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BERKELEY: DONNER LABORATORY AND DONNER PAVILION

November 22, 1976

Mr. George L. Pappas
50A-4119
LBL

Dear George:

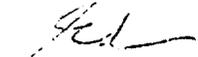
The UC San Francisco Committee for the Protection of Human Subjects has raised a jurisdictional question regarding human subjects review of Joe Castro's tumor treatment program at LBL. Since we do not employ Joe directly, but reimburse UCSF for 40% of his salary through a purchase order, they contend that he is a 100% UCSF employee and, as such, must secure UCSF-CPHS approval for any activity involving human subjects. The same considerations also apply to Dr. Jeanne Quivey, whose relationship to UCSF and LBL is identical to Castro's.

As an additional observation, Drs. Woodruff, Carlson, Sickles, Genant, and possibly others in the future, are under the same purchase of service arrangement. Presumably, these other names have not yet surfaced for the UCSF review committee, but they certainly will.

As I see it, Joe's activities at LBL are totally under our control, and the use of the purchase order reimbursement is merely the most convenient means of allocating the appropriate part of his salary to our funds. The UCSF-CPHS considers this an important point, and has asked us to seek General Counsel's opinion on the existence of an employer-employee relationship between Castro and LBL. Could you refer this matter to General Counsel's office?

The UCSF-CPHS has also asserted the need to review the Castro protocols because some of the patients treated here will be referred by UCSF faculty. However, the treatment will be carried out entirely on our premises, by staff under our control, with funds administered by LBL, and in conformity to protocols approved by the Berkeley campus CPHS. Under these circumstances I do not believe it is necessary for a dual review by UCSF.

At present, the basic protocol and consent form, as well as the specific documents for some tumor sites have been approved by both the Berkeley and San Francisco Committees (Castro submitted them to UCSF at their request). However, each added tumor site requires a separate approval, and there are a good many of them yet to come. The point is not whether the program will receive rigorous human subject review - we already have that through UCB - but whether it will become bogged down in duplicated paper work and alternating submissions to one Committee or minor adjustments desired by the other.


Edward L. Atpen

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Mr Pappas - Each campus has the prerogative to do this if they wish - SF is doing so & there is nothing we can do about it

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