GEIER CLINICAL STUDY PROTOCOL

TREATMENT PROTOCOL –

1. The child is to be injected with the non-depot form of Lupron, (Pediatric, leuprolide acetate) 0.2 mL given by subcutaneous injection.
2. The child is carefully observed for three days for any adverse events.
3. If no adverse reactions are observed the child is given the depot form of pediatric Lupron depot (28 Days – 15 mg) will be administered on what will be called day one. Additionally, the non-depot Lupron will be administered subcutaneously on a daily basis (0.4 mL / Day) also starting on day one. The patient's parents should begin a daily log to record daily behaviors (positive and negative).
4. Absent any significant adverse reactions the child will continue to receive Lupron depot shots (28 Days – 15 mg) every 28 days and daily non-depot Lupron injections. The child will be assessed to determine if the dosage is sufficient to control androgen activity. If needed, additional doses of daily non-depot Lupron or Lupron Depot injections will added.
5. Patients on the protocol are to be monitored for androgen (including: DHEA, DHEA-S, Androstenedione, and Testosterone), glutathione levels, liver and kidney testing, thyroid testing, and CBC with differential testing once per month.