The University of New Mexico Health Sciences Center
Consent to Participate in Research

Multisensory Integration in Fetal Alcohol Spectrum Disorders: A Possible Biological Marker from MEG

Purpose and General Information
You/your child are being asked to participate in a research study that is being done by Julia M. Stephen, PhD, who is the Principal Investigator, and her associates. This research is being done to look at differences in brain function between typically developing children and those exposed to alcohol during pregnancy. Specifically, we are studying how the brain responds to pictures, sounds and touch. We hope to find an early marker of exposure to alcohol to help future children get early treatment to improve their long-term outcomes. Your child is being asked to participate because your child is less than 18 years of age and was exposed to alcohol during pregnancy. We are also including children who are are in the following groups: 1) developing normally, 2) have a diagnosis of ADHD, 3) have a father diagnosed with substance use disorder (alcohol), or 4) raised in a household with food insecurity (limited or uncertain availablity of food). Approximately 200 people will take part in this study at the Mind Research Network (MRN) and the University of New Mexico. This study is being sponsored by the National Institute for Alcohol Abuse and Alcoholism, a part of the National Institutes of Health. Throughout this consent form, "you" refers to "you/your child".

This form will explain the study to you and your family, including the possible risks as well as the possible benefits of participating. This is 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:

Magnetoencephalography/Electroencephalography (MEG/EEG): MEG and EEG record the magnetic activity of the brain at rest and at work. The scan is performed in a special, magnetically shielded room. MEG does not expose you to any radiation or high magnetic fields.

- You will participate in at least one neuroimaging (MEG/EEG) testing session. This visit will take place at MRN. During the scan the following steps will be completed:
- The study procedures will be shown and described to you.
- You will be screened for metal before the session to be sure that you do not have metal on your body. We will provide you clothes to change into (if needed) and will give you a locker for your belongings.
- Electrodes will be attached to your head and sides of the face using a special scrub, conductive paste and secured with tape. An electrode cap may also be placed on the head. Your child may also wear a special cap where we tape head positioning coils. We use these electrodes/coils to monitor brain activity, eye movements, head position, and heartbeat. Older children will be seated and younger children will lay on a bed so that the head is inside the MEG detector helmet. You will need to hold still for the scan. When the scan is over, all of the electrodes/paste will be removed.
- Your child will be positioned in the MEG machine and a study team member may remain in the room with your child.
- If you choose to stay in the room with your child, you will be asked to remove all metal and electronic devices. A locker is available to store your belongings. You will also be asked to stand/sit at a distance from your child since movement close to the MEG machine can cause noise in the data. If you choose to stay outside of the room, you can watch and listen to your child through a video-monitor and a microphone.

- Your child may be video-recorded. This will allow us to monitor the video for signs of movement. Once the data is obtained from the video recording, the recording of your child will be erased.
- If your child is having difficulty during the scan, the investigators will try to encourage the child to participate through game-playing. If we are not successful at obtaining good data, we may ask to reschedule.
- The data collection time is between 1 - 1 ½ hours, depending on how many rest breaks are needed.
- The overall time for the scan session depends on your cooperation and number of rest breaks. The overall time may be as long as 4 hours. You will be given the option to reschedule for up to two additional attempts if your child cannot complete the scan during this MEG/EEG visit.

MRI (Magnetic Resonance Imaging): Another visit for this study includes one brain imaging session called MRI. For this study, you will lie down on a table and will then be placed into a long donut-shaped magnet. During the scan you will hear loud rapping and knocking noises coming from the magnet. You may feel warm during this procedure. In order to obtain good pictures, it is important that you do not move during the procedure. Although you should not talk during the MRI procedure, you will be able to talk with the technician during breaks or in case of emergency by pressing a call button or similar device. During the scan, you may be shown pictures and words and will be asked to make decisions about the information. An EEG may be done at the same time as the MRI scan. This means you may wear the elastic cap during the MRI. This scan takes about 1-2 hours.

For younger children, the MRI scan will be done with the child asleep, unless your child can follow instructions while lying completely still. For young adults, you will lay in the MRI while you remain completely awake and are lying completely still.

The MRI scan is being done to answer research questions, not to examine your brain for medical reasons. This MRI scan is not a substitute for a clinical scan (the type a doctor would order). The research scan may not show problems that may be picked up by a clinical MRI scan. However, all research MRI scans will be read by a neuroradiologist (a doctor with experience reading MRI scans) unless you have been scanned at MRN in the previous six months. If your child is less than 2 years of age, all MRI scans will be read. If the scan is read, you will receive the official report by mail. If we find an abnormality that requires urgent follow-up, we will contact you and your doctor (with your permission) by phone to help answer questions and get the right follow-up care for you. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found. Our Medical Director or the research team is always available to answer any questions you may have about your scan.

Developmental Testing: Children ages 5 and older will have a developmental testing session directed by a trained investigator. You will be asked to complete a series of paper-and-pencil tasks (that are like puzzles) that measure your child's motor coordination, their ability to attend to tasks, remember test items and solve problems. This testing will help us determine how you are developing relative to children your same age. We will ask your child to come when he/she is expected to be alert and able to play. This visit will take approximately 1 1/2 hours.

Infant Testing: Children under the age of 5 will have an infant testing session. This will include a play session that measures your child's development by interacting with the tester, and observing language, movement, and problem solving skills. This will take about 1 hour or less to complete.

Parent Questionnaires: Parents will complete questionnaires while children complete the developmental testing. These will take about 1 hour to complete.

- Socio-economic status questionnaire which asks questions such as "What is the highest level of education you have completed?"

- Behavioral ratings will be used to assess the aspects of your child's thinking.
- A questionnaire about your child's behaviors which includes questions about your child's ability to attend to tasks and other behaviors in children.
- A family history assessment will be used to determine paternal alcoholism and to rule out maternal alcoholism. Mothers with substance use during pregnancy will be excluded from all groups other than the prenatal alcohol exposed group.
- The food security questionnaire will ask questions about availability of food for the child participant.

If your child was exposed to alcohol during pregnancy, and your child has not already been seen by an expert in FAS, your child will be seen by an expert in FAS to confirm diagnosis. This session will consist of the doctor identifying and confirming facial and other features in your child that may be associated with exposure to alcohol during pregnancy. The doctor will perform a physical exam and review your child's medical records. If possible, this visit will be combined with the developmental testing session. This component will take approximately ½ hour. We would also like to request your permission to store all of the data that was collected in this study in The Mind Research Network Data Sharing Repository for 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 the course of 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.
YES _____ Initials
NO _____ Initials

There is also the possibility that you may qualify to participate in future related studies. Please circle one of the choices below if you would like Dr. Stephen or one of her associates at The Mind Research Network to contact you in the future about other related studies.

YES - Please contact me about related studies in the future. _____ Initials
NO - Please do not contact me about related studies in the future. _____ Initials

By signing this consent, you are also giving us permission to access your child's medical records in regards to their behavioral testing to inform us about your child's developmental level as well as information about your child's exposure to alcohol during pregnancy.

Participation in this study will take a total of up to 5 hours with up to 4 visits depending on the success of data collection on scanning visits.

What are the possible risks or discomforts of being in this study?
Every effort will be made to protect the information you give us. However, there is a small risk of loss of confidentiality that may lead to embarrassment or regret based on your child's diagnosis if your personal information became public. We try to minimize this risk by restricting access to personal identifiable information about your child (see below).

- The MEG machine does not involve any direct risk to you. The machine does not apply any external magnetic field and only measures the activity naturally coming from the brain. You may feel some discomfort from sitting/lying still for 1-2 hours during scanning. Throughout the sessions, assistants will be with you to ensure your safety. An assistant may be in the room with your child depending on your child's comfort level. There is a speaker and video camera in the MEG scan room which allows you and the assistants to hear and see your child at all times to ensure that they are comfortable and to allow us to stop data collection if your child needs to rest.
- The EEG electrodes are also passive measurement devices that do not involve any direct risk to you. However, in rare cases, individuals can have skin irritation from the EEG paste, tape, gel or saline solution. Irritation should resolve within 1-2 hours after the scan. The EEG electrodes will be removed if you experience skin irritation. The eye monitoring devices do not involve any direct risk to you. These devices use infrared light to monitor eye movement/eye blinks. Infrared light is found in normal room and in sun light and does not pose any danger to the eyes at a distance. It allows us to obtain good data even in low light conditions.
- Radio and magnetic waves associated with MRI examinations are not associated with any known adverse effects. MRI is non-invasive and considered minimal risk by the FDA. However, the scanner is a large magnet, so it could move iron-containing objects in the room during the examination. This means that loose metal objects, like coin currency or key chains, are not allowed in the MRI room. If you have/has a piece of metal in the body such as a pacemaker, nerve stimulator, piercings or certain metal surgical implants, you will not be allowed into the MRI room and cannot have an MRI. While in the scanner, you may be bothered by feelings of claustrophobia (fear of small spaces). If you feel uncomfortable (nervous or nauseous) in the MRI scanner for any reason, inform the research staff. The MRI also makes loud 'drum' beating noises 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 your child during data collection. This allows the assistants to hear and see your child at all times to ensure that your child is comfortable and to allow them to respond if your child is uncomfortable. You may have the scan stopped at any time. No long-term adverse effects from MRI are known. However, since the effect of MRI upon early development of the fetus is unknown, subjects who are pregnant should not go in the MRI. If you are a woman or girl of child bearing potential and there is a possibility that you may be pregnant, you will be asked to take a urine pregnancy test before being allowed to participate in the study. If you are under the age of 18 and have already had your first menstrual period, we require that a pregnancy test is done before the MRI scan, but you are the only one that will get the results; we will not report the results of the pregnancy test to your parent or guardian. Rarely, large or recent 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.
- The largest risk to your child is normal infant/child handling. To the extent possible, we allow you to carry/handle your child. In addition, the researchers are all experienced and trained in infant/toddler handling. This risk includes the risk of falling. We minimize the risk of your child falling by having an investigator within arm's length during the data collection process.
- There are risks of stress and frustration if you cannot remain still or go to sleep in the new environment or cannot participate in the task(s). We generally recommend that the session be re-scheduled before your child gets frustrated to eliminate this risk.
- There is no more than minimal risk associated with the developmental testing or meeting with the FAS expert beyond a potential loss of privacy. Any forms generated from these sessions will only include you's unique identifying number to minimize this risk. A child may get frustrated by the developmental testing or physical exam. Clinicians who are accustomed to working with children and young adults will perform both procedures, so they are familiar with minimizing frustration to minimize this risk. There is also a risk of emotional upset to you as a parent or as a participant if the results of your/your child's developmental test suggest that you are developmentally delayed in some fashion. You will be notified by a clinical neuropsychologist if there are any adverse findings based on the developmental testing.

However, these results are not considered a complete developmental evaluation. If your child tests below expected levels, the recommendation is for you to follow-up with your child's doctor.

How will my information be kept confidential?
Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. Except when obtaining necessary information from your medical record when the doctor associated with the study needs to obtain this information, all personal identifying information is maintained by the study coordinator. All other data is coded with the study ID number, which is a randomly chosen number. The link between your personal identifying information and the study ID number is stored in an online database at MRN and on the study coordinator's computer. Only non-identifying information such as gender and diagnosis is directly associated with the MEG/MRI data. Any personal identifying information will be made inaccessible to the study team when the study is completed (within 1.5 years of closure to new enrollment). The record linking your name to your study ID number (which the study data is labeled with) will be kept indefinitely (forever) at the MRN in a confidential manner so that you may continue to have access to your MRI information. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

Information from your participation in this study may be reviewed by the NIH federal and state regulatory agencies, MRN and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research.

What are the benefits to being in this study?
There will be no direct benefit to you from being in this study. However, you will be notified by a trained neuropsychologist if your child's developmental testing results are different than expected and you will receive a report about your MRI scan. We hope information from this study will provide clinically beneficial information to young adults and children exposed prenatally to alcohol in the future. Early identification of exposure to alcohol during pregnancy could help identify children earlier to begin treatment at a young age. Also, it may help us better identify individuals who might benefit from drugs developed to help normalize brain development.

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.

What will happen if my child is injured or becomes sick because my child took part in this study?
No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) or MRN to provide free medical care or money for injuries to participants in this study. If you is injured or become(s) sick as a result of this study, UNMHSC will provide your child with emergency treatment, at your cost. It is important for you to tell your study doctor immediately if you have been injured or becomes sick because of taking part in this study. If you have any questions about these issues, or believe that you have/has been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?
You will be compensated for your time and effort in participating in this study. We will pay you $50 per visit for successful data collection. This will include at least two visits, one for developmental testing and one for neuroimaging. If you cannot cooperate or sleep for the neuroimaging session(s), preventing us from collecting data, we will compensate you $25. You will be paid in cash at the end of each visit. If your child is unable to go to cooperate, we will reschedule the imaging visits up to two (2) times to attempt to collect data. Therefore, there will be a maximum of $200 paid to you for your/your child's participation in this study.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your child's medical care in any way. If your child is frustrated you may cancel a testing session at any time. You can choose whether to reschedule for another attempt up to two (2) times or you can choose to fully withdraw from the 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. The NIH may stop the study at any time.

Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you and using this information within the research team to better understand how prenatal exposure to alcohol affects brain development. This information is "protected" 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/your child's protected health information for the purposes of this study. This information may include: supporting information from your/your child's entire medical record, information and data collected during research visits, MEG/MRI recordings, and video-taped recordings from the MEG session.

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

Right to Withdraw Your Authorization
Your authorization for the use and disclosure of your/your child's health information for this study shall not expire unless you cancel this authorization. Your/your child's health information will be used or disclosed 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 a letter notifying them of your withdrawal to: Julia Stephen, PhD, Mind Research Network, 1101 Yale Blvd. NE, Albuquerque New Mexico 87106.

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 and disclosure of your/your child's 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, Julia M. Stephen, PhD, or her associates will be glad to answer them at (505) 504-1053 or (505) 272-9297 during regular business hours. 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 UNM and the community who provide independent oversight of safety and ethical issues related to research involving human subjects.

What are my/my child's rights as a research subject?
If you have questions regarding your/your child's rights as a research subject, you may call the HRRC at (505) 272-1129 or visit the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

Consent and Authorization

You are making a decision whether to have your child participate in this study, or you are a legally recognized young adult deciding to consent to 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 you/your child's legal rights as a research subject.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form, I agree to have myself/my child participate in this study and give permission for my own (as a legal young adult participating in this study), or my child's health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form will be provided to me.

_____	_____/_____
Name of Adult Participant (print or type) or for Child Enrollment Name of Parent/Child's Legal Guardian	Signature of Adult Participant or for Child Enrollment Signature of Parent/Child's Legal Guardian Date

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

_____	_____/ _____
Name of Research Team Member	Signature of Research Team Member/Date

CHILD ENROLLMENT

_____	_____
Name of Child Subject (print)	Age of Child*

**Ages 7-11 should read and sign a separate "Assent to Participate in Research" form; ages 12-17 sign below.*

Child Assent (for ages 12-17 only)

The study doctor has explained this study to me in a way that I understand. I have had a chance to ask questions about the study and I understand the answers that were given to me. I have been told that I do not have to be in this study if I do not want to and that I can quit at any time. I have talked to my parents about being in this study.

_____	_____
Signature of Child Subject	Date