



INSTRUCTIONS FOR EXACERBATION SUBSTUDY WITHDRAWAL FORM EWF, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Exacerbation Substudy Withdrawal Form (EWF) is to be completed when the participant withdraws from the SPIROMICS II Exacerbation Substudy.

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.

Item 1a. **Substudy Visit 1 completion:** Select only one option among the two possible choices.

- Select No if the participant **did not** complete the exacerbation substudy visit 1 prior to withdrawing. [Go to Q2]
- Select Yes if the participant **did** complete the exacerbation substudy visit 1 prior to withdrawing.

Item 1b. **Substudy Visit 2 completion:** Select only one option among the two possible choices.

- Select No if the participant **did not** complete the exacerbation substudy visit 2 prior to withdrawing.
- Select Yes if the participant **did** complete the exacerbation substudy visit 2 prior to withdrawing.

Item 2. **Date of substudy withdrawal:** Record the date of the participant's withdrawal from the substudy by either selecting the date from the pop-up calendar in the data management system (DMS) or entering the date using the mm/dd/yyyy format.

Item 3. **Reason for withdrawal:** Select **only one** from the list provided. Choose the option that best explains the participant's withdrawal.

- Select 'Participant no longer wishes to participate; withdrawal of consent' if the patient has withdrawn consent and no longer wishes to participate in the substudy. [Go to Q4]
- Select 'Participant is too sick to participate' if the participant is too sick to participate. [Go to Q4]
- Select 'Participant is lost to follow-up' if it is no longer possible to follow-up with the participant. [Go to Q4]
- Select 'Participant died' if the participant has died. [Go to Q4]

- Select 'Other' if none of the answers above are sufficient to explain the participant's withdrawal. [Go to Q3a]

Item 3a. **Specify reason for withdrawal:** Use the space provided to specify the other reason for withdrawal.

Item 4. **Reason for substudy withdrawal detailed:** Use the space provided to describe the reason for substudy withdrawal in more detail.

Item 5. **Participant's wishes regarding data and biospecimens:** Select only one from the list provided. Choose the option that best explains the participant's wishes.

- Select 'No change; keep data collected and biospecimens collected in repositories' if the participant wants no changes and wants data collected kept and biospecimens collected kept in repositories.
- Select 'Keep data collected, but remove all biospecimens collected from repositories' if the participant wants data collected kept but wants all biospecimens removed from repositories.
- Select 'Remove all data collected and remove all biospecimens collected from repositories' if the participant wants all data collected removed and all biospecimens collected removed from repositories.

NOTE: Complete the RSW form if the participant ALSO wishes to withdraw from the main SPIROMICS II Study (Visit 5 and FU phone calls).

Save and close the form.