



## Child Saliva Instrument

<b>Event Category:</b>	Time-Based
<b>Event:</b>	12M, 36M, 60M
<b>Administration:</b>	N/A
<b>Instrument Target:</b>	Child
<b>Instrument Respondent:</b>	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>	10 minutes
<b>Multiple Child/Sibling Consideration:</b>	Per Child
<b>Special Considerations:</b>	N/A
<b>Version:</b>	2.0
<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 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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## 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 CHARACTER	<ul style="list-style-type: none"> <li>DISPLAY AS MM/DD/YYYY</li> <li>STORE AS YYYY-MM-DD</li> <li>HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 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: HOURS MUST BE BETWEEN 00 AND 12; 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 CHILD SALIVA COLLECTION INSTRUMENT**

(TIME\_STAMP\_BCS\_ST).

<b>PROGRAMMER INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>• INSERT DATE/TIME STAMP</li> <li>• PRELOAD PARTICIPANT ID (<b>P_ID</b>) FOR CHILD AND RESPONDENT ID (<b>R_P_ID</b>) FOR ADULT CAREGIVER.</li> <li>• PRELOAD CHILD'S FIRST NAME AND DISPLAY NAME IN <b>C_FNAME</b> THROUGHOUT INSTRUMENT</li> <li>• OTHERWISE, IF <b>C_FNAME</b> = -1 OR -2, DISPLAY "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT.</li> </ul>

**BCS07000/(SALIVA\_INTRO\_COLLECTOR).** I would like to collect a sample of {C\_FNAME/the child}'s saliva. Before I do so, I will explain this collection and ask you some questions.

<b>DATA COLLECTOR INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>• EXPLAIN THE CHILD SALIVA COLLECTION PROCEDURES TO THE ADULT CAREGIVER.</li> <li>• BE SURE TO INFORM THE ADULT CAREGIVER THAT SHE/HE NEEDS TO BE PRESENT WHILE THE PROCEDURE IS BEING PERFORMED</li> <li>• IF THE ADULT CAREGIVER REFUSES THE COLLECTION, SELECT REFUSED. OTHERWISE, SELECT CONTINUE.</li> </ul>

<b>Label</b>	<b>Code</b>	<b>Go To</b>
CONTINUE	1	BCS11000
REFUSED	-1	

<b>SOURCE</b>
National Children's Study, Vanguard Phase (BIO Child Saliva)

**BCS08000/(COLL\_REFUSAL\_REASON).** I am sorry that you have chosen not to participate in this collection. Can you tell me why?

<b>DATA COLLECTOR INSTRUCTIONS</b>
<ul style="list-style-type: none"> <li>• SELECT REASON FOR REFUSAL.</li> </ul>

<b>Label</b>	<b>Code</b>	<b>Go To</b>
CHILD IS SLEEPING/TIRED	1	BCS10000
REFUSED	-1	BCS10000
DON'T KNOW	-2	BCS10000
OTHER	-5	

<b>SOURCE</b>
National Children's Study, Legacy Phase (6M Child)

**BCS09000/(COLL\_REFUSAL\_REASON\_OTH).** SPECIFY: \_\_\_\_\_

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

#### SOURCE

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

BCS10000. That's fine. Thank you for your time.

#### PROGRAMMER INSTRUCTIONS

- GO TO COLLECTION\_COMMENT.

BCS11000. When was the last time {C\_FNAME/the child} had anything to eat or drink?

#### DATA COLLECTOR INSTRUCTIONS

- RECORD THE LAST TIME CHILD ATE OR DRANK ANYTHING.
- RECORD THE TIME AS HH:MM, BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO MARK THE BOX TO CHOOSE "AM" OR "PM". FOR EXAMPLE, IF THE LAST TIME CHILD ATE OR DRANK WAS AT 2:05PM, RECORD "02:05" AND CHOOSE "PM".
- RECORD THE DATE AS A TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

#### SOURCE

National Children's Study, Vanguard Phase (BIO Child Saliva)

(LAST\_EAT\_TIME) LAST TIME ATE OR DRANK – TIME

				:				
H	H				M	M		

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

(LAST\_EAT\_TIME\_UNIT) LAST TIME ATE OR DRANK – AM/PM

Label	Code	Go To
AM	1	
PM	2	

(LAST\_EAT\_MM) LAST TIME ATE OR DRANK – DATE: MONTH

M	M

Label	Code	Go To
REFUSED	-1	



Label	Code	Go To
DON'T KNOW	-2	

(LAST\_EAT\_DD) LAST TIME ATE OR DRANK – DATE: DAY

D	D		

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

(LAST\_EAT\_YYYY) LAST TIME ATE OR DRANK – DATE: YEAR

Y	Y	Y	Y		

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

BCS15000/(SPECIMEN\_STATUS). STATUS OF THE SALIVA COLLECTION

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>ENTER THE STATUS OF THE SPECIMEN COLLECTION.</li> </ul>

Label	Code	Go To
COLLECTED	1	SALIVA_COLLECTOR
NOT COLLECTED	2	

BCS16000/(NO\_SPECIMEN\_REAS).

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> <li>ENTER THE PRIMARY REASON WHY THE SPECIMEN WAS NOT COLLECTED.</li> <li>SELECT ONLY ONE RESPONSE.</li> </ul>

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

BCS17000/(NO\_SPECIMEN\_REAS\_OTH). SPECIFY: \_\_\_\_\_

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"><li>GO TO COLLECTION_COMMENT.</li></ul>

BCS18000/(SALIVA\_COLLECTOR). WHO COLLECTED CHILD SALIVA SPECIMEN?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"><li>RECORD WHO COLLECTED THE CHILD SALIVA SPECIMEN.</li></ul>

Label	Code	Go To
DATA COLLECTOR	1	SPECIMEN_ID
MOTHER	2	SPECIMEN_ID
FATHER	3	SPECIMEN_ID
OTHER	-5	

BCS19000/(SALIVA\_COLLECTOR\_OTH). SPECIFY: \_\_\_\_\_

BCS20000/(SPECIMEN\_ID).  
|\_|\_|\_|\_|\_|\_|\_|\_|\_|-|\_|\_|\_|\_|

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"><li>RECORD SALIVA COLLECTION SPECIMEN ID.</li></ul>

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"><li>CANNOT BE NULL.</li><li>HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT TWO ALPHA, SEVEN NUMERIC CHARACTERS DASH TWO ALPHA, TWO NUMERIC CHARACTERS (AA#####-AA##).</li></ul>

BCS21000.

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"><li>RECORD DATE AND TIME THE CHILD SALIVA SPECIMEN WAS COLLECTED.</li><li>RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.</li><li>RECORD THE TIME AS HH:MM, BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND CHOOSE "AM" OR "PM". FOR EXAMPLE, IF THE CHILD SALIVA SAMPLE WAS COLLECTED AT 2:05PM RECORD "02:05" AND CHOOSE "PM".</li></ul>

(C\_SALIVA\_COLL\_MM) DATE CHILD SALIVA SPECIMEN WAS COLLECTED - MONTH

|\_|\_|  
M M

(C\_SALIVA\_COLL\_DD) DATE CHILD SALIVA SPECIMEN WAS COLLECTED - DAY

|\_|\_|

D D

(C\_SALIVA\_COLL\_YYYY) DATE CHILD SALIVA SPECIMEN WAS COLLECTED - YEAR

|\_|\_|\_|\_|  
Y Y Y Y

(C\_SALIVA\_COLL\_TIME) TIME CHILD SALIVA SPECIMEN COLLECTED

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

(C\_SALIVA\_COLL\_TIME\_UNIT) AM/PM CHILD SALIVA SPECIMEN COLLECTED

Label	Code	Go To
AM	1	
PM	2	

**BCS24000.** Thank you for providing the child's saliva sample.

**BCS25000/(COLLECTION\_COMMENT).** RECORD ANY COMMENTS ABOUT THE CHILD SALIVA COLLECTION PROCEDURE.

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"><li>RECORD ANY COMMENTS ABOUT THE CHILD SALIVA COLLECTION PROCEDURE.</li></ul>

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_BCS_ET
COMMENTS	2	

**BCS26000/(COLLECTION\_COMMENT\_OTH).** SPECIFY: \_\_\_\_\_

(TIME\_STAMP\_BCS\_ET).

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