TISSUE COMMITTEE; MINUTES AND CORRESPONDENCE, 9/82-7/84

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE
DEPARTMENT OF ANATOMIC PATHOLOGY

Please address reply to the undersigned at
UNIVERSITY OF CALIFORNIA SERVICE
SAN FRANCISCO GENERAL HOSPITAL
SAN FRANCISCO, CALIFORNIA 94110

September 30, 1982

TO: Jack McAninch, M.D.
Chairman, Executive Committee

FROM: William Margaretten, M.D.
Chairman, Tissue Committee

SUBJECT: Monthly Tissue Committee Report

MEMBERS PRESENT: Drs. Bunkis, Margaretten, Markison and Volberding

MEMBERS ABSENT: Drs. Bartkowski, Cohen, Green and McKay

The September meeting of the Tissue Committee was held in the Pathology Department Library on Wednesday, September 29, 1982, at 2:30 P.M. The Chairman reviewed 484 surgical pathology reports, prior to the meeting, for discrepancies between the clinical and pathologic diagnoses. Three cases of appendectomy were selected for further review of the charts by the Committee.

1. SS-82-4003 (B-756190) - 26-y.o. male with 12 hour history of RLQ pain, T=98.8 degrees, F., WBC=5,600 with 67% PMN's.

2. SS-82-3888 (B-755482) - 33-y.o. female with RLQ pain, T=101 degrees, F., WBC=13,700 with 77% PMN's.

3. SS-82-4130 (B-757289) - 43-y.o. female with RLQ pain, T=40 degrees, C., WBC-22,500 with 97% PMN's. Gynecologic consultation was obtained.

Since the previous meeting, there were 17 other cases in whom appendicitis was confirmed; therefore, the percentage of negative appendectomies is not excessive.

In addition to the above three cases, case B-202963 was reviewed by the Committee. The Medical Records Department notified Dr. Margaretten that orthopedic hardware removed at Surgery was not submitted for pathologic gross examination and there was no pathology report in the chart. Dr. Margaretten subsequently discussed with Dr. Bovill (Chief of Orthopedics) the requirement that all material or tissue removed at Surgery (except bullets) be submitted to Pathology.

The Chairman of the Tissue Committee also reviewed 274 surgical worksheets for which no tissue was removed. No discrepancies were noted between clinical diagnoses, operative findings and the need for surgery. These reports were sent to the respective clinical chairmen for further review.

RECOMMENDATIONS: No further action

Respectfully submitted,

William Margaretten

William Margaretten, M.D.
Chairman, Tissue Committee

WM:rrp
cc: Committee Members, File

N/R

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DEPARTMENT OF ANATOMIC PATHOLOGY

Please address reply to the undersigned at
UNIVERSITY OF CALIFORNIA SERVICE
SAN FRANCISCO GENERAL HOSPITAL
SAN FRANCISCO, CALIFORNIA 94110

October 29, 1982

TO: Dr. Jack McAninch
Chief of Staff, S.F.G.H.

FROM: Dr. William Margaretten
Chairman, Tissue Committee

SUBJECT: MONTHLY TISSUE COMMITTEE MEETING

MEMBERS PRESENT. Dr's Bunkis, Margaretten, Markison, Bartkowski

MEMBERS ABSENT: Dr's McKay, Cohen, Green, Volberding

The Tissue Committee met in the Pathology Department Library on Friday, October 29, 1982. Prior to the meeting Dr. Margaretten reviewed 469 surgical pathology reports for discrepancies between the clinical and pathologic diagnoses. None were noted.

He also reviewed 218 surgical worksheets, for which no specimens were submitted to Pathology, for the appropriateness of surgery. No discrepancies were noted. The worksheets were then sent to the respective clinical chiefs for further review.

The committee elected to meet on the last Friday of each month at 4:00 P.M.

RECOMMENDATIONS: None.

WM:rrp
cc: Membership

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SAN FRANCISCO, CALIFORNIA 94143

DEPARTMENT OF ANATOMIC PATHOLOGY

COPY

March 25, 1983

TO: JACK MC ANINCH, M.D.
CHAIRMAN, EXECUTIVE COMMITTEE

FROM: WILLIAM MARGARETTEN, M.D.
CHAIRMAN, TISSUE COMMITTEE

SUBJECT: MONTHLY TISSUE COMMITTEE REPORT

MEMBERS PRESENT: Drs. Margaretten, McKay, Markison and Green.

MEMBERS ABSENT: Drs. Volberding, Bartkowski, Cohen and Bunkis.

The Tissue Committee met in the Pathology Department library on Friday, March 25, 1983.

Prior to the meeting Dr. Margaretten reviewed 560 surgical reports for discrepancies between the clinical and pathologic diagnoses. One case was selected for further review by the committee because the clinical diagnosis of appendicitis was not confirmed by Pathology.

1. SS-83-847 (B-701254) - 32 year old male with fever and RLQ pain, normal WBC

Since the previous meeting there were 12 other cases in whom the diagnosis of appendicitis was confirmed by pathologic examination of the tissue.

The chairman also reviewed 221 surgical worksheets for which no tissue was submitted. There were no discrepancies between clinical operative findings and the worksheets were sent to the respective clinical chief for further review.

RECOMMENDATIONS: None

Respectfully submitted,

William Margaretten, M.D.
Chairman, Tissue Committee

WM:rrp

SAN FRANCISCO: SCHOOL OF MEDICINE
CANCER RESEARCH INSTITUTE

May 17, 1983

To: Jean Stead/Imelda Orlina
Accounting - CED 322

From: Elaine McLarin - CRI
1282-M

Re: Cooperative Agreement - 1 U01 CA34980
STUDIES OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
Principal Investigator - Paul Volberding

As we'd talked about yesterday, here is the distribution for the referenced Program Project - FY 01, 5/1/83 - 4/30/84. There are six separate budgets and I've assigned the account numbers in the order in which these budgets are listed in the composite proposal. The Principal Investigator for each section is indicated in parentheses.

(1) 555267-30310 - KAPOSIS SARCOMA CLINIC
(Conant, Marcus, M.D.)

Sub 0 -	Academic Personnel	$11,000
2	Staff Personnel	31,199
6	Benefits	11,927
4	Equipment	7,325
3	Supplies/Other	6,000
	Travel	1,000
		$68,451 Total Direct Cost

(2) 555268-30310 - EPIDEMIOLOGY
(Moss, Andrew, Ph.D.)

Sub 2 -	Staff Personnel	$22,746
6 -	Benefits	6,597
		$29,343 Total Direct Cost

(3) 555269-30310 - IMMUNOLOGY
(Amman, Arthur, M.D.)

Sub 2 -	Staff Personnel	$31,659
6	Benefits	9,339
4	Equipment	12,000
3	Supplies/Other	14,800
T	Travel	1,000
		$68,798 Total Direct Cost

(4) 555270-30310 - VIROLOGY I
(Levy, Jay, M.D.)

Sub 2 -	Staff Personnel	$34,647
6	Benefits	10,311
4	Equipment	12,500
3	Supplies/Other	26,510
T	Travel	1,000
		$84,968 Total Direct Cost

(5) 555271-30310 - VIROLOGY II
(Drew, Larry, M.D.)

Sub 2 -	Staff Personnel	$54,220
6	Benefits	15,183
3	Supplies/Other	20,000
		$89,403 Total Direct Cost

(6) 555272-30310 - THERAPY
(Volberding, Paul, M.D.)

Sub 0 -	Academic Personnel	$10,000
2	Staff Personnel	47,070
6	Benefits	16,330
4	Equipment	2,200
3	Supplies/Other	1,400
T	Travel	1,500
		$78,500 Total Direct Cost

$419,463 Composite Award, FY 1

/EMcL

[6/8/83]

PROPOSAL FOR A COMPUTER SYSTEM FOR THE AIDS/KS RESEARCH PROJECT

by Mark Bilk

Herein are presented several alternatives for a system to fulfill the data processing requirements for the Studies of AIDS, NIH Grant Number UO1 CA34980-01 , comprising clinics and labs at University of California, San Francisco and SFGH, under the direction of Paul Volberding, M.D. and John Ziegler, M.D.

Consultation with the investigators and with specialists in medical research information processing (at UCSF MIS department, UC Berkeley, CRI and in private practice) resulted in good agreement regarding the methods and computer capabilities required for this project.

Medical Data Processing Requirements

1. Easy entry of information both structured (from forms) and unstructured (from physicians' and nurses' notes).
2. Encoding of the information in the form of numerical values of numbered parameters, thus permitting retrieval via simple methods.
3. The parameters must be selected from a pre-existing standard compilation of medical terminology in order to ensure the compatibility of the databases of the several investigators.
4. Maintenance of each body of information in its own separate database with the ability to merge or cross-reference databases as desired.
5. Privacy of each investigator's databases and sharing of selected data with others by permission.
6. Operating on one or several databases in combination, the ability to add, delete, sort, rearrange, select, correlate, tabulate, summarize, print out, and extract subsets for further processing.
7. Availability of the above operations in an easy, interactive fashion without requiring programming. Sequences of operations should later be recallable and executable without typing them in again.

8. Very extensive facilities for sophisticated statistical analysis of information extracted from the databases. Convenience as in point (7).
9. Facilities for graphical presentation of information, both directly from databases and as output from the statistical processing, in a wide variety of formats and styles, and on both CRT terminals and hard copy devices. Convenience as in point (7).
10. Automatic alerting of investigators on or before the day when patients are scheduled (according to treatment protocols) to have medication, tests, etc.
11. Compilation of required reports of clinical data (e.g., for Schering).

Miscellaneous Requirements

12. High quality word processing.
13. On-line storage for investigators' publications.
14. Inter-station mail facility.
15. A good assortment of well-proven programming languages and tools.
16. The capabilities of a professional operating system, including tree-structured directories, file-structured I/O, versatile file protection, incremental backup, multi-tasking, pipes, I/O redirection, filters, background execution and command files. (This is a shameless compilation of UNIX features.)
17. Adequate processor speed (CPU power).
18. Adequate disk storage space.
19. Data communication by phone and standard magnetic tape with other computer systems.
20. Ability to use IBM Personal Computers as terminals if desired.
21. Letter quality printing.
22. Standard, widely used hardware with many peripheral devices available from many manufacturers and free help available from other users at UCSF.
23. Standard, widely used operating system with many programs available both free from universities and from many software houses. Free advice available from other UCSF and UCB users.

Software Considerations and CPU Selection

The work requires the following software:

1. High quality relational database management system (RDBMS)
2. Data entry programs
3. Statistical packages
4. Graphics package(s)
5. Word processor programs
6. High quality operating system and associated utility programs

All of the statistical packages of sufficient power are very large (several M bytes) and require a computer with virtual memory. Such machines can execute a program without requiring more than a small part of it to reside in memory at any one time. The only common virtual memory computers are the IBM 370, DEC VAX, and Data General Eagle. A 370 is too expensive. While the Eagle is cheaper than the VAX for the same CPU power, it is a new machine and does not have much software beyond what is supplied by DG. Virtual memory microcomputers based on the 68000, 16032, 80286 and 432 are in the works but are not yet available.

Thus, the VAX is the only possible choice. Fortunately, it supports the best operating system presently in existence, UNIX. ("Best" refers to quantity and quality of operating system functions, associated utility programs and available application software).

INFORMIX is a commercial quality, user-friendly RDBMS on UNIX. It contains a structured-data input capability of its own and can also work with IMP, another forms management input package.

For abstracting, indexing and entering into the RDBMS of non-structured data, there is PROMS (PRoblem Oriented Medical Synopsis) which works in conjunction with SNOMED, a standard database of 45,000 medical terms. Three statistical packages, PSTAT, BMDP, and S run on VAX UNIX and have all the capabilities that the work requires.

Extensive graphics capabilities are provided by S and also by the newly available SIMPLEPLOT package.

UNIX itself provides excellent word processing capability.

The total cost of all of this software is about $8,000.

HARDWARE OPTIONS

OPTION	Our MB	Rel Speed	$1K Hdwe Initial	Hdwe/ Yr.	Rent	Total* Initial	Total* Per Yr.	Total* for 3 Yrs.
1. UCSF-TS	100	.3	0	0	37/yr	18	38/yr	132
2. RENT ¼ of DR.M's VAX 750	100	.25	0	0	18/yr	17	19/yr	74
3. ONYX & UCSF-TS	100	.2	35	2/yr	9/yr	53	12/yr	89
4. BUY ¼ of DR. M's VAX 750	100	.25	50	2/yr	0	68	3/yr	77
5. VAX 730	320	.3	53	5/yr	0	71	6/yr	89
6. VAX 750	320	1.0	70	5/yr	0	88	6/yr	108
7. VAX 750 & RENT TIME TO OTHERS	220	.5	74	5/yr	-37/yr	92	-31/ yr	-1
8. VAX 750 & SELL 1/3 TO OTHERS	220	.6	34	3/yr	0	52	4/yr	64

*Includes $18K and $1K/year for CRT's, lines, printers, and software -- same for all options.

OPTION CHART NOTES

1. Totals include (10+1/yr) for 6 CRTs and 6 lines and 2 Daisywheels, plus 8 for softward.
2. MB= megabytes on disk for our data (this space is not required for programs.
3. Speed is relative to a VAX 750 with 6 users and is approximate.
4. All figures to right of double bar are in units of $1000;

DESCRIPTION OF OPTIONS

1. UCSF time-sharing UNIX system, assuming 100 MB storage and 3 hr/day /lab connect time.
2. Rental of 6 ports on VAX 750 of Dr. Hugo Martinez w/100 MB. He will have 24 users total.
3. Purchase of ONYX (Z8000) computer for the database and word processing; rent UCSF-TS for statistics at 1 hr/day/lab and 20 MB storage.
4. Purchase of ¼ of Dr. Martinez VAX for $50K.
5. Purchase VAX 730 (cheaper, slower than 750) with 420 MB disk and magtape.
6. Purchase VAX 750 and disk and tape.
7. Purchase 750 system and rent time to 6 users w/100 MB at 3 hr/day/user.
8. Purchase 750 system and sell 4 ports & 100 MB @ $40K + $2K/yr.

Hardware Configuration

The eight options presented here (see Hardware Options chart) fall into three categories:

A. Rent time and space on a pre-existing VAX (options 1 & 2).

B. Buy a cheaper machine (the ONYX) which can run only UNIX and the RDBMS. Rent VAX time for the statistics (option 3).

C. Buy all or part of a VAX (options 4-8).

For a meaningful comparison, total cost over a three year period is shown for each option. All installation and repair service contract charges are included.

In order to compute the time sharing rental charges for options 1,2 and 3, it was estimated that each lab or clinic would average 3 hours/day on the machine, of which 1 hour/day is on the statistics packages. Total storage was estimated at 100 MB with 20 MB for statistics.

All of the options include $10K and $1K/yr for the cost of 6 CRTs, 6 phone lines (with installation and monthly charge), 2 daisywheel printers (which may reside at any of the six locations ; additional printers cost $1500 each), and $8000 for the software.

Option 1 is the UCSF Computer Center VAX UNIX system. It turns out to have the highest 3-year cost, and, of course, leaves the project with no computer at the end of the time unless further money is paid.

Dr. Hugo Martinez (UCSF) has kindly offered to rent $\frac{1}{4}$ of his VAX 750 at $18K/yr. for 6 ports and 100 M bytes of disk (option 2). This results in a lower cost, but again , continuing high payments.

Option 3 saves on initial cost over buying a VAX 730 but has about the same 3-year cost. It involves extra shuffling of data compared to all the other approaches, has lower speed, and restricts use of the statistical programs to one user at a time, requiring scheduling of users. It would cost $12,000/yr indefinitely.

Option 4 is the purchase of permanent ownership of ¼ of Dr. Martinez' machine for $50K in a lump sum. This would include use of his laser printer, 100 MB of disk, 6 dedicated lines and one dial-up line.

Option 5 is the purchase of a VAX 730; the slowest and cheapest of the line, it is fully software compatible with the 750 and 780. It might be noticeably slow, especially if two people were doing database searches simultaneously, but the price is reasonable.

Options 6,7 and 8 involve the purchase of a VAX 750, which is about three times as fast as a 730. To reduce the cost (options 7 & 8) time and storage could be rented or sold to other people (there would be no problem with data privacy -- each user has total control over his own files' access privilege). Note that under option 7, the system could totally pay for itself in three years (but would cost $92K initially). Under option 8, the initial cost drops to $52K.

Both of these schemes involve a total of only 10 or 12 users (6 plus 4 sold or 6 rented), giving a much faster machine than option 4, where Dr. Martinez will be running a total of 24 users. Also, if we buy from him, the number of our terminals could not exceed 7, whereas under options 6-8, additional CRTs could be put in any lab for a total of $1100 each (including the modems and line). This would allow easy, cheap expansion of word processing or data access capability.

Dr. Martinez' laser printer is capable of producing camera-ready copy for publication at high speed. We might be able to buy printer privileges even if we get our own VAX.

June 24, 1983

MEMORANDUM

TO: NIH AIDS Study Group

FROM: Bobbi Wilson

SUBJ: Virology II Section
Mt. Zion vs. UCSF Administration of Funds

In an effort to meet Dr. Drew's request to have Mt. Zion administer this section of the NIH grant, a meeting was held with Lorraine Petrakis from Contracts and Grants.

Ms. Petrakis' comments and recommendations were as follows:

The grant should have been written, originally, with a sub-contract line item request for Dr. Drew's portion to be administered by Mt. Zion. The problem with rectifying the oversight at this time is supplementing the indirect costs and the fact that some of Dr. Drew's staff are UCSF employees.

Ms. Petrakis suggested that the NIH be requested to sub-contract the equipment & supplies portion of the section. This would involve $20,000 with approximately $6,000 in indirect costs. The problem of supplementing the indirect costs still remains, however. The options to solve that are;

1. Request supplement from NIH
   (She doesn't think this is likely to be granted)
2. Request that the costs be shared by the other sections.

Another suggestion for having money turned over to Mt. Zion is to set up a rental contract. In this situation, UCSF would pay Mt. Zion for space. Dr. Drew's indirect costs would be supplemented in the form of rent to Mt. Zion.

Her final suggestion is that nothing be pursued at this time. When the grant continuation budget is proposed a request for indirect cost supplement or a rental contract through a sub-contract should be proposed.

No action has been taken, as yet. The NIH AIDS Study group should discuss the comments and recommendations, as soon as possible.

Marcus Augustine Conant M.D.
A PROFESSIONAL CORPORATION
DERMATOLOGY
(415) 661-2614

350 Parnassus Avenue, Suite 808,
San Francisco 94117

June 27, 1983

MEMORANDUM

TO: Paul Volberding, M.D.

FROM: Marcus A. Conant, M.D. Marc

RE: AIDS Research Ongoing at UCSF

We are attempting to obtain a list of those projects that are underway at UCSF for the study of AIDS. What is needed is a title, a brief two or three sentence description of the project and the name of the principal investigator.

This document will be used by Senator Roberti's committee to coordinate the state research activities and will be used by the President's staff to coordinate national activities. If you could have Bobbie begin work on this list for me, so that we can have it within the next two or three weeks, it will be greatly appreciated.

MAC:ig

cc: Dr. Jay Levy, M 1282

UNIVERSITY OF CALIFORNIA: CLINICAL LABORATORY
SAN FRANCISCO GENERAL HOSPITAL
MEDICAL CENTER

To: Paul Volberding, M.D.
Chief, Oncology Service

From: Pearl Toy, M.D.
Chief, Blood Bank Pearl Toy

Date: June 29, 1983

Attached is a copy of our study protocol and consent form. Thank you for your assistance.

Debbie

SPECIALIST IN BLOOD BANK TECHNOLOGY EDUCATION PROGRAM
American Red Cross Blood Services
Central California Region

STUDENT PROJECT — Debbie Warren 1983

I. Purpose

A. To determine whether males with Acquired Immune Deficiency Syndrome (AIDS) have an unusually high incidence of allo and/or autoantibodies, and if they do, determine if there is a predominant specificity.

II. Experimental Design

A. Specimens

1. Obtain specimens as available from male homosexuals diagnosed as having AIDS. Specimens will be drawn at San Francisco General Hospital AIDS Clinic. It will be noted (see attached specimen log) whether the specimen is from a patient with Kaposi's Sarcoma and/or PCP, and what treatment the patient is receiving.

2. Obtain specimens as available from male homosexuals who have been examined and found to be AIDS free. Specimens will be drawn at San Francisco General Hospital AIDS Clinic.

3. Obtain specimens from male blood donors in the same age bracket as the males with AIDS. The number of specimens in this category will depend upon the number of specimens available in the categories outlined in numbers 1 and 2 above. In an attempt to preclude potential AIDS victims from donating (and being used in this control group), donors are required to read a bulletin explaining AIDS and outlining the increased risk groups. Donors are asked to disqualify themselves if they are a member of one of the increased risk groups.

4. Each specimen will consist of one 10 ml clot tube and one 7 ml EDTA tube.

5. Specimens will be assigned a number by an independent worker. A specimens source (AIDS or control) will not be known until testing is completed.

B. Procedure

The following tests will be performed on each specimen:

1. Saline panel: read at I.S. and 30 minutes at 16C.

a. Use selected panel plus cord cell and auto control.

2. Albumin - AHG panel: read at 45 minutes at 37C and at AHG phase.

a. Use selected panel and auto control.
b. Use polyspecific AHG.

3. Direct Antiglobulin Test (3 techniques)

a. Standard method with polyspecific AHG.
b. Polybrene method with polyspecific AHG.
c. 4% ficin capillary method with polyspecific AHG.
d. Any positive DAT will be further tested with monospecific anti-IgG and anti-C3.

4. DCM Elution Technique

a. The following tests will be performed on every eluate:

i. 37C albumin - AHG mini panel using eluate plus: R1R1 cells; R2R2 cells; specimen's own cells (auto). Use polyspecific AHG.
ii. 37C - AHG mini panel using eluate plus ficin treated R1R1 cells, R2R2 cells and specimen cells (auto). Use polyspecific AHG.

5. Additional Testing

a. Antibody titer to be run on cold antibodies that have a score 10 or higher at 16C.

b. Antiglobulin Inhibition Test

i. Test all negative eluates using antiglobulin inhibition to detect immune complexes that may have been nonspecifically bound to red blood cells.
ii. Use monospecific anti-IgG antiglobulin.

III. Techniques (attached)

IV. Weekly Schedule

A. Mon., Tues., Thurs.

1. Perform saline and albumin panels on all specimens.

2. Perform direct antiglobulin tests on specimens using the three outlined methods.

3. Using DCM technique, perform elutions on all specimens.

4. Perform testing on eluates as outlined. Freeze a sample from each eluate for antiglobulin inhibition test.

B. Friday

1. Perform antiglobulin inhibition test on eluates.

2. Finish any testing not completed on Mon., Tues., or Thurs.

V. Daily Schedule

0830 - Saline panels
1000 - Albumin - AHG panels
1200 - Standard DAT
1230 - Polybrene DAT
1300 - 4% ficin capillary DAT
1330 - Lunch
1400 - DCM elutions
1530 - Ficin treat cells
1545 - Test eluates
1700 - Cleanup

VI. Year Schedule

A. 4/4/83 - 6/25/83

1. Order reagents.
2. Literature search.
3. Prepare reagents (4% ficin; sensitized rbc for antiglobulin inhibition test).
4. Draw specimens for selected panel.

B. 7/5/83 - 8/12/83

1. Perform testing.

C. 8/15/83 - end of year

1. Write project report.

CONSENT FORM

I agree that a sample of blood may be drawn and used for serologic testing. The tests will be aimed towards determining whether persons with AIDS have: 1)red blood cell antibodies in their serum and 2)antibodies which have attached to their red blood cells.

_____

Name Date

Name	Birthdate	Diagnosis				Treatment			Comments	Date Known
		NoAIDS	Kaposi	Early Advanced	PCP	Chemo	Interferon	Other		

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SCHOOL OF MEDICINE

Please address reply to undersigned at
THE MEDICAL SERVICE
Room 5 H 22
San Francisco General Hospital
San Francisco, California 94110

July 1, 1983

Lorraine Petrakis
Contracts and Grants Office
1483-4th Avenue
UCSF

Dear Ms. Petrakis:

This note is simply to assure you that I am aware of the supplemental application of Dr. Jay A. Levy for additional work to be performed in the AIDS grant from the NIH. I enthusiastically support Dr. Levy's application for this supplemental budget, as it is essential for the completion of additional projects in his laboratory.

If you have any questions, I would be happy to answer them directly. Thank you for your help.

Sincerely,

Paul Volberding, M.D.
Assistant Professor, Medicine
Chief, Medical Oncology

City and County of San Francisco

Department of Public Health

San Francisco General Hospital Medical Center

August 5, 1983

TO: NIH AIDS Group
FROM: Paul Volberding, M.D. PV.
SUBJ: Brief Update on Several Issues

1. Computers. Although we have yet to hear final word on the State AIDS money, which we are counting on to purchase a VAX, we do have access to funds from the City for computer consultation, and Mark Bilk is continuing to help advise us on our needs. Pending the purchase of a VAX, IBM PCs are being purchased by the therapy and epidemiology subsections with the expectation that they will be part of an overall network in a reasonably short time. We are working with Frank Baumgartner to coordinate the computerization of patient data both here and at the Moffitt KS clinic. I would recommend that anyone ready to purchase a personal computer contact Mark Bilk, who can help in the purchase with a 20% price reduction available to UC faculty. Because Scott Blois feels unable to wait any longer for the resolution of the State funding, the $10,000 initially allocated to computerization to his facility will presumably be available in the purchase of separate equipment.

2. Specimen Distribution. The SFGH AIDS clinic continues to be busy, especially with the addition of Donald Abrams and Steve Follansbee so staffing is less of a problem than before. Therefore, specimen acquisition should also be less of a problem. We have contracted with the same messenger service that Larry Drew has used to transport specimens to his laboratory, and this person will be available whenever needed to pick up specimens from our clinic at the General and deliver them to your laboratories or tissue bank at other facilities. We can collect essentially any type of specimen you desire, including skin biopsy material. The latter material is most easily available on Mondays, as Jim Groundwater is now attending in the AIDS clinic and biopsy facilities are available here. We are in the process of hiring a separate AIDS nurse who will be directly responsible for specimen requests, but in the interim contact Gayling Gee, who should be able to coordinate things for you.

3. Clinical Trials. Clinical trials in KS using several new agents are expected to begin relatively soon, or are in earlier stages of planning. These include the chemotherapy drug ICRF 159, and the biologic response agents gamma interferon and interleukin 2. Anyone interested in potential laboratory spinoff studies from these clinical trials should contact me for further information.

1001 Potrero Ave., San Francisco, CA 94110

FACULTÉ DE MÉDECINE BROUSSAIS-HOTEL-DIEU
Service d'Hématologie
15, rue de l'École de Médecine, 75006 PARIS

LABORATOIRE D'IMMUNOBIOLOGIE
DOCTEUR D. VIZA
TÉL. : 354-98-66

DV/ST/FG 185

Dr. Paul Volberding
Assistant Professor of Medicine
San Francisco General Hospital
Ward 86
995 Portero
San Francisco CA 94110
U.S.A.

30 September 1983

Dear Professor Volberding,

My colleagues and I have been working on Transfer Factor, its in vitro effects, biological activity and its clinical applications for several years. We have recently shown that some viral infections such as those caused by Herpes Simplex Virus Type 1 or Type 2 can be successfully treated by specific Transfer Factor.

Since Transfer Factor contains specific informational molecules for cell mediated immunity and also moieties which non-specifically stimulate T Helper cells, I thought that it could perhaps be used with some success for the management of AIDS in its early stages, i.e. in patients in high risk groups who present low numbers of T4 cells and lymphadenopathy, or patients in stage 2, i.e. with impaired T4 function, low lymphokine production and repeated infections.

I understand from my friends in San Francisco that you treat AIDS patients and that you might be interested in our proposal. If this is the case we could offer you partially purified Transfer Factor specific for HSV, EBV and CMV in order to assay its clinical effect. The patients receiving this treatment should be monitored for T4 and T8 lymphocyte numbers, PHA stimulation and also restoration of delayed hypersensitivity as assayed by skin-tests for antigens such as tuberculin, candidin, trichophyton and streptokinase-streptodornase. Clinical improvement should be assessed by decrease of oportunistic infections, disappearance of adenopathy and herpes relapses in patients already suffering from these disorders before the begining of the TF therapy.

If this proposal if of interest to you, I will be pleased to discuss a detailed protocole.

Looking forward to hearing from you in the near future.

Yours sincerely,

Dimitri Viza M.D.

cc. Mr. Stanley Friedman.

City and County of San Francisco

Department of Public Health

San Francisco General Hospital Medical Center

January 13, 1984

Dimitri Viza, M.D.
Faculté de Médecine Broussais-
Hotel-Dieu
Laboratoire d'Immunobiologie
Service d'Hématologie
15, Rue de l'École de Médecine
75006 Paris

Dear Dr. Viza:

In looking through my correspondence I came across your letter, which I regret to say I had misplaced and therefore not answered. I do apologize for this, and assure you that it has no reflection on my interest in talking with you more about your experience with transfer factor.

I am, as you realize, very involved in the care of patients with AIDS in San Francisco, and am currently caring for nearly one half of all the patients diagnosed in San Francisco since the epidemic began here in 1981. I have been very interested in finding non-immunosuppressing therapies, especially for the treatment of patients with Kaposi's sarcoma.

I have had a good deal of experience in the use of recombinant alpha interferon and, while this drug appears to be effective in some of the patient's tumors, it does not appear to significantly restore their immune system. Therefore, I am currently interested in clinical protocols involving the use of recombinant interleukin-2 and gamma interferon.

Similarly, I would be very happy to learn more about the transfer factor which you have experience with and would be very eager to hear more from you concerning this agent. Please again accept my apologies for the delay in correspondence.

Sincerely,

Sig

Paul Volberding, M.D.
Assistant Professor, Medicine
University of California, San Francisco
Chief, Medical Oncology
San Francisco General Hospital

1001 Potrero Ave., San Francisco, CA 94110

29 November, 1983

Mark Bilk
Oncology Department
Ward 86
S.F.G.H.

Dear Mark:

Enclosed please find two forms referring to the Tissue Specimen Bank. The first, is the original form in use at present. The second, is the proposed revised form with minor changes as discussed with Dr. John Greenspan.

It is hoped that the proposed form can be modified for computer compatibility relatively soon as to facilitate additional tissue collection from other patient and research areas. This form would serve as a universal form for all collaborative research areas including UCLA's AIDS Research Center.

This form , of course, requires the approval of all involved principal investigators of the AIDS Research Network including those investigators at UCLA.

Thank you for your assistance with this project and please feel free to call me or John Greenspan with any questions or comments.

Sincerely,

Frank Baumgartner RN, NP
Nurse Coordinator
Kaposi's Sarcoma Clinic
UCSF 666-1407

CC: M. Conant
P.Volberding
J. Greenspan

BIOPSY OR BLOOD SPECIMEN INFORMATION FORM
AIDS RESEARCH PROJECT

LEAVE BLANK
R# = TISSUE
AS# = SERUM

CONTENT IS
FIVE = 0500

BIRTHDATE _____ *

AGE _____

(5) PATIENT NAME _____ SEX _____

(6) CLINICAL DIAGNOSIS KS LYMPHADENOPATHY

PCP OTHER _____

CURRENT TREATMENT NONE

CHEMOTHERAPY TYPE, DURATION _____

INTERFERON DURATION _____

OTHER _____

IF NONE, HAS PT. EVER BEEN TREATED FOR KS, AND WITH WHAT?

_____

(7) SPECIMEN
BIOPSY SKIN: SITE _____ AMOUNT TISSUE _____

TYPE TISSUE NORMAL SKIN TUMOR

NODE: SITE _____

OTHER: (BE SPECIFIC) _____

HAS TISSUE BEEN SENT ELSEWHERE? YES NO

IF "YES", WHERE? _____

TYPE OF
BLOOD SPECIMEN WHOLE
BLOOD SERUM PLASMA

NUMBER OF TUBES _____

(3) (4) TYPE OF TUBES _____

DATE OBTAINED: _____

RESULTS:

PATH Dx _____

BLOOD WORK _____

COMMENT:

NAME OF MD _____ SENDING SPECIMEN

(2) SP or D.P.#
Pt. Unit #

23 December 1983

Kline - Skin Lichelon EBV in Lymphomas

Dr. John Greenspan
HSW 604

Dear John,

Thank you for lunch this afternoon. This particular meeting was very informative for me and clarified some important issues; The main concern being prioritizing research tissue for the tissue bank at present.

Enclosed please find copies of the skin biopsy protocol and tissue distribution protocol which I have been following. Please note that this protocol was dated 2/10/83. Also, note that with this protocol -- three punch biopsies are done on one patient. If Dr. Levy is included, an additional 6mm biopsy is needed. Also included please find copies of lymph node biopsy protocol.

I am meeting with Yvonne on January 6, 1984 to discuss several issues:

1. How many tissue specimens are being submitted monthly and from what source.

2. The procedure for transporting tissue material from SFGH to VAMC to Tissue Bank.

3. The procedure for distribution of specimens to approved research projects.

If you have any questions or comments please call me. Thank you.

Sincerely,

FRANK BAUMGARTEN, RN, NP
Nurse Coordinator
K.S. Clinic

cc: M Conant
P Volberding
J Ziegler

FB/smhb

KAPOSI SARCOMA CLINIC
UC Departments of Dermatology-Oncology

SKIN BIOPSY PROTOCOL

Patients with skin lesions are re-biopsied during the staging period, before treatment is begun, if they agree. The biopsies are for research purposes. The following is a list, in prioritized order, of the studies for which the tissue is used.

1. BIOPSY FOR DIAGNOSIS

   A. Paperwork -

      1. Patient signs biopsy permit for any biopsy performed in the clinic, to be put in the chart.

      2. Pathology consultation is filled out, signed by the M.D. -- Top copy goes in chart.

   B. Medium - Punch biopsy is put in formalin, labeled with name, unit #, birthdate, location of biopsy, date.

   C. Disposition - Specimen and bottom copies of Path Consultation go to Medical Mycology room in Dermatology Clinic to be picked up.

~~2.~~ SKIN BIOPSIES FOR DNA PROBES FOR HEPATITIS B, EBV, AND CMV VIRUSES

Dr's Schwartz and Rutter -

Hold

   A. Paperwork

      1. Label tube with patient's name, unit #, date, biopsy site, diagnosis.

      2. Log in Biopsy file.

   B. Specimen

      1. At least a 4mm punch is needed for these studies. (50mg of tissue is preferred.)

      2. 25 cc's heparinized blood, unrefrigerated. (3 greentopped 10 cc tubes containing Lithium Heparin.)

   C. Medium -- Snap freeze in liquid nitrogen.
      (Put tissue in aluminum foil, in glass tube, cotton in top of tube.)

   C. Disposition -- Call Marilyn Ziemer at x-4516 for prompt pickup, or deliver to HSE 962. If biopsy is on Wednesday, call a day ahead so that Marilyn can arrange for someone else to handle specimen, as she is not there on Wednesday.

3. DR. MODLIN'S STUDY

A. Paperwork -

1. Label tube with patient's name, age, location of biopsy, date.

2. Log biopsy in file folder in K.S. office marked "Biopsies".

B. Medium - Put specimen (preferably a 4mm punch or 1/2 of 6mm punch), in special clear viscous medium. Handle specimen gently, taking care not to pinch tissue and injure cells. Use wooden end of Q-Tip to adjust it horizontally in test tube, skin end to one side, fatty end to the other side. Snap freeze in liquid nitrogen.

C. Disposition - Store in Dr. Edward Shillitoe's Revco (604 HSW), to be mailed to Dr. Modlin later.

4. DR. EVELYNE LENNETTE'S STUDY - EBV ANTIBODY ASSAY --

A. Paperwork

1. Write name, diagnosis, location of biopsy tissue, and date on label and put on tube so that label sticks to itself.

2. Log biopsy in file folder.

B. Medium - Put specimen in aluminum foil. Snap freeze in liquid nitrogen.

C. Disposition - Deliver to Dr. Ed Shillitoe's lab, HSW 604, to be stored until he processes the tissue and mails it to Dr. Evelyne Lennette at Virolab.

5. DR. JAY LEVY'S STUDY - ANGIOGENESIS

A. Paperwork

1. Label tube with name, diagnosis, date.

B. Medium - Put specimen in pink medium in capped tube.

C. Disposition

1. Call Jay Levy's lab at x-4071 for immediate pickup.

2. If no one is able to pickup specimen, deliver to 1280 Medical Sciences Building within 1 (one) hour of surgery.

6. DR. LARRY DREW'S STUDY - CMV VIROLOGY

A. Paperwork

1. Fill out Mount Zion lab slips with name, etc.

2. Label containers with patient's name, date, type tissue (normal skin or skin tumor tissue), site of biopsy, Kaposi Patient and Dr. Conant's name.

B. Medium - Put specimens of tumor tissue and of normal tissue in separate sterile containers, in sterile normal saline. Specify whether normal or tumor tissue on label. Put in paper bag labelled "Mount Zion".

C. Disposition

1. Put bag in refrigerator in Dermatology Clinic, Medical Mycology lab.

   a. If Thursday, ~~specimens will be picked up.~~ * call Dick Miner anyway.
   b. If other days, notify Virology (567-9465) or Dick Miner (567-6600, ext. 2132) to arrange pickup that day.

Log all biopsies except routine H+E

1. in Log Book of all biopsies + sera collected
2. in Black notebook of individual studies
3. in patient chart

2/10/83

BIOPSIES FOR RESEARCH

Either: 2 6 mm punches tumor tissue
1 4mm punch normal skin

OR: Lg exision, cut into 3 parts
1 4mm punch normal skin

To be divided as follows:

1. Drew - 1/2 6mm punch tumor
1/2 4mm punch normal

2. Levy - 6 mm punch tumor

3. Greenspan - 1/2 6mm punch tumor
1/2 4mm punch normal

KAPOSI'S SARCOMA CLINIC

LYMPH NODE BIOPSY PROTOCOL

Patients with suspicious lymph nodes are scheduled for a biopsy. The decision to biopsy is made during the initial clinic visit by Dr. Conant or during the staging.

Dr. David Hohn does most of the biopsies through the Surgery Faculty Practice. Appointments are made for the patient at extension 1161 (ask for Gerte).

If the patient has a clinic discount, he will be seen in the Sugery Clinic in order to receive the discount. Here, appointments are made through Patti Schulte, RN (666-4332) or Elaine Park, RN, same extension.

Fill out the Outpatient Consultation Sheet with clinical history. Request that two lymph nodes be removed if the surgeon feels this is possible. Include name and phone number of person who will be contacted to handle the biopsies. (This will be Helen Schietinger or the Clinic Assistant.)

When the procedure is beginning, the nurse in O.R. should call this person to come to the 6th floor Surgical Suites to be ready to pick up the specimens immediately.

The specimens should be taken in a sterile container by the K.S. Clinic person to surgical pathology (M-576) to be divided for the rest of the lymph node protocol, as below. *

Ask for Dr. Jay Beckstead, or one of the surgical pathology faculty, to examine the nodes for gross indications of tumor tissue and determine what specimens are needed for diagnosis.

1. Biopsy for diagnosis

   A. Paperwork

      1. Pathology consultation is filled out during the surgical procedure, top copy stays with chart, carbons go with specimens to path lab.

      2. Consultation sheet stays with chart to be filled out by surgeon.

      3. Label specimen container with patient stamp, site of biopsy and date.

   B. Medium and Disposition - Taken care of by pathologist who will prepare tissue for routine H&E, plastics embedding, and probably do a touch prep.

* It is important to take the biopsy tray in order to have a sterile scalpel & materials for obtaining sterile tissue in the path lab.

2. Dr. Modlin's study

12/16/82 Hold

A. Paperwork

1. Label tube with patient's name, age, location of biopsy, date.

2. Log biopsy in file folder in K.S. office marked Biopsies.

B. Specimen - Lymph tissue without K.S. tumor involvement is preferred. A thin slice (4 mm) taken perpendicular to the axis of the node. A second specimen, from the other end of the node, in a separate container would be helpful.

C. Medium - Put specimen in special clear, viscous medium, using wooden end of Q tip to adjust it horizontally towards bottom of test tube. Snap freeze in liquid nitrogen. If specimen is too large to be put in test tube, pour some medium on a piece of aluminum foil, lay specimen on medium, pour medium over it, cover with foil, turn up edges and snap freeze in liquid nitrogen.

D. Disposition - Store in Dr. Ed Shillitoe's Revco (604 HSE), to be mailed to Dr. Modlin later.

Greenspan's lab - stored tissue

3. Dr. ~~Evelynd Lennette's study = EBV antibody assay~~

12/16/82 Hold

A. Paperwork

1. Write name, diagnosis, location of biopsy tissue, and date on label and put on tube so that label sticks to itself.

2. Log biopsy in ~~file folder~~. Biopsy Book

B. Medium - Put specimen in aluminum foil, inside empty test tube, snap freeze in liquid nitrogen.

C. Disposition - Deliver to Dr. Greenspan's lab ~~Ed Shillitoe's lab~~, HSW 604, to be stored ~~until he processes the tissues and mails it to Dr. Evelyne Lennette at Virolab.~~ under pt. name

4. Dr. Jay Levy's Study - Angiogenesis

A. Paperwork - Label tube with name, diagnosis, date.

B. Medium - Put specimen in pink medium in capped tube. Tumor tissue preferred.

C. Disposition

1. Call Jay Levy's lab, ext. 4071, for immediate pickup.

2. If no one is able to pick up specimen, deliver to 1280 Medical Sciences Building within one hour of surgery.

5. Dr. Larry Drew's Study - CMV Virology

A. Paperwork - Fill out Mt. Zion lab slip with name, etc. Label containers with patient name, date, type tissue, site of biopsy, Kaposi patient and Dr. Conant's name.

B. Medium - Put lymph tissue in sterile container in sterile normal saline. specify site of lymph node. Put in a paper bag labelled Mt. Zion.

C. Disposition

1. Put bag in refrigerator in Dermatology Clinic, Medical Mycology Lab.

~~a. If Thursday, specimens will be picked up.~~
b. ~~If other day~~, notify Virology (567-9465) or Dick Miner (567-6600 Ext. 2132) to arrange for pickup that day.

Log all biopsies (except routine H+E when no research studies are done)

1. Biopsy + Serum Log book
2. Log book of individual studies (Black notebook)
3. In patient chart -

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UNIVERSITYWIDE TASK FORCE ON AIDS
OFFICE OF HEALTH AFFAIRS
785 UNIVERSITY HALL
UNIVERSITY OF CALIFORNIA
BERKELEY, CA 94720

To: Tissue Sub-Committee Members

From: Laura Driemeyer, Administrative Assistant

Re: Meeting on Wednesday, January 25, 1984

Date: January 17, 1984

The meeting is definitively scheduled for WEDNESDAY, JANUARY 25 at 10:00 AM at the SAN FRANCISCO AIRPORT HILTON. Coffee will be available immediately and lunch will be provided at 12:30 PM.

Enclosed please find a tentative list of items to be discussed at the meeting. If you have any additions or alternative suggestions please contact either myself (415-642-0732) or Dr. Greenspan (415-666-2220).

Also enclosed is a list of the individuals on the sub-committee and their addresses, for your information.

As I mentioned to you on the phone you will be reimbursed for your travel expenses incurred by attending this meeting. For this purpose I have enclosed a sheet that outlines the travel reimbursement procedure.

If you have any questions please call me at (415) 642-0732.

AGENDA

WEDNESDAY, JANUARY 25, 1984

TISSUE SUB-COMMITTEE

1. Objectives
   What are we trying to accomplish from the point of view of:
   - -AIDS Task Force
   - -Tissue Banks
   - -Investigator "Clients"

2. Guidelines
   What should be the general criteria? See Freedman's remarks.

3. Mechanism
   a. How many banks should there be?
   b. How do we avoid duplication, or should we?
   c. What should be stored?
   d. How should the specimens be prepared, handled and stored
   e. Procedure for the review of projects.

4. Biohazard Aspects

5. Safeguards/Monitoring

6. Documentation, Data Handling and Retrieval, Reports

7. Future Plans

NAMES AND ADDRESSES OF TISSUE SUB-COMMITTEE MEMBERS

Robert D. Cardiff, M.D.
Medical Pathology
Room 3422, MS-1A
University of California
Davis, CA 95616
(916) 752-7356

Thomas C. Cesario, M.D.
Infectious Diseases, Rt. 81
University of California, Irvine
Medical Center
101 City Drive South
Orange, CA 92668
(714) 634-5134

Marcus Conant, M.D.
Dermatology
A-312
Univeristy of California
San Francisco, CA 94143
(415) 661-2614

Michael Gottlieb, M.D.
Medicine/Clinical Immunology-Allergy
CHS 52-175
University of California
Los Angeles, CA 90024
(213) 825-1251

J. Allen McCutchan, M.D.
Infectious Diseases
H-811-F
UCSD Medical Center
225 Dickinson Street
San Diego, CA 92103
(619) 294-6146

Ronald T. Mitsuyasu, M.D.
Medicine/Hematology-Oncology
CHS 42-121
University of California
Los Angeles, CA 90024
(213) 206-8359

Merle Sande, M.D.
Dept. M., Room 5H22
San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110
(415) 821-8317

Nora Sun, M.D.
Pathology
Harbor-UCLA Medical Center
1000 West Carson
Torrance, CA 90509
(213) 533-2261

Paul Volberding, M.D.
Ward 86
995 Potrero
San Francisco General Hospital
San Francisco, CA 94110
(415) 821-8830

John S. Greenspan, Ph.D., FRC Path
HSW 604
University of California
San Francisco, CA 94143
(415) 666-2220

Travel Reimbursement Procedure

Submit completed UC Travel Vouchers to:	Laura Driemeyer Universitywide Task Force on AIDS c/o Office of Health Affairs 785 B University Hall University of California Berkeley, CA 94720
Name and Number of account to be charged:	Health Affairs J-668801-19900-3
Receipts:	Attach <u>all</u> original receipts for air tickets, rental car and parking.
Please remember to:	Indicate: 1) time of departure <u>and</u> return, 2) sign the voucher, 3) keep yellow copy for your records.
Mileage:	Rate for private car mileage is 20.5¢/mile. If the optional 25¢/mile is used, please <u>add</u> the following certification paragraph to the voucher:

I certify that the actual cost of operating the vehicle was equal to or greater than the rate claimed in this Travel Expenses Voucher, and that I will maintain substantiating records of fixed and variable costs of operating my automobile in support of this claim in the manner and for the period prescribed by law.

Thank you.

If you have any questions I can be reached at Berkeley Campus: (415) 642-0732.

4/24

PV —

Is there a real list?

Please advise

TBD

This is for you, Susan

P.V.

Hospitals and Clinics
San Francisco, California 94143

UCSF
University of California, San Francisco . . . A Health Sciences Campus

17 April, 1984

Bobbi Wilson AA
Ward 86 SFGH

Dear Bobbi:

Hope this finds you well. I need a list of the research studies approved by Paul and the Tissue Committee. More specifically, I need to know the principal investigators involved in obtaining patient materials ie: serum, fresh tissue etc. and their protocols.

I am personally getting requests from various researchers for materials and I am telling them to speak to Paul. So it would be helpful for me to know which studies have been approved and for how long.

Could you also send me a copy of the contract form or application request form for researchers appling to the Tissue Committee for patient materials.

If you could send this to my office as soon as possible I would greatly appreciate it.

Thank you!

Sincerely,

Frank Baumgartner, RN, FNP
Kaposi's Sarcoma Clinic
UCSF-1407

FCB:fcb

cc: M. Conant MD

Marcus Augustine Conant M.D.
A PROFESSIONAL CORPORATION
DERMATOLOGY
(415) 661-2613

350 Parnassus Avenue, Suite 808,
San Francisco 94117

May 2, 1984

TO: Paul Volberding, M.D.
Chairman
Principal's Investigator's Meeting

FR: Marcus A. Conant, M.D. Marc'

RE: Proposal of William J. Woods

Attached please find a proposal from Mr. Woods, who is a psychologist on the faculty of the University of California in Santa Barbara. Mr. Woods wants to study some of our Kaposi's Sarcoma patients, who were diagnosed prior to March of 1984. We have checked with Jeff Mandel and Lydia Temoshok and this project is acceptable to them and does not conflict with the psychological project that we have already approved.

I recommend that the principal investigators approve this study.

MAC/bc

cc: Frank Baumgartner

enc:

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COUNSELING CENTER
Counseling, Career Planning,
and Placement Services

SANTA BARBARA, CALIFORNIA 93106

April 24, 1984

Marcus A. Conant, M.D.
Dermatology
350 Parnassus Avenue
Suite 808
San Francisco, California 94117

Dear Dr. Conant:

I received your recent letter with great delight. I would like to express my appreciation to you for the swiftness with which you considered my proposal. Of course, I am also quite pleased and grateful that my project does not conflict with the current investigation at UCSF.

As you requested in the letter, I am enclosing a one page synopsis of the purpose of the study. Such a brief description is not easy to accomplish, but I think I covered enough of the bare essentials to give a clear picture of the purpose and a rough outline of the design.

I expect to be in the Bay Area for a few days in the last week of May, and to be moving to Berkeley in July. I will, of course stay in touch, and I hope that I may have the opportunity to meet with you soon. If I need to present anything, or prepare anything to further explain or clarify my research, I would be more than happy to do so.

Thank you very much for what you have already done to move this research along for me. And thank you, also, for presenting my study to the Primary Investigators Committee for their approval.

Sincerely,

Bill Woods

Willaim J. Woods, M.A.

Encl.

A COMPARISON STUDY OF PSYCHOLOGICAL RESPONSES TO ACUTE LEUKEMIA AND KAPOSI'S SARCOMA

The purpose of this study is to learn more about the psychological response of people with life-threatening illnesses by assessing self-esteem, depression, anxiety, distress, and locus of control. Four groups of men, ages 30-50, will be used for this study. Non-gay patients with acute leukemmia, a non-contagious life-threatening illness, will compose the first group. Kaposi's sarcoma patients who are gay or bisexual men with Acquired Immune Deficiency Syndrome (AIDS), a contagious life-threatening illness, will make up the second group. To control for sexual orientation differences, two groups of healthy men will be used, gay and non-gay. The results of the study will be helpful in understanding what special psychological needs may exist for persons with life-threatening illnesses, specifically acute leukemia and Kaposi's sarcoma.

The Tennessee Self Concept Scale (TSCS) will be used to assess self-esteem. The Brief Symptom Inventory (BSI) will measure depression, anxiety, and distress. To measure locus of control, the Multidimensional Health Locus of Control Scales (MHLC Scales) will be employed. Finally, a biographical data sheet will be included to collect descriptive data.

Univariate analysis of variance will be used to test the following hypothesis:

> There are no significant differences on the mean raw scores for the four groups (acute leukemia patients, Kaposi's sarcoma patients, healthy gay men, and healthy non-gay men) on the Total Self Esteem score of the TSCS; the Depression and Anxiety scales, and the General Indices of the BSI; and the three subscales of the MHLC Scales.

Journal of Clinical Oncology

The Official Journal of the American Society of Clinical Oncology

333 CEDAR STREET
P.O. BOX 3333

NEW HAVEN, CT 06510
(203) 785-4535

Return Manuscript and Review by July 13, 1984

June 25, 1984

Paul A. Volberding, M.D.
San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110

Dear Dr. Volberding:

The enclosed manuscript has been submitted for consideration for publication in the JOURNAL OF CLINICAL ONCOLOGY . The Editors would be most grateful if you would review the paper in detail and provide us with your comments that might be forwarded to the author and your advice about its suitability for acceptance. If not acceptable in its present form, we would value your suggestions about outright rejection or revision. Forms for providing comments to the author and for your confidential remarks are also enclosed. On the Confidential Memorandum form, please indicate your rating with a priority score from 1 to 5 (with one being the highest rating), your opinion about any possible violations of the protection of human subjects, and whether or not you wish to see a revised manuscript. In the Remarks section, please summarize your opinions about the originality of the discussion and conclusions, and the clarity of the overall presentation.

Please use our review forms to communicate your confidential remarks to me and your priority ranking (on a scale from 1 to 5; one being the highest rating), and on a separate sheet comments that may be transmitted to the author.

Your help in the review process is the key to making our new journal an outstanding one.

Sincerely,

Paul A Rosenberg, MD/skm

Saul A. Rosenberg, M.D.
Associate Editor

SAR:skm
Enclosure

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HOSPITALS AND CLINICS

SAN FRANCISCO, CALIFORNIA 94143

June 27, 1984

TO: Dr. Paul Volberding
Dr. John Ziegler
Dr. Andrew Moss
Dr. Jay Levy
Dr. John Greenspan

FROM: Marcus A. Conant, M.D.

RE: Access to Tissue Bank Specimens

A question has arisen over the fact that certain investigations were performed by Dr. Levy on specimens stored in our AIDS Clinical Research Center Tissue Bank that were collected by Dr. Andrew Moss.

On Wednesday June 20, 1984 I spoke with Dr. Levy who made the following three points:

1) He was not aware that the 30 specimens furnished to him by Dr. Greenspan had been collected by Dr. Andrew Moss.

2) Dr. Levy can obtain specimens from other specimens from other investigators from the AIDS Clinical Research Center Tissue Bank and will specifically request that no further specimens from Dr. Moss be sent to him for study.

3) Dr. Levy views the information obtained on the 30 specimens as "raw data" and he is not prepared to release this information to Dr. Moss at the present time.

At lunch on Thrusday June 21 Dr. Moss made the following four points:

1) He understands Dr. Levy's position

2) He requests that Dr. Levy furnish him the data that was obtained on the sera from his patients.

3) That Dr. Levy use him name jif a publication results from the use of this raw data.

4) That he would be delighted to enter into collaborate studies with Dr. Levy in the future.

Dr. Volberding and I were pleased that it appears that this particular issue has been solved by mutual cooperation, but we note that this issue demonstrates that certain issues regarding the acquisition and disposition of tissue from the tissue bank have not been resolved and that these issues must be explored and settled as quickly as possible. To that end Dr. Volberding will call a meeting with Dr. Ziegler, Dr. Greenspan and myself in the next week.

MAC/alt

SCOTT WINSLOW
303-221-2050

TISSUE COMMITTEE REQUISITION/PARVOVIRUS

--Fecal samples in any patient with AIDS during diarrhea.
(1-2 gms. frozen -20°)

--Peripheral blood cells
Ficoli-hypaque -- cells into SDS
Buffer to be supplied -- frozen -20°

±Thymic material from autopsy

Collect about 5 spec/W~~K~~ and send q 3-4 weeks

MICHAEL S. STULBARG, M.D.
JEFFREY A. GOLDEN, M.D.
UNIV. OF CALIF. MEDICAL CENTER, ROOM A-539
SAN FRANCISCO, CALIFORNIA 94143

PULMONARY DISEASES

TEL.: (415) 666-1596

July 25, 1984

Paul Volberding, M.D.
Director AIDS Clinic
San Francisco General Hospital

Dear Paul:

Thanks for your letter of July 17, 1984. I would like to add specimens to your tissue bank vis a vis a collaborative study I have undertaken with Linda Pifer in Tennessee regarding pneumocystis antigen in the blood. Basically John Greenspan tells me that there is a fairly easy logistical way of doing this through his tissue bank endeavors in terms of obtaining, storing, randomizing, and eventually sending blinded samples of blood specimens to Tennessee for her to assess for possible pneumocystis antigen.

I was not aware of this committee aspect of the AIDS tissue bank endeavor. I would be happy to be a part of this effort and I am appreciative of you sending me the rules for the AIDS tissue bank and committee. I am delighted that I can take part and I certainly find the enclosed rules acceptable. The only question in terms of my eligibility is that my funding presently, especially vis a vis DFMO, approaches may not go over the $50,000 limit you mentioned in your tissue committee requirements. On the other hand, I have other grants pending which will probably put me over that arbitrary number.

In short, I would like to participate. As I hope it is clear, I am tremendously excited about continuing to evaluate ways to strengthen the relationship between the AIDS programs at the two hospitals within our school. I have already told John Mills that I am anxious to have the NIHS use DFMO in a randomized study with Dapsone and Septra. Presently I am trying to put together a protocol on first-line use of DFMO after which, if the drug works, John Mills and Connie Wolfsy will help me coordinate between the two AIDS programs this randomized use of possible pneumocystis therapies.

I will ask John Greenspan to get back to me soon regarding the logistics of getting the blood sent to Tennessee so I can undertake this study of pneumocystis antigen. Thanks for your nice note.

Sincerely,

Jeff

JAG:akt/fg
cc: John Greenspan, M.D.

THERAPY OF KS

*CHEMOTHERAPY

- -Vinblastine, ABV
- -Single agent Adriamycin
- -VP-16
- -ICRF (pending NCI review)

*BIOLOGIC AGENTS

- -Alpha-interferon
- -Gamma-interferon (in preparation)
- -IL-2 (in preparation)
- -Levamisole derivatives (in planning)

*RADIOTHERAPY (with Ruth Grobstein)

- -Dose responsive cure
- -Palliation of unresponsive lesions
- -Randomized surgical adjuvant (in preparation)

*OTHER

- -Cis-retinoic acid (with John Ziegler)

SCREENING FOR AIDS

Prospective study of screened patients (in preparation).
Screening of IV drug abusers (in planning).

THERAPY OF PCP

Prospective randomized TMP/SM vs. Pentamidine (with Pulmonary, Infectious Disease Groups).

AIDS ETHICS (with Molly Cooke, Al Johnson)

Prospective study of UCSF Housestaff concerns.

MISCELLANEOUS STUDIES

Secretory and serum I_gA (with John Alverdy)

AIDS registry at SFGH (with Connie Wofsy)

Psychosocial prospective study (with Temoshok et al)

Natural history of untreated KS (with John Ziegler)

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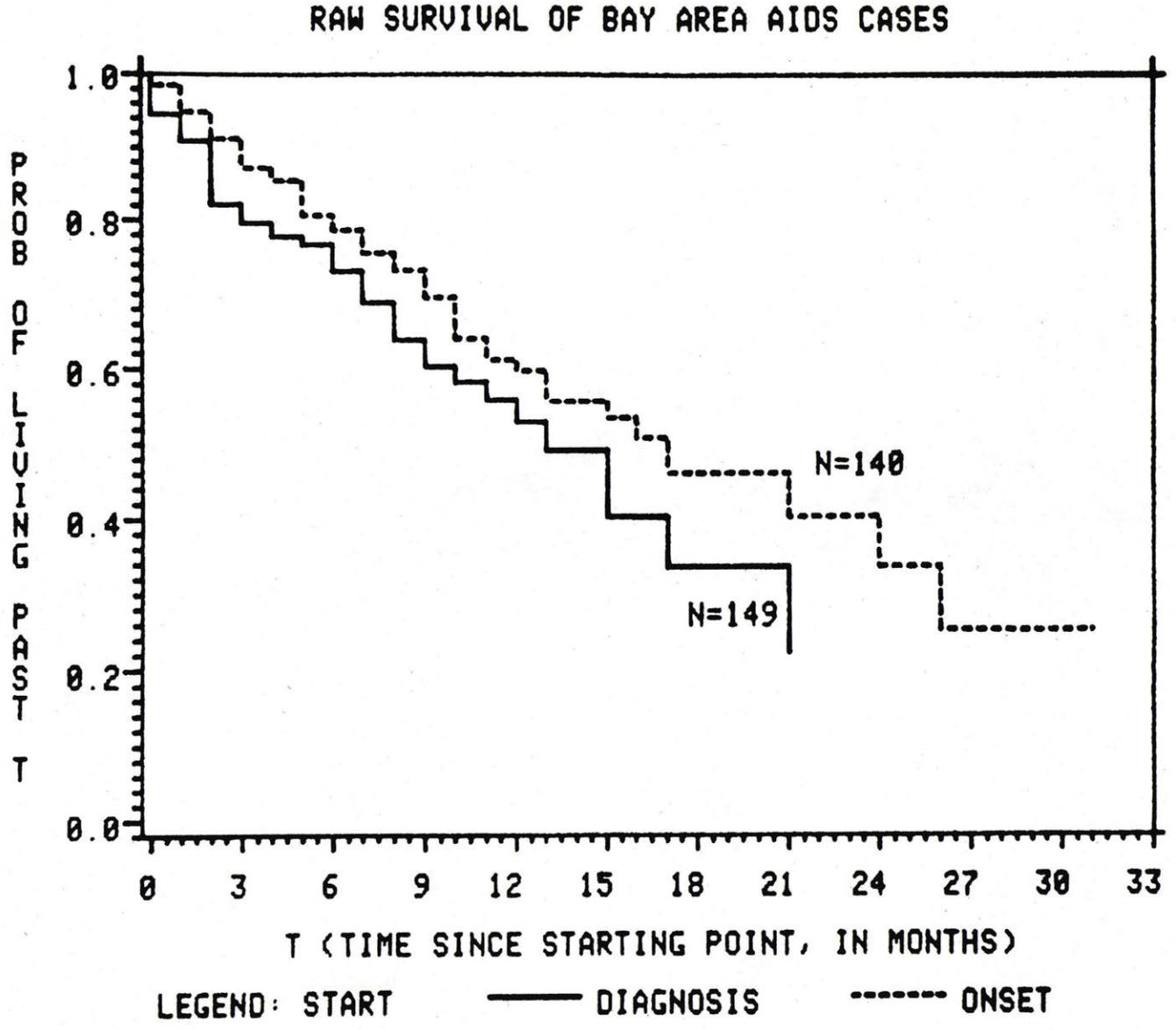
RAW SURVIVAL OF BAY AREA AIDS CASES
PROB OF LIVING PAST T
1.0
0.8
0.6
0.4
0.2
0.0
N=140
N=149
0
3
6
9
12
15
18
21
24
27
30
33
T (TIME SINCE STARTING POINT, IN MONTHS)
LEGEND: START
DIAGNOSIS
ONSET

AIDS CLINICAL RESEARCH GROUP

Form: Biopsy or Specimen Information Form

Leave Blank

Date_____
Acct#_____
R#-Tissue_____
AS#-Serum_____

Date Specimen Obtained_____
Contributing M.D._____
Facility_____

Patient Code #_____

Birth Date_____

Age_____ Sex_____

Risk Group_____

Clinical Diagnosis:

KS_____
PCP_____
Lymphadenopathy_____
ITP_____
Other Infection_____
Other Malignancy_____
Coded Study_____ Study #_____

Current Therapy:

Therapy for Malignancy_____
Therapy for Infection_____
Ever Received Chemotherapy yes_____ no_____

Specimen:
Blood

Type of Blood Specimen_____
Whole Blood_____ Plasma____ Serum____ Separated Cells____

Number of Tubes_____
Tube Type_____

Biopsy:

Skin_____ Node____ KS____ Normal Skin____ Other____

Amount of Tissue_____gms (estimation)

Location Tissue Sent (if elsewhere)_____

SP or DP #_____
Patient Unit #_____

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AIDS SPECIMEN BANK
HSW-604
(415) 666-2943

SAN FRANCISCO, CALIFORNIA 94143

NOTICE

AIDS TISSUE AND SERUM BANKS

The Specimen Banking Committee of the University of California Taskforce on AIDS announces the establishment of repositories of specimens obtained from AIDS patients and associated groups, as well as controls.

The specimens include aliquots of serum (stored at -70°C), surgical biopsy specimens (stored in liquid N_2) of Kaposi's sarcoma and neighboring uninvolved skin and mucosa, Kaposi's sarcoma and lymphadenopathy syndrome lymphnodes, autopsy specimens of Kaposi's sarcoma tumors, lymphnodes and spleen. Population groups represented include several forms of AIDS, (Kaposi's sarcoma, pneumocystis pneumonia, idiopathic thrombocytopenic purpura); ARC, including candidiasis, herpesvirus infections and lymphadenopathy syndrome; healthy male homosexuals, and other controls. Two banks have been established, at U.C. San Francisco and at U.C.L.A. Requests for specimens should be accompanied by full details of the proposed studies, including the nature of the problem to be investigated, the methods to be used, and by whom. Specimens will be released for defined and agreed upon studies only. Recognition of the role of those providing the specimens is expected in abstracts and publications resulting from these collaborations. Address inquiries and requests to one of the following:

1) John S. Greenspan, Ph.D., FRCPath
Chairman, Specimen Banking Committee
U.C. Systemwide Taskforce on AIDS,
Room HSW 604
U.C.S.F., San Francisco, CA. 94143

2) Paul Volberding, M.D.
Chairman, U.C.S.F. AIDS Tissue Committee
5H22, S.F.G.H.
San Francisco, CA. 94110

3) Ron Mitsuyasu M.D.
U.C.L.A. Aids Center
Wadsworth V.A. Medical Center
Building 500
Los Angeles, CA 90026

Supported by the University of California AIDS Taskforce (Chairman, Merle Sande M.D.) with funds provided by the State of California. The support of NIH UOI, CA, 34980-01 for the AIDS research program at UCSF is also acknowledged.

JSG/cf