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June 22, 2005

Kevin Prohaska, D.O.
Children's Coordination
Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: FWA00005565/45 CFR 46.407 Review for Protocol #13472A
"Gonadotropin releasing Hormone (GnRH) Agonist Test in Disorders of Puberty" – PI, Dr. Robert Rosenfield

Dear Dr. Prohaska:

In compliance with 45 CFR 46.407, the University of Chicago is requesting that OHRP submit the above cited protocol for DHHS/OHRP review. This protocol has been reviewed by IRB 000331 (IRBA University of Chicago/University of Chicago Hospitals). Initial approval for the child and adult patient population and adult volunteers was granted January 11, 2005 excluding those subjects who are healthy children as controls. That portion of the study proposing to involve healthy children as volunteers is on hold pending this review.

The proposed research would use the General Clinical Research facilities and resources supported through DHHS/NIH/NCRR award #M01RR00055.

Attachments to this letter are organized with separately tabbed sections, and should provide the background information and documents necessary for the 407 review. To facilitate review of the protocol, the first sections are the final research narrative and GCRC grant application that are the approved IRB documents, including the final approved child patient consent/assent and child volunteer consent/assent. These documents constituted **Amendment 2** to the protocol. The initial protocol received two "pre-reviews" prior to the protocol being submitted for formal IRB review at the November 9, 2004 meeting. Documents from pre-review through Amendment 1 are organized in chronological order.

We understand that if OHRP solicits public comment on the proposed research, as required by 46.407 before HHS support for such research may be approved, OHRP will seek written permission from the institution, the IRB and the principal investigator before allowing public review of the grant application, protocol application, permission/assent documents, and relevant IRB records.

Please contact me if any further information or documentation would be helpful. We look forward to completing the 407 review and approval process and initiating this component of the research program.

Sincerely yours,

Mary Ellen Sheridan, Ph.D.

Attachments

c: James Madara M.D., Dean, Division of Biological Sciences
Jonathan Moss, M.D., Ph.D., Chair, UC/UCH IRB
Steve Goldstein, M.D., Chair, Department of Pediatrics
Robert Rosenfield, M.D., Principal Investigator

Index of Attachments
University of Chicago
IRB Protocol # 13472A

Tab A	March 4, 2005 Correspondence from IRB Chair to Institutional Official June 20, 2005 Correspondence from IRB Assistant Director to Institutional Official. PLEASE NOTE THE ATTCHMENTS ARE NOT IN THE ORDER OF CITED DOCUMENTS IN THESE LETTERS.
Tab B	Letter to IRB Chair (Dr. Moss) from Dr. Lainie Ross addressing the use of child volunteers in Dr. Rosenfield's research. (Although written with direct application to another protocol, the issues are the same ones applicable in the protocol in question.)
Tab C	Amendment #2-Submission Form with Approved Research Narrative
Tab D	Amendment #2- Final Version GCRC application
Tab E	Amendment #2- Child Patient Consent & Child Patient Assent Forms; Child Volunteer Consent & Child Volunteer Assent Forms
Tab F	Final IRB Approval Amendment #2 at May 3, 2005 IRB meeting with minutes of the meeting
Tab G	October 13, 2004 Protocol Submission Form (this is revised version in response to pre-review), including Supplement Form A listing Coinvestigators and Supplement Form B Other Research Personnel
Tab H	IRB Supplement Form D Research Involving Drug; Package Insert Lupron Adults; Package Insert Lupron Pediatric Use
Tab I	Response to second pre-review October 29, 2004 – Supplement C Research Involving Children (Patients); Supplement C Research Involving Children (Normal Volunteers)
Tab J	Supplement Form G Genetic Testing
Tab K	First pre-review and response from investigator
Tab L	Approved Study Advertisement – Volunteers
Tab M	2nd Pre-review and PI Response to 2nd Pre-Review
Tab N	FDA IND Application
Tab O	IRB Pending Conditional Letter from Meeting of November 9, 2004 and pertinent Minutes of Meeting
Tab P	PI Response to Pending Conditional Letter from IRB
Tab Q	Adult Patients Consent Form/Adult Volunteer Consent Form (THESE ARE THE FINAL APPROVED FORMS); Child Patient Consent & Assent Forms and Child Volunteer Consent & Assent Forms. Child forms were later amended, re-reviewed and approved – see Tab E above
Tab R	GCRC Review letter to PI December 7, 2004 and PI responses to GCRC Review
Tab S	IRB Revised Pending Conditional Letter of November 9, 2005 and Minutes of November 9, Meeting
Tab T	Amendment 1 – IRB Approval March 8, 2005. Amendment Submission Form, Initial assessment by IRB Chair and Reviewers.