Appendix N: Invitation Phone Call

TELEPHONE SCRIPT
Invitation Telephone Call

	CALLER GUIDELINES & NOTES
1. INTRODUCTION **1a. Introduction of Self, Length of Call** Hello, may I speak with <*first and last name of potential participant from response card/* *OR* *First and last name of birth mom if child selected from subcohort* *OR* a parent or legal guardian of *child's name if from NIC/Case source*>? IF POTENTIAL PARTICIPANT IS UNAVAILABLE: When would be a good time to call them back? IF AVAILABLE: My name is <*name*> and I am calling from <*site*>. We are conducting a national health study in collaboration with the US Centers for Disease Control and Prevention. My supervisor may listen in from time to time to make sure that I am doing the best job that I can. If you agree to be interviewed, will it be OK for my supervisor to listen? IF NO: SET UP "NO MONITORING SIGNAL OR SIGN" FOR SUPERVISOR IF POTENTIAL PARTICIPANT RETURNED RESPONSE CARD INDICATING INTEREST: We recently mailed you a letter about a research study called <*name of study*> and you indicated interest in learning more. Is this a good time for me to talk to you further about the study? GO TO 1B IF NO.	*If calling a Subcohort birth mother who has not returned the response card, do not mention the child's name unless you know you are speaking with the birth mother.* *If respondent asks how you got their number:* <Site specific…explain how you received respondent's telephone number…*I received your telephone number from a response card that you sent to us indicating that you are interested in learning more about the study*>. *If respondent asks why you want to speak with potential participant: I am calling for a research project and I will just call back at another time.*

GO TO 1C IF YES. IF NO RESPONSE CARD WAS RETURNED YET, OR SITE DOES NOT USE RESPONSE CARDS: We recently mailed you a letter about a research study called <*name of study*>. Did you receive the letter? IF YES, RECEIVED LETTER: As you might recall, the study is looking at possible causes of autism and other developmental disabilities. Is this a good time for me to talk to you further about our study? GO TO 1B IF NO. GO TO 1C IF YES. IF NO, DOES NOT RECALL LETTER: The study is looking at possible causes of autism and other developmental disabilities. As part of the study, we hope to enroll children with a possible developmental delay or disability and children who are typically developing. Can I talk with you further about the study or would you prefer that I send you another letter? WANTS NEW LETTER: May I confirm your name and mailing address? END CALL WILLING TO TALK NOW, GO TO 1C WILL TALK WITHOUT LETTER, BUT NOT NOW, GO TO 1B **1b. Not a Good Time for Respondent** Thank you for your time. Is there a better time that I can reach you? **END CALL** **1c. Record Respondent & Child's Information** First, I'd like to get some information about you and your child. What is your full name? What is your child's full name?	*RECORD UPDATED CAREGIVER CONTACT INFORMATIONAND LETTER REQUEST. ASK SPECIFICALLY ABOUT ANY APARTMENT NUMBER. SCHEDULE NEXT CALL IN ONE WEEK.* *RECORD BEST TIME TO REACH RESPONDENT.* *RECORD NAME.* *RECORD CHILD'S NAME.*
2. STUDY INTRODUCTION	

2a. Study Introduction I would like to tell you a little more about the study at this time. This is a study on child development. One focus of the study is to look at possible causes of autism. Results may lead to better services and treatments for children with autism and other developmental disabilities. The study is being conducted at 6 sites throughout the US. <*Site*> is one of the sites taking part in the study. Hundreds of families in the <*location*> area are being asked to be in the study. We are inviting families of children with and without disabilities to participate. It is important for all families who are invited to participate so that we can look at possible risk factors among children who develop differently. The study consists of several different components; including completing some interviews, allowing project staff to review the medical records of you and your child, participating in a child developmental evaluation, and participating in photographs and a brief exam. We ask that you complete all study components. It should take no more than <*time*>(6 or 10) hours to complete the entire study. Your participation time will be divided into segments that are most convenient for you. Your participation is completely voluntary and you can drop out of the study at any time. We realize that your time is valuable. Therefore, you will be compensated for the time and effort it takes to be in the study. You can receive up to <*amount*> for your total participation.	
2b. Study Eligibility Screen We would like for everyone who is invited to participate in this study. You might be eligible for the study, but before we can enroll you I need to ask you a few questions to see if you qualify.	
What is your date of birth?	*RECORD RESPONDENT'S DATE OF BIRTH (MM/DD/YYYY).*
What is <*CHILD*>'s date of birth?	*RECORD CHILD'S DATE OF BIRTH (MM/DD/YYYY).*
Is <*CHILD*> a boy or a girl?	

IF CHILD NOT IN BIRTH COHORT, GO TO 2J For this study we will be asking questions about the mom's health during her pregnancy with <*CHILD*>. What is your relationship to <*CHILD*>? IF MOTHER OR FATHER, GO TO 2C. IF OTHER, GO TO 2E. **2c. Determine if Biologic Mother or Father** Are you <*CHILD*>'s biological <*mother/father*>? IF YES, GO TO 2G. IF NO, GO TO 2D. **2d. Determine if Child is adopted** Is <*CHILD*> adopted? IF YES, GO TO 2F. IF NO, GO TO 2E. **2e. Determine Legal Guardianship** Are you <*CHILD*>'s legal guardian? IF YES, GO TO 2G. IF NO: May I please have the legal guardian's name and contact information? **END CALL.** **2f. Determine if Bioparent present in household** Does <*CHILD*>'s biological mother or father live in your house? IF YES: May I please have their name and contact information? IF NO, GO TO 2J. **2g. Determine Primary Caregiver** We also need to ask questions of an adult who can answer questions about the child's health, development, and day to day activities. We would like to talk with a person who has been primarily responsible for caring for <*CHILD*> since <*he/she*> was 6 months old and would be knowledgeable about <*CHILD*>'s health, development, and daily activities. Have you been a primary caregiver for <*CHILD*> since <*he/she*> was 6 months old?	

GO TO 2H IF NO. GO TO 2I IF YES. **2h. Respondent is not Primary Caregiver** Is there another person who is currently a primary care-giver for [child] and has lived with [child] since [he/she] was 6 months old? IF NO, GO TO 2J. IF YES: May I please have that person's name and contact information? **2i. Child Residency Information** Was <*CHILD*> born in <catchment area>? Does <*CHILD*> currently reside in <catchment area>? Does <*CHILD*> currently live in your house? IF CHILD ELIGIBLE, GO TO 3. GO TO 4A IF RESPONDENT IS ELIGIBLE AND SCQ IS *NOT* ADMINSTERED. IF CHILD ELIGIBLE, BUT CALLER NOT SPEAKING TO PRIMARY CAREGIVER: We need to call back and speak with <*primary caregiver's name*>. Do you know when would be a good time to call them? Thank you. **END CALL**. IF CHILD IS NOT ELIGIBLE, GO TO 2J. **2j. Respondent is NOT Eligible for Study** I'm sorry, but you are not eligible to participate in this study. Unfortunately, we require that <*specify reason why respondent is not eligible*>. Would you like to receive a newsletter describing the progress of the study and overall results? **END CALL**	
3. SCQ VERBAL CONSENT (if needed) Before I can invite you to be in the study I described above, I need to ask you some questions about your child's development. These questions are part of this research	

study. I will ask you a list of questions and ask you to respond “yes” or “no” to each question. It should take about 10 minutes to answer these questions. These questions will help us to learn more about your child’s development. They will also help us to determine whether you are eligible to participate in the study. Your participation in this part of the research study is voluntary; you can choose to stop at any time. There is little risk in taking part in the interview. You may feel uncomfortable answering sensitive questions about your child’s development. You can also skip any questions you feel uncomfortable answering. Answering these questions will not benefit you or your family directly. Findings may help us learn more about what causes autism and other developmental problems. This may lead to better services and treatments for children with developmental disabilities. We understand that you may have concerns about your privacy. In order to protect the privacy of all participants, CDC applied for and received a Certificate of Confidentiality. A Certificate of Confidentiality guarantees that any information that is collected that could identify you or your child will be used only for this project. It cannot be given to anyone else unless you give your written consent or unless otherwise required by law. All of the responses from these questions will be kept private. 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 the necessary study staff will have access to your personal information. If you have any concerns about the study or how it is conducted or if you feel you have been harmed by participating in the study, you may contact <Study	

Coordinator for site> at <phone number of Coordinator>. If you have questions about your rights as a research subject, you can call the Institutional Review Board representative < Representative's Name> at <Phone number of rep>. Again, I want to remind you that your participation in this part of the research study is voluntary; you can choose to stop at any time. You can also skip any questions you feel uncomfortable answering. Before I ask you these questions, I would like to get your verbal consent. Are you willing to allow me to ask you questions about your child's development? GO TO 3a IF NO. GO TO 3b IF YES.	
3a. Respondent Does NOT Want To answer the questions. I understand. Is there a better time when we could talk to you? IF YES, RECORD CALL BACK INFORMATION. **END CALL** IF NO, Thank you for your time. If you change your mind, please call <*name*> at <*number*>. **END CALL**	DOCUMENT VERBAL CONSENT ON LOG RECORD APPOINTMENT RECORD REFUSAL REASON AND WHETHER HARD OR SOFT REFUSAL
3b. Consent Obtained Thank you. I will document your verbal consent to answer these questions. *ADMINSTER SCQ.* **3c. IF RESPONDENT SCORES NEGATIVE ON SCQ:** NOTE: IF SAMPLING STRATEGY ALLOWS FOR IMMEDIATE ENROLLMENT – then a sample of these participants will be enrolled – go to 4A Thank you for participating in the screening phase of this study. You are eligible to participate, but we only are asking a certain number of people to be invited into the study. You may be called in the next week to be enrolled in the study. Thank you again for your time. If you have any questions, please feel free to contact the study at < insert	

study coordinator number>. **END CALL** **3d. IF RESPONDENT SCORES POSITIVE (automatically enrolled), GO TO 4A.**	
4. STUDY OVERVIEW **NOTE: This MAY be a second phone call for sites using the SCQ as noted above. If this is a second call, steps 1a & 2a will be repeated before moving to step 4a – study overview.** **4a. Study Overview** You are eligible for the study. Let me tell you a little more so you can see whether or not you would like to participate. The first part of the study is an enrollment packet that will be mailed to your home. The enrollment packet will contain some questionnaires and a form for you to complete that will allow project staff to review the medical records of the biological mother and your child. It will also contain a kit to collect cheek swabs by brushing <*your and your child's*> inner cheek with a soft brush. The reason why we are collecting cheek swabs is to collect cheek cells for genetic samples. It should take about <*time*> hours to complete the enrollment packet. Do you have any questions about the enrollment packet? The second part of the study is the caregiver interview. The interview will ask about the biological mother's health before and during pregnancy and <*child's name*> development after birth. It should take about <*time*> hours to complete the first interview. Are you the person who knows the most about <*CHILD*>'s health, development, and daily activities? IF YES, GO TO 4B. IF NO: Would you please give me the name and contact information for the person who is? IF YES, BUT THE RESPONDENT IS NOT THE BIO MOM: Because so many of the questions in the caregiver interview	*ANSWER QUESTIONS.* *RECORD….*

pertain to the health of the mother during her pregnancy, we prefer that the child's biological mother participates in this portion of the study if possible. We would like to contact your child's birth mother to see if she would be willing to provide a blood sample. Does she live with you at this residence? IF YES, GO TO 4B. IF NO: Would you be willing to provide me with either her telephone number or address so we can get in touch with her? What is the best way to reach her? **4B. Parent Interview** After this interview, the most knowledgeable adult will be asked to complete a second interview. This interview will contain questions about <*child's name*> development and behavior. The most knowledgeable adult can choose to do these interviews over the phone or at a study clinic. It should take about <*time*> hours to complete these interviews. Do you have any questions about the interviews? The last part of the study is a clinic or home visit. We would like to see <*child's name*> in person so that we can conduct a developmental evaluation. The evaluation will be conducted by a trained professional who has experience working with children. It includes playing some games with <*child's name*> and asking him/her some questions. You or another primary caregiver are encouraged to sit with <*child's name*> while the evaluation is administered. You will receive a letter about the results of the developmental evaluation. It should take about <*time*> hours to complete the developmental evaluation. Do you have any questions about the child developmental evaluation? We would like to conduct a brief physical exam on <*child's name*> and take photographs of his/her hands and face and look at his/her skin and features. We would also like for <*child's name*> <*and the birth parents*> to provide a blood	RECORD……..

sample and for your child to provide a hair sample. The hair sample will be analyzed for mineral content. The blood sample will be used to look at genetic and other biologic factors. The exam will be conducted by a trained professional at a study clinic. The blood and hair samples will also be collected by a trained professional at a study clinic. If you cannot come to a study clinic we can arrange to collect this information in your home. It should take about <*time*> hours to complete all of the photographs and exams and to get the samples. Do you have any questions about the photographs, exams, or blood samples? We understand that you may have concerns about your privacy. In order to protect the privacy of all participants, CDC applied for and received a Certificate of Confidentiality. A Certificate of Confidentiality guarantees that any information that is collected that could identify you or your child will be used only for this project. It cannot be given to anyone else unless you give your written consent or unless otherwise required by law. 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. It is important that we collect all of this information so we can look at possible causes of autism and other developmental disabilities. Your participation can help us reach this goal. You will be asked to sign a consent document stating that you agree to take part in the study. The consent document describes each part of the study in greater detail. It will be included in the enrollment packet for you to review and will be signed during your first face-to-face visit.	
5. CONSENT TO PARTICIPATE IN STUDY **5a. Consent** Before signing the consent document we would like to get	

your verbal consent to be enrolled in the study. If you have any concerns about the study or how it is conducted, you may contact <Study Coordinator for site> at <phone number of Study Coordinator>. If you have questions about your rights as a research subject, you can call the Institutional Review Board representative < Representative's Name> at <Phone number of rep>. At this time I would like to confirm that you want to be enrolled in the study. This means that we will send you the enrollment packet including the written consent form. This packet will have questionnaires for you to complete, and a cheek swab kit. We will call you after you have received this packet to schedule the interviews and clinic visit. Remember, you can stop participating in the study at any time. Are you willing to be enrolled in the study and be sent the enrollment packet? GO TO 5B IF NO. GO TO 5C IF YES. **5b. Respondent Does NOT Want To Be in the Study** Thank you for your time. If you change your mind, please call <*name*> at <*number*>. **5c. Consent Obtained** Thank you. I will document your verbal consent to be in the study.	RECORD REFUSAL REASON AND WHETHER HARD OR SOFT REFUSAL DOCUMENT VERBAL CONSENT ON LOG
6. INFORMATION ON ENROLLMENT PACKET **6a. General Information** You will receive an enrollment packet within one week. The enrollment packet will contain written information about the study; some questionnaires for you to complete; a release form for you to complete that will allow project staff to review you and your child's medical records; and a cheek swab kit for you to complete. There will be detailed instructions on how to complete each part of the packet and what to do next. We will call you within 2 weeks to find out	*EMPHASIZE AND/OR REPEAT THAT THE PACKET COMES WITH STEP-BY-STEP INSTRUCTIONS.*

if you have any questions. You can return the materials in a self-addressed, stamped envelope that will be provided. You will be compensated up to <*amount*> for the time and effort it takes to complete the enrollment packet.	
7. CONTACT INFORMATION **7a. Contact Information** Before we get off of the phone I would like to get some general contact information. How can I get in touch with you? How do you prefer to be contacted? What is the best time to reach you? **7b. Contact Information for Biological Father** We would like to contact your child's birth father to see if he would be willing to provide a blood sample. Does he live with you at this residence? GO TO 8A IF YES. GO TO 7C IF NO. **7c. Contact Information for Biological Father if He Does NOT Live in Household** Would you be willing to provide me with either his telephone number or address so we can get in touch with him? What is the best way to reach him?	 *GET ALL CONTACT INFORMATION.* *RECORD PREFERRED MODE OF CONTACT.* *RECORD PREFERRED TIMES AND DAYS.* *GET ALL CONTACT INFORMATION.* *RECORD BEST WAY TO REACH BIOLOGICAL FATHER.*
8. THANK YOU **8a. Thank You** Again, thank you for your interest and willingness to take part in this study. If you think of anything else you would like to know about the study or have additional questions you can call <*name*> at <*number*>.	

Appendix N