

Appendix E.4 Clinic Visit Prep Guide: Case Group

The National CADDRE Study: Child Development and Autism

PARTICIPANT CLINIV 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 | | | |
| Clinic Visit: Child developmental evaluation | | | |
| Clinic Visit: Child blood and hair sample and brief exam | | | |
| Clinic Visit: Parent blood sample | | | |
| Clinic Visit: Parent Interviews | | | |

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 be childcare available at the clinic for your other children. If you prefer to find your own childcare, you will be reimbursed for childcare expenses.

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.

Project staff will need to look in your home for the most appropriate place to conduct 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 Exam

What to expect:

We ask that you allow us to get 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 who has experience working with children will then 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.

Project staff would also like to collect a sample of hair from your child. We would like to get the sample 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 project staff to conduct a brief exam on your child. A trained professional will measure your child's height and weight. They 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:

You may want to talk with your child before the visit to explain the blood draw and hair cut procedures. You may also want to bring a favorite snack or treat that can be given to your child after he/she has completed this part of the study. You may want to bring one of your child's favorite toys for them to play with during the visit. Please allow 20 minutes for the collection of blood and hair samples. Allow 15 minutes to complete the physical exam.

Parents' Blood Sample

What to expect:

All 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 professional will insert a small needle into your arm to get the blood. We will do everything we can to make you feel at ease.

How to prepare:

You may want to wear a shirt or dress with sleeves that are loose fitting and can comfortably be pulled above your elbow. Please allow 15 minutes for each blood draw.

Clinic Visit: 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 conducted either over the telephone or during an in-person visit. It 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/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. Please allow 3 hours to complete the interview.

Please use the services and treatments list on the next page to help you remember what services and treatment your child is currently receiving. During the interview we will ask you to look at the list in this guide. All you need to do is have looked at the list before your appointment and have it with you during 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 specific to 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 those items handy during the interview. Having these items handy will help you answer the questions in the interview.

Alternative or Biological Treatments

Acidophilus/ mixed probiotics

Alkaline Salts

Antacids or Histamine 2 blockers – (Ex. Cimetadine or Zantac)

Antifungal medications: (Ex. Nystatin, Diflucan, Sporonax)

Antiviral medications: (Ex. Valtrex; Acyclovir, Famvir, Immunovir)

Aqua Flora

B6 and Magnesium (SuperNuThera)

Bethanecol/ urocholine

Chelation agents: (Ex. DMSA, DMPS, EDTA)

Colustrum

Special Diets: (Ex. 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 Intravenous or Oral (Ex. BayGam)

Methyl-B12

Methylcobalamin (concentrated Vitamin B12) injections

Natural anti-virals: (Ex. Lauricidin, Larch araginogalactins, IP-6 (Inositol hexaphosphate), Myco-Immune)

Natural chelators: (Ex. 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)

Clinic Visit Prep Guide: NIC/Subcohort Groups

The National CADDRE Study: Child Development and Autism

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| Clinic Visit: Child developmental evaluation | | | |
| Clinic Visit: Child blood and hair sample and brief exam | | | |
| Clinic Visit: Parent blood sample | | | |
| Clinic Visit: Parent Interviews (NOT ALL PARTICIPANTS WILL BE CONTACTED) | | | |

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 one test that takes about 45 minutes to complete. The test 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 be childcare available at the clinic for your other children. If you prefer to find your own childcare, you will be reimbursed for childcare expenses.

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.

Project staff will need to look in your home for the most appropriate place to conduct 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.

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How to prepare:

You may want to talk with your child before the visit to explain the blood draw and hair cut procedures. You may also want to bring a favorite snack or treat that can be given to your child after he/she has completed this part of the study. You may want to bring one of your child's favorite toys for them to play with during the visit. Please allow 20 minutes for the collection of blood and hair samples. Allow 15 minutes to complete the physical exam.

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How to prepare:

You may want to wear a shirt or dress with sleeves that are loose fitting and can comfortably be pulled above your elbow. Please allow 15 minutes for each blood draw.

Clinic Visit: Parent Interviews

What to expect:

Study staff may want to ask you more 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 conducted either over the telephone or during an in-person visit. It will ask about your child's personal and social functioning and developmental skills. 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/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. Please allow 45 minutes to complete the interview.