

XXXXX Nuclear Laboratory

Informed Consent Policy

Purpose:

This policy establishes guidelines for obtaining informed consent from patients prior to administering stress tests.

Rationale:

Individuals should sign an informed consent form prior to exercise testing. The purpose of the consent form is to make certain the patient is aware of the small, but real risk of exercise testing. This risk, according to present data, is approximately one death (and three cardiac events) per 10,000 tests in large, varied populations. Equally important than having a patient sign a consent form is taking the time to explain possible risks, the purpose of testing, and the testing protocol itself. Clear and complete instructions prior to testing will significantly reduce patient anxiety. It is important to give patients time to ask questions prior to testing.

Policy:

1. The capacity to give informed consent means the cognitive ability to understand and appreciate the elements of informed consent and to make a reasoned decision whether or not to participate in a the proposed procedure.
2. The person providing information must convey it in a manner that another person can understand, including discussion, and providing other information such as literature as necessary.
3. The following information is necessary:
 - a. The nature and character of the proposed procedure
 - b. The material facts involved to which a reasonably prudent person would believe significant in deciding whether or not to participate in the procedure
 - c. The anticipated results of the proposed procedure
 - d. The possible risks and benefits of the proposed procedure
 - e. Alternative procedures reasonable available including the ability to decline the proposed procedure.
4. All patients undergoing the following tests are required to give informed consent.
 - a. Treadmill exercise tests
 - b. Pharmacological stress tests
 - i. Adenoscan
 - ii. Persantine
 - iii. Dobutamine
 - iv. Lexiscan
 - c. Eyebrow waxing
5. Consent may be obtained by either the technologist or physician.
6. Consent must be given by the patient or patient's guardian or spouse.
7. The patient's name and physician performing the stress test must be filled in on the consent form.
8. After discussing the procedure as described above. The patient must sign and date the appropriate consent form. The form must also be witnessed and dated.
9. See attached exercise stress test and adenosine stress test consent forms.

10. Information for patients:

- a. A cardiac stress test is also called an exercise test or a treadmill test. This test may help your caregiver see how well your heart works during exercise. Exercise is a form of body stress. The longer you exercise, the harder your body needs to work. The heart must work double time to pump more blood to supply the body with more oxygen. A cardiac stress test may check for risks of a possible heart problem or diagnose an existing heart problem. It will also tell caregivers the type and level of exercise that will be best for you.
- b. During a cardiac stress test, you may be asked to walk or jog on a treadmill. While doing this, your heart will be watched on a monitor. An electrocardiogram (ECG) is used to have tracings of your heart activity. Your caregiver will be watching you during this test. Your breathing, blood pressure, and heart rate are also checked while you are exercising. You may get tired, have trouble breathing, or start having chest pains while doing the test. Your caregiver may give you medicines or ask you not to continue doing the test.
- c. A cardiac stress test has risks. Problems can happen during or after the test. Your blood pressure may decrease, and you may feel dizzy, lightheaded, and weak. You may feel your heart throbbing or have extra heartbeats. You may have experience chest pain, or in rare cases, have a heart attack chest pain or heart attack. Caregivers are there before, during, and after the test to help you. Call your caregiver if you are worried or have questions about the test, your medicine or care.
- d. You have the right to understand your health condition in words that you know. You should be told what tests, treatments, or procedures may be done to treat your condition. Your doctor should also tell you about the risks and benefits of each treatment. You may be asked to sign a consent form that gives caregivers permission to do certain tests, treatments, or procedures. If you are unable to give your consent, someone who has permission can sign this form for you. A consent form is a legal piece of paper that tells exactly what will be done to you. Before giving your consent, make sure all your questions have been answered so that you understand what may happen.
- e. Vital signs: This includes taking blood pressure, pulse (counting your heartbeat), and respirations (counting your breaths). To take your blood pressure, a cuff is put on your arm and tightened. The cuff is attached to a machine which gives your blood pressure reading. Caregivers may listen to your heart and lungs by using a stethoscope. Your vital signs are taken so caregivers can see how you are doing.
- f. You may be asked to change your clothes. Electrodes (sticky patches) are put on your chest and attached to the electrocardiogram (ECG) monitor and recorder. A wrap or belt is placed around your waist to hold the cables in place. A baseline ECG is then recorded on paper. Additional recordings are made during and following exercise. You are asked to start mild exercise on the stationary bike or treadmill. The exercise gets harder as the test progresses.
- g. During the test, your heart rhythm is always shown on a heart monitor. This allows your caregiver to watch out for ECG changes and arrhythmias (irregular heartbeats). When you reach your highest exercise level, your caregiver asks you to slow your exercise. The test is continued until you reach a target heart rate. It may be stopped early if you develop symptoms such as chest pain, shortness of breath, weakness, tiredness, or dizziness. More ECG recordings are done after you stopped exercising. The electrodes are removed from your chest after the test is done.
- h. After the test, you will be monitored until your ECG returns to normal, your heart rate returns to normal and your breathing returns to normal.
- i. It is important that you communicate with your caregiver at all times during the test and let them know if you are experiencing any symptoms such as chest pain, shortness of breath, leg pain, dizziness, fatigue. You need to let your caregiver know when you are tired and don't believe you can walk for more than one to two more minutes so that the injection of radioisotope may be given for the imaging portion of the procedure.
- j. Generally, there are no symptoms or side effects from the injection of the radioisotope.

Written: _____	Date: _____
Revised: _____	Date: _____
Reviewed: _____	Date: _____
	Date: _____

XXXX Nuclear Laboratory

CONSENT FOR EXERCISE MYOCARDIAL PERFUSION SCAN

I, _____ authorize Dr. _____ and his assistants to administer and conduct an exercise stress test. This test is designed to determine the presence or absence of clinically significant heart disease; to evaluate the effectiveness of my current therapy; and/or to measure my fitness for work or sport.

I understand that I will walk on a treadmill at a specific speed and grade and at three-minute intervals the speed and elevation will increase. While walking on the treadmill, my electrocardiogram and blood pressure will be monitored. Exercise will be progressively increased until I attain a predetermined end point corresponding to moderate exercise stress, or become distressed in any way or develop any abnormal response the physician considers significant, whichever of the above occurs first. Just before the test is terminated an injection of radioisotope (Tc99M tetrofosmin) is given through an intravenous site and I am required to walk an additional minute on the treadmill to allow significant circulation and accumulation of the isotope in my heart.

Every effort will be made to conduct the test in such a way as to minimize discomfort and risk. However, I understand that just as with other types of diagnostic tests there are potential risks (approximately 2 to 3 per 10,000) associated with an exercise test. These include episodes of lightheadedness, fainting, chest discomfort, leg cramps and very rarely heart attacks or sudden death. There is no risk or side effects associate with the radioisotope injection. I further understand that the laboratory is properly equipped for such situations and that its professional personnel are trained to administer any emergency care necessary. I voluntarily accept the risks associated with the above procedures.

Signature of Patient

Signature of Witness

Date

XXXXX Nuclear Laboratory

CONSENT FOR ADENOSINE MYOCARDIAL PERFUSION SCAN

I, _____, authorize Dr. _____ and his assistants to administer and conduct an adenosine myocardial perfusion stress test. This test is designed to determine the presence or absence of clinically significant heart disease; to evaluate the effectiveness of my current therapy; and/or to measure my fitness for work or sport.

I understand that I will be given a dose of medicine, adenosine. I will walk in place for 2 -4 minutes to minimize or reduce side-effects of the adenosine. After 2 minutes a radioisotope substance (Tc99M tetrofosmin) will be injected intravenously.

Every effort will be made to conduct the test in such a way as to minimize discomfort and risk. However, I understand that just as with other types of diagnostic tests there are potential risks (approximately 2 to 3 per 10,000) associated with adenosine myocardial perfusion test. These include episodes of dizziness, headaches, flushing, nausea or vomiting. Rarely extra heartbeats may occur. There is a very slight possibility of heart attack or sudden death, although these have not been reported. There is no risk or side effect associated with the radioisotope injection. I further understand that the laboratory is properly equipped for such situations and that its professional personnel are trained to administer any emergency care necessary. I voluntarily accept the risks associated with the above procedures.

Signature of Patient

Signature of Witness

Date