

SEED Follow-up – Call Script for SEED 1-3 Caregivers (1st Follow-Up)

PRIOR TO CALL, CHECK DATABASE TO DETERMINE NEED TO OBTAIN SUPPLEMENTAL CONSENT FOR SHARING GENETIC DATA – criteria = FAMILY PARTICIPATED IN SEED 1, PREVIOUSLY AGREED TO STORE BIOSAMPLES WITH IDENTIFIERS, BUT WAS NOT ENROLLED IN SEED TEEN]

SECTION A: INTRODUCTION

SECTION 1: Initial Contact

SECTION 1: NO ANSWER

Voicemail Script:

Hi, my name is [NAME] and I'm calling on behalf of the Centers for Disease Control and Prevention. I am trying to reach [PARTICIPANT'S NAME (SEED1-3 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 [phone number]. Thank you.

[TERMINATE CALL] [DOCUMENT CALL IN DATABASE]

SECTION 1: ANSWER

Contact Script:

Hi, my name is [INTERVIEWER'S NAME] and I'm calling on behalf of the Centers for Disease Control and Prevention. May I please speak to [PARTICIPANT'S NAME (SEED1-3 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 AND CONTACT NEXT GATEKEEPER AS AVAILABLE OR CONDUCT ADDITIONAL CONTACT TRACING. END CALL].

If participant is no longer at the number on file, CNI will carry out the following activities:

1. Look for contact info for another caregiver/parent
2. If contact information for another caregiver/parent is not on file, CNI will conduct additional contact tracing to identify current contact information for the potential participant.
3. If contact information for another caregiver is not on file AND additional contact tracing is unable to identify current contact information for the potential participant, CNI will update the potential participant's status in the participant tracking database as 'Lost to follow-up' or LTFU

Public reporting burden of this collection of information is estimated to average 10 minutes per response, 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, GA 30333: ATTN: PRA (0920-xxxx).

[Type here]

SECTION A3: Introduction to the Study

[IF SPEAKING TO PARENT WHO PARTICIPATED – IF GATEKEEPER PROVIDE SKIP TO A.3.2]

A3.1. Hi, [PARTICIPANT'S NAME]. I am calling because in the past, you and [CHILD'S NAME] participated in the Study to Explore Early Development, or SEED, that was conducted by [ORIGINAL STUDY SITE] in collaboration with the Centers for Disease Control and Prevention (CDC). [CHILD'S NAME] would have been between the ages of 2-5 when you first participated in the study. At that time, you had indicated we could contact you about future research studies.

We are now conducting a follow-up study to SEED. This study will help us learn more about different types of children as they grow older. One of our goals is to identify how we can support people with autism and other developmental delays or disabilities as they mature. To reach our goals, we need different types of families and children, adolescents and young adults to participate in the study. 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]

A3.2. Hello, May I speak with [CAREGIVER'S NAME]?

My name is [INTERVIEWER'S NAME] and I am calling because in the past [CHILD'S NAME] participated in a national research study called the Study to Explore Early Development or SEED. SEED was conducted by [ORIGINAL STUDY SITE] in collaboration with the Centers for Disease Control and Prevention. [CHILD'S NAME] would have been between the ages of 2-5 when [He or She] first participated in the study.

We are now conducting a follow-up study to SEED. This study will help us learn more about different types of children as they grow older. One of our goals is to identify how we can support people with autism and other developmental delays or disabilities as they mature. To reach our goals, we need different types of families and children or adolescents to participate in the study. [CHILD'S NAME] parents/guardian indicated we could contact you about this study. 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]

SECTION A4: Reschedule

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

SECTION A5: Response to Refusals

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

[Type here]

[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?
RECORD REASON HERE: _____

[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. IF NO: Thank you for your time. I understand you do not want to participate today.
Can I ask you about other opportunities?

YES..... 1 [GO TO SECTION H]

NO.....2 .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 remainder of this call will be 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 ALL RESPONDENTS]

Thousands of families across the country who participated in SEED when their children were 2-5 years are being asked to be in a new series of SEED Follow-up Studies. SEED staff from the Centers for Disease Control and Prevention (CDC) and other SEED sites are working together to conduct the Follow-up Studies.

The first study involves completing a survey about your child’s health and development. It should take about one hour to complete the questionnaire. We know your time is valuable. You will be given a \$30 gift card to thank you for your time. (FOR SEED 1 AND 2 PARTICIPANTS ONLY: Once you have completed that questionnaire, we might ask if you and your child wish to participate in additional parts of the SEED Follow-up Studies. This could include additional questionnaires or an in-person developmental evaluation of your child. You will receive additional gift cards if you complete more study steps. If your child is 18 years or older, or will be soon, we may also ask if your child would like to participate in additional steps.)

SECTION C: ELIGIBILITY SCREENING

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

1a. What is [CHILD’S] current living situation?

[Type here]

- BIOMOM..... 01 [GO TO 1b.]
- BIODAD.....02 [GO TO 1b.]
- BIOMOM & BIODAD02 [GO TO 1b.]
- STEP PARENT.....03 [GO TO 1b.]
- GRANDPARENT04 [GO TO 1b.]
- OTHER RELATIVE05 [GO TO 1b.]
- OTHER05 [GO TO 1b.]
- RESIDENTIAL FACILITY...06 [GO TO 1b.]
- JUV JUS/JAIL.....07 [INELIGIBLE GO TO AA.C]
- FOSTER CARE.....08 [INELIGIBLE GO TO AA.D]
- DECEASED.....09 (END CALL.)

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

1b. The caregiver who participates in the SEED Follow-up Studies should be an adult who is familiar with this CHILD's health, health care, education, and current activities. Would you be able to answer questions about this child's health, education, and current activities?

- YES.....01 [GO TO D.1]
- NO.....02 [GO TO 1c]

1c. If NO, is there someone familiar enough with the child to answer questions about the child's health, health care, education, and current activities?

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

1d. Do we have your permission to contact this person to see if they might be interested in participating in this SEED Follow-up study?

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

1d.1 Can you provide [HIS/HER] contact information?

RELATION TO CHILD _____

FIRST NAME _____

LAST NAME _____

ADDRESS _____

PHONE NUMBER _____

EMAIL ADDRESS _____

DK CONTACT INFO..... [GO TO 1d.2.]

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

[Type here]

1d.2 That's fine, we understand. We would like to leave our contact information for you to pass on to [CHILD's] legal guardian in case they are interested. 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].

SECTION D: STUDY STEPS OVERVIEW

D.1 Your family is eligible to participate in the study. Next, I'd like to tell you some details about the study so you can make a better-informed decision about whether you would like to participate. The part of the study we would like to talk with you about today involves filling out a survey and some questionnaires about your child's health and development. We estimate that it will take approximately 1 hour total to complete the survey and questionnaires. You will receive a \$30 gift card to thank you for the time it takes to fill out the survey and questionnaires.

You may choose to complete the survey online via a weblink. If you choose to complete the questionnaire by web, we can email you a link to the survey.

If you prefer, you can also complete the survey over the phone with a study team member. I can set up a time for someone to call you back – or if you have time, I could also complete the survey with you now.

Do you prefer to complete the questionnaire online, or over the phone?

ONLINE.....1 go to D.3

PHONE.....2 go to D.3

NEITHER....3 go to D.2

D.2 [ONLY OFFER IF PARTICIPANT INDICATES UNABLE TO COMPLETE BY WEB OR PHONE]

I am sorry that neither one of the options will work for you. Would you prefer to complete the questionnaire by mail?

If YES, verify contact information and notify SEED site:

Address: _____

Phone 1: _____

Phone 2: _____

Email: _____

D.3 Do you prefer to complete the survey in English or Spanish?

D.4 No matter how you complete the questionnaire, we will ensure you receive 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 the SEED Follow-up Study. I can email a link for you to download this information sheet – or take your email address to send you a copy.

EMAIL.....1 record in database

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[Type here]

If you choose to complete the questionnaire by paper, we will also send you a packet of materials that contains:

- The information sheet with your rights as a participant
- The questionnaire for you to fill out and mail back to us
- Prepaid envelope to mail the completed questionnaire back to us.

[READ TO ONLINE AND MAIL PARTICIPANTS]

If you find you have any questions about these forms as you complete them then you can call us. We may also contact you to set up a time to speak with you if we need to clarify any of your responses.

SECTION E: VERBAL CONSENT TO ENROLL

Next, I will read the Verbal Consent regarding enrollment in the SEED Follow-up Study. 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 will help us better meet the needs of children with and without autism and their families as they grow into adolescence and adulthood.

We understand that you may have concerns about your privacy. To protect the privacy of all participants, CDC has received a Certificate of Confidentiality. This means 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. By law, we mean that we must report to the State if you tell us, or we suspect, 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 include 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 contact information.

If you have any concerns about the study, you may contact <site PI/PC and phone>. If you have any questions about completing the survey, you may contact <CNI staff and phone>. If you have questions about your rights as a research participant, you can call the <IRB office contact> at <phone number>. All of these contact numbers will be included in the packet we send you with information about the study and your rights as a participant.

Again, I want to remind you that your participation in this research study is voluntary. You are allowed to drop out of the study at any time without penalty. 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 <CNI staff 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.

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[Type here]

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

YES 1 [GO TO SECTION F]

NO2 [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: PREFERENCE FOR INCENTIVES

Once we receive your completed questionnaire, we will send you a \$30 gift card to thank you for your time. Would you prefer to receive an electronic gift card that will be sent to you by email, or a physical gift card mailed to your address?

- Electronic gift card
- Physical gift card

SECTION H: OTHER PERMISSIONS

H.1. Permission to contact you for future studies

Do you agree to allow SEED staff to continue to contact you about future studies? If you agree, then you are providing your permission for SEED staff to contact you in the future. SEED staff will explain the new study and you can agree or decline to participate. These studies would be related to ASD and/or other developmental delays or disabilities. The person contacting you would be SEED staff working at CDC or one of the other SEED sites that has been collaborating with CDC. All SEED sites are held to the same confidentiality standards and are bound by the CDC Certificate of Confidentiality.

YES, I AGREE to be contacted for future research studies.....

NO, I DO NOT WANT to be contacted for future research studies.

H.2 Permission to link your information in future studies

In the future, SEED researchers may want to link the information we collect about you with other data

[Type here]

sets. For example, this could be census data or data on environmental chemicals in areas where you lived. If you agree, researchers from the SEED sites listed above may link your data with other data sets. We will not contact you again or ask you to give us more information for these linkages.

YES, I AGREE to allow my information to be linked in future research studies.

NO, I DO NOT WANT my information to be linked in future research studies.

H.3 Overview of supplemental consent form to share genetic information

[IF CHILD BIOSAMPLE COLLECTED IN SEED I, AND PARENT AGREED FOR BIOSAMPLE TO BE STORED WITH IDENTIFIERS, AND PARENT WAS NOT INVITED TO SEED TEEN PILOT, PROCEED WITH THIS SCRIPT]

During the original SEED study, we collected blood and or saliva specimens from you and your child. These samples have DNA in them. We are using them to learn more about how genes might be connected to autism or child development. Since that time, there have been several national efforts through the U.S. National Institutes of Health for studies such as SEED to share information to help the progress of scientific discoveries.

We would like to mail you a form that provides more information on these national efforts and the type of information we would provide to them. Please read over the form and if you agree to share your genetic information, we will need you to fill out the form and mail it back to us. This form is not part of the SEED Follow-up Study and will not affect your eligibility to be in the study.

YES, please mail me the consent form.

NO, please do not mail me the consent form. I do not want my genetic information to be shared.

SECTION I: END CALL

Thank you for your time today.

If participant chooses to complete questionnaire online:

We will email you a weblink to complete the questionnaire online soon. The email will come from [CNI email] with the subject "SEED Survey." We will follow-up in about a week or so to make sure you received the weblink and to answer any questions you may have. In the meantime, if you have any questions, please call us at <PHONE #>.

If participant chooses to complete questionnaire by phone:

Let's go ahead and set up an appointment for us to complete the questionnaire with you by phone.

If participant chooses to complete questionnaire by mail:

You can expect to receive your packet in the mail soon. 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]

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[Type here]

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].