



Biospecimen Child Saliva Collection Instrument

Event:	12 Month
Participant:	Child
Respondent:	Parent/Caregiver
Domain:	Biospecimen
Type of Document:	Data Collection Instrument
Allowable Mode:	In Person
Allowable Method:	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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(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**
 - o IF **CHILD_SEX** = 1, DISPLAY "his" AND "he" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
 - o 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 COMPLICATED3 **(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