



## INSTRUCTIONS FOR SPIROMICS-HF STUDY WITHDRAWAL FORM HFW, VERSION 1.0, QUESTION BY QUESTION (QxQ)

### I. GENERAL INSTRUCTIONS

The SPIROMICS-HF Study Withdrawal Form (HFW) is to be completed when the participant withdraws from the SPIROMICS Heart Failure ancillary study.

**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

Please answer every question on this form.

- Item 1. **Echo testing completion:** Select only one option among the two possible choices.
- Select No if the participant did not complete the Echo testing.
  - Select Yes if the participant did complete the Echo testing.
- Item 2. **MRI completion:** Select only one option among the two possible choices.
- Select No if the participant did not complete the MRI.
  - Select Yes if the participant did complete the MRI.
- Item 3. **Date of SPIROMICS-HF withdrawal:** Record the date of the participant's withdrawal from the SPIROMICS Heart Failure ancillary study by either selecting the date from the pop-up calendar in the data management system (DMS) or entering the date using the mm/dd/yyyy format.
- Item 4. **Reason for withdrawal:** Select only one from the list provided. Choose the option that best explains the participant's withdrawal from the SPIROMICS Heart Failure ancillary study.
- Select 'Participant no longer wishes to participate; withdrawal of consent' if the patient has withdrawn consent and no longer wishes to participate in the study.
  - Select 'Participant is too sick to participate' if the participant is too sick to participate.
  - Select 'Participant is lost to follow-up' if it is no longer possible to follow-up with the participant.
  - Select 'Participant deceased' if the participant is deceased.
  - Select 'Other' if none of the answers above are sufficient to explain the participant's withdrawal.

- Item 5. **Reason for study withdrawal detailed:** Use the space provided to describe the reason for study withdrawal in more detail.
- Item 6. **Participant's wishes regarding SPIROMICS Heart Failure data:** Select only one option among the two possible choices.
- Select 'No change; keep all data collected' if the participant wants no changes and wants already collected data kept.
  - Select 'Remove all data collected' if the participant wants all data collected removed.

**NOTE: If the participant wishes to also withdraw from the main SPIROMICS II study (Visit 5 and FU phone calls), please also complete the RSW form.**

Save and close the form.