## APPENDIX D

## NONTECHNICAL ABSTRACT OF PROTOCOL

One effective treatment for many types of cancers is autologous bone marrow transplantation. In this treatment the patient is treated until the disease can no longer be detected. At this point, about 1.5 pints of marrow are removed and stored frozen. The patient is then given extremely intensive drug and radiation treatment aimed at destroying any cancer cells which may be left. This intensive treatment also destroys the patient's remaining bone marrow cells. However, the individual is "rescued" by injecting back the marrow that has been stored for them.

Although this treatment has proven to be encouraging, there are two problems. The first is that the stored marrow, although taken when the patient has no visible cancer, may still contain some cancer cells. These unseen cancer cells could then regrow and cause the disease to return. In addition, the stored marrow is sometimes slow to grow. This means the patient lacks vital bone marrow cells for a longer period of time. Without these marrow cells the patient cannot adequately fight infection and may suffer bleeding. These problems are often life threatening.

The aim of the present protocol is to get information that will allow clinicians to devise ways to overcome or lessen these problems. Genetic markers will be used to trace the development and behavior of cells within the marrow. As the marrow cells harvested from the patient look the same as the cells remaining within the body, a way is needed to mark these cells. Gene marking is the only way to distinguish the returned cells from cells remaining in the patient's body. About 30% of the patient's marrow that is removed will be marked with a marker gene. These marked cells will then be stored with the untouched marrow and both will be given back to the patient after their intensive drug treatment.

If the patient does suffer a return of their cancer, we will look at their cancer cells for the marker gene. If no marker gene can be found, then the cancer probably regrew from cells left in the patient's body. This is possible even though no visible cancer cells may have been seen in the patient. The doctors would then know that they needed to work on better methods to get rid of the cancer cells left in the body. If the gene is found in the cancer cells, then we know cancer cells were hiding with the returned marrow cells. If we know cancer cells are hiding in the returned marrow, the doctors can work harder to kill the cancer cells hiding in the marrow before returning the marrow to the patient. No matter which answers are obtained, the doctors will then be able to develop better treatments for similar cancer patients.

After marrow transplantation with marked marrow we will also look for the appearance of the marker gene in the patient's blood and marrow. By studying the normal cells which contain the marker gene, the doctors will learn more about the transplanted marrow cells. We will learn better ways to treat the patient before removing the marrow. We will also learn how to best treat the patient after the transplant so that the returned marrow grows as quickly as possible. The more that is learned about the marrow cells, the better the doctors will be able to use the marrow cells to help the patient.

The doctors hope that by using a gene to mark the marrow removed from a patient that they will learn how to better treat the patients. This knowledge will not only help patients with cancers similar to the ones studied, but also many other patients as well.