



Participant ID:

Participant Initials:

Site:

RC ID:

CRF Date:

SPIROMETRY ASSESSMENT

Time at start of assessment: _____ : _____ (military time)

A. Assessment of eligibility to do spirometry

1. Blood pressure on today's exam of systolic > 180 mmHg or diastolic > 110mmHg? Yes No
2. Heart Rate < 50 or > 110 today? Yes No
3. Pregnant or positive pregnancy test? Yes No
4. Has the participant had any of the following in the past 3 months:
 - a. Major surgery (chest, abdomen, or brain)? Yes No
 - b. Eye surgery? Yes No
 - c. Heart attack? Yes No
 - d. Stroke or diagnosis of aneurysm of the brain? Yes No
5. Oral surgery within the past two weeks? Yes No
6. New chest pain within the past week? Yes No

If answers are **YES** to question 1-6, **DO NOT PERFORM SPIROMETRY**. Otherwise, please answer questions 7a-d and the participant may proceed to perform spirometry.

B. Recent inhaler or nebulizer use

7. Does the participant use one or more inhaled medications for breathing? Yes No
IF NO SKIP QUESTIONS 7a-d
 - a. Did the participant use a short-acting/rescue inhaler or nebulizer treatment today? (Refer to the pulmonary medications list) Yes No



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If **YES**, please specify the medications. If **NO**, skip to question 7c.

Medication(s): _____

b. If **YES**, what was the time of the participant's most recent dose?

____:____ (record using military time)

c. Did the participant use a long-acting bronchodilator inhaler or nebulizer treatment in the past 24 hours? (Refer to the pulmonary medications list)

Yes No

If **YES**, please specify the medications. If **NO**, skip to question 8.

Medication(s): _____

d. If **YES**, what was the time of the participant's most recent dose?

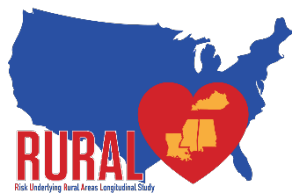
____:____ (record using military time)

If answer to question 7 is **YES**, please make sure to write a comment recording what medication and when the last time the participant used the medication on the spirometry comment section.

C. Baseline spirometry completion

8. Was spirometry completed?

Yes No



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a. If **NO**, please select a reason:

- Protocol exclusion
- Participant refused
- Equipment malfunction
- MEU malfunction
- Weather not permitting outdoor spirometry protocol
- Other (please specify): _____

D. Spirometry results to assess eligibility for bronchodilator testing

9. Did baseline spirometry meet acceptability and reproducibility criteria? Yes No
10. FEV1 % predicted: _____ %
11. FEV1/FVC ratio: _____
12. FEV1/FVC ratio lower limit of normal (as reported on spirometry results screen): _____
13. Was FEV1/FVC < 70% or FEV1/FVC ratio less than the lower limit of normal (LLN) or FEV1 < 80% of the predicted value? Yes No

If answer to questions 9 and 13 is YES, then proceed to screening for bronchodilator testing. If NO to either questions 9 or 13, then form is complete and DO NOT proceed to screening for bronchodilator testing.

E. Medical and medication criteria to assess eligibility for bronchodilator testing

If participant **successfully** performed the spirometry and participant has **FV1/FVC < 70% or FEV1/FVC ratio less than the lower limit of normal (LLN) or FEV1 is < 80% of the predicted value**, please complete the following questions:

14. History of episodic tachycardia, atrial fibrillation, or other heart rhythm problems that have required medical treatment? Yes No



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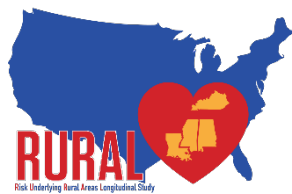
(NOTE: Chronic atrial fibrillation with an irregular rhythm and heart rate \leq 110 per minute on today's exam is not included)

15. History of ablation for tachycardia or atrial fibrillation? Yes No
16. History of having an adverse reaction to albuterol? Yes No
17. Is the participant breast feeding? Yes No
18. Is the participant taking antiarrhythmic medications?
(These include: *Flecainide, Propafenone, Encainide, Moricizine, Tocainide, Mexiletine, Lidocaine, Procainamide, Disopyramide, Quinidine*) Yes No
19. Is the participant taking monoamine oxidase inhibitors – MAOI?
(These include: *Isocarboxazid, Isoniazid, Nialamide, Phenelzine, Procarbazine, Hydracabazine, Tranylcypromine, Moclobemide, Pirlindole, Toloxatone, Rasagiline, Selegiline*) Yes No
20. Is the participant taking anticonvulsant medication for epilepsy or mood disorder?
(These include: *Phenytoin, Fosphenytoin, Valproic acid, Tevetiracetam, Carbamazepine*) Yes No
21. Is the participant taking tricyclic antidepressants – TCAs?
(These include: *Clomipramine, Imipramine, Desipramine, Nortriptyline, Protriptyline, Amitriptyline, Amoxapine, Doxepin, Trimipramine*) Yes No

If answers are **YES** to any of questions 14-21, **DO NOT PROCEED TO BRONCHODILATOR TESTING**. Otherwise, invite the participant to undergo bronchodilator testing and proceed with administration of albuterol and bronchodilator testing.

F. Post-bronchodilator spirometry completion

22. Was post-bronchodilator spirometry completed? Yes No
- a. If **NO**, please select a reason:
- Protocol exclusion
- Participant refused
- Equipment malfunction



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- MEU malfunction
- Weather not permitting outdoor spirometry protocol
- Unable to administer albuterol
- History of not tolerating albuterol
- Other (please specify): _____

23. Select "yes" if procedure was lost after initially being completed and is not recoverable.

Yes

23a. Please specify reason for loss:

Time at end of assessment:

_____ : _____ (military time)

COMMENTS: _____