SOURCE
SPIROMICS Study of Early COPD Progression

CLINICALLY SIGNIFICANT FINDINGS FORM

ID NUMBER:									

FORM CODE: CSF
VERSION: 1.0 07/26/2022

Event: _____

0a) Date of Collection: ☐☐ / ☐☐ / ☐☐☐☐ 0b) Staff Code: ☐☐☐

Instructions: *All pertinent test results should be reviewed for abnormal findings. This form should be completed during the participant's clinic visit in order to identify findings that require urgent follow-up and therefore would need to be communicated by phone or equivalent method to allow for close follow-up with the participant's healthcare team to further evaluate these findings. Other abnormal findings should also be communicated to the participant or their physician. The methods of that communication can be at the discretion of the local PI/IRB.*

1) Does the participant have either or both of the following blood abnormalities that requires immediate contact by phone or equivalent?

☐ No$_0$ → **Go to 2**
☐ Yes$_1$

If Yes, please check all that apply.

1a) ☐ Hemoglobin concentration < 10 g/dl

1b) ☐ Platelet count < 100 k/microL

1c) Did the site PI or other study staff successfully contact the participant about these values and convey plans to provide a copy of abnormal values to participant and medical provider?

☐ No$_0$
☐ Yes$_1$

1c1) If No, please specify: _____

1c2) If Yes, when was the participant contacted? ☐☐ / ☐☐ / ☐☐☐☐

2) HADS Depression Score: ☐☐

NOTE: This field will populate based on the HADS depression score calculated from the HDS (i.e., even numbered questions).

If the participant's Hospital Anxiety and Depression Scale (HADS) depression score is ≥ 15, immediate contact by phone or equivalent is required. If the participant's depression score is < 15, go to item 3.

2a) Did the site PI or other study staff successfully contact the participant about these values and convey plans to provide information about the abnormal values to the participant and medical provider?

☐ No$_0$
☐ Yes$_1$

2a1) If No, please specify: _____

2a2) If Yes, when was the participant contacted? ☐☐/☐☐/☐☐☐☐

3) Does the participant have any of the following CT findings that require immediate contact by phone or equivalent?

☐ No$_0$ → **Go to 4**
☐ Yes$_1$

If Yes, please check all that apply.

3a) ☐ Aortic aneurysm > 45 mm

3b) ☐ Dense aortic valve calcification

3c) ☐ Lung nodules or masses with the following characteristics based upon findings consistent with LungRADS "Suspicious" categorization:

- solid nodules ≥ 6 mm if new, ≥ 8 mm if present at baseline, or if present at baseline and growing for any size
- partially solid nodules ≥ 6 mm with solid component ≥ 6 mm, or with new or growing solid component of any size
- endobronchial nodules

3d) ☐ Pneumonia or imaging finding strongly suspicious for pneumonia

3e) ☐ Large pericardial or pleural effusion

3f) ☐ Other finding needing urgent follow-up

3f1) If Other, please specify_____

3g) Did the site PI or other study staff successfully contact the participant about these values and convey plans to provide information about the abnormal values to the participant and medical provider?

☐ No$_0$
☐ Yes$_1$

3g1) If No, please specify: _____

3g2) If Yes, when was the participant contacted? ☐☐/☐☐/☐☐☐☐

4) Does the participant have any other finding that requires immediate contact by phone or equivalent?

☐ No$_0$ → **Go to 5**
☐ Yes$_1$

4a) If Yes, please indicate the findings below.

4a1) _____

4a2) _____

4a3) _____

4b) Did the site PI or other study staff successfully contact the participant about these values and convey plans to provide information about the abnormal values to the participant and medical provider?

☐ No$_0$
☐ Yes$_1$

4b1) If No, please specify: _____

4b2) If Yes, when was the participant contacted? ☐☐ / ☐☐ / ☐☐☐☐

5) Did a PI review and sign off on this form?

☐ No$_0$ → **Go to End**
☐ Yes$_1$

5a) PI signature: _____

5b) Date of PI signature: ☐☐ / ☐☐ / ☐☐☐☐

END OF FORM