

6. The Institutional Review Board meeting minutes dated May 3, 2005.

Minutes for 5-3-05 Meeting

Protocol: 13472A, Amendment 2

Principal Investigator: Robert Rosenfield

Title: Gonadotropin Releasing Hormone (GnRH) Agonist Test in Disorders of Puberty

The child consent forms (both for patients and volunteers) have been revised to include changes as requested by Dr. Sheridan. Specifically, 1) the number of study subjects has been added to the child volunteer form, 2) clarification regarding the absence of side effects from leuprolide in healthy children has been added to the risks sections of both the child and patient forms), 3) pregnancy testing has been removed from the consent forms and assent forms as PI stipulates that all study subjects are in early puberty, not sexually mature. The benefits section of the volunteer assent form has been changed to indicate subjects “may benefit”. Formerly it stated volunteers would not benefit from the study.

Administrative Note: Staff noted that the grant contained reference to pregnancy testing although PI stated he removed pregnancy testing from the consent forms. PI clarified that he accidentally kept that phrase in the grant and has now removed it and provided the IRB with a revised grant. The reviewer recommends approval of the amendment.

Vote: For 8 Against 0 Abstain 0, Non-Scientist Voting