

17. UC Institutional Review Board memorandum from Dr. Moss dated March 7, 2005.

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

Institutional Review Board

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Monday, March 07, 2005

MEMORANDUM

Principal Investigator: Robert Rosenfield

Re: **Protocol#:** 13472A **Amendment #:** 1

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

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. I do note 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. I do not have the new revised protocol 13472A in front of me but my recollection is that it is very much the same sort of protocol with the same investigator so it may well pass muster here.

I believe that this is an issue that will require more thorough review and would ask that it be given to one of our member so that it can be reviewed for that purpose.

3/02/05: Sent to Reviewer 1 and Reviewer 2

Jonathan Moss, M.D., Ph.D.
Chairman
Institutional Review Board