Vanderbilt University Institutional Review Boar
Informed Consent Document for Research

Principal Investigator: XXXXXXXXXX Revision Date: XXXXXX
Study Title: XXXXXXXXXX
Institution/Hospital: Vanderbilt Children's Hospital

This informed consent applies to: Parents of typically developing children

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

1 What is the purpose of this study?
You and your child are being asked to participate in this research study because: 1) your child is a younger sibling of a child with typical development; and 2) s/he is participating in an ongoing study conducted by XXXXXXXXXX or XXXXXXXXXX. The purpose of this project is to understand the early social and physical development of younger siblings of children with autism. We are especially interested in whether particular patterns of head growth in the early years may be an early marker of autism. To learn about this, we need to also study a comparison group of children (like yours) who are at elevated risk for autism.

2. What will happen and how long will you be in the study?
At each visit (up to 7 visits depending on how young your child is when you enter the study); we would like to measure your child's head size, along with his/her height and weight. We will take these measurements just like they do in your doctor's office; we will use a soft single-use tape measure to measure your child's head, will measure weight by having your child either lay down or stand on a scale, and will measure height either lying down or standing tall next to the wall. We will ask for your permission to contact your child's primary health care provider to obtain copies of these same growth measurements that were taken since your child was 2 months old. At your child's regularly scheduled visits that are closest to ages 6 months, 12 months, and 18 months, one of our researchers will play with your child to measure his or her social and communicative responses. This additional set of procedures will add about 1/2 hour to your visit.

We will give children as many breaks as they need during these evaluations. The diagnostic assessments may be videotaped so they can be scored accurately.

3. Costs to you if you take part in this study:
There are no costs related to your participation in this study. Your health Insurance will not be charged. The time you spend traveling to Vanderbilt and participating in research procedures may be considered an inconvenience.

4. Side effects and risks that you can expect if you take part in this study:
There are no risks associated with this study. Our evaluation procedures are designed in a manner that sensitive to the needs of children. However, sometimes children can become tired or distressed during evaluations. If your child becomes upset, we will consult with you to determine how and whether to proceed. Options will include giving your child a break, providing distractions such as a snack or a preferred toy, discontinuing and rescheduling the session, or discontinuing participation in the study. We will respect your decision. There may be unknown or unforeseeable risks associated with participation.

5. Payment in case you are injured while in this study:
Immediate and necessary care for accidents that cause harm to your child will be provided at Vanderbilt University without charge if you are hurt from being in this research study. Vanderbilt will not pay for further treatment beyond this care nor provide money for such injury.

6. Good effects that might result from this study:
There are no direct benefits to you from participating in this study: However, the benefits to science and humankind that result from this study are an increased understanding of whether the physical growth patterns of children might be early markers of autism. This understanding may help us identify autism earlier so that children can begin to receive intervention at younger ages.

***7.* Other treatments you could get if you decide not to be in this study:**
Measures of head size, height, and weight are available through routine pediatric care.

8. Payments for your time spent taking part in this study or expenses:
There is no additional compensation available for this study. You will be compensated through the original research project in which you are already participating.

9. Reasons why the study doctor may take you out of this study:
Children will not be able to participate or continue to participate in this research project if they do not meet the inclusion criteria. The investigators may end your participation if you miss scheduled appointments without notifying us in advance, if you are no longer able to travel to the medical center for these appointments, or if we are unable to accommodate any unanticipated needs you may have. If while participating in any stage of this study, your child becomes upset and shows by their actions (e.g., increases in aggression, repeated removal of the measuring tape) or their words that they don't want to participate anymore, we will consult with you to make a decision about honoring your child's desire to withdraw from participation.

10. What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell XXXXXXXXXX or one of the research assistants.

11. Who to call for any questions or in case you are injured:
If you should have any questions about this research study, or if you feel you have been hurt by being a part of this study, please feel free to contact XXXXXXXXXX at (XXX) XXX-XXXX or the research staff at (XXX) XXX-XXXX. If you cannot reach the research staff, please page XXXXXXXXXX at (XXX) XXX-XXXX.

For additional information about giving consent of your child's rights as a person in this study, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273, or email at http://mcapps01.mc.vanderbilt.edu/IRB/WkshpReg.nsf/SuggestionForm?OpenForm.

12. Confidentiality and Privacy of Protected Health Information:
All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt University Medical Center (VUMC) as a result of your child's healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your child's PHI as described below.

As part of the study, XXXXXXXXXX and XXXXXXXXXX and their study team may share the results of your study and/or non-study linked diagnostic and developmental evaluation results, as well as the height, weight and head circumference information, as well as parts of your child's medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and the National Institute of Child Health and Human Development (NICHD). Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your child's research record for at least six years after the study is finished. At that time, the research data that has not been put in your child's medical record will be destroyed. Any research data that has been put into your child's medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact XXXXXXXXXX or XXXXXXXXXX in writing and let her know that you withdraw your consent. Her mailing address is XXXXXXXXXX. At that time, we will stop getting any more data about your child. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your child's treatment, payment or enrollment in any health plans or affect your child's ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title