of legally authorized representative

_____ _____
Signature of legally authorized representative **Date Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion **Date Time**