EXHIBIT 3-1

MULTICENTER STUDY OF HYDROXYUREA IN SICKLE CELL ANEMIA

(Consent Form)

1. Nature and Purpose of the Study

You have sickle cell anemia and you suffer from attacks of pain. The purpose of this study is to see if a medicine called "hydroxyurea" can reduce the number of your painful attacks. Over 250 patients with sickle cell anemia are expected to join this study.

The time between your own painful attacks may be short or long. The reason some patients go for a long time with no attacks and then have many of them is not known. Because painful attacks vary so much, it can be hard to tell if a new medicine really works. To find out if hydroxyurea can make patients have fewer attacks, we have to test it along with an inactive "look-alike" capsule.

Hydroxyurea is used to treat other sicknesses. It can change some of the hemoglobin in your red blood cells from sickle cell to fetal (baby) hemoglobin, which was in them before you were born. This baby hemoglobin does not sickle and may help prevent your red cells from sickling which causes pain.

2. What to Expect

If you agree to join this study you will be asked to take capsules every day. Half of the patients will get capsules of hydroxyurea and the other half will get a capsule with the inactive "look-alike". This will be decided by chance, like a lottery. Neither you nor your doctor will know which of the two kinds of capsules you are taking. However, the study office will keep a record of what you are taking, should it become necessary for your doctors to know this. You will be asked to

take your capsules every day for 2-3 years or as long as you are in the study. You will also receive folic acid vitamin pills. You should not join the study unless you are ready to continue for 2-3 years.

As long as you are in the study, you will need to be seen every two weeks. Each visit will take about half an hour. At each visit a blood sample from a vein will be drawn with a needle and a test tube to be sure that your treatment is safe, and to decide on any changes in the dosage of your medicine. These samples will also be used to see if you are taking your medicine. Each sample will use only about two teaspoons of blood (about one pint per year).

We will ask you to keep a record, every day, of whether you have had any pain. At each visit we will go over your medicine and your pain records. We will ask if you have had to visit a hospital or clinic because of pain. Someone from the study office in Maryland will call you at home once a month to ask how you have been feeling. Pain medicine will be prescribed for you if you need it. Twice a year we will fill out a form about how much you can do and how well you feel.

Dr. _____ and the study staff will ask about your health in the past. You will be asked to sign forms so that we can get records from your private doctor or hospitals where you have been treated.

Hydroxyurea could be harmful to someone with the AIDS virus so you will be tested before you join the study. Only you will be told of the result. If the AIDS virus test is positive you will not be able to join this study, but we will give you advice on how to get good medical care for this infection.

3. Risks of Taking Hydroxyurea

Sometimes hydroxyurea can cause a sick stomach and vomiting, skin rash, hair loss, liver or kidney disease, infection, or bleeding. These bad effects have not been seen so far in studies of sickle cell patients. As far as is known these bad effects of hydroxyurea happen to fewer than one in a hundred patients and usually clear quickly when the drug is stopped.

There is a small risk that you may gain a lot of weight.

Because hydroxyurea can reduce your blood count we will check it every two weeks. If your blood counts are too low, or if other side effects occur, or when study plans call for a break in treatment, your study treatment will be stopped until study plans call for you to start your treatment again.

Hydroxyurea might increase the risk of some cancers. Although this risk is not certain to exist and at the most is small, you should be aware of this possibility.

Hydroxyurea could damage an unborn baby. If you are planning a pregnancy you should not join this study. All patients (or their partners) must use birth control. You may only join this study if you and your partner agree to use birth control (pills, rubbers, or diaphragm, for example), or have had an operation to prevent pregnancy (tubes tied, womb removed, or vasectomy). If you are not already using birth control, we will help provide it. All women who enter this study will be tested for pregnancy. If a pregnancy occurs while you are in this study you will be offered the most complete advice available. You cannot continue to take hydroxyurea while pregnant.

If any man treated in the study fathers a child he will have to think about the possibility of bad effects on the baby even though it is he and not the woman who is taking the study medicine. Men in the

study and their pregnant partners will need advice of the same sort as any woman who enters the study and becomes pregnant. We do not know if it will be safe to have a pregnancy after treatment is stopped.

As with studies of all new treatments, there may be other risks to using hydroxyurea that are not now known. If any new bad effects are observed, patients in the study will be told as soon as possible and action taken to protect their safety.

4.Benefits

You may have pain less often if you take hydroxyurea. If a good effect is seen, it may take several months to develop. Any important medical information about you or about the results of this study will be available to the doctors who take care of you.

5.Privacy

In this study only your own clinic and the central, assistant coordinator will know your name. They will make note of your initials, age, sex, weight, and height. Only that identification will be stored in the study computer. You will not be identified personally in any report from this study. Your personal medical reports will be kept private. At the end of the study a computer tape of the study results will be made for future use. It will not include any information that could identify you directly. Information may be given to the National Institutes of Health or the Food and Drug Administration, but your name will not be used in such files.

6.Other choices

If you join this study, it is your own choice. You may refuse to take part in it or you may leave it at any time. If you do not join, or leave, doing so will not harm your present or future care at the

hospital or clinic. Instead of taking part in this study you may go to your doctor for your usual treatment of sickle cell anemia.

7. Costs paid for by the study

You will not be charged for any of the study visits, treatments or procedures. The cost of the hydroxyurea, folic acid, and blood tests for this study will be covered by the study.

8. Costs not paid for by the study

If you need medicine other than hydroxyurea or folic acid the study will not pay for it. If you must visit your private doctor or emergency room, or must stay in the hospital, those costs will not be covered by this study.

9. Payments to you

You will be paid $5.00 per week for filling out the pain record each day. You will also be paid $40.00 a month for travel and telephone costs. You will receive this money (a total of $60.00 each month if all pain records are complete) from the clinic once a month during one of your study clinic visits. If you do not attend study clinic visits or become unable to take part in the study then you will no longer be paid that money.

10. Rights

You will be given a copy of this consent form to keep. If at any time you have questions or concerns about the study you may call either _____, the study staff, or _____, a person whose job is to watch over the well being of patients in medical research projects. Should you have any bad effect of treatment during the study, care will be provided to you. The cost of treating such bad

effects is not covered in the study, and no money has been set aside to pay for these bad effects.

11.Questions

This study has been explained to you by Dr. _____ and your questions were answered. If you have any other questions about this study you may call Dr. _____ at _____.