



**EXACERBATION SUBSTUDY
BIOSPECIMEN COLLECTION FORM
EBI, VERSION 1.0, QUESTION BY QUESTION (QxQ)**

I. GENERAL INSTRUCTIONS

The Exacerbation Substudy Biospecimen Collection Form (EBI) is to be completed during the participant's Exacerbation Substudy Visit 1 and Visit 2.

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.

Fasting Status

Item 1. **Did participant fast:** Select only one option among the two possible choices.

- Select No if the participant **did not** fast before today's appointment.
- Select Yes if the participant **did** fast before today's appointment.

Item 2. **At what time did participant last eat:** Record the time that the participant last ate in hours: minutes.

Blood Specimen Collection

Item 3. **Time of blood collection:** Record the time that the participant last ate in hours: minutes.

Item 4. **Venipuncture attempts:** Record the number of venipuncture attempts including the successful attempt.

Item 5. **Blood drawing incidents or problems:** Select only one option among the two possible choices.

- Select No if there **were no** blood drawing incidents or problems. [Go to Q8]
- Select Yes if there **were** blood drawing incidents or problems.

Item 6. **Blood drawing incident documentation:** Use items 6a – 6g to document problems with venipuncture.

- Item 6a. **Sample not drawn:** Place an “X” in the box or boxes corresponding to the tubes for which a sample was not drawn.
- Item 6b. **Partial sample drawn:** Place an “X” in the box or boxes corresponding to the tubes for which a partial sample was drawn.
- Item 6c. **Tourniquet reapplied:** Place an “X” in the box or boxes corresponding to the tubes for which a tourniquet was reapplied.
- Item 6d. **Fist clenching:** Place an “X” in the box or boxes corresponding to the tubes for which there was fist clenching.
- Item 6e. **Needle movement:** Place an “X” in the box or boxes corresponding to the tubes for which there was needle movement.
- Item 6f. **Participant reclining:** Place an “X” in the box or boxes corresponding to the tubes for which the participant was reclining.
- Item 6g. **Sample re-drawn:** Place an “X” in the box or boxes corresponding to the tubes for which a sample was re-drawn.
- Item 7. **Other blood drawing problems:** Specify and describe any other blood drawing problems or incidents not listed previously (e.g., fasting status, etc.).
- Item 8. **Phlebotomist’s staff code:** Record the phlebotomist’s staff code.

Blood Specimen Collection

Items 9 – 15 ask specific information about each of the 7 tubes of blood collected. Please complete all fields for each tube.

- Item 9. **Tube 1, Red Top #1:** Select only one option among the two possible choices.
- Select No if the serum was not collected. [Go to Q10]
 - Select Yes if the serum was collected.
- Item 9a. **Time processed:** Record the time that Tube 1, Red Top #1 was processed in hours: minutes.
- Item 9b. **Problems processing:** Select only one option among the two possible choices.
- Select No if there were no problems processing. [Go to Q9c]
 - Select Yes if there were problems processing.
- If yes,** choose each of the listed problems that occurred while processing Tube 1, Red Top #1.
- Item 9b6a. **Other:** If there was a problem not listed in 9b, specify the problem here.
- Item 9c. **Number of aliquots:** Record the number of aliquots created from Tube 1, Red Top #1.

- Item 9d. **Volume in last aliquot:** Record the volume of the last aliquot created from Tube 1, Red Top #1.
- Item 9e. **Freezer box number:** Record the freezer box number where the aliquots from Tube 1, Red Top #1 were placed.
- Item 9f. **Time aliquots place in freezer:** Record the time when the aliquots from Tube 1, Red Top #1 were placed in the freezer in hours: minutes.
- Item 10. **Tube 2, Red Top #2:** Select only one option among the two possible choices.
- Select No if the serum was not collected. [Go to Q11]
 - Select Yes if the serum was collected.
- Item 10a. **Time processed:** Record the time that Tube 2, Red Top #2 was processed in hours: minutes.
- Item 10b. **Problems processing:** Select only one option among the two possible choices.
- Select No if there were no problems processing. [Go to Q10c]
 - Select Yes if there were problems processing.
- If yes,** choose all of the listed problems that occurred while processing Tube 2, Red Top #2.
- Item 10b6a. **Other:** If there was a problem not listed in 10b, specify the problem here.
- Item 10c. **Number of aliquots:** Record the number of aliquots created from Tube 2, Red Top #2.
- Item 10d. **Volume in last aliquot:** Record the volume of the last aliquot created from Tube 2, Red Top #2.
- Item 10e. **Freezer box number:** Record the freezer box number where the aliquots from Tube 2, Red Top #2 were placed.
- Item 10f. **Time aliquots place in freezer:** Record the time when the aliquots from Tube 2, Red Top #2 were placed in the freezer in hours: minutes.
- Item 11. **Tube 3, Lavender Top #1:** Select only one option among the two possible choices.
- Select No if the plasma – EDTA 10ml **was not** collected. [Go to Q12]
 - Select Yes if the plasma – EDTA 10ml **was** collected.
- Item 11a. **Time processed:** Record the time that Tube 3, Lavender Top #1 was processed in hours: minutes.
- Item 11b. **Problems processing:** Select only one option among the two possible choices.
- Select No if there were no problems processing. [Go to Q11c]
 - Select Yes if there were problems processing.
- If yes,** choose all of the listed problems that occurred while processing Tube 3, Lavender Top #1.

Item 11b6a. **Other:** If there was a problem not listed in 11b, specify the problem here.

Item 11c. **Number of aliquots:** Record the number of aliquots created from Tube 3, Lavender Top #1.

Item 11d. **Volume in last aliquot:** Record the volume of the last aliquot created from Tube 3, Lavender Top #1.

Item 11e. **Freezer box number:** Record the freezer box number where the aliquots from Tube 3, Lavender Top #1 were placed.

Item 11f. **Time aliquots place in freezer:** Record the time when the aliquots from Tube 3, Lavender Top #1 were placed in the freezer in hours: minutes.

Item 12. **Tube 4, Lavender Top #2:** Select only one option among the two possible choices.

- Select No if the plasma – EDTA 10ml **was not** collected. [Go to Q13]
- Select Yes if the plasma – EDTA 10ml **was** collected.

Item 12a. **Time processed:** Record the time that Tube 4, Lavender Top #2 was processed in hours: minutes.

Item 12b. **Problems processing:** Select only one option among the two possible choices.

- Select No if there were no problems processing. [Go to Q12c]
- Select Yes if there were problems processing.

If yes, choose all of the listed problems that occurred while processing Tube 4, Lavender Top #2.

Item 12b6a. **Other:** If there was a problem not listed in 12b, specify the problem here.

Item 12c. **Number of aliquots:** Record the number of aliquots created from Tube 4, Lavender Top #2.

Item 12d. **Volume in last aliquot:** Record the volume of the last aliquot created from Tube 4, Lavender Top #2.

Item 12e. **Freezer box number:** Record the freezer box number where the aliquots from Tube 4, Lavender Top #2 were placed.

Item 12f. **Time aliquots place in freezer:** Record the time when the aliquots from Tube 4, Lavender Top #2 were placed in the freezer in hours: minutes.

Item 13. **Tube 5, Lavender Top #3:** Select only one option among the two possible choices.

- Select No if the plasma – CBC 4ml **was not** collected. [Go to Q14]
- Select Yes if the plasma – CBC 4ml **was** collected.

Item 13a. **Time sent to clinical center lab:** Record the time that Tube 5, Lavender Top #3 was sent to the clinical center lab in hours: minutes.

Item 14. **Tube 6, P100:** Select only one option among the two possible choices.

- Select No if the plasma – P100 **was not** collected. [Go to Q15]
- Select Yes if the plasma – P100 **was** collected.

Item 14a. **Time processed:** Record the time that Tube 6, P100 was processed in hours: minutes.

Item 14b. **Problems processing:** Select only one option among the two possible choices.

- Select No if there were no problems processing. [Go to Q14c]
- Select Yes if there were problems processing.

If yes, choose all of the listed problems that occurred while processing Tube 6, P100.

Item 14b6a. **Other:** If there was a problem not listed in 14b, specify the problem here.

Item 14c. **Number of aliquots:** Record the number of aliquots created from Tube 6, P100.

Item 14d. **Volume in last aliquot:** Record the volume of the last aliquot created from Tube 6, P100.

Item 14e. **Freezer box number:** Record the freezer box number where the aliquots from Tube 6, P100 were placed.

Item 14f. **Time aliquots place in freezer:** Record the time when the aliquots from Tube 6, P100 were placed in the freezer in hours: minutes.

Item 15. **Tube 7, PAXgene:** Select only one option among the two possible choices.

- Select No if the PAXgene blood RNA sample **was not** collected. [Go to Q16]
- Select Yes if the PAXgene blood RNA sample **was** collected.

Item 15a. **Time processed:** Record the time that Tube 7, PAXgene blood RNA sample was processed in hours: minutes.

Item 15b. **Freezer box number:** Record the freezer box number where Tube 7, PAXgene blood RNA sample was placed.

Item 15c. **Volume in tube:** Record the volume of Tube 7, PAXgene blood RNA sample.

Urine Specimen Collection

Item 16. **Urine sample collection:** Select only one option among the two possible choices.

- Select No if a urine sample **was not** collected. [Go to 22 if participant is female, Go to 24 if participant is male]
- Select Yes if a urine sample **was** collected.

Item 17. **Time of urine sample collection:** Record the time that the urine sample was collected.

- Item 18. **Time urine sample processed:** Record the time that the urine sample was processed.
- Item 19. **Number of aliquots with preservative:** Record the number of aliquots with preservative.
- Item 20. **Number of aliquots without preservative:** Record the number of aliquots without preservative.
- Item 21. **Time urine samples placed in freezer:** Record the time that the urine samples were placed in the freezer.

NOTE: Q22- Q23 will only open if participant is female. If participant is male, Q22-Q23 will be skipped.

Item 22. **Is participant able to become pregnant:** Select only one option among the two possible choices.

- Select No if the participant is **not** able to become pregnant. [Go to Q24]
- Select Yes if the participant **is** able to become pregnant.

Item 23. **Pregnancy test required or requested:** Select only one option among the two possible choices.

- Select No if a pregnancy test **is not** required or requested. [Go to Q24]
- Select Yes if a pregnancy test **is** required or requested.

Item 23a. **Was participant pregnant:** Select only one option among the two possible choices.

- Select No if the participant **was not** pregnant.
- Select Yes if the participant **was** pregnant.

Item 24. **Biospecimen processing staff code:** Record the biospecimen processing staff code.

Save and close the form.