INSTRUCTIONS FOR INCLUSION/EXCLUSION CRITERIA
IEC, VERSION 3.0 (QxQ)

I. GENERAL INSTRUCTIONS

The Inclusion/Exclusion Criteria Form should be keyed immediately after the participant signs the informed consent. This form, along with spirometry data, determines the participant's eligibility.

Please Note: In order for a patient to be considered 'screened,' the IEC form must be entered into DMS, and all questions must be populated.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form.

FORM DATE: Record date this is being completed. Select the date from the pop up calendar or type in the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

INITIALS: Record the staff code of the person entering the data on this form. 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.

In order to determine a patient's eligibility, all of the questions on the IEC form must be answered

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Read the instructions as they are written to the participant. Each question should be read exactly as written to allow for consistency in screening data collection.

Item1.   Enter the patient's age. Between the age of 40 and 80 (inclusive) is eligible.

Item2.   Select 'Yes' if the participant has smoked at least 100 cigarettes in his/her life. Select 'No' if the participant has not smoked at least 100 cigarettes in his/her life. If 'Yes' go to item 2a; if 'No' the form will skip to item 3.

Item2a.   Enter the number of years smoked.

Item2b.   Enter the number of packs of cigarettes smoked each day.

Item2c.   The DMS will calculate the number of pack years smoked by the participant and automatically populate the field.

Item3.   This question asks about a diagnosis of COPD, emphysema or chronic bronchitis at any point in the participant's life. Select 'Yes' or 'No'.

Item4.   Do not ask this question to the participant. Select 'Male' or 'Female.' If 'Male' the form will skip to item 5.

Item4a.   Select 'Yes' or 'No.' If 'Yes' she will need to be on adequate birth control in order to be eligible.

Item4b.   Select 'Yes' or 'No.' If 'Yes' she will need to take a pregnancy test in order to determine eligibility. If 'No' she will need to be on adequate birth control in order to eligible.

Item4c. Enter 'Yes' or 'No.' No is eligible.

Item5a. Enter the patient's height in inches. Round to the nearest inch.

Item5b. Enter the patient's weight in pounds. Round to the nearest tenth of a pound.

Item5c. The DMS will automatically calculate the patient's BMI.

If the participant's self-reported BMI is greater than 35 but less than 40 it is recommend that, if the participant passes the rest of the eligibility criteria, the coordinator collect the ANT immediately to obtain a BMI based on measured height and weight. A participant whose measured BMI is greater than 40 does not qualify for the study, even if their self-reported BMI was less.

Item6. Carefully read out loud the instructions and all the questions regarding different lung conditions. If **any** of the statements apply to the participant select 'Yes.' 'No' is eligible.

Item7. Carefully read out loud the instructions and all the questions regarding other medical conditions. If **any** of the statements apply to the participant select 'Yes.' 'No' is eligible.

Item8. Carefully read out loud the instructions and all the questions regarding past medical procedures. If **any** of the statements apply to the participant select 'Yes.' 'No' is eligible.

Item9. Carefully read out loud the instructions and all the questions regarding certain medications and drug usage. If **any** of the statements apply to the participant select 'Yes.' 'No' is eligible.

For the purposes of this question, current is defined as within the last 30 days. If the participant queries, you may clarify this but only if the participant asks. For the purposes of this questionnaire, marijuana is not considered an illegal drug regardless of the laws of a specific state.

Item10a. Select 'Yes' or 'No.' If 'No' the form will skip to item 11. If 'Yes' provide information regarding specifics of immunosuppressives in the space provided on item 10b.

Item10b. List all immunosuppressives the participant is currently taking.

Item10c. Do not read this question out loud to the participant. Select 'Yes' or 'No.' Please see MOP 1 for a list of exclusionary immunosuppressives.

Item11. Carefully read out loud the instructions and all the questions regarding other conditions that effect eligibility. If **any** of the statements apply to the participant select 'Yes.' 'No' is eligible.

Item12. Carefully read out loud the instructions and all the questions regarding conditions that may have occurred over the past six weeks. If **any** of the statements apply to the participant select 'Yes.' 'No' is eligible. If 'Yes' is selected the participant is currently ineligible and will need to be re-screened after six-weeks have passed from the current screening date.

If the participant has had a biopsy in the last six weeks, that will be included under the temporary exclusion criteria, "Have you had eye, chest, or abdominal surgery within the past six weeks?"

Item13. Carefully read out loud the instructions and all the questions regarding conditions that may have occurred over the past 30 days. If **any** of the statements apply to the participant select 'Yes.' 'No' is eligible. If 'Yes' is selected the participant is currently ineligible and will need to be re-screened after 30 days have passed from the current screening date.

Item14.   Only present this question to female participants. If the response is 'Yes' she will need to be re-screened after 3 months have passed from the current screening date. 'No' is eligible today.

Item15a. Select 'Yes' if the participant has been diagnosed with any other heart or lung disease not covered in the previous questions on this form. If 'Yes' provide details in item 15b. If 'No' the form will skip to item 16.

Item15b. Use the space provided to give details provided by the participant.

Item15c. Do not ask the participant this question. If the heart and/or lung disease described results in the ineligibility of the participant select 'Yes.' Otherwise, select 'No.'

Item16a. Select 'Yes' if the participant has ever had any other type of lung surgery not covered in the previous questions on this form. If 'Yes' provide details in item 16b. If 'No' the form will skip to item 17.

Item16b. Use the space provided to give details provided by the participant.

Item16c. Do not ask the participant this question. If the lung surgery described results in the ineligibility of the participant select 'Yes.' Otherwise, select 'No.'

Item17a. Select 'Yes' if the participant has any other significant illness not covered in the previous questions on this form. If 'Yes' provide details in item 17b. If 'No' the form will skip to Item 18.

Item17b. Use the space provided to give details provided by the participant.

Item17c. Do not ask the participant this question. If the illness described results in the ineligibility of the participant select 'Yes.' Otherwise, select 'No.'

Item18a. Select 'Yes' if the participant has any metal implants in the chest. If 'Yes' provide details in item 18b. If 'No' the form will skip to Item 19.

Item18b. Use the space provided to give details provided by the participant.

Item18c. Do not ask the participant this question. If the metal implant listed in 18b makes the participant ineligible select 'Yes'. Otherwise, select 'No'.

Item19a. Select 'Yes' if the participant is currently undergoing chemotherapy or radiation treatments. Otherwise select 'No'.

Item19b. Use the space provided to give details provided by the participant.

Item19c. Do not ask the participant this question. If the chemotherapy or radiation treatment listed in 19b makes the participant ineligible select 'Yes'. Otherwise select 'No'.

Item20a. Select 'Yes' if the participant is currently enrolled in another clinical trial or research study. Otherwise select 'No'. If the response is 'Yes' answer questions 20b and 20c.

Item20b. Briefly describe the other clinical trial/research study the participant is currently enrolled in.

Item20c. Select 'Yes' if the participant is part of the control group in the current study. Otherwise select 'No', 'Unknown' or 'Does not apply'.

Item20d. Do not ask the participant this question. If the study described in 20b makes the participant ineligible select 'Yes'. Otherwise select 'No'.

Item21. Select 'Yes' if the participant is currently or ever enrolled in the COPDGene Study. Otherwise select 'No'. 'Yes' is ineligible.

Item22. Select 'Yes' if the participant has ever been diagnosed with asthma. Otherwise select 'No'. 'Yes' is ineligible for non-smokers (Stratum 1).