Response to 1st pre-review

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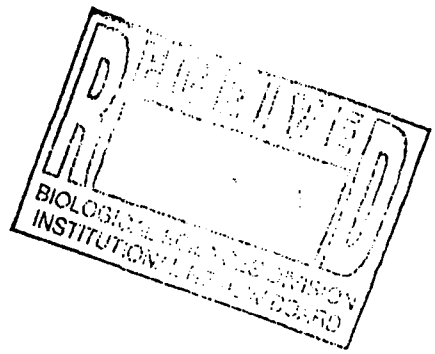

October 12, 2004

Tasha Osafo
Administrator of Regulatory Compliance
Institutional Review Board
Biological Sciences Division
The University of Chicago

Dear Tasha,

This is in response to some issues on the pre-review for new submission #13472A.

1) We have attached another Supplemental C Form specifically addressing volunteers.
2) Specific mention of potential collaborators has been removed from the protocol and the narrative. The consent forms have been accordingly modified.
3) See the attached, corrected Protocol Submission Form. Regarding page 7, question 1, please see page 4 of the grant under "Criteria for GnD" which indicates that adult patients will be included in the study population for comparison.
4) See attached, corrected Narrative.
5) See the attached, revised Supplemental Form D. The IND is "functionally inactive" because we are using generic leuprolide acetate (not Lupron). Since TAP, the maker of Lupron, is not interested in supporting the study, the use of leuprolide acetate as a diagnostic agent does not meet the criteria for requirement of an IND outlined in Supplemental Form D. All mention of the IND number has now been removed from the current protocol and its consent forms.
6) Attached package insert.
7) See attached, revised consents.
8) See attached, revised ad.

9) In regard to subject age, the age of onset of premature puberty can be as young as 6 months of age (now defined). We also now state that "The critical (diagnostic) samples can be obtained from children as small as 10 kg."

Thanks Tasha. Call if any questions.

Sincerely,

Debbie Walsh, MS, RN
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