



INSTRUCTIONS FOR BRONCHOSCOPY SUBSTUDY WITHDRAWAL FORM BWF, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Bronchoscopy Substudy Withdrawal Form (BWF) is to be completed when the participant withdraws from the SPIROMICS II Bronchoscopy 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 1. **Bronchoscopy Substudy Visit 1 (sputum induction) completion:** Select only one option among the two possible choices.
- Select No if the participant **did not** complete the sputum induction visit.
 - Select Yes if the participant **did** complete the sputum induction visit.
- Item 2. **Bronchoscopy Substudy Visit 2 (bronchoscopy visit) completion:** Select only one option among the two possible choices.
- Select No if the participant **did not** complete the bronchoscopy visit.
 - Select Yes if the participant **did** complete the bronchoscopy visit.
- Item 3. **Date of Bronchoscopy Substudy withdrawal:** Record the date of the participant's withdrawal from the Bronchoscopy 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 4. **Reason for withdrawal:** Select **only one** from the list provided. Choose the option that best explains the participant's withdrawal from the Bronchoscopy Substudy.
- Select 'Participant no longer wishes to participate; withdrawal of consent' if the patient has withdrawn consent and no longer wishes to participate in the substudy.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 Q5]
 - Select 'Participant is too sick to participate' if the participant is too sick to participate. [Go to Q5]
 - Select 'Participant is lost to follow-up' if it is no longer possible to follow-up with the participant. [Go to Q5]
 - Select 'Participant died' if the participant has died. [Go to Q5]
 - Select 'Participant failed to complete baseline visit' if the participant failed to complete the baseline visit. [Go to Q5]

- Select 'Other' if none of the answers above are sufficient to explain the participant's withdrawal. [Go to Q5]

Item 5. **Reason for substudy withdrawal detailed:** Use the space provided to describe the reason for substudy withdrawal in more detail.

Item 6. **Participant's wishes regarding SPIROMICS II Bronchoscopy Substudy data and biospecimens:** Select only one from the list provided. Choose the option that best explains the participant's wishes.

- Select 'No change; leave already collected data and biospecimens in repositories' if the participant wants no changes and wants already collected data and biospecimens to be left in repositories.
- Select 'Keep collected medical records data, but remove all biospecimens from repositories' if the participant wants collected medical records data kept but wants all biospecimens removed from repositories.
- Select 'Remove all data collected and remove all biospecimens from repositories' if the participant wants all data collected and all biospecimens collected removed from repositories.

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

Save and close the form.