

Child Saliva Instrument

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| --- | --- |
| Event Category: | Time-Based |
| Event: | 12M, 36M, 60M |
| Administration: | N/A |
| Instrument Target: | Child |
| Instrument Respondent: | 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: | 10 minutes |
| Multiple Child/Sibling Consideration: | Per Child |
| 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.

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Child Saliva Instrument

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Child Saliva 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 | * 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 DESIGNATION | 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 CHILD SALIVA COLLECTION INSTRUMENT

**(TIME\_STAMP\_BCS\_ST).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP * PRELOAD PARTICIPANT ID **(P\_ID)** FOR CHILD AND RESPONDENT ID **(R\_P\_ID)** FOR ADULT CAREGIVER. * PRELOAD CHILD’S FIRST NAME AND DISPLAY NAME IN **C\_FNAME** THROUGHOUT INSTRUMENT * OTHERWISE, IF **C\_FNAME** = -1 OR -2, DISPLAY “the child” IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT. |

**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.

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * EXPLAIN THE CHILD SALIVA COLLECTION PROCEDURES TO THE ADULT CAREGIVER. * BE SURE TO INFORM THE ADULT CAREGIVER THAT SHE/HE NEEDS TO BE PRESENT WHILE THE PROCEDURE IS BEING PERFORMED * IF THE ADULT CAREGIVER REFUSES THE COLLECTION, SELECT REFUSED.  OTHERWISE, SELECT CONTINUE. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| CONTINUE | 1 | BCS11000 |
| REFUSED | -1 |  |

|  |
| --- |
| SOURCE |
| 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?

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * SELECT REASON FOR REFUSAL. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| CHILD IS SLEEPING/TIRED | 1 | BCS10000 |
| REFUSED | -1 | BCS10000 |
| DON’T KNOW | -2 | BCS10000 |
| OTHER | -5 |  |

|  |
| --- |
| SOURCE |
| 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 |  |
| 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 |
| * ENTER THE STATUS OF THE SPECIMEN COLLECTION. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| COLLECTED | 1 | SALIVA\_COLLECTOR |
| NOT COLLECTED | 2 |  |

**BCS16000/(NO\_SPECIMEN\_REAS).**

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * ENTER THE PRIMARY REASON WHY THE SPECIMEN WAS NOT COLLECTED. * SELECT ONLY ONE RESPONSE. |

|  |  |  |
| --- | --- | --- |
| 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 |
| * GO TO **COLLECTION\_COMMENT**. |

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

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD WHO COLLECTED THE CHILD SALIVA SPECIMEN. |

|  |  |  |
| --- | --- | --- |
| 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).**

|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|- |\_\_|\_\_|\_\_|\_\_|

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| DATA COLLECTOR INSTRUCTIONS |
| * RECORD SALIVA COLLECTION SPECIMEN ID. |

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * CANNOT BE NULL. * HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT TWO ALPHA, SEVEN NUMERIC CHARACTERS DASH TWO ALPHA, TWO NUMERIC CHARACTERS (AA # # # # # # #-AA##). |

**BCS21000.**

|  |
| --- |
| DATA COLLECTOR INSTRUCTIONS |
| * RECORD DATE AND TIME THE CHILD SALIVA SPECIMEN WAS COLLECTED. * RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR. * 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”. |

**(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 |
| * RECORD ANY COMMENTS ABOUT THE CHILD SALIVA COLLECTION PROCEDURE. |

|  |  |  |
| --- | --- | --- |
| Label | Code | Go To |
| NO COMMENTS | 1 | TIME\_STAMP\_BCS\_ET |
| COMMENTS | 2 |  |

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

**(TIME\_STAMP\_BCS\_ET).**

|  |
| --- |
| PROGRAMMER INSTRUCTIONS |
| * INSERT DATE/TIME STAMP |