



SYRACUSE UNIVERSITY

DEPARTMENT OF PUBLIC HEALTH, FOOD STUDIES AND NUTRITION

DAVID B. FALK COLLEGE
OF SPORT AND HUMAN DYNAMICS

Title of Study: Syracuse Lead Study

INVESTIGATORS:

| | | | |
|--|----------------------|---|-----------------------|
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Consent/Authorization Form

Background/Purpose:

Your child is being asked to take part in a research study in order to (1) check how your child's heart reacts to some computer games, (2) measure chemicals in your child's blood, urine, and hair, including (but not limited to) lead, cadmium (a chemical that is a metal and is used, for example, in making batteries), mercury, and fats, (3) measure genetic material in your child's blood, (4) measure how your child's heart works and looks, and (5) collect information from questionnaires and interviews that ask questions such as how your child might act and feel.

Your child was selected because s/he is between the ages of 9 and 11 and lives in certain areas of

Syracuse that are known to include some children with higher levels of lead. However, we did not pick your child because of any warning that s/he specifically has these higher levels of lead or other chemicals in his/her blood.

Research studies are voluntary (include only people who choose to do the study). Please take your time to make your decision. Please ask the study doctor or the study staff to explain any words or information that you do not understand. You may also want to discuss it with family members, friends or other health care workers.

In our earlier studies, we found that children with slightly higher levels of lead in their blood responded to computer games with somewhat higher blood pressure. We are still working on this research and trying to see if these blood pressure changes are also linked with slight changes in the shape of their hearts.

300 children are likely to take part in this study.

Study Procedures:

Your child's involvement will occur in 2 parts:

1. On a Saturday morning, your child will be scheduled to have fasting (nothing to eat or drink after midnight) blood drawn at Syracuse University (Location: 500 Crouse Avenue, Syracuse). This blood will be drawn from a vein in your child's arm. The amount of blood that will be taken is around 4 tablespoons. This amount is well within what is thought to be an okay amount of blood that can be drawn safely from a child. Your child should not take any medications that have an impact on their heart before the blood draw as discussed on the phone when you scheduled the appointment. We will collect a hair sample from the back of your child's head (leaving no noticeable bald spots) and ask them to provide us with a urine sample. In addition, we will collect body measurements such as height, weight, BMI (body mass index), waist and hip circumference.

During this visit, we will ask your child to fill out some surveys about how nervous or angry he/she feels, questions about your family, and a brief test of intelligence.

NY State Department of Health requires us to report high levels of certain metals in the blood and the Onondaga County Health Department will follow-up on these higher levels. However, all the results of these blood tests will also be given to your child's family doctor, or to Dr. Robert Morgan, if your child does not have a doctor. Dr. Morgan is part of this research study. Levels of fats and sugar in your child's blood will also be given to your family doctor (or Dr. Morgan) and follow-up care will be their job. Your child will get this care from Dr. Morgan even if your child has no health insurance. This entire visit should last about 3 hours.

Your child will be sent home wearing a device on his/her wrist that looks like a watch but actually measures movement. We will also send home some special tubes to collect your child's saliva over a few days. The saliva will be used to measure cortisol, which is a stress hormone.

Finally, we will be phoning you a few different mornings for a brief review of what your child ate

during the day.

2. Next, we will schedule your child for a visit to the Syracuse University area for testing at 3 different locations (once you arrive, we will help you and your child get to each of these locations). Your child should not take any medications before this appointment, just like the first visit. One test (an echocardiogram or “echo”) will be done by another doctor who is part of this study (Dr. Atallah-Yunes). This echo will be done at Dr. Atallah- Yunes office at 725 Irving Avenue (8th floor – room 804). This test involves the use of a pen-like gadget and some gel placed on your child’s chest by a female assistant. The device is used to create a kind of picture of your child’s heart. This picture will be evaluated by Dr. Atallah-Yunes and the results will be sent to your child’s family doctor. Your child’s doctor will be responsible for your child’s follow-up care, if needed. If your child does not have a doctor, Dr. Atallah-Yunes will be responsible for your child’s follow-up care, if needed. Again, your child will receive this care regardless of whether or not your child has health insurance. A second echo (slightly different) will be conducted by Dr. Heffernan at 201 Women’s Building, Syracuse University. This echo will also involve a pen-like gadget and gel, but, we will measure areas in the neck and legs. Finally, we will bring you and your child to our lab at 500 Crouse Ave, Syracuse University. During this visit, a female researcher will put some sensors on your child’s chest and neck, and a blood pressure cuff on one arm. We will measure heart rate, blood pressure, and blood flow rate with these sensors. All the sensors are painless. After all of the sensors are in place, your child will sit comfortably in a lounge chair and rest for about 10 minutes. Following this, your child will play 4 computer games. A few more surveys may be done during this visit and at the end one of our lab staff will tape record a session where they briefly talk to you and then your child about their feelings and stress. The audio tape will only be used by the research team for analysis and will be destroyed at the conclusion of the study in 2016. The total time for this campus area visit should be around 4 hours.

Parent’s tasks for the study: In addition to your help getting your child to these appointments, we will be asking you to complete a series of questionnaires and assessments during the 3 hours of your child’s first visit (the one that includes the blood draw). These measures will help us better understand why your child responds in a certain way to the computer game s/he will be playing. The surveys are similar to many that your child will complete, and include questions about your feelings, attitudes, as well as surveys regarding your child’s diet. You will also be asked to complete a 15-minute intelligence test and the audio taped interview mentioned above.

Feedback: For some measures (such as your child’s depressive symptoms), we know what is considered “normal”. If your child’s score is outside of a normal range, we will discuss the results with you shortly after the measure is taken during your first visit to campus and send a copy of this information to your child’s primary care physician. Because this is a research study, we do not make clinical determinations and I would encourage you to only consider these scores as something potentially requiring follow-up.

Saving Blood Specimens for Future Genetic Testing:

In addition to the research to which you are allowing your child to participate under this study, Dr. Gump and other researchers at this or other institutions may wish to study your child's left over blood sample in future genetic research; however, any samples sent to other researchers or institutions would be "de-identified" (meaning, they will only be sent to other researchers with a code number and not your child's name or other identifying information). Information from this genetic testing of your child's samples would be able to be linked back to your child by us until your child's 18th birthday. However, at that time the names and identification numbers will be decoupled in all records, meaning that we will no longer be able to link the sample back to your child. For research purposes, these de-identified sample(s) may be kept for an additional period, possibly up to 50 years. **Parent or Guardian initials** _____

Genes are the basic biological unit of heredity. Genes are composed of the genetic material called DNA (deoxyribonucleic acid). DNA is the part of the cell that is responsible for providing hereditary characteristics (such as eye color) and is used to build proteins. The measurement of genetic material (DNA) may be used to see if each child responds differently to lead because of differences in genes. Since the significance of these tests is not known for you, we will not release the results of any genetic testing. No formal counseling will be provided under this study.

Risks & Discomforts:

- **Heart sensors** on your child's chest and neck may feel uncomfortable when the sensors are removed, much like removal of a Band-Aid. There may be some redness on the neck and chest where the sensors were placed, but this redness should not last more than a few hours or a few days, depending on your child's skin.
- **Computer games** may create some stress, but this will be no worse than many things that happen in normal everyday life, such as playing videogames at home.
- **Blood drawing** may cause pain and/or bruising at the location on your child's arm where the blood was taken. On rare occasions, it may cause dizziness or fainting and an infection.
- **Answering Study Surveys** should not pose any risk to you or your child.
- **Echocardiograms** should pose no risk or discomfort to your child.
- **Privacy:** Because your child's medical and genetic data is coded and will NOT have any identifying information about your child (for example, your child's name, address, telephone number, birth date, or medical record number), the risk of linking this back to your child by those outside our research team is very small. Only Dr. Gump will have the key to the code which links your child's unique study ID number and personal data and this information will only be shared with others as part of the research or for purposes outlined below (see "Confidentiality of Records and Authorization to Use/Share Protected Health Information for Research" below).
- **Genetic Testing:** Some tests reveal information that may affect a person's

ability to get or keep medical and/or life insurance. It is very unlikely that the tests in this study will have any effect on your child's ability to obtain or keep health insurance.

Genetic tests may reveal other information unrelated to this study. For example, in cases where parents and children are both tested, the test may disclose the possibility that the father is not the biological parent.

Medical research has already shown that some people have a higher chance of developing certain medical diseases or disorders. It is possible that this research could lead to genetic stereotypes that could stigmatize all members of a population group, whether they possess the gene or not. For example, people who live in a certain area, or people belonging to a particular ethnic group, etc. Such information may affect insurance coverage or employment.

Benefits:

Your child's doctor will be provided with information on the levels of possible harmful chemicals, including lead and mercury. In addition, we will get information about how these chemicals might relate to some changes in how your child's heart reacts to computer games. This study may also help us to better understand responses to stress that may lead to health problems in adulthood.

Voluntary Participation/Study Withdrawal:

You do not have to allow your child to have these blood samples taken and tests conducted. These are all being done for research purposes only. Your child's participation in this study is entirely voluntary. You and your child have the right to have your child leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which your child is entitled. Your decision about whether or not to allow your child to take part in the study will not affect any relationship you or your child might have with Syracuse University.

If you withdraw your permission for your child to participate in this study, your child's biological samples will be destroyed. Please notify the study team if you no longer want your child's samples to be included in this research study.

Costs/Payments:

Your child will be paid \$100 after they are done with all parts of the study. In addition, you will be given \$50 for your time and any transportation costs. If a subject and/or parent/guardian withdraws prior to the completion of the study compensation will be prorated at \$30 for each part completed; 1) blood draw, 2) Gump Laboratory testing, 3) echocardiograms. Parental/guardian reimbursement for travel will be \$25 per visit for a total of \$50 regardless of amount of the study completed by subject. Payment is allocated at the end of the second visit or time of withdrawal. Missing minor components of the study (e.g. surveys, saliva samples, nutrition information) will not result in any reduction of payment. Subjects are informed in the assent/consent process and it is reiterated verbally that they can stop any survey or task at any time during the study. Subject

pay of up to \$100 is given to the subject, the reimbursement for travel of up to \$50 is given to the parent/guardian.

In addition, by accepting payment for participating in this study, certain identifying information about you and your child may be made available to professional auditors to satisfy audit and Federal reporting requirements, but confidentiality will be kept. Please note that if you earn \$600 or over in a calendar year as a research subject, you may have to pay taxes on these earnings.

Questions:

If you have any questions about the research, or in the event of a research-related injury, please contact Dr. Gump at (315) 443-2208. If you have any questions about your child's rights as a research subject, please contact the Syracuse University Institutional Review Board Office at (315) 443-3013.

In Case Of Injury:

In the event of illness or physical injury resulting from taking part in this research study, medical treatment will be provided at University Hospital. You will be responsible for any costs not paid by your child's insurance company. No other compensation is offered by Syracuse University. Syracuse University has no plans to give you or your child money if your child is injured. You have not waived any of your child's legal rights by signing this form.

Confidentiality of Records and Authorization to Use/Share Protected Health Information for Research:

If you agree to allow your child to participate in this research, identifiable health information about your child will be used and shared with others involved in this research. For your child to be in this research we need your permission to collect and share this information. Federal law protects your child's right to privacy concerning this information.

When you sign this consent form at the end, it means that you have read this section and authorize the use and/or sharing of your child's protected health information as explained below. Your signature also means you have received a copy of Syracuse University's Notice of Privacy Practices.

Individually identifiable health information under the federal privacy law is considered to be any information from your child's medical record, or obtained from this study, that can be associated with your child, and relates to your child's past, present, or future physical or mental health or condition. This is referred to as protected health information.

Your child's protected health information will be kept confidential. Your child's identity will not be revealed in any publication or presentation of the results of this research.

Why is it necessary to use/share your child's protected health information with others?

The main reason to use and share your child's health information is to conduct the research as described in this consent form. Your child's information may also be shared with people and

organizations that make sure the research is being done correctly, and to report unexpected or bad side effects your child may have.

In addition, we may be required by law to release protected health information about your child; for example, if a judge requires such release in a lawsuit, if your child tells us of his/her intent to harm himself/herself or others, or in instances of child abuse or neglect.

What protected health information about your child will be used or shared with others as part of this research?

We may use and share the results of tests, questionnaires, and interviews. We may also use and share information from your child's research records. We will only collect information that is needed for the research.

Who will be authorized to use and/or share your child's protected health information? The researchers and the staff participating in the research will use your child's protected health information for this research study. In addition, the Syracuse University IRB, committees responsible for protecting the rights of research subjects, and other Syracuse University staff who supervise the way the research is done may have access to your child's protected health information.

The researchers and their staff will determine if your child's protected health information will be used or shared with others outside of Syracuse University for purposes directly related to the conduct of the research.

With whom would the protected health information be shared?

Your child's protected health information may be shared with:

- Federal agencies that supervise the way the research is conducted, such as the Department of Health and Human Services' Office for Human Research Protections, or other governmental offices as required by law.

All reasonable efforts will be used to protect the confidentiality of your child's protected health information. However, not all individuals or groups have to comply with the Federal privacy law. Therefore, once your child's protected health information is disclosed (leaves Upstate Medical University), the Federal privacy law may not protect it.

For how long will your child's protected health information be used or shared with others?

There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be used and analyzed for many years and it is not possible to determine when this will be complete.

Can you withdraw your authorization to collect/use/share your child's protected health information?

You always have the right to withdraw your permission (revoke authorization) for us to use and

share your child's health information, by putting your request in writing to the investigator in charge of the study. This means that no further private health information will be collected. Revoking your authorization only affects uses and sharing of information obtained after your written request has been received, but not information obtained prior to that time.

Even after you withdraw your permission Syracuse University may continue to use and share information needed for the integrity of the study; for example, information about an unexpected or bad side effect your child experienced related to the study.

Can you have access to your child's health information?

At the end of the study, you have the right to see and copy health information about your child in accordance with the Syracuse University policies; however, your access may be limited while the study is in progress.

*Departments of Child and Family Studies / Marriage and Family Therapy /
Public Health, Food Studies and Nutrition / Sport Management / School of Social Work*

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<http://falk.syr.edu>

315-443-4907

Consent To Participate In Research & Authorization To Use And Share Personal Health Information:

For the Parent:

I hereby give my consent to participate in this research study and agree that my personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form.

Signature of subject

Date

For Subjects less than 18 Years of Age

The nature and the purpose of the above Research Study have been explained to my child and me; we have agreed to have my child participate in the research study. We also agree that my child’s personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. We will receive a signed copy of this consent form.

Name of Child (Print): _____

Name of Parent/Guardian (Print): _____

Audio Recording, please mark one choice below for your child and yourself:

Child:

_____ I agree to have my child recorded (audio)

_____ I do not agree to have my child recorded (audio)

Parent/Guardian:

_____ I agree to be recorded (audio)

_____ I do not agree to be recorded (audio)

Signature of Parent/Guardian

Date

Signature of Person Obtaining Consent/Authorization

Date

Name of Person Obtaining Consent/Authorization