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BRI - IRB
Houston, TX
DEC 0 5 2002

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9432 Old Katy Road
Houston, Texas 77055

STATEMENT OF INFORMED CONSENT FOR INVESTIGATIONAL CLINICAL STUDY

You are being asked to allow your child to participate in the treatment with investigational drugs. The doctors at Burzynski Clinic study the nature of disease and attempt to develop improved methods of diagnosis and treatment. This is called clinical research. In order to decide whether or not you should agree that your child will receive this treatment, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent.

This consent form gives detailed information about the treatment the doctor will discuss with you. Once you understand the treatment, you will be asked to sign this form if you wish your child to participate. You will have a copy to keep as a record.

The treatment being proposed to you is under: SPECIAL EXCEPTION TO:

PHASE II STUDY OF ANTINEOPLASTON A10 AND AS2-1
IN
CHILDREN WITH PRIMARY MALIGNANT BRAIN TUMOR

PURPOSES OF THE STUDY

The purposes of this clinical study are: 1) to find out whether or not infusions containing Antineoplastons A10 and AS2-1 will produce objective tumor shrinkage and an overall improvement in the condition of children with primary malignant brain tumor. 2) to identify and describe any toxic effects of this treatment.

Your child has primary malignant brain tumor . While conventional treatment with surgery and chemotherapy may cure children with primary malignant brain tumor , some children are not cured. Experimental protocols, such as studies of the administration of Antineoplastons, may be considered after conventional treatments have failed.

The dose of antineoplastons to be administered will be based on the doses that were used in the patients previously.

DESCRIPTION OF THE TREATMENT PROCEDURES

In order to determine if you or your child is eligible you have been presented this consent form. You have already been interviewed, in addition you or your child will be examined and have a series of tests, usually as an outpatient. Such tests may include x-rays, CT scans (a special type of x-ray using a computer), MRI scans, nuclear medicine tests, blood and urine tests, and in some instances a urine pregnancy test will be performed to determine whether or not you or your child

[redacted]

qualify to participate in this study. A urine pregnancy test will be performed on qualifying females prior to study entry and at least quarterly during treatment. If your child is a female and is pregnant or breast-feeding she must not participate in the treatment. If your child is female and capable of becoming pregnant, she should have been practicing an acceptable method of birth control for four weeks prior to starting the study. She should continue to do so during the study and for at least four weeks following completion of the study. Acceptable methods would include a birth control pill, use of a diaphragm, or intrauterine device, or the use of a condom by your sexual partner. If your child is a male, he should use appropriate contraception, such as a condom, during the study and for at least four weeks following completion of the study.

Drug administration requires the use of catheter (plastic tube) placed in a large vein in the upper part of the body; these catheters are widely used to permit administration of a variety of medications to patients. If you do not already have a central venous catheter, it will be necessary to place one in order for you to participate in this study. The risks of placement of the catheter can include pain or discomfort at the site of insertion, injury to the blood vessels or the lung resulting in leakage of blood or air. Leakage of large volumes of antineoplaston under the skin from broken catheter or port located under the skin may cause swelling and blister formation followed by ulceration of the skin. Additionally central catheters may become infected by bacterial or fungal organisms. Under most circumstances, these complications can be treated by administration of anticlotting or antibacterial medications through the catheter. In some patients the device must be removed.

You and your family members or care giver will be trained in monitoring the infusion pump and replacing the plastic bag which contains the Antineoplastons as the infusion of the contents of the previous bag has been completed. In addition to receiving support and advice from this clinic, you may be visited in your home by nurses who are trained in infusion therapy. Prior to the starting of administration of antineoplastons (if you are living outside of the Houston area), arrangement must be made with a qualified physician in your local area to provide continuing medical care and submit medical reports on your progress to the study sponsor.

During the course of your child's participation in this clinical trial you and/or your child will be required to comply with the schedule as specified in the study protocol. This schedule requires monthly physical examinations performed by your Investigator while on study. Laboratory tests will be performed on your or your child's blood. In order to obtain a specimen it is necessary to draw blood from your catheter. If it is not possible to obtain a specimen from the catheter it will need to be taken from a vein in your child's arm using a sterile needle. This can cause slight pain and/or bruising at the site. A total of 15cc (or 3 teaspoons) of blood will be drawn as often as every other day. Since a significant volume of fluids will be administered during the course of treatment, which can result in electrolyte abnormalities, it is extremely important to adhere to the blood testing schedule. After 60 days on treatment and provided that your child do not have any major electrolyte abnormalities, the frequency of the blood tests can be reduced to two times per week. Your child will also be required to have radiological testing performed periodically during the course of your enrollment. This testing involves injecting a small amount of dye or radiolabeled material into your child's vein using a sterile needle. There is a possibility of an allergic reaction to this dye.

Although the precise duration of therapy cannot be predicted, it is planned that it will be continued until it is clear whether it is producing beneficial effects on the tumor. It is expected that the majority of patients will receive the treatment for at least a two-month period. Your child may continue to receive Antineoplastons as long as the study lasts, provided that there is no evidence of progression of your cancer, and you are willing to continue receiving therapy. If we detect evidence that the drug is not working against the tumors, you will be offered suitable alternative therapy. If Antineoplastons produce improvement or stabilization of your child's cancer (either shrinkage or no further growth), it is planned to continue treatment until such time as your child no longer benefit from them.

POSSIBLE SIDE EFFECTS AND RISKS OF THIS TREATMENT PROGRAM

Currently, all treatments for your child's cancer, either conventional or experimental, have potential side effects, including those that may be life threatening; you should be aware that there are risks associated with this study. The antineoplastons and their waste products that appear in the urine have a strong and unpleasant odor; this odor may be strong enough to be detectable by family members and social contacts during the treatment period.

Based on previous clinical studies, Antineoplastons treatment can produce the following side effects: Central nervous system toxicity including blurred vision, ringing in ears, hearing loss, headache, dizziness, slurred speech, hallucinations, depression, tiredness, mood changes, sleepiness, polyneuropathy (numbness and tingling) and thickening of the skin, arrhythmia (changes in your heart rate), nausea, vomiting, diarrhea, anemia, increase of blood pressure, swelling, fluid retention or fluid loss (both of which may be serious), weakness, electrolyte imbalance including: decrease of calcium, sodium, potassium, magnesium, and/or increase in sodium concentration in blood (forgetfulness, confusion, cramps) which in extreme cases may become life-threatening. Other side effects may include: Decreased white blood cell count which can result in an increased chance of infection, a decrease in platelet count (increased chance of bleeding), blood in the urine, an elevated bilirubin which can result in jaundice (yellowing of the skin and whites of the eye), fever, chills, skin rash, muscle aches, joint pain, abdominal pain. There is a possibility of liver toxicity, increased urination, increased thirst. You or your child may also experience a metallic taste or shortness of breath while on therapy. AS2-1 also has a distinct chemical smell.

Your child will be closely observed and supportive therapy will be directed towards minimizing side effects. If during the course of treatment we become aware of significant drug-induced side effects, we will provide this information to you and discuss its effect on your child's continued participation in this study. If your child encounters severe side effects, drug treatments will be interrupted and consideration given to discontinuing them. You or your child should also be aware that Antineoplaston therapy may involve risks of which we are not currently aware. If your child is a female of childbearing age and may become pregnant during this treatment, there may be risks to your child and to the fetus (unborn child) that are unknown and may result in unforeseen events including disability and death. If your child is a sexually active man, he should use a condom or other technique to prevent pregnancy in a sexual partner with sperm that may have been affected by this drug treatment.

COMPENSATION

If you or your child is injured as a result of participation in this research study, emergency care will be made available by the hospital and billed to you as part of your or your child's medical expenses. No financial consideration or compensation will be provided for a research-related injury. You should be aware that your insurance provider may not cover study related costs.

RIGHT TO REFUSE OR WITHDRAW

Participation in this treatment is entirely voluntary; the choice to have your child to take or not take this treatment is yours. If you decide your child will not participate, other choices are available without prejudice. If your child begins the treatment, you still have a right to withdraw him or her at anytime. You will be notified of significant new findings developed during this treatment that may influence your willingness to continue participation. If you should withdraw your child, he or she will be offered other available care that suits his or her needs and medical condition. Such alternative therapy could include other forms of chemotherapy with other experimental or conventional drugs.

BENEFIT OF PARTICIPATION

Although we hope that this treatment will be of benefit to your child and that the information derived from participation in it will help others, we cannot say that it will be directly beneficial to your child.

PRIVACY

The research and hospital records that identify your child by name will be maintained in strict confidence, except that they may be inspected by the sponsor of the protocol, the Food and Drug Administration, and other government agencies; they will not otherwise be released except by law.

INVOLUNTARY REMOVAL FROM THE STUDY

The Investigator may discontinue patient from the study at any time when he feels that this is in the best interest of the patient. Patient may be discontinued from the study in the event of progressive disease after six weeks of treatment, the development of unacceptable side effects, or other adverse experiences, initiation of treatment with other cancer therapy in addition to the test drug, intercurrent illness which in the judgement of the investigator affect the assessment of clinical status to a significant degree which would require discontinuation of the test drug, or patient's serious or repeated participation non-compliance with the protocol specifications.

INSTITUTIONAL REVIEW BOARD

This Board reviews study protocols to ensure that research with patients is appropriate and that the patient rights and welfare are protected, and this Board has reviewed this protocol.

Any patient with questions about their rights and whom to contact in the event of research related injury should contact the IRB Chairman by mail at: 9432 Old Katy Road, suite 370, Houston, Texas 77055, phone # (713) 365-0222

QUESTIONS

The physician in charge of this treatment is: Dr. Stanislaw R. Burzynski, Telephone number: (713) 335-5697. If you need more information about this treatment before you decide to join, or at any other time, you may contact this physician. In the event that you do decide to participate, the physician in charge should also be called if there are side effects from the research study.

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PATIENT INFORMED CONSENT FOR CLINICAL RESEARCH

Title: Phase II Study of Antineoplaston A10 and AS2-1 in Children with Primary malignant brain tumor

Purpose: The purposes of this treatment protocol are to find out whether or not infusions of these antineoplastons will reduce the tumor size and benefit children with Primary malignant brain tumor and to describe any toxic effects of this treatment.

PATIENT'S PARENT STATEMENT

I have read the description of the treatment protocol, I have also talked it over with the doctor to my satisfaction. I understand that my child's participation is voluntary. I know enough about the purpose, methods, risks, and benefits of the treatment to judge that I want my child to take part in it. I understand that I may freely stop my child's participation in this treatment at any time. I have received a copy of this consent form to keep for myself.

[redacted]
Patient Name (print)

[redacted]
Patient's Parent Signature

009896
Patient Number

Date: 9-29-04

WITNESS SIGNATURE

[redacted]
Witness Name (print)

[redacted]
Witness Signature

Date: 9-29-04