Form Approved
OMB No. 0920-XXXX
Exp. Date: XX/XX/XXXX

# **INVITATION CALL SCRIPT: POTENTIAL POP**

NOTE: RESPO	NSE FROM SUBJECT .			(GOTO IN	NTRO I)
	CT DID NOT RESPONI				
<u>INTRODUCTI</u>	ON I - RESPONSE RI	ECEIVED	_		
Hello, May I spe	eak with <b>[SUBJECT NA</b>	ME/BION	MOM].		
	SUBJECT: How can I rea			to call back?	
	(UPI	DATE CONTA	CT INFO/END CAL	 L)	
Early Development Prevention. I rece	ME] and I'm calling regard nt or SEED. The study is sived your [RESPONSE Modes]  Jy. (GO TO 2 BELOY)	sponsored by ODE] and w	y the US Centers	s for Disease (	Control and
<u>INTRODUCTI</u>	<u>ON II - NO RESPONS</u>	E RECEI	<u>VED</u>		
Hello, May I spe	eak with <b>[SUBJECT N</b> A	ME/BION	<b>MOM</b> ].		
a. If not	SUBJECT: How can I rea	ach her? / W	hat time is best	to call back?	
	(UPI	DATE CONTA	CT INFO/END CAL	 L)	
national research	ME] and I'm calling to follo study called the Study to E s for Disease Control and P	Explore Early			
1. Did you r	eceive the invitation?		(CONT (VERIF	,	S/CONTINUE)
2. Is this a g	ood time to talk to you abo	out the study		. (GO TO REC . (go to 3.)	CORD CALL) below
3. When is a	better time to call back?				

Public reporting burden of this collection of information is estimated to average 20 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 (0920-0010).

DAY_	DATE		TIME(S)	AM/PM
RECO	ORD CALL			
If it's	okay with you, I'd like to record this call for training purp	oses.	(TURN ON RECORDER)	
4.	The recorder is on will it be OK to record this call?	YES		
		NO	(TURN OFF RECOR	DER/CONT)
INVI	<b>FATION</b>			
and au childre	is one of the largest studies about child development and tism spectrum disorders. To make the study a success, we must and without developmental disabilities. We would pate in this study. But the first step in the process is to see	e hope Id like	e to enroll mothers a for everyone who is	nd their s invited to
<b>ELIG</b>	IBILITY SCREENING:			
E1. A	re you the biological mother of a child born January 1, 20 TO a. / CONFIRM BELOW)	14 – I	December 31, 2017?	$\mathbf{Y}$ $\mathbf{N}$ (IF
,	a. If not SUBJECT: How can I reach her? / What time	e is be	st to call back?	
	(UPDATE CONTACT INFO/	END C	 ALL)	
	b. If no child born in that date range, thank person, EN	ND CA	LL.	
	c. If more than one child born in that date range, speci	fy chi	ld's name, go to E2b	).
E2a. W	Vhat is your child's full name			
	What is < CHILD > date of birth?///_BLE BLOCK A)		(VERIFY	/ <mark>IF INELIG GO TO</mark>
E3. Do	oes < <i>CHILD</i> > live with you?	Y	N (IF NO/ GO TO INEL.	IGILBE BLOCK B)
E4. Do	you have legal guardianship of <i><child></child></i>	Y	${f N}$ ( ${}^{f IF}$ NO/ ${}^{f GO}$ TO ${}^{f INEL}$	LIGILBE BLOCK E)
E5. Ha	eve you cared for <i><child></child></i> since birth (or since 6 months F)	s old)?	Y N (IF NO/ GO	O INELIGILBE
E6. W	hat county were you living in when < <i>CHILD</i> > was born?  OF AREA/ GO TO INELIGILBE BLOCK D)			
	hat county do you currently live in?  OF AREA/ GO TO INELIGILBE BLOCK C)			
	English [OR SPANISH – select sites] the main language ASK a.) below)  a. Do you and <child>understand and speak English/(IF NO/ GO TO INELIGILBE BLOCK H)</child>	_	•	Y N
E.9.	Does < CHILD > have problems seeing/hearing/or moving	g arou	and by him/herself?	<b>N</b> Y (ASK a, b,

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- a. Please describe condition
- b. Has the problem been corrected?

 $\mathbf{N}$  Y (GO TO E10 BELOW)

c. A trained professional will assess your child's development thru games that require seeing, hearing, and moving around. Do you think your child will be able to participate in the developmental evaluation?  $\mathbf{Y}$  (GO TO NOTE BELOW)  $\mathbf{N}$ 

(IF NO TO b or c/ GO TO INELIGILBE BLOCK G)

**NOTE:** OUR STUDY CLINICIAN MAY CALL TO INQUIRE ABOUT *CHILD* CONDITION AS IT RELATES TO THE DEVELOPMENTAL EVALUATION. When is the best time to call?

E10. Has <*CHILD*> been dx with Autism or an Autism Spectrum Disorder (ASD)? Y

E11. Have any of your other children ever participated in SEED? **N Y** (Ask a, b, c, d)

- **a.** How many? (If more than one other child, for each child ask questions b, c and d)
- **b.** What is your child's full name?
- **c.** What is your child's date of birth?
- **d.** What is your child's sex? (or, based on name, confirm if it is a boy or girl)

(IF OTHER CHILDREN IN SEED, SUBJECT IS INELIGIBLE/ GO TO INELIGIBE BLOCK I)

Thank you! You are eligible to participate. (VERIFYCONTACT INFO BEFORE ENDING CALL—SEE BIOLOGICAL MOTHER CONTACT INFO BLOCK)

# **BACKGROUND AND STUDY STEPS OVERVIEW**

Next, I'd like to tell you a bit more about the study including what you would be asked to do if you decide to participate. If you decide to enroll, you will receive an additional incentive for your participation in the rest of this call. (~ 25 mins)

SEED is a national research study being conducted at 6 sites throughout the US in *<participating sites>*. As I said, SEED is one of the largest studies about child development and the causes of developmental disabilities and autism spectrum disorders.

The study consists of several different parts including a telephone interview, completing questionnaires, a developmental assessment with the child, and a brief physical exam.

Your participation in each component is voluntary and consented separately.

Before I can tell you what your total involvement might be and the amount of incentives you might receive, I'll have to ask you some questions about <CHILD's> development. Before I can do that, I would like to get your verbal consent to ask these questions.

#### **VERBAL CONSENT TO ADMINISTER SCQ**

Your participation is voluntary. You can choose to stop at any time. There is little risk in taking part in this study; however, you may feel uncomfortable answering sensitive questions about *<CHILD>* development. You can also skip any questions you feel uncomfortable answering.

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Answering these questions will not benefit 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, *<site>* applied for and received a Certificate of Confidentiality. The Certificate of Confidentiality guarantees that any information that is collected that could identify you or *<CHILD>* will be used only for this project. It cannot be given to anyone else unless you give your written consent or 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 *<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. The study ID will be recorded 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 *Project Coordinator*> at *number*. "If you have any questions about your rights as a participant in this study, please contact *site specific* at *phone number*. Leave a message with your name, phone number, and refer to *site specific protocol number*, and someone will call you back."

Again, I want to remind you that your participation in this research study is voluntary; you can choose to stop at any time

Do you have any questions about the consent form? NO YES

Do you verbally consent to me asking you questions about *<CHILD>* development?

**NO:** Thank you for your time. If you change your mind please call *site main number*. **END CALL, after getting contact information to mail incentive**)

**YES:** Thank you. Please answer "YES" or "NO" if any of the following behaviors were present during the past 3 months. There are no right or wrong answers; our goal is to get a general idea of how <CHILD> responds in certain situations.

# **ADMINISTER SCQ**

SCQ Score:	(Index child)
	<b>11 or higher (Score)</b> 9.0 hours - \$325
	0 - 10 (Score)
If Score < 11, w YES NO	hat was Question E10 response on previous ASD Diagnosis? 9.0 hours - \$300 5.5 hours - \$175

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# If SCQ ≥ 11 OR E10 response was YES -- assigned to ASD workflow:

Thank you! We estimate that your total involvement will take approximately 9 hours over the course of several months and you can receive an incentive up to \$300 depending on the number of components you complete. The incentive is to thank you for your time and to cover any out of pocket expenses.

### If SCQ < 11 AND E10 response was NO – assigned to POP workflow:

Thank you! We estimate that your total involvement will take approximately 5.5 hours over the course of several months and you can receive an incentive up to \$175 depending on the number of components you complete. The incentive is to thank you for your time and to cover any out of pocket expenses.

Now, I will explain the specific steps of the study.

# **Enrollment Packet** - The EP contains...

-Written materials that will further explain the study (Informed Consent/ Bill of Rights)

#### Maternal Interview (1 hour - \$30)

Next will be a telephone interview about your health before & during pregnancy & *<CHILD*'s> development after birth

<u>One packet of forms</u> – (about 2 hours - \$40) After the maternal interview we will send you a packet of forms for you to complete about your child's development and your family's health. These can be done at home alone or with help from study staff at the clinic visit or over the phone. This packet will also have information that will help you prepare for the clinic visit.

<u>Clinic/Home Visit</u> - (Approx. 5. 5 hours for ASD -\$200; Approx. 2.0 hours for POP - \$75) We will also arrange for an evaluation of your child's development either at a clinic or in your home. At this visit, we will obtain your written consent, review study documents, administer the Developmental Evaluation and have a brief physical examination. The clinic visit can be conducted at <site specific locations> and we require you to sit in during the visit.

a. **Developmental Evaluation of** *<CHILD>* (*cognitive &emotional dev.*, *lang, adaptive & motor skills*) -A trained professional will assess *<CHILD*'s> development through games & provide a feedback letter with results & recommendations if necessary, approx. 4 weeks after the visit.

#### FOR ASD Only:

Also during CV a trained professional will ask you additional questions about *CHILD's* development and behavior and services *CHILD* may be receiving. **(ADI-R, VINELAND, AND SERVICES AND TREATMENTS QUESTIONNAIRES)** 

- b. **Brief Physical Exam** during the brief physical exam we will:
  - Collect saliva from you and < CHILD>, and from < CHILD's> biological father, if he is available
  - Measure height and head circumference of you and <CHILD> and weigh <CHILD>
  - Draw blood from you & <CHILD>

Do you have any questions about the study?

NO YES

#### VERBAL CONSENT TO ENROLL

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Consent Form that I just read to you is also used to obtain your verbal consent for these questions. Would you like me to re-read the verbal consent form? NO YES (REREAD CONSENT) Do you verbally consent to me enrolling you in the study? NO: Thank you for your time. If you change your mind please call <site main number>. END CALL, after getting contact information to mail incentive) YES: Proceed with next section. Thank you! Now I would like to ask you just a few questions about yourself, <child's> father and <child>. Is <CHILD> Male\_\_\_\_\_ Female \_\_\_\_\_ (This may have already been ascertained) What is your date of birth? \_\_\_\_\_/ Next, I'd like to get some information on where to mail study materials and the best way to reach you for future calls. (complete BIOLOGICAL MOTHER CONTACT INFO BLOCK) Does <CHILD'> biological father live with you and <*CHILD*>? Y Ν **IF NO:** Are you able to provide the father's name and contact information? Y N (If YES, complete BIOLOGICAL FATHER CONTACT INFO BLOCK) We would also like the name of another person we can contact in case we need to reach someone for you during our visit with you and your child. (complete EMERGENCY CONTACT INFO BLOCK) Twice a year we email participants a SEED newsletter informing them of the progress we're making in the study. Are you interested in receiving the newsletter? Y N **IF YES**/ What is your email address? (Record below) **IF NO** (GO TO UPCOMING APPTS. below) Email: \_\_\_\_\_

The next step in this call is to enroll you into the study if you are interested. The Verbal

#### **UPCOMING APPOINTMENTS**

The final step in the process today is to schedule your two telephone interviews.

#### Follow-Up 1 Call

The first telephone interview is to obtain specific dates relating to your pregnancy with *<CHILD>*. This call will take approximately 15 minutes. When is the best time to call?

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DAY	DATE	TIME(S)	AM/PM
before and during yo	v will take approximately 60 minutes our pregnancy and < <i>CHILD</i> > develop	oment after birth. This 2 <sup>nd</sup> appo	
need to be scheduled	at least 2 weeks after the first call.	When is the best time to call?	
DAY	DATE	TIME(S)	AM/PM_
Thank you for your	time and willingness to take part i	n the SEED study.	(END CALL)

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#### INELIGIBLE – if ineligible, read only the option below that pertains to this family

Unfortunately, you are not eligible to participate. One of the requirements of the study is that.....

- A. The *<CHILD>* must be born between 1/1/2014 12/31/2017
- B. The *<CHILD>* must currently live with biological mother to participate
- C. The *<CHILD>* must currently live in a participating county
- D. The biological mom must have lived in one of the participating counties when *<CHILD>* was born
- E. Biological mother must have Legal Guardianship of *<CHILD>*
- F. Biological mother must have cared for child since birth or (since 6 months old).
- G. Child must not be deaf or blind and must not have mobility restrictions that would greatly restrict participation in the developmental evaluation.
- H. The bio mom must be able to "competently" communicate orally in English [or SPANISH select sites]
  - I. Child must not have a sibling taking part in the study.

Thank you for your time today. (VERIFYCONTACT INFO BEFORE ENDING CALL-GO TO BIOLOGICAL MOTHER CONTACT INFO BLOCK)

REFUSAL Is there any particular reason you decided not to participate?			
I respect your decision! Do you mind answering a few screening questions, before hang	ging up	o?	
R1. Are you the bio mother <i>of</i> < <i>CHILD</i> > born between 1/1/2008 - 12/31/2011?	Y	N	
R2. Do you have legal guardianship of <i>CHILD</i> ?	Y	N	
R3. Have you cared for <child> since birth/6 months of age?</child>	Y	N	
R4. Does < CHILD > live with you?	Y	N	
R5. Is < CHILD > Male Female			
R6. What county were you living in when <i><child></child></i> was born?			
R7. Is <child> deaf or blind?</child>	Y	N	
R8. Do you/< <i>CHILD</i> > currently live in <site counties="" specific="">?</site>	Y	N	
R9. Is English [or SPANISH select sites] the main language spoken in the home?	Y	N	

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R10. Does < CHILD > have an Autism Spectrum Disorder diagnosis?	Y	N	
R.11 Have any of your children ever participated in SEED?	Y	N	
IF MOTHER ANSWERED ELIGIBILITY QUESTIONS, VERIFYCONTACT INFO BEFORE ENDING CALL-GO TO BIOLOGICAL MOTHER CONTACT INFO BLOC	CK)		

Thank you for your time. If you change your mind please call <site main number> **(END CALL)** 

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#### **CONTACT INFORMATION**

# **BIOLOGICAL MOTHER** ☐ Contact info in CIS NAME \_\_\_\_ ADDRESS\_\_ PHONE NUMBER\_\_\_\_\_ Alt: \_\_\_\_\_ DAY \_\_\_\_\_TIME(S)\_\_\_\_AM/PM **BIOLOGICAL FATHER** ☐ Contact info in CIS NAME ADDRESS\_\_\_\_ PHONE NUMBER Alt: \_\_\_\_\_ DAY \_\_\_\_\_ TIME(S)\_\_\_\_AM/PM EMERGENCY/ALTERNATE CONTACT NAME ADDRESS

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DAY \_\_\_\_\_ TIME(S) \_\_\_\_AM/PM

PHONE NUMBER\_\_\_\_\_ Alt: \_\_\_\_\_

RELATIONSHIP TO < CHILD> \_\_\_\_\_