DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date November 3, 1981

From Acting Chief, CIB, CTEP, DCT, NCI

Subject Kaposi's Sarcoma Studies

To Acting Director, DCT, NCI

In response to your query of October 13 regarding protocols for Kaposi's sarcoma, I am currently working with the support personnel at the ECTO office to develop a comprehensive protocol based on the proceedings of the September 15 workshop. The protocol will include: 1) collection of relevant materials for virologic studies, 2) characterization of the patient's immunologic status, 3) staging for extent of disease, and 4) entry into a treatment regimen based on the tempo and extent of the patient's disease. We are also drafting an RFA for cooperative agreements to support the proposed studies. We would visualize that current holders of cooperative agreements would enter their Kaposi's sarcoma patients into the protocol being developed while institutions not holding cooperative agreements through the cooperative group mechanism might be recipients of small awards through the cooperative agreement mechanism to support studies of Kaposi's sarcoma patients. As we develop our study we will maintain our contact with the investigators of the CDC and if their case-control study requires additional patient entry we will coordinate our efforts with theirs so that patients entering our protocol also enter their case control study.

We have not planned any studies of the carcinogenicity of either viral isolates or chemicals to which patients may have been exposed, but expect that studies of this nature will be conducted by interested investigators without further stimulation.

We appreciate that it would be of interest to have parallel studies on clinically unaffected homosexual men and are encouraged that Dr. Goedert of the DCCP is pursuing studies in this direction. We also understand that Dr. Biggar of the DCCP is interested in doing chromosomal studies on tumor tissue and such studies can be encouraged as reasonable uses of the materials collected as part of our proposed comprehensive protocol. Dr. Biggar is also proposing a questionnaire for study of these patients and it may be possible to coordinate this with the data collection on patients entered into the protocol.

I would like to propose the following timetable:

1. Review of the proposed cooperative agreement package by CTPS at its November 23rd meeting.

Memorandum

2. Review of the cooperative agreement package by the DCT Board of Scientific Counselors at its February meeting.

3. Development of a final protocol by mid-December.

4. Announcement of the availability of cooperative agreements for this protocol in late December with a deadline for response of the first of March (if the DCT Board of Scientific Counselors does not approve the procurement it could be cancelled prior to this deadline).

5. Award of cooperative agreements in May of 1982.

The above timetable is quite tentative at this point, and I appreciate that the wheels of the bureaucracy may not be able to move as quickly as outlined above. Also, we could initiate the protocol in mid-December using the currently funded cooperative group members as a starting point with other institutions to be added when the cooperative agreement funding is activated.

William D. DeWys, M.D.

cc: Dr. J.J. Goedert
Dr. George Vande Woude
Dr. Richard Adamson