SPIROMICS – HEART FAILURE
INSTRUCTIONS FOR CONSENT TRACKING FORM
HCT, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The SPIROMICS-HF Consent Tracking Form (HCT) is to be completed after obtaining the participant's witnessed signature on the informed consent document during the clinic visit. Key the responses on this screen from that document. If any aspect of consent is modified by the participant at a later date (such as a new restriction) please enter a new HCT form.

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. **Participation agreement:** Select only one option from among the three possible choices.
- Select No if the participant does not agree to participate in SPIROMICS Heart Failure and to share data with SPIROMICS Heart Failure investigators, including those not funded by enrolling institution. [Go to End]
- Select Yes if the participant agrees to participate in SPIROMICS Heart Failure and to share data with SPIROMICS Heart Failure investigators, including those not funded by enrolling institution.

Item 2. **Data use only for research related to COPD and heart disease including both disease progression and susceptibility to exacerbations:** Select only one option among the three possible choices.
- Select No if the participant does not agree to allow data to be used only for research related to COPD and heart disease including both disease progression and susceptibility to exacerbations.
- Select Yes if the participant agrees to allow data to be used only for research related to COPD and heart disease including both disease progression and susceptibility to exacerbations.
- Select 'Not applicable to my site's informed consent form' if this item is not applicable to your site's informed consent form.

Item 3. **Data use for COPD and heart disease and any other type of research:** Select only one option among the three possible choices.
- Select No if the participant does not agree to allow data to be used for COPD and heart disease and any other type of research.

- Select Yes if the participant agrees to allow data to be used for COPD and heart disease and any other type of research.
- Select 'Not applicable to my site's informed consent form' if this item is not applicable to your site's informed consent form.

Item 4. **Data sharing with non-SPIROMICS investigators:** Select only one option among the three possible choices.
- Select No if the participant does not agree to allow data to be shared with non-SPIROMICS and non-SPIROMICS Heart Failure investigators, including those who are not working for the National Heart, Lung, and Blood Institute or on studies not funded by enrolling institution for research purposes.
- Select Yes if the participant agrees to allow data to be shared with non-SPIROMICS and non-SPIROMICS Heart Failure investigators, including those who are not working for the National Heart, Lung, and Blood Institute or on studies not funded by enrolling institution for research purposes.
- Select 'Not applicable to my site's informed consent form' if this item is not applicable to your site's informed consent form.

Item 5. **Data sharing with commercial companies:** Select only one option among the three possible choices.
- Select No if the participant does not agree to allow data to be shared with commercial companies for research purposes.
- Select Yes if the participant agrees to allow data to be shared with commercial companies for research purposes.
- Select 'Not applicable to my site's informed consent form' if this item is not applicable to your site's informed consent form

Item 6. **Sharing important health-related findings with personal doctor:** Select only one option among the three possible choices.
- Select No if the participant does not agree to allow important findings regarding his/her health from the SPIROMICS Heart Failure tests and examinations to be shared with his/her personal doctor.
- Select Yes if the participant agrees to allow important findings regarding his/her health from the SPIROMICS Heart Failure tests and examinations to be shared with his/her personal doctor.
- Select 'Not applicable to my site's informed consent form' if this item is not applicable to your site's informed consent form.

Item 7. **Gadolinium use:** Select only one option among the three possible choices.
- Select No if the participant does not agree to receive gadolinium as part of the MRI.
- Select Yes if the participant agrees to receive gadolinium as part of the MRI.
- Select 'Not applicable to my site's informed consent form' if this item is not applicable to your site's informed consent form.

Save and close the form.