EXACERBATION PHONE VISIT FORM (BASELINE)

ID NUMBER:									

FORM CODE: EPV
VERSION: 1.0 03/03/2021

Event: _____

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

Instructions: *This form should be completed primarily over the phone for the participant's Exacerbation Substudy Phone Visit at Baseline. Please note that items 1 and 2 are populated based on the TEA data collection form entry.*

1) Date of phone contact ☐☐ / ☐☐ / ☐☐☐☐

2) Date symptoms first started ☐☐ / ☐☐ / ☐☐☐☐

3) Was the participant able to self-collect samples within seven days of exacerbation event onset?

☐ No$_0$ → **End Form**

☐ Yes$_1$

4) Are the exacerbation event symptoms ongoing?

☐ No$_0$

☐ Yes$_1$ → **Go to 5**

4a) If No, when did the exacerbation event symptoms stop? ☐☐ / ☐☐ / ☐☐☐☐

4b) Has it been more than 48 hours since the exacerbation event symptoms stopped?

☐ No$_0$

☐ Yes$_1$ → **End Form; participant does not meet inclusion criteria for Exacerbation Phone Visit.**

Review of Symptoms

5) Since the start of your exacerbation event symptoms, have you experienced an increase and/or change in the following **major** symptoms for at least two or more consecutive days?

	No$_0$	Yes$_1$
5a) Shortness of breath	☐	☐
5b) Change in sputum discharge color (yellow/green)	☐	☐
5c) Sputum volume	☐	☐

6) Since the start of your exacerbation event symptoms, have you experienced an increase in the following **minor** symptoms for at least two or more consecutive days?

	No$_0$	Yes$_1$
6a) Nasal discharge	☐	☐
6b) Wheeze	☐	☐
6c) Sore throat	☐	☐
6d) Cough	☐	☐
6e) Fever	☐	☐

Review of Vital Signs

7) Are you able to take your temperature?

☐No$_0$ → **Go to 8**
☐Yes$_1$

7a) Temperature: ☐☐☐.☐° F

8) Are you able to measure your oxygen saturation level?

☐No$_0$ → **Go to 9**
☐Yes$_1$

8a) Oxygen saturation: ☐☐☐ %

8b) Do you currently use supplemental oxygen?

☐No$_0$ → **Go to 9**
☐Yes$_1$

8b1) Is this a newly prescribed oxygen therapy?

☐No$_0$
☐Yes$_1$

8b2) Is it an increase to your usual oxygen therapy?

☐No$_0$
☐Yes$_1$

Exacerbation Event Determination

*Definition: A probable exacerbation event is defined as an increase in two or more major symptoms **or** one major symptom and two minor symptoms.*

9) Is this a probable exacerbation event based on the above definition?

☐ No$_0$ → **Go to 10**
☐ Yes$_1$

9a) If Yes, what is the event duration to date?

- ☐ Less than 1 day$_1$
- ☐ 1-2 days$_2$
- ☐ 3-5 days$_3$
- ☐ 1 week$_4$
- ☐ More than 1 week$_5$

9b) Suspected cause (etiology)

- ☐ Infection$_1$
- ☐ Weather$_2$
- ☐ Treatment non-compliance$_3$
- ☐ Unknown$_4$

10) Have you been **tested** for COVID-19 as part of this illness?

- ☐ No$_0$ → **Go to 11**
- ☐ Yes$_1$
- ☐ Unsure$_2$ → **Go to 11**

10a) If Yes, what was the result?

- ☐ Negative$_0$
- ☐ Positive$_1$
- ☐ Unsure$_2$

11) Have you been in contact with anyone with COVID-19 in the last two weeks?

- ☐ No$_0$
- ☐ Yes$_1$
- ☐ Unsure$_2$

12) Have you been **vaccinated** against COVID-19?

- ☐ No$_0$ → **Go to 13**
- ☐ Yes$_1$
- ☐ Unsure$_2$ → **Go to 13**

12a) If Yes, when were you vaccinated: ☐☐ / ☐☐ / ☐☐☐☐

Sample Collection Tracking

13a) Did the participant collect and freeze the self-collected spontaneous sputum sample within seven days of exacerbation event onset?

- ☐ No$_0$
- ☐ Yes$_1$

13b) Did the participant collect the nasal swab sample within seven days of exacerbation event onset?

☐ No$_0$

☐ Yes$_1$

13c) Did the participant collect the dried blood spot sample within seven days of exacerbation event onset?

☐ No$_0$

☐ Yes$_1$

Exacerbation Event Treatment

14) Was the participant's clinical treatment or medication(s) changed?

☐ No$_0$ → **Go to 15**

☐ Yes$_1$

If Yes, Complete items 14a-14g.

14a) Antibiotics

☐ No$_0$ → **Go to 14b**

☐ Yes$_1$

14a1) If Yes, please specify: _____

14a2) Number of days prescribed: ☐☐☐

14b) Oral glucocorticosteroids

☐ No$_0$ → **Go to 14c**

☐ Yes$_1$

14b1) Number of days prescribed: ☐☐☐

14c) New inhaled glucocorticosteroid

☐ No$_0$ → **Go to 14d**

☐ Yes$_1$

14c1) Number of days prescribed: ☐☐☐

14d) Increased inhaled glucocorticosteroid dosage

☐ No$_0$ → **Go to 14e**

☐ Yes$_1$

14d1) Number of days prescribed: ☐☐☐

14e) Methylxathines (new)

☐ No$_0$ → **Go to 14f**

☐ Yes$_1$

14e1) Number of days prescribed: ☐☐☐

14f) ß$_2$-agonists (short-acting) (new or increased)

☐ No$_0$ → **Go to 14g**

☐ Yes$_1$

14f1) Number of days prescribed: ☐☐☐

14g) Other significant clinical treatments or medications

☐ No$_0$ → **Go to 15**

☐ Yes$_1$

14g1) If Yes, please specify: _____

14g1a) Number of days prescribed: ☐☐☐

14g2) If Yes, please specify: _____

14g2a) Number of days prescribed: ☐☐☐

14g3) If Yes, please specify: _____

14g3a) Number of days prescribed: ☐☐☐

14g4) If Yes, please specify: _____

14g4a) Number of days prescribed: ☐☐☐

NOTE: The Exacerbation Phone Visit may end at this point and item 15 completed and entered at a later time if you are unable to communicate with the reviewing physician right away.

Physician Review

15) Does the reviewing physician suspect any conditions other than or in addition to Acute Exacerbation COPD (AECOPD)?

☐ No$_0$ → **Go to End**

☐ Yes$_1$

If Yes, please specify the conditions that were ruled out.

15a) ☐ Pneumonia

15b) ☐ Acute Respiratory Failure

15c) ☐ Other

15c1) If Other, please specify: _____

END OF FORM