



## SPIROMICS-HEART FAILURE ADDITIONAL MEDICAL HISTORY FORM, HFA, VERSION 1.0, QUESTION BY QUESTION (QxQ)

### I. GENERAL INSTRUCTIONS

The SPIROMICS-Heart Failure Additional Medical History Form (HFA) is to be completed during the participant's Visit 5 or SPIROMICS-HF study visit after they have consented into SPIROMICS-HF.

**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. **Migraines:** Select only one option among the three possible choices.

- Select No if a medical professional has never told the participant that they have migraines. [Go to Q2]
- Select Yes if a medical professional has ever told the participant that they have migraines.
- Select 'Don't know' if the participant does not know if a medical professional has ever told them that they have migraines. [Go to Q2]

Item 1a. **Migraines with aura:** Select only one option among the three possible choices.

- Select No if the participant does not have migraines with aura.
- Select Yes if the participant does have migraines with aura.
- Select 'Don't know' if the participant does not know if they have migraines with aura.

Item 1b. **See/hear/smell things with migraine:** Select only one option among the three possible choices.

- Select No if the participant does not see, hear, or smell things when they get a migraine.
- Select Yes if the participant does see, hear, or smell things when they get a migraine.
- Select 'Don't know' if the participant does not know if they see, hear, or smell things when they get a migraine.

- Item 2. **Pulmonary hypertension (high blood pressure in the lungs):** Select only one option among the three possible choices.
- Select No if a medical professional has never told the participant that they have pulmonary hypertension.
  - Select Yes if a medical professional has ever told the participant that they have pulmonary hypertension.
  - Select 'Don't know' if the participant does not know if a medical professional has ever told them that they have pulmonary hypertension.
- Item 3. **Cor pulmonale (right heart failure due to COPD):** Select only one option among the three possible choices.
- Select No if a medical professional has never told the participant that they have cor pulmonale.
  - Select Yes if a medical professional has ever told the participant that they have cor pulmonale.
  - Select 'Don't know' if the participant does not know if a medical professional has ever told them that they have cor pulmonale.
- Item 4. **Atrial fibrillation:** Select only one option among the three possible choices.
- Select No if a medical professional has never told the participant that they have atrial fibrillation.
  - Select Yes if a medical professional has ever told the participant that they have atrial fibrillation.
  - Select 'Don't know' if the participant does not know if a medical professional has ever told them that they have atrial fibrillation.
- Item 5. **Stroke:** Select only one option among the three possible choices.
- Select No if a medical professional has never told the participant that they have had a stroke. [Go to Q6]
  - Select Yes if a medical professional has ever told the participant that they have had a stroke.
  - Select 'Don't know' if the participant does not know if a medical professional has ever told them that they have had a stroke. [Go to Q6]
- Item 5a. **Blood clot:** Select only one option among the three possible choices.
- Select No if the stroke was not due to a blood clot.
  - Select Yes if the stroke was due to a blood clot.
  - Select 'Don't know' if the participant does not know if the stroke was due to a blood clot.
- Item 5b. **Bleed in the head:** Select only one option among the three possible choices.
- Select No if the stroke was not due to a bleed in the head.
  - Select Yes if the stroke was due to a bleed in the head.
  - Select 'Don't know' if the participant does not know if the stroke was due to a bleed in the head.
- Item 6. **Stents:** Select only one option among the three possible choices.
- Select No if the participant has not had stents placed in their heart.
  - Select Yes if the participant has had stents placed in their heart.
  - Select 'Don't know' if the participant does not know if they have had a stent placed in their heart.

- Item 7. **Bypass surgery:** Select only one option among the three possible choices.
- Select No if the participant has not had bypass surgery of the heart.
  - Select Yes if the participant has had bypass surgery of the heart.
  - Select 'Don't know' if the participant does not know if they have had bypass surgery of the heart.

- Item 8. **Gender:** Select only one option among the two possible choices. This item is auto-populated in CDART. Use the arrows in the box if value is not already displayed.
- Select Male if the participant is male. [Go to END]
  - Select Female if the participant if female.

### **Pregnancy History Questionnaire (Women Only)**

NOTE: The following questions are about any pregnancies the participant has had that lasted over 6 months.

- Item 9. **Pregnant for over 6 months:** Select only one option among the two possible choices.
- Select No if the participant has never had a pregnancy that lasted over 6 months. [Go to END]
  - Select Yes if the participant has had at least one pregnancy that lasted over 6 months.

- Item 10. **Number of pregnancies:** Enter the number of pregnancies the participant has had that lasted over 6 months.

NOTE: The following questions will be answered for each pregnancy the participant has had that lasted over 6 months. If you are unable to capture specific details in the options provided, there will be space provided at the end of the survey where those details can be recorded (Q16a).

### **First Pregnancy**

- Item 11a. **First pregnancy outcome:** Select only one option among the three possible choices.
- Select 'Live birth' if the pregnancy resulted in a live birth. [Go to 11b]
  - Select 'Stillbirth' if the pregnancy resulted in stillbirth. [Go to 11b]
  - Select 'Multiple gestation' if this was a multiple gestation pregnancy.

- Item 11a1. **Number of babies delivered:** Enter the number of babies the participant delivered as a result of the multiple gestation pregnancy.

- Item 11b. **Date of end of pregnancy:** Enter the date the pregnancy ended or the child's birthdate.

NOTE: If the participant seems unsure about the exact date (particularly for the stillbirths) prompt for the month and year.

- Item 11c. **Length of pregnancy:** Select only one option among the two possible choices.
- Select No if the participant does not know how many weeks pregnant she was at delivery.
  - Select Yes if the participant knows how many weeks pregnant she was at delivery. [Go to Q11d]

Item 11c1. **Delivery early or on time:** Select only one option among the two possible choices.

- Select Early if the participant delivered early.
- Select On time if the participant delivered on time.

NOTE: Skip Q11d if the response to 11c was 'No.'

Item 11d. **Number of weeks pregnant at delivery:** From the seventeen possible choices, select only one option for the number of weeks pregnant the participant was at delivery.

NOTE: Skip Q11e1 if the response for Q11a was stillbirth.

Item 11e1. **Baby's birth weight:** Enter the baby's weight with pounds in 11e1a and ounces in 11e1b.

NOTE: If this was a multiple birth with more than one baby, enter each additional baby's weight in Q11e2 – Q11e5, if applicable.

Item 11f. **Maternal weight gain:** Enter the number of pounds the participant gained over the course of this pregnancy.

NOTE: If the participant is unsure about how much weight she gained during this pregnancy ask her to take her best guess.

Item 11g. **Cigarette smoking during pregnancy:** Select only one option among the two possible choices.

- Select No if the participant did not smoke during this pregnancy.
- Select Yes if the participant did smoke during this pregnancy.

Item 11h. **High blood pressure or hypertension:** Select only one option among the two possible choices.

- Select No if the participant did not have high blood pressure or hypertension during this pregnancy.
- Select Yes if the participant did have high blood pressure or hypertension during this pregnancy.

Item 11i. **Pre-eclampsia, eclampsia, pregnancy induced hypertension, or toxemia:** Select only one option among the two possible choices.

- Select No if the participant did not have pre-eclampsia, eclampsia, pregnancy induced hypertension, or toxemia during this pregnancy.
- Select Yes if the participant did have pre-eclampsia, eclampsia, pregnancy induced hypertension, or toxemia during this pregnancy.

Item 11j. **Gestational diabetes:** Select only one option among the two possible choices.

- Select No if the participant did not have gestational diabetes (i.e. diabetes in pregnancy, high blood sugar) during this pregnancy.
- Select Yes if the participant did have gestational diabetes (i.e. diabetes in pregnancy, high blood sugar) during this pregnancy.

NOTE: If the participant had more than one pregnancy, complete the questions for each additional pregnancy.

After you have completed the responses for the last pregnancy, ask the participant Q16.

Item 16. **Additional details:** Select only one option among the two possible choices.

- Select No if the participant has details to add.
- Select Yes if the participant has no other details to add.

Item 16a. Record any other details from the participant in the space provided.

Save and close the form.