



Adult Microbiome Swab Instrument

Event Category:	Time-Based
Event:	Birth, 6M, 24M, 48M
Administration:	N/A
Instrument Target:	Biological Mother; Primary Caregiver
Instrument Respondent:	Biological Mother; 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:	14 minutes
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.

Public reporting burden for this collection of information is estimated to average 14 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.

This page intentionally left blank.

Adult Microbiome Swab Instrument

TABLE OF CONTENTS

GENERAL PROGRAMMER INSTRUCTIONS:.....	1
BIOSPECIMEN ADULT MICROBIOME SWAB INSTRUMENT.....	3

This page intentionally left blank.

Adult Microbiome Swab Instrument

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 ADULT MICROBIOME SWAB INSTRUMENT

(TIME_STAMP_BAM_ST).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT ID (P_ID) FOR ADULT.
- IF EVENT_TYPE ≠ 18, GO TO ADULT_MICROBIOME_SWAB_INTRO.
- OTHERWISE, IF EVENT_TYPE = 18, GO TO BIRTH_MICROBIOME_SWAB_INTRO.

BAM01000/(BIRTH_MICROBIOME_SWAB_INTRO). I would like to collect a swab of your mouth. Then I will also collect swabs of your vagina and your rectum. Before I do so, I will explain the collection and ask you some questions.

DATA COLLECTOR INSTRUCTIONS

- EXPLAIN THE ADULT MICROBIOME SWAB COLLECTION PROTOCOL AT BIRTH TO THE WOMAN.
- RECORD AGREEMENT OR REFUSAL TO COLLECT MICROBIOME SPECIMEN.

Label	Code	Go To
CONTINUE	1	TAKEN_MED
REFUSED	-1	REFUSE_REASON

SOURCE

NEW

BAM02000/(ADULT_MICROBIOME_SWAB_INTRO). I would like to collect swabs of your nose and mouth. Then I will ask you to collect your own rectal swab. Before I do so, I will explain the collection and ask you some questions.

DATA COLLECTOR INSTRUCTIONS

- EXPLAIN THE ADULT MICROBIOME SWAB COLLECTION PROTOCOL TO THE ADULT CAREGIVER
- RECORD AGREEMENT OR REFUSAL TO COLLECT MICROBIOME SPECIMEN.

Label	Code	Go To
CONTINUE	1	TAKEN_MED
REFUSED	-1	

SOURCE

NEW

BAM03000/(REFUSE_REASON). I am sorry that 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
PHYSICAL LIMITATION	1	BAM05000
PARTICIPANT ILL/EMERGENCY	2	BAM05000
LANGUAGE ISSUE	3	BAM05000
NO TIME	4	BAM05000
UNCOMFORTABLE WITH COLLECTION PROCEDURES	5	BAM05000
OTHER	-5	
REFUSED	-1	BAM05000
DON'T KNOW	-2	BAM05000

SOURCE

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

BAM04000/(REFUSE_REASON_OTH). SPECIFY: _____

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

SOURCE

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

BAM05000. That's fine. Thank you for your time.

PROGRAMMER INSTRUCTIONS

- GO TO COLLECTION_COMMENT

BAM06000/(TAKEN_MED). In the past month, have you taken, used or received any of the following?

DATA COLLECTOR INSTRUCTIONS

- 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	2	

Label	Code	Go To
capsules)		
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.

BAM07000/(TAKEN_PROBIOTIC). In the past month, did you take any probiotic supplements (such as Culturelle) or have yogurt (such as Activia) in your diet at least once a week?

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

SOURCE

New

BAM08000/(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_COMMENTS_OTH** (IF NEEDED) FOR ALL 3 SWAB TYPES.
- DISPLAY CORRECT SWAB AS A REFERENCE FOR EACH LOOP:
 - IF **EVENT_TYPE** = 18 (BIRTH EVENT) AND:
 - IF FIRST CYCLE OF THE LOOP, SET **SWAB_TYPE** = 1, AND DISPLAY "MOUTH SWAB"
 - IF SECOND CYCLE OF THE LOOP, SET **SWAB_TYPE** = 2, AND DISPLAY "VAGINAL SWAB"
 - IF THIRD CYCLE OF THE LOOP, SET **SWAB_TYPE** = 3, AND DISPLAY "RECTAL SWAB"

PROGRAMMER INSTRUCTIONS

- MN30
- o IF **SWAB_TYPE**=6, DISPLAY "RECTAL SWAB", AND FORMAT AA# # # # # # - MR30

PROGRAMMER INSTRUCTIONS

- IF **EVENT_TYPE** ≠ 18, AND
 - o IF FIRST OR SECOND LOOP, GO TO **SWAB_STATUS** TO LOOP THROUGH REMAINING MICROBIOME SPECIMENS.
 - o OTHERWISE, GO TO **COLLECTION_LOCATION**.
- IF **EVENT_TYPE** = 18,
 - o IF FIRST OR SECOND LOOP, GO TO **SWAB_STATUS** TO LOOP THROUGH REMAINING MICROBIOME SPECIMENS.
 - o OTHERWISE, GO TO **BIRTH_MICROBIOME_SWAB_TIME**

BAM10000/(SWAB_COMMENTS). REASON MICROBIOME {**SWAB_TYPE**} WAS NOT COLLECTED

DATA COLLECTOR INSTRUCTIONS

- ENTER REASONS **SWAB_TYPE** WAS NOT COLLECTED.
- SELECT ALL THAT APPLY.

PROGRAMMER INSTRUCTIONS

- DISPLAY CORRECT SWAB AS A REFERENCE FOR EACH LOOP:
 - o IF **SWAB_TYPE**=1, DISPLAY "MOUTH SWAB"
 - o IF **SWAB_TYPE**=2, DISPLAY "VAGINAL SWAB"
 - o IF **SWAB_TYPE**=3, DISPLAY "RECTAL SWAB"
 - o IF **SWAB_TYPE**=4, DISPLAY "MOUTH SWAB"
 - o IF **SWAB_TYPE**=5, DISPLAY "NARES SWAB"
 - o IF **SWAB_TYPE**=6, DISPLAY "RECTAL SWAB"

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

PROGRAMMER INSTRUCTIONS

- IF **SWAB_COMMENTS** = -5, GO TO **SWAB_COMMENTS_OTH**.
- IF **SWAB_COMMENTS** ≠ -5, AND

PROGRAMMER INSTRUCTIONS

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

BAM11000/(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_COMMENT**.

BAM12000/(BIRTH_MICROBIOME_SWAB_TIME). WERE THE SPECIMENS COLLECTED PRE- OR POST-DELIVERY?

Label	Code	Go To
PRE-DELIVERY	1	
POST-DELIVERY	2	

BAM13000/(COLLECTION_DONE_BY). WHO COLLECTED THE ADULT MICROBIOME SWAB SPECIMENS?

DATA COLLECTOR INSTRUCTIONS

- RECORD WHO COLLECTED THE ADULT MICROBIOME SWAB SPECIMENS.
- IF OTHER THAN DATA COLLECTOR OR HOSPITAL STAFF, SPECIFY.

Label	Code	Go To
DATA COLLECTOR	1	COLLECTION_LOCATION
HOSPITAL STAFF	2	COLLECTION_LOCATION
OTHER	-5	

BAM14000/(COLLECTION_DONE_BY_OTH).
SPECIFY _____

BAM15000/(COLLECTION_LOCATION). WHERE DID THE MICROBIOME SWAB SPECIMEN COLLECTION OCCUR?

DATA COLLECTOR INSTRUCTIONS

- RECORD WHERE MICROBIOME SWAB SPECIMEN COLLECTION OCCURRED OR WAS ATTEMPTED.

Label	Code	Go To
HOME	1	BAM17000

Label	Code	Go To
CLINIC	2	BAM17000
HOSPITAL	3	BAM17000
OTHER LOCATION	-5	

BAM16000/(COLLECTION_LOCATION_OTH).

SPECIFY:

BAM17000. DATE AND TIME ADULT MICROBIOME SWAB SPECIMENS WERE COLLECTED

DATA COLLECTOR INSTRUCTIONS

- 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 ADULT MICROBIOME SWAB SPECIMENS WERE COLLECTED

|_|_|:|_|_|
H H M M

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

Label	Code	Go To
AM	1	
PM	2	

BAM20000. Thank you for your participation in this sample collection.

BAM21000/(COLLECTION_COMMENT). RECORD ANY PROBLEMS OR CONCERNS ABOUT THE COLLECTION.

DATA COLLECTOR INSTRUCTIONS

- DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE ADULT MICROBIOMESWAB SPECIMEN COLLECTION PROCEDURE.

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_BAM_ET
COMMENTS	2	

BAM22000/(COLLECTION_COMMENT_OTH).

SPECIFY: _____

(TIME_STAMP_BAM_ET).

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