



## Adult Microbiome Swab Instrument

|  |                                      |
|--|--------------------------------------|
| <b>Event Category:</b>                       | Time-Based                           |
| <b>Event:</b>                                | Birth, 6M, 24M, 48M                  |
| <b>Administration:</b>                       | N/A                                  |
| <b>Instrument Target:</b>                    | Biological Mother; Primary Caregiver |
| <b>Instrument Respondent:</b>                | Biological Mother; Primary Caregiver |
| <b>Domain:</b>                               | Biospecimen                          |
| <b>Document Category:</b>                    | Sample Collection                    |
| <b>Method:</b>                               | Data Collector Administered          |
| <b>Mode (for this instrument*):</b>          | In-Person, CAI                       |
| <b>OMB Approved Modes:</b>                   | In-Person, CAI                       |
| <b>Estimated Administration Time:</b>        | 14 minutes                           |
| <b>Multiple Child/Sibling Consideration:</b> | Per Event                            |
| <b>Special Considerations:</b>               | N/A                                  |
| <b>Version:</b>                              | 1.0                                  |
| <b>MDES Release:</b>                         | 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"> <li>Limit text to 255 characters</li> </ul>  |
| FIRST NAME AND LAST NAME                             | 30   | CHARACTER            | <ul style="list-style-type: none"> <li>Limit text to 30 characters</li> </ul>   |
| 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<br>CHARACTER | <ul style="list-style-type: none"> <li>DISPLAY AS MM/DD/YYYY</li> <li>STORE AS YYYY-MM-DD</li> <li>HARD EDITS:<br/>MM MUST EQUAL 01 TO 12<br/>DD MUST EQUAL 01 TO 31<br/>YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.</li> </ul> |
| TIME VARIABLES                                       | TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION | NUMERIC              | <ul style="list-style-type: none"> <li>HARD EDITS:<br/>HOURS MUST BE BETWEEN 00 AND 12;<br/>MINUTES MUST BE BETWEEN 00 AND 59</li> </ul>  |

### 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  |
|--|
| <ul style="list-style-type: none"> <li>o IF <b>EVENT_TYPE</b> = 24 (6-MONTH EVENT) AND: <ul style="list-style-type: none"> <li>▪ IF FIRST CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 4, AND DISPLAY "MOUTH SWAB"</li> <li>▪ IF SECOND CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 5, AND DISPLAY "NARES SWAB"</li> <li>▪ IF THIRD CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 6, AND DISPLAY "RECTAL SWAB"</li> </ul> </li> <li>o IF <b>EVENT_TYPE</b> = 31 (24-MONTH EVENT) AND: <ul style="list-style-type: none"> <li>▪ IF FIRST CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 4, AND DISPLAY "MOUTH SWAB"</li> <li>▪ IF SECOND CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 5, AND DISPLAY "NARES SWAB"</li> <li>▪ IF THIRD CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 6, AND DISPLAY "RECTAL SWAB"</li> </ul> </li> <li>o IF <b>EVENT_TYPE</b> = XX (48-MONTH EVENT) AND: <ul style="list-style-type: none"> <li>▪ IF FIRST CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 4, AND DISPLAY "MOUTH SWAB"</li> <li>▪ IF SECOND CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 5, AND DISPLAY "NARES SWAB"</li> <li>▪ IF THIRD CYCLE OF THE LOOP, SET <b>SWAB_TYPE</b> = 6, AND DISPLAY "RECTAL SWAB"</li> </ul> </li> </ul> |

| Label         | Code     | Go To         |
|---------------|----------|---------------|
| COLLECTED     | <b>1</b> |               |
| NOT COLLECTED | <b>2</b> | SWAB_COMMENTS |

**BAM09000/(SPECIMEN\_ID)**. ASSIGN SPECIMEN ID FOR {**SWAB\_TYPE**}

|  |  |  |  |  |  |  |  |  |  |  |  |  |   |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  | - |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|

| DATA COLLECTOR INSTRUCTIONS  |
|--|
| <ul style="list-style-type: none"> <li>SCAN <b>SWAB_TYPE</b> BARCODE.</li> <li>IF THE BARCODE SCANNER IS NOT WORKING, MANUALLY ENTER THE INFORMATION.</li> </ul> |

| PROGRAMMER INSTRUCTIONS  |
|--|
| <p>DISPLAY CORRECT <b>SWAB_TYPE</b> DESCRIPTION AS A REFERENCE AND FORMAT FOR <b>SPECIMEN_ID</b> FOR EACH LOOP:</p> <ul style="list-style-type: none"> <li>o IF <b>SWAB_TYPE</b>=1, DISPLAY "MOUTH SWAB", AND FORMAT AA# # # # # # -MM10</li> <li>o IF <b>SWAB_TYPE</b>=2, DISPLAY "VAGINAL SWAB", AND FORMAT AA# # # # # # -MV10</li> <li>o IF <b>SWAB_TYPE</b>=3, DISPLAY "RECTAL SWAB", AND FORMAT AA# # # # # # -MR10</li> <li>o IF <b>SWAB_TYPE</b>=4, DISPLAY "MOUTH SWAB", AND FORMAT AA# # # # # # -MM30</li> <li>o IF <b>SWAB_TYPE</b>=5, DISPLAY "NARES SWAB", AND FORMAT AA# # # # # # -</li> </ul> |

**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"> <li>• INSERT DATE/TIME STAMP</li> </ul> |