

Child Blood Pre-Screening 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; 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.

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Child Blood Pre-Screening Instrument

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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:

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| **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.**

CHILD BLOOD PRE-SCREENING INSTRUMENT

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

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| 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 QUESTIONNIARE 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.

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| SOURCE |
| National Children’s Study, Legacy Phase |

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

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| DATA COLLECTOR INSTRUCTIONS |
| * RESPONSE DETERMINES ELIGIBILITY OF CHILD FOR BLOOD DRAW. |

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

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| --- |
| SOURCE |
| National Children’s Study, Legacy Phase  National Children’s Study, Vanguard Phase (Modified Adult Blood) |

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| 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?

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| DATA COLLECTOR INSTRUCTIONS |
| * RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW. |

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

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| 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?

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| DATA COLLECTOR INSTRUCTIONS |
| * RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW |

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

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| 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.

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| SOURCE |
| National Children’s Study, Legacy Phase  National Children’s Study, Vanguard Phase (Modified Adult Blood) |

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| 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.

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| SOURCE |
| National Children’s Study, Legacy Phase  National Children’s Study, Vanguard Phase (Modified Adult Blood) |

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| 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.

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| SOURCE |
| NEW |

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| 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.

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| DATA COLLECTOR INSTRUCTIONS |
| * SCHEDULE CLINIC VISIT FOR CHILD. |

**CBP11000/(COLLECTION\_COMMENT).** RECORD ANY COMMENTS ABOUT THE CHILD BLOOD PRE-SCREENING PROCEDURE.

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| DATA COLLECTOR INSTRUCTIONS |
| * DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE CHILD BLOOD PRE-SCREENING PROCEDURE. |

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

**CBP12000/(COLLECTION\_COMMENT\_OTH).** SPECIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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