

Appendix E.1 Enrollment Packet Cover Letter: Case Group



Date

Name
 Address
 City, State, Zip

Dear:

Thank you for your interest in the *National CADDRE Study: Child Development and Autism*. This packet contains information to get you started in the study. The package has **3 folders** that will guide you through the study. **Someone from the study will call you in the next week** to make sure you received the packet, help you complete materials if needed, schedule the next part of the study, and answer your questions. The folders contained in this packet are:

Yellow Folder: <u>Things You Should Keep</u>	Green Folder: <u>Forms to Fill out and Return</u>	Blue Folder: <u>Cheek Swab Kit</u>
<ul style="list-style-type: none"> ◆ Information about the study. ◆ Checklists to help you complete the study. ◆ Copy of the study consent form. 	<ul style="list-style-type: none"> ◆ Questionnaires that you can fill out at home. ◆ HIPAA (Health Insurance Portability and Accountability Act) /Medical Records Release Forms to complete & sign. 	<p style="text-align: center;">—</p> <ul style="list-style-type: none"> ◆ Instructions and information on how to collect a cheek swab. ◆ Two copies of each cheek swab consent form.

Please read over all of the materials in all three folders.

If you feel that you can complete all of the materials in the green and blue folders on your own go ahead and fill them out. Please send them back according to the instructions. If you have any questions while you are completing these forms (or want help before you begin), please call <site specific name and number>. <She or he> will be able to help you over the phone or can arrange for study staff to meet you in person.

There is a \$10 <site specific...money order, certificate> enclosed for your first compensation. An additional \$80 will be sent to you once we have received **all** the materials in the green and blue folders. If you complete the entire study, you will receive a total of \$310.00. You may also be reimbursed for travel and childcare expenses accrued from being in the study.

We are grateful to you for your willingness to participate in this important research study. If you would like to speak to anyone at any point during the study, please call <site specific name and number>. You may also call me directly at <number>.

Sincerely yours,
 <Site specific... principal investigator name>

**Follow Up Call**

Study Staff will contact you one week after the enrollment letter is mailed. During this phone call, the study staff will:

1. Answer any questions you have about the study or the materials sent to you in the enrollment packet.
2. Schedule follow up visits with you and your child to complete the remaining parts of the study. The scheduling of these will be flexible to fit your schedule.

**Caregiver Telephone Interview**

The study staff will set up a time to call to ask you questions about the medical history of your child. This interview will also include questions about when you (or the biological mom) was pregnant with your child. Only the biological mom will be asked the questions about her pregnancy. If someone else completes the interview, certain sections will be skipped. The interview will last between 30 and 50 minutes. If you have given us permission to view your medical records, the interview will be shorter.

**Clinical Visit (In your home or at a clinic)**

The study staff will meet with you to complete some parts of the study and answer questions. Study staff will:

1. Review the study informed consent with you and ask you to sign it for you and for your child.
2. Review the enrollment packet. If you haven't already mailed this back to the study, they will help you to complete the enrollment packet & answer any questions you may have about this packet.
3. Ask questions about your child's development and behaviors. They can ask them by phone or meet you in person. It will take around 3 hours to complete this interview. You may be asked questions about how they react.
4. Take a sample of your blood.
5. Play with your child using specific toys during a child developmental evaluation. Take blood from your child. We will also collect a small sample of hair from your child's head. This visit will last around 2 hours.

This visit will last around 6 hours, but can be scheduled in parts if you think this is too long.



Thank you for taking part in our important study!

Introductory Letter sent to your home.

This packet will include:

1. An introductory letter & study brochure.
2. A <<yellow?>> response postcard to let us know if you are interested in the study.

After you send in your response card letting us know you are interested in the study, we will send you the enrollment packet.

An Enrollment Packet will be sent to your home.

This packet will include:

YELLOW Things You Keep Folder

1. \$10.00
2. A copy of the overall consent form and a study bill of rights for you to review and keep.
3. Information about the study including a study flow sheet and guides for the interview and clinic visits.

GREEN "Forms to Return"

This packet will include all the forms we are asking you to fill out at home and return to the study (using the enclosed pre-stamped mailer). It also includes HIPAA medical records release forms to sign. It will take about 2 hours and 20 minutes to complete this packet.

BLUE "Cheek Swab Kit"

This includes cheek swab consent forms, instructions on how to collect cheek swabs, and the swabs you use. We ask you to complete these and return them to the study in the enclosed <<blue>> mailer. This will take about 20 minutes to complete.

Study staff can assist you with completion of the green and blue folders. If you think you would like their help with the kit or other parts of the study, staff can help you at the first clinic visit.

Follow Up Call

Study Staff will contact you one week after the enrollment letter is mailed. During this phone call, the study staff will:

1. Answer any questions you have about the study or the materials sent to you in the enrollment packet.
2. Schedule follow up visits with you and your child to complete the remaining parts of the study. The scheduling of these will be flexible to fit your schedule.

Caregiver Telephone Interview

The study staff will set up a time to call to ask you questions about the medical history of your child. This interview will also include questions about when you (or the biological mom) was pregnant with your child. Only the biological mom will be asked the questions about her pregnancy. If someone else completes the interview, certain sections will be skipped. The interview will last between 30 and 50 minutes. If you have given us permission to view your medical records, the interview will be shorter.

Clinical Visit (In your home or at a clinic)

The study staff will meet with you to complete some parts of the study and answer questions. Study staff will:

1. Review the study informed consent with you and ask you to sign it for you and for your child.
2. Review the enrollment packet. If you haven't already mailed this back to the study, they will help you to complete the enrollment packet & answer any questions you may have about this packet.
3. Ask questions about your child's development and behaviors. They can ask them by phone or meet you in person. It will take around 3 hours to complete this interview. You may be asked questions about how they react.
4. Take a sample of your blood.
5. Play with your child using specific toys during a child developmental evaluation. Take blood from your child. We will also collect a small sample of hair from your child's head. This visit will last around 2 hours.

This visit will last around 6 hours, but can be scheduled in parts if you think this is too long.

Thank you for taking part in our important study!

Appendix E.1 Enrollment Packet Cover Letter:
NIC/Subcohort Groups



Date

Name
Address
City, State, Zip

Dear:

Thank you for your interest in the *National CADDRE Study: Child Development and Autism*. This packet contains information to get you started in the study. The package has **3 folders** that will guide you through the study. **Someone from the study will call you in the next week** to make sure you received the packet, help you complete materials if needed, schedule the next part of the study, and answer your questions. The folders contained in this packet are:

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Please read over all of the materials in all three folders.

If you feel that you can complete all of the materials in the green and blue folders on your own go ahead and fill them out. Please send them back according to the instructions. If you have any questions while you are completing these forms (or want help before you begin), please call <site specific name and number>. <She or he> will be able to help you over the phone or can arrange for study staff to meet you in person.

There is a \$10 <site specific...money order, certificate> enclosed for your first compensation. An additional \$80 will be sent to you once we have received **all** the materials in the green and blue folders. If you complete the entire study, you will receive a total of \$200.00. You may also be reimbursed for travel and childcare expenses accrued from being in the study.

We are grateful to you for your willingness to participate in this important research study. If you would like to speak to anyone at any point during the study, please call <site specific name and number>. You may also call me directly at <number>.

Sincerely yours,
<Site specific... principal investigator name>

Introductory Letter sent to your home.

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BLUE "Cheek Swab Kit"

This includes cheek swab consent forms, instructions on how to collect cheek swabs, and the swabs you use. We ask you to complete these and return them to the study in the enclosed <<blue>> mailer. This will take about 20 minutes to complete.

Study staff can assist you with completion of the green and blue folders. If you think you would like their help with the kit or other parts of the study, staff can help you at the first clinic visit.

Follow Up Call

Study Staff will contact you one week after the enrollment letter is mailed. During this phone call, the study staff will:

1. Answer any questions you have about the study or the materials sent to you in the enrollment packet.
2. Schedule follow up visits with you and your child to complete the remaining parts of the study. The scheduling of these will be flexible to fit your schedule.

Caregiver Telephone Interview

The study staff will set up a time to call to ask you questions about the medical history of your child. This interview will also include questions about when you (or the biological mom) was pregnant with your child. Only the biological mom will be asked the questions about her pregnancy. If someone else completes the interview, certain sections will be skipped. The interview will last between 30 and 50 minutes. If you have given us permission to view your medical records, the interview will be shorter.

Clinical Visit (In your home or at a clinic)

We are asking that the primary caregiver and the child both come to the initial clinic visit. This visit can be done either in your home or at the study clinic. During this visit study staff will:

1. Review the study informed consent with you and ask you to sign it for you and for your child.
2. Review the enrollment packet. If you haven't already mailed this back to the study, they will help you to complete the enrollment packet & answer any questions you may have about this packet.
3. Conduct a developmental evaluation on your child. We will invite you to sit with your child during this developmental evaluation.
4. Ask permission to take a sample of you & your child's blood and also collect a sample of hair from your child's head.

This visit will last around 1 ½ hours, but can be scheduled in parts if you think this is too long.

Parent Interview (NOT ALL PARTICIPANTS WILL BE CONTACTED)

Study staff may want to ask you more questions about your child's development. If study staff want to conduct a second interview, someone will contact you by phone and set up a time to ask more questions. They can ask them by phone or visit with you in person at your home or in a clinic. This interview will take around 45 minutes to complete and may not be requested of all participants.

Thank you for taking part in our important study!