



INSTRUCTIONS FOR BIOSPECIMEN COLLECTION FORM BIO, VERSION 3.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Biospecimen Collection Form is filled out by the study coordinator and/or any other individual certified to collect specimens for the SPIROMICS study. This form should be completed when specimens are collected during the participant's visit.

Please note that this form is necessary to run the following reports: "Visit 5 Shipping Manifest-Box 1", "Visit 5 Shipping Manifest-Box 2", "Visit 5 Shipping Manifest-PAXgene", and "Visit 5 Shipping Contents Report". Ensure that this form has been entered before any of the listed reports are run.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form. For the Event field, record if this is happening at Visit 5 or another event.

0a. Date of Collection: Record the date the data was collected or abstracted. Select the date from the pop-up calendar in the data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

0b. Staff Code: Record the SPIROMICS 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 data, please contact the GIC in order to receive your own individual staff code.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Please answer every question on this form. The Biospecimen Collection Form should be completed before the end of participant's visit. It is recommended that this form is completed during sample collection or directly after. 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.

- Item 1. Ask the participant if s/he fasted before today's appointment. Select 'Yes' or 'No' from the drop down menu to match the answer received.
- Item 2. Ask the participant the last time s/he had something to eat and record the time. This does not include clear liquids (such as water, or black coffee).
- Item 3. Select from the calendar or enter the date the blood was collected.
- Item 4. Record the time the blood sample was taken.
- Item 5. Record the number of times venipuncture was attempted for the blood collection, including the successful attempt. If only one puncture was necessary, record '1' in the space provided.
- Item 6. If any problems or incidents occurred during blood draw, select 'Yes' and use items 7 and 8 to specify what problems occurred and which tubes were effected. Select 'No' if not incidents occurred and skip to item 9.
- Item 7. Read each description in items 7a-7g; if any of these match an incident that occurred check the box next the corresponding tubes. For example, if the tourniquet had to be reapplied for tubes

7, 8 and 9 check the boxes beside 'Tube 7', 'Tube 8' and 'Tube 9' on the screen as shown below:

7c. Tourniquet reapplied

Tube 1	<input type="checkbox"/>	>>
Tube 2	<input type="checkbox"/>	>>
Tube 3	<input type="checkbox"/>	>>
Tube 4	<input type="checkbox"/>	>>
Tube 5	<input type="checkbox"/>	>>
Tube 6	<input type="checkbox"/>	>>
Tube 7	<input checked="" type="checkbox"/>	>>
Tube 8	<input checked="" type="checkbox"/>	>>
Tube 9	<input checked="" type="checkbox"/>	>>

Item 8. If any problem or incident occurred that is not listed above use the space provided here to describe the incident and indicate which tubes this applies to.

Item 9. Enter the initials of the phlebotomists that drew these blood samples.

BLOOD PROCESSING

Items 10-17 ask specific information about each of the 8 tubes of blood collected. Please complete all fields

Items 10 and 11 and are both collecting information regarding the processing of the red/gray top tubes for Serum-SST

Item 12 is for collecting information regarding the processing of the yellow top tube for Plasma-ACD

Item 13 through 16 are for collecting information regarding the processing of the lavender top tubes for

Tube 4: Plasma EDTA

Tube 5: Plasma cell/lysate

Tube 6: CBC 4ml

Tube 7: P100 – Plasma P100\

Item 18 is for collecting information regarding the processing of Tube 8 for PAX Gene - RNA

For items 10-16 follow these directions:

- a. Enter the time that the tube was processed.
- b. If there were any problems processing this tube, select 'Yes' and select the check box beside EACH problem that occurred. If no problems occurred, select 'No' and go to c.
- c. Record the number of aliquots from this tube.
- d. Record the volume in the last four aliquots.
- e. Record the number on the freezer box. It is very important that this number is recorded correctly as it is used for finding the aliquots later.
- f. Enter the time the aliquots were placed in the freezer.

Item 17. Tube 8 should be sent to the clinical center lab for processing. Record the time the tube was sent in this item.

URINE SAMPLE

- Item 18. Each participant should provide a urine sample. Select 'No' if a urine sample was not collected and move to item 28. If a urine sample was collected select 'Yes' and answer the questions regarding the urine sample.
- Item 19. Select from the calendar or record the date the urine sample was collected.
- Item 20. Enter the time the sample was collected.
- Item 21. Enter the time the sample was processed.
- Item 22. Record how many aliquots were collected with preservative.
- Item 23. Record how many aliquots were collected without preservative.
- Item 24. Enter the time the sample was placed in the freezer.
- Item 25. If the participant is a female of child bearing potential, select 'Yes' and answer item 27. If the participant is not of child bearing potential, select 'No' and move to item 28.
- Item 26. Select 'Yes' if a pregnancy test was ordered and give the results in item 27a. Select 'No' if a pregnancy test was not ordered and skip to item 28.
- Item 26a. Select 'Yes' if the pregnancy test was positive or 'No' if the pregnancy test was negative.
- Item 27. Enter the code number of the person responsible for processing the urine sample.
- Item 28. This space allows for any comments to be recorded regarding the blood and urine collection and processing that have not been detailed in the previous questions.
- Save and close the form.