

INSTRUCTIONS FOR SPIROMICS-HF CARDIOLOGIST SAFETY REVIEW FORM - ECHO ESR, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The SPIROMICS-HF Cardiologist Safety Review Form – ECHO (ESR) is to be completed after the safety review of the echo images has been performed by the site cardiologist. The cardiologist should also review the findings on the SPIROMICS-HF Echo Completion Form before signing this form. 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 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

- Item 1. Cardiologist reviewer: Select only one option among the three possible choices.
 - Select 'I have reviewed the echo images and confirm that there are NO alerts' if there were no alerts. [GO TO Q2]
 - Select 'I have reviewed the echo images and confirm the suspected alerts indicated by the site sonographer' if suspected alerts indicated by the site sonographer have been confirmed. [GO TO Q2]
 - Select 'I have reviewed the echo images and detected an alert finding not reported by the site sonographer' if alert findings were detected that were not reported by the site sonographer.
- Item 1a. **Alert finding not reported by site sonographer:** If an alert finding was detected and not reported by the site sonographer, specify the alert finding here.
- Item 2. Cardiologist reviewer name: Enter cardiologist reviewer name.
- Item 2a. **Date of review:** Enter the date of cardiologist's review.
- Item 2b. **Cardiologist Signature:** Confirm that the cardiologist's signature has been received by entering the cardiologist's name again. File the signed paper form for documentation.

Save and close the form.