Reconsideration Questionnaire - Adult

Event Category:	Trigger-Based, Pre-Preg, PV1, PV2; Time-Based, 6M, 12M, 24M, 36M, 48M, 60M
Event:	Pre-Preg, PV1, PV2, 6M, 12M, 24M, 36M, 48M, 60M
Administration:	N/A
Instrument Target:	Pre-Pregant Woman (Pre-Preg); Pregnant Woman (PV1, PV2); Primary Caregiver (6M, 12M, 24M, 36M, 48M, 60M)
Instrument Respondent:	Pre-Pregant Woman (Pre-Preg); Pregnant Woman (PV1, PV2); Primary Caregiver (6M, 12M, 24M, 36M, 48M, 60M)
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 Event
Special Considerations:	N/A
Version:	1.0
MDES Release:	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.

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Reconsideration Questionnaire - Adult

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Reconsideration Questionnaire - Adult

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	• Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	• Limit text to 30 characters
ALL ID FIELDS	36	CHARACTER	
ZIP CODE	5	NUMERIC	
ZIP CODE LAST FOUR	4	NUMERIC	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	NUMERIC CHARACTER	• 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	• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59

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 - ADULT

(TIME_STAMP_RQA_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP. • PRELOAD **P_ID** FOR ADULT. • PRELOAD MOST RECENT **SAMPLE_CONSENT_GIVEN** AND **SAMPLE_CONSENT_TYPE** FROM **PARTICIPANT_CONSENT_SAMPLE** TABLE FOR ADULT. • PRELOAD **EVENT_TYPE**. • IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH) PRELOAD **C_FNAME** FROM **INSTRUMENT_ID** = XX (PVST). o IF **C_FNAME** ≠ -1 OR -2, DISPLAY C_FNAME AS APPROPRIATE THROUGHOUT INSTRUMENT. o OTHERWISE, IF **C_FNAME** = -1 OR -2, DISPLAY "the child" AS APPROPRIATE THROUGHOUT INSTRUMENT.

RQA01000/(RECON_INTRO). We understand that you {gave/did not give} us your permission to collect some samples from you when you consented to join the Study. You do not have to agree to provide any samples 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 {PRE-PREGNANT WOMAN/PREGNANT WOMAN/ADULT CAREGIVER} {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/REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES/CONSENTED TO PROVIDE BIOLOGICAL SAMPLES. NO NEW INFORMED CONSENTS FORMS SHOULD BE ADMINISTERED/DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES}. • THIS QUESTIONNAIRE WILL ASK FOR {CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW CONSENT FORMS SHOULD BE ADMINISTERED/RECONSIDERATION OF ENVIRONMENTAL SAMPLES/RECONSIDERATION OF BIOLOGICAL SAMPLES/RECONSIDERATION OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES}.

PROGRAMMER INSTRUCTIONS
• IF **EVENT_TYPE** = 11 (PRE-PREGNANCY), DISPLAY "PRE-PREGNANT WOMAN" IN INTERVIEWER INSTRUCTIONS. • IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) OR 15 (PREGNANCY VISIT 2), DISPLAY “PREGNANT WOMAN” IN INTERVIEWER INSTRUCTIONS. • IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTHS), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH), DISPLAY “ADULT CAREGIVER” IN INTERVIEWER INSTRUCTIONS.

PROGRAMMER INSTRUCTIONS

- IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1):
  - AND **SAMPLE_CONSENT_GIVEN** = 1 AND:
    - **SAMPLE_CONSENT_TYPE** INCLUDES BOTH 1 AND 2, DISPLAY "CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES" AND "CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW INFORMED CONSENT FORMS SHOULD BE ADMINISTERED" IN INTERVIEWER INSTRUCTIONS.
    - **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.
    - **SAMPLE_CONSENT_TYPE** = 2, DISPLAY "CONSENTED TO PROVIDE ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES" AND "RECONSIDERATION OF BIOLOGICAL SAMPLES" IN INTERVIEWER INSTRUCTIONS.
  - AND **SAMPLE_CONSENT_GIVEN** = 2, DISPLAY "REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES" AND "RECONSIDERATION OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES".
- IF **EVENT_TYPE** = 11 (PRE-PRENGANCY), 15 (PREGNANCY VISIT 2), 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTHS), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH);
  - AND **SAMPLE_CONSENT_GIVEN** = 1:
    - AND **SAMPLE_CONSENT_TYPE** INCLUDES 1, DISPLAY "CONSENTED TO PROVIDE BIOLOGICAL SAMPLES. NO NEW INFORMED CONSENTS FORMS SHOULD BE ADMINISTERED" IN INTERVIEWER INSTRUCTIONS.
    - AND **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 1, DISPLAY "DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES".
  - AND **SAMPLE_CONSENT_GIVEN** = 2, DISPLAY "DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES".
- IF **EVENT_TYPE** = 11 (PRE-PRENGANCY), 15 (PREGNANCY VISIT 2), 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTHS), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH) AND:
  - IF **SAMPLE_CONSENT_GIVEN** = 2 OR **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 1, DISPLAY "did not give" IN QUESTION TEXT.
  - OTHERWISE, IF **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** INCLUDES 1, DISPLAY "gave" IN QUESTION TEXT.
- IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) AND:
  - IF **SAMPLE_CONSENT_GIVEN** = 2 OR **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE BOTH 1 AND 2, DISPLAY "did not give" IN QUESTION TEXT.
  - OTHERWISE, IF **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** INCLUDES BOTH 1 AND 2, DISPLAY "gave" IN QUESTION TEXT.

RQA02000/(RECON_BIO). Would you like to {allow us/continue to allow us} to collect biological specimens from you for this Study visit?

INTERVIEWER INSTRUCTIONS

- {PRE-PREGNANT WOMEN/PREGNANT WOMEN/ADULT CAREGIVERS} WHO PROVIDE A CONTRADICTORY RESPONSE TO THE INITIAL CONSENT RESPONSE TO ANY SAMPLE COLLECTION SHOULD BE RE-ADMINISTERED CONSENT USING THE *INFORMED CONSENT FORM WHAT YOU SHOULD KNOW ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: INFORMED CONSENT FORM {FOR PREGNANT WOMAN}* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS

- DISPLAY INTERVIEWER INSTRUCTIONS IF EITHER:
  - **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** = 2 (I.E., DOES NOT INCLUDE 1)
  - **SAMPLE_CONSENT_GIVEN** = 2
- IF **EVENT_TYPE** = 11 (PRE-PREGNANCY), DISPLAY "PRE-PREGNANT WOMEN" IN INTERVIEWER INSTRUCTION.
- IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) OR 15 (PREGNANCY VISIT 2), DISPLAY "PREGNANT WOMAN" AND "FOR PREGNANT WOMAN" IN INTERVIEWER INSTRUCTIONS.
- IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTH), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH), DISPLAY "ADULT CAREGIVERS" IN INTERVIEWER INSTRUCTIONS.
- IF **SAMPLE_CONSENT_GIVEN** = 2 OR **SAMPLE_CONSENT_TYPE** = 2 (I.E., DOES NOT INCLUDE 1), DISPLAY "allow us" IN QUESTION TEXT.
- OTHERWISE, DISPLAY "continue to allow us" IN QUESTION TEXT.

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 **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) GO TO **RECON_ENV**.
- OTHERWISE,
  - IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH) AND:
    - **SAMPLE_CONSENT_GIVEN** = 2 OR (**SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 2 (I.E., = 1 OR = 1 AND 3)) FOR **R_P_ID** (ADULT) AND:
      - **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** INCLUDES 2 FOR **P_ID** (CHILD), GO TO **RECON_ENV_DISC**.
      - **SAMPLE_CONSENT_GIVEN** = 2 OR (**SAMPLE_CONSENT_GIVEN** = 1

PROGRAMMER INSTRUCTIONS
AND **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 2 (I.E., = 1 OR = 1 AND 3)) FOR **P_ID** (CHILD), GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV_DISC**. ▪ **SAMPLE_CONSENT_GIVEN** = 1 AND INCLUDES 2, GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV**. o IF **EVENT_TYPE** = 11 (PRE-PREGNANCY), 15 (PREGNANCY VISIT 2), OR 31 (24-MONTH), GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV_DISC**.

RQA03000/(RECON_ENV). Would you like to {allow us/continue to allow us} to collect environmental samples from your home for this Study visit?

INTERVIEWER INSTRUCTIONS
• PREGNANT WOMEN WHO PROVIDE A CONTRADICTORY RESPONSE TO THE INITIAL CONSENT RESPONSE TO ANY SAMPLE COLLECTION SHOULD BE RE-ADMINISTERED CONSENT USING *THE INFORMED CONSENT FORM WHAT YOU SHOULD KNOW ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: INFORMED CONSENT FORM FOR PREGNANT WOMAN* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS
• 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 • DISPLAY "allow us" IN QUESTION TEXT IF EITHER: o **SAMPLE_CONSENT_GIVEN** = 2. o **SAMPLE_CONSENT_TYPE** ≠ 2 (I.E., = 1 OR = 1 AND 3). • OTHERWISE, DISPLAY "continue to allow us" IN QUESTION TEXT.

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 OR ▪ **SAMPLE_CONSENT_TYPE** ≠ 1 o **RECON_ENV** = 1 AND EITHER: ▪ **SAMPLE_CONSENT_GIVEN** = 2 OR

PROGRAMMER INSTRUCTIONS
▪ **SAMPLE_CONSENT_TYPE** ≠ 2 • OTHERWISE, GO TO **RQA05000**.

RQA03100/(RECON_ENV_DISC). We noticed on your consent form in the past you did not agree to allow us to collect environmental samples, but you agreed to allow us to collect environmental samples on {C_FNAME/the child}'s consent form. Today, would you like to agree to collection of environmental samples on your consent form as you have agreed to environmental collections for {C_FNAME/the child}?

Label	Code	Go To
YES	**1**	
NO	**2**	**RQA05000**
REFUSED	**-1**	**RQA05000**
DON'T KNOW	**-2**	**RQA05000**

RQA04000/(READM_CON). Thank you for agreeing to provide samples. We will now review the consent form to record that you have agreed to provide these samples.

INTERVIEWER INSTRUCTIONS
• RE-ADMINISTER CONSENT USING THE *INFORMED CONSENT FORM WHAT YOU SHOULD KNOW ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: INFORMED CONSENT FORM {FOR PREGNANT WOMAN}* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS
• IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) OR 15 (PREGNANCY VISIT 2), DISPLAY "FOR PREGNANT WOMAN" IN INTERVIEWER INSTRUCTIONS.

Label	Code	Go To
CONTINUE	**1**	
REFUSED	**-1**	

SOURCE
National Children's Study, Vanguard 2 Phase

RQA05000. Thank you for your time.

(TIME_STAMP_RQA_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.