Appendix E.3 Informed Consent Document: Case Group

You are invited to be in a research study being done by <*or being done with*> the Centers for Disease Control and Prevention (CDC). CDC is a federal agency that works to improve the health and safety of the general public. This data is collected under the authority of Section 301 of the Public Health Service Act. The study is called The National CADDRE Study: Child Development and Autism. It is being done by 6 different sites in the US. <*Location*> is one of the sites taking part in the study.

The study in <*location*> is being done through a partnership with schools in the <*location*> area and local healthcare providers. <*Site specific…The <federal department of education> gave <CDC> permission to work with the schools*.>

What is the purpose of the study?

This is a study on child development. One focus of the study is to look at possible causes of autism. We know that many children have autism and other related disabilities. Autism spectrum disorders (ASD) are a set of disorders that are usually found in early childhood. There are many signs for ASD. The most common signs involve social, communication, and behavioral delays. However, we want to learn more about these children. We also want to learn more about risk factors and possible causes.

We are looking at things that occur during pregnancy or in the early stages of a child's life. The results may lead to better services and treatments for children with autism and other related disabilities.

Who can participate?

Hundreds of families across the country are being asked to be in the study. More than <*number*> families living in <*location*> will be asked to be in the study. Some families were randomly chosen by birth certificate records. The names of other families were given to us by local school systems or healthcare providers. <*Site specific…The <federal department of education> gave <CDC> permission to work with the schools*.>

We are enrolling families of children with and without developmental disabilities. It is important that different types of families participate. This will help us find clues about what causes children to develop differently. Children should be 3-5 years old as of <*insert study year*>.

What will my child and I have to do to be in the study?

Families who take part in the study will be asked to do each of the tasks listed below. You can refuse any task and still participate in the study. The tasks include:

1. Complete questionnaires and interviews.

2. Allow project staff to review medical records.
3. Provide a cheek swab sample from the biological parents and your child.
4. Provide about 4 teaspoons of blood. The blood samples will be analyzed for biologic and genetic substances.
5. Allow project staff to conduct an evaluation on your child.
6. Allow project staff to videotape the evaluation.
7. Allow project staff to conduct a brief exam on your child.
8. Allow project staff to take photographs of your child during the physical exam.
9. Allow your child to provide 4 teaspoons of blood. The blood samples will be analyzed for biologic and genetic substances.
10. Allow your child to provide a hair sample. The hair sample will be analyzed for mineral content.

It takes about 10 hours to finish the entire study. We ask that you complete all parts of the study. A detailed description of each part of the study is included in the yellow "things you keep" folder. Even if you do not complete all parts of the study you are still considered a study participant. You are allowed to drop out of the study at any time without penalty. We also ask that you to let us contact you for future studies we may conduct.

Are there any risks involved with the study?

There is little risk involved with the study. You may feel nervous answering questions during the interviews. Some questions are sensitive in nature and may cause you to have negative feelings (like feeling embarrassed). You are free to skip any questions that you do not want to answer or that make you uncomfortable to talk about. Your responses will not be shared with people outside of the study. The evaluation will take several hours and some children may become tired. Short breaks will be offered during the testing. You may get feedback that is unexpected and/or that indicates some developmental delays. The developmental testing results are for research only and do not substitute for a clinical evaluation and diagnosis. Study personnel will be available to answer questions and will provide a list of local resources. But we will not be able to give a specific diagnosis.

You and your child may feel a little discomfort when having blood drawn. In children, we may apply a numbing cream on the arm before inserting the needle after discussing with you. Side effects from the cream are uncommon but include temporary redness, paleness and swelling, and very rarely a blood disorder. In rare instances, bruising or infection may occur at the puncture site. Study staff will take every precaution when drawing blood.

Why should I be in the study?
There is no personal benefit to you for taking part in the study. Your participation will help us understand what causes developmental problems in young children. The results of the study may help us learn more about autism and other developmental disabilities. Results may also lead to better services and treatments for children with developmental disabilities. We will analyze the blood, hair, and cheek samples for biologic and genetic substances. This will help us look for genes or other substances that may be related to autism and child development.

Is this going to cost me anything?

There are no costs associated with the study.

Will I be reimbursed in any way?

We understand that your time is valuable. We also understand that we are asking you to devote much of your time to take part in the study. You will be compensated for the time and effort it takes to complete each part of the study. You can receive up to $310 for completing the entire study. You do not have to wait until the end of the study to receive your compensation. You will be compensated after you complete each part of the study.

You will also be compensated for travel costs and costs for childcare. You can receive $10 an hour for childcare (up to $50) and $.360 for the cost of travel (up to $43.20). You will need to submit receipts for all childcare and travel reimbursements.

If you wish, you may donate all proceeds of the study to autism support groups or other charities. Please contact the charity of your choice if you want to donate your compensation.

Will the information I give be kept private?

Your study data will be stored in a database at Michigan State University. The information you give will only be used for this study. Your information will remain confidential unless otherwise required by law. We will never use your name or your child's name in any report. The information you give will always be combined with information from all other participants.

You will be given a study ID. This study ID will be the only information on all study forms. Your name or other identifying information will not be on the study forms. Only people working on the study will have access to your personal information. Results from the study will only be linked to your study ID, not your name. This link will be maintained on a database that is kept on a secure computer (password protected) in the study manager's office. If a hardcopy list is printed linking your ID and identifiers this will kept in a locked file cabinet in the study manager's office.

Your biologic sample will be stored at the study lab at Johns Hopkins University. The people working on the study at the lab will enter and store your biologic sample. You can choose to store your biologic sample with or without a link to your name. Please see the form entitled 'frequently asked questions about biologic samples' for details of what this means.

Consent forms will be kept in locked file cabinets. Only study staff will have access to your consent forms.

We may share some study data with other researchers. They will be approved by our team. We will not give them any information that could identify you. Other researchers will not have access to the list that links your study ID with your name.

Because sensitive information is collected in this study, <*site*> received a 'Certificate of Confidentiality.' This means that any information that <*site*> has that identifies you or your child will be used only for this project. It cannot be given to anyone else unless you give your written consent.

Will I be told about the results of the study?

You will get a letter about the results of your child's developmental evaluation. You should get this letter within 3 months of the clinic visit. The letter will explain each test your child was given. It will explain your child's scores on each test. It will tell you if your child performs at the same level as most children his/her age. It will also tell you if your child has any social, communication, or other delays. You will not receive a diagnosis. We are not giving diagnoses

because the evaluation is part of a research study and is not given in order to get services or treatments.

You may learn that your child is performing below average in certain areas. If this happens, you can speak with a study representative to get information on developmental specialists located in your area.

<Site specific… You will be contacted by study staff if your child's diet or stool record shows any concerns. Study staff will explain the results in detail. They will also refer you to a local physician for further follow-up.>

Little is known about which genes and other biologic substances are related to autism. The results from this study will only be initial leads. The same findings will have to be seen again in other studies before they can be considered useful to a particular child or family. Also, the labs that do our tests are research labs. These labs are not always approved for doing tests that are normally done on clinical patients. Because of these reasons, you will not receive individual results from the biological samples that we collect for this study.

We will send you a study newsletter up to two times per year. It will be mailed directly to your home. It will tell you general study results including genetic and lab results. You can discuss any of these findings with your medical provider. It is important to remember that it will be some time (up to several years) before all results are available.

Do I have to be in the study?

Your decision to be in the study is up to you. Your participation is voluntary. There is no penalty if you do not want to be in the study. Your child's school and healthcare services will not be affected if you decide not to be in the study. You can drop out of the study at any time.

Certificate of Confidentiality

All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under law, we must report to the state suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

Who can I call if I have questions?

If you have questions about the study you can call <*PI or project coordinator*> at <*phone number*>.

If you feel you have been harmed by participating in this research study, please contact << PI or Project Coordinator>> at <insert phone number>.

If you have questions about your rights as a research participant you can call <*name of local IRB contact*> at <*number at local IRB contact*>.

Other Permissions

Permission to videotape the child developmental evaluation

☐ I AGREE to have my child's developmental evaluation videotaped.

I understand that the tapes will be used to record certain behaviors. The tapes will also be used to make sure that the person giving the tests is doing a good job. All tapes will be stored in locked areas.

☐ I DO NOT WANT my child's developmental evaluation videotaped.

Permission to contact family for future studies
We would like to ask you to allow us to contact you for future studies. If you agree, you will allow us to contact you by mail or telephone to ask your permission to be in another study. These studies would be related to developmental disabilities. These studies may include biologic testing for genetic research.

☐ I AGREE to be contacted for future research studies.

☐ I DO NOT WANT to be contacted for future research studies.

Permission to store biologic samples for future research
PLEASE READ BIOLOGIC SAMPLES INFORMATION FORM BEFORE COMPLETING THIS SECTION!

Mother biologic samples (cheek cells, blood, DNA extracted)

☐ I AGREE to have my biologic samples stored for future research studies (WITH identifiers – you may be contacted for future studies)

☐ I AGREE to have my biologic samples stored for future research studies (WITHOUT identifiers – you will not be contacted for future studies)

☐ I DO NOT WANT my biologic samples stored for future research studies (samples will be destroyed after the study is over)

Child biologic samples (cheek cells, blood, DNA extracted)

☐ I AGREE to have my child's biologic samples stored for future research studies (WITH identifiers – you may be contacted for future studies)

☐ I AGREE to have my child's biologic samples stored for future research studies (WITHOUT identifiers – you will not be contacted for future studies)

☐ I DO NOT WANT my child's biologic samples stored for future research studies (samples will be destroyed after the study is over)

Informed Consent Statement:

Permission to Enroll Child:
I have been told about the study. I know what is expected of my child. I was allowed to ask questions. I had all my questions answered. I give permission to enroll my child in this study.

_____ _____
Signature of mother/legal guardian Date

_____ _____
Printed name (Mother/legal guardian) Last 4 digits Mother/guardian SSN

_____ _____

Printed name (Child) Last 4 digit's of Child SSN

Permission to Enroll Self:
I have been told about the study. I know what is expected of me. I was allowed to ask questions. I had all my questions answered. I voluntarily agree to enroll in this study.

_____ _____
Signature of mother/legal guardian Date

_____ _____
Printed name (Mother/legal guardian) Last 4 digits Mother/guardian SSN

Appendix E.3 Informed Consent Document: NIC/Subcohort Groups

You are invited to be in a research study being done by <*or being done with*> the Centers for Disease Control and Prevention (CDC). CDC is a federal agency that works to improve the health and safety of the general public. This data is collected under the authority of Section 301 of the Public Health Service Act. The study is called The National CADDRE Study: Child Development and Autism. It is being done by 6 different sites in the US. <*Location*> is one of the sites taking part in the study.

The study in <*location*> is being done through a partnership with schools in the <*location*> area and local healthcare providers. <*Site specific…The <federal department of education> gave <CDC> permission to work with the schools.*>

What is the purpose of the study?

This is a study on child development. One focus of the study is to look at possible causes of autism. We know that many children have autism and other related disabilities. Autism spectrum disorders (ASD) are a set of disorders that are usually found in early childhood. There are many signs for ASD. The most common signs involve social, communication, and behavioral delays. However, we want to learn more about these children. We also want to learn more about risk factors and possible causes.

We are looking at things that occur during pregnancy or in the early stages of a child's life. The results may lead to better services and treatments for children with autism and other related disabilities.

Who can participate?

Hundreds of families across the country are being asked to be in the study. More than <*number*> families living in <*location*> will be asked to be in the study. Some families were randomly chosen by birth certificate records. The names of other families were given to us by local school systems or healthcare providers. <*Site specific…The <federal department of education> gave <CDC> permission to work with the schools.*>

We are enrolling families of children with and without developmental disabilities. It is important that different types of families participate. This will help us find clues about what causes children to develop differently. Children should be 3-5 years old as of <*insert study year*>.

What will my child and I have to do to be in the study?

Families who take part in the study will be asked to do each of the tasks listed below. You can refuse any task and still participate in the study. The tasks include:

11. Complete questionnaires and interviews.
12. Allow project staff to review medical records.
13. Provide a cheek swab sample from the biological parents and your child
14. Provide about 4 teaspoons of blood. The blood samples will be analyzed for biologic and genetic substances.
15. Allow project staff to conduct an evaluation on your child.
16. Allow project staff to videotape the evaluation.
17. Allow project staff to conduct a brief exam on your child.
18. Allow project staff to take photographs of your child during the exam.
19. Allow your child to provide 4 teaspoons of blood. The blood samples will be analyzed for biologic and genetic substances.
20. Allow your child to provide a hair sample. The hair sample will be analyzed for mineral content.

It takes about 6 hours to finish the entire study. We ask that you complete all parts of the study. A detailed description of each part of the study is included in the yellow "things you keep" folder. If you only complete one part of the study you are still considered a study participant. You are allowed to drop out of the study at any time without penalty. We also ask that you to let us contact you for future studies we may conduct.

Are there any risks involved with the study?

There is little risk involved with the study. You may feel nervous answering questions during the interviews. Some questions are sensitive in nature and may cause you to have negative feelings (like feeling embarrassed). You are free to skip any questions that you do not want to answer or that make you uncomfortable to talk about. Your responses will not be shared with people outside of the study. The evaluation will take several hours and some children may become tired. Short breaks will be offered during the testing. You may get feedback that is unexpected and/or that indicates some developmental delays. The developmental testing results are for research only and do not substitute for a clinical evaluation and diagnosis. Study personnel will be available to answer questions and will provide a list of local resources. But we will not be able to give a specific diagnosis.

You and your child may feel a little discomfort when having blood drawn. In children, we may apply a numbing cream on the arm before inserting the needle after discussing with you. Side effects from the cream are uncommon but include temporary redness, paleness and swelling, and very rarely a blood disorder. In rare instances, bruising or infection may occur at the puncture site. Study staff will take every precaution when drawing blood.

Why should I be in the study?
There is no personal benefit to you for taking part in the study. Your participation will help us understand what causes developmental problems in young children. The results of the study may help us learn more about autism and other developmental disabilities. Results may also lead to better services and treatments for children with developmental disabilities. We will analyze the blood, hair, and cheek samples for biologic and genetic substances. This will help us look for genes or other substances that may be related to autism and child development.

Is this going to cost me anything?

There are no costs associated with the study.

Will I be reimbursed in any way?

We understand that your time is valuable. We also understand that we are asking you to devote much of your time to take part in the study. You will be compensated for the time and effort it takes to complete each part of the study. You can receive up to $200 for completing the entire study. You do not have to wait until the end of the study to receive your compensation. You will be compensated after you complete each part of the study.

You will also be compensated for travel costs and costs for childcare. You can receive $10 an hour for childcare (up to $50) and $.360 for the cost of travel (up to $43.20). You will need to submit receipts for all childcare and travel reimbursements.

If you wish, you may donate all proceeds of the study to autism support groups or other charities. Please contact the charity of your choice if you want to donate your compensation.

Will the information I give be kept private?

Your study data will be stored in a database at Michigan State University. The information you give will only be used for this study. Your information will remain confidential unless otherwise required by law. We will never use your name or your child's name in any report. The information you give will always be combined with information from all other participants.

You will be given a study ID. This study ID will be the only information on all study forms. Your name or other identifying information will not be on the study forms. Only people working on the study will have access to your personal information. Results from the study will only be linked to your study ID, not your name. This link will be maintained on a database that is kept on a secure computer (password protected) in the study manager's office. If a hardcopy list is printed linking your ID and identifiers this will kept in a locked file cabinet in the study manager's office.

Your biologic sample will be stored at the study lab at Johns Hopkins University. The people working on the study at the lab will enter and store your biologic sample. You can choose to store your biologic sample with or without a link to your name. Please see the form entitled 'frequently asked questions about biologic samples' for details of what this means.

Consent forms will be kept in locked file cabinets. Only study staff will have access to your consent forms.

We may share some study data with other researchers. They will be approved by our team. We will not give them any information that could identify you. Other researchers will not have access to the list that links your study ID with your name.

Because sensitive information is collected in this study, <*site*> received a 'Certificate of Confidentiality.' This means that any information that <*site*> has that identifies you or your child will be used only for this project. It cannot be given to anyone else unless you give your written consent.

Will I be told about the results of the study?

You will get a letter about the results of your child's developmental evaluation. You should get this letter within 3 months of the clinic visit. The letter will explain each test your child was given. It will explain your child's scores on each test. It will tell you if your child performs at the same level as most children his/her age. It will also tell you if your child has any social, communication, or other delays. You will not receive a diagnosis. We are not giving diagnoses because the evaluation is part of a research study and is not given in order to get services or treatments.

You may learn that your child is performing below average in certain areas. If this happens, you can speak with a study representative to get information on developmental specialists located in your area.

<Site specific… You will be contacted by study staff if your child's diet or stool record shows any concerns. Study staff will explain the results in detail. They will also refer you to a local physician for further follow-up.>

Little is known about which genes and other biologic substances are related to autism. The results from this study will only be initial leads. The same findings will have to be seen again in other studies before they can be considered useful to a particular child or family. Also, the labs that do our tests are research labs. These labs are not always approved for doing tests that are normally done on clinical patients. Because of these reasons, you will not receive individual results from the biological samples that we collect for this study.

We will send you a study newsletter up to two times per year. It will be mailed directly to your home. It will tell you general study results including genetic and lab results. You can discuss any of these findings with your medical provider. It is important to remember that it will be some time (up to several years) before all results are available.

Do I have to be in the study?

Your decision to be in the study is up to you. Your participation is voluntary. There is no penalty if you do not want to be in the study. Your child's school and healthcare services will not be affected if you decide not to be in the study. You can drop out of the study at any time.

Certificate of Confidentiality

All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under law, we must report to the state suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

Who can I call if I have questions?

If you have questions about the study you can call <*PI or project coordinator*> at <*phone number*>.

If you feel you have been harmed by participating in this research study, please contact << PI or Project Coordinator>> at <insert phone number>.

If you have questions about your rights as a research participant you can call <*name of local IRB contact*> at <*number at local IRB contact*>. **Other Permissions**

Permission to videotape the child developmental evaluation (if required)

☐ I AGREE to have my child's developmental evaluation videotaped.

I understand that the tapes will be used to record certain behaviors. The tapes will also be used to make sure that the person giving the tests is doing a good job. All tapes will be stored in locked areas.

☐ I DO NOT WANT my child's developmental evaluation videotaped.

Permission to contact family for future studies
We would like to ask you to allow us to contact you for future studies. If you agree, you will allow us to contact you by mail or telephone to ask your permission to be in another study. These studies would be related to developmental disabilities. These studies may include biologic testing for genetic research.

☐ I AGREE to be contacted for future research studies.

☐ I DO NOT WANT to be contacted for future research studies.

Permission to store biologic samples for future research
PLEASE READ BIOLOGIC SAMPLES INFORMATION FORM BEFORE COMPLETING THIS SECTION!

Mother biologic samples (cheek cells, blood, DNA extracted)

☐ I AGREE to have my biologic samples stored for future research studies (WITH identifiers – you may be contacted for future studies)

☐ I AGREE to have my biologic samples stored for future research studies (WITHOUT identifiers – you will not be contacted for future studies)

☐ I DO NOT WANT my biologic samples stored for future research studies (samples will be destroyed after the study is over)

Child biologic samples (cheek cells, blood, DNA extracted)

☐ I AGREE to have my child's biologic samples stored for future research studies (WITH identifiers – you may be contacted for future studies)

☐ I AGREE to have my child's biologic samples stored for future research studies (WITHOUT identifiers – you will not be contacted for future studies)

☐ I DO NOT WANT my child's biologic samples stored for future research studies (samples will be destroyed after the study is over)

Informed Consent Statement:

Permission to Enroll Child:
I have been told about the study. I know what is expected of my child. I was allowed to ask questions. I had all my questions answered. I give permission to enroll my child in this study.

_____ _____
Signature of mother/legal guardian Date

_____ _____
Printed name (Mother/legal guardian) Last 4 digits Mother/guardian SSN

_____ _____
Printed name (Child) Last 4 digit's of Child SSN

Permission to Enroll Self:
I have been told about the study. I know what is expected of me. I was allowed to ask questions. I had all my questions answered. I voluntarily agree to enroll in this study.

_____ _____
Signature of mother/legal guardian Date

_____ _____
Printed name (Mother/legal guardian) Last 4 digits Mother/guardian SSN