



INSTRUCTIONS FOR INFORMED CONSENT TRACKING FORM ITF, VERSION 4.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Informed Consent Tracking Form is completed after obtaining the participant's witnessed signature on the informed consent document during the clinic visit or obtaining verbal consent if participant is doing a comprehensive phone contact. 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 ITF 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.

0c. Contact Type: Select only one option among the three possible choices.

- Select 'In person visit' if the consent was signed during an in person visit. [Go to Q1]
- Select 'Comprehensive phone contact' if participant is verbally consented over the phone during the comprehensive phone contact.
- Select 'Other' if participant requests a consent change during contact other than those listed above. [Go to Q1 after specifying other contact type in Q0c1]

0c1. Other: If the answer to 0c is 'Other' please specify. [Go to Q1]

0d. Reason for comprehensive phone contact: Select only one option among the four possible choices.

- Select 'Participant refused in person visit due to time commitment' if the participant refused in person visit due to time commitment.
- Select 'Participant refused in person visit due to illness/injury' if participant refused in person visit due to illness/injury.
- Select 'Participant moved; and unable to transfer to another SPIROMICS clinical center' if participant moved and is unable to transfer to another SPIROMICS clinical center.
- Select 'Other' if this is a comprehensive phone contact for a reason other than those listed above.

0d1. Other: If the answer to 0d is 'Other' please specify.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

NOTE: If this is a comprehensive phone contact, complete ONLY items 1, 2, 3, 4, 10, and 12.

Item 1. **Participant agrees to participate:** Select only one option among the two possible choices.

- Select No if the subject does not agree to participate in in SPIROMICS and to share data and biological specimens (if collected), excluding DNA, with SPIROMICS investigators, including those not funded by enrolling institution. [Go to End]
 - Select Yes if the subject agrees to participate in in SPIROMICS and to share data and biological specimens (if collected), excluding DNA, with SPIROMICS investigators, including those not funded by enrolling institution.
- Item 2. **Types of research agrees to participate in:** Select only one option among the two possible choices.
- Select 'Only COPD Research' if the subject agrees to allow data and biological specimens (if collected) to be used for only COPD research.
 - Select 'COPD and any other type of research' if the subject agrees to allow data and biological specimens (if collected) to be used for COPD and any other type of research.
- Item 3. **Participant agrees to allow data to be shared with non-SPIROMICS investigators:** Select only one option among the two possible choices.
- Select No if the subject does not agree to allow data to be shared with non-SPIROMICS investigators
 - Select Yes if the subject agrees to allow data to be shared with non-SPIROMICS investigators.
- Item 4. **Participant agrees to allow data to be shared with commercial companies for research purposes:** Select only one option among the two possible choices.
- Select No if the subject does not agree to allow data to be shared with commercial companies for research purposes.
 - Select Yes if the subject agrees allow data to be shared with commercial companies for research purposes.
- Item 5. **(Do not complete for comprehensive phone contact) Participant agrees to allow biological specimens collected to be stored and used for research purposes:** Select only one option among the two possible choices.
- Select No if the subject does not agree to allow biological specimens collected to be stored and used for research purposes.
 - Select Yes if the subject agrees to allow biological specimens collected to be stored and used for research purposes.
- Item 6. **(Do not complete for comprehensive phone contact) Participant agrees non-genetic biological specimens may be shared with non-SPIROMICS investigators for research purposes:** Select only one option among the two possible choices.
- Select No if the subject does not agree to non-genetic biological specimens being shared with non-SPIROMICS investigators for research purposes
 - Select Yes if the subject agrees to non-genetic biological specimens being shared with non-SPIROMICS investigators for research purposes.
- Item 7. **(Do not complete for comprehensive phone contact) Participant agrees to non-genetic biological specimens may be shared with commercial companies for research purposes:** Select only one option among the two possible choices.
- Select No if the subject does not agree to non-genetic biological specimens being shared with commercial companies for research purposes.
 - Select Yes if the subject agrees to non-genetic biological specimens being shared with commercial companies for research purposes.

- Item 8a. **(Do not complete for comprehensive phone contact) Participant agrees to allow blood to be used to obtain genetic material (DNA/RNA) to be stored for future use by SPIROMICS;** Select only one option among the two possible choices.
- Select No if the subject does not agree to allow blood to be used to obtain genetic material (DNA/RNA) to be stored for future use by SPIROMICS.
 - Select Yes if the subject agrees to allow blood to be used to obtain genetic material (DNA/RNA) to be stored for future use by SPIROMICS.
- Item 8b. **(Do not complete for comprehensive phone contact) Participant agrees to allow sputum to be used to obtain genetic material (DNA/RNA) to be stored for future use by SPIROMICS;** Select only one option among the two possible choices.
- Select No if the subject does not agree to allow sputum to be used to obtain genetic material (DNA/RNA) to be stored for future use by SPIROMICS.
 - Select Yes if the subject agrees to allow sputum to be used to obtain genetic material (DNA/RNA) to be stored for future use by SPIROMICS.
- Item 9. **(Do not complete for comprehensive phone contact) Participant agrees to allow important findings regarding his/her health from SPIROMICS tests and examinations to be shared with his/her personal doctor:** Select only one option among the two possible choices.
- Select No if the subject does not agree to allow important findings regarding his/her health from SPIROMICS tests and examinations to be shared with his/her personal doctor.
 - Select Yes if the subject agrees to allow important findings regarding his/her health from SPIROMICS tests and examinations to be shared with his/her personal doctor.
- Item 10. **Participant agrees to allow SPIROMICS staff and investigators to contact him/her regarding participating in additional future research studies:** Select only one option among the two possible choices.
- Select No if the subject does not agree to allow SPIROMICS staff and investigators to contact him/her regarding participating in additional future research studies.
 - Select Yes if the subject agrees to allow SPIROMICS staff and investigators to contact him/her regarding participating in additional future research studies.
- Item 11. **(Do not complete for comprehensive phone contact) Confirmation of printed copy:** Select only one option among the two possible choices.
- Select No if the staff member cannot confirm that the subject was given a printed copy of the signed informed consent.
 - Select Yes if the staff member can confirm that the subject was given a printed copy of the signed informed consent .
- Item 12. **Confirmation of no previous participation:** Select only one option among the two possible choices.
- Select No if you did not confirm that the participant did not participate in any SPIROMICS II study related activities or procedures prior to signing (or agreeing to via phone if not in person) the informed consent.
 - Select Yes if you did confirm that the participant did not participate in any SPIROMICS II study related activities or procedures prior to signing (or agreeing to via phone if not in person) the informed consent.

Save and close the form.