DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205
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Attention Writers and Editors:

The enclosed item describes the award of a contract to the Research Triangle Institute by the National Institute of Allergy and Infectious Diseases to establish an AIDS Clinical Trials Coordinating Center.

For further information, please call me or Elaine Baldwin at 301-496-5717.

Sincerely,

Patricia Randall

Patricia Randall

Chief, ORRPR

National Institute of Allergy and

Infectious Diseases

# UPDATE

**NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES** October 1986

Elaine Baldwin

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The National Institute of Allergy and Infectious Diseases (NIAID) today announced the award of a five-year $4.4 million contract to establish an AIDS Clinical Trials Coordinating Center (ACTCC) at Research Triangle Institute (RTI), Research Triangle Park, N. C. Under terms of the contract, RTI will coordinate and analyze all information reported by NIAID's recently established AIDS Treatment Evaluation Units (ATEU's) on their AIDS experimental treatment studies.

The 14 ATEU's will receive $100 million over a five year period, through contracts awarded to 14 medical centers in 8 states, to conduct clinical trials of experimental agents in the treatment of AIDS (acquired immunodeficiency syndrome) and associated opportunistic infections and cancers. Intial plans call for the testing of several antiviral drugs, including AZT (azidothymidine), and agents for use against opportunistic infections.

In a press conference held June 30 to announce the ATEU contracts, Dr. Anthony S. Fauci, Director of NIAID, said, "The AIDS Treatment Evaluation Units will comprise a network that will provide significant research advantages and speed the evaluation of drugs with therapeutic potential against AIDS. We will be able to facilitate collaborative

(more)

studies between institutions, and rapidly compare research findings by means of a computerized data base system."

RTI will develop and maintain the data base system and will arrange for professional staff, including a physician, to make periodic site visits to each participating unit in order to monitor accuracy of data, as well as compliance with protocols and regulatory requirements. RTI will also provide technical assistance in the design of data forms and computer training of staff at the ATEU's and will design and implement an inventory tracking system for the disbursement of experimental drugs used in the studies.

Reports on the progress of all ongoing studies will be provided to a Data and Safety Monitoring Board, including data from each protocol on early signs of both adverse and beneficial effects of treatment.

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