



Recruitment Strategy Substudy

Event Name(s):

**Biospecimen Blood Instrument (EH, PB, HI) – 1.0
(Pregnancy Visit 1, Pregnancy Visit 2)**

Instrument Name(s) and Versions:

**Biospecimen Blood Instrument (EH, PB, HI) – 1.0
(Pregnancy Visit 1, Pregnancy Visit 2)**

Recruitment Groups:

Enhanced Household, Provider-Based, and High Intensity

Biospecimen Blood Instrument (EH, PB, HI) (Pregnancy Visit 1, Pregnancy Visit 2)

TABLE OF CONTENTS

CAPI.....	1
BIOSPECIMEN BLOOD COLLECTION.....	1

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CAPI

BIOSPECIMEN BLOOD COLLECTION

(TIME_STAMP_1) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

BL0100 (BLIntro). I will now collect a blood sample. I will need to ask you some questions before I collect your blood sample.

CONTINUE..... 01
REFUSED..... 02 (BL2060)

BL0200 (BLHemophilia). Do you have hemophilia or any bleeding disorder?

YES..... 01 (BL1800)
NO..... 02
REFUSED..... 9-97 (BL2050)
DON'T KNOW..... 9-98 (BL2050)

DATA COLLECTOR INSTRUCTIONS:

RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

BL0300 (BLBloodThinner). Do you take any blood thinning medication, such as Coumadin or warfarin?

YES..... 01 (BL1900)
NO..... 02
REFUSED..... 9-97 (BL2050)
DON'T KNOW..... 9-98 (BL2050)

DATA COLLECTOR INSTRUCTIONS:

RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

BL0400 (BLChemo). Have you had cancer chemotherapy within the past 4 weeks?

YES..... 01 (BL2000)
NO..... 02

Public reporting burden for this collection of information is estimated to average 15 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.

REFUSED.....	9-97 (BL2050)
DON'T KNOW.....	9-98 (BL2050)

DATA COLLECTOR INSTRUCTIONS:

RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

BL0500 (BLBloodDraw). Have you had any problems with taking blood in the past?

YES.....	01 (BL0700)
NO.....	02
REFUSED.....	9-97 (BL0700)
DON'T KNOW.....	9-98 (BL0700)

BL0600 (BLCmpBloodDraw). What problems did you have with taking blood in the past?

FAINTING.....	01
LIGHT-HEADEDNESS.....	02
HEMATOMA.....	03
BRUIISING.....	04
OTHER.....	
SPECIFY _____	96
REFUSED.....	9-97 (BL0700)
DON'T KNOW.....	9-98 (BL0700)

DATA COLLECTOR INSTRUCTIONS:

CHECK ALL THAT APPLY.

BL0700 (BL0700-CmpBILastTime). When was the last time you had anything to eat or drink other than water?

BL0700a (BL0700a-BILastTimeEat) |_____|:|_____|

(BL0700c-BIDateLastTimeEat)) |_____|/|_____|/|_____| MM/DD/YYYY

(BL0700b-BIAmPmLastTimeEat)

AM.....	01 (BL0700)
PM.....	02
REFUSED.....	9-97 (BL0700)
DON'T KNOW.....	9-98 (BL0700)

DATA COLLECTOR INSTRUCTION:

- {PARTICIPANT REPORTED {UrLastTimeEat} {UrAmPmLastTimeEat} {UrDateLastTimeEat} AT URINE COLLECTION. VERIFY AND} ENTER TIME AS HH:MM AND AM OR PM.
- ENTER TIME AS HH:MM AND AM OR PM.
- ENTER A TWO DIGIT MONTH, TWO DIGIT DAY, AND A FOUR DIGIT YEAR.

BL0900 (BLCoffeeTea). Have you had coffee or tea with sweetener or milk in the last 8 hours?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

BL1000 (BLAlcohol). Have you had alcohol such as beer, wine, or liquor in the last 8 hours?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

BL1100 (BLCoughCold). Have you chewed gum, used breath mints, lozenges or cough drops, or other cough or cold remedies in the last 8 hours?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

BL1200 (BLLaxative). Have you used antacid, laxatives, or anti-diarrheal medication in the last 8 hours?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

BL1300 (BLVitamin). Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

BL1400 (BLDiabetes). Are you diabetic? This includes gestational diabetes?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

BL1500 (BLInsulin). Have you taken any insulin in the last 8 hours?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

BL1600 (CmpBLKit). Thank you for answering my questions. I am now going to prepare to draw your blood

REFUSED..... 9-97 (End of Module)

(BL1800) STATEMENT: Because you have hemophilia, we will not be able to draw your blood for this study. GO TO END OF MODULE.

(BL1900) STATEMENT: Because you are taking a blood thinning medication, we will not be able to draw your blood at this time. GO TO END OF MODULE.

(BL2000) STATEMENT: Because you've had chemotherapy recently, we will not be able to draw your blood at this time. GO TO END OF MODULE.

(BL2050) STATEMENT: Because you do not know or declined to answer questions about your hemophilia or chemotherapy status and the use of blood thinners we will not be able to draw your blood. GO TO END OF MODULE.



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**Biospecimen Urine Instrument (EH, PB, HI) – 1.0
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TABLE OF CONTENTS

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Biospecimen Urine Instrument (EH, PB, HI)

(Pregnancy Visit 1, Pregnancy Visit 2)

CAPI

BIOSPECIMEN URINE COLLECTION

(TIME_STAMP_1) PROGRAMMER INSTRUCTION: INSERT DATE/TIME STAMP

UR0900. You will now collect a urine sample. I will need to ask you some questions before you collect your urine sample.

CONTINUE..... 01
REFUSED..... 02 (BL2060)

UR1000. When did you last urinate? █

____ : ____

AM..... 01
PM..... 02
REFUSED..... 9-97
DON'T KNOW..... 9-98

DATA COLLECTOR INSTRUCTIONS:

ENTER TIME AS HH:MM AND AM OR PM.

UR1100 When was the last time you had anything to eat or drink other than water? █

____ : ____

____ / ____ / ____ MM/DD/YYYY

AM..... 01
PM..... 02
REFUSED..... 9-97
DON'T KNOW..... 9-98

DATA COLLECTOR INSTRUCTIONS:

ENTER TIME AS HH:MM and AM OR PM

ENTER TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.

UR1200 How much of what you ate was beef, pork, tuna, or salmon? █

NONE.....	01
Less than one quarter of the meal.....	02
One quarter to one half of the meal.....	03
Less than three quarters of the meal.....	04
Three quarters to all of the meal.....	05
All of the meal.....	06
REFUSED.....	9-97
DON'T KNOW.....	9-98

UR1300 Do you take creatine supplements?

YES.....	01
NO.....	02
REFUSED.....	9-97
DON'T KNOW.....	9-98

DATA COLLECTOR INSTRUCTIONS:

IF THE PARTICIPANT ASKS, EXPLAIN THAT CREATINE SUPPLEMENTS ARE OFTEN TAKEN BY ATHLETES WISHING TO GAIN MUSCLE MASS.

STATEMENT: Here are your urine collection materials. Please review the instructions with me.

DATA COLLECTOR INSTRUCTIONS:

HAVE PARTICIPANT PROVIDE URINE SAMPLE. UPON COMPLETION ASK THE FOLLOWING:

UR1400 Was the urine collection difficult for you?

YES.....	01
NO.....	02
REFUSED.....	-1
DON'T KNOW.....	-2

UR1500 Is there anything that would make the urine sample collection easier for you?

SPECIFY _____

REFUSED.....	-1
DON'T KNOW.....	-2