SPIROMICS-HF
RADIOLOGIST SAFETY REVIEW FORM - MRI
MSR, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The SPIROMICS-Heart Failure Radiologist Safety Review Form (MSR) is to be completed after the safety review of all MRI images (including the heart, lungs, and other imaged regions) has been performed by the site radiologist. The radiologist should also review any potential alert findings noted on the SPIROMICS-HF MRI Tech Completion Form (MRT) before signing this form.

SPIROMICS staff will open this form in CDART in order to populate Items 1a, 1b, and 1c. Staff should also complete the header information including 0a and 0b and save prior to delivering the printed form to the radiologist for completion. The Date of Collection should be the date the form is loaded for the first time. SPIROMICS staff will also print a copy of the completed SPIROMICS-HF MRI Tech Completion Form (MRT) for the radiologist.

After completion by the radiologist, SPIROMICS staff will enter the completed form into CDART.

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 this form is loaded for the first time and prepared for the radiologist. 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 loaded and printed the form for the radiologist. 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.

INSTRUCTIONS: The radiologist should complete and sign the form. Previous alerts from the SPIROMICS-HF echo of the heart will have populated in the SPIROMICS electronic data system and will be shown in items 1a – 1c. If there was not an echo alert, the item(s) will have populated with 'No alert'. If the echo safety read was not yet available, the items will be blank. For your information, as part of SPIROMICS, all participants should also have had a recent chest CT scan which should be available in the clinical EMR.

Alerts from SPIROMICS-HF echo results

Item 1a. Urgent alert – baseline echo findings: This item will populate if there was an urgent alert from the baseline echo findings. If the echo safety read was not yet available, this item will be blank.

Item 1b. Non-urgent alert – baseline echo findings: This item will populate if there was a non-urgent alert from the baseline echo findings. If the echo safety read was not yet available, this item will be blank.

Item 1c. Non-urgent alert – exercise echo findings: This item will populate if there was a non-urgent alert from the exercise echo findings. If the echo safety read was not yet available, this item will be blank. If the participant was not eligible for the exercise portion, this item will have populated with 'Ineligible for exercise portion.'

Item 2. **Radiologist review:** Select only one option among the three possible choices.
- Select 'I have reviewed the MRI heart, lung, and other images and confirmed that there are NO new alerts' after reviewing the available images and confirming that there are NO "new" alerts. (A "new" alert is one NOT noted in item 1, the echo alert fields above, or reported on prior imaging (e.g. chest CT).) [Go to Q3]
- Select 'I have reviewed the MRI images and confirmed the prior alert(s) noted on the echo or other prior imaging' after reviewing the MRI images and confirming the prior alert(s) noted on the echo or other prior imaging.
- Select 'I have reviewed the MRI images and detected a new alert that was not previously reported' after reviewing the MRI images and detecting an alert not previously reported.

Item 2a. **Alert finding:** Specify the alert finding. Ensure all procedures in place at your site are followed for documentation and communication of the alert, especially if the alert has not previously been noted or if it indicates a significant change from previous imaging.

Item 3. **Radiologist's name:** Enter the radiologist's printed name.

Item 3a. **Date of review:** Enter the date of radiologist's review.

Item 3b. **Radiologist signature:** Confirm that the radiologist reviewer's signature has been received by entering the radiologist's name again. File the signed paper form.

Save and close the form.