Reconsideration Questionnaire - Adult

Event Category:	Trigger-Based, Pre-Preg, PV2; Time-Based,12M, 24M, 36M, 48M, 60M
Event:	Pre-Preg, PV2, 12M, 24M, 36M, 48M, 60M
Administration:	N/A
Instrument Target:	Pre-Pregnant Woman (Pre-Preg); Pregnant Woman (PV2); Primary Caregiver (12M, 24M, 36M, 48M, 60M)
Instrument Respondent:	Pre-Pregnant Woman (Pre-Preg); Pregnant Woman (PV2); Primary Caregiver (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:	4.1

*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.

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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	• 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	CHARACTER	
ZIP CODE LAST FOUR	4	CHARACTER	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	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
NUMBER OF HOURS PER DAY	TWO-DIGIT HOUR	NUMERIC	• HARD EDITS: HOURS MUST BE BETWEEN 0 AND 24
NUMBER OF DAYS PER WEEK	ONE-DIGIT	NUMERIC	• 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
FIRST_NAME	PERSON	FOR NCS CHILD	V3.5	Operational
PERSON_PID_ID	LINK_PERSON_PARTICIPANT	FOR NCS CHILD	V3.5	Operational
SAMPLE_CONSENT_GIVEN	PARTICIPANT_CONSENT_SAMPLE		V3.5	Operational
SAMPLE_CONSENT_TYPE	PARTICIPANT_CONSENT_SAMPLE		V3.5	Operational

RECONSIDERATION QUESTIONNAIRE - ADULT

(TIME_STAMP_RQA_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP. • PRELOAD **INS_TARGET_PID** FOR PARTICIPANT AND **INS_RESPONDENT_PID** FOR RESPONDENT. • IF **EVENT_TYPE** = 27 (12-MONTH), 37 (36-MONTH), 40 (48-MONTH), OR 41 (60-MONTH) AND IF **FIRST_NAME** ≠ -1 OR -2, DISPLAY CHILD'S FIRST NAME IN C_FNAME AS APPROPRIATE THROUGHOUT INSTRUMENT.

RQA01000/(RECON_INTRO). As part of the research activities for today's visit, we would like to collect some samples from you. You can always say no, but we would like to offer you the opportunity to provide samples to help us reach the goals of the Study.

DATA COLLECTOR INSTRUCTIONS

• DURING THE LAST INFORMED CONSENT, THE PRE-PREGNANT WOMAN/PREGNANT WOMAN/ADULT CAREGIVER EITHER
  o CONSENTED TO PROVIDE BIOLOGICAL SAMPLES AND NO NEW INFORMED CONSENTS FORMS SHOULD BE ADMINISTERED, OR
  o DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES.
• IF THE PRE-PREGNANT WOMAN/PREGNANT WOMAN/ADULT CAREGIVER DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES, THIS QUESTIONNAIRE WILL ASK FOR RECONSIDERATION OF BIOLOGICAL SAMPLES.

PROGRAMMER INSTRUCTIONS
• IF **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** = 2, GO TO **TIME_STAMP_RQA_ET**. • IF **SAMPLE_CONSENT_GIVEN** = 2 AND **SAMPLE_CONSENT_TYPE** =2, GO TO **RECON_BIO_ADULT**.

RQA02000/(RECON_BIO_ADULT). 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 you?

DATA COLLECTOR INSTRUCTIONS

• PRE-PREGNANT WOMEN/PREGNANT WOMEN/ADULT CAREGIVERS WHO AGREE TO ANY SAMPLE COLLECTION SHOULD
  o 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* OR 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*
  o MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM.

Label	Code	Go To
YES	**1**	
NO	**2**	

Label	Code	Go To
REFUSED	-1	
DON'T KNOW	-2	

PROGRAMMER INSTRUCTIONS
- IF **EVENT_TYPE** = 27 (12-MONTH), 37 (36-MONTH), 40 (48-MONTH), OR 41 (60-MONTH) AND:
  - o **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** = 1, GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV_DISC**.
  - o **SAMPLE_CONSENT_GIVEN** = 2 AND **SAMPLE_CONSENT_TYPE** = 1 FOR **INS_TARGET_PID** (ADULT) AND:
    - ▪ **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** = 1 FOR **PERSON_PID_ID** (CHILD), GO TO **RECON_ENV_DISC**.
    - ▪ **SAMPLE_CONSENT_GIVEN** = 2 AND **SAMPLE_CONSENT_TYPE** = 1 FOR **PERSON_PID_ID** (CHILD), GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV_DISC**.
- IF **EVENT_TYPE** = 11 (PRE-PREGNANCY), 15 (PREGNANCY VISIT 2), OR 31 (24-MONTH), GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV_DISC.**

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}'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}?

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

PROGRAMMER INSTRUCTIONS
- IF **RECON_BIO_ADULT** = 1 AND/OR **RECON_ENV_DISC** = 1, GO TO **READM_CON.**
- OTHERWISE, GO TO **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.

DATA COLLECTOR 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* OR *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 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_RQA_ET
REFUSED	-1	TIME_STAMP_RQA_ET

SOURCE
National Children's Study, Vanguard 2 Phase

RQA05000. Thank you for your time.

(TIME_STAMP_RQA_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.