Committee on Research

Annual Report 2004 – 2005

John Kurhanewicz, PhD, Chair

During 2004-2005, the Committee on Research enjoyed a productive year during which it met six times. The Committee’s work was augmented by the use of electronic communications to gather data and facilitate communication among Committee members. Wendy Max, PhD represented the Committee on the State-Wide Academic Senate Committee on Research Policy (UCORP). Professor Sally J. Marshall served as Committee chair from September 1, 2004 through March 2005, at which time she was appointed Associate Vice Chancellor for Academic Affairs at UCSF and resigned her position as Chair of the Committee. The Committee on Committees appointed Professor John Kurhanewicz to assume the role of Chair in March 2005. He will continue in his role as Chair during 2005-06.

Issues reviewed and acted on by the Committee included:

- Review and award of two cycles of Individual Investigator grants
- Review and award of Shared Equipment grants
- Selection of 48th Faculty Research Lecturer
- Selection of 5th Distinguished Clinical Research Lecturers

**Individual Investigator Grants**

In 2003-2004, the Committee received seventy-two (72) applications in total for Individual Investigator Grants. There was a slight decrease in these numbers in 2004-2005. At its meetings of November 14, 2004, December 8, 2004 and June 22, 2005, the Committee reviewed forty-eight (48) applications for Individual Investigator Grants requesting a total of $1,564,060.80. Committee members ranked each application using secret ballots and a scoring system similar to that of the NIH, where 1.0 = strongly recommend for full funding through 3.0 = not fundable. Additionally, this year, the Committee did not review any applications ranked 2.0 or higher by the initial reviewer unless the reviewer requested discussion. The Committee approved seventeen (17) grants in the total amount of $587,500.80.

**Shared Equipment Grants**

This year, there was a marked increase in Shared Equipment Grants as the Committee received twenty (20) applications as opposed to only twelve (12) during the 2003-2004 season. At its meeting of March 23, 2004 the Committee reviewed the twenty (20) applications totaling $599,601.32. Committee members ranked each application in a secret ballot and approved eleven (11) grants totaling $287,737.17.
Selection of 48th Annual Faculty Research Lecturer

The Committee received several competitive nominations for the 48th Faculty Research Lecture and was delighted to approve the selection of Shaun Coughlin, MD, PhD – Professor of Medicine, Professor of Cellular and Molecular Pharmacology and Director of the Cardiovascular Research Institute. Dr. Coughlin joined UCSF in 1984. He has achieved international renown in the field of signal transduction via thrombin receptors. His groundbreaking work has led directly to new therapies for patients with unstable angina and acute myocardial infarction and he has, throughout his career, embraced the interaction between basic and clinical research. He is recognized as a respected and inspirational mentor as well as a scientist of consummate talent. Dr. Coughlin was elected to the National Academy of Sciences in 2004.

Dr. Coughlin’s lecture, entitled “Protease-Activated Receptors: Medicine to Science and Back” was delivered to the campus community during Founder’s Week on Monday, April 25, 2005 at 3:30 p.m. in Cole Hall.

Each year, the Faculty Research Lecture proudly acknowledges the outstanding scientific achievements made by a member of the Academic Senate. Academic Senate members are asked to consider the contributions of their colleagues so that the University community may recognize their achievements.

5th Annual Distinguished Clinical Research Lecturer

The Committee was delighted to approve the selection of R. Curtis Morris Jr. and Anthony Sebastian as co-recipients of the Fifth Annual Distinguished Clinical Research Lectureship for their shared preeminence in the field of patient oriented research related to hypertension, renal disease, electrolyte and acid-base physiology, vitamin D and mineral metabolism, and nutrition. Both are renowned for their success in shaping the direction of clinical research in multiple areas.

Since 2001, this award has been bestowed on an individual member of the UCSF faculty with outstanding achievements in clinical research. Nominations are made by UCSF faculty, who consider the clinical research contributions of their colleagues and submit nominations for this prestigious award to the Academic Senate Committee on Research. Each year, the Committee on Research selects the recipient of this award. This year, the Academic Senate is honored to recognize the joint achievements of Drs. Morris and Sebastian.

The Fifth Annual Distinguished Clinical Research Lecture will take place on Wednesday, October 12, 2005 at 3:30 p.m. in Cole Hall on the Parnassus Heights Campus and will be broadcast to other UCSF sites as availability permits. Drs. Morris and Sebastian will each present aspects of their work. The lecture is open to the campus community and the general public.

Restrictions on Research Funding

In a communication dated November 15, 2004 George Blumenthal, Chair of the Academic Council, requested that each division of the Academic Senate review and provide comments on the Academic Council Resolution on Research Funding Sources. (Appendix 1) UCSF Academic Senate Chair Leonard Zegans created a Task Force consisting of members from the Committees on Research, Academic Planning and Budget, Academic Freedom, and each of the four Faculty Councils. Catherine Chesla of the Committee
on Research chaired the Task Force. The charge of the Task Force was to review the report and recommendations of the University Committee on Research Policy (UCORP) related to Restrictions on Research Funding Sources and assess the impact on the UCSF campus and faculty.

At the request of the task force, the Committee on Research reviewed the resolution and considered whether to recommend that it be accepted, modified or rejected.

Key issues of concern raised by the Committee included:

Several non-governmental funding sources have adopted policies which restrict funding to institutions which do not refuse funding from certain industries. The resolution as written would prevent units from accepting funding from a certain source by prohibiting them from complying with the funding restriction requirements of these sources. For example – the American Legacy Foundation “will not award a grant to any applicant that is in current receipt of any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity”. The UCORP Resolution may prevent units of the University accepting funds from the Legacy Foundation because they will be unable to implement policies prohibiting funding from the tobacco industry.

In prohibiting any unit within the University from adopting a policy restricting funding from a particular source, the policy would deny faculty the opportunity to voluntarily restrict funding sources for their unit. Such a prohibition would deny units the ability to restrict funding sources as a means of assuring the unbiased nature of their research and might undermine the credibility of their work.

Restrictions on the “strings” that may be imposed by a funding source on the research methods and reporting of research by an investigator are have already been established by the University. Several policies are currently in place which have as their goal the preservation of academic freedom and the protection of the reputation and credibility of the University. These include conflict of interest policies and policies relating to the disclosure of funding sources in publications. Allowing units to further restrict funding sources themselves may be unnecessary. Should current policies be shown to be inadequate, they should be strengthened and clarified.

Committee members broadly agreed that the tobacco industry has a unique history of manipulating and distorting the research of UC investigators and investigators at other universities. The committee acknowledged that many faculty may choose to reject research funding from the industry. However, the Committee expressed concern that to ban funding from one source may lead to the setting of a precedent which will allow for the banning of other sources of funding. There is no mechanism in place to ensure that decisions to restrict funding sources would be arrived at using due process. Neither are there mechanisms in place to ensure that faculty who disagreed with such restrictions would have recourse to an appeals process. In the absence of such protections, the prohibition of restrictions on funding sources seems warranted.

The Committee moved to accept the resolution with no modifications. The motion was carried by a vote of fourteen to two with no abstentions.

Dr. Chesla conveyed the discussion and vote of the Committee to the Task Force reviewing the resolution. The Task Force, after holding several meetings and consulting with the Divisional Committees and School faculties, concluded that the UCSF campus should SUPPORT the UCORP resolution but believes that there
are a number of issues which merit the Academic Council’s close consideration as it moves forward. The UCSF Division respectfully requests consideration by the Academic Council related to the following issues: 1) Concerns related to the organizational level at which restrictions might be applied, so as to protect academic freedom of individuals as well as groups of faculty and at the same time protecting the reputation of the University. 2) Consideration of a modification of the resolution limiting the academic units to which it could be applied and specifying the processes by which units might decide to restrict funding. The entire report can be found in Appendix 2.

### Task Force Reviewing Draft Policy on Human Subject Injury

At the request of the Provost, the Academic Council was asked to solicit for review and comment the University of California Draft Policy on Human Subject Injury and accompanying Draft Guidance on Implementation. (Appendix 3)

The current 1979 Policy on Human Subject Injury provides that the University will pay the cost of medical care for a participant in a research study who is injured. The policy is silent on the question of the fund source for the cost of care for subject injury. The proposed draft policy affirms the University's position that research subjects should not bear the cost of medical care for research injury and directs each campus and program that funds human subject research to establish a funding mechanism to cover injury costs. The draft policy also incorporates recent legislation and government policy that allows a research subject's insurance to be billed for qualified clinical trials.

At UCSF, the Task Force consisted of: V. Courtney Broaddus, MD, Chair (Committee on Research), John Kurhanewicz, PhD (Committee on Research), Susan Sniderman, MD (Academic Planning and Budget), and William Seaman, MD (Academic Planning and Budget).

Upon reviewing the proposed draft policy on Human Subject Injury, the Task Force found strongly in support of the goal of protecting human subjects from harm. Overall, the Task Force was concerned with the phrasing of some of the policies. The task force was also concerned that research not be subjected to undue burdens. The Task Force’s findings can be found in their entirety in Appendix 4. In a June 27, 2005 Communication to the Provost, the Academic Council relayed varying concerns expressed by all campuses reviewing draft policy. (Appendix 5)

### Reinstatement of Travel Grants

The Academic Senate Travel Grant Program was indefinitely suspended due to budget reductions in 2003-2004. Following extensive discussion at its December meeting, the Committee resolved to reinstate the Academic Senate Travel Grant Program. The Committee recommended that $20,000 from Chancellor’s Opportunity Funds currently available to the Academic Senate be used to fund travel grants for new faculty each year (July 1 – June 30) with no more than 20 grants awarded during the period July 1 – December 31 and the remainder of the grants to be awarded during the period January 1 – June 30. Individual grants will not exceed $500 and individual faculty may receive no more than one grant in any twenty-four (24) month period. The grants will be awarded on a “first come, first served basis” to faculty at 50% time or more, at the associate rank or lower, with five years of service or less at UCSF.
**Formation of Subcommittees to Review Grant Application Procedures**

Due to the need for increased clarity and consistency within current Academic Senate Individual Investigator and Shared Equipment grant application procedures the Committee agreed to form a task force which will review existing grant guidelines and make recommendations for improvement. Committee Vice-Chair John Kurhanewicz agreed to chair this task force. Committee members B. Aouizerat, C. Broaddus, S. Habelitz, R. Oka, M. Springer, and K. Yang also agreed to serve on the task force.

Another task force was formed to examine ways in which grant applications may be facilitated by the use of online application submission. The Committee task force will be chaired by Chuck McCulloch. C. Barton, K. Delucchi and K. Phillips volunteered to participate in the task force.

**Issues for 2005 – 2006 Academic Year**

The following are a list of ongoing issues for consideration by the 2005-06 Committee:

1. Identify resources necessary for the Senate Office to support and institute measures to more adequately monitor expenditures by faculty in receipt of Academic Senate funding.
2. Continue the work of the two newly formed Task Forces Reviewing Grant Guidelines and Online Application Submission.
3. Develop more specific criteria for selection of both the Distinguished Clinical Research Lecturer and Faculty Research Lecturer.

**Appendices**

Appendix 1: Letter from George Blumenthal to All Campuses Requesting Input on the Restrictions on Research Funding, November 17, 2004.


Appendix 5: Systemwide Response to the Provost Regarding Comments on the Draft Policy on Human Subject Injury, June 27, 2005

Respectfully Submitted,

**The Committee on Research 2004-2005**

**John Kurhanewicz, PhD, Chair (Radiology)**

**Wendy Max, PhD, UCOR Rep (Institute for Health and Aging)**

**Donna Albertson, PhD (CRI)**

**Bradley Aouizerat, PhD (Physiological Nursing)**

**Christopher Barton, MD (Emergency Services)**
Sigurd Berven, MD (Orthopedic Surgery)
Courtney Broaddus, MD (Medicine)
Catherine (Kit) Chesla, RN, DNS (Family Health Care Nursing)
Ken Covinsky, MD, MPH (Medicine)
Kevin L. Delucchi, PhD (LPPI)
Shareen El Ibiary, PharmD (Clinical Pharmacy)
Stefan Habelitz, PhD (Preventive and Restorative Dental Sciences)
John Huang, DMD (Growth and Development)
Jane Koehler, MD (Medicine)
Wu Li, PhD (Growth and Development)
Pam Ling, MD, MPH (Medicine)
Robert Lustig, MD (Pediatrics)
Chuck McCulloch, PhD (Epidemiology and Biostatistics)
Ed Murphy, MD, MPH (Epidemiology and Biostatistics)
Roberta Oka, RN, DSc (Community Health Systems)
Kathryn Phillips, PhD, MPA (Clinical Pharmacy/Cancer Center)
Eric Small, MD (Medicine/Urology)
Jeanine Wiener-Kronish, MD (Anesthesia)
Kathy Yang, PharmD, MPH (Clinical Pharmacy)
Matt Springer, PhD (Cardiology)

Prepared by:
Shilpa Patel
Senior Senate Analyst
514-2696
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November 17, 2004

DIVISIONAL CHAIRS
SENATE-WIDE COMMITTEE CHAIRS

Re: Academic Council Resolution on Restrictions on Research Funding Sources

Dear Colleagues:

At its October 20 meeting, the Academic Council unanimously agreed that the Academic Council Resolution on Restrictions on Research Funding Sources, which was adopted by the Council on July 21, 2004, should be sent out for general review by the systemwide Senate Standing Committees and the Divisions. The Council felt that concerns expressed by some faculty members subsequent to the Council's July endorsement regarding both the content of the resolution and the need for members of the Senate to have their views heard warrants a full and open discussion of the resolution before any final action is taken.

I therefore am enclosing the Academic Council Resolution on Restrictions on Research Funding Sources for review by your respective constituencies. After the divisions and statewide committees have commented, the Academic Council will decide whether the Resolution should stand as written and adopted, or should be amended and/or rescinded. The Council might also decide to forward this to the Academic Assembly for action. I would like to receive responses from Systemwide committees by February 10, 2005 and from the Divisions of the Academic Senate by March 14, 2005.

I also refer you to the Academic Council’s “Report on Problematic Restrictive Clauses in Contracts, Grants and Gifts for Research,” for the larger context in which the University Committee on Research Policy (UCROP) formulated this resolution. In what follows, I would like to provide a brief overview of the document’s background and the debate associated with it.

Last July, the University Committee on Research Policy (UCROP) brought to the Academic Council the above report on “strings” attached to research awards. Attending that report, both as a separate document and incorporated into the report, was UCROP’s Resolution on Restrictions on Research Funding Sources, which was developed as a response to faculty votes within individual units of the University to ban the acceptance of research funding from the companies associated with the tobacco industry. The Resolution is, however, not particular to that one source or issue. The Academic Council adopted both the report and the resolution, and they were subsequently sent to President Dynes with the request that they be distributed to the various campus administrations. The Resolution now out for review concludes that:
“The principles of academic freedom and the policies of the University of California require that individual faculty members be free to accept or refuse research support from any source, consistent with their individual judgment and conscience and with University policy. Therefore, no unit of the University should be directed (by faculty vote or administrative decision) to refuse to process, accept, or administer a research award based on the source of the funds; and no special encumbrances should be placed on a faculty member’s ability to solicit or accept awards based on the source of the funds.”

The Resolution was developed within the larger context of UCORP’s almost two-year-long engagement with the issue of restrictions on research awards. The committee had, in October 2002, identified tobacco industry funding as one of its key issues, and throughout the year discussed the UCSF vote on whether to accept tobacco funding and the University’s negotiations with the American Legacy Foundation (ALF) regarding a clause in its grants that prohibits the broad organization receiving ALF funding from also receiving funds from the tobacco industry. In July 2003, UCORP received a formal charge from Academic Council Chair Binion to review UC’s stance on the issue of banning tobacco funding at the University, along with the broader charge to review research funding policies at UC, the fulfillment of which was the July ’04 report and its attendant Resolution on Restrictions on Research Funding Sources. In endorsing the Resolution, the Academic Council was expressing the belief that banning certain sources of funds, such as tobacco funding, by a majority vote of the faculty within a unit is a fundamental infringement of the academic freedom of the individual UC researcher who may wish to accept such funding and who is otherwise acting in compliance with UC policy. UC policy requires that scholarship be judged solely by professional standards, and the Resolution was aimed at showing that bans based upon judgments regarding the funding source or speculations about how the research might be used fundamentally interfere with a faculty member’s freedom to carry out a research program.

UCORP’s view of the academic freedom issues was based, in part, on the American Association of University Professors’ (AAUP’s) academic freedom position. The 2002-03 AAUP Committee A Report states in part:

“A very different situation obtains, however, when a university objects to a funding agency because of its corporate behavior. As a practical matter, the distinction between degrees of corporate misdeeds is too uncertain to sustain a clear, consistent, and principled policy for determining which research funds to accept and which to reject. An institution which seeks to distinguish between and among different kinds of offensive corporate behavior presumes that it is competent to distinguish impermissible corporate wrongdoing from wrongful behavior that is acceptable. A university which starts down this path will find it difficult to resist demands that research bans should be imposed on other funding agencies that are seen as reckless or supportive of repellent programs. If the initiative in calling for these bans on the funding of faculty research comes from the faculty itself, our concerns about the restraints on academic freedom are not thereby lessened.”
Holding a contrary position, some faculty members believe that self-governance allows a unit of the faculty to restrict research awards based on the source of funds. For example, a group of faculty members active in opposing the acceptance of tobacco money have formally objected to the Resolution, and cite the Regents’ 1970 resolution on research, which states that UC research “makes a vital contribution to […] the health and well-being of all mankind” as the reason some faculty units have adopted no-tobacco money policies. They raise several procedural issues, one of which is that UCORP’s initial consultative process was not broad enough and not held with “interested parties.” It is the Academic Council’s intention to address this particular criticism through discussions involving broad constituencies within Senate committees and the Divisions.

Key among the other objections raised by the group is the argument that the tobacco industry’s history of systematically distorting scientific research is inconsistent with and undermines the University’s fundamental academic mission. In support of this argument, it is pointed out that tobacco companies are now under federal RICO\(^1\) indictment, and that the Council for Tobacco Research and the Center for Indoor Air Research were disbanded based on allegations of fraud by law enforcement officials. The current racketeering lawsuit alleges a criminal conspiracy by the tobacco industry to corrupt and misdirect university research, to preempt research results contrary to its interests, and to produce and disseminate disinformation under the guise of independent research. This group of faculty argues that in accepting research funding from the tobacco industry, the University is acting as an unintentional collaborator with the tobacco industry. Those with this point of view would draw a clear distinction between freedom of speech, which they agree is protected by academic freedom, and the acceptance of funding from a particular source. They also argue that this resolution inappropriately limits the grounds under which the University may refuse funding from a source.

In the same vein, the anti-tobacco money group argues that the UC Regents have divested their holdings in the tobacco industry, and therefore, it is inconsistent and questionable that the Regents (who as a body are the legal recipients of funding awards) should accept research sponsorship from the same source. On the other hand, it can be argued that investment choices (for monetary profit), which might provide financial support for repugnant behavior, may not be strictly analogous to accepting research funding that comes without strings and is in support of fundamental research.

Those opposing the resolution may also argue that each unit (e.g., campus, college or department) should have the right to set its own policy by majority vote of the faculty. According to university policy, funding is approved by the head of a unit (a chair, dean, director) if the project is deemed an “appropriate university activity.” They ask, then, if the majority of faculty members of a particular unit decide that accepting funding from a certain source is not an appropriate university activity, then “should the unit head be forced to host that activity?” However, UCORP has pointed out that policy is made at much higher levels and that a unit head, when approving a research grant or contract, is acting as an administrator, not as the head of a Senate unit; therefore that unit head must follow broader University policy.

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\(^1\) The Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968, prohibits individuals or entities from engaging in racketeering activity associated with an "enterprise," which includes corporations, partnerships and other legal entities and associations. The RICO statute also makes it illegal for individuals or entities to profit from a pattern of racketeering activity, and allows for the confiscation and seizure of such ill-gotten gains.
I realize that in summarizing these arguments, I may not have done justice to all points of view within the University regarding this Resolution. I hope that discussions within committees and divisions will help to clarify the issues further. Clearly, the issues associated with the Resolution on Restrictions on Research Funding Sources have significant ramifications for research policy and for individual UC researchers. I look forward to hearing your responses.

Sincerely yours,

George Blumenthal, Chair
Academic Council

Encl: 1

GB/bg
Resolution of the Academic Council
Restrictions on Research Funding Sources

Submitted by the University Committee on Research Policy;
Adopted by the Academic Council July 21, 2004

Whereas, Freedom of inquiry is a fundamental principle of the University of California; and

Whereas, The University of California faculty code of conduct requires that “[Professors] respect and defend the free inquiry of associates”; and

Whereas, The University of California policy on academic freedom requires that scholarship be judged solely by reference to professional standards, and that researchers “must form their point of view by applying professional standards of inquiry rather than by succumbing to external and illegitimate incentives such as monetary gain or political coercion”; and

Whereas, The University of California has existing policies that encourage the highest ethical standards in the conduct of research, require disclosure of conflicts of interest, guarantee the freedom of publication, and prevent misuse of the University's name; and

Whereas, Restrictions on accepting research funding from particular sources on the basis of moral or political judgments about the fund source or the propriety of the research, or because of speculations about how the research results might be used, interfere with an individual faculty member’s freedom to define and carry out a research program; and

Whereas, No Committee, Faculty, or Division of the Academic Senate of the University of California has the plenary authority either to set aside the principles of academic freedom or to establish policies on the acceptance of research funding; now, therefore, be it

Resolved, That the principles of academic freedom and the policies of the University of California require that individual faculty members be free to accept or refuse research support from any source, consistent with their individual judgment and conscience and with University policy. Therefore, no unit of the University should be directed (by faculty vote or administrative decision) to refuse to process, accept, or administer a research award based on the source of the funds; and no special encumbrances should be placed on a faculty member’s ability to solicit or accept awards based on the source of the funds.
Communication from the Task Force on Review of Academic Council Resolution on Research Funding

Kit Chesla, RN, DNSc, FAAN, Chair

Leonard S. Zegans, MD
Chair, UCSF Academic Senate
Box 0764

March 4, 2005

Re: Task Force Review of Academic Council Resolution on Restrictions on Research Funding

Dear Chair Zegans,

At your request, a Task Force of the Academic Senate recently reviewed the UC Academic Council Resolution on Restrictions on Research Funding Sources. The Task Force was comprised of representatives from the committees on Academic Freedom, Academic Planning and Budget, Research and from the faculty councils of the schools of Medicine, Nursing and Pharmacy. School of Dentistry was invited to participate but could not identify a representative to the committee and did not respond to the resolution. Each committee / council represented on the Task Force reviewed the resolution and communicated to the Task Force a recommendation of approval, rejection or modification. These communications are attached as appendices. Four of the six groups recommended approval of the resolution and two of the groups recommended approval with modifications. In light of these recommendations, and of extensive discussion at meetings of the Task Force held on January 10 and February 7, 2005, the Task Force recommends that the resolution be approved, but believes that there are a number of issues which merit the Academic Council’s close consideration as it moves forward.

Summary of Process and Voting

Committee on Academic Freedom
The Committee on Academic Freedom reviewed the resolution at its meeting of January 18, 2005. The Committee returned a unanimous vote of members present at the meeting to recommend approval of the resolution with modifications. Concerns focused on the organizational level at which restrictions might be applied, protecting academic freedom of individuals as well as groups of faculty and protecting the reputation of the University. (Appendix 1)
Committee on Academic Planning and Budget
The Committee on Academic Planning and Budget reviewed the resolution at its meetings of January 13 and February 10, 2005. At its meeting of January 13, the Committee returned a vote of 7:2 in favor of recommending approval of the resolution. At a subsequent meeting the Committee further recommended that the Academic Council consider a modification of the resolution limiting the academic units to which it could be applied and specifying the processes by which units might decide to restrict funding. (Appendix 2)

Committee on Research
The Committee on Research reviewed the resolution at its meetings of December 7 and January 20, 2005. At its meeting of January 20, the Committee voted by 13:2 to recommend approval of the resolution. (Appendix 3)

School of Medicine Faculty Council
The faculty council reviewed the resolution at its meeting of January 24, 2005 and returned a 7-2 vote of members present at the meeting to recommend approval of the resolution. The Council further recommended that investigators applying to the tobacco industry for funding receive a white paper detailing the past history of the industry’s involvement in scientific research. (Appendix 4)

School of Nursing Faculty Council
The Faculty Council requested that each of the school’s four departments, and the Institute on Health and Aging, review the resolution. Discussion and voting procedures were determined by each department. The departments of Physiological Nursing and Family Health Care Nursing, and the Institute of Health and Aging each voted to approve the resolution. The Department of Community Health Systems and Social and Behavioral Sciences voted to reject the resolution. In light of these results, the Faculty Council returned a recommendation of approval of the resolution to the Task Force. (Appendix 5)

School of Pharmacy Faculty Council
The faculty council distributed an electronic survey to all faculty salaried at 50% time or more (n=80) requesting responses to three questions:

1. “Please read and vote on whether to support or oppose the proposed resolution which reads: "Resolved, That the principles of academic freedom and the policies of the University of California require that individual faculty members be free to accept or refuse research support from any source, consistent with their individual judgment and conscience and with University policy. Therefore, no unit of the University should be directed (by faculty vote or administrative decision) to refuse to process, accept, or administer a research award based on the source of the funds; and no special encumbrances should be placed on a faculty member’s ability to solicit or accept awards based on the source of funds."

2. “An issue that has been raised is whether an individual unit (e.g., an Organized Research Unit) could have a policy restricting funding sources for that unit only. [For example, while special units, such as Organized Research Units, could have policies restricting funding sources for research attributable to that unit, such policies would not restrict individual faculty from receiving funding independent of that unit through their primary Departmental appointment.] Do you support a policy in which individual units of the University could use due process and defined criteria to establish a policy to refuse to process, accept or administer a research award based on the source of funds?”
3. “Should we, the faculty, at UCSF refuse to accept any funding from the tobacco industry, and the foundations it supports, an agreement that would be binding for all UCSF faculty?”

Thirty-seven faculty responded for a 46% response rate.

In response to question one, the faculty returned a vote of 28:9 in favor of recommending approval of the resolution.

In response to question two, the faculty returned a vote of 20:17 in favor of allowing individual units to establish policies to restrict research funding sources.

In response to question three, the faculty returned a vote of 13:21 against adopting a policy to ban funding from the tobacco industry. (Appendix 6)

Concerns Expressed in Support of the Resolution

Redundancy of restrictions on research funding sources

The University has established protections against the “strings” that may be imposed by a funding source on the research methods and reporting of research by an investigator. Several policies are currently in place which has as their goal the preservation of academic freedom and the protection of the reputation and credibility of the University. These include conflict of interest policies and policies relating to the disclosure of funding sources in publications. Allowing units to restrict funding sources outright in order to further protect research and researchers from manipulation by funding bodies is unnecessary. Should current policies and protections be shown to be inadequate, they should be strengthened and clarified.

The Task Force recognizes that the tobacco industry has a unique history of manipulating the conduct, results and dissemination of research. The Academic Council should consider encouraging individual campuses of the University to provide faculty applying for funding from the tobacco industry with a white paper detailing the past history of the industry’s interaction with universities. This measure would ensure that, while free to accept funding from any source, faculty are aware of the potential for negative interaction with the tobacco industry.

Protection of faculty opposed to restrictions

The prohibition of funding from one source may lead to the setting of a precedent that will allow for the banning of other sources of funding. Faculty may choose to refuse funding from a particular source because of the past actions and policies of that source. However, this decision is an individual one. Allowing units within the University to adopt policies prohibiting funding from a certain source may lead to the political manipulation of such policies and the infringement of academic freedoms of dissenting faculty. There is no mechanism in place to ensure that decisions to restrict funding sources are arrived at using due process. Neither are there mechanisms in place to ensure that faculty who disagree with such restrictions would have recourse to an appeals process. In the absence of such protections, the prohibition of restrictions on funding sources as provided for in the resolution is warranted.

Concerns Expressed in Opposition to the Resolution

Issues of concern were raised primarily by the committees on Academic Freedom and Academic Planning and Budget. These committees believe that the resolution will be strengthened by a thorough consideration of the issues outlined below. The Academic Council is encouraged to examine these issues and consider
ways in which they may be addressed - through careful implementation and possible modification of the resolution.

**Limitation of funding opportunities**
Several funding groups restrict funding to institutions that have in place policies prohibiting funding from specified industries. As written, the resolution precludes funding from these sources by prohibiting such policies and preventing units within the University from voluntarily complying with the requirements of these groups. Notable among the groups with such requirements is the American Legacy Foundation, which “will not award a grant to any applicant that is in current receipt of any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity.”

In limiting the ability of individual faculty or groups within the University to comply with the requirements of some funding sources, the Council’s resolution may limit both the funding opportunities and academic freedom of individuals by denying them the opportunity to pursue research paths with monies from these sources, which may be the only monies available.

Should the resolution apply only to larger units of the University (divisions, department, schools, campuses) and not to smaller groups such as Organized Research Units (ORUs) and Multi-Campus Research Units (MRUs) this concern would be mitigated. Specialized units would be free to adopt a policy prohibiting research funding from a particular source; individual faculty affiliated with the unit would be free to obtain funding from that source through their primary Department appointment. [Please refer to appendices 1 and 2 for further discussion.]

**Protection of integrity of research and collective academic freedom**
The University of California fosters research of international renown. Objectivity is of critical importance in maintaining the quality and credibility of this research. While partnerships with industry may engender world-class, creative research, faculty should have the freedom to reject funding from industries with a history of manipulation of research projects and findings. This freedom must reside with the faculty as a group as defined in APM 010 (General University Policy Regarding Academic Appointees: Academic Freedom) which states:

“Academic freedom requires that ... scholarship be assessed by reference to the professional standards that sustain the University’s pursuit and achievement of knowledge. The substance and nature of these standards properly lie within the expertise and authority of the faculty as a body.”

Protection of an individual’s freedom of inquiry and research is of fundamental importance. However, it should not supersede the obligation of the faculty as a whole – or at the level of a unit – to protect the integrity of their research by prohibiting funding from a particular source.

**Protection of University reputation**
The resolution, in preventing the University or a unit of the University from restricting research funding sources, may undermine the credibility of the University as a whole. Should the University accept funding from a source that is perceived to conflict with its mission, public trust in the University may be jeopardized? This may be particularly true for health science campuses in receipt of funding from the tobacco industry or other industries with products known to negatively impact human health. An erosion of
the reputation of the University may in turn impact the academic freedom of faculty by hindering their ability to obtain funding, conduct research and publish their work.

The Task Force thanks you for the opportunity to review this important Academic Council policy. Please do not hesitate to contact me should you have any questions or require clarification of any of the points raised in this communication.

Sincerely,

TASK FORCE ON REVIEW OF ACADEMIC COUNCIL RESOLUTION ON RESEARCH FUNDING

Kit Chesla, RN, DNSc, FAAN (Chair / Committee on Research)
Lisa Bero, PhD (Committee on Academic Planning and Budget)
Quinn Cheng, MD (School of Medicine Faculty Council)
Jim Lightwood, PhD (Committee on Academic Freedom)
Norman Oppenheimer, PhD (School of Pharmacy Faculty Council)
Kathleen Puntillo, RN, DNS, FAAN (School of Nursing Faculty Council)

**APPENDICES**

**Appendix 1:** Communication from the Committee on Academic Freedom

**Appendix 2:** Communication from the Committee on Academic Planning and Budget

**Appendix 3:** Minutes of the Committee on Research

**Appendix 4:** Communication from the School of Medicine Faculty Council

**Appendix 5:** Overview of the School of Nursing Consideration of UCORP Resolution on Restrictions on Research Funding Sources

**Appendix 6:** Communication from the School of Pharmacy Faculty Council
COMMUNICATION FROM THE COMMITTEE ON ACADEMIC FREEDOM
Mark Eisner, MD - Chair

Catherine Chesla, RN, DNSc, FAAN
Chair, Senate Task Force Reviewing Academic Council Resolution on Restrictions on Research Funding Sources
Box 0606

January 24, 2005

Re: Academic Council Resolution on Restrictions on Research Funding Sources

Dear Dr. Chesla:

The UCSF Committee on Academic Freedom has reviewed the Resolution on Research Funding sources and endorses the resolution with recommended modifications. Based on our deliberations, the Committee has decided that the resolution, which requires that "individual faculty members be free to accept or refuse research support from any source....," is consistent with academic freedom, as defined by APM 010. In particular, the resolution is consistent with the "freedom of inquiry and research" which is central to this definition of academic freedom.

We have two reservations about the Resolution as it is currently written.

1) Prohibiting faculty members from voluntarily agreeing to accept restrictions in contracts and grants may limit their ability to secure funding for research. Such restrictions, which may be acceptable to a group of faculty, may be necessary to satisfy the requirements of a funding agency. Consequently, the resolution could actually impair the freedom of inquiry and research by reducing available funding avenues.

Pursuant to this modification, the CAF believes that it is critical to distinguish the organizational level at which restrictions are applied. At the level of a Division, Department, School, or higher, in which a faculty member holds his or her primary appointment, the committee agreed that the resolution should fully apply and not allow any restriction on funding sources. This is because faculty who wish to pursue a "restricted" funding source would have no recourse or alternatives and might suffer reduction in their academic freedom. At smaller organizational levels, such as the ORU or MRU, faculty may have shared research interests and views that make voluntary restriction of funding advantageous in terms of applying to specific funding agencies, allowing them to pursue a desired avenue of inquiry. Moreover, such voluntary restrictions at this level may have minimal or no limitation of faculty academic freedom because of the shared mission of these faculty and their ability to leave the ORU or MRU, should they disagree with the
policy, and maintain their primary Divisional and Departmental appointments intact. An example is the UCSF Center for Tobacco Control Research and Education, who has a policy prohibiting tobacco industry funding, which is consistent with the scientific and public health mission of the Center and facilitates funding from organizations such as the Flight Attendants Medical Research Institute and the American Legacy Foundation.

(2) The resolution, by preventing any unit of the University from accepting restrictions on funding, could ultimately result in damage to the overall credibility of the University. If faculty accept funding from sources that are widely perceived to conflict with the mission of the University, such as the tobacco industry, the reputation of the University, and its faculty, could suffer. If the reputation of the University declined in this fashion, it could negatively affect the ability of faculty to secure funding, conduct their research, and publish their work. Consequently, academic freedom, which has the freedom of inquiry and research at its core, could suffer. An example may be the University of California Energy Institute, which voluntarily declines funding from the energy industry in order to maintain its neutrality and credibility.

Thank you for your consideration of this important matter.

Sincerely,

Mark Eisner, MD - Chair
Chair, Committee on Academic Freedom
February 10, 2005

TO: Task Force on Funding Resolution

FROM: Academic Planning and Budget Committee, Lisa Bero representative

RE: Reconsideration of Resolution on Research Funding Sources

At its January 13 and February 10, 2005 meetings, the APB committee discussed the University Committee on Research Policy Resolution “Restrictions on Academic Funding Sources,” adopted by the Academic Council July 21, 2004. The APB committee was asked by the Task Force to vote in support of or in opposition to the Resolution and provide a memo listing the main concerns of the Committee. The Committee did not reach a consensus on this issue, except regarding the Committee Recommendation (see below).

At the January 13 meeting, the APB committee voted 7 in SUPPORT of and 3 in OPPOSITION to the Resolution as stated below:

“Resolved, that the principles of academic freedom and the policies of the University of California require that individual faculty members be free to accept or refuse research support from any source, consistent with their individual judgment and conscience and with University policy. Therefore, no unit of the University should be directed (by faculty vote or administrative decision) to refuse to process, accept, or administer a research award based on the source of the funds; and no special encumbrances should be places on a faculty member’s ability to solicit or accept awards based on the source of funds.”

There were no abstentions.

The main concerns raised by those in support of the resolution were: 1) The “slippery slope” concern (if a unit restricted funding from one source, it might restrict funding from many more sources), and 2) a formal policy is not necessary.

The main concern raised by those in opposition to the resolution was that UC policy (APM 010) states that the substance and nature of standards of academic freedom reside with the faculty collectively. Thus, the integrity of academic research units should not be abandoned in the name of academic freedom for an individual faculty member. (see further discussion in January 14, 2005 memo from Michael Parrish, Chair – UCPB.)

Committee Recommendation

Both those in support of and in opposition to the resolution agreed to the following modification of the resolution:

[Further text on the modification of the resolution]
Individual units should have the freedom to develop policies restricting research funding sources if:

a. The unit uses a due process among the faculty to establish such a policy.
b. The unit establishes criteria for unacceptable funding sources, for example: funding source violated academic freedom, funding source has a history of manipulating research and not adhering to standards of research integrity, funding source sponsors research that is antithetical to the mission of the unit.
c. The unit believes that accepting funding from certain sources will damage the credibility of the unit.

However, while special units could have policies restricting funding sources for research attributable to that unit, such policies would not restrict individual faculty from accepting funding independent of that unit through their primary Departmental appointment.

The APB committee members recognize that without modification of the resolution support of this resolution by the full Academic Senate will repeal all existing unit policies, passed by vote of the unit faculty; e.g., those that prohibit the acceptance of tobacco industry funding.
APPENDIX 3

COMMITTEE ON RESEARCH
Sally J. Marshall, PhD – Chair

Minutes
January 20, 2005
10am – 12pm


The Committee on Research convened at 10:10am on Thursday, January 20, 2005, in Room S30. A quorum was present.

Chair’s Report

Chair Marshall thanked Kit Chesla for her work and leadership in chairing the Senate Task Force reviewing the Resolution on Restrictions on Research Funding (see below).

Approval of Minutes

The minutes of December 7, 2004 were approved unanimously and with no changes.

UCORP Report

No report.

Restrictions on Research Funding

In a communication dated November 15, 2004 George Blumenthal, Chair of the Academic Council, requested that each division of the Academic Senate review and provide comments on the Academic Council Resolution on Research Funding Sources. UCSF Academic Senate Chair Leonard Zegans has created a Task Force consisting of members from the committees on Research, Academic Planning and Budget, Academic Freedom, and each of the four Faculty Councils. Kit Chesla chairs this task force. The charge of the Task Force is to review the report and recommendations of the University Committee on Research Policy (UCORP) related to Restrictions on Research Funding Sources and assess the impact on the UCSF campus and faculty.
At the request of the task force, the Committee reviewed the resolution and considered whether to recommend that it be accepted, modified or rejected.

In providing an introduction to the review of the resolution, Dr. Chesla provided the Committee with the names of the members of the task force and gave an overview of the documents provided as background materials, all of which are available on the Academic Senate website (ww.ucsf.edu/senate) and include the following:

- UCORP Resolution on Restriction of Research Funding Sources
- UCORP “Report on Problematic Restrictive Clauses in Contracts, Grant and Gifts for Research”
- University Committee on Planning and Budget (UCPB) Reconsideration of the Resolution on Research Funding Sources

During extensive discussion of the issues arising from a consideration of the resolution, the committee emphasized the need to consider the resolution in the context of all actual and potential funding sources and not just the tobacco industry. The funding of research by the tobacco industry has itself generated extensive debate across UC and particularly at UCSF. [The Committee, as part of a larger Senate effort, considered the wider issues related to whether or not UCSF should adopt a policy to reject funding from the tobacco industry in 2003-2004. Details of their debate and actions are available by clicking here].

Key issues of concern raised by the committee include:

Several non-governmental funding sources have adopted policies which restrict funding to institutions which do not refuse funding from certain industries. The resolution as written would prevent units from accepting funding from a certain source by prohibiting them from complying with the funding restriction requirements of these sources. For example – the American Legacy Foundation “will not award a grant to any applicant that is in current receipt of any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity”. The UCORP Resolution may prevent units of the University accepting funds from the Legacy Foundation because they will be unable to implement policies prohibiting funding from the tobacco industry.

In prohibiting any unit within the University from adopting a policy restricting funding from a particular source, the policy would deny faculty the opportunity to voluntarily restrict funding sources for their unit. Such a prohibition would deny units the ability to restrict funding sources as a means of assuring the unbiased nature of their research and might undermine the credibility of their work.

Restrictions on the “strings” that may be imposed by a funding source on the research methods and reporting of research by an investigator are have already been established by the University. Several policies are currently in place which have as their goal the preservation of academic freedom and the protection of the reputation and credibility of the University. These include conflict of interest policies and policies relating to the disclosure of funding sources in publications. Allowing units to further restrict funding sources themselves may be unnecessary. Should current policies be shown to be inadequate, they should be strengthened and clarified.

Committee members broadly agreed that the tobacco industry has a unique history of manipulating and distorting the research of UC investigators and investigators at other universities. The committee acknowledged that many faculty may choose to reject research funding from the industry. However, the Committee expressed concern that to ban funding from one source may lead to the setting of a precedent
which will allow for the banning of other sources of funding. There is no mechanism in place to ensure that
decisions to restrict funding sources would be arrived at using due process. Neither are there mechanisms in
place to ensure that faculty who disagreed with such restrictions would have recourse to an appeals process.
In the absence of such protections, the prohibition of restrictions on funding sources seems warranted.

In light of the discussion outlined above, the committee moved to accept the resolution with no
modifications. The motion was carried by a vote of fourteen to two with no abstentions.

Dr. Chesla agreed to convey the discussion and vote of the committee to the Task Force reviewing the
resolution.

Travel Grants

The Academic Senate Travel Grant Program was indefinitely suspended due to budget reductions in 2003-
2004. Following extensive discussion at its December meeting, the Committee agreed to recommend that
the program be reinstated using up to $20,000 from funds currently allocated to Individual Investigator and
Shared Equipment awards. The Committee will further recommend that the maximum amount available for
each travel grant be $500 (less than the $750 previously available). Senate staff prepared a motion to reflect
these recommendations. This motion was approved with modifications by the Committee and will be
conveyed, as follows, to the Academic Senate Coordinating Committee for consideration:

The UCSF Academic Senate Committee on Research resolves to reinstate the Academic Senate Travel Grant
Program. The Committee recommends that $20,000 from Chancellor’s Opportunity Funds currently
available to the Academic Senate be used to fund travel grants for new faculty each year (July 1 – June 30)
with no more than 20 grants awarded during the period July 1 – December 31 and the remainder of the
grants to be awarded during the period January 1 – June 30. Individual grants shall not exceed $500 and
individual faculty may receive no more than one grant in any twenty-four (24) month period. These grants
shall be awarded on a “first come, first served basis” to faculty at 50% time or more, at the associate rank
or lower, with five years of service or less at UCSF. The Office of the Academic Senate shall modify current
grant application guidelines to reflect these recommendations.

Old Business

Chair Marshall informed the Committee at its December 7, 2004 meeting that the recently created National
Institutes of Health (NIH) Director’s Pioneer awards (http://nihroadmap.nih.gov/highrisk/initiatives/pioneer/)
were presented only to men. No woman received one of these prestigious awards. The Committee agreed to send a communication to Senate Chair Len Zegans, requesting that he convey to the NIH the Senate’s hope that more women and underrepresented minorities will be in receipt of these awards in future years. Senate staff will draft this communication for review and approval by the Committee at its next meeting.

New Business

None.

The meeting adjourned at 11:36a.m.

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COMMUNICATION FROM THE SCHOOL OF MEDICINE FACULTY COUNCIL
Wade Smith, MD, PhD – Chair

Catherine Chesla, RN, DNPc, FAAN
Chair, Senate Task Force Reviewing Academic Council Resolution on Restrictions on Research Funding Sources
Box 0606

March 1, 2005

Re: Academic Council Resolution on Restrictions on Research Funding Sources

Dear Dr. Chesla:

The School of Medicine Faculty Council is responding to your request that it review the Academic Council Resolution on Restrictions on Research Funding. The Council understands that this resolution has its roots in the ongoing debate regarding whether investigators should be prohibited from accepting funds from the tobacco industry.

In its consideration of this issue, the Council recognizes the need to acknowledge the unique and reprehensible past actions of the tobacco industry, but at the same time understands the importance of upholding protections for UCSF investigators. The Council also recognizes that acquiring tainted money may limit academic freedoms as much or more than imposing a restriction in the first place. In this regard, we do not view this purely as an academic freedom issue. Nevertheless, the adoption of specific preclusions to certain funding sources may limit investigators’ ability to research in unpredictable ways. Rather than endorsing a line-item approach to restricting funding sources, the Council supports the current model whereby no specific exception to funding sources may be adopted. However, in light of the aforementioned concerns, the Council suggests an amendment to this policy that would require investigators to be informed about the potential consequences of obtaining funding from a tainted source, such as tobacco. Toward this end, the Council recommends that the UCSF Academic Senate sponsor a white paper on the past consequences to investigators of accepting tobacco funding and create a system through contracts and grants whereby investigators are provided with this material prior to obtaining any money. This structure would allow for future tainted funding sources to be identified and investigators to be rapidly educated without the lengthy process required by changes in system-wide policy.

Thank you for your consideration of this important matter.

Sincerely,

Wade Smith, MD, PhD
Chair, School of Medicine Faculty Council
Consideration of UCORP Resolution on Restrictions on Research Funding Sources

At the request of the School of Nursing Faculty Council, departments within the School of Nursing reviewed the University Committee on Research Policy (UCORP) Resolution on Restrictions on Research Funding Sources. Each department considered whether to recommend that the resolution be accepted, rejected or modified. A summary of the department reviews follows.

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<th>Votes to Amend Resolution</th>
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<td>Department of Social and Behavioral Sciences</td>
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* One faculty member voted to amend the resolution and stated that “there should be some prefatory language to the effect that institutions and individual researchers should carefully consider the ethical dimensions of their research funding, and that it is the responsibility of the individual researcher not to accept funding from entities whose ethical standards might compromise the academic freedom of the researcher, through restrictions on publication, limitations on dissemination of study results, distortion of study results, etc.”

Additional Points Raised

The following points are of note:

- Faculty in the Department of Community Health Systems suggested that an electronic vote of all faculty in the School of Nursing be conducted on this issue.
- Faculty in the Department of Community Health Systems expressed concern that too little time was devoted to a consideration of this important issue.

Prepared by:
Elizabeth Langdon-Gray
Senior Senate Analyst
elangdon-gray@senate.ucsf.edu / 415 476-1307
COMMUNICATION FROM THE SCHOOL OF PHARMACY FACULTY COUNCIL
Lisa Kroon, PharmD, Chair

February 25, 2005

TO: Task Force on Resolution on Restrictions on Research Funding Sources
FROM: School of Pharmacy Faculty Council
RE: Reconsideration of Resolution on Research Funding Sources

The School of Pharmacy Faculty Council conducted a survey to collectively gather its faculty opinions on the University Committee on Research Policy Resolution “Restrictions on Academic Funding Sources,” adopted by the Academic Council July 21, 2004. A summary of the results of the survey is attached for your consideration.
SCHOOL OF PHARMACY FACULTY COUNCIL
Lisa Kroon, Pharm.D., – Chair
Norman Oppenheimer, Ph.D. – Vice-Chair

February 2005

Summary of the Results of the Pharmacy Faculty Council Survey on Restrictions on Research Funding Sources

All faculty at 50% time or more in the School of Pharmacy were surveyed starting on January 28th and ending February 4th. Of the 80 faculty who were sent surveys, 37 faculty responded; a 46% response rate: 21 (57%) from the Department of Clinical Pharmacy, 11 (30%) from the Department of Pharmaceutical Chemistry, and 5 (14%) from the Department of Biopharmaceutical Sciences. The survey (appended below) was in two parts. The first part, Question 1, was a simple yes or no vote on the UCORP proposal prohibiting any restrictions on research funding and the vote was overwhelmingly in favor of the resolution; 28 (76%) in support and 9 (24%) in opposition.

The second part of the survey was to provide further information to the Faculty Council regarding the attitude of the faculty to related issues. Question 2 addressed the issue as to whether the resolution was too broad and if there might be circumstances where specific units could be allowed to have restrictions on funding. This question received a majority of votes although the margin was much smaller; 20 (54%) for and 17 (46%) against. Question 3 was asked in order to register the sense of the faculty to a specific funding situation regarding grants from the tobacco industry. This question was the same question that the entire UCSF faculty voted on in December 2002 for which the vote could not be broken down by school. The vote was overwhelmingly against any mandatory restrictions on funding from the tobacco industry. Out of 34 faculty who chose to answer the question, 13 (38%) approved restrictions on tobacco funds and 21 (62%) were against these restrictions.

The results for questions 1 and 3 are clear: a large majority of the faculty who voted did not want mandatory restrictions on their ability to seek grant support, either as a general concept or for the specific example of tobacco funding. The response to question 2 is harder to gauge. This may be due to an unfamiliarity with the issue and lack of any faculty discussion regarding the more subtle points involved with question 2. Still a majority of faculty did agree that there were circumstances where special units could have restrictions as long as those restrictions did not extend beyond the unit.
Survey Results

Survey Demographics

All faculty at 50% time or more in the School of Pharmacy were surveyed. Of the respondents, 21 (57%) are from the Department of Clinical Pharmacy, 11 (30%) are from the Department of Pharmaceutical Chemistry, and 5 (14%) are from the Department of Biopharmaceutical Sciences.

80 faculty were sent surveys. 37 faculty responded. This represents a response rate of 46%.

Question One

Please read and vote on whether to support or oppose the proposed resolution which reads: "Resolved, That the principles of academic freedom and the policies of the University of California require that individual faculty members be free to accept or refuse research support from any source, consistent with their individual judgment and conscience and with University policy. Therefore, no unit of the University should be directed (by faculty vote or administrative decision) to refuse to process, accept, or administer a research award based on the source of the funds; and no special encumbrances should be placed on a faculty member’s ability to solicit or accept awards based on the source of funds."

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<th>Responses of Respondents Who Completed All Questions</th>
<th>Responses of Respondents Who Completed Some Questions</th>
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<td>Support Resolution</td>
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<tr>
<td>Reject Resolution</td>
<td>9 (26%)</td>
<td>0 (0%)</td>
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Question Two

An issue that has been raised is whether an individual unit (e.g., an Organized Research Unit) could have a policy restricting funding sources for that unit only. [For example, while special units, such as Organized Research Units, could have policies restricting funding sources for research attributable to that unit, such policies would not restrict individual faculty from receiving funding independent of that unit through their primary Departmental appointment.] Do you support a policy in which individual units of the University could use due process and defined criteria to establish a policy to refuse to process, accept or administer a research award based on the source of funds?

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<td>Yes</td>
<td>18 (53%)</td>
<td>2 (67%)</td>
<td>20 (54%)</td>
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<tr>
<td>No</td>
<td>16 (47%)</td>
<td>1 (33%)</td>
<td>17 (46%)</td>
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Additional comments:
“This should be left up to the conscience of the individual faculty member.”
“I would support the resolution with modification if it included a policy as above in #3.”
“I fully agree that there is no circumstance where tobacco would be of benefit to human health. The problem I struggle with is that this sets precedence--philosophically where do we draw the line [e.g. what about other substances, alcohol and marijuana just to name a few]?”

Question 3

The resolution on which you were asked to vote in question one pertains to all research funding sources. UCSF Faculty were surveyed on the question below, regarding tobacco industry funding, in December 2002. As a point of information, we are now soliciting your input on this question so that we may have a clear idea of the opinion of Pharmacy faculty, whose vote was not recorded separately in the 2002 ballot. “Should we, the faculty as UCSF, refuse to accept any funding from the tobacco industry and the foundations it supports, an agreement that would be binding for all UCSF faculty?”

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<td>Yes</td>
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Additional Comments
"Academic freedom is not to be trifled with."
“I fully agree that there is no circumstance where tobacco would be of benefit to human health. The problem I struggle with is that this sets precedence--philosophically where do we draw the line [e.g. what about other substances, alcohol and marijuana just to name a few]?”
April 19, 2005

SYSTEM-WIDE COMMITTEE CHAIRS
DIVISION CHAIRS


Dear System-wide Committee and Division Chairs:

On behalf of Academic Council Chair Blumenthal, please find attached the above document, which is being sent to you for review by your committee or division as appropriate.

Chair Blumenthal would like to place this issue before the Council at its June 22 meeting. In order to do so, it would be necessary for us to receive your comments by no later than Friday, June 10.

Please note that only the draft policies are attached. I have been unsuccessful in obtaining electronic copies of the additional information noted in the memo, which I was unsuccessful in scanning. Hard copies of the complete package is available upon request.

As a reminder, please note that all requests for comments are sent out to all System-wide Committees and Divisions. Each Committee and Division may decide whether or not to opine. For System-wide Committee Chairs please notify the Senate Office either directly by emailing me or through your Committee Analyst, if your committee chooses not to participate in this review. For Division Chairs, please notify the Senate Office either directly by emailing me or through your Senate Director, if your Division chooses not to participate in this review.

Thank you for taking this matter under consideration.

Cordially,

Maria Bertero-Barcelo, Executive Director
Academic Senate

Encl: 1
Copy: Academic Senate Committee Analysts
Senate Directors
Dear Chancellors and Academic Senate Chair Blumenthal:

Enclosed for your review and comment are a University of California Draft Policy on Human Subject Injury and accompanying Draft Guidance on Implementation. The draft policy, when finalized, will supersede current UC policy on human subject injury, University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research (January 19, 1979). The draft guidance assists in applying the provisions of the draft policy.

The current 1979 policy on human subject injury provides that the University will pay the cost of medical care for a participant in a research study who is injured. The policy is silent on the question of the fund source for the cost of care for subject injury. The proposed draft policy affirms the University's position that research subjects should not bear the cost of medical care for research injury and directs each campus and program that funds human subject research to establish a funding mechanism to cover injury costs. The draft policy also incorporates recent legislation and government policy that allows a research subject's insurance to be billed for qualified clinical trials.

The enclosed drafts are the result of the deliberations of the Human Subject Injury Task Force which was convened by former Provost and Senior Vice President C. Judson King in January 2002. Enclosed is a summary of Task Force member comments on the most recent iterations of the draft policy and draft guidance and responses to those comments from the Office of Research at UCOP. Also enclosed are two legal opinions from University Counsel Dan Stein of the Office of General Counsel addressing two issues raised by Task Force members: 1) whether health insurance co-payments can be waived for research injury medical care; and 2) whether, under applicable governmental statutes and policies, insurance may be charged for a service or item in an industry sponsored trial if any subject in the trial receives a service or item free of charge from the sponsor.

The following issues are addressed in the draft policy and guidance:

**Fund Source for Research Injury Costs** – The Task Force discussed possible fund sources for research injury costs, including a shared risk pool for the entire UC system. After exploring the requirements to establish and maintain such a pool, the Task Force
determined that the costs outweighed the benefits. The enclosed draft policy therefore directs each campus or UC program that funds human subject research to establish its own funding mechanism for injury costs arising from research initiated at or by the campus or program. A model for such a funding mechanism, adopted by UC San Diego in June 2004, is enclosed.

**Statutes and Governmental Policies** - The draft policy allows injury costs to be charged to a subject’s insurance where allowed by federal or state statute or policy. This provision addresses recent governmental actions that allow insurance to be billed for clinical trial costs. The guidance provides further detail on the policies and statutes that allow injury costs to be charged to a subject’s insurance, the Medicare National Coverage Decision for Clinical Trials and the Knox-Keene Act, California Health & Safety Code § 1370.6. Both the Medicare National Coverage Decision and the Knox-Keene Act exclude from coverage those costs that are customarily paid for by a research sponsor without charge to any subject in the study. Accordingly, in an industry sponsored trial, if any subject receives a service or item free of charge from the sponsor, then no subject in the study nor their insurance may be charged for the service or item.

I solicit your comments on the enclosed drafts and ask you to forward them to me by March 25, 2005. I thank you in advance for your input. I also invite you to share the drafts with officers on your campus, such as the Vice Chancellor for Research, the Director of the Human Subject Protection Program, and the Medical Director if applicable. If you have questions, please contact Rebecca Landes, the staff director for this project, at 510-987-9556 or <rebecca.landes@ucop.edu>.

Sincerely,

M.R.C. Greenwood
Provost and Senior Vice President
Academic Affairs

Encl.

cc: Vice Provost Coleman
    Human Subject Injury Task Force Members
    University Counsel Beam
    Executive Director Auriti
    Coordinator Landes
University of California Policy on Human Subject Injury
February 2005

I. Preamble - The University of California is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The University recognizes and accepts responsibility, which it shares with its investigators and other researchers, for determining that research involving human subjects fulfills these ethical principles.

II. Policy and Definitions - The University of California will provide all medical care reasonably necessary for any injury that results directly from participating in authorized UC research that comes under the UC Policy on the Protection of Human Subjects in Research. Medical care for research injury will be provided at no direct cost to the research subject. This policy addresses medical care for research injury only. This policy does not provide compensation to research subjects or to their families for any other direct or consequential damages such as loss of income or emotional pain and suffering. This Policy on Human Subject Injury is subject to the following definitions and conditions:

A. Definition of "Injury" - "Injury" is an event that generates medical costs and that is directly caused by the research study described in the research protocol and in the informed consent form. Injury specifically excludes the natural progression of an underlying or preexisting condition, unless the worsening condition is determined to be a direct result of the subject's participation in the research study described in the protocol and in the consent form.

B. Definition of "Reasonably Necessary Medical Care" - "Reasonably necessary medical care" is the accepted standard of care for the injury in question.

C. Provision of Medical Care – If possible, all medical care under this Policy shall be provided at the UC campus responsible for the research study. Research subjects may obtain medical care at non-UC locations, however, and such care will be reimbursed by UC at a reasonable
rate provided that the basis for use of the non-UC location and the claim for reimbursement are supported by sufficient written documentation.

III. Responsibilities of Parties - Responsibility for claiming, reporting, and paying for subject injury under this Policy on Human Subject Injury is as follows:

A. Responsibilities of Injured Research Subjects - If a research subject discovers an injury while or after participating in a study, the subject or the subject's representative should inform the study investigator or the local human subject protection program. At the discretion of the campus, research subjects may be asked to submit written notification of the injury to UC within a reasonable time of the occurrence of the injury or when the subject or the subject's representative becomes aware of, or reasonably should become aware of, the causal relationship between the injury and participation in the research.

B. Responsibilities of Investigators - Investigators are responsible for reporting to the campus human subject protection program all subject injury events, including those occurring in collaborative research projects conducted at other institutions. Investigators are responsible for providing information about the University's subject injury policy to potential research subjects. Investigators are responsible for making sure that a subject's need for care stemming from research injury is met, by either providing or arranging for medical care, or by coordinating with care providers to make sure that medical care is delivered.

C. Responsibilities of Research Funders for Cost of Care for Research-Related Injury – Except in cases where negligence or malpractice is found, the responsibility of funders for cost of care for research-related injury is as follows:

1. For-Profit Corporations – When the research is initiated by a for-profit corporation and conducted pursuant to a protocol provided by the corporation, the for-profit corporation shall be responsible for reimbursing the University for the cost of care for research-related injury. In limited circumstances and only where explicitly authorized by federal or state statute, regulation, or policy, some or all of the cost of care for research-related injury may
be recovered from the subject’s health insurance. The sponsor shall reimburse any costs
to the subject not covered by insurance such as co-payments or deductibles. Specific
guidance will be provided by the UC Office of the President concerning the statutes,
regulations and policies, and the conditions and circumstances, under which a subject’s
health insurance may be billed for research injury. Research agreements with for-profit
corporations shall make explicit that the sponsor assumes responsibility for reimbursing
the University of California for human subject injury costs, and that the sponsor may not
require the University of California to bill third party insurers.

2. **Government Agencies and Non-Profit Organizations** - When the research is funded
by a government agency or a non-profit organization, the agency or non-profit
organization shall be responsible for reimbursing the University for the cost of care for
research-related injury insofar as claims for cost of care for injury are an allowable
expense under the funding entity’s regulations, policies, or standard practices.

3. **The University of California** – When the research is not initiated by a for-profit
corporation or not funded by a nonprofit organization or government agency, or when the
research is funded by a government agency or non-profit organization and claims for cost
of care for injury are not an allowable expense under the regulations, policies, or standard
practices of the agency or non-profit organization, the University of California shall be
responsible for the cost of care for research-related injuries that result directly from such
research. Each campus and each UC entity that funds human subject research shall
identify a specific mechanism to pay for any reasonably necessary research-related
medical care resulting from research for which the campus or program is responsible and
to which research injury costs may be assigned. This mechanism shall identify which
units, departments, divisions, or programs shall be responsible for paying for the cost of
care for research injury. In limited circumstances and only where explicitly authorized by
federal or state statute, regulation, or policy, some or all of the cost of care for research-related injury may be recovered from the subject’s health insurance.

IV. Collaborative Research - This policy applies to all research carried out under awards administered by the University of California. The University is not responsible for cost of care for injury resulting from collaborative research carried out under awards administered by other institutions.

V. Research in Foreign Countries - Responsibility for the cost of care for subject injury sustained in the course of research carried out in a foreign country shall be negotiated in advance of the study between the host entity and the investigator and shall be included in the research agreement.
GUIDANCE ON IMPLEMENTING UC POLICY ON HUMAN SUBJECT INJURY

University of California Office of the President

February 2005

I. Introduction - This Guidance is issued in conjunction with the University of California’s Policy on Human Subject Injury (Policy). The Policy provides generally that individuals who volunteer to be research subjects shall not bear the cost of care for injury incurred as a direct result of that participation. This Guidance is provided to assist campuses in applying the Policy and in making determinations concerning the assignment of costs of medical care for research injury.

II. Campus Authority for Subject Injury Issues - Each campus shall designate an authority, such as an office, official, or committee, to handle issues arising under the University of California’s Policy on Human Subject Injury, and shall inform the Office of the President who that individual, office or committee is. The campus authority for subject injury shall handle issues such as: determining if the injury was directly caused by the research; authorizing reimbursement of costs when care is provided at a non-UC facility; and determining whether a subject injury cost should be billed to a sponsor, to the campus, to the UC funding program, or to the subject’s insurance as allowed under the Policy. The campus authority for subject injury is also responsible for confirming that documentation is in place to support any instance of charging insurance for subject injury. The campus authority will also track research injury costs and other data, such as whether or not insurance was billed. The campus should carefully consider the organizational placement of the campus authority for subject injury issues so that the authority is in a position to act independently and objectively concerning injury costs.

III. Federal and State Statutes, Regulations, and Policies Governing Payment for Costs of Subject Injury - The University of California’s Policy on Human Subject Injury allows cost of care for research-related injury to be charged to the subject’s health insurance where explicitly authorized by federal or
state statute, regulation, or policy. The following federal and state statutes, regulations, and policies currently authorize health insurers to be charged for subject injury:

A. Medicare National Coverage Decision for Medicare Recipients Participating in Clinical Trials - The Medicare National Coverage Decision for Clinical Trials (Medicare NCD) is a national coverage policy issued on September 19, 2000 by the Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration). The Medicare NCD provides that Medicare may be charged for certain routine costs of qualifying clinical trials, including the costs of diagnosis and treatment of complications.

1. Requirements to Qualify for Medicare NCD – In order to receive Medicare coverage of routine costs, including cost of care for injury, a clinical trial must meet all of the following criteria:
   a. Has a Therapeutic Intent - The trial must have a therapeutic intent, i.e., the trial must not be designed exclusively to test toxicity or disease pathophysiology;
   b. Evaluates a Medicare Benefit - The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category, e.g., physicians’ service, durable medical equipment, or diagnostic test; the trial may not test an item or service that is statutorily excluded from coverage, e.g., cosmetic surgery, hearing aids; and
   c. Enrolls Diagnosed Beneficiaries - Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers; trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
   d. Has Desirable Characteristics – The desirable characteristics are listed in the NCD.

2. Deemed Trials with Desirable Characteristics – Some clinical trials are considered automatically deemed as having desirable characteristics and therefore qualified under the Medicare NCD. They include:
   a. Trials funded by the National Institutes of Health (NIH), the Centers for Disease Control (CDC), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing
Administration (HCFA)), the Department of Defense (DOD), and the Department of Veterans Affairs (VA);

b. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;

c. Trials conducted under an Investigational New Drug (IND) application reviewed by the Food and Drug Administration (FDA); and

d. Trials exempt from having an IND application under 21 CFR 312.2(b)(1) until such time as

3. **Trials Not Automatically Deemed** – Clinical trials that are not automatically deemed as having desirable characteristics will have to be registered by the investigator with a Medicare clinical trials registry. The Agency for Healthcare Research and Quality is charged with establishing the registry and with convening a federal panel that will develop qualifying criteria. As of February 2005 the registry has not been established.

4. **Routine Costs Eligible for Medicare Reimbursement** - Routine costs of a clinical trial eligible for Medicare reimbursement include all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial. In the context of subject injury, routine patient care costs include items and services needed for reasonable and necessary care arising from the diagnosis or treatment of complications.

5. **Costs Ineligible for Medicare Reimbursement** - The following costs are not eligible for Medicare reimbursement:

   a. The investigational item or service itself, except for certain devices that have been deemed eligible for Medicare coverage by CMS;

   b. Items and services for which there is no Medicare benefit category, which are statutorily excluded, or that fall under a national noncoverage policy;
c. Items and services furnished solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient, e.g., monthly CAT scans for a condition usually requiring only a single scan;

d. Items and services provided solely to determine trial eligibility;

e. Items and services customarily provided by the industry sponsor free of charge to any subject in the trial. In other words, if the industry sponsor is obligated to pay for subject injury costs for non-Medicare subjects, then Medicare may not be charged for subject injury costs for any subject in the trial.

B. California Knox-Keene Act - The California Knox-Keene Act, Health & Safety Code § 1370.6, requires health plans, health insurers and Medi-Cal to provide coverage for all routine patient care costs arising in cancer clinical trials, including the costs of health care services for treatment of complications.

1. Requirements for Trial Qualification - To be eligible for the Knox-Keene Act, the cancer clinical trial must:

   a. Have a therapeutic intent; and

   b. Meet one of the following requirements:

      i. Involve a drug that is exempt under federal regulations from a new drug application; or

      ii. Be approved by:

         1. One of the National Institutes of Health;

         2. The federal Food and Drug Administration, in the form of an investigational new drug application;

         3. The United States Department of Defense; or

         4. The United States Veterans Administration.

2. Requirements for Subject Qualification - To be eligible for the Knox-Keene Act, the research subject in the cancer clinical trial must meet all of the following criteria:

   a. The subject must have a diagnosis of cancer;
b. The subject must be enrolled in a Phase I, Phase II, Phase III, or Phase IV cancer clinical trial; and

c. The subject’s treating physician providing covered health care services to the subject under the subject’s health plan must recommend participation in the clinical trial after determining that such participation has a meaningful potential to benefit the subject.

3. **Documentation of Eligibility** - The following procedures must be met to document subject eligibility:

   a. If the treating physician who recommends participation in the clinical trial is also a member of the clinical trial research team, the principal investigator must obtain independent verification from another qualified physician who is not a member of the research team that participation in the clinical trial has a meaningful potential to benefit the subject; and

   b. The recommendation of the treating or other qualified physician that the subject be allowed to participate in the cancer clinical trial must be obtained prior to submission of any charge to the subject’s insurer.

4. **Eligible Costs** – The Knox-Keene Act defines routine patient care costs as the costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the health plan or contract if those drugs, items, devices, and services were not provided in connection with a clinical trial. In the context of subject injury, routine patient care costs include costs of health care services needed for reasonable and necessary care in diagnosis or treatment of complications arising from participation in the trial.

5. **Ineligible Costs** - Routine patient care costs do not include costs associated with the provision of:

   a. Health care services customarily provided by the industry sponsor free of charge for any enrollee in the trial. In other words, if uninsured subjects would not be charged for cost of care for injury in industry-sponsored research, then insurance may not be charged for any subject in the trial.
b. Drugs or devices that have not been approved by the federal Food and Drug Administration and that are associated with the clinical trial.

c. Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.

d. Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee’s health plan.

IV. Waiver of Beneficiary Cost Sharing Fees - The Federal Anti-kickback Statute, 42 U.S.C. §1320a-7b(b), and the Federal Civil Monetary Penalty Statute, 42 U.S.C. §1320a-7a(a)(5), place limitations on the circumstances in which a health care provider may waive a beneficiary’s cost sharing fees such as co-payments and deductibles. These statutes are designed in part to prevent inducement of referrals of patients, items, or services for reimbursement by a federal healthcare program. After consultation with the Office of General Counsel, the University of California Office of the President has determined that the federal statutes governing waiver of cost-sharing fees do not prohibit the University of California from waiving an injured research subject’s co-payment or deductible, as permitted by the Policy. This is, in part, because the University’s research injury policy is a limited, cost sharing waiver program that applies only to injured research subjects participating in non-industry sponsored research, which research inures to the public benefit. The policy is consistent with prevailing ethical and legal norms requiring investigators and research institutions to minimize risks to research subjects, including financial risks, and does not entail fraudulent or abusive billing practices.

V. Ethical Issues to Consider In Determining Whether to Charge Insurance - In addition to determining whether the eligibility requirements outlined above are met, the campus authority for subject injury issues should consider whether a charge to insurance will have a negative consequence for the research subject. For example, the campus authority should consider whether the subject will exceed the lifetime capitalization limits of his or her coverage, or whether annual premiums will increase due to claim activity, or whether the subject is at risk of becoming uninsurable due to claims activity. While UC
policy allows insurance to be billed where authorized, this does not mean insurance should necessarily be billed irrespective of the negative financial consequences to the subject.

VI. Mitigating Impact on Subject of Injury Billing Processes - Campus billing processes should mitigate any negative short-term financial impact on the research subject. Campuses should establish billing processes for subject injury costs that ensure that the subject will have no out-of-pocket expenses, e.g., co-payments or medical bills that must be reimbursed. If the subject is treated at a UC campus, he or she should not be charged out-of-pocket for any co-payments, deductibles, or increased premiums. If the subject is treated at a non-UC location, the campus or program responsible for the research should establish a procedure for prompt reimbursement to the subject of any out-of-pocket expenses, such as a cash account for immediate reimbursements.

VII. Fund Source for Unreimbursed Injury Costs - In trials in which the industry sponsor has assumed the obligation to pay for subject injury or in which the government or non-profit research funder will pay for injury costs, all unreimbursed injury costs should be charged directly to the study budget or to the clinical trial account. In studies that are not sponsored or for which there is no outside source for subject injury costs, all unreimbursed injury costs should be charged to the funding mechanism established by the campus or program as required under the UC Policy on Human Subject Injury.

VIII. Clinical Trial Contracts - In clinical trial agreements with industry sponsors, UC contracting officers should continue to use current standard subject injury contract language that requires the sponsor to reimburse the University of California for cost of care for subject injury. In the unlikely event that an industry initiated trial is eligible for the Medicare NCD or the Knox-Keen Act, the sponsor should be informed that the costs of subject injury may be billed to the subject's insurer or third party payor, consistent with this guidance. The university should not be contractually obligated to charge insurance in the case of subject injury.

IX. Informed Consent Form – The informed consent form should advise the subject to the effect that:

“If you are injured as a direct result of participating in this study, you will be given reasonable and
necessary medical care to treat the injury at no cost to you. The University of California does not provide any other form of compensation for injury."

X. **When Medical Care is Obtained at a Non-UC Location** - The University of California’s Policy on Human Subject Injury allows a UC research subject to obtain medical care for research injury at a non-UC facility. This provision recognizes that the UC campus where the research occurred may not have a medical center or that the subject may need medical care when he or she is outside the service area of the UC campus where the research took place. In cases where treatment is obtained at a non-UC location, the rate of reimbursement shall be at a reasonable rate or at the existing negotiated rate that is established with the non-UC institution.

XI. **Changes or Additions to Guidance on UC Policy on Human Subject Injury** - The Office of Research at the University of California Office of the President will monitor federal and state legislative and regulatory activity pertaining to subject injury issues. In the event that current law or policy is modified or new law or policy is enacted, the Office of Research will modify this guidance accordingly. Changes to this guidance will be consistent with the University of California’s Policy on Human Subject Injury. This guidance may be modified only by the Office of the President.
COMMUNICATION FROM THE TASK FORCE REVIEWING UNIVERSITY OF CALIFORNIA DRAFT POLICY ON HUMAN SUBJECT INJURY

V. Courtney Broaddus, MD, Chair

June 6, 2005

Leonard S. Zegans, MD
Professor and Chair
UCSF Academic Senate

Re: Faculty Comments on Policy on Human Subject Injury

Dear Dr. Zegans:

At your request, we have reviewed the proposed draft policy on Human Subject Injury that was submitted to the San Francisco Division for feedback by the Academic Council. The Task Force is strongly in support of the goal of protecting human subjects from harm. Overall, the Task Force was concerned with the phrasing of some of the policies. The task force is also concerned that research not be subjected to undue burdens.

The Task Force identified a number of areas where the proposed draft policy could be strengthened by clarification. Our comments and recommendations are outlined below.

1) **Inclusion of Uninsured Patients in Sponsored Trials** The “guidance On Implementing UC Policy on Human Subject Injury, Section (III)(A)(5)(e)(page 8)states that if an industry sponsor pays for injury costs for uninsured patients or if uninsured subjects would not be charged [Section (III)(B)(5)(a)], then insurance may not be charged for injury costs for any subject, and this is reinforced by the letter from Special Counsel S. Daniel Stein dated August 11, 2004. While this may be a matter of law rather than policy, we are concerned that this provision could result in uninsured patients being excluded from sponsored clinical trials, so that the sponsors can avoid assuming the cost for all patients, both insured and uninsured. Uninsured patients may also be excluded simply to avoid confusion about the ability to bill insurance for the insured patients. We ask clarification about the means of ensuring continued access of all patients, regardless of insurance status, to sponsored clinical trials. Is there a mechanism by which study sponsors can assume liability for uninsured subjects, while still allowing appropriate billing of insurance for insured subjects?

2) **Confusion Regarding Whether Insurance Can Be Billed** In the Guidelines, the Task Force found the wording confusing and perhaps conflicting in Section VIII which states, “In the unlikely event
that an industry initiated trial is eligible for the Medicare NCD or the Knox-Keene Act, the sponsor
should be informed that the costs of subject injury may be billed to the subject’s insurer or third
party payor, consistent with this guidance.” This allowance for payment seems to be in conflict
with the section discussed above. Perhaps it would be clearer to outline which sponsored trials
would be eligible.

3). **Research in Foreign Countries** Section V of the Policy (page 8) states that the responsibility for
injury costs should be negotiated in advance. This may be difficult if not impossible in many
countries; in developing countries, few if any financial resources exist for such payments. We agree,
as stated in Section V that UCSF and UCSF investigators should not be held responsible for the costs
of liability for such research, and this should be stated in any agreements and in the consent forms.
However, the negotiated transfer of this liability to another entity may not be possible in many cases,
and the requirement that this be accomplished prior to studies is likely to impede clinical research
and care in countries that may need it most. We suggest that extra attention be paid to the special
situations raised by research in foreign countries, particularly impoverished countries.

4) **Meaning of Therapeutic Intent** In the Guidelines, Section (III)(A)(1)(a)(page 6) states that
qualifying trials under Medicare NCD must have a ‘therapeutic intent’. Subsequently, Sections
(III)(A)(1)(b) and (c) include categories such as ‘diagnostic tests’ and mention ‘trials of diagnostic
interventions’. We ask that the term ‘therapeutic intent’ be clarified. For example, are Phase I
cancer treatment trials (which are not intended to demonstrate therapeutic benefit) or imaging trials
of patients considered eligible? As noted in Section (III)(B)(2)(6), Phase I trials are specifically
included as eligible under the Knox-Keene act.

5) **Implementation Concerns** Implementation of these policies will have far-reaching implications in
the way research is conducted. It is critical that investigators be made aware of these changes. We
suggest that the policy and/or guidelines provide concrete examples of:
a) scenarios involving different types of research trials and how they would be affected;
b) specific language that should be included in contracts with industry sponsors; and
c) specific language that should be added to consent forms.

Thank you again for the opportunity to review these important policies. Should you have any questions or
concerns, please do not hesitate to contact V. Courtney Broaddus at (415) 206-3513.

Sincerely,

**Task Force Reviewing University Of California Draft Policy on Human Subject Injury**
V. Courtney Broaddus, MD, Chair (Committee on Research)
John Kurhanewicz, PhD, Task Force Member (Committee on Research)
Susan Sniderman, MD, Task Force Member (Academic Planning and Budget)
William Seaman, MD, Task Force Member (Academic Planning and Budget)
June 27, 2005

M.R.C. GREENWOOD
PROVOST AND SENIOR VICE PRESIDENT - ACADEMIC AFFAIRS

Re: Draft Human Subject Injury Policy and Guidelines on Implementation

Dear M.R.C.:

At its June 22, 2005 meeting, the Academic Council discussed responses from the Senate’s general review of the draft policy on Human Subject Injury. We applaud the efforts of the task force that worked over a number of years to develop a policy to take the place of what have been ad hoc decisions or reactions to specific injury cases. UCORP, UCPB and the Senate Divisions of Berkeley, Irvine, Riverside, San Diego, and San Francisco submitted formal comments, and in all, the Senate groups strongly support the intent of protecting human subjects from costs resulting from their participation in studies conducted by UC researchers. The extent of support for the draft policy, however, varied among the reviewers, most of whom suggested substantive changes and raised concerns to be addressed in a revised draft and/or supplementary document before implementation. San Diego and UCLA withheld endorsement entirely. San Diego also noted that even though its plan is cited in your letter as a possible model for other campuses, their Senate Council members felt that the UCSD plan has serious flaws. Below is a fairly comprehensive summary of the points raised in the Senate’s review. Please see the enclosed individual responses for further detail.

Needed clarifications:

- The policy as written is vague about exactly who at each campus will be responsible for development of a mechanism for covering injury costs. This authority should be explicitly indicated and a deadline set for the establishment of that person or office (UCORP, Irvine, Riverside, San Diego).
- The definition, mechanism for, establishing a timely claim of injury is inadequate. These are not addressed in the Policy and are incompletely detailed in the Guidelines (UCSD).
- The guidelines for insuring the welfare of victims for the cases not covered by government or for-profit organizations/companies are too vague and unstructured (Riverside).
- The draft refers (on page 3) to “each UC entity that funds human subject research.” The referent here needs to be made explicit (Irvine).
- Would claims relating to psychiatric or mental problems be covered? The policy says pain and suffering would not be covered, but does not define the term (Irvine).
- Wording in Section VIII regarding insurance billing seems to conflict with what is stated in Section III. It would be clearer to outline which sponsored trials would be eligible (UCSF).
- The term “therapeutic intent” needs to be clarified in application to patient eligibility in certain trials (UCSF).

**Costs to PIs / impact on research**

- Where would the funds come from to cover the injury costs? Would overhead increase? What sources have historically been used for this? What are the costs or other implications that will have an impact on researchers’ ability to conduct studies involving human subjects? (Irvine).
- The expectation stated on page 2 of the policy places an unreasonable burden on the investigator not only to arrange care for an injured subject, but to make sure the individual follows through. This responsibility should be shifted to the campus (Irvine).
- It is strongly recommended that campus-level funding mechanisms not be financed at the expense of individual researchers (Berkeley), and that because of possible impact on grants, faculty be involved at an early stage in campus implementation plans (UCORP).
- The financial burden of injury costs for industry sponsors may limit the ability of small companies to fund research (Irvine).
- Section IV, entitled “Collaborative Research” requires clarification of UC’s liability in multi-university research collaborations, and may need to be revised so as to avoid possible discouragement of such collaboration (UCPB).
- The policy could result in uninsured patients being excluded from sponsored clinical trials. Assurance is needed of continued access of all patients, regardless of insurance status, to sponsored clinical trials (UCSF).
- Negotiating injury costs in advance (Section V) may be difficult if not impossible in many foreign countries; in developing countries few financial resources exist for such payments. It is recommended that a revised policy pay extra attention to the special situations that arise in connection with research abroad (UCSF).

**Procedures and patient protection:**

- The policy should state that patients on placebo arms of trials are equally protected (UCSD).
- The policy basically applies only to cancer patients and to those in Medicare. There are no specifics about other types of clinical subjects, of which there are obviously many (UCSD).
- Documentation of eligibility is probably impossible to obtain as suggested on page 9 and most likely not necessary, as prior required FDA review already provides what is needed (UCSD).
- Patient protection from unpaid bills remains scant. The issue of insurance companies paying for medical costs is, in fact, far from resolved (UCSD).
General follow up:
The changes may have a detrimental effect on research without any clear benefits (Irvine), and it
is difficult to determine what the practical consequences of the policy as worded might be or
what may be specific consequences of the adoption of the guidelines (Riverside). Because of
this, it is recommended that a supplemental document be drafted stating current practices
regarding contract wording, sources of funding for injuries, IRB statements on the issue, and
rationales given for each proposed change. UCSF stresses the need for investigators to be made
aware of the changes, and recommends that a revised policy or supplement include concrete
examples of: 1) scenarios involving different types of trials and how they would be affected; 2)
specific language that should be included in contracts with industry sponsors; and 3) specific
language that should be added to consent forms.

Both UCLA and UC San Diego felt that a systemwide solution to handling the costs of injuries
to human subjects that are not covered by sponsors was called for, and that this issue should be
treated under general liability plans. San Diego saw the draft policy as amounting to an
unfunded mandate to campuses, and UCLA was concerned about the potential liability impact on
small research units. Related to these comments on applying a systemwide approach, I will note
that the Senate fully supports any current efforts on the part of the Office of Risk Management to
determine whether this category of injury can be covered at the systemwide level by one of the
University’s existing plans. Such a solution would not only be elegant, but would also obviate
the need to put resources into developing campus plans and avoid possible negative impacts on
research. Please keep the Senate apprised of progress made in that direction.

The Council requests that the draft policy be reconsidered in light of the number of concerns
raised in our review and the number and severity of suggested changes. We hope that the
additional time taken to do so will not unduly extend what has already been a lengthy
development phase, and will welcome the opportunity to review a revision in the near future.

Best regards,

George Blumenthal, Chair
Academic Council

Copy: Academic Council
Lawrence Coleman, Vice Provost-Research
Rebecca Landes, Research Policy Coordinator
María Bertero-Barceló, Executive Director

Encl: 8
June 10, 2005

GEORGE BLUMENTHAL
ACADEMIC COUNCIL CHAIR

Re: Draft Policy on Human Subject Injury and Guidelines on Implementation

Dear George,

At its June 6, 2005 meeting, UCORP approved the main intention and provisions of this draft policy and commends the efforts of the task force that came up with a policy solution for the coverage of human subject injury that assigns costs to the sources of risk and avoids having the subject’s insurance bear costs. The committee notes areas of potential concern associated with the implementation of the policy, and, therefore, our recommendations have mainly to do with shaping the guidance that will be given to the campuses, who, according to the draft policy, would each be responsible for setting up or refining a mechanism for covering costs of injuries that are not covered by industry research sponsors.

First, the policy as written is vague about exactly who at each campus will be responsible for development of a mechanism for covering injury costs. This authority should be explicitly indicated and a deadline set for the establishment of that person or office. Next, since the costs will in some form involve a tax on overhead or on research grants themselves, each campus authority should clearly indicate how the mechanism is to work. In addition, there should be faculty involvement at an early stage in implementation plans in light of the impact plans may have on the research and funding of individual PIs. Lastly, the committee recommends that data on subject injury be continually collected for use in future policy decisions.

UCORP appreciates the opportunity to comment on this policy, which will have an impact on the UC research environment.

Respectfully submitted,

Max Neiman, Chair
UCORP

Copy: UCORP
Executive Directory Bertero-Barcelo
June 13, 2005

GEORGE BLUMENTHAL, CHAIR
ACADEMIC COUNCIL

RE: University of California Draft Policy on Human Subject Injury and Draft Guidelines on Implementation

Dear George,

At its June 7, 2005 meeting, the University Committee on Planning and Budget (UCPB) discussed the UC Draft Policy on Human Subject Injury and Draft Guidelines on Implementation. UCPB members unanimously endorsed the draft policy and guidelines pending the following observation regarding Section IV of the draft policy entitled “Collaborative Research.” The committee is concerned that the current language in Section IV could be read to discourage multi-university research collaborations, and therefore the language requires further clarification. As it stands, the policy directs that if the primary grant in joint trials with other universities is administered outside of UC, then UC washes its hands of any financial liability in paying for any mistakes made by UC that occur under the outside award. If UC’s liability in such situations is to be dealt with by subcontracting options, which may often be the case, then the draft policy should read as such.

Respectfully submitted,

Michael E. Parrish, Chair
UCPB

cc: UCPB
Executive Director Bertero-Barcelo
May 31, 2005

GEORGE BLUMENTHAL
Chair, Academic Senate

Subject: University of California Draft Policy on Human Subject Injury

At its meeting on May 16, 2005, the Divisional Council (DIVCO) of the Berkeley Division discussed the draft policy cited above and the comments of the Committee on Research (COR). While DIVCO supports the concept of establishing a campus-level funding mechanism for injury costs resulting from research, it strongly recommends that the fund not be financed at the expense of individual researchers.

Sincerely,

Robert C. Knapp
Chair, Berkeley Division of the Academic Senate

Cc: George Sensabaugh, Chair, Committee on Research
    Diane Sprouse, Senate staff, Committee on Research
RE:  Draft Policy and Implementation Guidelines on Human Subject Injury

The Irvine Divisional Senate applauds the efforts of the Human Subject Injury Task Force in bringing UC policy and implementation up to date for this important issue. Subjects who are injured as the result of a research study should be protected. We found it difficult, however, to review the proposed policy and guidelines without having background information on how subject injury is currently handled and on whether these documents represent a change in policy or were codifying how the campuses currently implement the 1979 policy. Several concerns were raised about the draft dated 4/19/05, including the potentially serious impact of costs passed on to campuses and the possible loss of protection for subjects and faculty researchers. A summary of our concerns follows.

- The paragraph on the responsibilities of investigators (page 2) states: “Investigators are responsible for making sure that a subject’s need for care stemming from a research injury is met, by either providing or arranging for medical care, or by coordinating with care providers to make sure that medical care is delivered.” This imposes an extremely unreasonable burden on the investigator, not only to arrange care but to make sure that the subject follows through. We suggest that the investigator be notified, but that the requirement for subject care is shifted onto the local Campus Authority designated to handle issues arising under the Human Subject Injury Policy. This will ensure proper care for the injured party, consistent treatment of all subjects, establishment of an appropriate paper trail, HIPAA compliance, etc.

- On page 3, “Each campus and each UC entity that funds human subject research…” It is not clear what is meant by a “UC entity.” Might this mean entities within each campus, such as ORUs? There should only be one entity responsible for human subjects’ injury issues on each campus. Is this what the proposal is recommending?

- It is unclear when claims regarding psychiatric or mental problems (e.g., depression) would be covered. Would such claims only be covered if the research involves a psychiatric drug or treatment? The policy indicates that pain and suffering would not be covered, but does not define this term.
• The policy and guidelines appear to be silent on residual injuries that are only learned about years later. For instance, if a subject who participated in a study using Vioxx developed cardiac problems stemming from the Vioxx and this was discovered several years after the end of the study, who would pay for the injured subject’s ongoing cardiac treatment?

• Imposition of the financial burden for potential subject injury onto all for-profit corporations might limit the ability of small companies to sponsor research. This would have a negative impact in that it would diminish opportunities for UC researchers and the public would not benefit from the research results.

• Some felt it was unfair to give non-profit and government entities a loophole permitting them not to pay for subject injuries, but require all for-profit corporations to pay. It was felt that some for-profits (particularly small startups) might refuse to sponsor UC research for this reason, and that government and nonprofit groups might always invoke the loophole.

• Where would the pool of money come from to cover human subjects’ injuries that UCI would be responsible for? Would overhead costs increase? What are historical fund sources, and have they been adequate? More fundamentally, are there cost or insurance implications for the University that might adversely affect researchers’ ability to conduct studies involving human subjects?

• Is there a compelling need to change the current policy? Have problems arisen that have indicated a need for a change? In practice, are we already implementing some or most of these policies (e.g., in contract wording) and, if so, how have they worked out?

• Overall the policy changes might have a detrimental effect on research funding and administration, without any clear-cut benefits. We would like to see a supplemental document that clearly states current practices regarding contract wording, sources of funds for injuries, IRB statements regarding subject injuries, etc. along with each proposed change, rationale for the change, and likely implications (both pro and con).

I hope these concerns will be helpful in drafting the final policy and implementation guidelines.

Joseph F.C. DiMento, Senate Chair
Dear George,

The following is UCLA’s response to the issues raised in terms of Human subjects. We do, of course, recognize the difficulties in human subjects injuries. We offer the following consideration from my Executive Board:

As to Human subject protection, we have no objections to protecting human subjects, but to make each unit responsible for running an insurance program is unfeasible. The University should deal with this as a general liability issue, determine loss ratios, and assess each IRB proposal a risk category and overhead to cover such risk. A small unit cannot be responsible for the occasional large accident by itself. It must belong to a larger consortium in order to share the risk, and the expertise of determining local liability. I am not sure why they decided it was unfeasible to do this on a University wide basis. I concluded the opposite.

The concern here is that small units will find research impossible if they are responsible for their own insurance on this important issue.

Thanks,
Kathy
UCR

George R. Blumenthal
Professor of Astronomy & Astrophysics
Chair, UC Systemwide Academic Senate
1111 Franklin St., 12th Floor
Oakland, CA 94607


Dear George:

The above policy was reviewed by the appropriate committee of our Division and below is a summary of their discussion:

- The consensus was that the guidelines for insuring the welfare of victims for the cases not covered by government or for-profit organizations/companies are too vague and unstructured. The process for creating the responsible office in each campus is not specified, and an oversight mechanism is not included. Who will appoint the members of this office? Is the length of tenure to be decided by the campuses, and, if so, by whom? Will the OP exercise some overall oversight role? By when are the campus offices to be created? Are funds from any source to be allowed?
- We requested that the draft proposal be distributed among all departments and programs that deal with human subjects, requesting comments.
- While the general intent of the policy was not problematic, it was difficult to determine what the practical consequences of the policy as worded might be. The implementation principles, for their part, were particularly difficult to interpret insofar as what the specific consequences of their adoption might be.
- It is our hope that any new system-wide policies adopted that involve enhancing the safety of campus activities would be used to address ongoing problems with traffic management.

Please do not hesitate to contact me if you have any questions.

Sincerely,

Manuela Martins-Green
Chair, Riverside Division
June 10, 2005

PROFESSOR GEORGE BLUMENTHAL, Chair
Academic Senate
University of California
1111 Franklin Street, 12th Floor
Oakland, California 94607-5200

SUBJECT: University of California Draft Policy on Human Subject Injury and Draft Guidelines on Implementation

Dear George:

The Senate Council of the San Diego Division received comment from the appropriate committees and considered the Draft Policy at its June 6, 2005 meeting. The Council found the initiative necessary and timely, but had sufficient concerns about the content that it withheld its endorsement.

Senate Council members concluded that the draft policy essentially amounts to an unfunded mandate for campuses. The suggestion that campuses might negotiate a different indirect cost rate for clinical trials received some support among Council members, although more members supported the concept of systemwide self-insurance. Concern was expressed that the policy would shift some portion of the liability to the patient.

The following specific comments were raised in committee reports:

- The definition of, mechanism for, establishing a timely claim of injury is inadequate. These are not addressed in the Policy and are incompletely detailed in the Guidelines.
- The Campus Authority (page 5, par. II) is poorly defined as an entity. Its decision-making and executive powers are also unclear.
- The policy should state that patients on placebo arms of trials are equally protected.
- The policy basically applies only to cancer patients and to those in Medicare. There are no specifics about other types of clinical subjects, of which there are obviously many.
- Documentation of eligibility is probably impossible to obtain as suggested in page 9 and most likely not necessary, as prior required FDA review already provides what is needed.
- Patient protection from unpaid bills remains scant. The issue of insurance companies paying for medical costs is, in fact, far from resolved.

As an aside, although UCSD’s model is referenced in Provost Greenwood’s letter as a possible funding mechanism model, various Council members expressed their opinion that the local model was less than ideal.
The issues surrounding funding for human subject injury are broad and sufficiently complex to require a systemwide, not campus by campus, approach. Concern was expressed that federal funding for clinical trials would decrease substantially, or even disappear, if a satisfactory policy is not in place. The Council expects to continue to work with the Administration on this issue and would welcome the opportunity to review the draft policy again.

Sincerely,

Donald F. Tuzin, Chair
Academic Senate, San Diego Division

cc: J.B. Minster
    ChronFile
George Blumenthal, PhD
Professor and Chair, Academic Council
1111 Franklin Street, 12th Floor
Oakland, CA 94607-5200

June 9, 2005

Dear Chair Blumenthal:

I am forwarding to you the UCSF response to your request for review and comment on the University of California Draft Policy on Human Subject Injury and Draft Guidelines on Implementation. A special UCSF Task Force was formed with representatives from the Committee on Research and Academic Planning and Budget to review and consider the proposed changes to the policy. I enthusiastically support and concur with the recommendations of the Task Force related to suggestions made to the draft policy.

Thank you for the opportunity to review this important matter before the UCSF Division. Please do not hesitate to contact me should you have any questions.

Sincerely,

Leonard S. Zegans, MD
Professor and Chair
UCSF Academic Senate

/enclosure- Communication From The Task Force Reviewing University Of California Draft Policy On Human Subject Injury

cc: Maria Bertero-Barcelo, Executive Director, Academic Council
    UCSF Academic Senate Task Force Reviewing University Of California Draft Policy On Human Subject Injury
COMMUNICATION FROM THE TASK FORCE REVIEWING UNIVERSITY OF CALIFORNIA DRAFT POLICY ON HUMAN SUBJECT INJURY
V. Courtney Broaddus, MD, Chair

June 6, 2005

Leonard S. Zegans, MD
Professor and Chair
UCSF Academic Senate

Re: Faculty Comments on Policy on Human Subject Injury

Dear Dr. Zegans:

At your request, we have reviewed the proposed draft policy on Human Subject Injury that was submitted to the San Francisco Division for feedback by the Academic Council. The Task Force is strongly in support of the goal of protecting human subjects from harm. Overall, the Task Force was concerned with the phrasing of some of the policies. The task force is also concerned that research not be subjected to undue burdens.

The Task Force identified a number of areas where the proposed draft policy could be strengthened by clarification. Our comments and recommendations are outlined below.

1) **Inclusion of Uninsured Patients in Sponsored Trials** The “guidance On Implementing UC Policy on Human Subject Injury, Section (III)(A)(5)(e)(page 8)states that if an industry sponsor pays for injury costs for uninsured patients or if uninsured subjects would not be charged [Section (III)(B)(5)(a)], then insurance may not be charged for injury costs for any subject, and this is reinforced by the letter from Special Counsel S. Daniel Stein dated August 11, 2004. While this may be a matter of law rather than policy, we are concerned that this provision could result in uninsured patients being excluded from sponsored clinical trials, so that the sponsors can avoid assuming the cost for all patients, both insured and uninsured. Uninsured patients may also be excluded simply to avoid confusion about the ability to bill insurance for the insured patients. We ask clarification about the means of ensuring continued access of all patients, regardless of insurance status, to sponsored clinical trials. Is there a mechanism by which study sponsors can assume liability for uninsured subjects, while still allowing appropriate billing of insurance for insured subjects?

2) **Confusion Regarding Whether Insurance Can Be Billed** In the Guidelines, the Task Force found the wording confusing and perhaps conflicting in Section VIII which states, “In the unlikely event
that an industry initiated trial is eligible for the Medicare NCD or the Knox-Keene Act, the sponsor should be informed that the costs of subject injury may be billed to the subject’s insurer or third party payor, consistent with this guidance.” This allowance for payment seems to be in conflict with the section discussed above. Perhaps it would be clearer to outline which sponsored trials would be eligible.

3) **Research in Foreign Countries** Section V of the Policy (page 8) states that the responsibility for injury costs should be negotiated in advance. This may be difficult if not impossible in many countries; in developing countries, few if any financial resources exist for such payments. We agree, as stated in Section V that UCSF and UCSF investigators should not be held responsible for the costs of liability for such research, and this should be stated in any agreements and in the consent forms. However, the negotiated transfer of this liability to another entity may not be possible in many cases, and the requirement that this be accomplished prior to studies is likely to impede clinical research and care in countries that may need it most. We suggest that extra attention be paid to the special situations raised by research in foreign countries, particularly impoverished countries.

4) **Meaning of Therapeutic Intent** In the Guidelines, Section (III)(A)(1)(a)(page 6) states that qualifying trials under Medicare NCD must have a ‘therapeutic intent’. Subsequently, Sections (III)(A)(1)(b) and (c) include categories such as ‘diagnostic tests’ and mention ‘trials of diagnostic interventions’. We ask that the term ‘therapeutic intent’ be clarified. For example, are Phase I cancer treatment trials (which are not intended to demonstrate therapeutic benefit) or imaging trials of patients considered eligible? As noted in Section (III)(B)(2)(6), Phase I trials are specifically included as eligible under the Knox-Keene act.

5) **Implementation Concerns** Implementation of these policies will have far-reaching implications in the way research is conducted. It is critical that investigators be made aware of these changes. We suggest that the policy and/or guidelines provide concrete examples of:
   a) scenarios involving different types of research trials and how they would be affected;
   b) specific language that should be included in contracts with industry sponsors; and
   c) specific language that should be added to consent forms.

Thank you again for the opportunity to review these important policies. Should you have any questions or concerns, please do not hesitate to contact V. Courtney Broaddus at (415) 206-3513.

Sincerely,

**Task Force Reviewing University Of California Draft Policy on Human Subject Injury**

V. Courtney Broaddus, MD, Chair (Committee on Research)
John Kurhanewicz, PhD, Task Force Member (Committee on Research)
Susan Snideman, MD, Task Force Member (Academic Planning and Budget)
William Seaman, MD, Task Force Member (Academic Planning and Budget)