

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
 - 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...... (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.

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)
REFUSED1	(SV1220)
DON'T KNOW2	(SV1220)
OTHER	

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

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 UNHAPPY1CHILD SLEEPY2PHYSICAL LIMITATION3PARENT/CAREGIVER ILL/EMERGENCY4CHILD ILL/EMERGENCY5COLLECTION SUPPLIES MALFUNCTIONED6NO TIME7	(TIME_STAMP_2) (TIME_STAMP_2) (TIME_STAMP_2) (TIME_STAMP_2) (TIME_STAMP_2)
OTHER5 REFUSED1 DON'T KNOW2	(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|__|_|

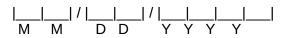
DATA COLLECTOR INSTRUCTIONS:

- 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



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.

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