CONSENT FORM

TITLE OF RESEARCH: Vestibular function and balance in children with congenital cytomegalovirus (cCMV) infection.

IRB PROTOCOL NO.: X150219002

INVESTIGATORS: Suresh Boppana, MD, Jennifer B. Christy, PhD, Karen Fowler, DrPH

SPONSOR: Department of Pediatrics, UAB

For Children (persons under 18 years of age) participating in this study, the term “You” addresses both the participant ("you") and the parent or legally authorized representative ("your child").

Purpose of the Research

You are being asked to participate in a research study of cytomegalovirus infection. Cytomegalovirus (or CMV) is the leading cause of congenital infection—infestation of the baby while it is still in the mother's womb. It is estimated that 5 to 10 out of every 1000 babies born will have a congenital CMV infection. Although most babies with congenital CMV infection do not have any problems due to the virus, around 15% will have hearing loss, visual problems, physical or developmental disabilities. Studies have recently showed that children with congenital CMV infection are also at risk to develop disorders of the vestibular system, which is responsible for postural control, motor abilities, stable gaze and balance. This study is being done to find out more about the link between CMV and vestibular system abnormalities. You are being asked to participate in this study because your child was born with a congenital CMV infection.

Approximately 15 participants will be enrolled and evaluated for vestibular function and balance disorders. It is important to learn more about the extent of vestibular involvement in children with congenital CMV infection to enable early identification and look for ways to reduce and prevent problems associated with CMV and vestibular dysfunction.

Explanation of Procedures

The anticipated time for the single clinic visit for participation in this study is approximately 90 minutes and will involve the activities listed in items 1-8. You may also be offered the opportunity for a separate hearing examination, as described in item 9 below.

1. One visit in the Vestibular and Oculomotor Research Laboratory located in the Henry Peters Building (Dept. of Optometry) on UAB Campus.
2. A member of the research team will gather basic information such as name, address, contact phone numbers, and pediatrician.

3. An enrollment interview so that we can obtain information concerning your child’s medical history related to CMV, hearing loss and vestibular function. The doctor or qualified study personnel will also ask questions and discuss your child’s developmental history.

4. Permission for us to review a copy of your and your child’s records from the CHIMES study to gather information important to the study.

5. A developmental assessment.

6. Completion of a questionnaire called the Questionnaire of Dizziness, Eye and Balance (QDEB). The QDEB asks questions about developmental milestones and a child’s ability to do tasks that require good balance (for example, riding a two-wheeled bicycle). It also asks about how dizzy a child feels during daily activities.

7. Tests to assess vestibular function and balance which will include the following:
   a) Dynamic Visual Acuity Test: This test will allow us to know how well you are able to see with your head still, and then with your head moving from side to side. You will sit in front of an eye chart and will be asked to identify symbols. You will complete the test again, but with the examiner moving your head as if you are shaking your head saying “no.” This test will be done twice. This test will not be done if you have neck problems or pain.

   b) Head Thrust Test: You will be asked to focus your eyes on the examiner’s nose. The examiner will grasp your head and then quickly move your head a small amount to one side and then the other as you attempt to keep your eyes on the examiner’s nose. This will be done 6 times. This test will not be done if you have neck problems or pain.

   c) Tympanogram: This is a test of how well your eardrum is working. During this test, you will feel some pressure and hear some sounds but it will not be painful.

   d) Vestibular Evoked Myogenic Potentials (VEMP): This is a test of how well your inner ear works in response to audible clicks in your ear. You will lie on an examination table. We will clean the skin over your neck and forehead, and place recording electrodes (like stickers) on your neck muscles, under your eyes, on your forehead and on your chest. We will then place a soft earphone in your ear canal. For the first test, you will raise your head as you look to the side while clicks are delivered into the earphone. This will take about 30 seconds. For the second part of the test, you will lie still and look up with your eyes while the clicks are delivered into each ear. You can take a break at any time during the testing.

   e) Rotary Chair Test: You will sit in the motorized chair and we will place seatbelts around your lap and shoulders and put padded straps around your ankles. You will then put on goggles similar to a scuba mask that will measure your eye movements. Your head will then be secured with pads on your forehead so that you cannot move your head during the test. You will be asked to put on headphones with a microphone. The rotary chair is in a small room that will be completely dark when
the door is closed. However, cameras will enable us to see you at all times, you will be able to hear the examiner through the headphones and talk to the examiner through the microphone. At any time you can tell the examiner to stop the test and we will immediately do so. If the chair is rotating, it will gently slow down to a complete stop. During the tests, you will be asked to be still as you: 1) look at lights as they move on the wall; 2) are moved in the chair from side to side at various speeds and 3) slowly spin in a circle to the right or the left. We will measure your eye movements during these tests. You will be free to blink at any time, but we need you to keep your eyes open so that your eye movements can be recorded. We will explain each aspect of the test. You can take a break at any time during the testing by letting the examiner know that you need a break.

f) Sensory Organization Test (SOT): This will test your ability to maintain balance under various conditions. You will be placed in a safety harness and will stand on a platform which can move in response to your sway. Safety straps will attach to the harness to prevent falls. The examiner will constantly guard you throughout the testing. You will be asked to stand as still as possible under 6 conditions: 4 with eyes open and 2 with eyes closed (blindfolded). Each condition is measured for 20 seconds and 3 trials of each condition will be completed.

h) Standardized Balance Test: You will be asked to try 9 activities to evaluate balance, such as walking on a line and a low 2 inch high beam, standing on one leg, and walking heel-to-toe. Six activities will be with eyes open and 3 with eyes closed. You will complete each task up to 2 times.

8. If applicable, permission will be requested to obtain results of any tests or evaluations your child may have had that are related to hearing or the diagnosis of congenital CMV infection (for example, additional hearing tests, CT scans, or developmental evaluations). Before we obtain any results, you would be asked to sign an additional medical information release form.

9. If your child has not had a complete hearing exam with in the last year, we can schedule a hearing evaluation at the Sparks Clinics at your convenience. This will be a behavioral test conducted in a hearing booth. Your child will wear insert style headphones and respond to sounds with age appropriate responses. You can be with your child during the testing. This evaluation will be paid for by the study.

Risks and Discomforts

Potential risks are minimal. The physical risks are related to mild pain and discomfort during lead placement for VEMP test and dizziness during rotary chair test. We do not expect significant psychological, social, legal, or other risks. The information collected will be maintained confidentially. We are not investigating treatments.
Benefits

Participation of your child in this research project may provide useful information about CMV and vestibular and balance disorders which could help other children in the future. Also, you will receive a report with the results of the test and an explanation of the results. If any of the results are abnormal you will be referred to the appropriate health care provider for follow-up.

Alternatives

The alternative to participation in this research study is not to participate.

Confidentiality

All of the information gathered during this study will be kept confidential to the extent permitted by law. The study records are kept in locked file drawers or secure computer files accessed only by login and password. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf the Office for Human Research Protections (OHRP).

The information from the research may be presented at scientific or professional meetings or published for scientific purposes; however, your and your child’s identity will not be given out.

Your medical record might indicate that you are participating in a research study and will provide the name and contact information for the principal investigator.

A specific limitation to the confidentiality is that the healthcare professionals involved in this research have a legal responsibility to report suspected cases of abuse, neglect, or exploitation to the appropriate legal authorities in the interest of protecting the rights and welfare of those at potential risk.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

Cost of Participation

There will be no cost to you for taking part in this study. All procedures related to this study will be provided to you at no cost during the study period. The costs of standard medical care will be billed to you and/or your insurance company in the usual manner.
Payment for Participation in Research

You will be paid $75 to compensate you for your time and any inconvenience. Payment will be made by cash or a gift card and given to you at the clinic visit.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Boppana. He will be glad to answer any of your questions. Dr. Boppana's number is 205-996-7765. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

You are making a decision whether or not to have your child participate in this study. Your signature indicates that you have read (or been read) the information provided above and decided to allow your child to participate.

You will be given a copy of this signed informed consent document.

Signature of Parent or Guardian  Date

Signature of Principal Investigator or Person Obtaining Consent  Date

Signature of Witness  Date

Waiver of Assent

The assent of __________________________ (name of child/minor) was waived because of: Age ______  Maturity ______  Psychological state of the child ______

Page 5 of 6
Version Date: 08/15/16
University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION
FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name: ___________________________ UAB IRB Protocol Number: X150219002
Research Protocol: Vestibular function and balance in children with congenital cytomegalovirus (cCMV) infection.
Principal Investigators: Suresh Boppana, MD; Jennifer B. Christy, PhD; Karen B. Fowler, DrPH
Sponsor: Kaul Pediatric Research Institute Foundation

What health information do the researchers want to use? All medical information and personal identifiers, including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children’s of Alabama, Eye Foundation Hospital and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: ___________________________ Date: _________
or participant’s legally authorized representative: ___________________________ Date: _________
Printed Name of participant’s representative: ___________________________
Relationship to the participant: ___________________________

Page 6 of 6
Version Date: 08/15/16