

18. Institutional Review Board meeting minutes dated March 8, 2005

Minutes for 3-8-05 Meeting

Protocol #: **13472A AD 1**

Principal Investigator: Robert Rosenfield

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

Summary of protocol:

1st reviewer: This is a protocol that seeks to use two antecedent protocols (6585 and 9214) to amalgamate these data and to allow data collection with them. This is a rather complex issue as it involves using data from the pre-HIPAA era in whom the information was not regarded quite so scrupulously. The reviewer noted that in the updated form of 9214 the consent form indicates current aspects of confidentiality which are in line with current guidelines. The question here involves whether this new protocol entitled 13472A amendment 01 in fact can legitimately incorporate data from these previously approved studies. The reviewer noted the new revised protocol 13472A is very much the same sort of protocol with the same investigator so it may well pass muster here. The reviewer requested that the amendment be given a more thorough review by another reviewer.

2nd reviewer: Because the antecedent protocols are old and were written prior to HIPPA, this new protocol is just a continuation of the former study. The data should be allowed to go forward.

Discussion: None

Issues: None

Recommendation: The Committee recommended approval

Recommendation: Approval

Vote: 10 For 0 Against 0 Abstaining 10 TOTAL
Non-Scientist voting
