3. Correspondence dated June 20, 2005 from UC Institutional Review Board A, Division of Biological Sciences to the UC Associate Vice-President for Research providing information on two amendments approved by the IRB.

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

**Institutional Review Board**
*5841 S. Maryland Ave.*
*AMB S-138 • MC 1108*
*Chicago, Illinois 60637*
(773) 702-6505

Mary Ellen Sheridan, Ph.D. June 20, 2005
Associate Vice-President for Research and
Director of Research Administration
The University of Chicago
970 E. 58th St., 3rd fl
Chicago, Illinois 60637

Dear Dr. Sheridan,

In a letter dated March 4, 2005, Dr. Jonathan Moss had requested that the Biological Sciences Division (BSD), Institutional Review Board (IRB) Protocol #13472A, "Gonadotropin Releasing Hormone (GnRH) Agonist Test in Disorders of Puberty" be forwarded to the Office for Human Research Protections for 407 review consideration. I wish to inform you that since that time, two amendments to the protocol have been submitted and approved by the BSD IRB, one of which involved a change to the protocol, grant and consent forms.

For your convenience, listed below is the timeline of events related to the original submission, as well as Amendments #1 and #2. In addition, for easy identification, I have bolded the documents that are currently approved for use.

Original Submission:

1. Full Approval letter dated 1/11/05
2. Meeting minutes from 1/11/05
3. GCRC review dated 12/7/04
4. Principal Investigator's response to the Pending-Conditional letter
   a. e-mail dated 11/29/04
   b. e-mail dated 12/20/04
   c. e-mail dated 1/5/05
   d. e-mail dated 1/6/05
5. Pending-Conditional letter dated 11/23/04
6. Meeting minutes for 11/9/04
7. **The Protocol Submission Form dated 9/7/04**
8. **Supplemental Forms A and B (co-investigators and research staff)**
9. **Supplemental Form C for research in children (2):**
   **a. Form C for healthy volunteers**

**b. Form C for children with a disorder**

**10. Supplemental Form D for research involving drugs**

**11. Leuprolide Package Inserts (for adult and pediatric use)**

**12. Supplemental Form G for genetic testing**

13. The portion of the GCRC grant that describes this study
14. The approved detailed narrative dated 12/15/04
15. The approved written consent forms (4):
    a. Parental consent for child patients dated 1/7/05
    b. Parental consent for child volunteers dated 1/7/05
    **c. Adult volunteer consent dated 1/7/05**
    **d. Adult patient consent dated 1/7/05**
16. The approved child assent forms (2):
    a. Volunteer assent dated 11/23/04
    b. Patient assent dated 11/23/04

**17. The approved study advertisement dated 10/5/04**

18. FDA IND application dated 9/16/04
19. Principal Investigator's response to IRB pre-reviews
20. 2nd IRB pre-review and PI response
21. 1st IRB pre-review and PI response

Amendment 1:

1. Minutes dated 3/8/05
2. Approval letter dated 3/8/05
3. Amendment submission form dated 2/9/05

Amendment 2:

1. Minutes dated 5/3/05
2. Approval letter dated 5/3/05
3. Amendment submission form dated 4/3/05
4. E-mail communication dated 4/9/05

**5. Revised grant dated 4/19/05**

**6. Revised protocol dated 4/19/05**

**7. Consent form (child patients) dated 4/3/05**

**8. Consent form (child volunteers) dated 4/3/05**

**9. Assent form (child volunteers) dated 4/3/05**

**10. Assent form (child patients) dated 4/3/05**

Please feel free to contact me with any questions regarding this matter.

Sincerely,

Tasha Osafo
Assistant Director
Biological Sciences Division
Institutional Review Board
773-834-8994