



Child Blood Pre-Screening Instrument

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; Phone, CAI
OMB Approved Modes:	In-Person, CAI; Phone, CAI
Estimated Administration Time:	2 minutes
Multiple Child/Sibling Consideration:	Per Child
Special Considerations:	N/A
Version:	1.0
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.

Public reporting burden for this collection of information is estimated to average 2 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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Child Blood Pre-Screening 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	<ul style="list-style-type: none">Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	<ul style="list-style-type: none">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	<ul style="list-style-type: none">DISPLAY AS MM/DD/YYYYSTORE AS YYYY-MM-DDHARD 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	<ul style="list-style-type: none">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.**

CHILD BLOOD PRE-SCREENING INSTRUMENT

(TIME_STAMP_CBPO_ST).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT ID (**P_ID**) FOR CHILD AND RESPONDENT ID (**R_P_ID**) FOR ADULT CAREGIVER.
- PRELOAD FIRST NAME OF CHILD (**C_FNAME**) FROM PARTICIPANT VERIFICATION, SCHEDULING, & TRACING QUESTIONNAIRE AND DISPLAY APPROPRIATE NAME IN "**C_FNAME**" THROUGHOUT THE INSTRUMENT.
- OTHERWISE, IF **C_FNAME** IN PARTICIPANT VERIFICATION, SCHEDULING, & TRACING QUESTIONNAIRE=-1 OR -2, DISPLAY "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT.
- PRELOAD **CHILD_SEX** FROM PARTICIPANT VERIFICATION & TRACING QUESTIONNAIRE AND
 - IF **CHILD_SEX** = 1, DISPLAY "his" AS APPROPRIATE THROUGHOUT THE INSTRUMENT.
 - IF **CHILD_SEX** = 2, DISPLAY "her" AS APPROPRIATE THROUGHOUT THE INSTRUMENT.

CBP01000. I will need to ask you some questions to determine if {C_FNAME/the child} is eligible for a blood draw before I schedule a clinic visit to have {C_FNAME/the child}'s blood drawn.

SOURCE

National Children's Study, Legacy Phase

CBP04000/(HEMOPHILIA). Has {C_FNAME/the child} been diagnosed with hemophilia or any bleeding disorder?

DATA COLLECTOR INSTRUCTIONS

- RESPONSE DETERMINES ELIGIBILITY OF CHILD FOR BLOOD DRAW.

Label	Code	Go To
YES	1	CBP07000
NO	2	
REFUSED	-1	CBP08000
DON'T KNOW	-2	CBP08000

SOURCE

National Children's Study, Legacy Phase

National Children's Study, Vanguard Phase (Modified Adult Blood)

PROGRAMMER INSTRUCTIONS

- SET HEMOPHILIA FLAG TO YES IN ODE TABLE IF **HEMOPHILIA** = 1. [THIS INSTRUCTION IS A PLACEHOLDER UNTIL FLAGS ARE DEFINED AND CREATED]

CBP05000/(CHEMO). Has {C_FNAME/the child} had cancer chemotherapy within the past 4 weeks?

DATA COLLECTOR INSTRUCTIONS

- RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

Label	Code	Go To
YES	1	CBP07000
NO	2	
REFUSED	-1	CBP08000
DON'T KNOW	-2	CBP08000

SOURCE

National Children's Study, Legacy Phase

National Children's Study, Vanguard Phase (Modified Adult Blood)

CBP06000/(LAST_BLOOD_DRAW). Has {C_FNAME/the child} had blood drawn in the last 24 hours?

DATA COLLECTOR INSTRUCTIONS

- RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW

Label	Code	Go To
YES	1	CBP07000
NO	2	CBP10000
REFUSED	-1	CBP08000
DON'T KNOW	-2	CBP08000

SOURCE

NEW

CBP07000. Because {C_FNAME/the child} {has been diagnosed with a bleeding disorder/had cancer chemotherapy/blood drawn in last 24 hours}, we will not be able to schedule a visit to draw {his/her} blood at this time.

SOURCE

National Children's Study, Legacy Phase

National Children's Study, Vanguard Phase (Modified Adult Blood)

PROGRAMMER INSTRUCTIONS

- IF HEMOPHILIA = 1, DISPLAY "has been diagnosed with a bleeding disorder"
- IF CHEMO = 1, DISPLAY "had cancer chemotherapy"
- IF LAST_BLOOD_DRAW = 1, DISPLAY "blood drawn in last 24 hours"
- GO TO CBP09000.

CBP08000. Because you do not know or declined to answer questions about {C_FNAME/the child}'s {hemophilia/chemotherapy status/blood drawn in last 24 hours}, we will not be able to schedule a visit to draw {his/her} blood at this time.

SOURCE

National Children's Study, Legacy Phase

National Children's Study, Vanguard Phase (Modified Adult Blood)

PROGRAMMER INSTRUCTIONS

- IF HEMOPHILIA = -1 OR -2, DISPLAY "hemophilia."
- IF CHEMO = -1 OR -2, DISPLAY "chemotherapy status."
- IF LAST_BLOOD_DRAW = -1 OR -2, DISPLAY "blood drawn in last 24 hours."

CBP09000. That's fine. Thank you.

SOURCE

NEW

PROGRAMMER INSTRUCTIONS

- GO TO COLLECTION_COMMENT.

CBP10000. Your responses indicate that {C_FNAME/the child} is eligible for a blood draw. Thank you for your participation.

DATA COLLECTOR INSTRUCTIONS

- SCHEDULE CLINIC VISIT FOR CHILD.

CBP11000/(COLLECTION_COMMENT). RECORD ANY COMMENTS ABOUT THE CHILD BLOOD PRE-SCREENING PROCEDURE.

DATA COLLECTOR INSTRUCTIONS

- DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE CHILD BLOOD PRE-SCREENING PROCEDURE.

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_CB_P_
COMMENT	2	TIME_STAMP_CB_P_

CBP12000/(COLLECTION_COMMENT_OTH).

SPECIFY:

(TIME_STAMP_CB_P_).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP