

**SPIROMICS-HF
MRI EXCLUSION FORM, MRE,
VERSION 1.0, QUESTION BY QUESTION (QxQ)**

I. GENERAL INSTRUCTIONS

The SPIROMICS-Heart Failure MRI Exclusion Form (MRE) is to be completed at either the participant's clinic visit (if scheduling then) or during the scheduling phone call for SPIROMICS-HF. This form, along with your MRI facility's local MRI exclusion form, will determine if the participant is eligible for the MRI. It would be helpful to administer both forms at the same time since they must be eligible on both forms in order to proceed with the MRI.

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 the clinic visit 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. **Claustrophobia:** Select only one option among the two possible choices.
- Select No if the participant is not claustrophobic.
 - Select Yes if the participant is claustrophobic. [Participant is ineligible for MRI; Go to Q7]
 - Select Don't know if the participant does not know if they are claustrophobic.

- Item 2. **Aneurysm clip:** Select only one option among the two possible choices.
- Select No if the participant does not have an aneurysm clip in their brain. [Go to Q3]
 - Select Yes if the participant does have an aneurysm clip in their brain.

INSTRUCTIONS: If the answer to Q2 is 'Yes', further evaluation is required before the MRI can be completed – the local MRI screening form should be administered and discussion should occur with the MRI facility. Items 2a, 2b, and 2c should be verified from medical records.

- Item 2a. **Manufacturer and model:** Specify the aneurysm clip manufacturer and model (this needs to be verified from medical records).

- Item 2b. **Hospital Name:** Specify the hospital name where the participant received the aneurysm clip (this needs to be verified from medical records).
- Item 2c. **Hospital city, state:** Specify the city and state of the hospital where the participant received the aneurysm clip (this needs to be verified from medical records).
- Item 3. **Metal worker, welder or grinder:** Select only one option among the two possible choices.
- Select No if the participant is not and has never been a metal worker, welder, or grinder in their job.
 - Select Yes if the participant is or has been a metal worker, welder, or grinder in their job. [If Yes, further evaluation is required before the participant can have the MRI – administer the local MRI screening form and discuss with your MRI facility.]
- Item 4. **Metal fragments:** Select only one option among the two possible choices.
- Select No if the participant does not have metal fragments in their eyes, brain, or spinal cord.
 - Select Yes if the participant does have metal fragments in their eyes, brain, or spinal cord. [Go to Q7 – participant is ineligible for MRI]
- Item 5. **Internal electrical devices:** Select only one option among the two possible choices.
- Select No if the participant does not have any internal electrical devices, such as a cochlear implant, spinal cord stimulator, pacemaker, or ICD that are MRI-incompatible. Consult with the local MRI facility to assess MRI compatibility using the local MRI screening form as needed.
 - Select Yes if the participant does have any internal electrical devices, such as a cochlear implant, spinal cord stimulator, pacemaker, or ICD that are MRI-incompatible. Consult with the local MRI facility to assess MRI compatibility using the local MRI screening form as needed. [Go to Q7 – participant is ineligible for MRI]
- Item 6. **(FEMALE ONLY) Current pregnancy:** Select only one option among the two possible choices.
- Select No if the participant is not or does not believe she may currently be pregnant.
 - Select Yes if the participant is or believes she may be currently pregnant. [Participant is temporarily ineligible; reschedule 3+ months after pregnancy]
- Item 7. **MRI eligibility:** Select only one option among the two possible choices.
- Select No if the participant does not pass all MRI exclusion criteria. [Go to END – participant is ineligible for the MRI. Participant is still eligible for the rest of SPIROMICS HF and the echo should still be scheduled.]
 - Select Yes if the participant does pass all MRI exclusion criteria.
- Item 8. **Confirm local MRI eligibility:** Select only one option among the three possible choices.
- Select No if the participant is not eligible based on the local MRI exclusion form. [Go to END – participant is ineligible for the MRI. Participant is still eligible for the rest of SPIROMICS HF and the echo should still be scheduled.]
 - Select Yes if the participant is eligible based on the local MRI exclusion form.
 - Select 'Not available' if the local MRI eligibility is not available.

MRI Appointment Information

- Item 9. **Participant eligibility and agreement:** Select only one option among the three possible choices.
- Select No if the participant does not agree to MRI. [Go to Q9d]
 - Select Yes if the participant does agree to MRI. [Go to Q9a]
 - Select Yes, but another time if the participant agrees to MRI at another time. [Go to Q9c]
- Item 9a. **MRI appointment date:** Record the date of the participant's MRI appointment using the mm/dd/yyyy format.
- Item 9b. **MRI appointment time:** Record the time of the participant's MRI appointment in the hh:mm format.
- Item 9c. **Date for future contact:** Record the date after which the participant may be contacted to schedule an appointment for the MRI using the mm/dd/yyyy format.
- Item 9d. **Reason for refusal:** Choose only one option from among the five possible choices.
- Select Not interested if the participant is not interested in having the MRI.
 - Select Sick/Ill if the participant is too sick or ill to have the MRI
 - Select Caring for person at home if the participant cannot have the MRI because they are caring for a person at home.
 - Select Claustrophobia if the participant refuses the MRI because of claustrophobia.
 - Select Other if the reason for refusal is not listed.

Save and close the form.