U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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National Human Research Protections Advisory Committee



00N-0074

2070 01 JUL 23 A9:38

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20857

July 20, 2001

Dear Director:

Thank you for the opportunity to provide you with our comments on the Food and Drug Administration's (FDA) Interim Rule: Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products; Request for Comments [Docket No. 00N-0074]. We look forward to submitting our perspective on this issue and if desired, would be willing to meet with FDA representatives to further explain our position and the importance of enabling mature adolescents to consent to participation in a research study without parental permission in certain limited circumstances or with appropriate procedural safeguards.

On behalf of the Chairperson and the members of the National Human Research Protections Advisory Committee (NHRPAC) we wish to reserve the right to submit a comment on the FDA's Interim Rule. The NHRPAC will be meeting on July 30-31 at which time there will be an opportunity to review and discuss the proposed comments for submission to the FDA. Thus, the Committee would like to submit its more extensive comments by August 17, 2001.

Thank you in advance for your consideration.

Sincerely yours,

Kate-Louise Gottfried, J.D., M.S.P.H.
Executive Director, NHRPAC
on behalf of Mary Faith Marshall, Ph.D.,
Chair and the NHRPAC Membership

cc: Mary Faith Marshall
Alan Fleischman
NHRPAC Committee

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