

Veterans Walk For Health Participant Safety

The Basics:

Every participant in the VWH trial is at high risk for having a heart attack. There is a very good chance that at least one participant will have a heart attack and die during the time they are participating in our study. Therefore, it is critical that all proper procedures have been followed in the recruitment, enrollment, safety screening, medical clearance, and informed consent process for every single participant.

Adverse Event Reporting: Whenever something bad, no matter how minor, happens to a participant, it **MUST** be reported to your site PI and to the Ann Arbor coordinating center as an adverse event!!! Whose job is it to report an adverse event? Whoever learns about it first. One of the primary jobs of the site coordinator will be to make sure all adverse events are reported appropriately.

Adverse Event Reporting Procedure (from recruitment site to Ann Arbor coordinating center)

- 1) Make sure the participant is safe or obtain emergency services immediately
- 2) Fill out an adverse event reporting form
 - available from your site coordinator
- 3) Submit the form to your site PI before the end of the day.
- 4) Fax the report to Ann Arbor: 734-761-2939 before the end of the day.

No participant identification information should be on the Adverse Event form when it is faxed to Ann Arbor, only site and study ID should identify the participant.

In Ann Arbor, all serious events will be classified according to three scales

- severity,
- expectedness
- relatedness to study interventions.

Unexpected, serious adverse events will be reported immediately to all 7 IRB's. This may result in immediate suspension of the study until the IRB gives approval to continue the study.

Even minor adverse events (harms to the patient) must be reported. There was a study at Johns Hopkins for in which the investigators gave a drug to healthy volunteers and several of the volunteers coughed a little after taking the drug. Finally, a healthy volunteer participant had such a severe asthmatic reaction to the drug that she died. The expert review panel found that if the minor adverse events of coughing had been reported, the pattern might have been recognized as potentially dangerous and the death of the healthy volunteer might have been prevented. Minor harms will not be reported immediately to the IRBs, however they will be reviewed monthly in the coordinating center to look for patterns that could lead to more serious problems. A summary of minor adverse reactions will be given to the IRBs each year for annual review. Contrary to what you might think, a long list of Adverse Events reported is actually seen favorably rather than unfavorably by the IRBs.

There are 5 expected adverse events, one of them serious. From the informed consent document:

- 1) Muscle and joint injuries are possible in a walking program. It is possible that you get an injury such as an ankle sprain, sore feet, sore legs or experience a fall as a result of increasing your walking. By gradually increasing your walking, walking in safe places, and wearing proper shoes, you can minimize these risks.
- 2) For most people, even those at high risk for having a heart attack, starting a walking program reduces the overall risk of having a heart attack. However, for a few individuals it might not be safe to start an exercise program. Therefore, prior to starting the walking program, your doctor must sign a form stating that it is ok for you to start a walking program. By gradually increasing your walking goals and by teaching you signs and symptoms that might indicate that you are having heart trouble, we will further decrease your risk of having a heart attack while walking.
- 3) If you have diabetes, a walking program is an important part of managing your blood sugar levels. However, walking can also increase your risk of very low blood sugar episodes and of problems with your feet. To reduce this risk, your dietitian will provide you with a copy of an "Exercising with Diabetes" handout and discuss with you how to exercise safely.
- 4) If you have high blood pressure, a walking program is an important part of managing your blood pressure. However, if your blood pressure is not well controlled, walking may increase your risk of having a heart attack or stroke. To reduce this risk we will check your blood pressure at each nutritional counseling visit and we will recommend that you talk to your doctor if your blood pressure is high.

There is also the possibility of loss of confidentiality, which means that someone not on the study team could obtain your data from the study. As described above, even if someone obtained your study data, they would not know your identity, because your name will not be included anywhere with your data. If someone was able to obtain the file linking your name with your study identification number, AND they were able to obtain your study data with your study identification number, then they could link your identity with your data. As described above, we will take many precautions to keep this from happening; so, it is very unlikely this will happen.

Additional Points:

Every member of the research team must have completed training in the Human Subjects Protection in research prior to assisting with recruitment, enrollment or data collection or any other aspect of the study. This includes all site coordinators, principle investigators and dietitians. If you have not completed the web-based training modules on Human Subjects Protection, please contact your site Principle Investigator to find out how to log on and complete this module.

Every member of the research team is responsible for protecting the participants in our study. Our participants are at particularly high risk for adverse cardiovascular events such as heart attacks and stroke. Any research staff person who has any reason for concern about the safety of a participant, no matter how small, must report the concern immediately to either the site principle investigator or to the study principle investigator. Every dietitian and site coordinator in the study has the authority to suspend participation until medical clearance has been obtained. Thus, any new symptoms of chest pain, shortness of breath, light headedness, passing out, swelling in the legs or any other concerning symptoms that might represent heart disease must be addressed immediately. Arrangements must be made for a medical evaluation by the patient's usual physician and the participant's nutritional counseling visits must be suspended until written medical clearance has been obtained. Any adverse cardiovascular events such as heart attack must be reported as an adverse event to the Human Subjects Protection or IRB committee at all participating sites. It is the responsibility the principle investigator in Ann Arbor to make sure that this happens, however, it is the responsibility of the site coordinators and dietitians to notify the site coordinators, site principle investigators and the Ann Arbor coordinating center.