



The University of Chicago

The Division of Biological Sciences The Pritzker School of Medicine
The University of Chicago Hospitals

Institutional Review Board

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INSTITUTIONAL REVIEW BOARD CERTIFICATION

Principal Investigator: Robert Rosenfield
Facex: [REDACTED]
IRB Protocol Number: 13472A
Type of Submission: Revised Pending-Conditional
Meeting Date: 11/09/04
Informed Consent: Written
Special Population: Children
Advertisement Used: Yes
Protocol Title: Gonadotropin Releasing Hormone (GnRH) Agonist Test in Disorders of Puberty
Protocol Version: Dated 12-15-04
Grant: Date stamped 12-20-04
Child Volunteer Assent Form: Dated 11-23-04
Child Patient Assent Form: Dated 11-23-04
Parent (Volunteer) Consent: Dated 1-7-05
Parent (Patient) Consent: Dated 1-7-05
Adult Volunteer Consent: Dated 1-7-05
Adult Patient Consent: Dated 1-7-05
Advertisement: Dated 10-5-04
Risk Level: *Children with a pubertal disorder-* Minor increase over minimal risk
Children without a pubertal disorder- Minor increase over minimal risk
Adults (18 years and older)- More than minimal risk

- STATUS:**
1. Approved for adults (volunteers and patients) and children with a pubertal disorder
 2. Unapproved for children without a pubertal disorder

THE RESEARCH PROTOCOL AND/OR CONSENT FORM DESCRIBED ABOVE HAVE BEEN REVIEWED BY THE IRB WITH THE RESULTS AS INDICATED.

Please note that any externally funded research, even if approved by the IRB, may not be initiated until a fully executed agreement has been approved by the University Research Administration.

Federal regulations require that any severe drug reaction and unexpected or adverse occurrence to subjects during the conduct of this research be reported to the IRB. Any changes to this protocol must be submitted for review to the IRB.

Date: JAN 11 2005

Signature of Chair: _____


Jonathan Moss, M.D., Ph.D.

**Approval Period: January 11, 2005 through November 8, 2005*