



SPIROMICS-HF SCREENING FORM

ID NUMBER:									
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FORM CODE: HFS
VERSION: 1.0 1/30/2020

Event: _____

0a) Date of Collection / /

0b) Staff Code

Instructions: This form should be completed during a phone call, SPIROMICS II follow-up phone call, or during SPIROMICS Visit 5, Bronchoscopy substudy visit, or Exacerbation substudy visit to discuss the SPIROMICS-HF Ancillary Study and to determine whether the participant is interested in participating and should be scheduled or delayed. This form should also be reviewed and completed at the beginning of the SPIROMICS-HF visit after informed consent has been obtained to ensure that the visit can be conducted safely.

[Phone script and Clinic script] Thank you for your participation in the SPIROMICS study. We have made some important findings in COPD. We are pleased to say that NIH has funded a new ancillary study on heart function in COPD for SPIROMICS participants which will be the largest study to date on how the heart and lungs work together. We are inviting all SPIROMICS participants with a history of smoking to participate in this important ancillary study, which includes an echo ultrasound of the heart and an MRI scan of the heart and lungs. I am [calling/asking] to see if you would be interested in participating in this SPIROMICS-HF study, which takes about 4 hours, usually on a separate day, and for which you will be compensated \$200 for your time, if you complete both of the main components (echo and MRI) of the study.

1) Are you interested?

- No₀ → **Go to END**
 Yes₁

If Yes, **[phone script and clinic script]** Great, let's find a convenient time for you to come in to the clinic for your SPIROMICS-HF visit. But before I schedule the visit, I would like to ask you some questions to determine whether it is a good time to schedule you for this visit. Would it be ok to ask you some questions about eligibility now? [If yes, continue; if no, reschedule the call or perform in clinic.]

2) Would you be willing to have an MRI scan of your heart and lungs as part of this study? **[Phone script and clinic script]** It takes about 45 minutes and we will reimburse you \$100 for your time.

- No₀
 Yes₁ → **Administer the MRI Exclusion Form (MRE) and site MRI screener before scheduling the MRI**

3) **(do not ask)** What is the sex of the participant?

- Male_M → **Go to 4a**
 Female_F

3a) Are you of child-bearing potential?

- No₀
 Yes₁
 Don't know₂

3b) Is there any chance you are pregnant?

- No₀
 Yes₁

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If Yes to 3a or 3b, **Instructions:** A pregnancy test should be performed to determine if the participant is eligible for the MRI. Record the result in 3c.

If No to BOTH 3a and 3b → **Go to 3d**

3c) Record the result of the pregnancy test here.

Negative₀

Positive₁ → **Go to END**

If Positive, **Instructions:** The participant should be phoned and re-screened a minimum of three months after the birth to schedule the SPIROMICS-HF visit.

3d) Have you given birth in the last 3 months?

No₀

Yes₁

If Yes, **Instructions:** The participant should be phoned and re-screened a minimum of three months after the birth to schedule the SPIROMICS-HF visit.

Instructions: If any of the following occurred within the last 6 weeks the participant should be phoned and re-screened after six weeks has passed prior to scheduling the SPIROMICS-HF visit.

Do any of the following statements apply to you (within the last 6 weeks)?

4a) You have had a pulmonary exacerbation or worsening of your COPD symptoms in the last 6 weeks.

No₀

Yes₁

4b) You have had an upper respiratory infection (a cold) in the last 6 weeks.

No₀

Yes₁

4c) You have had a heart attack within the last 6 weeks.

No₀

Yes₁

4d) You have been told you have unstable angina, unstable heart disease, a heart failure flare or exacerbation, or uncontrolled irregular heart beat within the last 6 weeks.

No₀

Yes₁

4e) You have had eye, chest, or abdominal surgery within the last 6 weeks.

No₀

Yes₁

Instructions: If the following occurred within the last month the participant should be phoned and re-screened after one month has passed prior to scheduling the SPIROMICS-HF visit. This does not apply to participants who are on chronic prednisone therapy of <10 mg per day or <20 mg every other day, or participants who are currently on chronic, prophylactic, or suppressive antibiotic therapy, or participants on their standard dose (or slightly varying dose) of Lasix.

5) Have you taken antibiotics or steroids or increased Lasix dose for an acute or sudden problem within the last month?

No₀

Yes₁

Instructions: Schedule the participant for the SPIROMICS-HF visit unless there are any temporary exclusions.

END OF FORM