OMB #: 0925-0593 OMB Expiration Date: 8/31/2014 Adult Blood Pre-Screening Instrument OMB Specification



# **Adult Blood Pre-Screening Instrument**

Event Category:	Trigger-Based, Pre-Preg, PV1, PV2; Time-Based, Birth, 6M, 12M, 36M, 60M	
Event:	Pre-Preg, PV1, PV2, Birth, 6M, 12M, 36M, 60M	
Administration:	N/A	
Instrument Target:	Pre-Pregnant Woman; Pregnant Women; Biological Mother; Primary Caregiver	
Instrument Respondent:	Pre-Pregnant Woman; Pregnant Women; Biological Mother; 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 Event	
Special Considerations:	N/A	
Version:	1.0	
MDES Release:	4.0	

<sup>\*</sup>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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# **Adult Blood Pre-Screening Instrument**

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# **Adult 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 CHARACTE RS 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 DESIGNATI ON	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.** 

#### ADULT BLOOD PRE-SCREENING INSTRUMENT

(TIME\_STAMP\_ABP\_ST).

# PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT ID (P ID) FOR ADULT

**ABP01000.** I will need to ask you some questions to determine if you are eligible for a blood draw before I schedule a visit for your blood to be drawn.

#### SOURCE

National Children's Study, Legacy Phase

ABP02000/(HEMOPHILIA). Do you have hemophilia or any bleeding disorder?

# **DATA COLLECTOR INSTRUCTIONS**

 RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

Label	Code	Go To
YES	1	ABP04000
NO	2	
REFUSED	-1	ABP06000
DON'T KNOW	-2	ABP06000

#### SOURCE

National Children's Study, Legacy Phase

#### PROGRAMMER INSTRUCTIONS

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

ABP03000/(CHEMO). Have you 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	ABP05000
NO	2	ABP08000
REFUSED	-1	ABP06000
DON'T KNOW	-2	ABP06000

#### SOURCE

National Children's Study, Legacy Phase

**ABP04000.** Because you have hemophilia, we will not be able to draw your blood for this study.

#### SOURCE

New

#### PROGRAMMER INSTRUCTIONS

• GO TO ABP07000.

**ABP05000.** Because you've had chemotherapy recently, we will not be able to schedule a visit to draw your blood at this time.

#### SOURCE

New

#### PROGRAMMER INSTRUCTIONS

• GO TO ABP07000.

**ABP06000.** Because you do not know or declined to answer questions about your {hemophilia/chemotherapy status} we will not be able schedule a visit to draw your blood at this time.

#### SOURCE

New

ABP07000. That's fine. Thank you.

#### SOURCE

New

# PROGRAMMER INSTRUCTIONS

• GO TO COLLECTION\_COMMENT

**ABP08000.** Your responses indicate that you are eligible for a blood draw. Thank you for your participation.

# **DATA COLLECTOR INSTRUCTIONS**

• SCHEDULE VISIT FOR PARTICIPANT'S BLOOD DRAW.

ABP09000/(COLLECTION\_COMMENT). RECORD ANY COMMENTS ABOUT THE ADULT BLOOD PRE-SCREENING PROCEDURE.

# **DATA COLLECTOR INSTRUCTIONS**

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

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_ABP_ET
COMMENT	2	

ABP10000/(COLLECTION_COMMENT_OTH).	SPECIFY
(TIME STAMP ABP ET).	-

# PROGRAMMER INSTRUCTIONS

INSERT DATE/TIME STAMP