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



Breast Milk SAQ

Event Category:	Time-Based
Event:	Birth, 3M
Administration:	N/A
Instrument Target:	Biological Mother
Instrument Respondent:	Biological Mother
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-Based, CAI
Estimated Administration Time:	40 minutes
Multiple Child/Sibling Consideration:	Per Event
Special Considerations:	N/A
Version:	2.0
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 40 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 SAQ

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Breast Milk SAQ

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 $\mathbf{R}_{-}\mathbf{P}_{-}\mathbf{ID}$ (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.**

BREAST MILK DATA COLLECTION SAQ

BMD01000. As part of the National Children's Study, we are asking you to provide a breast milk sample from one breast. Please follow the instructions provided in the breast milk collection kit to collect the sample.

After you have collected the breast milk sample, please complete the information on both sides of this form.

BMD02000. On what date did you collect the sample?

SOURCE
National Children's Study, Legacy Phase (Modified) (1M & 6M)
(P_BMQ_MM) M M
(P_BMQ_DD) D D
(P_BMQ_YYYY) _ Y Y Y Y

BMD03000. At what time did you collect the sample?

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

Label	Code	Go To
AM	1	
PM	2	

BMD04000/(P_BMQ_HOW_LONG). How long did it take you to collect this sample?

Label	Code	Go To
0 - 10 minutes	1	
11 - 20 minutes	2	
Over 20 minutes	3	

SOURCE	
National Children's Study, Vanguard Phase	

BMD05000/(P_BMQ_LAST_FEED). How long before collecting the breast milk sample did you last breast-feed your baby or pump milk from this breast?

Label	Code	Go To
Less than 2 hours	1	
2-4 hours	2	
Over 4 hours	3	

SOURCE

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

BMD06000/(P_BMQ_PUMP). Did you use a pump to collect the sample?

Label	Code	Go To
Yes	1	
No	2	P_BMQ_EMPTY

SOURCE

National Children's Study, Vanguard Phase

BMD07000/(P_BMQ_TYPE_PUMP). What type of pump did you use to collect the sample?

Label	Code	Go To
Electric pump	1	
Hand pump	2	

SOURCE

National Children's Study, Vanguard Phase

BMD08000/(P_BMQ_BRAND_PUMP). What is the brand of the pump you used to collect the sample? (Mark one)

Label	Code	Go To
Medela®	1	P_BMQ_EMPTY
AVENT ®	2	P_BMQ_EMPTY
Playtex®	3	P_BMQ_EMPTY
Ameda®	4	P_BMQ_EMPTY
Evenflo®	5	P_BMQ_EMPTY
Lansinoh®	6	P_BMQ_EMPTY
Other	-5	
Don't Know	-2	P_BMQ_EMPTY

SOURCE

National Children's Study, Vanguard Phase

BMD09000/(P_BMQ_BRAND_PUMP_OTH).	
SPECIFY:	

SOURCE

National Children's Study, Vanguard Phase

BMD10000/(P_BMQ_EMPTY). Did you completely empty the breast when collecting the sample?

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

SOURCE

National Children's Study, Vanguard Phase

BMD11000/(P_BMQ_CAFFEINE). During the 2 hours prior to collecting the breast milk sample, did you eat or drink any food or beverage containing caffeine (for example, coffee, tea, soda, chocolate)?

Label	Code	Go To
Yes	1	
No	2	

SOURCE

National Children's Study, Vanguard Phase

BMD12000/(P_BMQ_ALCOHOL). During the 2 hours prior to collecting the breast milk sample, did you drink any alcohol?

Label	Code	Go To
Yes	1	
No	2	

SOURCE

National Children's Study, Vanguard Phase

BMD13000. Please write down the name of any prescription, over-the-counter, homeopathic, or non-traditional medicines you have taken in the last 24 hours (including prenatal vitamins). Please be specific. For example, if you took Robitussin DM®, write Robitussin DM®, not Robitussin®. If you did not take any prescription or over-the-counter medications in the last 24 hours, please mark None.

SOURCE

National Children's Study, Vanguard Phase

(P_BMQ_PRSC_OTC_1)

Label	Code	Go To
None	1	P_BMQ_FREEZER

(P_BMQ_PRSC_OTC_2)	
(P_BMQ_PRSC_OTC_3)	
(P_BMQ_PRSC_OTC_4)	
(P_BMQ_PRSC_OTC_5)	
(P_BMQ_PRSC_OTC_6)	
(P_BMQ_PRSC_OTC_7)	
(P_BMQ_PRSC_OTC_8)	
(P_BMQ_PRSC_OTC_9)	<u></u>
(P BMO PRSC OTC 10)	

BMD14000/(P_BMQ_FREEZER). How long after collecting your sample did you place it in the freezer?

Label	Code	Go To
0-10 minutes	1	
11-20 minutes	2	
Over 20 minutes	3	
Not Applicable (did not	-7	
place in freezer)		

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

BMD15000. 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). Participant ID:		
FOU03000/(R_P_ID). Respondent ID:		
FOU04000/(EVENT_ID).	Visit	Type/Event