

Safety Assessment

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Coordinator: Ask the subject to answer each question below before you administer albuterol to the subject and have the subject perform the 6-min walk test and the sit to stand test.

Vitals:

1. Blood Pressure

Note: If BP is greater than 170/100, then contact the physician investigator before you proceed.

Systolic 1

_____ (nn or nnn)

Diastolic 1

_____ (nn or nnn)

Systolic 2

_____ (nn or nnn)

Diastolic 2

_____ (nn or nnn)

Systolic 3

_____ (nn or nnn)

Diastolic 3

_____ (nn or nnn)

2. Resting SaO2 (%)

Per protocol, for subjects using supplemental oxygen, the oxygen needs to be withheld and subjects breathe room air for 10 minutes prior to recording oxygen saturation.

If the subject is not willing to stop oxygen to do this test, leave this measure blank and check the box below.

_____ (% (max 100%))

Subject was unwilling to stop supplemental oxygen.

Subject unwilling

3. Heart rate

Note: If HR is less than 50 bpm or greater than 120 bpm, then contact the physician investigator before you proceed.

_____ (bpm)

Safety questions

1. Have you ever had albuterol (albuterol, Combivent, DuoNeb, Proventil, ProAir, Ventolin, Xopenex) prescribed by a physician?

- Yes
 No

2. Have you ever had an allergic or adverse reaction to albuterol or another inhaled bronchodilator?

- Yes
 No
(Coordinator: If yes, DO NOT administer Albuterol. Contact the physician investigator.)

If yes, what was the reaction?

3. Have you been diagnosed with abnormal heart rhythm? (For example: Arrhythmia, Atrial Fibrillation, Atrial Flutter)

- Yes
 No
(Coordinator: If Yes, contact the physician investigator before you proceed with administering albuterol. Share any medications the subject may be on for the condition with the physician.)

a. If yes, what diagnosis did you get?

b. In what year did you get this diagnosis?

4. Have you been told by a physician that you have heart disease? (For example: Angina, Congestive Heart Failure, Heart Attack, Stroke).

- Yes
 No
(Coordinator: If Yes, contact the physician investigator before you proceed with administering albuterol. Share any medications the subject may be on for the condition with the physician.)

a. If yes, what diagnosis did you get?

b. In what year did you get this diagnosis?

5. In the last three months, have you had chest pain or discomfort?

- Yes
 No
(Coordinator: If Yes, contact the physician investigator before you proceed with administering albuterol. Share any medications the subject may be on for the condition with the physician.)

6. Does the subject have any contraindications to performing the sit to stand test, such as fear of falling, or lower extremity impairments?

- Yes
 No

(Coordinator: If Yes, contact the physician investigator before you proceed with Sit-to-stand test.)

Coordinator:

This subject has potential safety concerns. Please consult the Physician Investigator.

1. Does the subject have any safety concerns?
- Subject has no safety concerns. Albuterol to be given. Spirometry, 6-min walk and sit to stand test to be done according to protocol
 - Subject has safety issues. These were reviewed with the COPD Gene Investigator.

2. If yes, review with physician investigator.

- a. Proceed with visit or reschedule
- Ok to proceed with visit
 - Study visit will be rescheduled pending evaluation by personal physician

b. Which procedures may be performed (if okay to proceed with visit)

	Ok to Proceed	Not Ok
Spirometry	<input type="radio"/>	<input type="radio"/>
Albuterol, post-BD spirometry & DLco	<input type="radio"/>	<input type="radio"/>
6-minute walk	<input type="radio"/>	<input type="radio"/>
Sit to Stand	<input type="radio"/>	<input type="radio"/>