



## Reconsideration Questionnaire - Child

<b>Event Category:</b>	Time-Based
<b>Event:</b>	12M, 24M, 36M, 48M, 60M
<b>Administration:</b>	N/A
<b>Instrument Target:</b>	Child
<b>Instrument Respondent:</b>	Primary Caregiver
<b>Domain:</b>	Consent
<b>Document Category:</b>	Questionnaire
<b>Method:</b>	Data Collector Administered
<b>Mode (for this instrument*):</b>	In-Person, CAI; Phone, CAI
<b>OMB Approved Modes:</b>	In-Person, CAI; Phone, CAI
<b>Estimated Administration Time:</b>	1 minute
<b>Multiple Child/Sibling Consideration:</b>	Per Child
<b>Special Considerations:</b>	N/A
<b>Version:</b>	1.0
<b>MDES Release:</b>	4.0

\*This instrument is OMB-approved for multi-mode administration but this version of the instrument is designed for administration in this/these mode(s) only.

Public reporting burden for this collection of information is estimated to average 1 minute 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: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593\*). Do not return the completed form to this address.

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# Reconsideration Questionnaire - Child

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## Reconsideration Questionnaire - Child

### GENERAL PROGRAMMER INSTRUCTIONS:

WHEN PROGRAMMING INSTRUMENTS, VALIDATE FIELD LENGTHS AND TYPES AGAINST THE MDES TO ENSURE DATA COLLECTION RESPONSES DO NOT EXCEED THOSE OF THE MDES. SOME GENERAL ITEM LIMITS USED ARE AS FOLLOWS:

DATA ELEMENT FIELDS	MAXIMUM CHARACTERS PERMITTED	DATA TYPE	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	CHARACTER	
UNIT AND PHONE FIELDS	10	CHARACTER	
_OTH AND COMMENT FIELDS	255	CHARACTER	<ul style="list-style-type: none"> <li>• Limit text to 255 characters</li> </ul>
FIRST NAME AND LAST NAME	30	CHARACTER	<ul style="list-style-type: none"> <li>• Limit text to 30 characters</li> </ul>
ALL ID FIELDS	36	CHARACTER	
ZIP CODE	5	CHARACTER	
ZIP CODE LAST FOUR	4	CHARACTER	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	NUMERIC CHARACTER	<ul style="list-style-type: none"> <li>• DISPLAY AS MM/DD/YYYY</li> <li>• STORE AS YYYY-MM-DD</li> <li>• HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.</li> </ul>
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	<ul style="list-style-type: none"> <li>• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59</li> </ul>
NUMBER OF HOURS PER DAY	TWO-DIGIT HOUR	NUMERIC	<ul style="list-style-type: none"> <li>• HARD EDITS: HOURS MUST BE BETWEEN 1 AND 24</li> </ul>
NUMBER OF DAYS PER WEEK	ONE-DIGIT	NUMERIC	<ul style="list-style-type: none"> <li>• HARD EDITS: DAYS PER WEEK MUST BE BETWEEN 1 AND 7</li> </ul>

### **Instrument Guidelines for Participant and Respondent IDs:**

PRENATALLY, THE **P\_ID** IN THE MDES HEADER IS THAT OF THE PARTICIPANT (E.G. THE NON-PREGNANT WOMAN, PREGNANT WOMAN, OR THE FATHER).

POSTNATALLY, A RESPONDENT ID WILL BE USED IN ADDITION TO THE PARTICIPANT ID BECAUSE SOMEBODY OTHER THAN THE PARTICIPANT MAY BE COMPLETING THE INTERVIEW. FOR EXAMPLE, THE PARTICIPANT MAY BE THE CHILD AND THE RESPONDENT MAY BE THE MOTHER, FATHER, OR ANOTHER CAREGIVER. THEREFORE, MDES VERSION 2.2 AND ALL FUTURE VERSIONS CONTAIN A **R\_P\_ID** (RESPONDENT PARTICIPANT ID) HEADER FIELD FOR EACH POST-BIRTH INSTRUMENT. THIS WILL ALLOW ROCs TO INDICATE WHETHER THE RESPONDENT IS SOMEBODY OTHER THAN THE PARTICIPANT ABOUT WHOM THE QUESTIONS ARE BEING ASKED.

### **A REMINDER:**

ALL RESPONDENTS MUST BE CONSENTED AND HAVE RECORDS IN THE PERSON, PARTICIPANT, PARTICIPANT\_CONSENT AND LINK\_PERSON\_PARTICIPANT TABLES, WHICH CAN BE PRELOADED INTO EACH INSTRUMENT. ADDITIONALLY, IN POST-BIRTH QUESTIONNAIRES WHERE THERE IS THE ABILITY TO LOOP THROUGH A SET OF QUESTIONS FOR MULTIPLE CHILDREN, IT IS IMPORTANT TO CAPTURE AND STORE THE CORRECT CHILD **P\_ID** ALONG WITH THE LOOP INFORMATION. IN THE MDES VARIABLE LABEL/DEFINITION COLUMN, THIS IS INDICATED AS FOLLOWS: **EXTERNAL IDENTIFIER: PARTICIPANT ID FOR CHILD DETAIL.**

## RECONSIDERATION QUESTIONNAIRE - CHILD

(TIME\_STAMP\_RQC\_ST).

### PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP.
- PRELOAD **EVENT\_TYPE**.
- PRELOAD **P\_ID** FOR CHILD.
- PRELOAD FIRST NAME OF CHILD (**C\_FNAME**) FROM **INSTRUMENT\_ID = XX** (PARTICIPANT VERIFICATION, SCHEDULING, & TRACING QUESTIONNAIRE)
- IF **C\_FNAME** ≠ -1 OR -2, DISPLAY APPROPRIATE NAME IN “C\_FNAME” THROUGHOUT THE INSTRUMENT.
- OTHERWISE, IF **C\_FNAME** = -1 OR -2, DISPLAY “the child” IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT.
- PRELOAD **CHILD\_SEX** FROM **INSTRUMENT\_ID = XX** (PARTICIPANT VERIFICATION, SCHEDULING, & TRACING QUESTIONNAIRE).
- IF **CHILD\_SEX** = 1, DISPLAY “him” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
- IF **CHILD\_SEX** = 2, DISPLAY “her” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
- PRELOAD MOST RECENT **SAMPLE\_CONSENT\_GIVEN** AND **SAMPLE\_CONSENT\_TYPE** FROM **PARTICIPANT\_CONSENT\_SAMPLE** TABLE FOR CHILD (PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY).

**RQC01000/(RECON\_INTRO)**. We understand that you {gave/did not give} us your permission to collect some samples from {C\_FNAME/the child} when you consented for {him/her} to participate in the Study. You do not have to agree to provide any samples from {C\_FNAME/the child} today, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study.

### INTERVIEWER INSTRUCTIONS

- DURING THE LAST INFORMED CONSENT, THE LEGAL GUARDIAN {CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES/ CONSENTED TO PROVIDE BIOLOGICAL SAMPLES BUT NOT ENVIRONMENTAL SAMPLES/ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES/ REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES}
- THIS QUESTIONNAIRE WILL ASK FOR {CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW INFORMED CONSENT FORMS SHOULD BE ADMINISTERED/RECONSIDERATION OF ENVIRONMENTAL SAMPLES/RECONSIDERATION OF BIOLOGICAL SAMPLES/RECONSIDERATION OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES}.

### PROGRAMMER INSTRUCTIONS

- IF **SAMPLE\_CONSENT\_GIVEN** = 2 OR **SAMPLE\_CONSENT\_TYPE** DOES NOT INCLUDE 1 AND 2, DISPLAY “did not give” IN QUESTION TEXT.
- OTHERWISE, DISPLAY “gave” IN QUESTION TEXT.
- IF **SAMPLE\_CONSENT\_GIVEN** = 1 AND

**PROGRAMMER INSTRUCTIONS**

- o **SAMPLE\_CONSENT\_TYPE** INCLUDES 1 AND 2, DISPLAY “CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES”, “CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW INFORMED CONSENT FORMS SHOULD BE ADMINISTERED” IN INTERVIEWER INSTRUCTIONS.
- o **SAMPLE\_CONSENT\_TYPE** INCLUDES 1 BUT NOT 2, DISPLAY “CONSENTED TO PROVIDE BIOLOGICAL SAMPLES BUT NOT ENVIRONMENTAL SAMPLES” AND “RECONSIDERATION OF ENVIRONMENTAL SAMPLES” IN INTERVIEWER INSTRUCTIONS.
- o **SAMPLE\_CONSENT\_TYPE** INCLUDES 2 BUT NOT 1, DISPLAY “CONSENTED TO PROVIDE ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES” AND “RECONSIDERATION OF BIOLOGICAL SAMPLES” IN INTERVIEWER INSTRUCTIONS.
- **SAMPLE\_CONSENT\_GIVEN** = 2, DISPLAY “REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES” AND “RECONSIDERATION OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES” IN INTERVIEWER INSTRUCTIONS.

**RQC02000/(RECON\_BIO\_CHILD).** Would you like to {allow us/continue to allow us} to collect biological specimens from {C\_FNAME/the child} for this Study visit?

**INTERVIEWER INSTRUCTIONS**

- LEGAL GUARDIANS WHO PREVIOUSLY REFUSED BIOLOGICAL SAMPLE COLLECTIONS AND AGREE TO BIOLOGICAL SAMPLE COLLECTION DURING THE RECONSIDERATION QUESTIONNAIRE SHOULD BE RE-ADMINISTERED CONSENT USING THE INFORMED CONSENT FORM *WHAT YOU SHOULD KNOW ABOUT ENROLLING YOUR CHILD IN THE NATIONAL CHILDREN’S STUDY (NCS) VANGUARD STUDY: PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

**PROGRAMMER INSTRUCTIONS**

- DISPLAY “allow us” IN QUESTION TEXT IF EITHER:
  - o **SAMPLE\_CONSENT\_GIVEN** = 2
  - o **SAMPLE\_CONSENT\_TYPE** ≠ 1
- OTHERWISE, DISPLAY “continue to allow us” IN QUESTION TEXT.
- DISPLAY INTERVIEWER INSTRUCTIONS IF EITHER:
  - o **SAMPLE\_CONSENT\_GIVEN** = 1 AND **SAMPLE\_CONSENT\_TYPE** ≠ 1 (I.E., = 2 OR = 2 AND 3)
  - o **SAMPLE\_CONSENT\_GIVEN** = 2

Label	Code	Go To
YES	1	
NO	2	
REFUSED	-1	
DON'T KNOW	-2	

**SOURCE**



**RQC03000/(RECON\_ENV\_CHILD).** Would you like to {allow us/continue to allow us} to collect environmental samples from {C\_FNAME/the child}'s home for this Study visit?

**INTERVIEWER INSTRUCTIONS**

- LEGAL GUARDIANS WHO PREVIOUSLY REFUSED A SAMPLE COLLECTION AND AGREE TO ANY SAMPLE COLLECTION DURING THE RECONSIDERATION QUESTIONNAIRE SHOULD BE RE-ADMINISTERED CONSENT USING THE INFORMED CONSENT FORM *WHAT YOU SHOULD KNOW ABOUT ENROLLING YOUR CHILD IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

**PROGRAMMER INSTRUCTIONS**

- DISPLAY "allow us" IN QUESTION TEXT IF EITHER:
  - o SAMPLE\_CONSENT\_GIVEN = 2
  - o SAMPLE\_CONSENT\_TYPE ≠ 2
- OTHERWISE, DISPLAY "continue to allow us".
- DISPLAY INTERVIEWER INSTRUCTIONS IF EITHER:
  - o SAMPLE\_CONSENT\_GIVEN = 1 AND SAMPLE\_CONSENT\_TYPE ≠ 2 (I.E., = 1 OR = 1 AND 3)
  - o SAMPLE\_CONSENT\_GIVEN = 2

Label	Code	Go To
YES	1	
NO	2	
REFUSED	-1	
DON'T KNOW	-2	

**SOURCE**

National Children's Study, Vanguard 2 Phase

**PROGRAMMER INSTRUCTIONS**

- GO TO READM\_CON IF EITHER:
  - o RECON\_BIO = 1 AND EITHER:
    - SAMPLE\_CONSENT\_GIVEN = 2
    - SAMPLE\_CONSENT\_TYPE ≠ 1
  - o RECON\_ENV = 1 AND EITHER:
    - SAMPLE\_CONSENT\_GIVEN = 2
    - SAMPLE\_CONSENT\_TYPE ≠ 2
- OTHERWISE, GO TO RQC05000.

**RQC04000/(READM\_CON).** Thank you for agreeing to provide samples from {C\_FNAME/the child}. We will now review the consent form to record that you have agreed for {C\_FNAME/the child} to provide these samples.

**INTERVIEWER INSTRUCTIONS**

- RE-ADMINISTER CONSENT USING THE INFORMED CONSENT FORM *WHAT YOU SHOULD KNOW ABOUT ENROLLING YOUR CHILD IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

Label	Code	Go To
CONTINUE	1	
REFUSED	-1	

**SOURCE**

National Children's Study, Vanguard 2 Phase

RQC05000. Thank you for your time.

(TIME\_STAMP\_RQC\_ET).

**PROGRAMMER INSTRUCTIONS**

- INSERT DATE/TIME STAMP.