Genetic Centers of America

Consent for Enrolment in the Geier Experimental Protocol For the Treatment of Autism

Patient: Date:

1. I request that my child be enrolled in the Geier Experimental Protocol for the treatment of autism. The Institutional Review Board (IRB) of the Institute for Chronic Illnesses (Office for Human Research Protections, US Department of Health and Human Services IRB number: IRB00005375) has approved this study protocol.

2. This protocol utilizes Lupron to lower testosterone (the male hormone) levels. Lupron is an FDA approved drug for lowering testosterone levels in cases of precocious puberty by inhibiting the release of FSH and LH from the pituitary in the brain. Lupron is also approved for use in lowering testosterone in cases of benign prostatic hypertrophy, prostate cancer, and in other conditions where it is helpful to lower testosterone levels. The package insert for Lupron lists the following as potential adverse events: In two studies of children with central precocious puberty, in 2% or more of the patients receiving the drug, the following adverse reactions were reported to have a possible or probable relationship to drug as ascribed by the treating physician. Reactions which are not considered drug-related are excluded. Body as a Whole - General Pain, Acne/Seborrhea, Abscess, Rash, Erythema Multiforme, and Vaginitis/Bleeding/Discharge. In those same studies, the following adverse reactions were reported in less than 2% of the patients. Body Odor, Fever, Headache, Infection, Syncope, Vasodilation, Dysphagia, Gingivitis, Nausea/Vomiting, Accelerated Sexual Maturity, Peripheral Edema, Weight Gain, Emotional Lability, Nervousness, Personality Disorder, Somnolence, Epistaxis; Alopecia, Skin Striae, Cervix Disorder, Gynecomastia/Breast Disorders, and Urinary Incontinence. FSH and LH stimulate the production of testosterone in the body. Thus by inhibiting FSH and LH, Lupron temporarily halts the production of testosterone.

3. At some point on the protocol heavy metals may be removed by means of chelation. Chelation is a process by which patients are given medicines which bind mercury and help to eliminate it from the body. The chelation agents utilized in this protocol would be DMSA. DMSA is an FDA approved chelating agent. The package insert lists the following as potential adverse events: nausea, vomiting, diarrhea, appetite loss, hemorrhoidal symptoms, loose stools, metallic taste in mouth, back pain, abdominal cramps, stomach pains, head pain, rib pain, chills, flank pain, fever, flu-like symptoms, heav head/tired, head cold, headache, moniliasis, elevated SGPT, SGOT, alkaline phosphatase, elevated serum cholesterol, drowsiness, dizziness, sensorimotor neuropathy, sleepiness, paresthesia, papular rash, herpetic rash, rash, mucocutaneous eruptions, pruritus, cloudy film in eye, ear plugged, otitis media, eyes watery, throat sore, rhinorrhea, nasal congestion, cough, decreased urination, voiding difficulty, proteinuria increased, arrhythmia, mild to moderate neutropenia, increased platelet count, intermittent eosinophilia, kneecap pain, and leg pain. In order to attempt to ensure maximum safety of chelation, if employed, essential mineral levels are monitored and kept within normal levels by supplementation to assure that the chelation process does not interfere with normal minerals in the body.

4. Children on the protocol will have kidney, liver, and thyroid function tests routinely monitored. When the protocol is complete the chelation, if employed, and anti-testosterone medications are discontinued.

5. I understand that this protocol is experimental. I further understand that although some initial success has been observed in children undergoing this protocol, there is no assurance that it will help my child.

6. I understand that although the medicines and procedures used in this protocol are believed to be relatively safe, since the protocol is experimental and the drugs are being used in a new way, there may be some yet to be determined risks associated with it.

7. I have had all of my questioned about this protocol answered and I full understand the potential risks and benefits of this protocol. I have made an informed consent decision to have my child undergo treatment under this protocol and I agree to follow the protocol. I agree to allow the publication of results obtained from my child's participation in this study with identifying information removed. I fully understand that I may withdraw my child from the protocol at any time that I so desire. I also understand that the medical personnel may ask me to withdraw my child from the protocol if they determine in their minds that it is not working well for my child.

8. No warranty, guarantee, or assurance has been given to me by anyone as to the results that may be obtained from the protocol described above.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT AND AGREE WITH IT

Parent or Guardian

Counselor/Physician