

Laboratory Tests (LAB)

CON100 Has the subject changed their mind about the donation of specimens or the extent of their participation in SHOW?

<1> YES (go to CONINS) **CONS200 FMT_YES_NO.**
 <2> NO (Skip to LABdate)

CONINS Interviewer needs to clarify with the subject how their initial decisions have changed and have the SP complete the consent signature page again.

(INTERVIEWER: PRESS ENTER TO CONTINUE)

CONS1a2 TERMS OF CONSENT (AS TAKEN FROM THE APPROVED CONSENT SIGNATURE PAGE)

Date Consent Signed **CONS2_DATE DATE.**
 MONTH
 DAY
 YEAR
 Interviewer's name
 Interviewer's number
 VERSION NUMBER OF CONSENT **CONS2_VERSION MT_NUMERIC.**
[IF VERSION NUMBER IS LESS THAN 21, DISPLAY THE FOLLOWING WARNING:
"YOU HAVE ENTERED A VESRION NUMBER LOWER THAN 21"]

CONS22 THE SP INITIALED THE FOLLOWING FOLLOW-UP OPTIONS – MARK YES OR NO FOR EACH ONE.

<1> YES <2> NO

1. I **have read or am aware** of all the facts in the **consent brochure**. I have asked questions and all of my questions have been answered to my satisfaction. I have read the consent brochure describing how my information will be shared. I know that I can call the SHOW main office if I have any other questions.

CONS221_1 FMT_YES_NO.

2. I understand that I can **choose to participate** in the survey and I can choose to stop participating at any time. I know that I may **refuse to answer** any question.

CONS221_2 FMT_YES_NO.

3. I agree to do the **interview and physical measurements in my home**. I understand that these include tests of blood pressure, heart rate, height, weight, waist, hips and arms, and breathing capacity.

CONS221_3 FMT_YES_NO.

4. I agree to **complete the packet** of questions that will be left at my house and understand that I will mail this back to SHOW.

CONS221_4 FMT_YES_NO.

5. I agree to meet with SHOW staff for the **blood draw** and urine collection.

CONS221_5 FMT_YES_NO.

6a. I agree to allow a trained phlebotomist to **draw my blood**. I understand that some tests and results will be sent to me.

CONS221_6A FMT_YES_NO.

Laboratory Tests (LAB)

6b. I agree to allow you to take a saliva sample for future DNA testing.

CONS221_6B FMT_YES_NO.

6c. I agree to allow you to take a blood spot for future unspecified research.

CONS221_6C FMT_YES_NO.

7. I understand and agree to having my blood stored for future unspecified research.

CONS221_7 FMT_YES_NO.

8. I agree to provide you with a **urine sample**. I understand and agree to have my urine stored for future unspecified research.

CONS221_8 FMT_YES_NO.

9. I allow you to use a portion of my blood or saliva for **DNA testing**. I understand that the sample will be used to look for genetic causes of disease. I understand that my genetic information will not be sold and will not be used for cloning or stem cell research and will not be reported to me. I agree to have this stored for future unspecified research.

CONS221_9 FMT_YES_NO.

10. I agree that SHOW may call, send me a letter, and/or email me **about future studies** related to SHOW.

CONS221_10 FMT_YES_NO.

11. I agree to have my **interview taped**. I understand that this is for quality assurance of the conduct of the study and that this tape will be destroyed and not kept as part of the database.

CONS221_11 FMT_YES_NO.

LABdate

Date of Lab:

<d> Don't know <r> Refused

Date:

MM/DD/YYYY

[import today's date]

LABDATE DATE.

LAB010

Check for any of the follow that restricted your choice of arm/vein:
(CHECK ALL THAT APPLY, ENTER 'x' WHEN DONE)

<1>	Mastectomy	LAB010_A	FMT_LAB010_.
<2>	Hematoma	LAB010_B	FMT_LAB010_.
<3>	Burns, Scars, Tattoos	LAB010_C	FMT_LAB010_.
<4>	Damaged veins	LAB010_D	FMT_LAB010_.
<5>	Shunt, Fistula or Graft	LAB010_E	FMT_LAB010_.
<6>	Recent IV	LAB010_F	FMT_LAB010_.
<7>	Caste	LAB010_G	FMT_LAB010_.
<8>	Edema	LAB010_H	FMT_LAB010_.
<9>	Obesity	LAB010_I	FMT_LAB010_.
<10>	Skin sores	LAB010_J	FMT_LAB010_.

LAB020

Phlebotomist Numbers:

LAB020 FMT_NUMERIC.

<0-9999>

Laboratory Tests (LAB)**(ENTER ALL THAT APPLY, ENTER 'x' WHEN DONE)**LAB030 Processor Numbers: **LAB030 FMT_NUMERIC.**

<0-9999>

(ENTER ALL THAT APPLY, ENTER 'x' WHEN DONE)

LAB040

When was the last time you ate or drank anything other than plain water?

[INTERVIEWER: THIS QUESTION ELICITS THE LAST TIME THE SP ATE OR DRANK ANYTHING AND DETERMINES FASTING TIME. SPS ARE ALLOWED TO CONSUME DIET SODA, BLACK COFFEE, OR TEA WITH ARTIFICIAL SWEETENERS LIKE SWEET'N LOW, NUTRASWEET, EQUAL, OR SPLENDA SINCE THESE HAVE NO EFFECT ON STUDY ANALYTES.

PARTICIPANTS ARE NOT ALLOWED TO HAVE CONSUMED: COFFEE OR TEA WITH CREAM OR SUGAR, FLAVORED WATER, ALCOHOL, GUM, MINTS, LOZENGES, COUGH DROPS, COLD REMEDIES, ANTACIDS, ANTI-DIARRHEALS, LAXATIVES, OR DIETARY SUPPLEMENTS SUCH AS VITAMINS AND MINERALS.]

Last Ate:

<d> Don't know <r> Refused

Date: **LAB040_DATE DATE.**
MM/DD/YYYY

Time: (Military time)
HH:MM **LAB040_TIME HHMM5.**

Timecalc2

[CALCULATE TIME SINCE SUBJECT LAST ATE]

Hrsncate: xx

Minsncate: xx

timeverIt has been [#] hours and [#] minutes since you last had anything other than water?

<1> YES

<2> NO

LAB050 1ST Draw Attempt TIME

Laboratory Tests (LAB)

(Military time)

<d> Don't know <r> Refused

HH:MM

Draw Time:

HH:MM

LAB050 HHMM5.LAB060 Type: **5mL SST Gold top for ML**ML Label (**SCAN**):

Status:

LAB060 FMT_LAB_STATUS.

<d> DONE

<f> FAILED

<p> PARTIAL

<r> REFUSED

<na> NOT ATTEMPTED

QC: <1> Checked <2> Unchecked

Comments?

<1> Enter Comments

<2> No Comments

LAB070 Type: **10mL Redtop for Repository 1**SPID Label (**SCAN**):

Status:

LAB070 FMT_LAB_STATUS.

<d> DONE

<f> FAILED

<p> PARTIAL

<r> REFUSED

<na> NOT ATTEMPTED

QC: <1> Checked <2> Unchecked

Comments?

<1> Enter Comments

<2> No Comments

LAB080 Type: **10mL Redtop for Repository 2**SPID Label (**SCAN**):

Status:

LAB080 FMT_LAB_STATUS.

<d> DONE

Laboratory Tests (LAB)

<f> FAILED
<p> PARTIAL
<r> REFUSED
<na> NOT ATTEMPTED

QC: <1> Checked <2> Unchecked

Comments?

<1> Enter Comments
<2> No Comments

LAB090 Type: **10 mL Lavender 1**

SPID Label (**SCAN**):

Status:

LAB090 FMT_LAB_STATUS.

<d> DONE
<f> FAILED
<p> PARTIAL
<r> REFUSED
<na> NOT ATTEMPTED

NO DNA: <1> Checked <2> Unchecked

QC: <1> Checked <2> Unchecked

Comments?

<1> Enter Comments
<2> No Comments

LAB100 Type: **10 mL Lavender 2**

SPID Label (**SCAN**):

Status:

LAB100 FMT_LAB_STATUS.

<d> DONE
<f> FAILED
<p> PARTIAL
<r> REFUSED
<na> NOT ATTEMPTED

NO DNA: <1> Checked <2> Unchecked

QC: <1> Checked <2> Unchecked

Comments?

<1> Enter Comments
<2> No Comments

Laboratory Tests (LAB)LAB110 Type: **3 mL Lavender for ML 1**

ML Label:

Status:

LAB110 FMT_LAB_STATUS.

<d> DONE
<f> FAILED
<p> PARTIAL
<r> REFUSED
<na> NOT ATTEMPTED

QC: <1> Checked <2> Unchecked

Comments?

<1> Enter Comments
<2> No Comments

LAB120 Type: **3 mL Lavender for ML 2**

ML Label:

Status:

LAB120 FMT_LAB_STATUS.

<d> DONE
<f> FAILED
<p> PARTIAL
<r> REFUSED
<na> NOT ATTEMPTED

QC: <1> Checked <2> Unchecked

Comments?

<1> Enter Comments
<2> No Comments

LAB125 Type: **2.5 mL PaxGene Redtop for Biorepository**

SPID Label:

Status:

LAB125 FMT_LAB_STATUS.

<d> DONE
<f> FAILED
<r> REFUSED
<na> NOT ATTEMPTED

QC: <1> Checked <2> Unchecked

Laboratory Tests (LAB)

Comments?

<1> Enter Comments

<2> No Comments

LAB130

Number of Attempted Sticks

Status:

LAB130 FMT_NUMERIC.

<1-10> ATTEMPTS

<f> FAILED

<r> REFUSED

<na> NOT ATTEMPTED

Comments?

<1> Enter Comments

<2> No Comments

LAB140

END DRAW TIME

(Military time)

<d> Don't know <r> Refused

HH:MM

LAB140 HHMM5.

LAB150

CENTRIFUGE START TIME

(Military time)

<d> Don't know <r> Refused

Blood: HH:MM

LAB150 HHMM5.

LAB160

Number of plasma vials:

<0-30> CRYOVIALS

LAB160 FMT_NUMERIC.

<d> Don't know <r> Refused

LAB170

Number of serum vials:

<0-30> CRYOVIALS

LAB170 FMT_NUMERIC.

<d> Don't know <r> Refused

LAB180

Freezer Entry Time

(Military time)

<d> Don't know <r> Refused

Laboratory Tests (LAB)

HH:MM **LAB180** **HHMM5.**

LAB190 Urine Sample Collection time
(Military time)

<d> Don't know <r> Refused

HH:MM **LAB190** **HHMM5.**

Urine Sample Centrifuge Time

HH:MM **LAB191** **HHMM5.**

LAB200 Type: **Urine Sample**

SPID Label:

Status: **LAB200** **FMT_LAB_STATUS.**

<1> DONE

<3> INSUFFICIENT

<7> REFUSED

<8> FAILED

<9> NOT ATTEMPTED

Comments?

<1> Enter Comments

<2> No Comments

LAB210 Urine Sample **LAB210** **FMT_NUMERIC.**

<0-50> mL of urine centrifuged

<d> Don't know

<r> Refused

LAB220 Number of urine vials: **LAB220** **FMT_NUMERIC.**

<0-30> CRYOVIALS

<d> Don't know <r> Refused

QC: <1> Checked <2> Unchecked

LAB230 Urine Freezer Time
(Military time)

Laboratory Tests (LAB)

HH:MM **LAB230** **HHMM5.**

<d> Don't know <r> Refused

LAB235

BLOOD SPOTS

SPID Label: **LAB235_SC** **FMT_NUMERIC.**

Blood draw refused or inadequate:

Blood Spot Status: **LAB235_BS** **FMT_LAB_STATUS.**

<d> DONE <r> REFUSED (Skips to LAB250)

<f> FAILED (skips to LAB250) <na> NOT ATTEMPTED (Skip to LAB240)

Blood Spot Collection Time
(Military time)

HH:MM **LAB235_TIM1** **HHMM5.**

Blood Spot Freezer Time
(Military time)

HH:MM **LAB235_TIM2** **HHMM5.**

LAB236

Blood Spots Comments?

LAB236 **\$FMT_CHAR.**

<1> Enter Comments

<2> No Comments

LAB240

Saliva Sample

SPID Label:

Blood draw was: **LAB240_A** **FMT_LAB_STATUS.**

<1> REFUSED <3> INADEQUATE

<2> FAILED <4> SUCCESSFUL (Saliva not collected)

<6> WILLING TO BE RESCHEDULED

Saliva Status: **LAB240_A2** **FMT_LAB_STATUS.**

<d> DONE <r> REFUSED

<f> FAILED <na> NOT ATTEMPTED

Saliva Collection Time
(Military time)

HH:MM **LAB240** **HHMM5.**

Saliva Freezer Time
(Military time)

Laboratory Tests (LAB)

HH:MM

LAB241**HHMM5.**

QC: <1> Checked <2> Unchecked

LAB250

Processing Problems/Comments

LAB250**\$FMT_CHAR.**

<1> Enter Comments

<2> No Comments