



Reconsideration Questionnaire - Child

Event Category:	Time-Based
Event:	12M, 24M, 36M, 48M, 60M
Administration:	N/A
Instrument Target:	Child
Instrument Respondent:	Primary Caregiver
Domain:	Consent
Document Category:	Questionnaire
Method:	Data Collector Administered
Mode (for this instrument*):	In-Person, CAI; Phone, CAI
OMB Approved Modes:	In-Person, CAI; Phone, CAI
Estimated Administration Time:	1 minute
Multiple Child/Sibling Consideration:	Per Child
Special Considerations:	N/A
Version:	1.0
MDES Release:	4.1

*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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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"> Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	<ul style="list-style-type: none"> Limit text to 30 characters
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	CHARACTER	<ul style="list-style-type: none"> DISPLAY AS MM/DD/YYYY STORE AS YYYY-MM-DD HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	<ul style="list-style-type: none"> HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59
NUMBER OF HOURS PER DAY	TWO-DIGIT HOUR	NUMERIC	<ul style="list-style-type: none"> HARD EDITS: HOURS MUST BE BETWEEN 0 AND 24
NUMBER OF DAYS PER WEEK	ONE-DIGIT	NUMERIC	<ul style="list-style-type: none"> HARD EDITS: DAYS PER WEEK MUST BE BETWEEN 1 AND 7

Guidelines for Instrument Target and Respondent :

IN MDES 4.0, THE INSTRUMENTS HAVE BEEN DIVIDED BASED ON INSTRUMENT TARGET AND INSTRUMENT RESPONDENT. THE INSTRUMENT TARGET AND INSTRUMENT RESPONDENT ARE PART OF THE STANDARD INSTRUMENT HEADER INFORMATION ON ALL INSTRUMENTS, AND ADDITIONAL TARGETS HAVE BEEN DEFINED, INCLUDING THE CHILD'S PRIMARY OR SECONDARY ADDRESS. REFER TO THE DATA DICTIONARY FOR A COMPLETE LIST OF ALL INSTRUMENT TARGETS AND RESPONDENTS.

PRELOADS

Preload Variable Name	Table Name	Preload Comment	Release Version	Table Type
EVENT_TYPE	EVENT		V3.5	Operational
LEGAL_AUTH_REP	LINK_PERSON_PARTICIPANT		V3.5	Operational
SAMPLE_CONSENT_GIVEN	PARTICIPANT_CONSENT_SAMPLE	FOR NCS CHILD	V3.5	Operational
SAMPLE_CONSENT_TYPE	PARTICIPANT_CONSENT_SAMPLE	FOR NCS CHILD	V3.5	Operational
SEX	PERSON		V3.5	Operational

RECONSIDERATION QUESTIONNAIRE - CHILD

(TIME_STAMP_RQC_ST).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP.
- PRELOAD **INS_TARGET_PID** FOR PARTICIPANT AND **INS_RESPONDENT_PID** FOR RESPONDENT.
- IF **FIRST_NAME** ≠ -1 OR -2, DISPLAY APPROPRIATE NAME IN “C_FNAME” THROUGHOUT THE INSTRUMENT.
- IF **SEX** = 1, DISPLAY “him” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
- IF **SEX** = 2, DISPLAY “her” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
- IF **LEGAL_AUTH_REP** = 1 FOR **INS_RESPONDENT_PID**, GO TO **RECON_INTRO**.
- IF **LEGAL_AUTH_REP** ≠ 1 FOR **INS_RESPONDENT_PID** AND
 - IF **SAMPLE_CONSENT_GIVEN** = 2 AND **SAMPLE_CONSENT_TYPE** = 1 AND 2, DISPLAY DATA COLLECTOR INSTRUCTIONS AND GO TO **TIME_STAMP_RQC_ET**.
 - IF **SAMPLE_CONSENT_GIVEN** = 1 AND
 - **SAMPLE_CONSENT_TYPE** = 1 AND 2, GO TO **RECON_INTRO**.
 - **SAMPLE_CONSENT_TYPE** ≠ 1 AND 2, GO TO **TIME_STAMP_RQC_ET**.

DATA COLLECTOR INSTRUCTIONS

- THE PRIMARY CAREGIVER IS NOT THE LEGALLY AUTHORIZED REPRESENTATIVE (LAR).
- PRIMARY CAREGIVER CANNOT RECONSENT FOR CHILD, THE LAR NEEDS TO BE CONTACTED TO COMPLETE THIS QUESTIONNAIRE.

RQC01000/(RECON_INTRO). As part of the research activities for today’s visit, we would like to collect some samples from {C_FNAME}. You can always say no, but we would like to offer you the opportunity to provide samples to help us better understand child health and development and reach the goals of the Study.

DATA COLLECTOR INSTRUCTIONS

- DURING THE LAST INFORMED CONSENT, THE LEGAL GUARDIAN EITHER
 - CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES,
 - CONSENTED TO PROVIDE BIOLOGICAL SAMPLES BUT NOT ENVIRONMENTAL SAMPLES,
 - CONSENTED TO PROVIDE ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES, OR
 - REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES.
- IF THE LEGAL GUARDIAN REFUSED TO PROVIDE BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES, THIS QUESTIONNAIRE WILL ASK FOR ONE OF THE FOLLOWING:
 - RECONSIDERATION OF ENVIRONMENTAL SAMPLES
 - RECONSIDERATION OF BIOLOGICAL SAMPLES

DATA COLLECTOR INSTRUCTIONS

- o RECONSIDERATION OF BIOLOGICAL AND ENVIRONMENTAL SAMPLES

PROGRAMMER INSTRUCTIONS

- IF **LEGAL_AUTH_REP = 1** FOR **INS_RESPONDENT_PID**, AND
 - o IF **SAMPLE_CONSENT_GIVEN = 1** AND
 - **SAMPLE_CONSENT_TYPE** INCLUDES 1 BUT NOT 2, GO TO **RECON_BIO_CHILD**.
 - **SAMPLE_CONSENT_TYPE** INCLUDES 2 BUT NOT 1, GO TO **RECON_ENV_CHILD**.
 - **SAMPLE_CONSENT_TYPE = 1 AND 2**, GO TO **TIME_STAMP_RQC_ET**.
 - o **SAMPLE_CONSENT_GIVEN = 2** AND **SAMPLE_CONSENT_TYPE = 1 AND 2**, GO TO **RECON_BIO_CHILD**.
- IF **LEGAL_AUTH_REP ≠ 1** FOR **INS_RESPONDENT_PID**, GO TO **TIME_STAMP_RQC_ET**.

RQC02000/(RECON_BIO_CHILD). We will explain what is involved in the collection of each sample when it is time to collect it. Will you allow us to collect biological specimens from {C_FNAME}?

DATA COLLECTOR INSTRUCTIONS

- LEGAL GUARDIANS WHO AGREE TO BIOLOGICAL SAMPLE COLLECTION SHOULD:
 - o 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
 - o MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM.

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

SOURCE

National Children’s Study, Vanguard 2 Phase

PROGRAMMER INSTRUCTIONS

- IF **SAMPLE_CONSENT_GIVEN = 1**, AND **SAMPLE_CONSENT_TYPE** INCLUDES 1 BUT NOT 2, GO TO PROGRAMMER INSTRUCTIONS FOLLOWING **RECON_ENV_CHILD**.
- IF **SAMPLE_CONSENT_GIVEN = 2** AND **SAMPLE_CONSENT_TYPE = 1**, GO TO **RECON_ENV_CHILD**.

RQC03000/(RECON_ENV_CHILD). We will explain what is involved in the collection of each sample when it is time to collect it. Will you allow us to collect environmental samples from {C_FNAME}'s home?

DATA COLLECTOR INSTRUCTIONS	
<ul style="list-style-type: none"> • LEGAL GUARDIANS WHO AGREE TO ANY SAMPLE COLLECTION SHOULD: <ul style="list-style-type: none"> o BE RE-ADMINISTERED CONSENT USING THE INFORMED CONSENT FORM <i>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</i> AND o MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM. 	

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

SOURCE
National Children's Study, Vanguard 2 Phase

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> • IF RECON_BIO_CHILD = 1 AND/OR RECON_ENV_CHILD = 1, GO TO READM_CON. • OTHERWISE, GO TO RQC05000.

RQC04000/(READM_CON). Thank you for agreeing to provide samples from {C_FNAME}. We will now review the consent form to record that you have agreed for {C_FNAME} to provide these samples.

DATA COLLECTOR INSTRUCTIONS	
<ul style="list-style-type: none"> • RE-ADMINISTER CONSENT USING THE INFORMED CONSENT FORM <i>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</i> 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	TIME_STAMP_RQC_ET
REFUSED	-1	TIME_STAMP_RQC_ET

SOURCE
National Children's Study, Vanguard 2 Phase

RQC05000. Thank you for your time.

(TIME_STAMP_RQC_ET).

PROGRAMMER INSTRUCTIONS

- | |
|---|
| <ul style="list-style-type: none">• INSERT DATE/TIME STAMP. |
|---|