

Appendix E.1 Enrollment Packet Cover Letter: Case Group



Study to Explore Early Development

Date

Name
Address
City, State, Zip

Dear:

Thank you for your interest in the **Study to Explore Early Development (SEED)**. 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">◆ HIPAA (Health Insurance Portability and Accountability Act) /Medical Records Release Forms to complete & sign.	<p>–</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 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 \$25 <site specific...money order, certificate> enclosed. If you complete the entire study, you will receive a total of \$315.00.

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>

An Enrollment Packet will be sent to your home.

This packet will include:

YELLOW Things You Keep Folder

1. \$25.00
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 HIPAA medical records release forms to sign and return to the study (using the enclosed pre-stamped mailer). It will take about 15 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 help you with the kit or other parts of the study.



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 about 1 hour.



First Questionnaire Packet

The study staff will assist you in answering questions about your family's medical history. These can be done with study staff at your home or the clinic, over the telephone, or mailed to you to complete on your own. These questionnaires will take about 1 hour to complete.



Follow Up Call

During this phone call, the study staff will:

1. Answer any questions you have about the study.
2. Explain and schedule the Second Questionnaire Packet.
3. Explain and schedule the clinical visits. The scheduling of these will be flexible to fit your schedule.



Second Questionnaire Packet

The study staff will assist you in answering questions about your child's behavior. These can be done with study staff at your home or the clinic, over the telephone, or mailed to you to complete on your own. These questionnaires will take about 1 hour to complete.



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. 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.



Third Questionnaire Packet

During the clinic visit, the study staff will show you how to fill out diet and stool diaries. You can complete these on your own at home. These diaries will take about 1 hour to complete.

Thank you for taking part in our important study!

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



Study to Explore Early

Development

Date

Name
Address
City, State, Zip

Dear:

Thank you for your interest in the **Study to Explore Early Development (SEED)**. 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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<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"> ◆ HIPAA (Health Insurance Portability and Accountability Act) /Medical Records Release Forms to complete & sign. 	<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 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 \$25 <site specific...money order, certificate> enclosed. If you complete the entire study, you will receive a total of \$235.00.

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>

An Enrollment Packet will be sent to your home.

This packet will include:

YELLOW Things You Keep Folder

1. \$25.00
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 HIPAA medical records release forms to sign and return to the study (using the enclosed pre-stamped mailer). It will take about 15 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 help you with the kit or other parts of the study.

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 about 1 hour.

First Questionnaire Packet

The study staff will assist you in answering questions about your family's medical history. These can be done with study staff at your home or the clinic, over the telephone, or mailed to you to complete on your own. These questionnaires will take about 1 hour to complete.

Follow Up Call

During this phone call, the study staff will:

1. Answer any questions you have about the study.
2. Explain and schedule the Second Questionnaire Packet.
3. Explain and schedule the clinical visits. The scheduling of these will be flexible to fit your schedule.

Second Questionnaire Packet

The study staff will assist you in answering questions about your child's behavior. These can be done with study staff at your home or the clinic, over the telephone, or mailed to you to complete on your own. These questionnaires will take about 1 hour to complete.

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. Take a sample of your blood.
3. 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 1 1/2 hours, but can be scheduled in parts if you think this is too long.

Third Questionnaire Packet

During the clinic visit, the study staff will show you how to fill out diet and stool diaries. You can complete these on your own at home. These diaries will take about 1 hour to complete.