



Center for
Autism and
Developmental
Disabilities
Research and
Epidemiology

Attachment 4

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SEED Teen

Invitation Call Script

Public reporting burden of this collection of information is estimated to average 15 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

SEED TEEN Invitation Call Script

SECTION A: Introduction

SECTION 1: Initial Contact

SECTION 1: NO ANSWER

Voicemail Script:

Hi, my name is [NAME] and I'm calling from the <University of North Carolina at Chapel Hill OR Centers for Disease Control and Prevention> [If PA R: I'm calling on behalf of the University of Pennsylvania and Children's Hospital of Philadelphia.] [If MD R: I'm calling on behalf of Johns Hopkins University] I am trying to reach [PARTICIPANT'S NAME (SEED1 R WHO GAVE CONSENT)]. I am sorry I missed you and will call you back later. You are also welcome to call us, toll-free at 1-866-633-8003. Thank you. [TERMINATE CALL] [DOCUMENT CALL IN DATABASE]

SECTION 1: ANSWER

Contact Script:

Hi, my name is [INTERVIEWER'S NAME] and I'm calling from the <University of North Carolina at Chapel Hill OR Centers for Disease Control and Prevention> [If PA R: I'm calling on behalf of the University of Pennsylvania and Children's Hospital of Philadelphia.] [If MD R: I'm calling on behalf of Johns Hopkins University]. May I please speak to [PARTICIPANT'S NAME (SEED1 R WHO GAVE CONSENT)]?

1. PARTICIPANT TEMPORARILY NOT AVAILABLE ☐☐CONTINUE TO A2
2. PARTICIPANT REACHED (CONTINUE) ☐☐GO TO A3
3. PARTICIPANT NO LONGER AT THIS NUMBER ☐☐GO TO A2.1

Participant Temporarily Not Available:

A2. I am sorry I missed [HER/HIM/NAME]. What is the best time to reach [HER/NAME]? [SCHEDULE CALL BACK IN DATABASE]

Participant No Longer At This Number:

A2.1 Do you have [HER/HIS] contact information? [IF YES: THANK GATEKEEPER. UPDATE DATABASE WITH NEW CONTACT INFO] [IF NO: THANK GATEKEEPER. END CALL].

SECTION A3: Introduction to the Study

A4. Hi, [PARTICIPANT'S NAME]. I am calling because in [INSERT YEAR OF FEEDBACK LETTER] you and [CHILD'S NAME] participated in a national research study called the Study to Explore Early Development or SEED. [CHILD'S NAME] would have been between the ages of 2-5 when you participated in the study. At that time you had indicated we could contact you about future research studies.

The Centers for Disease Control and Prevention is conducting a follow-up study to SEED called SEED Teen. This follow-up research study will collect updated health and developmental information about SEED children and their families. I would like to provide more information and describe the study in a little more detail. The call should only take about 10-15 minutes to complete. Have I reached you at a convenient time?

YES [CONVENIENT TIME] 1 [GO TO Section A6]
NO [NOT A CONVENIENT TIME]2 [GO TO Section A4]
NOT INTERESTED.....3 [GO TO Section A5]

[IF RECEIVED CONTACT INFO FOR LEGAL GUARDIAN FROM GATEKEEPER START HERE]

Hello, May I speak with [LEGAL GUARDIAN NAME]?

My name is [INTERVIEWER'S NAME] and I'm calling from <University of North Carolina at Chapel Hill OR Centers for Disease Control and Prevention> regarding the national research study called the Study to Explore Early Development or SEED. I spoke with (or- received your contact information from) [INSERT GATEKEEPER NAME HERE]. [CHILD] participated in the national research study called the Study to Explore Early Development or SEED when he/she was between the ages of 2-5. The Centers for Disease Control and Prevention is conducting a follow-up study to SEED called SEED Teen. This follow-up research study will collect updated health and developmental information about SEED children and their families. As [CHILD's] legal guardian we are calling you to provide more information and describe the study in a little more detail. The call should only take about 10-15 minutes to complete. Have I reached you at a convenient time?

YES [CONVENIENT TIME] 1 [GO TO Section A6]
NO [NOT A CONVENIENT TIME]2 [GO TO Section A4]
NOT INTERESTED.....3 [GO TO Section A5]

SECTION A4: Reschedule

A4. When would be a convenient time for you to receive a callback?
[TERMINATE CALL] [SCHEDULE CALL BACK IN DATABASE]

SECTION A5: Response to Refusals

[IF A REASON IS GIVEN FOR REFUSAL GO TO A5.a]

[IF A REASON IS NOT GIVEN FOR REFUSAL GO TO A5.b.]

SECTION A5.a: I understand you said ...

RESTATE REASONS AND USE TELEPHONE INTERVIEWING SKILLS TO ATTEMPT A CONVERSION

SECTION A5.b: May I ask why you do not want to participate?

[INTERVIEWER: USE TELEPHONE INTERVIEWING SKILLS TO RESPOND TO REASON FOR REFUSAL BY STATING THE BENEFITS]

A5.c. WAS A REFUSAL CONVERSION SUCCESSFUL?

YES 1 [GO TO A6]

NO 2 [QUICKLY CHECK SAVED EXPORT TO DETERMINE IF FAMILY PREVIOUSLY AGREED TO STORE WITH IDENTIFIERS] [IF NO: Thank you! If you change your mind about participating please call us at <phone number> [IF YES: Alright, that's fine. Since the time of your participation in SEED there have been several national efforts for studies such as SEED to share information to help the progress of scientific discoveries. Would you be willing to review a consent form that asks for your permission to share some of the genetic data we collected from you and [CHILD] in the first SEED study with national data repositories? IF YES: Thank you. [INTERVIEWER GO TO A6, then Section C to determine eligibility then Section F]. IF NO: Thank you! If you change your mind about participating, please call us at <phone number>.

SECTION A6: Quality Assurance

A6. Thank you! I would like to let you know that the call is being recorded for Quality Assurance purposes. Are you in a place where you can talk safely on the phone?

YES 1 [GO TO SECTION B]
NO 2 [GO TO SECTION A4]

SECTION B: Description of Study

[FOR NC and GA RESPONDENTS]

SEED Teen is funded by the national Centers for Disease Control and Prevention (CDC). SEED staff from the CDC and the University of North Carolina at Chapel Hill are working together to conduct the study. We are contacting families from four SEED sites located in Georgia, Maryland, North Carolina, and Pennsylvania.

What we learn from this research may lead to better services and treatments for children with autism and other developmental delays and will help us understand similarities and differences between teens with autism and teens without autism.

The study involves completing some questionnaires that will cover topics related to your child's development and family's health.

[FOR MD and PA RESPONDENTS]

SEED Teen is funded by the national Centers for Disease Control and Prevention (CDC). SEED staff from the CDC and the University of North Carolina at Chapel Hill are working together to conduct the study. We have also partnered with two other SEED sites – Johns Hopkins University in Maryland and University of Pennsylvania and Children's Hospital of Philadelphia. Thus, SEED Teen will include families from four SEED sites located in Georgia, Maryland, North Carolina, and Pennsylvania.

What we learn from this research may lead to better services and treatments for children with autism and other developmental delays and will help us understand similarities and differences between teens with autism and teens without autism.

The study involves completing some questionnaires that will cover topics related to your child's development and family's health.

SECTION C: ELIGIBILITY SCREENING

Now I have a few questions to help us determine your eligibility.

1. Do you currently live with [CHILD] YES, All of the time01[GO TO 2]
YES, Part of the time.....02 [GO TO 2]
NO, None of the time.....03 [GO TO 1a.]

[If Respondent reports child is deceased express condolences, thank them for their time, END CALL. GO TO AA.A]

1a. Are you still [CHILD's] legal guardian? YES.....01 [GO TO 3a]
NO.....02 [GO TO 1b.]

_____ NO is not legal guardian [GO TO 2.a.]

- 2a. Who is [CHILD's] current legal guardian?
- BIOMOM..... 01 [GO TO 2b.]
 - BIODAD.....02 [GO TO 2b.]
 - STEP PARENT.....03 [GO TO 2b.]
 - GRANDPARENT04 [GO TO 2b.]
 - OTHER RELATIVE05 [GO TO 2b.]
 - OTHER.....06 [GO TO 2b.]

2b. We would like to contact [CHILD's] legal guardian to see if they might be interested in participating in the follow-up study. Do we have your permission to contact the [CHILD'S LEGAL GUARDIAN RELATIONSHIP, E.G. CHILD'S FATHER, CHILD'S GRANDMOTHER]?

- YES.....01 [GO TO 2b.1]
- NO.....02 [GO TO 2b.2]

Can you provide [HIS/HER] contact information?

2b.1 LEGAL GUARDIAN

FIRST NAME _____

LAST NAME _____

ADDRESS _____

PHONE NUMBER _____

EMAIL ADDRESS _____

DK CONTACT INFO..... [Thank GK END CALL.]

Thank you for your help. We appreciate your time. [END CALL]

2b. 2 That's fine, we understand. We would like to leave our contact information for you to pass on to [CHILD's] legal guardian if you change your mind. Would that be OK? [IF YES: give site contact information, thank gatekeeper, END CALL. INELIGIBLE GO TO AA.B [Can re-status family if receive call] IF NO: Thank gatekeeper for their time. END CALL. INELIGIBLE GO TO AA.B].

3a. Who does [CHILD] currently live with _____ [RECORD VERBATIM]

[IF NEEDED PROBE FOR RELATIONSHIP]

- BIOMOM..... 01 [GO TO 3b.]
- BIODAD.....02 [GO TO 3b.]
- STEP PARENT.....03 [GO TO 3b.]
- GRANDPARENT04 [GO TO 3b.]
- OTHER RELATIVE05 [GO TO 3b.]

SECTION D: STUDY STEPS OVERVIEW

Your family is eligible to participate. Next, I'd like to tell you some details about the study so you can make a better informed decision whether or not you would like to participate. This study involves filling out two questionnaires about your child's health and development. We estimate that it will take approximately 1 hour total to complete both questionnaires. You will receive a \$30 <cash card or money order> if you take part in SEED Teen and complete the questionnaires.

If you decide to participate, we will send you a packet of materials. The Packet contains:

- An information sheet for you to keep – it provides information on your rights as a research participant and also gives information about your participation in SEED Teen.
- The two questionnaires for you to fill out will also be in the packet. The questionnaire topics will be about your child's health and development and your health and well-being. We ask you to complete these forms and return them to us in the prepaid mailing envelope that will also be in the packet.

If you have any questions about these forms or would like to complete them over the phone with us instead of on your own, you can call us. We are happy to set up a time that is convenient for you to complete these over the phone.

[IF CHILD BIOSAMPLE COLLECTED IN SEED CASE-CONTROL STUDY AND PARENT AGREED FOR BIOSAMPLE TO BE STORED WITH IDENTIFIERS, PROCEED WITH THIS SCRIPT]

- The packet also will include two other forms. These are both consent forms we ask you to read and consider. These two forms are not part of the SEED Teen Study and will not affect your eligibility to be in SEED Teen. They are about opportunities for your child to be in other research studies.
- One of the consent forms asks you to indicate whether or not SEED staff may contact you and/or your child in the future to talk about opportunities to participate in other SEED studies, when your child reaches adulthood.
- The second form asks you to indicate whether you consent to share some of the genetic data we collected from you and your child [or from your child IF RESPONDENT IS SOMEONE OTHER THAN MOTHER], with other autism researchers working with national research efforts through the US National Institutes of Health.

When you get the packet, please read over this consent form. It includes more information on these national research efforts and the type of information we would provide to them.

The choice to provide consent for either of the two opportunities I just described is completely up to you. You can be part of SEED Teen whether or not you give us these consents.

[IF NO CHILD BIOSAMPLE COLLECTED IN SEED CASE-CONTROL STUDY OR PARENT DID NOT CONSENT FOR BIOSAMPLE TO BE STORED WITH IDENTIFIERS, PROCEED WITH THIS SCRIPT]

- The packet also will include one other form for you to read and consider.
- It is a consent form that asks you to indicate whether or not SEED staff may contact you and/or your child in the future to talk about opportunities to participate in other SEED studies, when your child reaches adulthood.

The choice to provide consent for future contacts is completely up to you. You can be part of SEED Teen whether or not you give us this consent.

SECTION E: VERBAL CONSENT TO ENROLL

Next I will read the Verbal Consent regarding enrollment in SEED Teen. Afterwards, I am required to ask you for your decision so we can document your verbal consent for our records.

Your participation is voluntary. You can choose not to participate at any time or to skip any questions you do not want to answer. There is little risk in taking part in this study. You may feel uncomfortable answering sensitive questions about your child's health and development.

Your participation will not benefit your family directly. What we learn from this research may lead to better services and treatments for children with autism and other developmental delays and will help us understand similarities and differences between teens with autism and teens without autism.

We understand that you may have concerns about your privacy. In order to protect the privacy of all participants, we have received a Certificate of Confidentiality. The 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. However, by law, we must report to the State if you tell us you are planning to cause serious harm to yourself or others.

All of the information we collect from your family will be kept private. We will never use your name or [CHILD'S] name in any report. Information in reports or scientific papers from this study will be including only information from study participants combined together.

Rather than using your names, you will be given a study ID. The study ID will be recorded on all study forms. When we use data from the study to do analyses, only the study IDs will be used and not names. 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, you may contact our Principal Investigator, [NAME and PHONE]. If you have any questions about your rights as a research subject, you may call the [SITE IRB AND CONTACT NUMBER]. Both of these contact numbers will be included in the packet we send you.

Again, I want to remind you that your participation in this research study is voluntary. If you give your consent today you can still decide at any time that you do not want to participate. To withdraw from this study, you may contact our Project Coordinator [NAME and PHONE]. This number will also be included in the packet we send you.

Now I need to ask for and document your verbal response to our request to consent.

ENROLLMENT CONSENT: Are you willing to enroll in the study?

YES 1 [GO TO SECTION F]
NO 2 [IS THERE ANY PARTICULAR REASON YOU ARE NOT INTERESTED IN PARTICIPATING?] [SPECIFY _____]
Thank you! If you change your mind about participating, please call us at <phone number>.

SECTION F: CONTACT INFORMATION

Thank you! Now I would like to verify your contact information.

Name: (First) _____ (Last) _____

Address: _____

Phone 1: _____

Phone 2: _____

Email: _____

SECTION G: END CALL

Thank you for your time today.

You can expect to receive your packet over the next week. We will follow-up in about a week or so to make sure you received the packet and to answer any questions you may have. In the meantime, if you have any questions, please call us at <PHONE #>.

AA. INELIGIBLE/REFUSAL REASONS:

A. CHILD IS DECEASED. [Document call]

B. NO ACCESS TO LEGAL GUARDIAN. Unfortunately your family is not eligible to participate. We must have permission from [CHILD's] legal guardian in order for your family to participate. Thank you for your time. [END CALL]

C. CHILD CURRENTLY IN JUVENILE JUSTICE SYSTEM/JAIL. Unfortunately your family is not eligible to participate. Thank you for your time. [END CALL]

D. CHILD CURRENTLY IN FOSTER CARE. Unfortunately your family is not eligible to participate. Thank you for your time. [END CALL]

E. LEGAL GUARDIAN WHO IS NOT FAMILIAR WITH CHILD'S HEALTH, HEALTH CARE, EDUCATION, AND CURRENT ACTIVITIES. Unfortunately your family is not eligible to participate. Thank you for your time. [END CALL].