

## FOLLOW-UP BIOSPECIMEN COLLECTION FORM, BIF QUESTION BY QUESTION (QxQ), VERSION 1.0

### I. GENERAL INSTRUCTIONS

The Follow-up Biospecimen Collection Form (BIF) is filled out by the study coordinator and/or any other individual certified to collect specimens for the SPIROMICS III study. This form should be completed when specimens are collected during and before the end of the participant's visit. It is recommended that this form is completed during sample collection or directly after.

**NOTE:** This form is necessary to run the following reports: "Visit Shipping Manifest - Box 1", "Visit Shipping Manifest - Box 2", "Visit Shipping Manifest - PAXgene DNA", and "Visit Shipping Manifest - PAXgene RNA". Ensure that this form has been entered before any of the listed reports are run.

Please answer every question on this form. *NOTE: All response options in the paper form may not appear in CDART (e.g., 'Don't know', 'Declines to answer', etc.). Beside each item input is a small double bracket icon which looks like this: >>. Clicking this icon displays a field dialogue box in which the "Field Status" selection menu allows you to choose from the following options: 'Refused', 'No response', 'Doesn't know', 'Not applicable', 'Maximum value', 'Minimum value', and 'Missing'. See MOP 6 – Section 3.2 for additional instructions on how to select a Field Status option.*

Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes (e.g., enter 0.25 rather than .25).

### II. INSTRUCTIONS FOR INDIVIDUAL ITEMS

**Header Information:** Consists of key fields which uniquely identify each subject and recorded occurrence of a form. For the "ID NUMBER", record the 2 or 3-character, 6-digit number assigned to the specific participant. For the "Event," record that this is happening at the clinic visit (E1).

- Item 0a.** Record the date the data was collected or abstracted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 0b.** Record the SPIROMICS III staff code of the person who collected or abstracted the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS III data, please contact the GIC in order to receive your own individual staff code.
- Item 1.** Select only one option among the two possible choices.
- Item 2.** Record the time (i.e., hour/minute) the participant last ate in the HH:MM AM/PM format in the space provided. *NOTE: This does not include clear liquids such as water, or black coffee.*
- Item 3.** Record the date the blood was collected in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 4.** Record the time (i.e., hour/minute) the blood was collected in the HH:MM AM/PM format in the space provided.

**Item 5.** Record the number of times venipuncture was attempted for the blood collection, including the successful attempt, in the space provided.

**Item 6.** Select only one option among the two possible choices. If 'No' is selected, go to Item 9.

**Item 7.**

**Items 7a-7g.** Use the check boxes to answer all that apply to each tube. For example, if the tourniquet had to be reapplied for tubes 1, 2, and 3, check the boxes under 'Tube 1', 'Tube 2', and 'Tube 3' on the screen as shown below:

	Tube							
	1	2	3	4	5	6	7	8
7a. Sample Not Drawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7b. Partial Sample Drawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7c. Tourniquet Reapplied	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7d. Fist Clenching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7e. Needle Movement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7f. Participant Reclining	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7g. Sample Re-drawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**NOTE:** Tube 6 is not being collected for SPIROMICS III, and items 7a-7g will not be enabled for tube 6 in CDART.

**Item 8.** Describe any problem or incident not listed above that occurred and indicate to which tube(s) this applies in the space provided.

**Item 9.** Record the staff code of the phlebotomist who collected the blood. This person should have a SPIROMICS III staff code that is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS III data, please contact the GIC in order to receive your own individual staff code.

### **Blood Processing**

**Item 10.** Tube 1: Red Top 1 – Serum 8.5 mL

**Item 10a.** Record the time (i.e., hour/minute) Tube 1 – Red Top 1 was processed in the HH:MM AM/PM format in the space provided.

**Item 10b.** Select only one option among the two possible choices. If 'No' is selected, go to Item 10c.

**Items 10b1-10b6.** Use the check boxes to answer all that apply to the tube. If 'Other' is selected, go to Item 10b6a.

**Item 10b6a.** Specify other problem processing the tube in the space provided.

**Item 10c.** Record the number of Tube 1 – Red Top 1 aliquots in the space provided.

**Item 10d.** Record the volume of the last Tube 1 – Red Top 1 aliquot in  $\mu$ L in the space provided.

**Item 10e.** Record the freezer box number for Tube 1 – Red Top 1 aliquots in the space provided.

**Item 10f.** Record the time (i.e., hour/minute) Tube 1 – Red Top 1 aliquots were placed in the freezer in the HH:MM AM/PM format in the space provided.

**Commented [RP1]:** Do we need to update the screenshot since Tube 6 is being removed?

**Commented [MNC2R1]:** I don't think so, the screenshot will look the same because the questions weren't removed from CDART to maintain numbering.

**Item 11.** Tube 2: Red Top 2 – Serum 8.5 mL

**Items 11a-11f.** Follow the instructions as in Items 10a-10f as the question pattern is identical.

**Item 12.** Tube 3: Lavender Top 1 – Plasma-EDTA 10 mL

**Items 12a-12f.** Follow the instructions as in Items 10a-10f as the question pattern is identical.

**Item 13.** Tube 4: Lavender Top 2 – Plasma-EDTA 10 mL

**Items 13a-13f.** Follow the instructions as in Items 10a-10f as the question pattern is identical.

**Item 14.** Tube 5: Lavender Top 3 – CBC-EDTA 3 mL

**Item 14a.** Record the time (i.e., hour/minute) Tube 5 – Lavender Top 3 was sent to the clinical center lab for processing in the HH:MM AM/PM format in the space provided.

**Item 15.** This question (Tube 6) has been removed.

**Items 15a-15f.** These questions (Tube 6) have been removed.

**Item 16.** Tube 7: Blue Top 1 – PAXgene DNA 8.5 mL

**Item 16a.** Record the time (i.e., hour/minute) Tube 7 – Blue Top 1 was processed in the HH:MM AM/PM format in the space provided.

**Item 16b.** Record the freezer box number for Tube 7 – Blue Top 1 in the space provided.

**Item 16c.** Record the volume of Tube 7 – Blue Top 1 in  $\mu\text{L}$  in the space provided.

**Item 17.** Tube 8: Red Top 4 – PAXgene RNA 2.5 mL

**Items 17a-17c.** Follow the instructions as in Items 16a-16c as the question pattern is identical.

### **Urine Sample Collection**

**Item 18.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 25.

**Item 19.** Record the date the urine sample was collected in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

**Item 20.** Record the time (i.e., hour/minute) the urine sample was collected in the HH:MM AM/PM format in the space provided.

**Item 21.** Record the time (i.e., hour/minute) the urine sample was processed in the HH:MM AM/PM format in the space provided.

**Item 22.** Record the number of urine sample aliquots collected with preservative in the space provided.

**Item 23.** Record the number of urine sample aliquots collected without preservative in the space provided.

**Item 24.** Record the time (i.e., hour/minute) the urine samples were placed in the freezer in the HH:MM AM/PM format in the space provided.

**Item 24a.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 25.

**Item 24b.** Record the number of nasal swabs performed in the right naris.

**Item 24c.** Record the number of nasal swabs performed in the left naris.

**Item 24d.** Record the time (i.e., hour/minute) the nasal swab biospecimen was collected in the HH:MM AM/PM format in the space provided.

**Items 25-26.** Select only one option among the two possible choices. If 'No' is selected, go to Item 27.

**Item 26a.** Select only one option among the two possible choices.

**Item 27.** Record the staff code of the person who processed the biospecimens. This person should have a SPIROMICS III staff code that is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS III data, please contact the GIC in order to receive your own individual staff code.

**Item 28.** Provide any comments regarding the blood, urine, nasal swab, and/or CBC collection and/or processing that have not been detailed in the previous items in the space provided.

Select **Save and Close** at the bottom of the page/screen.