

Biospecimen Child Saliva Collection Instrument

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| --- | --- |
| Event: | 12 Month |
|  |  |
| Participant: | Child |
|  |  |
| Respondent: | Parent/Caregiver |
| Domain: | Biospecimen |
|  |  |
| Type of Document:  Allowable Mode:  Allowable Method: | Data Collection Instrument  In Person  CAPI |
|  |  |
| Recruitment Groups: | EH, PB, HI |
|  |  |
| Version: | 1.0 |
|  |  |
| Release: | MDES 3.0 |

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Biospecimen Child Saliva Collection Instrument

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**Biospecimen Child Saliva Collection Instrument**

**(TIME\_STAMP\_1) PROGRAMMER INSTRUCTION:**

* + INSERT DATE/TIME STAMP

PROGRAMMER INSTRUCTIONS:

* PRELOAD PARTICIPANT ID (**P\_ID**) FOR CHILD AND RESPONDENT ID (**R\_P\_ID**) FOR RESPONDENT,
* PRELOAD CHILD’S FIRST NAME AND DISPLAY NAME IN **C\_FNAME** THROUGHOUT INSTRUMENT.
* USE “the child” IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT IF CHILD’S NAME IS REFUSED OR DON’T KNOW.
* PRELOAD **CHILD\_SEX**
  + IF **CHILD\_SEX** = 1, DISPLAY “his” AND “he” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
  + IF **CHILD\_SEX** = 2, DISPLAY “her” AND “she” IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.

SV0100/(SALIVA\_COLLECT\_OPTION). MODE OF SALIVA COLLECTION

DATA COLLECTOR INSTRUCTION:

* FOLLOW THE STANDARD CHILD SALIVA COLLECTION PROCEDURES TO DETERMINE THE MODE OF CHILD SALIVA COLLECTION.

COLLECTION AT THE TIME OF VISIT 1 (SALIVA\_INTRO\_COLLECTOR)

CHILD’S PARENT/CAREGIVER AT HOME 2

SV0200/(SALIVA\_INTRO\_PARENT). Thank you for agreeing to collect a sample of

{C\_FNAME/the child}’s saliva. I will explain the collection materials and instructions.

DATA COLLECTOR INSTRUCTIONS:

* + IF THE CHILD’S MOTHER, FATHER, OR CAREGIVER AGREES TO COLLECT SALIVA SPECIMEN AT HOME, REVIEW THE COLLECTION MATERIALS, COLLECTION INSTRUCTIONS, AND DATA COLLECTION FORM WITH THE PARENT OR CAREGIVER.
  + RECORD AGREEMENT OR REFUSAL TO COLLECT SALIVA SPECIMEN.

AGREED 1 **(DISTRIBUTE)**

REFUSED -1

**SV0300.** Thank you for your time. **(KIT\_REAS\_RF)**

SV0400/(DISTRIBUTE). WERE YOU ABLE TO HAND THE KIT TO THE PARENT OR CAREGIVER?

YES 1

NO 2 **(N\_DISTRIB\_REAS)**

SV0500/(SPECIMEN\_ID) RECORD THE SPECIMEN ID

|A|A|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|- |S|C|\_\_|\_\_| **(TIME\_STAMP\_2)**

DATA COLLECTOR INSTRUCTION:

* + IF THE PARENT OR CAREGIVER AGREES TO COLLECT SALIVA SPECIMEN AT HOME, RECORD THE SPECIMEN ID OF THE OUTER PLASTIC CASE PROVIDED TO HIM/HER.

PROGRAMMER INSTRUCTIONS:

* + CANNOT BE NULL.
  + HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT AA # # # # # # #-SC## (FORMAT MUST BE AA # # # # # # #-SC##).

SV0600/(N\_DISTRIB\_REAS). WHY COULDN’T YOU GIVE THE KIT TO THE PARENT OR CAREGIVER?

NONE GIVEN…………………………………1 **(SV1000)**

NO TIME………………………………………2 **(SV1000)**

TOO COMPLICATED ……………………….3 **(SV1000)**

OTHER………………………………………. -5

**SV0700/(N\_DISTRIB\_REAS\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTION:

* + LIMIT TEXT TO 255 CHARACTERS.

SV1000. That’s fine. Thank you for your time. (TIME\_STAMP\_2)

SV1100/(SALIVA\_INTRO\_COLLECTOR). I would like to collect a sample of (CHILD’S NAME/ 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 PARENT OR CAREGIVER.
  + BE SURE TO INFORM THE PARENT OR CAREGIVER THAT SHE/HE NEEDS TO BE PRESENT WHILE THE PROCEDURE IS BEING PERFORMED
  + RECORD AGREEMENT OR REFUSAL TO COLLECT SALIVA SPECIMEN.

AGREED 1 **(SV1300)**

REFUSED -1

SV1200/(COLL\_REFUSAL\_REASON). I am sorry that you have chosen not to participate in this collection. Can you tell me why?

DATA COLLECTOR INSTRUCTION:

* + SELECT REASON FOR REFUSAL.

CHILD IS SLEEPING/TIRED 1 **(SV1220)**

REFUSED -1 **(SV1220)**

DON’T KNOW -2 **(SV1220)**

OTHER -5

**SV1210/(COLL\_REFUSAL\_REASON\_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (SV1220)

PROGRAMMER INSTRUCTION:

* + LIMIT TEXT TO 255 CHARACTERS.

**SV1220.** That’s fine. Thank you for your time. **(TIME\_STAMP\_2)**

SV1300. When was the last time {CHILD’S NAME/the child} had anything to eat or drink other than water?

DATA COLLECTOR INSTRUCTIONS:

* + RECORD THE LAST TIME CHILD ATE OR DRANK ANYTHING OTHER THAN WATER.
  + 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 TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.

**SV1310/(LAST\_EAT\_TIME).** LAST TIME ATE OR DRANK – TIME

|\_\_\_|\_\_\_|:|\_\_\_|\_\_\_|

H H M M

REFUSED -1

DON’T KNOW -2

**SV1320/(LAST \_EAT\_TIME\_UNIT).** LAST TIME ATE OR DRANK – AM/PM

AM 1

PM 2

**SV1330/(LAST\_EAT\_DATE).** LAST TIME ATE OR DRANK – DATE

|\_\_\_|\_\_\_|/|\_\_\_|\_\_\_|/|\_\_\_|\_\_\_|\_\_\_|\_\_\_|

M M D D Y Y Y Y

REFUSED -1

DON’T KNOW -2

PROGRAMMER INSTRUCTIONS:

* + HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH, OR DAY ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY).
  + HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
  + HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
  + HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
  + HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
  + HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
  + FORMAT DATE AS YYYYMMDD.

SV1400/(SPECIMEN\_STATUS). STATUS OF THE SALIVA COLLECTION

DATA COLLECTOR INSTRUCTION:

* + ENTER THE STATUS OF THE SPECIMEN COLLECTION.

COLLECTED 1 **(SALIVA\_COLLECTOR)**

NOT COLLECTED 2

SV1500/(NO\_SPECIMEN\_REASON).

DATA COLLECTOR INSTRUCTIONS:

* + ENTER THE PRIMARY REASON WHY SPECIMEN WAS NOT COLLECTED.
  + SELECT ONLY ONE RESPONSE.

CHILD UNHAPPY 1 **(TIME\_STAMP\_2)**

CHILD SLEEPY 2 **(TIME\_STAMP\_2)**

PHYSICAL LIMITATION 3 **(TIME\_STAMP\_2)**

PARENT/CAREGIVER ILL/EMERGENCY 4 **(TIME\_STAMP\_2)**

CHILD ILL/EMERGENCY 5 **(TIME\_STAMP\_2)**

COLLECTION SUPPLIES MALFUNCTIONED 6 **(TIME\_STAMP\_2)**

NO TIME 7 **(TIME\_STAMP\_2)**

OTHER -5

REFUSED -1 **(TIME\_STAMP\_2)**

DON’T KNOW -2 **(TIME\_STAMP\_2)**

**SV1510/(NO\_SPECIMEN\_REASON\_OTH).**

SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTIONS:

* + LIMIT TEXT TO 255 CHARACTERS
  + GO TO **TIME\_STAMP\_2**.

SV1520/(SALIVA\_COLLECTOR). WHO COLLECTED CHILD SALIVA SPECIMEN?

DATA COLLECTOR INSTRUCTIONS:

* RECORD WHO COLLECTED THE CHILD SALIVA SPECIMEN.

DATA COLLECTOR 1 **(SPECIMEN\_ID)**

MOTHER 2 **(SPECIMEN\_ID**)

FATHER……………………………… 3 **(SPECIMEN\_ID)**

OTHER……………………………….. -5

**SV1530/(SALIVA\_COLLECTOR \_OTH).**

SPECIFY \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROGRAMMER INSTRUCTION:**

* LIMIT TEXT TO 255 CHARACTERS.

SV1600/(SPECIMEN\_ID). RECORD THE SPECIMEN ID

|A|A|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|- |S|C|\_\_|\_\_|

DATA COLLECTOR INSTRUCTIONS:

* + RECORD SALIVA COLLECTION SPECIMEN ID.
  + FORMAT MUST BE AA # # # # # # #-SC##

PROGRAMMER INSTRUCTIONS:

* + CANNOT BE NULL.
  + HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT AA # # # # # # #-SC## (FORMAT MUST BE AA # # # # # # #-SC##).

**SV1610/(C\_SALIVA\_COLL\_DATE).** DATE CHILD SALIVA SPECIMEN WAS COLLECTED

|\_\_\_|\_\_\_| / |\_\_\_|\_\_\_| / |\_\_\_|\_\_\_|\_\_\_|\_\_\_|

M M D D Y Y Y Y

**SV1660/(C\_SALIVA\_COLL\_TIME).** TIME CHILD SALIVA SPECIMEN COLLECTED

|\_\_\_|\_\_\_|:|\_\_\_|\_\_\_|

H H M M

**SV1670/(C\_SALIVA\_COLL\_TIME\_UNIT)** AM/PM CHILD SALIVA SPECIMEN COLLECTED

AM 1

PM 2

**DATA COLLECTOR INSTRUCTION:**

* RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.

**PROGRAMMER INSTRUCTIONS:**

* HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH OR DAY ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
* HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12
* HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59
* HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
* HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
* HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME ARE GREATER THAN CURRENT DATE AND TIME.
* FORMAT DATE AS YYYYMMDD

SV1700/(COLLECTION\_COMMENT). RECORD ANY COMMENTS ABOUT THE COLLECTION.

DATA COLLECTOR INSTRUCTION:

* + DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE CHILD SALIVA COLLECTION PROCEDURE.

NO COMMENTS 1 **(SV1800)**

COMMENT 2

**SV1700A/(COLLECTION\_COMMENT\_OTH).**

SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROGRAMMER INSTRUCTION:

* + LIMIT TEXT TO 255 CHARACTERS.

SV1800. Thank you for providing your child’s saliva sample.

**(TIME\_STAMP\_2) PROGRAMMER INSTRUCTION:**

* + INSERT DATE/TIME STAMP