



INSTRUCTIONS FOR SPIROMICS-HF SCREENING FORM HFS, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The SPIROMICS-HF Screening Form (HFS) is to be completed during a phone call, SPIROMICS II follow-up phone call, or during SPIROMICS Visit 5, Bronchoscopy substudy visit, or Exacerbation substudy visit in order to discuss the SPIROMICS-HF Ancillary Study and in order to determine whether the participant is interested in participating and if the visit should be scheduled or delayed.

This form is also to be reviewed and completed at the beginning of the SPIROMICS-HF visit after informed consent has been obtained in order to ensure that the visit can be conducted safely.

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 CDART 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

Read the script to the participant. This script is the same for both phone call AND in person at a clinic visit.

Item 1. **Participant Interest:** Select only one option among the two possible choices.

- Select No if the participant is not interested. [Go to End]
- Select Yes if the participant is interested.

Read the script following Q1. If the participant agrees to answer eligibility questions now, continue with Q2. If the participant does not agree to answer eligibility questions now, reschedule the call or perform in clinic.

Item 2. **Participant willingness to have MRI:** Select only one option among the two possible choices.

- Select No if the participant is not willing to have an MRI.
- Select Yes if the participant is willing to have an MRI. [Administer the MRI Exclusion Form (MRE) and site MRI screener before scheduling the MRI]

Item 3. **Sex of participant:** (Do not ask the participant this question) Select only one option among the two possible choices.

- Select Male if the participant is male. [Go to Q4a]
- Select Female if the participant is female.

Item 3a. **Child-bearing potential:** Select only one option among the two possible choices.

- Select No if the participant is not of child-bearing potential.

- Select Yes if the participant is of child-bearing potential. [If Yes, a pregnancy test should be performed to determine if the participant is eligible for MRI. Record the result in Q3c]
- Select Don't know if the participant doesn't know if she is of child-bearing potential.

Item 3b. **Chance of pregnancy:** Select only one option among the two possible choices.

- Select No if the participant states that there is no chance she is pregnant.
- Select Yes if the participant states that there is a chance she is pregnant. [If yes, a pregnancy test should be performed to determine if the participant is eligible for the MRI. Record the result in Q3c]

Item 3c. **Results of pregnancy test:** Select only one option among the two possible choices.

- Select Negative if the result is negative.
- Select Positive if the result is positive. [If Positive, the participant should be phoned and re-screened a minimum of three months after the birth to schedule the SPIROMICS-HF visit]

Item 3d. **Given birth in last 3 months:** Select only one option among the two possible choices.

- Select No if the participant has not given birth in the last 3 months.
- Select Yes if the participant has given birth in the last 3 months. [If Yes, the participant should be phoned and re-screened a minimum of three months after the birth the birth to schedule the SPIROMICS-HF visit]

Item 4a. **Pulmonary exacerbation:** Select only one option among the two possible choices.

- Select No if the participant has not had a pulmonary exacerbation or worsening of COPD symptoms within the last 6 weeks.
- Select Yes if the participant has had a pulmonary exacerbation or worsening of COPD symptoms within the last 6 weeks. [Participant should be phoned and re-screened after six weeks have passed prior to scheduling the SPRIOMICS-HF visit]

Item 4b. **Upper respiratory infection:** Select only one option among the two possible choices.

- Select No if the participant has not had an upper respiratory infection (a cold) within the last 6 weeks.
- Select Yes if the participant has had an upper respiratory infection (a cold) within the last 6 weeks. [Participant should be phoned and re-screened after six weeks have passed prior to scheduling the SPRIOMICS-HF visit]

Item 4c. **Heart Attack:** Select only one option among the two possible choices.

- Select No if the participant has not had a heart attack within the last 6 weeks.
- Select Yes if the participant has had a heart attack within the last 6 weeks. [Participant should be phoned and re-screened after six weeks have passed prior to scheduling the SPRIOMICS-HF visit]

Item 4d. **Other heart issues:** Select only one option among the two possible choices.

- Select No if the participant has not been told they have unstable angina, unstable heart disease, a heart failure flare or exacerbation, or uncontrolled irregular heart beat within the last 6 weeks.
- Select Yes if the participant has been told they have unstable angina, unstable heart disease, a heart failure flare or exacerbation, or uncontrolled irregular heart beat within the last 6 weeks. [Participant should be phoned and re-screened after six weeks have passed prior to scheduling the SPRIOMICS-HF visit]

- Item 4e. **Eye, chest, or abdominal surgery:** Select only one option among the two possible choices.
- Select No if the participant has not had eye, chest, or abdominal surgery within the last 6 weeks.
 - Select Yes if the participant has had eye, chest, or abdominal surgery within the last 6 weeks. [Participant should be phoned and re-screened after six weeks have passed prior to scheduling the SPIROMICS-HF visit]

- Item 5. **Antibiotics, steroids, or increased Lasix dose:** Select only one option among the two possible choices.
- Select No if the participant has not taken antibiotics or steroids or increased Lasix dose for an acute or sudden problem within the last month.
 - Select Yes if the participant has taken antibiotics or steroids or increased Lasix dose for an acute or sudden problem within the last month. [The participant should be phoned and re-screened after one month has passed before the SPIROMICS-HF visit can be scheduled. NOTE: This does not apply to participants who are on chronic prednisone therapy of less than 10mg per day or less than 20mg every other day, or participants who are currently on chronic, prophylactic, or suppressive antibiotic therapy, or participants on their standard dose (or slightly varying does) of Lasix]

If there are no exclusions, schedule the participant for the SPIROMICS-HF visit.

Save and close the form.