UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
ASSENT FOR INVESTIGATIONAL STUDIES

IRB NUMBER: 05-17-23.
IRB APPROVAL DATE: 2/22/2021
IRB EFFECTIVE DATE: 2/22/2021
IRB EXPIRATION DATE: 11/23/2021

Study Title: MEASURING BRAIN ACTIVITY OF SCHOOL AGE CHILDREN

Person in Charge: Dr. Deanne Wilson-Costello

What is a research study?

A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study?

You are being asked to take part in this research study because we are trying to learn more about how a child's brain may look or work differently if they were born too early. Children who were born early have different experiences as newborns that can affect the brain. Premature babies often have breathing problems that affect oxygen to the brain. We are inviting you to be in the study because you were born between 2004 and 2012. We want to study children who were born too early and those who were born on time. About 30 children will be in this study.

Why is the study being done?

The results of the study will help us to understand parts of the brain that may be changed by oxygen levels during the newborn period. This can help us develop treatments for children who are born early.

If you join the study what will happen to you?

We want to tell you about some things that will happen to you if you are in this study.

You will be asked to come to University Hospitals one time. You will need to stay for about 2 to 3 hours. You will need to wash your hair that day. You cannot use any hair oils or hair products after your shampoo. Your hair should be dry and combed out straight when you come for the study.

First, we will ask you a few questions about your health. A doctor or nurse practitioner will do a quick physical exam. We may ask you to give us a urine sample.

For the study, we will take pictures of your brain. We will measure how it is working while you are playing a memory game and a board game.

First, we will take pictures of your brain. This will take about 30 minutes. We will ask you to lay down on a table in a special room. The machine that takes pictures surrounds your head without touching it. It takes pictures using a big magnet. This is called an MRI. During the entire scan, we will be able to see you, and we can hear you and talk to you through speakers.

The magnet makes clanging noises while it takes pictures. We will give you headphones or earplugs to wear for the noise. During this time, we will have you play a memory game. We will show you alphabet letters on a screen. You will push a button when you see a letter that we have shown to you before.

Next, we will put a stretchy hat on your head to measure the working parts of your brain. The hat has small holes filled with a clear gel. This hat and gel helps us see the electrical activity from your brain. This is called an EEG. While you have the hat on, you will sit at a table and play a 5-minute board game. You will put small pegs into holes in a board. You will also play the same memory game that you played when we were taking pictures of your brain with the MRI scanner.

When the game is finished, we will remove the special hat and help you clean up the gel from your head and your hair.

Will any part of the study hurt?

None of the study will hurt, but you might feel that wearing the special hat bothers you. We will try to make this comfortable for you. We will also give you a cushion for your head when we take the MRI pictures.

The MRI machine takes pictures using a big magnet. We have to make sure you do not have any metal in or on your body. You will wear hospital pajamas during the study.

The machine is noisy but you will get headphones or earplugs to wear so the noise does not hurt your ears.

It may be hard to lie still during the scan, but you will have a button you can press if you feel nervous or uncomfortable and the test can be stopped.

Will the study help you?

This study will not directly help you.

Will the study help others?

This study might help us learn more about how the brain works for children who were born early.

Do my parents know about this study?

This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

Who will see the information collected about you?

The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.

The study information about you will not be given to your parents or teachers. If we happen to see something abnormal, we will talk with your parents about that.

If you are a girl, you may need to have a urine pregnancy test if you join this study. The

results of the pregnancy test would be given to you. If you are younger than 14, we will also tell your parents about the pregnancy test results. If the pregnancy test is positive and you are less than 14 years old, we are required by law to report pregnancies to the Cuyahoga County Department of Children and Family Services. If you are 14 years of age or older, we will tell your parent about the pregnancy test results only if they ask us. We will tell the University Hospitals Social Work Department about any positive pregnancy test so they can provide support for you.

Government law requires us to post a description of this study on the internet at http://www.clinicaltrials.gov. This website will not include information that can be traced to you. When the study is finished, the website will include a summary of the results. You can search this website at any time.

What do you get for being in the study?

You will get a $50 Amazon gift card for finishing the entire study. Your parent will get a $50 gift card too.

Will it cost anything to be in the study?

It will not cost you any money if you join the study.

Do you have to be in the study?

You do not have to be in the study. No one will be upset if you don't want to do this study. If you don't want to be in this study, you just have to tell us. It's up to you.

You can also take more time to think about being in the study.

What if I have any questions?

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call the Research Principal investigator of the study, Dr. Elizabeth Damato. Her number is (216) 368-2597. The site principal investigator for the study is Dr. Deanne Wilson-Costello and she may be contacted at (216) 844-3387.

You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

What choices do you have if you say no to this study?

This study is extra, so if you don't want to do it, you don't have to.

Other information about the study.

If you decide to be in the study, please write your name below.

You can change your mind and stop being part of it at any time. All you have to do is tell the person in charge.

You will be given a copy of this paper to keep.

_____
Write your name

_____ _____
Witness Date

_____ _____
Person Obtaining Assent Date

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CONSENT FOR INVESTIGATIONAL STUDIES
(v. 09.2016)

Project Title: MEASURING BRAIN ACTIVITY OF SCHOOL AGE CHILDREN

Principal Investigator: Dr. Deanne Wilson-Costello

Introduction/Purpose
Your child is invited to participate in a research study because he/she was born between 2004 and 2012. We are interested in differences in how the brain *looks* and how the brain *works* in children who were born early compared to children who were born at full term. If your child was born early, we may have identified him/her through a database at University Hospitals Cleveland Medical Center or from a prior research database kept by Dr. Deanne Wilson-Costello. If available to us, we will use information from your child's birth hospitalization from the database as part of this study. We expect to enroll a total of 30 children for this study. Twenty will be children who were born prematurely and 10 will be children who were born at full term.

Before you decide whether or not to allow your child to volunteer for this study, you must be informed of the purpose of the research study, how this study may help you/your child, any potential risks, and what is expected for participation. This process is called "informed consent." Dr. Elizabeth Damato and Dr. Michael Decker are the Research Principal Investigators conducting this study. Dr. Deanne Wilson-Costello is the site principal investigator.

This research project will involve taking pictures of your child's head (MRI) and measuring patterns of brain activity (EEG) recorded on the surface of the head. Magnetic resonance imaging (MRI) involves using a strong magnet and radio waves to produce a picture of body parts. Electroencephalography (EEG) involves recording electrical activity of the brain from the scalp. We will ask your child to play a word memory game during the MRI scan and a board game and the word memory game during the EEG recording. Together, these tests will help us gain a better understanding of the human brain.

We will also ask the parent (or parent proxy if the child is under the care of another adult) to complete survey questions about your child's behavior.

Your child's participation in this study is voluntary. Before you decide to participate or not, you should read the information below. Please ask questions about anything you do not understand. The purpose of this document is to provide you with information to consider in deciding whether to participate in this research study.

Screening
We will go over some pre-screening questions to see if your child will be safe having an MRI. We will ask you questions about your child's health. We will also ask if your child has had any claustrophobia before. Claustrophobia is a fear of being in a closed or narrow space. If your child has experienced symptoms of claustrophobia before, your child will be excluded from the study for his/her own safety. We will also ask about any tattoos, metal filings, heart valves, or medical

conditions (e.g. a current pregnancy) that could affect your child's safety. If your child has a pre-existing condition or ineligibility for the study, you/your child will not be able to participate in the study.

Study Procedures- MRI and EEG

As a participant in this study, you and your child will be asked to come to Case Western Reserve University Magnetic Resonance (MR) Facility located within University Hospitals on 11100 Euclid Ave, Cleveland OH 44106. Your child's participation will involve one visit lasting approximately 2-3 hours in length. Your child should have washed their hair that day and not used any conditioner or oils. Dr. Damato or a member of the research team will describe the procedures to you prior to your child's scan session. First, you will be asked to complete a magnetic resonance imaging (MRI) screening form to ensure that it is safe for your child to be in the study.

We will ask you some questions about your child's health since he/she was born. A doctor or nurse practitioner will do a quick physical examination of your child. Female children who have reached puberty will be asked to give us a urine sample to test for pregnancy.

We *may* need to learn more about your child's birth history and health since birth.
Please indicate below your permission to contact your child's primary care doctor about your child's birth history and health since birth:

[ ] Yes, I agree to allow the study staff to contact my child's doctor to get more information about my child's birth and health history.

Health Care Provider_____
Provider's address_____
Phone number_____

[ ] No, I do not want the study staff to contact my child's doctor for more information about my child's birth and health history.

First, we will instruct your child how to play the word memory game and teach them strategies for lying very still in the scanner. Then we will take your child into the scanner room. Your child will then be asked to lie on a long narrow table for 30 minutes while the MRI machine gathers data. During the study, the staff will collect images of your child's brain. Your child will hear tapping noises from the MR scanner and we will provide earplugs or headphones that your child will be required to wear.

While in the MR scanner room, your child will be asked to respond to one or more of the following experimental conditions:
1. Respond to a visual stimulus (e.g. visually presented words, letters or numbers on a screen).
2. Make small movements (e.g. move fingers or toes)

3. Think about a task the research team will read to him/her
4. Count backwards from 100
5. Lie still with no stimulation

While your child is in the MR scanner room, we will ask the parent or parent proxy to complete a survey asking about your child's behaviors. Answering these questions will take approximately 25-30 minutes.

After the MRI scan, we will next place a stretchy cap with holes in it over the top of your child's head. Some gel will be put through the holes and some wires will be attached to the cap that will record brain activity across the scalp.

While we are recording the activity from the brain, we will ask your child to play a board game where they will place pegs into holes in a board. We will also have them respond to visually presented words, letters or numbers on a computer screen. This takes about 5 minutes.

The MRI scan, the EEG recording, and the tasks are all painless. The only discomfort your child may experience is having to lie quietly in a small space while the pictures are being taken. Also, the EEG cap and gel can become uncomfortable after a while. At the end of the EEG recording session, we will bring your child to washroom facilities to clean up the gel.

Risks

Collision Hazard: Your child's participation in this study involves minimal risk. MRI uses a powerful magnet to take pictures of the brain, and because of this, your child/you will have to follow certain safety precautions to make sure your child does not have any metal objects in, or on, his/her body. Any loose magnetic or metallic objects can fly into the magnet. The following items must be removed before your child can enter the magnet room: hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, hair bands, and tools. When possible, these items should be left at home before coming to the study location. We will ask your child to change into a hospital gown or other suitable garment to avoid the risk of hidden metallic material in some articles of clothing such as buttons and snaps. Finally, your child will be asked to remove any eye shadow/makeup they may be wearing, because eye shadow/makeup sometimes contains metallic substances.

Some individuals should not participate in an MRI study. These include persons with some types of metallic implants, such as aneurysm clips or some types of prostheses (fake body parts). It also includes persons with electronic implants, such as cardiac pacemakers, intravascular shunts, stents or filters, hearing aids, and dental devices such as braces or dentures. The magnetic field of

the scanner can cause movement or malfunction of these devices.

Hearing: The MRI scanner produces tapping sounds during the scan, which may reach objectionable levels. To minimize any discomfort, your child will be provided with disposable earplugs or headphones. You may stop your child's participation in the study if the noise of the MRI scanner becomes too loud for them to tolerate.

Radio Wave Exposure: MRI uses a magnet and radio waves to make images (pictures) of the brain. There have been no ill effects reported from exposure to the magnetism or radio waves used for these studies; however, it is possible that harmful effects could be recognized in the future.

EEG: This is a non-invasive procedure that collects electrical activity from the brain. The EEG recording is painless. Risks include the possibility for local skin irritation from the gel or the electrodes (wires). The EEG cap and gel can become uncomfortable after a while. At the end of the EEG recording session, we will take your child to facilities where we will help them clean off the gel from their hair and scalp.

Claustrophobia: The confining conditions of the MRI scanner can precipitate claustrophobia (feelings of being "closed in") in some people. You may stop your child's participation in the study if he/she has feelings of claustrophobia during the study.

Neuro-behavioral Testing: Risks related to the board game (placing pegs into a board as fast as they can) and playing a word memory game in the scanner are minimal and are limited to the time burden of completing the tasks. Likewise, responding to survey questions about your child's behaviors presents minimal risks to the parent or parent proxy and is limited to the time burden of answering the questions.

Reproductive Health/Sexual Activity: The effect of MRI on pregnancy and a fetus is not known. For that reason, if your child may be pregnant or planning to become pregnant, your child may not participate in this study. We will do a urine pregnancy test on all females in the study.

Confidentiality: Your name/your child's name will not be used in any written or oral report of the study. A number will be used to identify all information supplied. Your/your child's identity will be known only to the study staff.

A positive pregnancy test in girls under the age of 13 will be reported to you and to your child as well as to the Cuyahoga County Department of Children and Family Services (216-696-KIDS) as required by law. We will also notify University Hospitals Social Work about any positive pregnancy tests so they can provide support to your child. If your child is age 14 or older, we will report a positive pregnancy test to the child and will tell you about a positive pregnancy test only if

you ask for that information. Additionally, if the study personnel become aware of abuse or neglect of your child, we will notify the appropriate county social services agency as required by law.

Study Results

Research scans are not designed with the validity and vigor required for identification of any potential incidental findings. It is therefore standard practice at other institutes, as well in all other ongoing studies within the Case Center for Imaging Research at UHCMC, that no diagnostic review be conducted. However, it is possible that abnormalities will be noted. Less than 3 of every 100 healthy children will show an abnormality on brain MRI scans. Abnormal waveforms on the EEG may be detected in 2-3 of every 100 children without symptoms. If we note any abnormalities, we will advise you to seek care from your child's healthcare provider. Otherwise, you will not be informed of the results of the tests.

Benefits

There will be no direct benefits to you or your child. These studies are expected to help provide basic insight into how certain parts of the human brain may be affected by experiences following preterm birth.

Alternatives to Study Participation

The alternative to the study is simply not to participate.

Financial Information

Other than parking fees, there are no costs to you or your insurance for participation in this protocol. As a token of appreciation of the time and effort you/your child have made to be in this study, and to cover your expenses of parking, we will compensate you $100 (a $50 Amazon gift card for your child and a $50 Amazon gift card for the parent or parent proxy).

Student/Employee Rights

Participation in this study or refusal to do so will in no way influence the grades, employment, or subsequent recommendations for you or your child. Taking part in this study is voluntary. You/your child may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. We will tell you about new information that may affect your health/your child's health, welfare, or willingness to stay in this study.

Future Research Contact

The study staff may want to contact you after the completion of this study for future research studies. Participation of these future study opportunities for you/your child is strictly voluntary,

and you may refuse to be contacted for future research. If you agree, we would keep your name and phone number for 5 years from the day you consent in the event that you/your child would be eligible for future research.

Please indicate below your interest in being contacted for future related studies:

[ ] Yes, I agree to be contacted by the study staff for possible future research studies

[ ] No, I do not want to be contacted by the study staff for possible future research studies

Confidentiality

Your/your child's study information and results will be stored by an assigned number instead of your name, and your data will be encrypted or protected in a computer. The medical and research information recorded about you/your child will be used within University Hospitals/Case Western Reserve University and/or disclosed outside University Hospitals/Case Western Reserve University as part of this research. Upon completion of the study, you may have access to the research information. The results of your examinations will be collected in a centralized computer or data registry at UHCMC MRI facility, Cleveland, Ohio, 44106. Social security numbers will never be linked to names. Access is granted to the site principal investigator Dr. Deanne Wilson-Costello and approved faculty and staff working on the study.

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

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Measuring Brain Activity of School Age Children" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Research Principal Investigator, Dr. Elizabeth Damato, the site principal investigator Dr. Deanne Wilson-Costello, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

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Principal Investigator: Dr. Deanne Wilson-Costello

Generally, the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about your child: age, gender, medical history, MRI/EEG data. This PHI will be used to help us interpret information about brain function. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Damato, Dr. Decker, Dr. Wilson-Costello and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to the Research Principal Investigator Dr. Elizabeth Damato, Frances Payne Bolton School of Nursing, Case Western Reserve University, 2120 Cornell Rd, Cleveland, OH 44106. Alternatively, you may write to the site principal investigator Dr. Deanne Wilson-Costello, Department of Pediatrics, University Hospitals Cleveland Medical Center, 11100 Euclid Ave, Cleveland, OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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Principal Investigator: Dr. Deanne Wilson-Costello

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Case Medical Center Institutional Review Board may review your study records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed, your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Research Principal Investigator Dr. Elizabeth Damato can be contacted at (216) 368-2597 or the site principal investigator Dr. Wilson-Costello can also be contacted at (216) 844-3387. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the University Hospitals Case Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Case Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your/your child's participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	
Signature of Participant	Date
X	
Printed name of minor if used to obtain assent	
X	
Signature of Parent/Legal Guardian	Date
X	
Printed name of Parent/Legal Guardian	
X	
If Legal Guardian, indicate relationship to child	

Witness signature required only if included in the consenting process

X	
Signature of Witness	Date
X	
Printed Name of Witness	

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Study personnel (only individuals designated on the checklist may obtain consent)

X	
Signature of person obtaining informed consent	Date
X	
Printed name of person obtaining informed consent	