APAC

Acquired Immunodeficiency Syndrome Program Advisory Committee

National Institutes of Health
Office of AIDS Research

Building 31, Room 5C02
9000 Rockville Pike
Bethesda, Maryland 20892

JUL 16 1992

Curtis Wadlington
BEBASHI
1528 Walnut Street, Suite 200
Philadelphia, PA 19102

Dear Mr. Wadlington,

I would like to solicit your participation as a consultant on the National Human Subjects Protections Review Panel of the National Institutes of Health (NIH) AIDS Program Advisory Committee (APAC). The Office of AIDS Research, NIH, is in the process of establishing this ad hoc Subcommittee which was called for in the April 15 final policy notice on expanded access to experimental drugs (parallel track, notice enclosed) published in the Federal Register. The proposal that this Panel be established as a temporary ad hoc Subcommittee of the APAC was discussed at the November 1990 and April 1991 meetings of the APAC and, after deliberation, was accepted.

This Subcommittee is being established to advise and make recommendations to the Director, National Institutes of Health, the Commissioner, Food and Drug Administration, the Assistant Secretary for Health and the Secretary of Health and Human Services concerning activities associated with the protection of human subjects in the parallel track arm of a parallel track investigational new drug initiative. Specific areas of review will include determining: the adequacy of consent procedures; the equitability of protocol access to all individuals; confidentiality for participants; that physically or mentally impaired individuals are provided appropriate safeguards to protect their rights and welfare; the adequacy of plans to inform participants, physicians and organizations about parallel track and about particular protocols; and the adequacy of data collection to address safety concerns.

The Subcommittee will meet at the NIH in Bethesda, Maryland, as parallel track proposals arise. As such, the frequency of meetings during the year cannot yet be determined. The Subcommittee will be composed of five APAC members and designated alternates. At least five additional consultants with experience and/or interest in the area of HIV infection and AIDS will meet with the Subcommittee. Consultants will be requested to participate on a rotating basis. Non-Government members and consultants will receive honorarium of $150.00/day for their participation in Subcommittee activities. Government and non-Government members will be reimbursed for all expenses related to attendance at the meetings.

Enclosed is some background information regarding parallel track, the Subcommittee function, and elements of informed consent based on the regulations for protection of human subjects (Title 45 CFR Part 46). Also enclosed is an acceptance/refusal of the invitation to participate on this Subcommittee as a consultant and a self-addressed envelope for your convenience in returning this form. If possible, please return your response by fax to the attention of Ms. Deborah Fountain at 301-402-7769.

Ms. Fountain in the Office of AIDS Research will be available to answer any specific questions you may have regarding the Subcommittee. Please feel free to contact her at (301) 496-0358.

Sincerely,

Robert J. Levine /D.F.

Robert J. Levine, M.D.
Chair
APAC National Human Subjects
Protections Review Panel

Enclosures