



MEMORANDUM

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
2107 Ueberroth Building
169407

April 3, 2002

PAUL A. KROGSTAD, M.D.

RE: Request for Additional Information Prior to Issuing An Approval Notice
UCLA IRB #01-11-064-01
HIV Replication and Thymopoiesis in Adolescents

The Medical Institutional Review Board (M-IRB) wishes to thank you for your recent response, which was reviewed by the M-IRB during its meeting of March 13, 2002. The Committee found that more information is needed prior to issuing an Approval Notice. The Committee will be pleased to receive and review, as quickly as possible, your response to the questions on the following pages.

PLEASE NOTE: No subjects may be contacted, recruited, or enrolled into this study until an Approval Notice and approved informed consent form(s) have been issued.

It is the UCLA IRB policy that unless a response is received from you within 30 days of the date of this letter, your submission will be withdrawn from the approval process. Therefore, should there be reasons which make it impossible for you to respond before 30 days, please advise as soon as possible. If you have any questions, please contact

Sincerely,

Robert A. Figlin, M.D.
Chair
On behalf of the Medical Institutional Review Board

Please return two copies of your response to:

Office for Protection of Research Subjects
Medical Institutional Review Board
2107 Ueberroth Building
Campus Mail Code 169407

Paul A. Krogstad, M.D.

IRB #01-11-064-01

Page 2

- A. Please respond to the following, and make the necessary changes to the informed consent form(s) where appropriate; if you disagree with the Committee's requests for changes, please explain. **(Respond separately to each numbered item in sequence, employing the same number to identify your response.)**

1. The Board accepted your request to limit enrollment to adults, pending HHS review of the risks and benefits associated with involvement of children in this research study. When research reviewed under category 45 CFR 46.407 is federally funded, it must be submitted for review and approval by the Secretary of Health and Human Services (HHS), in consultation with appropriate experts. The IRB will submit this project of the Secretary of HHS for their deliberation. The IRB staff will contact you when notification of the decision is received.

In the interim, the Board accepts your request to "modify the substudy temporarily to include subjects 18 years of age or older only." However, the Committee noted that the revised consent forms include language regarding enrollment of "adolescents." Additionally, an assent form was submitted with your response. Please modify the consent forms accordingly, and forward the revised consent forms along with your response to this correspondence.

2. The Committee also concurs with your request to issue an administrative approval for the main study, pending further information regarding the deuterium labeled glucose that will be employed with this study.

Please note: The Approval Notice will be issued for administrative purposes only. No subjects may be contacted, recruited or enrolled. The related form(s) will be held on file with the M-IRB until the following information is received and approved by the M-IRB:

- a. Requested detail regarding the use and administration of the deuterium labeled glucose to be used in the main study.
 - b. The approval notice and consent documents reviewed and approved by the IRB of Children's Hospital Los Angeles.
 - c. A copy of the Medical Radiation Safety Committee approval for this study.
 - d. A copy of your revised Form 740.
- B. Please make the following modifications to the informed consent form: **(Please provide bold typeface or underline changes on one copy for the reviewers and provide two clean copies to be used as the official version of the consent form.)**

Paul A. Krogstad, M.D.

IRB #01-11-064-01

Page 3

1. Please fill-in all large gaps in each consent form.

2. Please indicate in the consent forms the number of subjects expected to enroll in this study at UCLA and in total.

3. Please clarify at the beginning of the “Procedures” section of the consent forms that the study procedures may involve a 24 hour stay at UCLA.

4. Please clarify in the “Procedures” section of the consent form the amount and at what intervals the “sugar solution” will be administered to subjects during the 24 hour stay at UCLA.

5. Please clarify in the “Procedures” section of the consent forms what part of the subject’s body will be imaged during the CT scans.