



SPIROMICS-HF MRI PRE-COMPLETION FORM, MRI, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The SPIROMICS-Heart Failure MRI Completion Form (MRI) is to be completed before the MRI testing for SPIROMICS-HF. Before starting this form, eligibility should be confirmed for MRI by reviewing the MRI Exclusion form with the participant and MRI staff.

It should be noted that all participants are selected for gadolinium administration but some will refuse and some will be ineligible for gadolinium administration as outlined below. In these cases, the MRI is to be performed without gadolinium.

All participants are also selected for metronome breathing but some will refuse and some will be ineligible as outlined below. In these cases, the MRI +/- gad is to be performed without the metronome breathing portion.

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 Completion: 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.

Assessment for Gadolinium (to be completed prior to MRI)

Instructions: The participant's consent response from the HCT form will populate in CDART.

- Item 1. **Participant consent to receive gadolinium:** After saving and reloading, this item will auto populate from the HCT.
- If No, the participant does not consent to receive gadolinium. [Go to Q4]
 - If Yes, the participant does consent to receive gadolinium.
 - If 'Not applicable to my site's informed consent form'
- Item 1a. **Serious kidney or liver disease:** Select only one option among the two possible choices.
- Select No if the participant does not have a history of serious kidney or liver disease.

- Select Yes if the participant does have a history of serious kidney or liver disease. [Participant is ineligible for gadolinium; Go to Q4]

Item 1b. **Gadolinium allergy:** Select only one option among the two possible choices.

- Select No if the participant is not allergic to gadolinium.
- Select Yes if the participant is allergic to gadolinium. [Participant is ineligible for gadolinium; Go to Q4]

Item 2. **Instructions:** Review the values for 2a-2c below. If the calculated eGFR result is >60 mL/min/1.73m², the result is valid for one month. If the calculated eGFR is ≥ 45 - ≤ 60 , the result is valid for two days. If the previous result is no longer valid or if point-of-care eGFR is provided, conduct the test and update the values below.

Instructions: On first load in CDART, previous creatinine test date and result will display. If the test has been repeated, enter the new date and value below.

Item 2a. **Date of creatinine/eGFR test:** Record the date of the creatinine/eGFR test.

Item 2b. **Serum creatinine:** Record the serum creatinine.

Instructions: "Save and Reload" the form to calculate eGFR based on the current value in 2b.

Item 2c. **Calculated eGFR:** The calculated eGFR will populate here.

Item 3. **eGFR <45:** Select only one option among the two possible choices.

- Select No if the calculated eGFR is equal to or greater than 45 mL/min/1.73m².
- Select Yes if the calculated eGFR is less than 45 mL/min/1.73m². [Participant is ineligible for gadolinium; Go to Q4]

Item 4. **Is participant willing and eligible to receive gadolinium:** Select only one option among the two possible choices.

- Select No if the participant is not willing or not eligible to receive gadolinium. [Proceed with MRI **WITHOUT** gadolinium]
- Select Yes if the participant is willing and eligible to receive gadolinium. [Proceed with MRI **WITH** gadolinium]

Baseline Assessment (to be completed prior to MRI)

Item 5. **Systolic blood pressure:** Record the patient's systolic blood pressure.

Item 6. **Diastolic blood pressure:** Record the patient's diastolic blood pressure.

Item 7. **Oxygen saturation:** Record the patient's oxygen saturation.

Item 8. **Heart rate:** Record the participant's heart rate.

Item 9. **EKG Heart Rhythm (approximate based on MRI leads):** Select only one option among the three possible choices.

- Select 'Normal Sinus Rhythm' if the approximate EKG heart rhythm based on MRI leads is normal sinus rhythm.

- Select 'Atrial-fibrillation' if the approximate EKG heart rhythm based on MRI leads is atrial-fibrillation.
- Select 'Other' if the approximate EKG heart rhythm is other than the options listed above.

Item 10. **Supplemental oxygen:** Select only one option among the two possible choices.

- Select No if supplemental oxygen is not to be used during MRI. [Go to Q11]
- Select Yes if supplemental oxygen is to be used during MRI.

Item 10a. **Number of oxygen liters:** Record the number of liters of oxygen to be used during MRI.

Assessment for Metronome Breathing (to be completed prior to MRI)

Item 11. **Participant willingness:** Select only one option among the two possible choices.

- Select No if the participant is not willing to do the Metronome Breathing during MRI. [Go to Q14]
- Select Yes if the participant is willing to do the Metronome Breathing during MRI.

Item 12. **Cardiovascular events or stable angina:** Select only one option among the two possible choices.

- Select No if the participant did not have any cardiovascular events (MI, unstable angina, or HF events) or stable angina in the last 3 months.
- Select Yes if the participant did have any cardiovascular events (MI, unstable angina, or HF exacerbation) or stable angina in the last 3 months. [Participant is ineligible for Metronome Breathing; Go to Q14]

Item 13. **O₂ saturation > 88% at rest:** Select only one option among the two possible choices.

- Select No if the participant's O₂ saturation is less or equal to 88% at rest with or without supplemental oxygen use. [Participant is ineligible for Metronome Breathing; Go to Q14]
- Select Yes if the participant's O₂ saturation is greater than 88% at rest with or without supplemental oxygen use.

Item 14. **Is participant willing and eligible to perform Metronome Breathing:** Select only one option among the two possible choices.

- Select No if the participant is not willing or not eligible to perform Metronome Breathing. [Proceed with MRI **WITHOUT** Metronome Breathing]
- Select Yes if the participant is willing and eligible to perform Metronome Breathing. [Proceed with MRI **WITH** Metronome Breathing]

Instructions: SPIROMICS staff must provide the MRI technician with a paper copy of the MRI Tech Completion Form (MRT) with the participant ID, Gender, Height, Weight, and Age filled out. The MRI technician will complete the rest of the MRT form. SPIROMICS staff are responsible for scanning and transmitting the MRT form to the MRI Reading Center.

Save and close the form.