

# INSTRUCTIONS FOR FOLLOW-UP EXACERBATION QUESTIONAIRE FORM FEQ, VERSION 1.0, QUESTION BY QUESTION (QxQ)

#### I. GENERAL INSTRUCTIONS

The Follow-up Exacerbation Questionnaire Form is interviewer administered and completed during Visit 5 with study participants. Every patient should complete the FEQ during Clinic Visit 5

**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

- Item 1. **Breathing problems in last 12 months** Select only one option among the two possible choices.
  - Select No if the subject reports not having any episodes of breathing problems in the last 12 months. [Go to End of Form]
  - Select Yes if the subject reports having any episodes of breathing problems in the last 12 months.

Item 2. **Number of episodes** Record how many episodes of breathing problems the subject reported having in the last 12 months. Note that the form will only give the option to record that number of episodes as entered here.

### First Episode of Breathing Problems:

Item 3. **Approximate month and year of first episode** The calendar icon can't be used here. Please type in the month and year using MM-YYYY format.

Item 3a. Took additional antibiotics Select only one option among the two possible choices.

- Select No if the subject reports not taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
- Select Yes if the subject reports taking additional antibiotics after contacting his/her healthcare provider by telephone or email.

- Item 3b. Took additional oral steroids Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
- Item 3c. **Took additional antibiotics without contacting provider** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
- Item 3d. Took additional oral steroids Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
- Item 3e. **Physician's office or urgent care evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in a physician's office or urgent care.
  - Select Yes if the subject reports being evaluated in a physician's office or urgent care.
- Items 3e1-4. **Physician's office or urgent care evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to a physician's office or urgent care.
- Item 3f. **Emergency department evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in an emergency department.
  - Select Yes if the subject reports being evaluated in an emergency department.
- Items 3f1-4. **Emergency department evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to an emergency department.
- Item 3q. Hospital admission Select only one option among the two possible choices.
  - Select No if the subject reports not being admitted to a hospital. [If a second episode occurred, go to 5. Otherwise, go to end of form]
  - Select Yes if the subject reports being admitted to a hospital.
- Item 4. **Date of Hospitalization** Record the date the participant was hospitalized. 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.
- Item 4a. **Name of medical facility** Record the name of the medical facility where the participant was hospitalized in the space provided.

- Item 4b. **Address of medical facility** Record the address of the medical facility where the participant was hospitalized in the space provided.
- Item 4c1. **First name on patient record** Record the first name used for the hospital record for this visit in the space provided.
- Item 4c2. **Second name on patient record** Record the second name used for the hospital record for this visit in the space provided.
- Item 4c3. **Last name on patient record** Record the last name used for the hospital record for this visit in the space provided.
- Item 4c4. **Maternal last name on patient record** Record the maternal last name used for the hospital record for this visit in the space provided.
- Item 4d. Time in ICU Select only one option among the two possible choices.
  - Select No if the subject reports not having spent any time in in the intensive care unit (ICU).
  - Select Yes if the subject reports being having spent any time in in the intensive care unit (ICU).
- Item 4e. Intubation Select only one option among the two possible choices.
  - Select No if the subject reports not having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.
  - Select Yes if the subject reports being having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.

## **Second Episode of Breathing Problems:**

- Item 5. **Approximate month and year of second episode** The calendar icon can't be used here. Please type in the month and year using MM-YYYY format.
- Item 5a. Took additional antibiotics Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
- Item 5b. Took additional oral steroids Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
- Item 5c. **Took additional antibiotics without contacting provider** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics without contacting his/her healthcare provider by telephone or email.

- Select Yes if the subject reports taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
- Item 5d. Took additional oral steroids Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
- Item 5e. **Physician's office or urgent care evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in a physician's office or urgent care.
  - Select Yes if the subject reports being evaluated in a physician's office or urgent care.
- Items 5e1-4. **Physician's office or urgent care evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to a physician's office or urgent care.
- Item 5f. **Emergency department evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in an emergency department.
  - Select Yes if the subject reports being evaluated in an emergency department.
- Items 3f1-4. **Emergency department evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to an emergency department.
- Item 5g. Hospital admission Select only one option among the two possible choices.
  - Select No if the subject reports not being admitted to a hospital. [If a second episode occurred, go to 7. Otherwise, go to end of form]
  - Select Yes if the subject reports being admitted to a hospital.
- Item 6. **Date of Hospitalization** Record the date the participant was hospitalized. 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.
- Item 6a. **Name of medical facility** Record the name of the medical facility where the participant was hospitalized in the space provided.
- Item 6b. **Address of medical facility** Record the address of the medical facility where the participant was hospitalized in the space provided.
- Item 6c1. **First name on patient record** Record the first name used for the hospital record for this visit in the space provided.
- Item 6c2. **Second name on patient record** Record the second name used for the hospital record for this visit in the space provided.

- Item 6c3. **Last name on patient record** Record the last name used for the hospital record for this visit in the space provided.
- Item 6c4. **Maternal last name on patient record** Record the maternal last name used for the hospital record for this visit in the space provided.
- Item 6d. Time in ICU Select only one option among the two possible choices.
  - Select No if the subject reports not having spent any time in in the intensive care unit (ICU).
  - Select Yes if the subject reports being having spent any time in in the intensive care unit (ICU).
- Item 6e. Intubation Select only one option among the two possible choices.
  - Select No if the subject reports not having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.
  - Select Yes if the subject reports being having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.

## **Third Episode of Breathing Problems:**

- Item 7. **Approximate month and year of third episode** The calendar icon can't be used here. Please type in the month and year using MM-YYYY format.
- Item 7a. Took additional antibiotics Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
- Item 7b. Took additional oral steroids Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
- Item 7c. **Took additional antibiotics without contacting provider** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
- Item 7d. Took additional oral steroids Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids without contacting his/her healthcare provider by telephone or email.

- Item 7e. **Physician's office or urgent care evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in a physician's office or urgent care.
  - Select Yes if the subject reports being evaluated in a physician's office or urgent care.
- Items 7e1-4. **Physician's office or urgent care evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to a physician's office or urgent care.
- Item 7f. **Emergency department evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in an emergency department.
  - Select Yes if the subject reports being evaluated in an emergency department.
- Items 7f1-4. **Emergency department evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to an emergency department.
- Item 7g. Hospital admission Select only one option among the two possible choices.
  - Select No if the subject reports not being admitted to a hospital. [If a second episode occurred, go to 9. Otherwise, go to end of form]
  - Select Yes if the subject reports being admitted to a hospital.
- Item 8. **Date of Hospitalization** Record the date the participant was hospitalized. 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.
- Item 8a. Name of medical facility Record the name of the medical facility where the participant was hospitalized in the space provided.
- Item 8b. **Address of medical facility** Record the address of the medical facility where the participant was hospitalized in the space provided.
- Item 8c1. **First name on patient record** Record the first name used for the hospital record for this visit in the space provided.
- Item 8c2. **Second name on patient record** Record the second name used for the hospital record for this visit in the space provided.
- Item 8c3. Last name on patient record Record the last name used for the hospital record for this visit in the space provided.
- Item 8c4. **Maternal last name on patient record** Record the maternal last name used for the hospital record for this visit in the space provided.
- Item 8d. Time in ICU Select only one option among the two possible choices.
  - Select No if the subject reports not having spent any time in in the intensive care unit (ICU).

• Select Yes if the subject reports being having spent any time in in the intensive care unit (ICU).

Item 8e. **Intubation** Select only one option among the two possible choices.

- Select No if the subject reports not having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.
- Select Yes if the subject reports being having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.

## Fourth Episode of Breathing Problems:

Item 9. **Approximate month and year of fourth episode** The calendar icon can't be used here. Please type in the month and year using MM-YYYY format.

Item 9a. Took additional antibiotics Select only one option among the two possible choices.

- Select No if the subject reports not taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
- Select Yes if the subject reports taking additional antibiotics after contacting his/her healthcare provider by telephone or email.

Item 9b. Took additional oral steroids Select only one option among the two possible choices.

- Select No if the subject reports not taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
- Select Yes if the subject reports taking additional oral steroids after contacting his/her healthcare provider by telephone or email.

Item 9c. **Took additional antibiotics without contacting provider** Select only one option among the two possible choices.

- Select No if the subject reports not taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
- Select Yes if the subject reports taking additional antibiotics without contacting his/her healthcare provider by telephone or email.

Item 9d. **Took additional oral steroids** Select only one option among the two possible choices.

- Select No if the subject reports not taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
- Select Yes if the subject reports taking additional oral steroids without contacting his/her healthcare provider by telephone or email.

Item 9e. **Physician's office or urgent care evaluation** Select only one option among the two possible choices.

- Select No if the subject reports not being evaluated in a physician's office or urgent care.
- Select Yes if the subject reports being evaluated in a physician's office or urgent care.

Items 9e1-4. **Physician's office or urgent care evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to a physician's office or urgent care.

- Item 9f. **Emergency department evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in an emergency department.
  - Select Yes if the subject reports being evaluated in an emergency department.
- Items 9f1-4. **Emergency department evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to an emergency department.
- Item 9q. Hospital admission Select only one option among the two possible choices.
  - Select No if the subject reports not being admitted to a hospital. [If a second episode occurred, go to 11. Otherwise, go to end of form]
  - Select Yes if the subject reports being admitted to a hospital.
- Item 10. **Date of Hospitalization** Record the date the participant was hospitalized. 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.
- Item 10a. **Name of medical facility** Record the name of the medical facility where the participant was hospitalized in the space provided.
- Item 10b. **Address of medical facility** Record the address of the medical facility where the participant was hospitalized in the space provided.
- Item 10c1. **First name on patient record** Record the first name used for the hospital record for this visit in the space provided.
- Item 10c2. **Second name on patient record** Record the second name used for the hospital record for this visit in the space provided.
- Item 10c3. **Last name on patient record** Record the last name used for the hospital record for this visit in the space provided.
- Item 10c4. **Maternal last name on patient record** Record the maternal last name used for the hospital record for this visit in the space provided.
- Item 10d. **Time in ICU** Select only one option among the two possible choices.
  - Select No if the subject reports not having spent any time in in the intensive care unit (ICU).
  - Select Yes if the subject reports being having spent any time in in the intensive care unit (ICU).
- Item 10e. **Intubation** Select only one option among the two possible choices.
  - Select No if the subject reports not having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.
  - Select Yes if the subject reports being having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.

## Fifth Episode of Breathing Problems:

- Item 11. **Approximate month and year of fifth episode** The calendar icon can't be used here. Please type in the month and year using MM-YYYY format.
- Item 11a. **Took additional antibiotics** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
- Item 11b. **Took additional oral steroids** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
- Item 11c. Took additional antibiotics without contacting provider Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
- Item 11d.**Took additional oral steroids** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
- Item 11e. **Physician's office or urgent care evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in a physician's office or urgent care.
  - Select Yes if the subject reports being evaluated in a physician's office or urgent care.
- Items 11e1-4. **Physician's office or urgent care evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to a physician's office or urgent care.
- Item 11f. **Emergency department evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in an emergency department.
  - Select Yes if the subject reports being evaluated in an emergency department.

- Items 11f1-4. **Emergency department evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to an emergency department.
- Item 11g. Hospital admission Select only one option among the two possible choices.
  - Select No if the subject reports not being admitted to a hospital. [If a second episode occurred, go to 13. Otherwise, go to end of form]
  - Select Yes if the subject reports being admitted to a hospital.
- Item 12. **Date of Hospitalization** Record the date the participant was hospitalized. 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.
- Item 12a. **Name of medical facility** Record the name of the medical facility where the participant was hospitalized in the space provided.
- Item 12b. **Address of medical facility** Record the address of the medical facility where the participant was hospitalized in the space provided.
- Item 12c1. **First name on patient record** Record the first name used for the hospital record for this visit in the space provided.
- Item 12c2. **Second name on patient record** Record the second name used for the hospital record for this visit in the space provided.
- Item 12c3. Last name on patient record Record the last name used for the hospital record for this visit in the space provided.
- Item 12c4. **Maternal last name on patient record** Record the maternal last name used for the hospital record for this visit in the space provided.
- Item 12d. **Time in ICU** Select only one option among the two possible choices.
  - Select No if the subject reports not having spent any time in in the intensive care unit (ICU).
  - Select Yes if the subject reports being having spent any time in in the intensive care unit (ICU).
- Item 12e. Intubation Select only one option among the two possible choices.
  - Select No if the subject reports not having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.
  - Select Yes if the subject reports being having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.

### **Sixth Episode of Breathing Problems:**

- Item 13. **Approximate month and year of sixth episode** The calendar icon can't be used here. Please type in the month and year using MM-YYYY format.
- Item 13a. Took additional antibiotics Select only one option among the two possible choices.

- Select No if the subject reports not taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
- Select Yes if the subject reports taking additional antibiotics after contacting his/her healthcare provider by telephone or email.
- Item 13b. **Took additional oral steroids** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids after contacting his/her healthcare provider by telephone or email.
- Item 13c. Took additional antibiotics without contacting provider Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional antibiotics without contacting his/her healthcare provider by telephone or email.
- Item 13d.**Took additional oral steroids** Select only one option among the two possible choices.
  - Select No if the subject reports not taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
  - Select Yes if the subject reports taking additional oral steroids without contacting his/her healthcare provider by telephone or email.
- Item 13e. **Physician's office or urgent care evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in a physician's office or urgent care.
  - Select Yes if the subject reports being evaluated in a physician's office or urgent care.
- Items 13e1-4. **Physician's office or urgent care evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to a physician's office or urgent care.
- Item 13f. **Emergency department evaluation** Select only one option among the two possible choices.
  - Select No if the subject reports not being evaluated in an emergency department.
  - Select Yes if the subject reports being evaluated in an emergency department.
- Items 13f1-4. **Emergency department evaluation actions** Select all the options among the four possible choices based on what the subject reports regarding his/her visit to an emergency department.
- Item 13g. Hospital admission Select only one option among the two possible choices.
  - Select No if the subject reports not being admitted to a hospital. [If a second episode occurred, go to 15. Otherwise, go to end of form]
  - Select Yes if the subject reports being admitted to a hospital.

- Item 14. **Date of Hospitalization** Record the date the participant was hospitalized. 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.
- Item 14a. **Name of medical facility** Record the name of the medical facility where the participant was hospitalized in the space provided.
- Item 14b. **Address of medical facility** Record the address of the medical facility where the participant was hospitalized in the space provided.
- Item 14c1. **First name on patient record** Record the first name used for the hospital record for this visit in the space provided.
- Item 14c2. **Second name on patient record** Record the second name used for the hospital record for this visit in the space provided.
- Item 14c3. **Last name on patient record** Record the last name used for the hospital record for this visit in the space provided.
- Item 14c4. **Maternal last name on patient record** Record the maternal last name used for the hospital record for this visit in the space provided.
- Item 14d. Time in ICU Select only one option among the two possible choices.
  - Select No if the subject reports not having spent any time in in the intensive care unit (ICU).
  - Select Yes if the subject reports being having spent any time in in the intensive care unit (ICU).
- Item 14e. Intubation Select only one option among the two possible choices.
  - Select No if the subject reports not having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.
  - Select Yes if the subject reports being having been intubated or placed on a breathing machine or ventilator through a tube in his/her mouth or nose.