Child Microbiome Stool SAQ

Event Category:	Time-Based
Event:	24M
Administration:	N/A
Instrument Target:	Child
Instrument Respondent:	Primary Caregiver
Domain:	Biospecimen
Document Category:	Sample Collection
Method:	Self-Administered
Mode (for this instrument*):	In-Person, PAPI
OMB Approved Modes:	In-Person, PAPI; Phone, PAPI; Web, CAI
Estimated Administration Time:	13 minutes
Multiple Child/Sibling Consideration:	Per Child
Special Considerations:	N/A
Version:	1.0
MDES Release:	4.0

*This instrument is a self-administered questionnaire (SAQ) that should be mailed to the participant prior to the visit/call. The participant should be asked to complete the SAQ prior to the scheduled visit/call and either mail it back to the ROC (in the case of the phone visit) or keep it and give it to the interviewer at the time of the in-person visit. *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	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.

<u>A REMINDER:</u>
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.**

CHILD MICROBIOME STOOL SAQ

CMS01000. As part of the National Children's Study, we are asking you to provide a sample of the child's stool. Please follow the instructions provided in the child stool collection kit to collect the sample.

After you have collected the stool sample, please complete the information on this form.

CMS02000/(COLLECT_STOOL). Were you able to collect the child's stool sample? Check one.

Label	Code	Go To
Yes	1	CMS03000
No	2	STOOL_COLLECTION_COMMENTS

SOURCE
National Children's Study, Vanguard Phase (Modified) (12M)

CMS03000. On what date did you collect the sample?

SOURCE
National Children's Study, Legacy Phase (Modified) (1M & 6M)

(COLLECT_STOOL_MM) |___|___|
  M   M

(COLLECT_STOOL_DD) |___|___|
  D   D

(COLLECT_STOOL_YYYY) |___|___|___|___|
  Y   Y   Y   Y

CMS04000. At what time did you collect the sample?

SOURCE
National Children's Study, Legacy Phase (Modified) (1M & 6M)

(COLLECT_STOOL_TIME) |___|___|:|___|___|
  H   H   M   M

(COLLECT_STOOL_TIME_UNIT) (circle one) AM/PM

Label	Code	Go To
AM	1	
PM	2	

CMS05000/(TAKEN_MED_CHILD). In the past month, has the child taken, used or received any of the following?

(Select all that apply)

Label	Code	Go To
Antibiotics (such as penicillin, Amoxil, Z-pak or other similar medicines)	1	
Antifungals (such as Lotrimin, Micatin, or similar medicated creams or capsules)	2	
Nasally-delivered live, attenuated influenza vaccine (flu shot given as a nose spray, such as Flu Mist)	3	
None	4	
Don't know	-2	

CMS06000/(TAKEN_PROBIOTIC_CHILD). In the past month, has the child taken any probiotic supplements (such as Culturelle) or had yogurt (such as Activia) in their diet at least once a week?

Label	Code	Go To
Yes	1	
No	2	
Don't know	-2	

CMS07000/(COLD_PACKS_FROZEN). Before placing the stool sample in the shipper, had the cold packs been frozen for 12 hours or more?

Label	Code	Go To
Yes	1	
No	2	
Don't know	-2	

CMS07100/(STOOL_COLLECTION_COMMENTS). Is there anything you want to tell us about collecting the child's stool sample? If you could not collect the stool sample, please tell us why:

_____

_____

_____

_____

_____

_____

CMS08000. Thank you for participating in the National Children's Study and for taking the time to complete this information.

Please call the Regional Operations Center number located on the last page if you have any questions.

FOR OFFICE USE ONLY

FOU01000/(SPECIMEN_ID). SPECIMEN_ID

|__|__|__|__|__|__|__|__|__| - |__|__|__|__|

FOU02000/(P_ID).   Child   Participant
ID

FOU03000/(R_P_ID). Respondent ID

FOU04000/(EVENT_ID). Visit Type/Event ID