INSTRUCTIONS FOR EXACERBATION SUBSTUDY
INFORMED CONSENT TRACKING FORM
ECT, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Exacerbation Substudy Informed Consent Tracking Form (ECT) is to be completed by the clinical coordinator or study team member after obtaining the participant's witnessed signature on the informed consent document during the Exacerbation Substudy Visit 1. This form should not be completed by the participant. There should only be one form completed per participant.

If any aspect of consent is modified by the participant at a later date (such as a new restriction) please update the collection date (item 0a) and the staff code (item 0b) fields to reflect the time of that change and who recorded the change.

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. The Exacerbation Substudy Informed Consent Tracking form is to be filled out by trained study personnel and should be the first item administered for the Exacerbation Substudy. A signed informed consent means the patient fully understands the requirements of the procedures and assessments included in the study as well as the risks of those procedures/assessments. It is important that the patient fully comprehends the time commitment required for participation, as well as the potential implications of specimen storage and dissemination of study findings.

Item 1. **Participation agreement:** Select only one option among the two possible choices.
- Select No if the participant **does not agree** to participate in the Exacerbations substudy. [Go to END]
- Select Yes if the participant **agrees** to participate in the Exacerbations substudy.

Item 2. **Data and biospecimen use:** Select only one option among the two possible choices.
- Select "Only COPD research" if the participant agrees to allow data and biospecimens collected to be used for **only** COPD research.
- Select "COPD and any other type of research" if the participant agrees to allow data and biospecimens collected to be used for COPD research **and** other types of research.

Item 3. **Data sharing with non-SPIROMICS investigators:** Select only one option among the two possible choices.
- Select No if the participant **does not agree** to allow data to be shared with non-SPIROMICS investigators.
- Select Yes if the participant **agrees** to allow data to be shared with non-SPIROMICS investigators.

Item 4. **Data sharing with commercial companies:** Select only one option among the two 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.

Item 5. **Biospecimen long-term storage and usage:** Select only one option among the two possible choices.
- Select No if the participant **does not agree** to allow biospecimens to be stored long-term and used for future research purposes not defined in the consent form.
- Select Yes if the participant **agrees** to allow biospecimens to be stored long-term and used for future research purposes not defined in the consent form.

Item 6. **Non-genetic biospecimen sharing with non-SPIROMICS investigators:** Select only one option among the two possible choices.
- Select No if the participant **does not agree** to allow non-genetic biospecimens to be shared with non-SPIROMICS investigators for research purposes.
- Select Yes if the participant **agrees** to allow non-genetic biospecimens to be shared with non-SPIROMICS investigators for research purposes.

Item 7. **Non-genetic biospecimen sharing with commercial companies:** Select only one option among the two possible choices.
- Select No if the participant **does not agree** to allow non-genetic biospecimens to be shared with commercial companies for research purposes.
- Select Yes if the participant **agrees** to allow non-genetic biospecimens to be shared with commercial companies for research purposes.

Item 8. **Genetic material (DNA/RNA) storage and usage:** Select only one option among the two possible choices.
- Select No if the participant **does not agree** to allow biospecimens to be used to obtain genetic material (DNA/RNA) to be stored and used by SPIROMICS investigators.
- Select Yes if the participant **agrees** to allow biospecimens to be used to obtain genetic material (DNA/RNA) to be stored and used by SPIROMICS investigators.

Item 9. **Genetic material (DNA/RNA) sharing with non-SPIROMICS investigators:** Select only one option among the two possible choices.
- Select No if the participant **does not agree** to share biospecimens to be used to obtain genetic material (DNA/RNA) and those data with non-SPIROMICS investigators for research purposes.
- Select Yes if the participant **agrees** to share biospecimens to be used to obtain genetic material (DNA/RNA) and those data with non-SPIROMICS investigators for research purposes.

Item 10. **Genetic material (DNA/RNA) sharing with commercial companies:** Select only one option among the two possible choices.

- Select No if the participant **does not agree** to share biospecimens to be used to obtain genetic material (DNA/RNA) and those data with commercial companies for research purposes.
- Select Yes if the participant **agrees** to share biospecimens to be used to obtain genetic material (DNA/RNA) and those data with commercial companies for research purposes.

Item 11. **Sharing important health-related findings with personal doctor:** Select only one option among the two possible choices.

- Select No if the participant **does not agree** to allow important findings regarding their health from the SPIROMICS II Exacerbation Substudy Visit 1 and Visit 2 tests and examinations to be communicated to his/her personal doctor.
- Select Yes if the participant **agrees** to allow important findings regarding their health from the SPIROMICS II Exacerbation Substudy Visit 1 and Visit 2 tests and examinations to be communicated to his/her personal doctor.

Save and close the form.