



Child Microbiome Swab Instrument

Event Category:	Time-Based
Event:	6M, 24M, 48M
Administration:	N/A
Instrument Target:	Child
Instrument Respondent:	Primary Caregiver
Domain:	Biospecimen
Document Category:	Sample Collection
Method:	Data Collector Administered
Mode (for this instrument*):	In-Person, CAI
OMB Approved Modes:	In-Person, CAI
Estimated Administration Time:	10 minutes
Multiple Child/Sibling Consideration:	Per Child
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.

Public reporting burden for this collection of information is estimated to average 10 minutes 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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Child Microbiome Swab Instrument

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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	NUMERIC	
ZIP CODE LAST FOUR	4	NUMERIC	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	NUMERIC 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

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.**

BIOSPECIMEN CHILD MICROBIOME SWAB INSTRUMENT

(TIME_STAMP_BCM_ST).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT ID (**P_ID**) FOR CHILD AND RESPONDENT ID (**R_P_ID**) FOR ADULT CAREGIVER.
- PRELOAD CHILD'S FIRST NAME AND DISPLAY NAME IN **C_FNAME** THROUGHOUT INSTRUMENT
- OTHERWISE, IF **C_FNAME** = -1 OR -2, DISPLAY "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT.
- IF **CHILD_SEX** IN PARTICIPANT VERIFICATION QUESTIONNAIRE = 1, DISPLAY "his", "he", OR "himself" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
- IF **CHILD_SEX** IN PARTICIPANT VERIFICATION QUESTIONNAIRE = 2, DISPLAY "her", "she", OR "herself" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT
- IF **EVENT_TYPE** = 24 (6-MONTH EVENT) OR XX (48 MONTH EVENT), GO TO **CHILD_MICROBIOME_SWAB_INTRO**
- OTHERWISE, GO TO **CHILD_STOOL_INTRO**.

BCM01000/(CHILD_STOOL_INTRO). We would like you to collect a sample of {C_FNAME/the child}'s stool. To do this we will provide you with materials to collect and mail us a stool sample.

DATA COLLECTOR INSTRUCTIONS

- IF THE ADULT CAREGIVER REFUSES THIS COLLECTION, SELECT REFUSED
- OTHERWISE, SELECT CONTINUE AND REVIEW THE COLLECTION MATERIALS, COLLECTION INSTRUCTIONS, AND DATA COLLECTION FORM WITH THE ADULT CAREGIVER.

Label	Code	Go To
CONTINUE	1	BCM03010
REFUSED	-1	

SOURCE

New

BCM02000/(STOOL_REFUSE_REASON). I am sorry you have chosen not to participate in this collection. Can you tell me why?

DATA COLLECTOR INSTRUCTIONS

- ENTER REASON FOR REFUSAL

Label	Code	Go To
TOO COMPLICATED	1	BCM05000
PHYSICAL LIMITATION	2	BCM05000
PARTICIPANT ILL/EMERGENCY	3	BCM05000
LANGUAGE ISSUE	4	BCM05000

Label	Code	Go To
NO TIME	5	BCM05000
UNCOMFORTABLE WITH COLLECTION PROCEDURES	6	BCM05000
OTHER	-5	
REFUSED	-1	BCM05000
DON'T KNOW	-2	BCM05000

SOURCE

National Children's Study, Legacy Phase (Modified from 6M Child)

BCM03000/(STOOL_REFUSE_REASON_OTH).

SPECIFY: _____

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

SOURCE

National Children's Study, Legacy Phase (Modified from 6M Child)

PROGRAMMER INSTRUCTIONS

- GO TO BCM05000.

BCM03010. Thank you for agreeing to collect and send us a sample of {C_FNAME/the child}'s stool.

BCM03100/(DISTRIBUTE_KIT). WAS THE KIT DISTRIBUTED TO THE ADULT CAREGIVER?

Label	Code	Go To
YES	1	STOOL_SPECIMEN_ID
NO	2	

BCM03200/(N_DISTRIB_REAS). WHY COULDN'T YOU GIVE THE KIT TO THE ADULT CAREGIVER?

Label	Code	Go To
ADULT CAREGIVER REFUSED	1	STOOL_COLLECTION_COMMENT
NO TIME TO DISTRIBUTE KIT	2	STOOL_COLLECTION_COMMENT
KIT UNAVAILABLE	3	STOOL_COLLECTION_COMMENT
OTHER	-5	

BCM03300/(N_DISTRIB_REAS_OTH).

SPECIFY:

Label	Code	Go To
REFUSED	-1	

SOURCE
New

BCM11000/(REFUSE_REASON). I am sorry that you have chosen not to participate in this collection. Can you tell me why?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> ENTER REASON FOR REFUSAL

Label	Code	Go To
CHILD UNHAPPY	1	BCM13000
CHILD SLEEPY	2	BCM13000
PHYSICAL LIMITATIONS	3	BCM13000
ADULT CAREGIVER ILL/EMERGENCY	4	BCM13000
CHILD ILL/EMERGENCY	5	BCM13000
COLLECTION SUPPLIES MALFUNCTIONED	6	BCM13000
NO TIME	7	BCM13000
UNCOMFORTABLE WITH COLLECTION PROCEDURES	8	BCM13000
OTHER	-5	
REFUSED	-1	BCM13000
DON'T KNOW	-2	BCM13000

SOURCE
National Children's Study, Legacy Phase (Modified from 6M Child)

BCM12000/(REFUSE_REASON_OTH). SPECIFY _____

SOURCE
National Children's Study, Legacy Phase (Modified from 6M Child)

BCM13000. That's fine. Thank you for your time.

PROGRAMMER INSTRUCTIONS
GO TO COLLECTION_COMMENT.

BCM14000/(TAKEN_MED_CHILD). In the past month, has {C_FNAME/the child} taken, used or received any of the following?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> READ THE CHOICES BELOW TO THE PARTICIPANT AND RECORD THE RESPONSE FOR EACH. 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	
REFUSED	-1	
DON'T KNOW	-2	

SOURCE

New

PROGRAMMER INSTRUCTIONS

- IF **TAKEN_MED** = 4, DO NOT ALLOW SELECTION OF ADDITIONAL RESPONSES.

BCM15000/(TAKEN_PROBIOTIC_CHILD). In the past month, has {C_FNAME/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	
REFUSED	-1	
DON'T KNOW	-2	

SOURCE

New

BCM16000/(SWAB_STATUS). MICROBIOME {SWAB_TYPE} COLLECTION STATUS

DATA COLLECTOR INSTRUCTIONS

- ENTER STATUS OF EACH MICROBIOME SWAB.
- SELECT "COLLECTED" TO INDICATE THAT THE SWAB WAS SUCCESSFULLY COLLECTED.
- SELECT "NOT COLLECTED" TO INDICATE THAT THE SWAB WAS NOT COLLECTED.

PROGRAMMER INSTRUCTIONS

- LOOP THROUGH **SWAB_STATUS**, **SPECIMEN_ID**, **SWAB_COMMENTS** AND **SWAB_CO**

Label	Code	Go To
CHILD SLEEPY	2	
PHYSICAL LIMITATION	3	
ADULT CAREGIVER ILL/EMERGENCY	4	
CHILD ILL/EMERGENCY	5	
COLLECTION SUPPLIES MALFUNCTIONED	6	
NO TIME	7	
UNCOMFORTABLE WITH COLLECTION PROCEDURES	8	
OTHER	-5	
REFUSED	-1	
DON'T KNOW	-2	

PROGRAMMER INSTRUCTIONS

- DISPLAY CORRECT SWAB_TYPE AS REFERENCE FOR LOOP:
 - o IF SWAB_TYPE=1 DISPLAY "MOUTH SWAB"
 - o IF SWAB_TYPE=2, DISPLAY "NARES SWAB"
 - o IF SWAB_TYPE=3 DISPLAY "RECTAL SWAB"
- IF SWAB_COMMENTS = ANY COMBINATION OF 1 THROUGH 8, AND
 - o IF FIRST OR SECOND LOOP, GO TO SPECIMEN_ID TO LOOP THROUGH REMAINING MICROBIOME SPECIMENS.
 - o IF THIRD LOOP, GO TO COLLECTION_LOCATION.
- IF SWAB_COMMENTS = -5 OR ANY COMBINATION OF 1 THROUGH 8 AND -5 SELECTED, GO TO SWAB_COMMENTS_OTH.
- IF SWAB_COMMENTS = -1 OR -2, DO NOT ALLOW ANY OTHER RESPONSES AND,
- IF FIRST OR SECOND LOOP, GO TO SPECIMEN_ID TO LOOP THROUGH REMAINING MICROBIOME SPECIMENS.
- IF THIRD LOOP, GO TO COLLECTION_LOCATION.

BCM19000/(SWAB_COMMENTS_OTH).

DATA COLLECTOR INSTRUCTIONS

- IF THERE ARE ANY OTHER REASONS THE MICROBIOME SWAB WAS NOT COLLECTED OTHER THAN THOSE LISTED IN THE PREVIOUS QUESTION, ENTER THEM BELOW.

PROGRAMMER INSTRUCTIONS

- IF FIRST OR SECOND LOOP, GO TO SWAB_STATUS TO LOOP THROUGH REMAINING MICROBIOME SPECIMENS.
- OTHERWISE, GO TO COLLECTION_LOCATION.

BCM20000/(COLLECTION_LOCATION). WHERE DID THE MICROBIOME SWAB SPECIMEN COLLECTION OCCUR?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> RECORD WHERE MICROBIOME SWAB SPECIMEN COLLECTION OCCURRED OR WAS ATTEMPTED.

Label	Code	Go To
HOME	1	BCM22000
CLINIC	2	BCM22000
OTHER LOCATION	-5	

BCM21000/(COLLECTION_LOCATION_OTH).
SPECIFY: _____

BCM22000. DATE AND TIME CHILD MICROBIOME SWAB SPECIMENS WERE COLLECTED

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

(MICROB_SWAB_COLLECT_MM) |__|__|
M M

(MICROB_SWAB_COLLECT_DD) |__|__|
D D

(MICROB_SWAB_COLLECT_YYYY) |__|__|__|__|
Y Y Y Y

(MICROB_SWAB_COLLECT_TIME) TIME CHILD MICROBIOME SWAB SPECIMENS WERE COLLECTED

|__|__| : |__|__|
H H M M

(MICROB_SWAB_COLLECT_TIME_UNIT) TIME CHILD MICROBIOME SWAB SPECIMENS WERE COLLECTED – AM/PM

Label	Code	Go To
AM	1	
PM	2	

BCM25000/(COLLECTION_DONE_BY). WHO COLLECTED THE CHILD MICROBIOME SWAB SPECIMENS?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> RECORD WHO COLLECTED THE CHILD MICROBIOME SWAB SPECIMENS. IF OTHER THAN DATA COLLECTOR OR ADULT CAREGIVER, SPECIFY.

Label	Code	Go To
DATA COLLECTOR	1	BCM27000
MOTHER	2	BCM27000

Label	Code	Go To
FATHER	3	BCM27000
OTHER	-5	

BCM26000/(COLLECTION_DONE_BY_OTH).

SPECIFY: _____

BCM27000. Thank you for the child's participation in this sample collection.

BCM28000/(COLLECTION_COMMENT). RECORD ANY PROBLEMS OR CONCERNS ABOUT THE COLLECTION.

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE CHILD MICROBIOME SWAB SPECIMEN COLLECTION PROCEDURE.

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_BCM_ET
COMMENTS	2	

BCM29000/(COLLECTION_COMMENT_OTH).

SPECIFY: _____

(TIME_STAMP_BCM_ET).

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> INSERT DATE/TIME STAMP