National Emphysema Treatment Trial (NETT)
Consent for Screening and Patient Registry

Instructions: This consent statement is to be signed and dated by the patient in the presence of a certified study staff member (not necessarily the study physician who also signs the statement), at the beginning of the initial visit for evaluation of his/her eligibility for enrollment in the NETT, after the patient has read the statement and has had a chance to ask any questions about its content.

1. Background Information

The National Emphysema Treatment Trial (NETT) is a research study of treatments for people with emphysema. Emphysema is a disease in which the lungs lose their normal elasticity. Healthy lungs must be elastic to expand and shrink during normal breathing. When this ability is lost, air remains trapped in the lungs, making breathing difficult. As a result, the person cannot get rid of carbon dioxide and cannot take in enough oxygen. The effort in breathing results in a constant shortness of breath.

Emphysema is most often caused by years of smoking and cannot be cured. The purpose of all present treatments for emphysema is to help people live with their disease and to make breathing easier. You may know of some such treatments from your own experience. Usual treatment for emphysema includes medicines and oxygen. We shall call this "medical treatment". Regular exercise and life style changes also may make life with emphysema easier.

Surgery to remove diseased parts of the lungs is another treatment. At present, doctors do not know whether this surgery is an effective treatment for emphysema. There is no convincing scientific evidence that surgery is better than medical treatment for improving patients' breathing, quality of life, physical condition, or length of life. Surgery may improve lung function and exercise ability. The NETT is designed to compare medical treatment to surgery for emphysema.

The NETT is funded by the National Heart, Lung, and Blood Institute and the Health Care Financing Administration (HCFA), the Government agency that oversees Medicare. The study will be done in 19 clinical centers in the United States. About 2,500 patients with emphysema will be enrolled over several years. This study is expected to continue until about the fall of the year 2002. Followup for a patient will probably not last longer than 4½ years.

2. You and the National Emphysema Treatment Trial (NETT)

You have a chronic lung disease. We are inviting you to undergo a series of screening tests and questionnaires. These tests and questionnaires will help us evaluate your general condition and whether you qualify for the study. The process may take one

week. If you agree to screening, we will start the tests. If we begin the tests, we will keep your name and data in a registry for future reference.

If the tests and questionnaires show that you qualify for the study, you can then decide whether to enroll in the study. We will give you more information later, to help you make this choice. If we find that you do not qualify, you cannot enroll in the study. In this case, we will provide your personal physician with the results of your tests.

To qualify for the study, you must have emphysema, you cannot have smoked tobacco products for the past 4 months, you must be healthy enough to have lung surgery, and you must be able to return for followup visits.

3. Risks and Benefits

The screening tests for the NETT include lung function and breathing tests, exercise tests, heart tests, blood and urine tests, chest X-ray, and CT scan examinations. Lung function and exercise tests may be tiring and hard to perform.

Blood tests require taking blood from veins and arteries. The needle puncture may be painful for a short while and cause bruising. An arterial puncture may cause more bleeding than a vein puncture. When blood is collected, about a tablespoon will be removed each time.

We will check your heart by recording its electrical activity. We also will get images of your heart, using an ultrasound device. In another heart test, you will be given an injection of a drug called dobutamine which will increase your heart rate in a controlled way. You will also be given an injection of a radioactive dye which will allow us to get images of your heart. The radiation exposure from this test is __[specify exposure associated with imaging agent used by the clinic]__. These tests will require that you remain still for a short period of time. We may do a cardiac examination in which a small probe is inserted through a vein into your heart. This test can cause heart rhythm changes, perforate a blood vessel, and may, in rare cases, cause death.

You will have a chest X-ray and CT scan. Both of these tests involve exposure to a small amount of radiation, 0.0072 rem for the X-ray and 0.697 rem for the CT scan. For the CT scan, you will need to lie still within a confined space for about 20 minutes. This may be uncomfortable.

You will also have a lung perfusion scan. This scan gives a detailed image of your lungs. A small amount of a radioactive substance will be injected into a vein. The radiation exposure from the perfusion scan is about 0.20 to 0.24 rem.

The total radiation exposure received from the chest X-ray, CT scan, dobutamine

heart scan, and lung perfusion scan is about _____[specify total for exposure at clinic]. Naturally occurring radiation (cosmic radiation, radon, etc) produces whole body radiation exposures of about 0.3 rem per year. Occupationally exposed individuals are permitted to receive whole body exposures of 5 rem per year.

We will ask you to fill out questionnaires about your quality of life and state of mind. You do not have to answer questions that you find embarrassing. However, your answers to these questions are important to the study, and all your answers will remain confidential.

You are not to smoke any tobacco products while in the study. We will ask you to report your smoking, and we will test your blood from time to time for evidence of smoking. If you smoke, we will not enroll you in the NETT.

If you qualify for the NETT after these screening tests, we will invite you to take part in a program of exercise and education. The education will teach you about emphysema and ways to help you manage your illness. This program is called pulmonary rehabilitation. After six to ten weeks in the program we will check your condition. If you remain eligible for the trial, and if you decide to continue with the NETT, we will assign you to receive one of two treatments, either:

(**1**) Usual medical treatment and eight more weeks of exercise and education, or
(**2**) Usual medical treatment, lung volume reduction surgery, plus eight more weeks of exercise and education.

Your treatment assignment will be decided by chance, much like flipping a coin. You and the NETT doctors will not be able to choose the treatment or to know your treatment assignment in advance.

The NETT may help doctors learn how best to care for emphysema patients like you in the future. If you qualify for the NETT after the screening tests, and if you choose to enroll, you may benefit from the treatment you receive. A lung expert will review your medical care on a regular schedule and make recommendations to your personal physician. If, during or at the end of the study, we find that lung surgery is better than medical treatment alone, we will offer surgery to those who are suitable for it and have not received it. To protect patient safety during the study, a panel of experts outside the study will monitor it. This panel will look at the data regularly and report any safety concerns. You will be informed of any information that may affect your decision to enroll or remain in the study.

If you enroll in the NETT, we may contact you after the conclusion of the study to find out the impact of your illness on the quality of your life. We will also collect

information from you and from your insurance company about all medical services which you receive during your participation in the NETT.

4. Alternatives to Participation in the NETT

You can receive medical treatment for your disease without taking part in this study. Other treatments for your disease include supportive care only or oxygen therapy. Your symptoms can be treated as they appear. You can have lung volume reduction surgery elsewhere or with other doctors, outside of the NETT and unpaid by Medicare. You could also receive a lung transplant, depending on your overall health and the severity of your disease. You may be able to receive pulmonary rehabilitation if your insurance covers this type of service.

5. Confidentiality

Information gathered from you is personal and confidential. We are collecting data for the purpose of this study and will keep the data at the NETT clinic and at the NETT Coordinating Center in Baltimore, Maryland and any subcontracted data center as determined by the NETT Coordinating Center. Personal identifiers will be kept in a secure location. We will keep your records confidential to the extent possible within the limits of the law and human error. However, authorized people from the National Heart, Lung, and Blood Institute and from the NETT Coordinating Center may inspect individual records if needed. If the findings from this study are published, no information will be included which would reveal your identity.

6. Voluntary Participation

Whether you take part in the screening is up to you. You may quit at any time during the screening process. However, we encourage you to complete the screening if you start. You also have the right to quit after you enroll in the NETT. A decision to quit will not prevent you from receiving regular care at this institution.

Agreeing to the screening does not mean that you agree to enroll in the NETT. You are not agreeing to any treatment at this time. We will discuss enrollment in the NETT with you after all screening tests are done. We will provide you with more information in a separate consent form later.

7. Research Related Injuries

If you are injured or disabled because of participation in the NETT, you can be treated at this institution. The costs for such treatment will be covered by _____. However, (specify institution) and the Federal Government do not have any program to provide compensation to you or to your family if you are disabled, experience other bad effects which are not the fault of the investigators, or die during the study.

8. Costs

Medicare will help cover the costs of the screening tests for the NETT after you have paid any deductible and coinsurance amounts that Medicare requires. You will have to pay the costs of traveling to the NETT clinic for screening. You will also have to pay any lodging costs if you have to stay in a hotel during screening.

If you enroll in the NETT, Medicare will help cover costs of treatment and followup directly related to the study. As before, you may have to pay any deductible or coinsurance amounts that Medicare requires. All regulations regarding Medicare coverage apply as indicated in the Medicare guidelines. You will be responsible for costs of travel and lodging. You also will need to pay for medicines, including inhalers and other drugs. Medicare will pay for lung volume reduction surgery only for patients assigned to have this surgery in this trial.

9. Consent

You should be sure to have all of your questions answered before you agree to take part in the screening. The principal investigator, Dr. _____, and the clinic staff are available at _(specify phone number)_ to answer any questions you may have about the study, now or later. If you believe that you are not being treated fairly or have been injured by taking part in the study, you may contact the person named above or _(specify IRB office)_ at _(specify phone number)_. The principal investigator or clinic staff will help you obtain medical care for such an injury.

If you are willing to participate in screening and in the patient registry, please indicate so by signing below. You are entitled to receive a signed copy of this statement.

Date Patient's signature Patient's study ID and name code

Date NETT study physician's signature Study physician's name (please print)

Note: Study physician must sign in the presence of the patient and staff member and on the same day on which the consent was signed by the patient.

National Emphysema Treatment Trial (NETT)
Consent for Pulmonary Rehabilitation

Instructions: This consent statement is to be signed and dated by the patient in the presence of a certified study staff member (not necessarily the study physician who also signs the statement), after determination of eligibility to enroll in the pulmonary rehabilitation program and prior to the beginning of the initial pulmonary rehabilitation program visit, after the patient has read the statement and has had a chance to ask any questions about its content.

1. Introduction

The National Emphysema Treatment Trial (NETT) is a clinical trial. A clinical trial is a research study to compare alternative treatments or test new ones. Such research is done when there is no clear evidence showing that one treatment is better than another. Persons asked to take part in a clinical trial must give consent to participate in that research. The consent must be based on an understanding of the nature and risks of the treatments. Doctors and other study personnel must provide the information needed for people to understand the study and agree to take part in it.

2. The National Emphysema Treatment Trial (NETT)

The purpose of the NETT is to compare two treatments for emphysema:

(1) Usual medical treatment with medicines, oxygen, and a program of exercise and education about emphysema and ways to manage it. We shall call this "medical treatment".
(2) Usual medical treatment with medicines, oxygen, and a program of exercise and education plus lung volume reduction surgery.

We do not know which treatment is better. That is, we do not know whether one treatment is more likely to reduce shortness of breath, improve the ability to walk a distance, increase general enjoyment of life, or prolong life.

The NETT is funded by the National Heart, Lung, and Blood Institute and the Health Care Financing Administration, the Government agency that oversees Medicare. Nineteen clinical centers across the United States will participate in the NETT. About 2,500 patients with emphysema will be enrolled over several years. The trial is expected to continue until about the fall of the year 2002. Followup for a patient will probably not last longer than 4½ years.

You agreed previously to be screened for the NETT. You have finished and passed the screening tests. We are now inviting you to enroll in a program of exercise and education about emphysema and ways to manage it. This program also involves

treatment with medicines and oxygen as needed, exercise, individual counseling, and group sessions. This program is called pulmonary rehabilitation.

The purpose of the rehabilitation is to try to improve your physical condition and breathing. The NETT staff will give you exercises to do to increase your strength and endurance. They will slowly increase the amount of exercise you do over time. You will also learn about your disease, breathing techniques, your medications, proper eating habits, and ways to relax. In the first week, you may be at the NETT clinic every day. After that, the program may take place at the NETT clinic or near your home.

After you have completed six to ten weeks of the rehabilitation program, NETT doctors will again check your condition. If you meet the goals set by the rehabilitation program and the tests show that you are healthy enough to have lung surgery, we will ask whether you want to consent to "treatment randomization". If you give your consent, your treatment will be decided by chance. In a process much like flipping a coin, you will be assigned to one of two treatments:

(1) Continued medical treatment and more rehabilitation, or
(2) Lung volume reduction surgery followed by continued medical treatment and more rehabilitation.

You will have an equal chance of assignment to either of these two treatment groups. Neither you nor your physician can choose which treatment you will receive.

After treatment randomization, you will have eight more weeks of rehabilitation. If you are assigned to medical treatment, you will start the eight weeks of rehabilitation immediately. If you are assigned to have lung surgery, the operation should be done within two weeks, and the eight weeks of rehabilitation will begin after the surgery. The surgery consists of removing a portion of your diseased lungs as determined by the surgeon. This is done because many patients with emphysema have "stretched out" lungs. It is thought, but not known, that removing the most damaged parts of the lungs may reduce shortness of breath. One of two possible surgery methods to reduce the lung volume will be used. In clinics that use both procedures, the type of surgery will be chosen by a process similar to flipping a coin. In this clinic, we are using _____method.

After treatment randomization, regardless of what treatment you receive, we will want you to come for regular visits for the duration of the study. Your medical treatment for emphysema will be reviewed during these visits and recommendations will be made to your personal physician. We want to see you twice a year for one year and once a year after that. Each visit will take one to two days and may require you to stay overnight near the clinic if you live far away. The NETT clinic will also contact you by phone or

in writing between visits.

If you withdraw from the rehabilitation program, or if we do not think that surgery is safe for you when we evaluate you after six to ten weeks in the rehabilitation program, you may not continue treatment within the NETT. We will provide your personal physician with results of your tests.

You do not have to consent now to have your treatment assigned by the chance process. We will not know if you are eligible for this until six to ten weeks from now. You may want to discuss this decision with your family, doctor, or friends while you are participating in the rehabilitation program. However, if you know now that you do not want your treatment assigned by chance, you should not continue with the NETT.

3. Risks and Discomforts

The exercise sessions may be tiring. They will require a lot of effort and your full cooperation. On rare occasions, exercise can lead to collapse, injury, or a heart attack. An exercise course is part of most rehabilitation programs and therefore is part of usual care. It is not an extra risk from being in this study.

The medicines that your doctor may prescribe have side effects. These side effects depend on the nature and dose of the drug and on your health. Medicines used may include drugs to open the airways to the lungs. Known side effects of these drugs (called bronchodilators) include irritation or dryness of the tongue and mouth, mild shakiness, rapid heart beat, and nausea. Most side effects can be controlled by reducing the dose of the medicine. These risks are part of usual medical care and are not extra risks from being in the study.

After six to ten weeks in the rehabilitation program, you will undergo various lung function and exercise tests, and some blood tests. Lung function tests may be tiring and hard to perform. We will check your heart by recording its electrical activity during exercise.

Blood tests require taking blood from veins and arteries. The needle puncture may be painful for a short while and cause bruising. An arterial puncture may cause more bleeding than a vein puncture. When blood is collected, about a tablespoon will be removed each time.

We will also ask you to fill out questionnaires about your quality of life and state of mind. You do not have to answer questions that you find embarrassing. However, your answers are important to the study, and all your answers will remain confidential. We will also collect information from you and from your insurance company about all medical services which you receive during your participation in the NETT.

You are not to smoke any tobacco products while in the study. We will ask you to report your smoking, and we will test your blood from time to time for evidence of smoking. If you smoke, we will not enroll you in the NETT.

Lung volume reduction surgery can be done by opening the chest wall or through small slits at the sides of your chest. The lung volume reduction surgery is a major operation. This surgery has some major risks related to the anaesthesia and the surgical trauma. Patients will have discomfort after the surgery, and recovery may take several weeks. Some patients may take longer to get well, and some may never fully recover to the lifestyle they had before the surgery. The lung volume reduction surgery may also shorten your life or cause death.

We do not know all of the risks of lung volume reduction surgery. It may not be effective, or the effects may not last. It can make breathing more difficult, and it may not improve the quality of your life. We will discuss the risks of lung volume reduction surgery with you later, in more detail, if you qualify for treatment randomization.

If you are waiting for a lung transplant and you agree in the future to treatment randomization, we may ask you to change your listing for lung transplant to inactive. However, you may refuse to do this and still participate in the NETT. While your listing is inactive you will not be offered a lung transplant. You will keep the waiting time you have collected so far, but you will not collect any more waiting time.

We may contact you after the conclusion of the study to find out the impact of your illness on the quality of your life.

4. Benefits

In this study you will benefit from the best known medical treatment for emphysema. A lung expert will review your treatment on a regular schedule and make recommendations to your personal physician. The rehabilitation program may help you cope better with your disease and improve your physical condition. We do not know whether lung surgery is effective. If during, or at the end of the study, we find that patients assigned to lung volume reduction surgery do better, we will offer lung surgery to patients who are suitable for surgery and who have not had it. In addition, you may help doctors learn how best to care for emphysema patients like you in the future. We hope to find out which emphysema patients benefit most from each treatment. Results from this trial will not cure their emphysema, but may improve their life. To protect your safety during the trial, a panel of experts outside the trial will monitor it. This panel will look at the data regularly and report any safety concerns. You will be informed in a timely fashion about any change in the risk to benefit balance of the two treatment options in the NETT.

5. Access to Medical Care

You are not obligated to enroll in the NETT. Emphysema can be treated with medicines and oxygen alone, involving less discomfort, risk, and personal effort than participation in the NETT requires. Though the information we will gain from you is important, you do not have to remain in the study. If you do not enroll, or if you withdraw from the NETT, you may continue to receive care at this institution. However, as presently designed, the NETT surgeons can only offer and perform this surgery on patients who enroll in the NETT. If you want to receive surgery outside of the NETT, we will refer you to another surgeon. In this case, the main NETT pulmonary physician will also have to refer you to another pulmonary physician for treatment.

6. Alternatives to Participation in the NETT

You can refuse to enroll in the NETT and continue with your current care. You may receive medical treatment without enrolling in this study. You may be able to receive rehabilitation if your insurance covers this type of service. Other treatments for your disease include supportive care only or oxygen therapy. Your symptoms can be treated as they appear. You can have lung volume reduction surgery elsewhere or with other doctors, outside of the NETT and unpaid by Medicare. You could also receive a lung transplant, depending on your overall health and the severity of your disease.

7. Confidentiality

Information gathered from you is personal and confidential. We are collecting data for the purpose of this study and will keep the data at the NETT clinic and at the NETT Coordinating Center in Baltimore, Maryland and any subcontracted data center as determined by the NETT Coordinating Center. Personal identifiers will be kept in a secure location. We will keep your records confidential to the extent possible within the limits of the law and human error. However, authorized people from the National Heart, Lung, and Blood Institute and from the NETT Coordinating Center may inspect individual records if needed. If the findings from this study are published, no information will be included which would reveal your identity.

8. Research Related Injuries

If you are injured or disabled because of participation in the NETT, you can be treated at this institution. The costs for such treatment will be covered by _____. However, _(specify institution)_ and the Federal Government do not have any program to provide compensation to you or to your family if you are disabled, experience other bad effects which are not the fault of investigators, or die during the study.

9. Costs

Medicare will help cover the costs of tests, exams by NETT doctors, and the rehabilitation program after you have paid any deductible and coinsurance amounts that Medicare requires. You will have to pay the costs of traveling to the NETT clinic. You

will also have to pay any lodging costs during the rehabilitation program or during followup visits.

If you continue to take part in the NETT, Medicare will help cover costs of treatment and followup directly related to the study. As before, you will need to pay any deductible and coinsurance amounts that Medicare requires. All regulations regarding Medicare coverage apply as indicated in the Medicare guidelines. You will be responsible for costs of travel and lodging. You will need to pay for medicines, including inhalers and other drugs. Medicare will pay for lung volume reduction surgery only for patients assigned to have this surgery in this trial.

10. Consent

You should be sure to have all your questions answered before you agree to take part in the rehabilitation program. The principal investigator, Dr. _____, and the clinic staff are available at (specify phone number) to answer any questions you may have about the study, now or later. If you believe that you are not being treated fairly or have been injured by taking part in the study, you may contact the person named above or (specify IRB office) at (specify phone number). The principal investigator or clinic staff will help you obtain medical care for such an injury.

If you are willing to participate in the pulmonary rehabilitation program, please indicate so by signing below. You are entitled to receive a signed copy of this consent statement.

Date	Patient's signature	Patient's study ID and name code

Date	NETT study physician's signature	Study physician's name (please print)

Note: Study physician must sign in the presence of the patient and staff member and on the day on which the consent was signed by the patient.

National Emphysema Treatment Trial (NETT)
Consent for Randomization to Treatment

Instructions: This consent statement is to be signed and dated by the patient in the presence of a certified study staff member (not necessarily the study physician who also signs the statement), at the beginning of the randomization visit, after the patient has read the statement and has had a chance to ask any questions about its content.

1. Introduction

The National Emphysema Treatment Trial (NETT) is a clinical trial (research study) to compare treatments for emphysema. Emphysema is a disease in which the lungs lose their normal elasticity. Healthy lungs must be elastic to expand and shrink during normal breathing. When this ability is lost, air is trapped in the lungs, making breathing difficult. As a result, the person cannot get rid of carbon dioxide and cannot take in enough oxygen. The person must make a big effort to breathe and is constantly short of breath.

2. Randomization

You have emphysema and you are eligible to enroll in the NETT. We invite you to enroll in the trial. Enrollment means that your treatment will be decided by chance. This process is called randomization. In a process much like flipping a coin, patients will be assigned to one of two treatments. The two treatments are:

(1) Continued usual medical treatment and rehabilitation, or
(2) Lung volume reduction surgery, continued usual medical treatment and rehabilitation.

The NETT is being done because there is no convincing evidence that one treatment for emphysema is better than the other. Patients will have an equal chance of assignment to either of the two treatments. Neither patients nor their doctors will choose the assigned treatment.

Patients may enter a clinical trial hoping for personal benefit and an improved and longer life. Many also enter a trial in the hope of helping others with the information obtained. However, nobody should decide to enter a trial unless convinced that doing so is the right thing to do. If, after you read this statement, you are not willing to accept assignment to either treatment, you should not enroll in the NETT.

3. Treatment and Followup

Once you are assigned to a treatment in the NETT, you are enrolled in the NETT. You will continue to see your personal physician for medical treatment for emphysema; the NETT physician will make recommendations to your personal physician. You will have eight more weeks of rehabilitation after your assignment to either treatment.

If you are assigned to receive lung volume reduction surgery, the operation should

be done within two weeks and the eight weeks of rehabilitation will begin after the surgery. One of two possible surgery methods to reduce the lung volume will be used. In clinics that use both methods, the type of surgery will be chosen by a process similar to flipping a coin. In this clinic, we are using _____ method. Both types of surgery consist of removing a portion of your diseased lungs as determined by the surgeon. This is done because many emphysema patients have "stretched out" lungs. It is thought, but not known, that removing the most damaged parts of their lungs may reduce shortness of breath and increase exercise capacity. Risks involved in this type of surgery are described in Section 5 below.

If your breathing condition worsens, or if you have a new health problem, NETT doctors may look again at your condition to see if you are still suitable for lung surgery. If you are no longer suitable for surgery and this happens before you receive a treatment assignment, you may not continue in NETT. In this case, we will provide your personal physician with the test results. If this happens after you have been assigned to a treatment in NETT, you will remain in the NETT and you may continue to receive treatment in the NETT, although surgery will not be done if you are no longer suitable for it.

If you do not agree to have your treatment assigned by the chance procedure, you may not continue in the NETT. In that case, we will provide your personal physician with your test results.

If you agree to have your treatment assigned by the chance procedure, we want you to come for regular visits for the duration of the study no matter what treatment you receive. We will see you at a NETT clinic twice a year for one year and once a year after that. Each visit will take one to two full days and may require you to stay overnight near the clinic if you live far away. The NETT clinic will also contact you by phone or in writing between visits. We expect to follow patients until about the fall of the year 2002, unless doctors get an answer to the study question sooner than that. Followup for a patient will probably not last longer than 4½ years.

We may contact you after the conclusion of the study to find out the impact of your illness on the quality of your life.

4. Benefits

In this study you will benefit from the best known medical treatment for emphysema. A lung expert will review your treatment on a regular schedule and will make recommendations to your personal physician. The rehabilitation program may help you cope better with your disease and improve your physical condition. We do not know whether lung surgery is effective. If during, or at the end of the study, we find that patients assigned to lung volume reduction surgery do better, we will offer lung surgery to patients who are suitable for surgery and who have not had it. In addition, you may help doctors learn how best to care for emphysema patients like you in the future. We

hope to find out which emphysema patients benefit most from each treatment. Results from this trial will not cure their emphysema, but may improve their life. To protect your safety during the trial, a panel of experts outside the trial will monitor it. This panel will look at the data regularly and report any safety concerns. You will be informed in a timely fashion about any change in the risk to benefit balance of the two treatment options in the NETT.

5. Risks and Discomforts

All treatments have risks and side effects. The risks and side effects depend on the type of treatment and the patient's condition. Side effects also may vary from patient to patient. In clinical trials of new treatments, some risks are not fully known ahead of time. For these reasons, taking part in the NETT can carry unknown dangers as well as hoped-for benefits.

The medicines that your doctor may prescribe have side effects. Side effects depend on the nature and dose of the drug and on your health. Medicines used may include drugs to open the airways to the lungs. Known side effects of these drugs (called bronchodilators) include irritation or dryness of the tongue and mouth, mild shakiness, rapid heart beat, and nausea. Most side effects can be controlled by reducing the dose of the medicine. These risks are part of your medical care and are not extra risks from being in the study.

During followup visits you will have blood, exercise, lung and heart function, and imaging tests similar to those you had during screening. Lung function and exercise tests may be tiring and hard to perform. We will check your heart by recording its electrical activity during exercise. We also will get images of your heart using an ultrasound device. This will require you to remain still for a short time.

Blood tests require taking blood from veins and arteries. The needle puncture may be painful for a short while and may cause bruising. An arterial puncture may cause more bleeding than a vein puncture. When blood is collected, about a tablespoon will be removed each time.

The chest X-ray and CT scan, which are done 6 months after randomization and 3 years after randomization, involve exposure to a small amount of radiation, 0.007 rem for the chest X-ray and 0.697 rem for the CT scan. The total radiation exposure at the 6 months visit is about 0.7 rem. The total radiation exposure received in the first year of NETT is therefore about 2.0 to 2.2 rem. The total radiation exposure received from the chest X-ray and CT scan at the 3 year visit is about 0.7 rem. Naturally occurring radiation (cosmic radiation, radon, etc) produces whole body radiation exposures of about 0.3 rem per year. Occupationally exposed individuals are permitted to receive whole body exposures of 5 rems per year. For the CT scan, you will need to lie still within a confined space for about 20 minutes. This may be uncomfortable.

As in earlier phases of the NETT, we will ask you to fill out questionnaires about your quality of life and your state of mind. You do not have to answer questions that you find embarrassing. However, your answers are important to the study, and we will keep them confidential. We will collect information from you and from your insurance company about all medical services which you receive during your participation in the NETT.

You are not to smoke any tobacco products while in the study. We will ask you to report your smoking, and we will test your blood from time to time for evidence of smoking. If you smoke, we will not enroll you in the NETT.

Lung volume reduction surgery can be done by opening the chest wall or through small slits at the sides of your chest. The lung volume reduction surgery is a major operation. The surgery has some major risks related to the anesthesia and the surgical trauma. The surgery may shorten your life or cause death. Based on surgical experience and opinion, the risk of death within the first month after surgery is thought to be about 4% to 8%. We do not have reliable data on the risk of death during the first year after surgery, though it may be as high as 15% to 20%. Patients will have discomfort after the surgery, and recovery may take several weeks. Some patients may take longer to get well, and some may never fully recover to the life style they had before the surgery.

Information collected earlier in NETT suggests that patients with very poor lung function have an increased risk of death after LVRS. These patients are no longer eligible for NETT. However, the information did not suggest that patients (like you), whose lung function is not as severely damaged, were at increased risk. These patients are still eligible for NETT.

We do not know all of the risks of lung volume reduction surgery. It may not be effective, or the effects may not last. It can make breathing more difficult, and it may not improve the quality of your life. Complications of surgery may include air leak from the lungs which requires prolonged chest tube management or re-operation, pneumonia, heart attack or irregular heart beats, stroke, blood clots, prolonged dependence on the ventilator (the machine that breathes for you when your lungs can't), and problems with the intestines such as bleeding or obstruction. Following surgery there is a stay in the intensive care unit lasting from a few days to weeks. This increases the risk of complications associated with intensive care unit stays such as infection.

If you are assigned to lung volume reduction surgery, we will ask you to sign a surgical consent statement prior to surgery. You are entitled to see that surgical consent statement now.

We do not have reliable data on the risk of death with medical treatment. The risk of death in the first year of medical treatment is probably lower than the risk of death in the first year after lung volume reduction surgery, but we cannot say by how much. Over

a longer period, the risk of death for persons who receive medical treatment may be lower than, the same as, or higher than the risk of death for persons who receive lung volume reduction surgery. This study may provide this information.

If you are waiting for a lung transplant and you agree to treatment randomization, we may ask you to change your listing for lung transplant to inactive. However, you may refuse to do this and still participate in the NETT. While your listing is inactive you will not be offered a lung transplant. You will keep the waiting time you have collected so far, but you will not collect any more waiting time.

6. Access to Medical Care

You are not obligated to enroll in the NETT. Emphysema can be treated with medicines and oxygen alone, involving less discomfort, risk, and personal effort than participation in the NETT. Though the information we will gain from you is important, you do not have to remain in the study. If you do not enroll, or if you withdraw from the NETT, you may continue to receive care at this institution. However, your care will not be provided through the NETT. As presently designed, the NETT surgeons can only offer and perform this surgery on patients who enroll in the NETT. If you want to receive surgery outside of the NETT, we will refer you to another surgeon. In this case, the main NETT pulmonary physician will also have to refer you to another pulmonary physician for treatment.

7. Alternatives to Participation in the NETT

You can decide to withdraw from the NETT and continue with your current care. You can receive medical care without enrolling in this study. You may be able to receive rehabilitation if your insurance covers this type of service. Other treatments for your disease include supportive care only or oxygen therapy. Your symptoms can be treated as they appear. You can have lung volume reduction surgery elsewhere or with other doctors, outside of the NETT and unpaid by Medicare. You could also receive a lung transplant, depending on your overall health and the severity of your disease.

8. Confidentiality

Information gathered from you is personal and confidential. We are collecting data for the purpose of this study and will keep the data at the NETT clinic and at the NETT Coordinating Center in Baltimore, Maryland and any subcontracted data center as determined by the NETT Coordinating Center. We will keep your records confidential to the extent possible within the limits of the law and human error. However, authorized people from the National Heart, Lung, and Blood Institute and from the NETT Coordinating Center may inspect individual records if needed. If the findings from this study are published, no information will be included which would reveal your identity.

9. Research Related Injuries

If you are injured or disabled because of participation in the NETT, you can be treated at this institution. The costs of such treatment will be covered by _____.

However, _(specify institution)_ and the Federal Government do not have any program to provide compensation to you or to your family if you are disabled, experience other bad effects which are not the fault of investigators, or die during the study.

10. Costs

Medicare will help cover the costs of treatment and followup exams by NETT doctors after you have paid any deductible and coinsurance amounts that Medicare requires. All regulations regarding Medicare coverage apply as indicated in the Medicare guidelines. You will have to pay the costs of traveling to the NETT clinic and any lodging costs during followup visits. You will also have to pay for medicines, including inhalers and other drugs. Medicare will pay for lung volume reduction surgery only for patients assigned to have this surgery in the NETT.

11. Consent

You should be sure to have all your questions answered before you agree to have your treatment assigned by randomization. The principal investigator, Dr. _____, and the clinic staff are available at _(specify phone number)_ to answer any questions you may have about the study, now or later. If you believe that you are not being treated fairly or have been injured by taking part in the study, you may contact the person named above or _(specify IRB office)_ at _(specify phone number)_. The principal investigator or clinic staff will help you obtain medical care for such an injury.

If you consent to randomization to treatment, please indicate so by signing below. You are entitled to receive a signed copy of this consent statement.

Date	Patient's signature	Patient's study ID and name code

Date	NETT study physician's signature	Study physician's name (please print)

Note: Study physician must sign in the presence of the patient and staff member and on the day on which the consent was signed by the patient.