

Study to Explore Early Development

PARTICIPANT CLINIC VISIT PREPARATORY GUIDE AND SCHEDULING BOOKLET

Please use the information in this booklet to help you prepare for the major parts of the study. You can use this front cover page to keep track of the dates and times of your scheduled interviews and home/clinic visits. You will be able to combine multiple steps into one visit if this is easier for you. Please check each study step once it is complete so that you can see what else needs to be completed before the end of the study.

Study Step	Date/Time Scheduled	Location of Appointment	Check Once Complete
Primary caregiver interview			
First Questionnaire Packet			
Second Questionnaire Packet			
Clinic Visit: Child developmental evaluation			
Clinic Visit: Child blood and hair sample and brief exam			
Clinic Visit: Parent blood sample			
Clinic Visit: Parent Interviews			
Third Questionnaire Packet			

If you have any questions about the study, please call <name> at <number>. Thank you for your participation.

Clinic Visit: Child Developmental Evaluation

What to expect:

We ask that you bring your child to a study clinic for a developmental evaluation. A trained professional will conduct the evaluation. The evaluator will first introduce herself and answer any questions you may have. She will then play with your child in order to make him/her more comfortable. The evaluation will begin after your child is comfortable with the evaluator. You can sit with your child during the evaluation in order to make him/her more comfortable. The evaluation will consist of two tests that take about 1 ½-2 hours to complete. The tests will involve asking your child some questions and engaging him/her in some structured play activities. Your child will be able to take a break if needed. You can come back at another time if your child cannot complete the evaluation.

How to prepare:

Children must be able to walk by themselves in order to complete the evaluation. The evaluation also requires that your child does not have any significant hearing or vision impairments. There will not be child care available for any other children who may be with you.

Please allow 2 hours to complete this part of the study. You should plan to arrive 15 minutes before your scheduled visit to become familiar with the clinic.

You may want to bring one of your child's favorite toys for them to play with during the visit. You also may want to bring a favorite snack in a small plastic container.

Home Visits

You can choose to have project staff come to your home to complete the child developmental evaluation. In order to do the evaluation in-home, you must be able to provide a private and quiet area. This area must be free from distractions. It is preferred that you find childcare for your other children so that you can sit with your child during the evaluation.

Study staff will need to look in your home for the best place to do the assessment. Staff will then need to set-up the room without your child present. After the room has been set-up, the evaluator will play with your child in order to make him/her more comfortable. The evaluation will begin after your child is comfortable with the evaluator.

Child Blood and Hair Sample and Brief Physical Exam

What to expect:

We will ask for a sample of blood from your child. Your child's blood sample will help us learn more about the biology of developmental problems. A trained professional will first put some cream on your child's arm that will numb the area where the needle goes in. The trained staff member will wait 20-30 minutes for the cream to work. Then he or she will insert a small needle into your child's arm. We will do everything we can in order to make your child feel at ease. You can decide to stop at any point during the blood draw.

Study staff would also like to collect a sample of hair from your child. The sample will be taken from the back of the head, close to the scalp, just above the nape of the neck. Before we collect the sample, we will ask you if you think this process will upset your child. If you and the team decide that your child would be too upset by the process, we will not try to collect the sample. You can decide to stop at any point during the hair sampling.

We ask that you allow study staff to conduct a brief physical exam on your child. A trained professional will measure your child's height and weight. He or she will take pictures of your child's hands, feet, and face. They will also measure your child's hands. All of this information will help us learn more about why children develop differently.

How to prepare:

If it will help your child feel at ease, talk with your child before the visit to explain the blood draw and hair cut procedures. Dress your child in a shirt with short sleeves or sleeves that are loose fitting and can be pulled up comfortably past the elbow. You might also bring a favorite snack or treat to give to your child after he or she has completed this part of the study. You might want to bring one of your child's favorite toys to play with during the visit. Please allow 20 minutes for the collection of blood and hair samples. Allow 15 minutes for the physical exam.

Parents' Blood Sample

What to expect:

Both biological parents will be asked to give a sample of blood. Your blood sample will help us learn more about the biology of developmental problems. A trained staff member will insert a small needle into your arm to get the blood. If blood cannot be drawn the first time the needle is put in, we will try again. We will do everything we can to make you feel at ease. You can ask us to stop at any time during the blood draw.

How to prepare:

Wear a shirt or dress with short sleeves that are loose fitting and can be pulled up comfortably past your elbow. Please allow 15 minutes for each blood draw.

Parent Interviews

What to expect:

As part of this study we would like to ask you questions about your child's development. All of the information you give will help us learn more about why children develop differently. The interview can be done either over the telephone or during a clinic visit. We will ask about your child's personal and social functioning, developmental skills, and current services and treatments. You can skip any question that makes you feel uncomfortable.

How to prepare:

Please look through your child's baby book or baby calendar to recall when your child reached developmental milestones. Write down what age your child first rolled over, sat alone, crawled, walked, used single words, and spoke in phrases. If there was a period when your child seemed to lose skills, please write down what skills he or she lost and about how many months the skill was lost.

Please take some time before the interview to write down all of the services and treatments your child is now receiving. Look at the services and treatments list on the next page to help you remember what services and treatment your child is currently receiving. Be sure to have this guide with you during the interview because we will ask you to refer to it.

Please allow 3 hours to complete the interview.

SERVICES AND TREATMENTS LIST

During your parent clinical visit, you will be asked questions about your child in a number of areas including behavioral regression, services and treatments, and current use of alternative or biological treatments. To help you answer the question about your child's use of biological treatments, various available treatments are listed below. The brand name is in parentheses.

The list below is not a complete list so if the treatment your child receives cannot be found below, please tell us about it during the interview. Also, if you have the medicine bottles or packages, we ask that you keep them handy during the interview to help you answer the questions.

Alternative or Biological Treatments

Acidophilus/mixed probiotics
Alkaline salts
Antacids or histamine 2 blockers (Cimetadine or Zantac)
Antifungal medications (Nystatin, Diflucan, Sporonax)
Antiviral medications (Valtrex, Acyclovir, Famvir, Immunovir)
Aqua Flora
B6 and Magnesium (SuperNuThera)
Bethanecol/urocholine
Chelation agents (DMSA, DMPS, EDTA)
Colustrum
Special diets, including gluten free/casein free diet or other elimination diet
DMG (Dimethylglycine)
Enzyme aide
Epsom salt baths
Fatty acids (EFA) or Omega-3 fatty acids
Glutathione (oral plus transdermal, IV)
Grapefruit seed extract
Immunoglobulins, IV or oral (BayGam)
Methyl-B12
Methylcobalamin (concentrated Vitamin B12) injections
Natural anti-virals (Lauricidin, Larch araginogalactins, IP-6 [Inositol hexaphosphate], Myco-Immune)
Natural chelators (alpha lipoic acid, vitamin C, glutathione)
Pepcid
Secretin
Transfer factor
Thiamine tetrahydrofurfuryl (TTFD); Allithiamine (Transdermal TTFD)
Vitamin A (as cod liver oil)
Vitamin C
Withhold immunization(s)