

Pulmonary Function Testing Protocol

Framingham Heart Study

Offspring 8 Examination

PFT dataset

PFT - OFFSPRING EXAM 8

PFT EXCLUSION CRITERIA

IN THE PAST 3 MONTHS HAVE YOU HAD:

- MAJOR SURGERY (Chest, abdominal, ^{month or} or brain, requiring hospitalization)?
- HEART ATTACK
- STROKE
- ANEURYSM OF THE BRAIN
- BP>210/110

DO YOU CURRENTLY HAVE ANY LIMITATION
ON PHYSICAL ACTIVITY PRESCRIBED BY
YOUR DOCTOR?

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Framingham Heart Study, Pulmonary Function Testing Manual of Procedures
Overview

Lung Function Testing at the Framingham Heart Study

1. Overview of pulmonary function testing at the Framingham Heart Study

Participants have undergone spirometry, which measures the ability to force air out of the lungs, at each exam cycle since the earliest days of the Original Cohort. Measurement of diffusion capacity, a measure of the lung's ability to exchange oxygen and carbon dioxide, began with the first Examination Cycle of Gen3.

Beginning with Examination 8 of the Offspring Cohort and its concurrent Omni Examination 3, a limited number of participants in each of the cohorts of the Framingham Heart Study will be undergoing post- bronchodilator spirometry, in addition to the pulmonary function testing that all participants undergo. Selection of participants to undergo post- bronchodilator testing is based on evidence of airflow obstruction and will help discriminate between participants with reversible airflow obstruction (i.e., asthma) and those with fixed disease (i.e., chronic obstructive pulmonary disease).

For those undergoing post- bronchodilator testing, the time spent in the Pulmonary Function Testing station will be somewhat longer, as a result of the additional spirometry testing and additional time needed to allow onset of medication effect. Subjects not performing post-bronchodilator spirometry will proceed through the station as follows-

- 1) spirometry
- 2) diffusion effort #1
- 3) questionnaire
- 4) diffusion effort #2. *At least 4 minutes should pass between diffusion maneuvers*

Subjects performing post-bronchodilator spirometry will proceed through the station as follows-

- 1) spirometry
- 2) diffusion effort #1
- 3) questionnaire
- 4) diffusion effort #2 (*at least 4 minutes should pass between diffusion maneuvers*)
- 5) completion of all remaining Cycle 8 exam components (*stations*)
- 6) administration of albuterol with the allowance of no less than 15 minutes and no more than 30 minutes
- 7) post-bronchodilator spirometry

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The timeline below summarizes the differences-

Table 1. Timeline for pulmonary function testing at FHS

	Pre- bronchodilator spirometry	First Diffusion capacity	Questionnaire	Second Diffusion Capacity	Respiratory Questionnaire		
Those doing only pre- bronchodilator spirometry and diffusion							
Those doing pre, post bronchodilator spirometry and diffusion					Bronchodilator Administration	Respiratory Questionnaire	Post- bronchodilator spirometry

2. Subject selection for pre- and post- bronchodilator administration

As noted above, some participants will have spirometry measured before and after inhaling a medication that may relax the airways of those with airflow obstruction. This will help discriminate between participants with reversible airflow obstruction (i.e., asthma) and those with fixed disease (i.e., chronic obstructive pulmonary disease). FHS will use the simple measure of ratio of FEV1-to-FVC; participants with a FEV1-to-FVC ratio of less than 70% (absolute ratio) will be asked to undergo pre- and post- bronchodilator testing.

A. Pre-identified subjects

The majority of subjects undergoing post- bronchodilator spirometry will be pre-identified, in order to more evenly spread the time burden in clinic. Subjects who, at their most recently attended examination with satisfactory spirometry data, meet the criteria below will be scheduled and appropriately identified as candidates for post- bronchodilator spirometry.

Table 2. Criteria for undergoing post- bronchodilator testing

Criteria	FEV1/FVC ratio*
	<70%

*ratio is absolute value, as opposed to percent predicted

B. Subjects identified at current examination

Subjects will also be identified during ongoing examination for eligibility for post- bronchodilator spirometry testing; the criteria for selecting subjects not previously identified will be the same as for pre-identified subjects (Table 3.). Participants meeting these standards will be asked to perform post- bronchodilator testing.

3. Protocol

The methods for each of the pulmonary function maneuvers are detailed in the appendices. The information below is intended as a summary.

A. Subjects not undergoing post- bronchodilator spirometry

1) Pre- bronchodilator spirometry

According to the American Thoracic Society, "spirometry is a medical test that measures the volume of air an individual... exhales as a function of time. Flow, or the rate at which the volume is changing as a function of time, may also be measured with spirometry. Spirometry, like the measurement of blood pressure, is a useful screen of general health." (ATS, Standardization of Spirometry, 1994 Update) During the test, participants will be asked to take a deep breath and then to force the air out as hard and fast as possible. The spirometer will measure these maximal flow rates and also volumes at particular time points. As the results of testing assume that these values are the maximum levels a participant can do, it is imperative that participants are coached to blast the air out of their lungs as hard and fast as possible. For specific instructions on performing the spirometry session, see Appendix 1.

2) Diffusion capacity

As mentioned, diffusion capacity measures the lungs ability to exchange oxygen and carbon dioxide. A gas that does not diffuse from the lung into the blood stream (a tracer gas, methane) and carbon monoxide (CO), which is quickly taken up by the blood, are inhaled at trace amounts. Participants will hold their breath for a fixed amount of time (9-11 seconds), and then exhale. The spirometer will then measure the difference between the CO and tracer gas as they are exhaled. This difference is due to the diffusion of CO and, as the time interval is known, we can calculate the rate of transfer. It is important that the participants take a deep breath (90% of their vital capacity). Ideally, at least 2 maneuvers should be performed and should agree within 10%. At least 4 minutes should be allowed between diffusion maneuvers to allow sufficient time for the CO and tracer gas to wash out. The average of 2 acceptable maneuvers is reported. For complete instructions on using the spirometer to obtain diffusion maneuvers, see Appendix 2.

3) Questionnaire

Technicians will also administer a respiratory questionnaire. The questionnaire will help investigators to understand whether the

participant has allergies, asthma v. COPD, and other pulmonary diseases. Further, the questionnaire will capture information on recent inhaler use, as it may affect the post-bronchodilator spirometry, and prompt technicians to administer post-bronchodilator spirometry.

B. Subjects undergoing post- bronchodilator spirometry

Subjects undergoing post-bronchodilator spirometry will move through the Pulmonary Function Testing station exactly as those not undergoing the post-bronchodilator spirometry, except that after completing all Cycle 8 exam components they will receive two puffs of albuterol, then repeat the spirometry (which is done exactly as the pre-bronchodilator spirometry). Their schedule is described below.

1) Pre- bronchodilator spirometry

2) Diffusion capacity

3) Questionnaire

The respiratory questionnaire will be modified to ask about most recent use of inhaled medications, particularly the beta agonists such as albuterol. Recent use of the medications may affect the results of the post-bronchodilator spirometry; consequently accurately recording the kind of medication and the time of most recent use is important. The table below lists the length of the effect of each of the medications.

Table 3. Bronchodilators and Generic names

	Short acting	Intermediate
	4-6 hours	12 hours
Drug trade names	<i>Proventil, Combivent, Ventolin, Maxair Xopenax, Volmax</i>	<i>Serevent, Advair, Foradil</i>
Generic drug names	<i>Albuterol, levalbuterol, pirbuterol</i>	<i>Salmeterol, fluticasone/salmeterol, formoterol</i>

4) Post- bronchodilator spirometry

Instructions for spirometry

The post-bronchodilator spirometry should be performed *no less than 15 minutes and no more than 30 minutes after* administering the albuterol. The procedures for using the spirometry are those for pre-bronchodilator spirometry; for specific instructions on performing the spirometry session, see Appendix 1.

Bronchodilator administration

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- For specific instructions, please see the appendix on albuterol administration. Below is a summary of the procedure.
- Use Albuterol for bronchodilator response testing.
 - Use a tube spacer with the metered dose inhaler.
 - Activate the inhaler in the air to check that it is operating adequately.
 - Instruct the participant to blow out to residual volume (RV), and then insert the tube in the participant's mouth.
 - Instruct the participant to inhale slowly, and activate the inhaler during inspiration.
 - The participant should hold their breath for about 10 seconds.
 - Wait one minute and repeat for another inhalation.
 - Repeat the spirometry (i.e., post-bronchodilator spirometry) no earlier than 15 minutes and no later than 30 minutes after administering the albuterol.

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Participant Testing Spirometry/Forced Vital Capacity

You, the technician, are the critical part of the pulmonary function testing system, since you must guide the participant through breathing maneuvers that are highly dependent on participant effort. You must coach the participant to inhale maximally and then to exhale maximally. You also must judge the quality of his effort. To obtain accurate results, the testing must be done in a standardized fashion.

Note: This manual refers to the participant as "he" or "him" for easy reading, although participants will be both male and female.

ANY MAJOR DENTAL SURG.
Ask PFT Exclusions Criteria – Ask the participant if he has, within the past three months, had any major surgery (chest, abdominal or brain), a heart attack, a stroke, or an aneurysm. If the participant has an aneurysm, ask where it is. The participant's blood pressure should be less than 210/110. If either the systolic or diastolic exceeds this limit, do not perform the PFT. Ask the participant if he has any other medical concerns about participating in the PFT.

Position the Participant – Testing should usually be conducted in the sitting position; however, ~~obese participants (BMI > 27) should stand.~~ A chair (without wheels) should be positioned behind participants who stand for the test. Use the chair if the participant becomes light-headed or feels faint during testing. Ask the participant to sit erect with chin slightly elevated.

Explain the Procedure - Explain that the purpose of the next test is to determine how hard and fast he can exhale air, "Like blowing out dozens of candles on a birthday cake." Explain that he should take in as deep a breath as possible, and when his lungs are completely full, blow out all the air as hard and fast as possible, until told to stop.

Dentures, if they are loose, should be removed and placed in a clean denture cup, since they will prevent a tight seal from being formed around the mouthpiece. If dentures are not loose, leave them in place.

Always Demonstrate the Maneuver. Ask the participant to watch you perform the FVC maneuver. Again demonstrate correct placement of the mouthpiece. If the participant does not adjust well to using the mouthpiece (i.e. strong gag reflex) the participant can use just the neck of the filter for a mouthpiece. His lips must remain tightly sealed using this also. Sit up straight. Take a deep breath, throw back your shoulders, and widen your eyes to emphasize the maximal depth of inhalation. Then dramatically **BLAST** out all of your air as hard and as fast as you can.

Your vigorous demonstration will prevent time and effort from being wasted on unacceptable forced expiratory efforts that result from the participant's failure to understand a verbal explanation of the procedure.

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FVC Test Steps

- 1) To begin doing the maneuvers, click on "Go to," then on "Forced Vital Capacity." This will bring you to the testing page.
- 2) Ensure that the participant has a clean filter and mouthpiece, but do not connect the participant until prompted by the computer. Click on "Start test."
- 3) The spirometer will fill the bell and prompt you- THEN have the participant connect to the mouthpiece and breathe normally.
- 4) Ensure that the participant has a noseclip in place. If the noseclip is uncomfortable for a participant, then instruct the participant to tightly pinch his nostrils shut throughout each maneuver.
- 5) Once the participant is connected to the spirometer, noseclip in place, and is breathing normally, press the space bar. This will prompt the computer to track the regular breathing of the participant.
- 6) Once you are both ready, instruct the participant take in as deep a breath as possible and press the space bar while they are inspiring.
- 7) Coach the participant through the FVC maneuver, encouraging him to blow out as hard as possible for at least 6 seconds (as seen at the red vertical line on the time axis on the screen) and until the red line tracking the participant's maneuver (on the right hand graph) becomes flat. Watch the participant inspire deeply and then shout "BLAST OUT!!!" Lower your voice a bit and coach the participant by saying "keep going...keep on pushing out all that air...a little bit more..."
- 8) Watch the body language of the participant as he attempts to follow your instructions. **Pay attention to him, not the instrument.**
- 9) Once he has "pushed" for at least six seconds and the participant tracking line has become flat and the "Good Effort" message appears over graph, push the space bar again to end the test, have the participant come off the mouthpiece, remove the noseclip and breathe normally.

To summarize the testing process:

- *Once the participant is connected to the spirometer with a noseclip on, push the space bar.*
- *After a couple of normal breaths, have the participant take as deep a breath as possible.*
- *While the participant is inspiring, press the space bar.*
- *As soon as the participant has reached maximal inspiration, have him blast out all the air in their lungs.*

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- *Once he has blown out for at least 6 seconds and the graph of his breathing has become flat and you see the "Good Effort" message, push the spacebar to end the test.*

The quality of the effort is seen at the top of the right hand graph- the quality is graded on (1) the initial effort (Extrapolated Volume, or EV), (2) flatness of the line or reaching of RV, Residual Volume, (End of Test, as defined by flow of less than 30mL/sec, or EOT), and (3) total expiratory time (TET).

You can repeat testing by starting again (with the participant off the mouthpiece initially) by going back to #2.

If the participant fails to perform the maneuver correctly, **again** demonstrate both the error and the correct performance yourself. You may have to repeat the demonstration after every maneuver for some participants!

FVC Maneuver Acceptability

According to the ATS standards, you should coach every participant to obtain at least three maneuvers that are "acceptable" and two that are "reproducible". The criteria for acceptability and reproducibility are described below. The accuracy of results depends much more on the quality of the maneuvers than on the instrument calibration.

Review the Results

According to the ATS standards, you should coach every participant to obtain at least three maneuvers that are "acceptable." The computer will show you the grades for "Effort Quality." When the grades are in green, they are acceptable and will have a "+" sign in front of each criteria. When one of the criterion was not reached, all three appear in red and the criteria not met have a "-" sign in front of them, so you can see what to have the participant correct on the next maneuver. Among those acceptable maneuvers, there must be two that are "reproducible," or within 5% of each other. In the chart at the bottom of the screen, the computer will put a (+) sign next to the value of FEV1 and FVC that are within 5% of each other- two of the acceptable maneuvers should have a (+) sign to demonstrate "reproducibility."

The "best" maneuver is the one with the highest sum of FVC + FEV1. Ignore the predicted and % predicted values displayed.

Maximum Number of Maneuvers

Don't exhaust the participant by asking him to perform more than **eight** FVC maneuvers. If you haven't obtained 3 acceptable maneuvers by the time you have done 8 maneuvers, it is unlikely that you will. Click on "Notes" which will bring you to a screen where you may add comments as to why the participant was not able to successfully complete testing.

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Saving the Results

Once you have three acceptable maneuvers, two of which are reproducible, testing is complete. Ensure that the "best" maneuver (highest sum of FEV1 and FVC) is highlighted by clicking on the box labeled "Effort ___" at the top of the appropriate column. Click on the "Choose" tab at the top of the page. Highlight the number of the best maneuver that you chose. Now click on "Save."

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Participant Testing Diffusion Capacity

Setting up

After completing the FVC maneuvers-

- Click on "Go to"
- Click on "Diffusion Capacity"
- Click on "START TEST"

Preparing the participant

While the machine prepares, explain to the participant that he will be asked to breathe normally and then to blow all his air out, just like the Vital Capacity maneuver. Once his lungs are as empty as possible, the participant will be asked to breathe in as deeply and quickly as possible and hold his breath for 12 seconds. The machine will close a valve, helping him to hold his breath and making it impossible for air to leak out- he will not be able to breathe while on the mouthpiece until the tester tells the participant to blow all his air out for the second time.

Starting the Test

- 1) You will get a series of messages as the machine prepares. The machine includes the volume of the filter in the calculations.
- 2) The computer will then display the following message- "Press the spacebar when the patient is connected to the mouthpiece and breathing normally." Ensure that the participant's lips are tightly sealed around the mouthpiece and that the noseclip is in place. Once the participant is attached and breathing normally, press the spacebar.
- 3) The graph will show the participant's tidal breathing. Once the participant is comfortable, have him breathe all the way out to Vital Capacity (the point at which the graph of his breathing becomes flat). Coach him, saying "Blow it out, blow it out" just as you would for the spirometry.
- 4) Once he has pushed all the air out, press the spacebar and **IMMEDIATELY** instruct him to take as deep an inspiration as possible. Ideally, the deep inspiration should take one to two seconds.
- 5) Once the graph of his breath has flattened out again at maximal inspiration, tell him to hold his breath. He must hold his breath for 12 seconds for the maneuver.
- 6) Push the "V" key, as soon as his breath has flattened out at maximal inspiration, to close the valve and keep air from escaping.

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- 7) Once the participant's graph crosses the vertical line on the screen, **IMMEDIATELY** instruct him to blow out all the air (if you closed the valve, it will open automatically at 12 seconds), just as though he was performing spirometry.
- 8) Have the participant keep blowing until the red line becomes horizontal.
- 9) Once the red line is horizontal, press the spacebar, ending the test.

To summarize-

- *Once in the Diffusion Capacity menu, Click on "Start Test" and prepare the participant*
- *Once the machine is set up, ensure that the participant is comfortable on the mouthpiece, with a good seal, and with a noseclip in place.*
- *Press the spacebar.*
- *After several breaths, have the participant blow out all the air he can.*
- *Once the graph flattens out horizontally, push the spacebar, then **IMMEDIATELY** have him breathe in as deeply and quickly as possible and hold his breath.*
- *Once the participant has taken as deep a breath as possible and the graph flattens out again, push the "V" key to keep him from breathing out.*
- *When the graph of the participant's breathhold crosses the vertical line, **IMMEDIATELY** have him blow out all the air he can, much like with the spirometry maneuvers.*
- *Once the graph flattens out at maximal expiration, push the spacebar, ending the test.*

Grading the Test

The screen will change, and the effort is graded at the top of the graph on the left. Three criteria are applied- Start of Test (SOT), Breathholding Time (BHT), and End of Test (EOT). If all three are acceptable, they will be displayed in green. If one criterion is not met, then all three appear in red. The failed criterion will have a (-) sign next to it. Review how to improve this result with the participant.

As with spirometry, maneuvers must be reproducible. For DLCO, two acceptable (all green effort marks) maneuvers must be within 10% of each other.

Per ATS standards allow 4 minutes between tests. Note that the machine takes several minutes to set up- you can start the setup process after two minutes.

Repeat the maneuver from "Starting the Test" until you have two acceptable and reproducible maneuvers.

Limit the number of attempts for DLCO to 3 per participant.

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Saving the Test

— DO NOT DO → MD³ WILL CHOOSE

Select the first acceptable and reproducible test by clicking on the top of the column label, which should read "Effort #_", then click on "Reported." Click on "Add to reported." Select the second acceptable and reproducible test by clicking on the top of the column label, then click on "Reported" and then on "Add to reported." This will report the average of the two maneuvers.

Click on "Save."

"Notes" Option

There is a tab on the upper left portion of the "Patient Information" page. If there is a comment regarding a participant that is beneficial and should be saved, enter the comment under "Technician Notes" and then click on "Save and Exit." Be concise with comments entered here, as the length of the comments can cause the PFT report to print onto a second page.

Printing Reports

The PFT report is printed after the test is reviewed and graded by a FHS physician (pulmonologist). After grading the test, this physician will select the "File" tab and click on "Print Report". The HP Deskjet 845c. is selected and 2 copies are printed.

Log Book

All participants are entered into the "PFT Daily Log, Comment, and Calibration" binder. Enter, by date, each participant name. An FHS generated sticker with the name and ID number can be used. An *A* is placed next to the name and sticker of all albuterol challenge participants (both pre-identified and clinic identified).

Participants Completing the PFT

Once the PFT is done, a green sheet labeled "PFT" is completed by attaching a participant label and the date onto the sheet and filing this in the participant's chart.

Participants Not Having a PFT

Participants not having a PFT during their Clinic visit are also put in the "PFT Daily Log, Comment and Calibration" binder with the reason that the PFT was not done.

A sheet labeled "PARTICIPANT DID NOT HAVE PULMONARY FUNCTION TEST" is completed by selecting the appropriate reason that the participant did not have the PFT.

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The date and participant label are entered onto the sheet and the sheet is filed in the participant's chart.

PARTICIPANTS REFUSING THE ALBUTEROL CHALLENGE

Occasionally a participant who is asked to participate in the post-bronchodilator test refuses to do so. This refusal is recorded next to the participant's identifying sticker in the PFT Daily Log Book and the refusal reason is also noted. For tracking purposes, the technician will also add the participant's sticker, the date and the refusal reason to the sheet titled "~~ALBUTEROL REFUSALS--CYCLE 8 OFFSPRING~~".

Go to Tech Notes & put in refusal w/ reason given *plr George O'Connor*

PARTICIPANTS DISQUALIFIED FROM ALBUTEROL CHALLENGE

Occasionally a participant who is pre-identified for the albuterol challenge cannot participate because he is disqualified from performing the PFT maneuver based on the clinical PFT protocol. The tech will add this participant's sticker to the sheet titled "~~PFT Disqualifications for Predetermined Albuterol Challenge: Offspring Cycle 8~~".

Go to tech notes & put in Disqualifications & reason for it.

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Participant Label:

PFT

Completed _____

Printed report to follow.

FHS-Clinic