OMB #: 0925-0593 OMB Expiration Date: 8/31/2014 Breast Milk Pick-Up Instrument, Phase 2g OMB Specification



Breast Milk Pick-Up Instrument

| Event Category: | Time-Based |
|---------------------------------------|-----------------------------|
| Event: | Birth, 3M |
| Administration: | N/A |
| Instrument Target: | Biological Mother |
| Instrument Respondent: | Data Collector |
| 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: | 2 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 2 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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Breast Milk Pick-Up Instrument

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Breast Milk Pick-Up 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 CHARACTE RS 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 DESIGNATI ON | 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.

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 BREAST MILK PICK UP

(TIME_STAMP_BBM_ST).

| P | R | \cap | GF | 2ΔΙ | MN | 1FR | INS ⁻ | TRI | ICT | TO! | NS |
|---|----|--------|----|-----|------|-----|------------------|-------|------------|-----|-----|
| | 1. | v | 91 | ותו | VIIV | | 1112 | 1 1/1 | ノしょ | - | 140 |

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT ID (**P_ID**) FOR THE BIOLOGICAL MOTHER.
- PRELOAD **STAFF ID**.

| BBM01000/(SPECIMEN II |)). | | | l | l | l | l | l | | I | - | | ΙI | | |
|-----------------------|-----|--|--|---|---|---|---|---|--|---|-----------|--|----|--|--|
|-----------------------|-----|--|--|---|---|---|---|---|--|---|-----------|--|----|--|--|

PROGRAMMER INSTRUCTIONS

• DISPLAY HARD EDIT IF FORMAT IS NOT TWO ALPHA, SEVEN NUMERIC CHARACTERS DASH TWO ALPHA, TWO NUMERIC CHARACTERS (AA#######-AA##)

BBM02000/(SPECIMEN_PICKUP_COND). CONDITION OF SPECIMEN UPON PICK-UP

| Label | Code | Go To |
|---------------------|------|-------|
| PICKED UP OK | 1 | |
| PICKED UP BROKEN | 2 | |
| PICKED UP LEAKING | 3 | |
| PICKED UP AT | 4 | |
| INCORRECT | | |
| TEMPERATURE | | |
| MISSING SPECIMEN ID | 5 | |
| LABEL | | |
| SPECIMEN LOST | 6 | |
| SPECIMEN NOT | 7 | |
| COLLECTED | | |

BBM03000/(BMILK_SAQ). WAS A BREAST MILK SAQ COMPLETED BY THE PARTICIPANT?

| Label | Code | Go To |
|-------|------|----------|
| YES | 1 | BBM06000 |
| NO | 2 | |

BBM04000/(BMILK_SAQ_NOCOLLECT). WHY WASN'T THE SAQ COMPLETED BY THE PARTICIPANT?

| Label | Code | Go To |
|-----------------|------|----------|
| LOST FORM | 1 | BBM06000 |
| NOT ENOUGH TIME | 2 | BBM06000 |
| TOO COMPLICATED | 3 | BBM06000 |
| OTHER | -5 | |

| BBM05000/(BMILK_SAQ_NO | COLLECT_OTH). | | | SPECIFY: |
|---|----------------------|------------|---------------------|----------|
| BBM06000. SPECIMEN PICK- | -UP DATE: | | | |
| (SPECIMEN_PICKUP_MM) _ M M | | | | |
| (SPECIMEN_PICKUP_DD) _ D D | _ | | | |
| (SPECIMEN_PICKUP_YYYY) Y Y Y Y | 2 0 | | | |
| BBM07000. SPECIMEN PICK- | -UP TIME: | | | |
| (SPECIMEN_PICKUP_TIME) | | | _ | _ : |
| H H M M | | | | |
| (SPECIMEN_PICKUP_TIME_I | UNIT) | | | |
| Label | Code | Go To | | |
| AM | 1 | | | |
| PM | 2 | | | |
| BBM08000/(SPECIMEN_PICK THE PICK-UP? | (UP_COMMENTS). DO YO | U HAVE ANY | COMMEN [®] | TS ABOUT |
| Label | Code | Go To | | |
| YES | 1 | | | |
| NO | 2 | BBM1000 | 0 | |
| BBM09000/(SPECIMEN_PICK | (UP_COMMENTS_OTH). | COMMENTS | ABOUT | PICK-UP: |
| BBM10000. DATE OF INSTRU | JMENT COMPLETION: | | | |
| (DATE_COMPLETE_MM) M M | | | | |
| (DATE_COMPLETE_DD) D D | | | | |
| (DATE_COMPLETE_YYYY) 2 YYYYY | 2 0 | | | |
| | | | | |

PROGRAMMER INSTRUCTIONS

INSERT DATE/TIME STAMP