COMMITTEE ON ACADEMIC FREEDOM
Stuart Gansky DrPH, Chair

Annual Report 2006-2007

The Committee on Academic Freedom (CAF) enjoyed a productive year in which it met eight times. The Committee was represented on the University Committee on Academic Freedom (UCAF) by Miriam Kuppermann, Ph.D, M.P.H. The major issues reviewed and acted on by the Committee during 2006-2007 are summarized in this report.

- *Task Force to Review Systemwide Report on Institutional Boards (IRB)*
- *UCSF Strategic Planning, Phase III – Strategy Development*
- *Reimbursement by Faculty of Grant Cost Overruns*
- *Relationship Between (Pharmaceutical) Vendors and Clinicians*
- *Task Force on Vendor Relations*
- *Task Force on Open Access*
- *Symposium on "Science, Government and Academic Freedom in a Polarized Political Environment"*

Task Force to Review Systemwide Report on Institutional Boards (IRB)

Committee on Academic Freedom members Elizabeth Boyd and Victor Reus served as representatives from CAF to the task force created to review the systemwide report on institutional review boards.

UCAF cited a growing number of reports of IRB interference with faculty research and suggested that the situation called for the establishment of systemwide standards for Institution Review Boards. (*Appendix 1*) The charge of an IRB is to protect human subjects by ensuring that the benefits of the research outweigh the risks, that subjects have given informed consent and that the selection of subjects if done equitably.

The Task Force, Chaired by Kathleen Puntillo, RN, Committee on Research, submitted their findings and recommendations to Deborah Greenspan, DSc, BDS, Chair, UCSF Academic Senate, in a communication dated November 28, 2006. The recommendations were subsequently reviewed at the December 12, 2007 Coordinating Committee meeting, were voted on and passed unanimously. (*Appendix 2*)

UCSF Strategic Planning, Phase III – Strategy Development

The UCSF Strategic Planning Initiative began in mid 2005 and was officially launched in February 2006, with the UCSF community participating in an extensive environmental assessment of the history and future factors to be considered in shaping a plan for the future. (Appendix 3)

Phase III, Strategy Development strategy design teams were tasked with developing recommended strategies and tactics in support of UCSF's vision. The teams completed their work in March 2007, with the Strategic Plan approved by the Board I April 2007.

Academic Senate Committees submitted a communication to Chair Greenspan and Vice-Chair David Gardner (Appendix 4). A communication was submitted to Co-Chairs of the UCSF Strategic Planning Board, EVC and Provost A. Eugene Washington, MD and Professor Elizabeth Blackburn, PhD. (Appendix 5)

Reimbursement by Faculty of Grant Cost Overruns

The committee discussed the lack of a clear and concise policy on the recourse of faculty overspending of contracts or grants awarded principal investigators. *Contracts and Grants policy 300-19, III. A.4* (Appendix 6) states that in the case of cost overrun, the PI is responsible for the transfer of such overrun out of the project, and policy *300-19, III .B.4* (Appendix 6) states that if an overdraft is not cleared by the PI in a timely manner, the accounting office has the authority to transfer the over-expenditures to other funds. The reported anecdotal incidences indicate that each department has its own policy and procedure. It was noted that there are several items which are beyond the control of the investigator. In the Coordinating Committee meeting, P. Fox gave the example of union contract renegotiations, which often have retroactive pay raises as one of the inefficiencies in the system in which faculty are put in an untenable situation.

Chair Gansky presented the outcome of the Committee's discussion to the Coordinating Committee and proposed forming a Task Force to review the situation on campus and to make recommendations as to what action is taken when one overspends on a grant.

At the request of Academic Senate Vice Chair Gardner Chair Gansky presented five questions to the Coordinating Committee on June 12, 2007. The Coordinating Committee had the opportunity review these questions and determine a course of action, including the focus of any Senate investigation and the appropriate Committees to be involved. (Appendix 7)

It was decided that an ad hoc committee will be formed in the fall and will feature members from the Committee on Academic Planning and Budget, Committee on Research, Academic Freedom, and the Committee on Privilege and Tenure. The ad hoc would survey departmental policies as well as the requirements of the APM and will report back to the Coordinating Committee.

Task Force on Vendor Relations

Chair Gansky is a member of the task force charged with reviewing and commenting on the Draft Proposal on the relationships between pharmaceutical vendors and UCSF clinicians. (Appendix 8) In the wake of an article in JAMA, January 25, 2006, *(Health Industry Practices that Create Conflict of Interest – A Policy Proposal for Academic Medical Centers,* UC medical schools are reviewing (or developing) their policies with respect to pharmaceutical vendor relationships in order to remove bias by employees and real or perceived conflict of interest. The Task Force met on February 22, 2007 to discuss the first of two stages of the proposal. A Communication was sent to Chair of the Academic Senate, Deborah Greenspan. (Appendix 9)

Task Force on Open Access

The Task Force on Open Access reviewed the UC policy that would enable open access to journal articles and conference proceeding authored by UC faculty members. The Task Force strongly supported the policy that would greatly improve the ability of researchers to share their finding while not transferring all of the rights for use of their work to the commercial publisher, faculty authors will be able to publish their work on open-access, non-commercial repositories. Such a policy would greatly improve the ability of researchers to advance their own research and education goals as well as those of the University. The Task Force felt an "opt out" option was the most in keeping with protecting the faculty member.

A Communication was sent to Academic Senate Chair Deborah Greenspan. (Appendix 10)

Symposium on "Science, Government and Academic Freedom in a Polarized Political Environment"

The Academic Freedom Symposium, presented by Professor Paul Berg, entitled "Brilliant Minds, Dark Politics, Uncertain Law", was greatly attended in June 5, 2007. Professor Berg, from Stanford University, is a Nobel Laureate (Chemistry, 1980).

Issues for 2007-2008

The Committee will continue to respond to issues brought to it by the University Committee on Academic Freedom and by the Chair of the UCSF Academic Senate.

Respectfully submitted,

Academic Senate Committee on Academic Freedom

Stuart Gansky, Dr. PH., C*hair*
Jim Lightwood, Ph.D., *Vice Chair*
Miriam Kuppermann, Ph.D., M.P.H.
Elizabeth Boyd, Ph.D.
C. Anthony Hunt, Ph.D.
Descartes Li, M.D.
Victor Reus, MD
Mary White, MPH, PhD
Maurice Zwass, M.D.

Prepared by:
Kathleen Dargan
Senate Analyst/Coordinator
476-1308

kdargan@senate.ucsf.edu
www.ucsf.edu/senate

Appendices

Appendix 1: Institutional Review Boards at UC: An inquiry into IRB Operations and the Researcher's Experience.
Appendix 2: Communication from Task Force Review and Recommending Comment to the Systemwide Report on Institutional Review Boards.
Appendix 3: UCSF – Strategic Planning Phase III, Strategy Development
Appendix 4: Communication from the Chair of the Committee on Academic: UCSF Strategic Planning Phase III.
Appendix 5: Letter to Drs. Washington and Blackburn from Chair Greenspan and Vice Chair Gardner regarding the UCSF Strategic Plan.
Appendix 6: AMP 300-19, Expenditures of Extramural Funds
Appendix 7: Communication from Chair S. Gansky to Coordinating Committee regarding extramural grant fund overspending.
Appendix 8: Request from the UCSF Task Force to Review the Draft Proposal on the Relationships between (Pharmaceutical) Vendors and Clinicians.
Appendix 9: Communication to Chair Greenspan regarding the Task Force on the Proposed Guidelines on the Relationships between (Pharmaceutical) Vendors and Clinicians.
Appendix 10: Communication from the Task Force Reviewing and Recommending Comment to the Proposed Policy on Open Access

UNIVERSITY OF CALIFORNIA, ACADEMIC SENATE

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

Office of the Executive Director
PHONE: (510) 987-9458
FAX: (510) 763-0309
E-MAIL: mbertero@ucop.edu

Assembly of the Academic Senate
Academic Council
1111 Franklin Street, 12th Floor
Oakland, CA 94607-5200

August 30, 2006

SYSTEM-WIDE SENATE COMMITTEE CHAIRS

DIVISIONAL SENATE CHAIRS

RE: System-wide Review of the Universitywide Committee on Research Policy (UCORP) Report "Institutional Review Boards (IRB) at UC: IRB Operations and the Researcher's Experience"

Dear System-wide Senate Committee and Divisional Senate Chairs:

On behalf of Chair Oakley, the above document is being forwarded for your review and comments. As background information, UCORP, in fulfillment of its charge from the Academic Council undertook an inquiry into the operation of the IRBs at UC in order to determine the need for systemwide IRB standards. At its July 26, 2006 meeting, the Academic Council endorsed that this report be sent out for system-wide review.

The Academic Council would like to finalize its position with respect to the report early in the 06-07 academic year. In order to do so, we would very much appreciate receiving responses by the date listed below:

For **System-wide Senate Committees** please submit responses by: **December 7, 2006**

For **Divisions** please submit responses by: **January 10, 2007**

As a reminder to System-wide Senate Committee Chairs, please note two points regarding the practice the Academic Council has established for general reviews:

1. **Request for comments are sent out to all System-wide Committees. Each committee may decide whether or not to opine.** 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.
2. **The Committee response due date is typically set a month before that of Divisions**. This two-stage review allows the Academic Council to conduct both a preliminary and a final discussion of the matter at hand. It also gives the Divisions the benefit of the committees' considerations for their own deliberations.

Cordially,

María Bertero-Barceló, Executive Director
Academic Senate

Encl: 1
Copy: Academic Council Chair John Oakley
Divisional Senate Directors
Academic Senate Committee Analysts

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP)
George Sensabaugh, Chair
sensaba@uclink.berkeley.edu

Assembly of the Academic Senate
1111 Franklin Street, 12th Floor
Oakland, CA 94607-5200
Phone: (510) 987-0630
Fax: (510) 763-0309

July 19, 20006

JOHN OAKLEY
CHAIR, ACADEMIC COUNCIL

Dear John,

In fulfillment of charge issued by the 2004-05 Academic Council, the University Committee on Research Policy (UCORP) has drafted the enclosed report "Institutional Review Boards at UC: An Inquiry into IRB Operations and the Researcher's Experience." On behalf of UCORP, I am submitting the report for consideration by the Academic Council and to be sent out for review by Senate Divisions and Committees.

While UCORP acknowledges the larger debate that revolves around the scope of IRB authority and human subjects research, our recommendations focus on the review process at UC. The report suggests a number of measures to increase communication and coordination and enhance the level of IRB staffing, training and education within the context of the University's ethical and legal responsibilities for the conduct of research involving human participants.

In preparing the report, UCORP gathered information and received comments from IRB members and Directors, Vice Chancellors for Research, individual UC researchers, and from the Office of Research. We hope that those same stakeholders will also be consulted in the course of the review; therefore, I request that the report be forwarded to Vice Provost Coleman for dissemination to the campus Vice Chancellors for Research and their respective Institutional Review Boards.

Sincerely,

George Sensabaugh, Chair
UCORP

Copy: UCORP
Senate Executive Director Bertero-Barcelo
Encl.: 1

INSTITUTIONAL REVIEW BOARDS AT UC:

IRB OPERATIONS AND THE RESEARCHER'S EXPERIENCE

REPORT OF THE UNIVERSITY COMMITTEE
ON RESEARCH POLICY
(UCORP)

July 2006

TABLE OF CONTENTS

INSTITUTIONAL REVIEW BOARDS AT UC:
AN INQUIRY INTO IRB OPERATIONS AND THE RESEARCHER'S EXPERIENCE

REPORT OF THE UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP)
JULY 2006

I. Introduction

This report was prepared in response to a request of the Academic Council in June of 2005 for UCORP, as the lead Senate committee acting in coordination with the University Committee on Academic Freedom, the Coordinating Committee on Graduate Affairs, and the Office of Research, to inquire into the operations of the Institutional Review Boards (IRBs) within the UC system. Established in accordance with federal regulations,[1] IRBs are the entities within universities, hospitals and other research institutions that must approve all federally funded research involving human subjects (California state law accords IRBs duties in addition to the ones set out by federal law, e.g., review of stem cell research**.)** Broadly, the charge of an IRB is to protect human subjects by ensuring that the benefits of the research outweigh the risks, that subjects have given informed consent, and that the selection of subjects is done equitably. An IRB's regulation of the safety of participants in research extends beyond consideration of physical or mental risk to include risks such as civil or criminal liability, or "damage to a subject's financial standing, employability, insurability, or reputation."[2] UC policy requires that all research conducted under the auspices of the University, regardless of funding source, be IRB-approved.

The Academic Council saw the need for an inquiry after reviewing concerns that were brought before the Council by the University Committee on Academic Freedom (UCAF). (See Appendix A.) In a letter of May 3, 2005 (Appendix B), UCAF cited a growing number of reports of IRB interference with faculty research and suggested that the situation called for the establishment of systemwide standards for Institutional Review Boards. UCAF pointed to complaints from faculty that IRBs were "overzealous" in their evaluation of research methodology and research quality and could be creating an "unreasonable level of difficulty with the IRB approval process." UCAF linked these problems to the make up of IRBs, administrative staff, and the absence of formal procedures to challenge IRB decisions. The Academic Council agreed that there were plausible grounds for concern, recognizing also the potential barrier that the lack of coordinated intercampus protocol review or systemwide guidelines might pose to multi-campus research.

The concerns identified by UCAF and the Academic Council are representative of questions raised at the national level regarding the regulation of human subjects research that have been voiced in published studies and commentaries, presentations to professional societies, and other reports. One broad criticism is that IRBs have extended their purview to regulate areas of research that pose no physical risk to research subjects, particularly research in the social sciences and humanities. It is argued that this expansion of purview has been accompanied by inconsistent interpretation of regulations, uncertainty as to the scope of IRB oversight, exaggerated precautions to protect against program shutdowns, a preoccupation with documentation and procedure rather than with

real ethical issues, and, of particular academic concern, intrusion on research activity and research design.[3] Additionally, some legal scholars have questioned the potential conflict between IRB regulations and First Amendment rights.[4]

Prominent recent publications that engage IRB reform include: the formal Statement of the American Association of University Professors specific to IRBs and social science research[5] ;a report of the National Bioethics Advisory Commission and testimony to the President's Council on Bioethics making recommendations toward streamlining policies[6];[7]; an Institute of Medicine report calling for fundamental structural change in ethics oversight[8]; a National Research Council report recommending guidelines to enhance the effectiveness of reviews commensurate with the level of risk[9]; and the "Illinois White Paper"[10], which recommends counteracting IRB 'mission creep. Thus, the questions posed regarding IRB operations within the UC system are reflective of a larger national debate.

II. History and Overview of IRBs

In the late 1970s and early 1980s, the Department of Health and Human Services revised and expanded its regulations for the protection of human research subjects. The new legislation was based on the work of a special Commission established by Congress in 1974 to examine and make recommendations on biomedical ethics issues. At the time the Commission was created, the federal government's debate on human subject protection was taking place within a heated political environment that was reacting to such topical issues as: psychosurgery, research with prisoners, research with mentally impaired people, research on children, and cases of research conducted without informed consent, such as the infamous Tuskegee syphilis study. The Commission's "Belmont Report" was published in 1978 (formally entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"). The report identifies three fundamental ethical principles for all human subject research – respect for persons, beneficence, and justice. These principles are elaborated in the Code of Federal Regulations, Title 45, Public Welfare Department of Health and Human Services, Part 46: Protection of Human Subjects. The current version of the regulations, as revised in 1991, is subscribed to by seventeen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, and the Department of Defense, and hence is known as the Common Rule. The Food and Drug Administration operates under a set of very similar regulations.

The administrative burden for implementing the Common Rule falls on universities, hospitals and other sites where research involving human subjects is done. Such institutions are required to establish IRBs whose task is to interpret and enforce the regulations on the local level and in ways sensitive to local community standards. Although strictly speaking only research funded by federal agencies is subject to regulation, most research institutions have extended application of the Common Rule to all research involving human subjects, regardless of funding source and often including unfunded research as well.

Constituted in accordance with the provisions of 45 CFR 46.107, IRBs are composed of at least five members with varying backgrounds and expertise, including at least one member with scientific expertise and background in the research area under review, at least one member who whose background and perspective is nonscientific, and one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. IRBs are to include both genders and fulfill federal requirements for diversity. No member of an Institutional Review Board may participate in the review of or vote on any project in which the member has a conflicting interest, except to provide information requested by the IRB. Consultants with specific expertise or background participate in reviews as needed. IRB members are trained by the IRB support staff and through other means such as online modules, national and local conferences, and publications. An IRB has the authority to approve, require modifications to, or disapprove research protocols based on whether or not in its judgment human subjects are adequately protected. IRB disapproval cannot be overturned by any other institutional authority. IRBs operate under federal oversight and are ultimately accountable to the Department of Health and Human Services' Office of Human Research Protection and the FDA.

III. Review Process

Investigators planning research involving human subjects must submit a research protocol to an IRB for review; they may not undertake the research until notified by the IRB that they may do so. IRBs thus serve as the gatekeepers for research involving human subjects. To qualify for IRB approval, the research protocol must meet basic criteria defined by the Common Rule, specifically:

1) the proposal must fit the definition of research, i.e.,"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge";
2) informed consent must be sought from each subject and appropriately documented (although this criterion may be waived under certain well-defined conditions);
3) the level of risk to the human subject participants is minimized and reasonable in relation to the anticipated benefit of the research; and
4) when appropriate, the privacy of the subjects is protected.

Levels of Review

The potential degree of risk to the human subject determines the level of IRB review. Risk is defined broadly; in addition to biological risk, the concept includes activity that might place the subject "at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation" [45 CFR 46. 101(b)].

- Research activities entailing no substantial risk to subjects may qualify as **exempt** from IRB review. The principal hallmarks of exempt status are that the human subjects will not be identified, will not be described in a way such that they would be identifiable, and do not fall in a protected group (e.g., children, prisoners, persons who are legally incompetent). An exception to the anonymity requirement is allowed for research involving observation of public officials. Six categories of research are

subject to exemption; the qualification requirements for each are explicitly described in the federal regulations [45 CFR 46. 101(b)]. Researchers believing their research to be exempt must submit a research protocol to their IRB accompanied by a request for exempt status; the IRB determines exempt status based on protocol conformance to the regulations.

- Research activities that present no more than minimal risk to human subjects and involve procedures falling in specified categories may be reviewed by the IRB through an **expedited** process. Nine categories of research activities are specified as subject to expedited review; these include non-invasive or minimally invasive collection of biological samples, the study of characteristics or behavior of individuals or groups not falling in the exempt category, and some types of continuing research previously approved by the convened IRB [45 CFR 46.110]. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

- Research activities that do not qualify for exempt status or for expedited review require **full review** by the convened IRB. Approval of a research protocol requires majority vote of the convened IRB; only the convened IRB can reject a protocol.

Regardless of the level of protocol review, no research activities may begin until the research protocol has been determined either exempt or approved and the investigator is notified. After-the-fact requests for IRB approval are not acceptable.

An IRB must notify the investigator in writing of its decision to approve, disapprove or require modifications of research protocols. Although it is often assumed that IRB disapproval cannot be appealed, 45 CFR 46.109 provides that if an IRB disapproves a research activity, "it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing."

IRB Oversight

IRBs are accountable to the Department of Health and Human Services' Office of Human Research Protection (OHRP). OHRP has the authority to suspend or shut down federally funded research at institutions it perceives to be out of compliance in overseeing the protection of human subjects; this is effectively a "death penalty" for a major research university. OHRP has exercised this authority in several well publicized cases at major medical schools, notably, Johns Hopkins, Duke, Rush, and the University of Illinois at Chicago.[11] Given these examples, IRBs regard part of their raison d'etre to be protection of their institution from OHRP suspension of federally funded research.

In 2001, following on some of the violation cases cited above, the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) was established out of a concern that institutions may not be providing adequate protection for research participants. AAHRPP is a nonprofit organization that accredits institutions based on their meeting standards and executing safeguards in the conduct of human subject

research that surpass those of state and federal requirements. AAHRPP uses what it characterizes as "a voluntary, peer-driven, educational model" as the basis for and institution being granted and maintaining accreditation. UC Irvine holds qualified accreditation from AAHRPP; UC San Francisco obtained full accreditation in December 2005. UC Davis is, at the time of writing, in the latter stages of the accreditation process, and UCLA is submitting its initial application in July of 2006. AAHRPP accredits not just the IRB but the research organization so, in these UC cases, each campus is or will be accredited. Part of that accreditation requires the establishment of a larger Human Research Protection Program of which an IRB is an integral but not the only part.

IV. UCORP's Investigation

UCORP held preliminary discussions of the Council's charge and UCAF's concerns at the end of the 04-05 academic year, and began its effort in earnest in September 2005. We requested information from three sources: (a) the UCOP Office of Research, (b) local campus IRB offices, and (c) principal investigators and other faculty. This allowed us to gain a picture of IRB operations from three distinct perspectives.

UCOP Office of Research

Consultations with Vice Provost for Research Lawrence Coleman, Executive Director Ellen Auriti, and Coordinator Rebecca Landes provided information regarding federal regulations, the mission of IRBs, training of staff and faculty, and the level of systemwide coordination in place. Additionally, we gained their views on the range of variation among campuses, general administrative staffing practices across the campuses, how faculty dissatisfaction may be perceived by IRB members and staff, board membership, and faculty participation and recruitment issues.

Campus IRB Offices

UCORP solicited information on local campus IRB operations by questionnaire (Appendix D). The survey interrogated the nature and make up of the committee, aspects of administrative support, and the protocol review process. Recent IRB annual reports were also received from those campuses that had them available. The compiled data were subsequently distributed to the campus Vice Chancellors for Research to verify correctness; several updates were obtained. Campus IRB websites were reviewed also. In June 2006, UCORP Chair George Sensabaugh met with the Directors of the UC campus IRBs to discuss and get feedback on a draft of this report.

Principal Investigators and Other faculty

UCORP's discussions engaged faculty who had both served on their local campus IRBs and interacted with IRBs in the course of seeking approval for research involving human subjects. We reviewed two scholarly articles by UC faculty members that focus on IRB issues relating to the experience of the social science researcher.[12] In addition, we issued an open invitation to faculty and other principal investigators to provide specific examples of difficulties they encountered with the IRB review process, hoping these examples, while gathered in an informal manner, would still provide a credible picture of the range and types of difficulties individuals have experienced at UC. We heard a large number of verbal accounts from faculty of their experiences working with UC IRBs, and

gathered additional written responses bearing on IRB operations at several campuses. In response to our requests for written accounts, we encountered a reluctance on the part of faculty members to translate their stories into written narrative form, and it was intimated that identification might lead to repercussions in future dealings with local IRBs. Thus, much of our evidence of the purported obstructions to research that prompted UCAF's academic freedom concerns is more anecdotal than attributable. Moreover, this information is non-quantitative; therefore, the situation is difficult to address conclusively. On the whole, the comments that were received indicated more dissatisfaction among behavioral and social science researchers than among biomedical researchers.

V. Overview of IRB Operations within the UC System

UC human subject protection policy applies to all research conducted under the school's auspices or with UC resources "regardless of the source of funding or whether the research is funded."[13] This University policy charges Chancellors, the Academic Vice President, the Vice President-Agriculture and the Directors of the Department of Energy Laboratories with responsibility for compliance with the federal regulations, and for identifying what constitutes research under the regulations and whether the research activity is exempt from formal review. The policy goes on to state that "as a minimum, such a process should provide some form of consultation by investigators."

Administrative Structure

There is considerable variation among the campuses with regard to IRB administrative structure, workload, and research areas covered. (See Appendix D for a breakdown of IRB workload by campus based on responses to the UCORP survey.) The medical campuses have multiple IRBs, a consequence both of the number of protocols to be reviewed and the need for reviews in specialized areas; typically, there are several IRBs for the review of biomedical protocols and one or two for non-biomedical protocols. Non-medical campuses have one IRB, though Berkeley is expanding to two. The Berkeley IRB is also the official IRB for the Lawrence Berkeley National Laboratory. UC Merced is at present served by the IRB at the Lawrence Livermore National Laboratory. The non-medical campus IRBs are necessarily more generalized, given that their purview covers the biological and social sciences and the humanities.

IRBs on all campuses are administrative committees under the local Office for Research. As previously noted, IRBs are made up primarily of academic faculty with outside community members as required by law. IRB members, both faculty and outside members, are formally appointed by the VCRs on all campuses. On some campuses, primarily the medical campuses, nominations for membership are made by department chairs; on others, calls are made for volunteers. On only one campus are nominations made by the local Academic Senate. It is important to note that, once constituted, IRBs are by federal law independent entities with irreversible power to deny human subjects protocols deemed unacceptable. Thus IRBs are answerable to the VCR with regard to operations but not to decisions.

IRB Personnel and Training

All campus IRBs have staff support. The primary functions of the support staff are to assess submitted protocols for basic compliance and completeness, to assist investigators in writing and/or revising protocols, and to maintain records on protocol actions. On some campuses IRB staff also provide education and training on human subjects protection for investigators. The support staff generally do not serve as sitting members of the IRB; however, on two campuses a staff member sits on the IRB to fill a vacant slot for which faculty could not be recruited. Besides helping to achieve quorum, this expedient can meet the requirement of having a nonscientist present at the meeting. The extent of support staffing varies from campus to campus.

IRB staff training on human subject protection varies from campus to campus. Most training occurs on the job. Almost all campuses send IRB members and/or staff to the annual conference on subject protection put on by Public Responsibility in Medicine & Research (PRIM&R), the primary professional organization for human subject protection. Other campuses train members through one-on-one tutoring by the IRB director and through review of policies and procedures. Budgets for staff training are small or nonexistent and workload often preempts training opportunities. Some campus IRBs have established a staff position to serve as an education coordinator for staff, faculty, and investigators, but this person may need to take on other tasks, given workload demands.[14]

The challenge of training faculty IRB members is exacerbated by the extreme time commitment of serving on the IRB. There is little time available to faculty to be trained on subject protection beyond the time committed to protocol review. Some campuses include training in the IRB meetings, devoting 5 to 15 minutes of meeting time to developments in subject protection. However, IRB staff report that when training is on the agenda of the IRB meeting, faculty members often skip that part of the meeting because they are so busy. Rarely is there funding to train faculty IRB members.

Staff Role in Review Process

The review process for human subjects protocols at UC typically involves two stages. First, the protocol is submitted to the IRB office where it undergoes a preliminary evaluation by the IRB support staff to determine the review level (exempt, expedited, or full review by the board) and for basic compliance and completeness correlative to that review level. Once the protocol is judged acceptable (a process that in some cases involves a number of revisions), it is then passed on to the IRB or the IRB chair for disposition. It is important to recognize that although the IRB has the ultimate decision power regarding approval or disapproval of protocols, it is the IRB support staff who initially evaluate protocols to determine what level of review is needed, and who act as the primary interface between the IRB and the researchers submitting protocols.

VI. Findings

UCORP observes that researcher complaints about IRB operations fall into two broad categories. The first can be characterized as dissatisfaction with IRB customer service. Included in this category are complaints of slow turnaround times, excessive paperwork,

staff non-responsiveness, rudeness and/or obstructionism, and so on. In fairness to IRB staff, it should be noted that reportedly some faculty are abusive, do not respond to requests for clarification in a timely fashion, and expect staff to kowtow to their authority. The second category of complaints is more substantial: that IRBs are inconsistent in their interpretation of the federal regulations. This category includes complaints that ongoing research projects have been suspended when previously approved protocols have been challenged at the time of renewal, that IRB staff within an office give contradictory instructions for protocol revision, that differences in research conditions imposed by IRBs on different campuses make it impossible to develop uniform research protocols, and that IRB constraints on certain kinds of observational research preclude the possibility of doing the research at all. The latter complaint in particular was attributed by behavioral and social science researchers to the poor fit of the federal regulations designed to protect human subjects in biomedical research to the experimental design problems associated with behavioral research projects.

As we note above, it is the IRB support staff who have the most contact with researchers submitting protocols. Accordingly, it is the interactions with the IRB staff that determine to a great extent the basis of the researcher's impression of how the IRB functions. Moreover, we see an inherent tension in the duties of the IRB staff between exercising regulatory caution and offering client support. On the one hand, IRB administrators are bound to ensure adherence to federal regulations and seek to protect the University from possible liability; on the other hand, they are expected to serve the needs of the researcher by providing aid and information in meeting application and renewal requirements and removing unnecessary obstructions to completing the review process. The fluid areas connecting these opposing demands are how the regulations are interpreted and how IRB staff (and board members) and researchers interact.

Based on information received in response to our questionnaire, on faculty comments and on published reports and commentary, UCORP has identified the following as significant issues bearing on IRB operations at UC.

There is marked variation among UC campuses in the level of IRB staffing and in the degree of professional training.

Responses to the UCORP questionnaire indicate the level of staffing at some campuses is acceptable, but a number of campus IRBs self-report that they are significantly understaffed. Berkeley, Riverside, San Diego, and Santa Cruz all reported inadequate staffing levels, and in one case this was confirmed by an external review of the human subjects protection program. In the past year, Berkeley has received temporary funding for increased support, but still cannot fully cover all administrative activities. San Francisco is currently evaluating its support need. There appears to be no standard for what constitutes adequate staff support; however, case load, number of personnel, and level of expertise are parts of the equation.

Lack of coordination between campus IRBs in protocol review and approval.

This was mentioned as a distinct administrative difficulty in the conduct of multi-site, multi-campus research collaborative research. In the course of our inquiry, a

Memorandum of Understanding (effective March, 2006 – March 32, 2007) was agreed to by all UC campuses and the DOE labs, which allows a lead campus IRB to conduct a single review for multi-campus research projects that are exempt or expedited. If maintained, this agreement will effectively address many UC intercampus concerns. In addition to the systemwide MOU, Berkeley, Davis, LBNL and UCSF have established an agreement among their IRBs to accept reviews from each other at all levels, and some campuses have signed on to the National Cancer Center Central IRB system and accept its review for some of the Phase II and III oncology group trials. Several campuses facilitate review of protocols approved at non-UC institutions.

An apparent difference among campuses in review standards and interpretation of federal regulations.

In UCORP's discussions, campus representatives reported several instances in which a protocol was deemed unacceptable by one campus IRB but regarded as exempt by the IRB on another campus. Local campus standards may, in some cases, be the reason for this divergence. AAHRPP accreditation may bring about some standardization; however, consistency among IRBs both within and without UC is seen as a difficult goal to achieve. In studies done outside of UC, variability of IRB interpretations has been found to affect multi-site research projects adversely.[15]

Faculty frustration with IRBs extends across all UC campuses and includes numerous complaints, from slow response times to outright obstructionism.

Timely processing is a pivotal issue and a primary complaint, since slow process time threatens funding and can halt a research project entirely. Without timely approval, of either an initial application or a renewal, funding agency money cannot be accepted or spent, nor can fees associated with research be collected. This impacts the ability to finish recruitment and interviewing according to the project schedule. The Berkeley campus alone documented dozens of instances of long process times and seemingly unnecessary delays. Some delays were considered to have jeopardized not only important current funding opportunities, but also potential future funding sources by raising doubts about the ability to complete the research and submit findings by required deadlines.

As is pointed out above, some of the delays may be attributable to investigator non-responsiveness. There is no quantitative data to put these complaints into context.

Among the examples of investigator complaints from the campuses:

- Reported process times across campuses ranged from one month to more than six months. In some cases, it has taken that long before notification of requests for changes were received.
- In one case, an initial application was submitted in August; by the end of November only contingent approval was given, but it was estimated that it would take three additional weeks to send out the letter outlining the required changes.
- For short or small studies in particular, the process of getting IRB approval can obstruct or prevent research. Obtaining provisional permission from prospective subjects is not allowed, so time and effort can be lost before finding out that not enough subjects have chosen to participate.

- In one case, the Vice Chancellor of Research was contacted to help complete the approval process.
- The application itself is time-consuming to fill out and unnecessarily bureaucratic.
- Examples of delays because of non-responsiveness, disorganization:
    - Submission of multiple applications for a multi-site study with no coordination of required revisions and contradictory requirements.
    - Several reports of lost or misplaced files.
    - The IRB office initially claimed an application missed the deadline. Two renewals had been submitted, but only one was late, the other mistaken as late.
    - Some pre-approved procedures were placed under new scrutiny when they were included on a newly submitted protocol.
    - After hand delivering an application, a PI was told it was not received.
    - At the point when NIH asked for confirmation of approval, the IRB asked that the protocol be resubmitted, but then could not locate the original version. Because of that and other delays, the grant was held up for one month.

Comment: "Processing delays and poor communication between the IRB and its "clients" have repeatedly frustrated the faculty's good-faith efforts to have well-prepared protocols reviewed and processed in a timely manner. The slow response times increase the risk of damaging our reputation among funding agencies by raising doubts about our ability to complete the research and submit our findings by required deadlines."

Faculty and other researchers feel they lack channels for registering dissatisfaction with the IRB process.

On the Berkeley campus faculty concerns led to a call for the Academic Senate to reassume responsibility for the appointment of the IRB chair and committee members. This resulted in greater Senate involvement in overseeing IRB operations, including the submission of an annual report from the IRB chair that includes an assessment of process time using established metrics. From Los Angeles it was reported that some faculty felt IRB non-approval has the potential to affect one's career negatively.

Faculty members often lack appreciation of the federal regulations and how these regulations apply to them.

Some IRBs reported that infrequent or new applicants tend to submit protocols that require one or more revisions to meet the requirements for review by the IRB. UC Davis observed that the greatest problem with regard to faculty seems to be a lack of awareness of IRB review requirements. In an effort to address this issue, the Davis IRB administration has engaged in outreach efforts to the UCD research community, including establishing of an IRB email list serve as well as conducting a bi-monthly IRB open forum. Other consultations and discussions with faculty brought to light specific instances of a lack of familiarity with or misunderstanding of the basic outline of federal regulations as well as with IRB procedures. Examples include: assuming that protocols cannot be re-submitted for approval; unnecessarily answering inapplicable questions on the review application; not being aware that federal regulations address conflict of interest for IRB members; not being aware that non-compliance can restrict the

publication of research results. Moreover, researchers often do not recognize that compliance with IRB regulations offers a legal safeguard against possible liability in the event of undesirable research outcomes.

In an informal survey of campus IRB Web sites, we found the UC Irvine's IRB website to offer a good model that other campuses might use for improving the delivery of information and advice.

A predominant complaint among social and behavioral science researchers is the inappropriateness of the medical model for use in ensuring the protection of human subjects participating in non-biomedical studies.

The use of a medical model for behavioral and social science protocols is a central criticism in the published discourse on IRB reform.[16] UC sources parallel this complaint. UC researchers in the behavioral and social sciences have reported the following:

- Review application forms are designed for clinical/medical research, even though it would be relatively simple to create applications tailored to the subjects addressed and methodologies used in the social sciences.
- IRBs lack recognition of the conventions and methodologies belonging to behavioral and social science research. For example:
    - interviews are often conducted in an unstructured manner or go in unforeseen directions while still yielding usable data. This common methodology is often inconsistent with a research design that will comply with IRB standards; or
    - data that was gathered before the research protocol is designed and submitted is not acceptable, although this data is often the basis or starting point of the proposed study.
- The amount of detail asked for in connection with basic interviews seems unnecessary and the manner of questions implies that faculty are not trusted to conduct research properly or ethically, despite that fact that they have gone through NIH-required IRB training in human subjects protection.
- Suggested revisions of protocols often are not sensitive to certain kinds of projects, and obtaining a waiver only takes up more time.
- Pedagogical research faces a particular disadvantage, since it is mainly based on approaches and outcomes in the actual teaching environment. But obtaining informed consent from all student participants (recent and past) is impracticable. This barrier to pedagogical research is especially troubling because it runs counter to the educational mission of the university.
- The disjunction between IRB regulations and the tools and needs of behavioral and social research leads many researchers to go "underground" by obtaining IRB approval from an outside institution or by avoiding the IRB altogether. Specific examples of this behavior at UC were reported to UCORP.

VII. Recommendations

1) Increase Funding for Staff Augmentation and Training

IRBs are an essential component of UC's research infrastructure. Efficient functioning of

IRBs requires well trained and sufficient IRB staff, for it is the staff who evaluate protocols for completeness and provide the interface between researchers and the IRB itself. Accordingly, the training and professionalism of IRB staff must be commensurate with the importance of the IRB's role in facilitating the research mission of the university. Our study indicated that some campus IRBs were understaffed and that all campuses were in need of increased support for staff training. Increases in staffing and training should enhance the quality and efficiency of the protocol review process, which in turn would improve IRB relations with faculty investigators. We recommend that:

- Adequate resources be allocated for hiring and training of IRB staff in accordance with identified needs of each campus.
- Indirect cost recovery funds at the systemwide level be applied to systemwide training of IRB directors, members and staff.

We reject on principle the idea of recharging investigators for protocol review as a means of sustaining IRB operations.

2) Facilitate Systemwide Coordination in Training

Inconsistent interpretation of federal regulations and dissatisfaction with customer service were major sources of faculty complaint about IRB operations. With regard to the former, faculty complaints ranged from the inability to get a consistent response from different staff persons within a campus IRB to difficulty in getting multiple IRBs to approve a common experimental protocol for large multicampus projects. With regard to the latter, some campus IRBs are viewed by faculty as adversarial whereas others are perceived as supportive. To address these problems, we recommend establishment of a systemwide training program for IRB staff to promote greater coordination among campus offices and to facilitate standardized interpretation of federal regulations. Specific coordination efforts would include:

- Discussion of IRB issues, such as communication with faculty and graduate students, examples of problematic reviews, the impact of extended, delayed, or withdrawn protocols on research, and coordination of reviews.
- Identification of needs and problems in IRB offices and among faculty "clients."
- Development of websites to provide guidance in the preparation of research protocols.
- Discussion and comparison of performance standards.
- Conducting systemwide training sessions for IRB chairs.
- Discussion of review procedures and other problems associated with behavioral and social science research protocol submissions.
- Comparison of UC IRB review standards with those at other academic institutions.
- Consider the advantages and disadvantages of obtaining accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

UCOP's Office of Research has recently implemented a one-year MOU for intercampus protocol review. Assuming no problems arise with the practice of intercampus protocol acceptance, we recommend continuation of the MOU for additional years. We strongly encourage maintaining agreements of this sort to ensure ongoing coordination.

3) Establish a Forum for the Systemwide Discussion of Major Issues in Human Subjects Research

A consistent underlying theme emerging from UCORP's review as well as in reports by other bodies is that many researchers believe IRBs are more concerned with the bureaucratic details of regulatory compliance than with meaningful assessment of risk to human subjects. There is also a belief that IRB review procedures are unnecessarily opaque and are not accommodating to the diverse domains of academic research. These views are most strongly held by researchers in the social and behavioral sciences, although they extend also into the biomedical area. The core concepts of human subjects protection - the definition of research, the assessment of risk, the nature of consent, and the protection of privacy - are at issue and deserve discussion in a forum that engages all stakeholders in human subject protection -- faculty involved in diverse areas of research, IRB members, ethicists, and administrators responsible for research compliance. Identification of areas of consensus and delineation of areas of difference would provide guideposts for both investigators and IRBs.

A forum for the discussion of human subjects protection issues could serve also to address emerging ethical issues in human subjects research, privacy protections in human genetics research being a current example. Finally, it might serve as a starting point for the collection of information on the functioning of the protection system for human research subjects; there is little data on effectiveness and efficiency of IRB operations nationally, much less for the UC system. This is recognized in one of the recommendations of the NRC report on human subjects.[17]

4) Evaluate Electronic Submissions and Review Tracking Systems

A common complaint among investigators is not knowing the progress of their submitted research protocols through the review process. This complaint can be addressed by the development of electronic submissions programs that allow the investigators to track the progress of a submission, the required modifications or actions, and the reasons for a change or action. This would be similar to the tracking function of online submissions of journals and will enable the researcher to monitor the review timeline and be better informed of the review process. The San Diego and Irvine campuses have electronic research protocol submission and are in the process of developing a tracking system. Their success should be evaluated and shared with other campuses.

5) Establish Mechanisms for Local Campus Oversight of IRB Operations

IRBs have an administrative function and are answerable in their operation to the campus Vice Chancellor of Research. At the same time, because the IRB interfaces with the faculty, local Academic Senates should have a voice in the evaluation of this administrative committee's performance, bearing in mind that in the case of IRBs, decisions are not subject to review by either faculty or administrative bodies. Not all campuses, however, have a mechanism by which faculty are informed about IRB performance, and no campus appears to have a mechanism by which faculty researchers can register dissatisfaction regarding IRB operations. We recommend that each campus:

- Establish a mechanism for IRB oversight to review operations and monitor the level of faculty satisfaction with the IRB review process. This oversight function

could be subsumed in the activities and charge of a general 'research compliance' committee or a stand-alone body that includes members of the local campus Senate. The UCOP Office of Research has recently established a systemwide Research Compliance Advisory Committee with which the local oversight bodies can liaise.

- Consider the benefits of AAHRPP accreditation, which requires a feedback mechanism and an official way to express dissatisfaction with the IRB review process.
- Set performance standards that are sensitive to local conditions and that will enable the Senate oversight bodies to evaluate IRB performance and make recommendations on resources, timeliness of reviews, and electronic submissions. Evaluations should include:
    - on-time performance of review processes compared to set benchmarks
    - assessment of reasons for withdrawn and failed protocols
    - number of transactions per protocol and review success rates
    - differences among disciplines in review performance metrics
- Establish an independent process by which faculty can voice dissatisfaction regarding IRB operations with the expectation of a reasonable response.
- Establish policy through the campus VCR calling for an annual report from the IRB to be delivered to an appropriate Senate body, e.g., the Committee on Research.

The annual reports for each campus can serve as the basis for the collection of empirical data on the functioning of IRBs systemwide as called for in recommendation #3.

6) Cultivate Greater Faculty Familiarity with Human Subjects Protection Issues and the IRB Review Process

Many faculty members do not have a full appreciation of federal human subjects regulations or of how their own campus IRB functions. UCOP should spearhead simple and direct tactics, to be implemented at the campus level, that will serve to raise faculty awareness of: 1) UC and federal requirements pertaining to research involving human subjects; 2) the potential impact of noncompliance on research projects and the publication of research results; 3) faculty rights within the review system; and 4) the legal benefits to researchers with IRB approved projects. This can be done through new faculty orientations, websites, direct communication with departments, and through other means as conceived of in systemwide coordination forums and on campuses.

7) Encourage Faculty Recruitment and Recognition of Service on IRBs

Service on an IRB represents a considerable commitment of time and energy. Many campuses noted difficulty in recruiting faculty to serve on IRBs and several campuses have added IRB staff as members to meet quorum requirements. IRB service should receive appropriate recognition and compensation.

- IRB chairs and members should be compensated commensurate to the workload and as appropriate to the campus context, e.g., partial teaching release.
- Campus Academic Personnel Committees should recognize that service on IRBs is essential to the research mission of the University and reward it accordingly.
- Deans and department heads in disciplinary areas utilizing human subjects research have a vested interest in supporting IRB operations and should be directly involved in the recruitment and recognition of faculty who serve on IRBs.

8) Contribute to the Discussion of IRB Reform at the National Level
IRBs are under challenge on many fronts at the national level. Included prominently among the criticisms are that IRBs are inconsistent in their interpretation of federal regulations, that the medical model for human subjects protection is inappropriately applied to most behavioral and social sciences research, that IRBs have become bureaucratic to the point that research is impeded, and that IRBs have placed restrictions on research protocols that undermine sound research design. Whatever course UC takes toward systemwide coordination and harmonization of IRB activities, given its size and the value of its research enterprise, it will influence human subjects policy at the national level. To broaden its position, UC should engage with professional societies as well as other academic institutions and groups.

END NOTES

[1] These are detailed in the Code of Federal Regulations Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects.
[2] Op cit; 45 CFR 46, 101b (2).
[3] For a comprehensive exposition of IRB "mission creep," see "The Illinois White Paper. Improving the System for Protecting Human Subjects: Counteracting IRB 'Mission Creep,'" C. K.Gunsalus, et al; The Center for Advanced Study Project Steering Committee to Study Human Research Protections, 2005. http://www.law.uiuc.edu/conferences/whitepaper/
[4] "The New Censorship: Institutional Review Boards," Philip Hamburger; *Supreme Court Review*, 2005 (271-354).
[5] *Protecting Human Beings: Institutional Review Boards and Social Science Research,* Statement of the American Association of University Professors.
[6] "Ethical and Policy Issues in Research Involving Human Participants" Report and Recommendations of the National Bioethics Advisory Commission, August 2001: http://www.georgetown.edu/research/nrcbl/nbac/human/overvol1.pdf.
[7] "The Crisis in Human Participants Research: Identifying the Problems and Proposing Solutions," Anne Wood, Christine Grady, Ezekiel J. Emanuel; presented to the President's Council on Bioethics September 2002, National Institutes of Health. http://www.bioethics.gov/background/emanuelpaper.html
[8] "Responsible Research: A Systems Approach to Protecting Research Participants" Daniel D. Federman, Kathi E. Hanna, and Laura Lyman Rodriguez, Editors, Committee on Assessing the System for Protecting Human Research Participants, National Research Council, National Academies Press, 2002 http://darwin.nap.edu/books/0309084881/html/70.html
[9] "Protecting Participants and Facilitating Social and Behavioral Sciences Research," Constance F. Citro, Daniel R. Ilgen, and Cora B. Marrett, Editors, Panel on Institutional Review Boards, Surveys, and Social Science Research, National Research Council, National Academies Press, 2003. http://darwin.nap.edu/books/0309088526/html/9.html
[10] Op cit., "The Illinois White Paper."
[11] For background on these and other shutdowns, see: "Shutdown at Hopkins Sparks a Debate," Science July 27, 2001 (Johns Hopkins); "Chancellor Quits After Research Shutdown," Science, September 24, 1999 (University of Illinois); "Shutdown of Research at Duke Sends a Message," Science, May 21, 1999 (Duke); "Hospital Failed in Human Research Policy," Science, November 6, 1998 (Rush); "Flawed Cancer Study Leads to Shake-Up at University of Oklahoma," Science, August 4, 200 (U. of Oklahoma); "Research Shutdown Roils Los Angeles VA," Science, April 2, 1999 (Los Angeles VA Hospital).
[12] See J. Katz, "Ethical Escape Routes for Underground Ethnographers."
UCORP also reviewed an article in press authored by UC researchers that details difficulties they encountered in trying to get IRB approval for a community based participatory research project. The paper points to a basic opposition between institutional/IRB and methodological/researcher needs as an obstruction to research.

[13] University of California Presidential Memorandum, September 2, 1981, University Policy on the Protection of Human Subjects in Research, # 2 http://www.ucop.edu/raohome/cgmemos/86-21.html

[14] One of the requirements of AAHRPP accreditation is having a dedicated education coordinator.

[15] See Greene, S., et al, "Impact of IRB Requirements on a Mulicenter Sruvey of Prophylactic Mastectomy Outcomes,"2005, Elsevier; also "Feasibility of a National Fatal Asthma Registry: More Evidence of IRB Variation in Evaluation of a Standard Protocol" Abstracts, AEP vol. 15 September 2005 p. 645. Abstracts(American College of Epidemiology)

[16] This issue is treated in almost every discussion of IRB reform. In addition to The Illinois White Paper and Katz, see also Jeffery Brainard "The Wrong Rules for Social Science?" *Chronicle of Higher Education,* May 9, 2001. http://chronicle.com/weekly/v47/i26/26a02101.htm; and Gunsalus, C. K., et al, "Mission Creep in the IRB World" *Science* 2006 312: 1441.

[17] Both the IOM report and the NRC report comment on the lack of information about the functioning of the human subjects protection system in the U.S. and recommend the collection of data to address this need.

UNIVERSITY OF CALIFORNIA, ACADEMIC SENATE

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

Office of the Chair
Telephone: (510) 987-9303
Fax: (510) 763-0309
Email: george.blumenthal@ucop.edu

Assembly of the Academic Senate, Academic Council
University of California
1111 Franklin Street, 12th Floor
Oakland, California 94607-5200

June 7, 2005

MAX NEIMAN
CHAIR, UCORP

Re: Establishment of Systemwide Standards for Review of Institutional Review Boards

Dear Max:

The Academic Council at its May meeting discussed concerns raised by the University Committee on Academic Freedom (UCAF) about the growing number of reports of interference by Institutional Review Boards (IRB) in faculty research. UCAF requests that the Senate look at the operation of IRBs in order to determine whether and how systemwide standards for IRBs should be established.

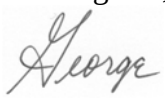
When considering the question of a systemwide IRB policy, the Council has in the past decided against the idea because of the wide variation in campus cultures and practices. In this more recent discussion, however, Council members noted that IRBs are in many cases a hindrance to faculty research activities and a significant barrier to multi-campus research. Therefore Council felt that the possibility of formulating some systemwide guidance for IRBs should be seriously explored. UCORP is asked to take the lead in this effort, in coordination with UCAF and CCGA. Specifically, the questions to be addressed are:

1) What are the IRB policies?
2) What assurances are there that these policies are being consistently implemented across the campuses?
3) How do we ensure that issues of safety drive the implementation of these policies?

While the bulk of this effort will fall to the 2005-06 committees, UCORP will be asked to report back to Council at the July meeting. In addition, we ask that UCORP act as liaison with the Office of Research on this issue. A letter will be going out to Vice Provost Coleman apprising him of the Council's action and asking him to coordinate with UCORP any studies that he may also wish to undertake.

On behalf of the Academic Council, I thank you and the members of UCORP for taking on this task. We look forward to your update in July and to an eventual outcome that will be of benefit to the UC research community.

Best regards,



George Blumenthal, Chair
Academic Council

Copy: Academic Council
Quentin Williams, Chair, CCGA
Patrick Fox, Chair, UCAF
María Bertero-Barceló, Executive Director
Brenda Foust, UCORP Analyst
Michael LaBriola, UCAF Analyst
Todd Giedt, CCGA Analyst

GBbgf

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

UNIVERSITY COMMITTEE ON ACADEMIC FREEDOM
PATRICK FOX, CHAIR
pf1965@itsa.ucsf.edu

Institute for Health and Aging
3333 California Street, Suite 340
University of California
San Francisco, CA 94143-0646
Phone: (415) 475-9483

May 3, 2005

GEORGE BLUMENTHAL, CHAIR
ACADEMIC COUNCIL

Re: Systemwide Standards for Institutional Review Boards

Dear George,

At its April 21, 2005 meeting, UCAF members heard a number of reports from our members about what appears to be a growing level of interference from Institutional Review Boards and Human Subjects Committees on some campuses into the way faculty conduct research. We believe the situation has serious implications both for academic freedom and shared governance, and requires systemwide action.

The problem appears to be most serious in peer reviewed, funded research in the Social Sciences, although it is not confined to those disciplines. Faculty members at UCLA in particular have expressed strong concerns that IRBs have strayed beyond their main charge—protection of the safety and the confidentiality of human subjects—into overzealous evaluation of research methodology and research quality beyond that associated with the protection of human subjects. Faculty members involved with animal research protocols have also expressed similar complaints about an unreasonable level of difficulty they have sometimes experienced with the IRB approval process. Although IRBs do need to evaluate methodology *to some extent* in order to draw conclusions about the risks and benefits to human or animal subjects, when an IRB review aimed at safety and risk-benefit analysis crosses the line into interference and obstruction, academic freedom is compromised.

One problem we see is that IRBs are often composed primarily of staff members who can impose what faculty perceive to be arcane requirements that have more to do with managing assumed legal risks than facilitating the conduct of faculty research. There have also been issues of IRB members having inadequate expertise to understand the research under review. In addition, there appear to be no formal procedures in place for a faculty member to challenge the decision of an IRB.

We appreciate the hard work of IRB staff and faculty IRB members, and the value and importance of the IRB in terms of human and animal subject protection, but UCAF believes it is inappropriate, both as a matter of academic freedom and shared governance, for an IRB

composed primarily of staff to have the power to penalize or punish a faculty member without additional faculty review. A more comprehensive, equitable and balanced approach is needed.

The conduct of IRB committees varies noticeably from campus to campus, and the rules under which they operate are primarily a function of local culture and interpretation. For this reason, we believe University Wide standards are necessary. The Office of Research at UCOP may be the appropriate entity (with Senate consultation) to develop and administer these standards. A systemwide policy should stipulate precisely the latitude and limits of IRB responsibilities. In addition, due process procedures should be written in that includes a provision for senate involvement and review.

Therefore, we ask Academic Council to request that the UCOP Office of Research initiate and undertake a full review of Institutional Review Boards and Human Subjects Committees policy and procedures.

Sincerely,

Patrick Fox
Chair, UCAF

PF/ml
cc: Academic Senate Director Bertero-Barceló
UCAF members

UNIVERSITY OF CALIFORNIA, ACADEMIC SENATE

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

Office of the Chair
Telephone: (510) 987-9303
Fax: (510) 763-0309
Email: george.blumenthal@ucop.edu

Assembly of the Academic Senate, Academic Council
University of California
1111 Franklin Street, 12th Floor
Oakland, California 94607-5200

June 20, 2005

LARRY COLEMAN
VICE PROVOST - RESEARCH

Re: Establishment of Systemwide Standards for Review of Institutional Review Boards

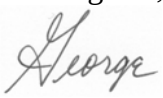
Dear Larry:

At its May 18, 2005 meeting the Academic Council discussed concerns raised by the University Committee on Academic Freedom (UCAF) about the growing number of reports of interference by Institutional Review Boards (IRB) in faculty research. UCAF suggests that the situation calls for the establishment of systemwide standards for Institutional Review Boards.

The Academic Council agrees that there are grounds for concern because RBs may, in their interpretation of federal guidelines, hinder faculty research activities and pose a significant barrier to multi-campus research as well. Council has, therefore, asked the University Committee on Research Policy (UCORP) to take the lead in looking at the operation of IRBs and at Human Subjects Committees' policies and procedures to determine whether systemwide policy/guidelines should be established. Since this effort will need to be carried out in close consultation with your office, we have also asked that UCORP coordinate the undertaking with any study that you feel may be advisable. Specifically, the questions that the committee will address are: 1) What are the IRB policies? 2) What assurances are there that these policies are being consistently implemented across the campuses? 3) How do we ensure that issues of safety are driving the implementation of these policies?

UCORP will be acting in coordination with UCAF and the Coordinating Council on Graduate Affairs (CCGA), and will report to Council in July with preliminary comments. The bulk of this effort will, however, be carried out in 2005-06, so next year's Academic Council Chair Cliff Brunk will follow up with you on its progress. In the meantime, though, I would be happy to talk with you if you have any questions or suggestions for proceeding. We look forward to working with the Office of Research on this project and to an eventual outcome that, we hope, will be of benefit to the UC research community.

Best regards,



George Blumenthal, Chair
Academic Council

Copy: Academic Council
Max Neiman, UCORP Chair
George Sensabaugh, UCORP Vice Chair
María Bertero-Barceló, Executive Director
Brenda Foust, UCORP Analyst

GB/bgf

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP)
George Sensabaugh, Chair
sensaba@berkeley.edu

Assembly of the Academic Senate
1111 Franklin Street, 12th Floor
Oakland, CA 94607-5200
Phone: (510) 987-0630
Fax: (510) 763-0309

October 13, 2005

UNIVERSITY COMMITTEE ON RESEARCH POLICY

Dear UCORP Members:

Last June, UCORP was given a charge by the Academic Council to address the concern raised by the University Committee on Academic Freedom (UCAF) that campus Institutional Review Boards (IRBs) may be interpreting federal guidelines in ways that hinder faculty research. In his June 7, 2005 letter to 2004-05 UCORP Chair Max Neiman, past Council Chair George Blumenthal asked UCORP to take the lead in looking at the operations of IRBs (or 'human subject committees') and at policies and procedures on the different campuses to determine whether systemwide IRB policies should be established. The specific questions UCORP has been asked to address are: 1) What are the IRB policies? 2) What assurances are there that these policies are being consistently implemented across the campuses? 3) How do we ensure that issues of safety are driving the implementation of these policies? UCORP will be consulting with the Office of Research in this effort, and working in coordination with the University Committee on Academic Freedom (UCAF) and the Coordinating Council on Graduate Affairs (CCGA), as needed. The Academic Council has requested that UCORP report back with its recommendations this year.

Toward the fulfillment of this charge, I ask that each of you gather substantive basic information about your local human subject committee, in answer to the questions listed below.

Constitution of the committee
Does your campus have one or multiple IRBs? If the latter, how is the work subdivided?
What is the composition of the IRB? Is it accountable to your Senate, your administration, or both?
If it is primarily an administrative group, what is its relationship to the Senate?
How are members appointed?
Is there adequate staff support?
How are members and staff trained?
Is the chair compensated? The members? If so, how?
To what extent is faculty commitment a problem?
Does your campus contract reviews out? If not, is this option being contemplated?

Reviews
What is the volume of protocols reviewed in a year? What is the distribution of exempt, expedited, and full board reviews? What is the turnaround time for each kind of review? Are there differences across disciplinary areas?

When the research entails human subjects activities at multiple sites (*e.g.*, on different campuses), how do the IRBs at the different sites interact? To what degree are the reviews coordinated? What fraction of protocols submitted for review do not progress to approval?

Given the varieties of structures and policies from campus to campus, it is likely that some of these questions will not apply to your individual situation, but please supplement your response as you see fit. I trust that your efforts, along with useful input from your local IRB chair, members and staff and from campus research administrators, will help address the Senate's concerns and lead to a better understanding of how our IRBs now function.

Sincerely,

George Sensabaugh, Chair
UCORP

Copy: Clifford Brunk, Academic Council Chair
Maria Bertero Barcelo, Executive Director, Academic Senate
Brenda Foust, UCORP Analyst

IRB Profile – Summary (rev. 7/19/06)

Constitution of the committee	
Does your campus have one or multiple IRBs? If the latter, how is the work subdivided?	Medical campuses have multiple IRBs, typically several for biomedical protocols and one (2 at UCLA) for non-biomedical. Most non-medical campuses have one IRB. Effective July 2006, Berkeley will be split into two committees to review a similar range of studies, although one may be designated to review the School of Optometry studies. Berkeley IRB is also the official IRB for LBNL.
What is the composition of the IRB?	On all campuses, most of the IRB membership is drawn from the faculty. Outside members and members representing vulnerable populations are present as required by law. There are currently two IRBs that include one staff member because faculty could not be recruited to fill the slots. UCR has one graduate student member.
Is it accountable to your Senate, your administration, or both? If it is primarily an administrative group, what is its relationship to the Senate?	IRBs on all campuses are administrative committees under the local Office for Research. Relations with the local Senate vary from none to consultation on membership (see below). At UCSC, the campus COR is charged with monitoring the campus research infrastructure, of which the IRB is part. Note: once constituted, IRBs are by federal law independent entities with irreversible power to deny human subjects protocols deemed unacceptable. Thus IRBs are answerable to the VCR with regard to operations but not to decisions.
How are members appointed?	Formal appointment of IRB members, both faculty and outside, is done by the VCRs on all campuses. Nominations may be made by the Senate [SC] or by Dept. Chairs [SD, SF, LA]. Calls for volunteers are made on some campuses.
Is there adequate staff support?	Responses range from "yes" to derisive laughter (construed as "no"). There appears to be no standard for what constitutes adequate staff support; case load, number of personnel, and level of expertise are parts of the equation. UCSC points out a potential conflict of interest between operations oversight and compliance functions. Specifically, Riverside, San Diego, and Santa Cruz indicated inadequate staffing levels. One campus reported that an outside review of the human subjects protection program identified the staffing level as being inadequate and unable to effectively oversee all aspects of the program. One campus noted understaffing affecting ability to conduct full administrative reviews and lack of sufficient ongoing administrative oversight. San Francisco is evaluating its support needs; Berkeley has received temporary funding for increased support, which is still not fully adequate to cover all administrative activities.

IRB Profile – Summary (rev. 7/19/06)

How are members and staff trained?	Training for faculty varies: Davis with a fairly formalized training program is at one end of the scale whereas UCR with what appears to be little more than on the job training is at the other. IRB staff play a substantial role in providing training for faculty on several campuses. Types of training include workshops, online modules, national and local conference participation, and review of publications. Training for IRB staff is more formalized on most campuses, but at a range of levels. UCOP has regular meetings.
Is the chair compensated? The members? If so, how?	Chairs receive stipend at Berkeley, UCI & SB, and teaching release SC. Departments receive compensation for chair (and vice chair in some cases) at SD, Davis, SF, & LA. Members receive compensation for S&E, travel, at Davis; member's Dept. receives compensation at LA. Service on other campuses not compensated.
To what extent is faculty commitment a problem?	Recruitment was reported to be a problem at Berkeley, UCSF and Irvine, and somewhat at San Diego; Riverside reported frequent turnover. LA is concerned about recruitment of members with special expertise. Attendance (meeting a quorum) also noted as a problem on two campuses. Santa Cruz reports stable long-term membership. Faculty who serve take their service seriously.
Does your campus contract reviews out? If not, is this option being contemplated?	External IRB used (Davis) or contemplated (UCI, SF, LA, SD) for particular kinds of clinical trial protocols. Not contemplated for run of mill protocols.
Reviews	
1) What is the volume of protocols reviewed in a year? 2) What is the distribution of exempt, expedited, and full board reviews? 3) What is the turnaround time for each kind of review? 4) Are there differences across disciplinary areas?	See attached spreadsheet for questions 1-3. Survey didn't distinguish between time from submission to 1st IRB response and time from submission to approval. Regarding differences across disciplinary areas (question 4), no significant differences reported. A more significant factor was PI familiarity with requirements for research with human subjects; irregular users tend to submit protocols that need revising, *i.e.*, multiple transactions. To enhance faculty awareness and maintaining compliance, the Davis IRB administrative office meets with departments to address unique research issues and uses modified process for submission in some cases. They also engage in outreach, e.g., and IRB email listserv and bi-monthly open forums.

IRB Profile – Summary (rev. 7/19/06)

When the research entails human subjects activities at multiple sites (*e.g.*, on different campuses), how do the IRBs at the different sites interact? To what degree are the reviews coordinated?	An MOU was implemented in March 1, 2006 for exempt and expedited reviews of protocols involving research conducted at and/or data collected from more than one campus. Berkeley, Davis and UCSF are working on an agreement and several campuses expedite protocols approved at other sites. Hopeful that some form of inter-campus coordination can be worked out; looking to UCOP. Berkeley and SF have shared programs and recognize each other's IRB approvals.
What fraction of protocols submitted for review do not progress to approval?	Considerable variation – may reflect different interpretations of questions. See spreadsheet. More specific data is needed.

UCORP - IRB WORKLOAD SUMMARIES

	Davis (3)		Irvine (3)		Los Ang. (5)	San Fran. (4)	San Diego (4)	Berkeley		Riverside		S. Barbara		S. Cruz	
Volume															
Total	1958		2538		>6400	5693	2100-2500	1335		350		473		125	
new			875	34%				925	69%	100	29%			71	57%
cont.			719	28%				410	31%					54	43%
mod.			944	37%											
Approx. no./unit	650		850		1280	1140	625	1335		350		473		125	
Distribution			#												
Full review	888	45%	721	28%	25-40%	1884	33%	90-95%	129	10%	20%	98	21%		3%
Expedited	577	29%	1817	72%	60-75%	3559	63%	5-10%	673	50%	50%	274	58%		48%
Exempt	495	25%			>550	250	4%		526	39%	30%	101	21%		47%
Turnaround times (days, typical)			#			#		#							
Full review	42		90		28-42	90				28		28		2-14	
Expedited	28		32		28-42	60				14				2-14	
Exempt	16				7	21				7				2-14	
Protocol failure (%)															
Total	75	4%			<0.01%	~10%	~2%	7	0.5%	<20%		29	6%	<1%	
Withdrawn	66	3%													
PI non-response	9	0%													
Rejected by IRB						0.1/yr						0.1/yr			

 # NOTES

Irvine: expedited and exempt numbers combined

San Francisco: target turnarounds are 42 days for full reviews, 21 for expedited, 7 for exempt.

San Diego: 14-28 days for initial decision, time to final approval depends on amount of paperwork to be completed.

UCORP 2005-2006

George Sensabaugh, Chair
Wendy Max, Vice Chair
Slawomir W. Hermanowicz (Berkeley)
James Murray (Davis)
Faryar Jabbari (Irvine – Fall 2005)
Richard McCleary (Irvine – Feb., March.)
Cornelia Pechmann (Irvine – April ~ Aug.)
Edwin Cooper (Los Angeles – Fall 2005)
Joel D. Aberbach (Los Angeles – Spring 2006)
David F. Kelley (Merced)
Jose Wudka (Riverside)
Gary C. Jacobson (San Diego)
Dorothy Bainton (San Francisco)
Arturo Keller (Santa Barbara)
Judith Aissen (Santa Cruz)
John Oakley, Academic Council Chair (ex officio)
Michael Brown, Academic Council Vice Chair (ex officio)
Brenda Foust, Analyst

The Task Force Reviewing and Recommending Comment to the Systemwide Report on Institutional Review Boards (IRB)

Kathleen Puntillo, RN, DNS, FAAN, Chair

November 28, 2006

Deborah Greenspan, DSc, BDS
Chair, UCSF Academic Senate
Office of the Academic Senate, Box 0764

Dear Chair Greenspan,

The Task Force Reviewing and Recommending Comment to the Systemwide Report on Institutional Review Boards (IRB), consisting of two Members of the Committee on Research (one serving as Chair), two Members from the Committee on Academic Planning and Budget, two Members from the Committee on Academic Freedom, and two Members from Graduate Council, met on November 14, 2006 to review these recommendations and to suggest a possible response from the San Francisco Division.

Before commenting on each of the eight recommendations made by UCORP in their report, the Task Force would like to express concerns about the limited data provided in the Report used to substantiate many of the perspectives derived from these sources of information. The Task Force believes it is unable to evaluate the main underlying premise that there are deficiencies in IRB operations or to make informed recommendations without a complete and systematic study of Principal Investigators' (PI) experiences at each campus IRB and complete data on local staffing levels, utilization rates, and turnaround times. For example, the Task Force feels that the methodology for soliciting information from faculty on local campus IRB operations was skewed towards Principal Investigators providing, "difficulties they encountered with the IRB review process" (p. 5). A more systematic solicitation of faculty input would have made the results less skewed toward negative experiences and, thus, more credible.

Report Recommendation 1: Increase Funding for Staff Augmentation and Training

The UCSF Task Force recommends that "and Standards" should be added to the title of this recommendation. We accept the comment that some campus IRBs are understaffed and feel that, on the UCSF campus and perhaps others, this is due to increased responsibilities requested/expected of them. We support the statement, "Adequate resources be allocated for hiring and training of IRB staff in accordance with identified needs of each campus." We suggest further consideration and quantification of "adequate resources." We suggest that, in order to determine the effectiveness of

staff augmentation, standards and guidelines regarding IRB committee workload be developed. Specific staffing and workload guidelines should be articulated; i.e., what is the appropriate number of committees to handle the number and complexity of the active protocols in a timely fashion, and how many staff are needed for each committee? We believe that such guidelines and standards should be instituted systemwide. If left to each campus, justifications would have to begin again with each new Vice Chancellor for Research (VCR). This could result in very different resources from campus to campus. It would be much better to have some actual numerical guidelines as a starting point for discussions when a new committee is needed as the research enterprise grows. UCSF's enterprise will surely grow with the new translational grant and, most likely, growth will be seen at the other campuses as well.

We support the recommendation that "indirect cost recovery funds at the systemwide level be applied to systemwide training of IRB directors, members and staff." However, we believe that the practice of "recharging investigators for protocol review as a means of sustaining IRB operations" cannot be universally rejected unless some current practices are eliminated. The recharging practice is already in effect under some circumstances. For example, investigators at the San Francisco Veterans Administration campus with NIH or industry sponsored grants pay $1400 for initial review and $300 for renewal. This money comes out of the indirect funds that the foundation collects. However, caution is advised in making decisions about recharging investigators, especially when studies are unfunded, pilot studies, and when investigators do not have discretionary funds to pay for recharges.

Report Recommendation 2: Facilitate Systemwide Coordination in Training

The UCSF Task Force supports this recommendation. Systemwide training programs for IRB staff could, indeed, promote greater coordination among campus offices and facilitate standardized interpretation of federal regulations. Currently Public Responsibility in Medicine and Research (PRIM&R) offers courses that are one intense day each, called IRB 101 and IRB 201; PRIM&R will provide on–site training for a fee. UCOP could facilitate and pay for a course that would involve all of the campuses for CHR members and staff every year or every other year. This could even be considered a benefit of being on an IRB committee.

Report Recommendation 3: Establish a Forum for the Systemwide Discussion of Major Issues in Human Subjects Research

The UCSF Task Force believes that the statement "IRB review procedures are unnecessarily opaque and are not accommodating to the diverse domains of academic research" is vague. Taskforce committee members agreed that a "forum for the discussion of human subject protection issues" is invaluable and identified forums that already exist. For example, PRIM&R currently serves as a venue for discussion of issues in human subject research. Anyone can join PRIM&R or attend the PRIM&R meeting without joining. In addition, the UC Office of the President convenes a systemwide IRB meeting annually and the next one is scheduled for January 24, 2007. These existing forums offer an appropriate venue for discussion and debate of these issues. UC faculty should be made more aware of these existing forums.

Report Recommendation 4: Evaluate Electronic Submissions and Review Tracking Systems

The UCSF Task Force strongly supports development of electronic submissions and review tracking systems. Online submission is used by UCSF Laboratory Animal Resource Center (LARC).

Protocols are submitted to the Institutional Animal Care and Use Committee (IACUC) which uses Research Information Online (RIO), a database management system that links and stores research protocols, authorized users, and online training programs and other data to facilitate quick turnaround times and maintain data integrity. The effectiveness of systems such as these should be evaluated, and information on the successful systems at the San Diego and Irvine campuses should be shared with other campuses. The UCSF IRB is already moving towards the development of such a system, but progress has been limited by insufficient funding.

Report Recommendation 5: Establish Mechanisms for Local Campus Oversight of IRB Operations

The UCSF Task Force agrees with the recommendation for campus oversight. Currently, the IRB at UCSF submits an annual self-evaluation report to the VCR, and there is monitoring by AHRP (Association for the Accreditation of Human Research Protection Programs). The chairs, vice-chairs and senior staff currently do have quarterly policy meetings with the VCR to discuss performance and policy issues and ways to implement changes. We suggest that a committee be instituted that could serve as a forum for complaints. Reports from this committee could be submitted to the VCR and the Academic Senate Committee on Research.

We agree that an evaluation of IRB operations could include "monitoring the level of faculty satisfaction with the IRB review process" but not final decisions. We also agree with the recommendation to "establish policy through the campus Vice Chancellor for Research calling for an annual report from the IRB to be delivered to an appropriate Senate body, e.g., the Committee on Research. However, we wish to stress that, while we agree that an "assessment of reasons for withdrawn and failed protocols" could be part of an oversight and evaluation process, decisions made by an IRB cannot be subject to outside influences.

The main concern about IRB oversight pertains to "quality of service" (QOS) of the IRBs, and there should be mechanisms for routine evaluation of QOS at each campus. There are standard ways of implementing QOS feedback systems which could easily be done on a local level.

Report Recommendation 6: Cultivate Greater Faculty Familiarity with Human Subjects Protection Issues and the IRB Review Process

The Task Force agrees with this recommendation. IRB committee meetings at UCSF have allowed attendance by outside observers. As an additional recommendation, the taskforce suggests that an on-line education courses be developed that would be required before submission of a first IRB or every five years. Similar courses are used for animal research training and laboratory safety.

Report Recommendation 7: Encourage Faculty Recruitment and Recognition of Service on IRBs

The Task Force agrees with this recommendation. However, it is not clear how this would be done and how recognition would be "rewarded." Some IRBs have been able to offer CME credit for IRB work. Recognition strategies such as this could be considered.

Report Recommendation 8: Contribute to the Discussion of IRB Reform at the National Level

The Task Force agrees with this recommendation in principle, but we encourage the development of a more specific plan that directly answers questions such as the following. Are social scientific

protocols evaluated differently from biomedical protocols? If so, how? What are the practical consequences? Are these protocols rejected at a higher rate? Are they subject to more revisions? While engaging the national debate is admirable, it does little to address whatever concerns exists at UC. The Task Force would like to see specific recommendations; i.e., supporting social science researchers with educational materials; providing online or in-person training of researchers; clarifying and simplifying existing forms to better suit the content of social scientific research, etc. Although not addressed in the systemwide report on IRBs, we also encourage IRBs to clarify the policy on classroom or pedagogical research.

The Task Force thanks you for the opportunity to review and comment on this report. Should you have any questions, please do not hesitate to ask.

Sincerely,

Task Force Reviewing and Recommending Comment to the Systemwide Report on Institutional Review Boards (IRBs)

Task Force Membership
Kathleen Puntillo, RN, DNS, FAAN, Committee on Research, Chair of the Task Force
John Huang, DDS, Committee on Research
Deborah Adey, MD, Academic Planning and Budget
Susan Sniderman, MD, Academic Planning and Budget
Elizabeth Boyd, PhD, Committee on Academic Freedom
Victor Reus, MD, Committee on Academic Freedom
David Saloner, PhD, Graduate Council
Jeff Lansman, PhD, Graduate Council

APPENDIX 3
Ac Freedom 2006-07

UCSF – STRATEGIC PLANNING PHASE III
STRATEGY DEVELOPMENT

Strategy Development (Phase III) will be completed through six "Design Teams" as proposed below. These design teams will be comprised of appropriate combinations of faculty, staff, students, residents, fellows, and post doctoral scholars. The teams will be charged with developing specific strategies and tactics within their respective theme that support the vision and goals defined for UCSF's future. These goals and team themes are reflective of all of the strategic planning work completed to-date, including the planning interviews, the on-line survey, environmental assessment, and preliminary mission, vision and goals discussed at Board meetings.

Proposed team assignments, or "charges," are presented on the following pages for each of the Design Teams. These charges are based on each of the UCSF goals that have been assigned to the six teams as part of their strategy development.

PROPOSED STRATEGY DESIGN TEAMS

Team A:	**Recruitment and Retention**
Team B:	**Research Directions**
Team C:	**Education and Training for the Future**
Team D:	**Clinical Care: Quality, Safety, Access and Patient Satisfaction**
Team E:	**Infrastructure and Resources**
Team F:	**Leadership and Governance**

We are asking the Board to provide input on the following questions:

- ***Do the proposed themes for the six teams reflect the priority areas identified through the strategic planning work completed to-date? Are there refinements you would recommend?***
- ***Are there charges (assignment questions) that are missing or should be revised, given the strategic planning discussions to-date?***
- ***What are your recommendations for membership for any of these strategy design teams (either Board or non-board members)?***

Please return your initial input to these three questions to Julie Kuznetsov (JKuznetsov@chanoff.ucsf.edu) by noon on September 11th so that we can summarize input for discussion at the September 14th Board meeting. At that meeting, Board members will also begin the process of assembling the teams. Thank you.

TEAM A: RECRUITMENT AND RETENTION

GOAL #1: Recruit, mentor and retain faculty, staff, students, resident, fellows, and post doctoral scholars of the highest caliber.

Team Charges to Address the Goal:

a. What are the factors that attract top recruits to UCSF? Are any of these factors deteriorating? What needs to be done to address deteriorating factors? How can we capitalize on existing strengths?

b. What are the factors that cause top candidates to choose another institution over UCSF? What can UCSF do strategically to overcome these obstacles?

c. What strategies should UCSF implement to recruit top:
   - Faculty?
   - Staff?
   - Students?
   - Residents?
   - Fellows?
   - Post doctoral scholars?

d. What strategies should UCSF implement to retain top:
   - Faculty?
   - Staff?
   - Students?
   - Residents?
   - Fellows?
   - Post doctoral scholars?

e. How can UCSF ensure that effective mentoring takes place for faculty, staff, students, residents, fellows and post-doctoral scholars? What programs and systems need to be established to reward good mentoring?

GOAL #2: Educate and employ a diverse workforce.

Team Charges to Address the Goal:

a. What methods for improving diversity have been successful at UCSF?

b. Are there specific obstacles at UCSF that inhibit recruitment and retention of a representative community?

c. What new strategies should be implemented to create a more diverse campus community? Differentiate between students, residents, fellows, post doctoral scholars, faculty and staff, as needed.

GOAL #3: Provide a supportive work environment that fosters communication and collaboration.*

Team Charges to Address the Goal (note that ALL teams will address this Goal):

a. What strategies should be employed to protect the culture of collaboration at UCSF?

b. How best can UCSF address the challenges of communication, which is increasingly taxed as UCSF grows across multiple campuses and diversifies its missions?

c. What steps should be taken to provide a supportive work environment that fosters the core values identified for UCSF's future?

(Note: The top ten values identified through the strategic planning work are Excellence, Integrity, Leadership, Innovation, Collaboration/Collegiality, Respect, Scholarship, Diversity, Supportive Environment, Community Service. Most of these values are being addressed elsewhere in all six team charges)

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

TEAM B: RESEARCH DIRECTIONS

GOAL #4: Foster the UCSF research enterprise across multiple sites; determine priority research areas, as well as the criteria for defining priorities, for further development.

Team Charges to Address the Goal:

a. What criteria should be used to select priority research areas for the future? Rank the criteria in order of importance.

b. What research areas should be considered for further development?

c. How does each research area rate relative to each criteria recommended above under question a?

d. How best can the UCSF research enterprise be fostered across multiple campuses and schools in the short- and long-term?

GOAL #5: Build novel interdisciplinary and inter-school approaches towards education, research and health care that prepare UCSF for the future.*

Team Charges to Address the Goal:

a. Given the priority research areas identified for UCSF's future (under Goal #4 charges above), what novel interdisciplinary and inter-school approaches should be developed to ensure success of the research enterprise?

b. What, if any, other resources (faculty, space, cores, etc.) are needed to ensure these approaches are successfully implemented?

GOAL #6: Develop innovative education and research programs across professional schools that support the vision for UCSF of promoting global health.*

Team Charges to Address the Goal:

a. What specific strategies are needed to advance innovative research in global health across professional schools at UCSF?

b. How can this best be accomplished across UCSF's professional schools?

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

GOAL #7: Strengthen relationships with other University of California campuses that provide collaborative opportunities with other science disciplines.

Team Charges to Address the Goal:

a. Given the priority research areas as well as the novel interdisciplinary and inter-school approaches identified above, what disciplines are not available at UCSF that will be needed in the future to advance the UCSF research agenda?

b. Which UC campuses have these disciplines as institutional strengths and represent potential collaborators?

c. What mechanisms and infrastructure are needed to facilitate these collaborations?

GOAL #8: Work in partnership with the community to reduce health disparities.*

Team Charges to Address the Goal:

a. How do we define "community" with respect to this goal?

b. In what ways, from a research perspective, is UCSF most likely to contribute to the reduction of health disparities?

c. Through which community partnerships can this goal be achieved? How can current community partnerships be strengthened to achieve this goal?

d. What are the objective measures to assess progress in meeting this goal?

GOAL #3: Provide a supportive work environment that fosters communication and collaboration.*

Team Charges to Address the Goal (note that ALL teams will address this Goal):

a. What strategies should be employed to protect the culture of collaboration at UCSF?

b. How best can UCSF address the challenges of communication, which is increasingly taxed as UCSF grows across multiple campuses and diversifies its missions?

c. What steps should be taken to provide a supportive work environment that fosters the core values identified for UCSF's future?

(Note: The top ten values identified through the strategic planning work are Excellence, Integrity, Leadership, Innovation, Collaboration/Collegiality, Respect, Scholarship, Diversity, Supportive Environment, Community Service. Most of these values are being addressed elsewhere in all six team charges.)

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

TEAM C: EDUCATION AND TRAINING FOR THE FUTURE

GOAL #5: Build novel interdisciplinary and inter-school approaches towards education, research and health care that prepare UCSF for the future.*

Team Charges to Address the Goal:

a. What are the educational needs of future students, residents, fellows, and post doctoral scholars?

b. Were interdisciplinary and inter-school educational programs and/or curricula identified as important pursuits for UCSF's future in response to question a?

c. What, if any, are the obstacles at UCSF to enhancing interdisciplinary and inter-school education? How should these be addressed to enhance interdisciplinary and inter-school education at UCSF?

d. What other steps need to be taken to build new educational programs and approaches?

GOAL #6: Develop innovative education and research programs across professional schools that support the vision for UCSF of promoting global health.*

Team Charges to Address the Goal:

a. What types of educational programs are needed in global health and population sciences at UCSF and why are they needed?

b. What steps need to be taken to institute these programs at UCSF?

c. Are there strong models or examples of these programs elsewhere that UCSF may want to emulate?

GOAL #9: Enhance cross-training for faculty, students, residents, fellows and post-doctoral scholars that provides greater exposure to basic science training for clinicians and to clinical and health sciences training for researchers.

Team Charges to Address the Goal:

a. What strategies can UCSF implement to provide greater exposure to basic science training for clinicians?

b. What strategies can UCSF implement to provide greater exposure to clinical and health sciences for researchers?

c. How will success be measured in attaining this goal?

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

GOAL #8: Work in partnership with the community to reduce health disparities.*

Team Charges to Address the Goal:

a. How do we define "community" with respect to this goal?

b. In what ways, from an educational perspective, is UCSF most likely to contribute to the reduction of health disparities?

c. Through which community partnerships can this goal be achieved? How can current community partnerships be strengthened to achieve this goal?

d. What are the objective measures to assess progress in meeting this goal?

GOAL #3: Provide a supportive work environment that fosters communication and collaboration.*

Team Charges to Address the Goal (note that ALL teams will address this Goal):

a. What strategies should be employed to protect the culture of collaboration at UCSF?

b. How best can UCSF address the challenges of communication, which is increasingly taxed as UCSF grows across multiple campuses and diversifies its missions?

c. What steps should be taken to provide a supportive work environment that fosters the core values identified for UCSF's future?

(Note: The top ten values identified through the strategic planning work are Excellence, Integrity, Leadership, Innovation, Collaboration/Collegiality, Respect, Scholarship, Diversity, Supportive Environment, Community Service. Most of these values are being addressed elsewhere in all six team charges.)

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

TEAM D: CLINICAL CARE: QUALITY, SAFETY, ACCESS AND PATIENT SATISFACTION

GOAL #10: Develop systematic approaches that enhance health care quality and patient safety, access and satisfaction.

Team Charges to Address the Goal:

a. What mechanisms are in place at UCSF to monitor and manage each of these parameters?

b. What evidence do we have of success or failure in these domains?

c. What strategies should be implemented to enhance UCSF's performance in health care quality and patient safety, access and satisfaction? Specifically consider both inpatient and outpatient care at all sites.

GOAL #5: Build novel interdisciplinary and inter-school approaches towards education, research and health care that prepare UCSF for the future.*

Team Charges to Address the Goal:

a. What interdisciplinary and inter-professional approaches towards health care are important pursuits for UCSF's future?

b. What, if any, are the obstacles at UCSF to enhancing interdisciplinary and inter-professional health care? How should these be addressed to enhance interdisciplinary and inter-professional health care at UCSF?

c. What steps need to be taken to accomplish this Goal from a health care perspective? What resources may be required for successful implementation?

GOAL #8: Work in partnership with the community to reduce health disparities.*

Team Charges to Address the Goal:

a. How do we define "community" with respect to this goal?

b. In what ways, from a health care perspective, is UCSF most likely to contribute to the reduction of health disparities?

c. Through which community partnerships can this goal be achieved? How can current community partnerships be strengthened to achieve this goal?

d. What are the objective measures to assess progress in meeting this goal?

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

GOAL #3: Provide a supportive work environment that fosters communication and collaboration.*

Team Charges to Address the Goal (note that ALL teams will address this Goal):

a. What strategies should be employed to protect the culture of collaboration at UCSF?

b. How best can UCSF address the challenges of communication, which is increasingly taxed as UCSF grows across multiple campuses and diversifies its missions?

c. What steps should be taken to provide a supportive work environment that fosters the core values identified for UCSF's future?

(Note: The top ten values identified through the strategic planning work are Excellence, Integrity, Leadership, Innovation, Collaboration/Collegiality, Respect, Scholarship, Diversity, Supportive Environment, Community Service. Most of these values are being addressed elsewhere in all six team charges.)

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

TEAM E: INFRASTRUCTURE AND RESOURCES

GOAL #11: Secure sustainable and diversified funding to carry out the vision.

Team Charges to Address the Goal:

a. Considering all of UCSF's funding sources (EA pgs IV-2 and IV-3), what sources are the most likely targets for growth in the future?

b. What steps should UCSF take to secure those funds?

c. What alternatives should UCSF pursue in the event that these funds cannot be reliably secured?

d. How can UCSF foster its development efforts and increase endowments?

e. Should UCSF strengthen partnerships with private industry to diversify funding, and if so, how?

GOAL #12: Develop communication systems, including information technologies, that bridge missions, campuses, schools and departments, that allow all to operate efficiently, facilitate collaboration, and build community.

Team Charges to Address the Goal:

a. What systems are already in place at UCSF to facilitate communication, efficiency and collaboration? How can these systems be enhanced?

b. What duplicative systems are maintained by different schools, campuses and operating units that should be centralized?

c. Are there systems that are currently centrally administered that should be decentralized?

d. What new technology and/or infrastructure is needed to enhance efficiency, collaboration, and communication across campuses and schools?

GOAL #13: Increase recognition of UCSF's contributions and status in the local community, the state, nation and the world.

Team Charges to Address the Goal:

a. What has UCSF already done well to improve its recognition and status?

b. What strategies can UCSF implement that would increase recognition of its contributions and status:

- Locally?
- State-wide?
- Nationally?
- Internationally?

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

c. What additional steps are needed to enhance the stature of UCSF?

d. How will we know that UCSF's recognition has improved?

e. How should UCSF address the following recommendations, which surfaced during the Strategic Planning interviews, if at all?

- Strengthen public relations and marketing to promote UCSF's strengths and contributions to the Bay Area.
- Effectively utilize advisory groups, grateful patients and donors.
- Prepare an economic impact/community benefit analysis and statement.
- Improve communication and involvement with the Bay Area community and UCSF's neighborhoods.

GOAL #14: Provide facilities and infrastructure that accommodate planned growth, academic strategic priorities and UCSF's vision.

Team Charges to Address the Goal:

a. Given that UCSF has increased its total available square footage by 36 percent in the last five years, is more space needed? If so for what purpose and where should it be located?

b. Describe an optimal process for allocating space. How can space-related decisions be more transparent?

c. What types of infrastructure will be needed to ensure that top priority strategies (as recommended by each of the Strategy Design Teams) are successfully implemented at UCSF? What already exists or is planned for, what needs improvement and what would be new resource requirements?

d. Assuming that a multi-campus configuration is likely to exist for several more years, if not permanently, what steps should be taken to maintain unity and ease the difficulties caused by geographic dispersion?

GOAL #15: Streamline or enhance management practices to ensure accountability and transparency throughout UCSF.

Team Charges to Address the Goal:

a. What processes and practices at UCSF need to be streamlined or enhanced?

b. Does "streamlining" necessitate greater centralization or decentralization? If so, how will departments be convinced/compelled to relinquish control and perhaps customization and flexibility and/or accept additional responsibility and accountability? If not, what is the definition of streamline?

c. What principles and techniques should be employed to streamline or enhance processes identified in question a?

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

d. What is currently obscured that should be made more transparent? What techniques should be used to increase transparency?

GOAL #3: Provide a supportive work environment that fosters communication and collaboration.*

Team Charges to Address the Goal (note that ALL teams will address this Goal):

a. What strategies should be employed to protect the culture of collaboration at UCSF?

b. How best can UCSF address the challenges of communication, which is increasingly taxed as UCSF grows across multiple campuses and diversifies its missions?

c. What steps should be taken to provide a supportive work environment that fosters the core values identified for UCSF's future?

(Note: The top ten values identified through the strategic planning work are Excellence, Integrity, Leadership, Innovation, Collaboration/Collegiality, Respect, Scholarship, Diversity, Supportive Environment, Community Service. Most of these values are being addressed elsewhere in all six team charges.)

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

TEAM F: LEADERSHIP AND GOVERNANCE

GOAL #16: Ensure top quality institutional leadership for UCSF to excel.

Team Charges to Address the Goal:

a. How does UCSF currently select senior institutional leaders? Outline an ideal selection process for the future.

b. What strategies should UCSF implement to recruit and retain top executive leadership?

c. What mechanisms are in place to evaluate leadership performance? What process and criteria should be considered to evaluate leadership across UCSF? Should specific rewards or consequences be assigned to enhance accountability? If so, what are they?

d. How does the current organizational structure inhibit or encourage strong leadership and accountability? What changes are needed to enhance these?

e. How should UCSF go about sustainably grooming next generations of leadership?

f. How can UCSF generate and foster a culture of leadership?

GOAL #3: Provide a supportive work environment that fosters communication and collaboration.*

Team Charges to Address the Goal (note that ALL teams will address this Goal):

a. What strategies should be employed to protect the culture of collaboration at UCSF?

b. How best can UCSF address the challenges of communication, which is increasingly taxed as UCSF grows across multiple campuses and diversifies its missions?

c. What steps should be taken to provide a supportive work environment that fosters the core values identified for UCSF's future?

(Note: The top ten values identified through the strategic planning work are Excellence, Integrity, Leadership, Innovation, Collaboration/Collegiality, Respect, Scholarship, Diversity, Supportive Environment, Community Service. Most of these values are being addressed elsewhere in all six team charges.)

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

APPENDIX - PRELIMINARY UCSF GOALS

GOAL #1: **Recruit, mentor and retain faculty, staff, students, resident, fellows, and post doctoral scholars of the highest caliber.**

GOAL #2: **Educate and employ a diverse workforce.**

GOAL #3: **Provide a supportive work environment that fosters communication and collaboration.***

GOAL #4: **Foster the UCSF research enterprise across multiple sites; determine priority research areas, as well as the criteria for defining priorities, for further development.**

GOAL #5: **Build novel interdisciplinary and inter-school approaches towards education, research and health care that prepare UCSF for the future.***

GOAL #6: **Develop innovative education and research programs across professional schools that support the vision for UCSF of promoting global health.***

GOAL #7: **Strengthen relationships with other University of California campuses that provide collaborative opportunities with other science disciplines.**

GOAL #8: **Work in partnership with the community to reduce health disparities.***

GOAL #9: **Enhance cross-training for faculty, students, residents, fellows and post-doctoral scholars that provides greater exposure to basic science training for clinicians and to clinical and health sciences training for researchers.**

GOAL #10: **Develop systematic approaches that enhance health care quality and patient safety, access and satisfaction.**

GOAL #11: **Secure sustainable and diversified funding to carry out the vision.**

GOAL #12: **Develop communication systems, including information technologies, that bridge missions, campuses, schools and departments, that allow all to operate efficiently, facilitate collaboration, and build community.**

GOAL #13: **Increase recognition of UCSF's contributions and status in the local community, the state, nation and the world.**

GOAL #14: **Provide facilities and infrastructure that accommodate planned growth, academic strategic priorities and UCSF's vision.**

GOAL #15: **Streamline or enhance management practices to ensure accountability and transparency throughout UCSF.**

GOAL #16: **Ensure top quality institutional leadership for UCSF to excel.**

** Goal will be addressed by more than one Strategy Design Team: Please see Appendix for a complete list.*

Appendix 4
Ac Freedom 2006-07

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

ACADEMIC SENATE www.ucsf.edu/senate

COMMUNICATION FROM THE CHAIR OF THE COMMITTEE ON ACADEMIC FREEDOM

Stuart Gansky, DrPH, Chair

September 14, 2006

Deborah Greenspan, DSc, BDS
Chair, UCSF Academic Senate
Campus Box 0764

RE: University of California San Francisco, Strategic Planning Phase III: Strategy Development

Dear Chair Greenspan,

The Committee on Academic Freedom (CAF) met on Tues 12 Sept 2006 and reviewed the document entitled *UCSF-Strategic Planning Phase III: Strategy Development*. Comments from members unable to attend the meeting were sought and incorporated into this summary. The Committee viewed this document paying particular attention to the questions:

Are there any possible academic freedom issues with the goals and charges?
Are the right goals listed under the correct teams?
Should any goals be added to the teams?
Are there any major areas of omission or error?

Recommendation, comments and concerns are compiled below. (Recommended deletions are shown with ~~strikethroughs~~ and additions with underlines.)

- CAF endorses the goal of strategic planning for UCSF and marshalling resources to support campus-wide strategic initiatives; CAF applauds the diligence and dedication of members of the UCSF community for their work so far.

- To have the widest acceptance, ownership and ultimately implementation of the Strategic Plan by faculty, CAF strongly recommends that additional efforts be undertaken to include a wide range of faculty from all schools, series and ranks throughout the continuing process within the dual governance structure.

    - Moreover, CAF strongly recommends adding an explicit goal that primarily falls under Team F: Leadership and Governance, but should be included for each of the design teams: Goal #17: Build upon the strengths of dual governance at UCSF*

    - Also, CAF recommends the appropriate modification:

Goal #16: Ensure top quality institutional leadership for UCSF to excel, within the dual governance structure.

- Although some CAF members' scholarly work dovetails with the directions of the Strategic Plan Goals, CAF had concerns that the Plan must include language explicitly stating that the diversity of ideas for faculty research, teaching, and clinical care will remain valued, respected and rewarded, so creativity can continue to flourish. CAF strongly recommends emending some of the goals accordingly.

    - Goal #4: Foster the UCSF research enterprise across multiple sites; determine priority research areas, as well as the criteria for defining priorities, for further development, while ensuring support for the diversity of ideas.

    - Goal #7: Strengthen relationships with other University of California campuses that provide collaborative opportunities with other ~~science~~ disciplines.

    - Goal #11, Charge e. Should UCSF strengthen partnerships with private industry to diversify funding, and if so, how in order to maintain academic independence and diversity of viewpoints?

- Goal #15, steps should be taken to ensure "streamlining" does not aversely impact academic freedom if faculty preferences (e.g. vendor choices), especially established and productive ones, do not meet with the strategic plan's management practices or if those processes slow or impede the progress of scholarly activity.

    - Goal #15: Streamline or enhance management practices to ensure accountability and transparency throughout UCSF, while ensuring that practices do not impede scholarly activity.

- Goal #1 in accordance with prior campus studies and reports, the appropriate balance of series and rank must be ensured for an equitable and sustainable faculty structure at UCSF. Also, research priorities set could well impact recruitment and retention efforts. Thus, the following charges should be added:

    - f. What strategies should UCSF implement to ensure an equitable and sustainable balance of faculty series and rank?

    - g. What is the impact of research, education, and clinical care priorities on recruitment and retention?

- Goal #6, some faculty and students have encountered barriers impeding their ability to freely pursue educational experiences to promote global health; thus, CAF suggests adding another charge:

    - d. What barriers (including legal ones) impede faculty from freely developing innovative educational pursuits promoting global health and how can those barriers be reduced?

Respectfully submitted,

Committee on Academic Freedom

Stuart Gansky, DrPh, Chair
Jim Lightwood, PhD
Miriam Kuppermann, PhD, MPH
Victor Reus, MD
Mary White, MPH, PhD
Elizabeth Boyd, PhD
C. Anthony Hunt, PhD
Descarte Li, MD
Maurice Zwass, MD

Appendix 5
Fac Wel 2006-07

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

ACADEMIC SENATE www.ucsf.edu/senate

Tamara Maimon, Director
500 Parnassus, MUE 230
San Francisco, California

Deborah Greenspan, DSc,BDS,
Chair
David Gardner, MD, MS Vice

EVC and Provost A. Eugene Washington, MD, Co-Chair
Professor Elizabeth Blackburn, PhD, Co-Chair
UCSF Strategic Planning Board
Campus Box 0400
ATTN: Julie Kuznetsov, Director, Strategic Planning

September 27, 2006

Dear Drs. Washington and Blackburn:

Thank you for the opportunity for the Academic Senate to review and comment on the UCSF Strategic Planning Phase III, Strategy Development document.

Enclosed, please find individual communications from Academic Senate Committees, a summary overview of Senate Committee responses by goals, a revised table (dated September 26, 2006) with additional names suggested for Academic Senate faculty to participate on UCSF strategic planning teams and a copy of the Academic Senate Task Force Report on Faculty Recruitment, Retention and Promotion (also available online at the following URL: http://www.ucsf.edu/senate/0-taskforcesadhoc/v2-FRRP-Report.html).

We would like to highlight the four key areas noted below as specific concerns that should be addressed:

Make recruitment and retention of a diverse and outstanding faculty among the highest priorities. Particular focus should be given to the findings and recommendations contained in the Academic Senate Report on Faculty Recruitment, Retention and Promotion.
Care should be taken when defining “priority research areas” so that it is not exclusionist in nature. Academic Senate members believe that while emphasizing specific research areas might be beneficial, prioritizing specific areas might lead to problems with recruitment and retention.
The Academic Senate favors the more detailed approach listed in Dr. Irby’s list of goals in defining what the needs will be in sustaining educational excellence.
Development of new infrastructure and allocation of resources should be balanced across all campus sites in the system, not just focused on Mission Bay.

Please feel free to contact us if you have any questions or need additional information.

Yours sincerely,

Deborah Greenspan, DSc, BDS
Chair, Academic Senate

David Gardner, MD, MS
Vice Chair, Academic Senate

300-19 Expenditures of Extramural Funds

Effective Date: 1/1/92 (revised 2/1/97)
Office of Origin: *Budget and Finance--Accounting*

I. Purpose

Expenditures of extramural funds are subject to audit by funding agencies. To avoid financial liability as a result of audit disallowance, it is the responsibility of the principal investigator to incur expenditures in accordance with applicable guidelines: (a) the cost principles contained in the *Office of Management and Budget (OMB) Circular A-21*, Cost Principles for Educational Institutions; (b) the terms and conditions of each extramural award; and (c) any other applicable University policies.

II. Definitions

Extramural funds: contracts and grants awarded through, and formally accepted by, the Contracts and Grants Division of the Office of Research Affairs for research, instruction, training, or public services.

III. Policy

A. Expenditures Under Extramural Funds

1. The principal investigator must incur expenditures within the project period as outlined in the award document. Exceptions must be authorized by the Contracts and Grants Office or the appropriate official from the funding agency.

2. The general ledgers should be reviewed regularly to ensure budgetary control and appropriate recording of expenditures.

3. The expenditures incurred must be allowable as per project terms and conditions and, as applicable, defined by *Office of Management and Budget (OMB) Circular A-21*, Cost Principles for Educational Institutions.

4. The principal investigator must exercise caution so that the expenditures incurred under each project are within the total authorized budget. In the event of cost overrun, the principal investigator is responsible for the transfer of such overrun out of the project.

B. Transfer of Expenditures of Extramural Funds

1. Initial care should be exercised to ensure that expenditures are charged to the correct account. However, if an error needs correction, a transfer of expenditures is necessary (see Administrative Policy 300-22, Cost Transfers).

2. When employees transfer from, to, or between governmentally funded projects the vacation accrual liability is transferred at the current pay rate from the old funding source to the new one. If the funding change is partial, the accrual is split on a pro-rata basis and the

appropriate amount of accrued vacation is transferred accordingly.

3. A cost transfer is required when the sole purpose is to clear an overdraft of the extramural funds.

4. If an overdraft is not cleared by the principal investigator in a timely manner, the Accounting Office has the authority to transfer the over-expenditures to other funds.

C. Financial Reporting of Extramural Funds

1. The principal investigator must ensure that all financial transactions are recorded properly and timely on the general ledgers so that financial reporting responsibility can be carried out by the Accounting Office.

2. The general ledger is the official record of financial detail and is the basis for all financial reports.

IV. Responsibility

A.Principal Investigator

The principal investigator is responsible for the fiscal management of the project. It is operationally feasible for the principle investigator to delegate financial management to his or her administrative staff.

B.Accounting Office

Accounting is responsible for the set-up and close-out of contracts and grants, financial reporting, and collection of reimbursement of expenditures incurred.

V. Related Policies

- Cost Transfers (Expenditure Adjustments) (Policy 300-22)
- Award Acceptance and Execution of Contracts and Grants (Policy 400-16)

VI. References

- *Contract and Grant Manual*, Office of the President
- *Office of Management and Budget (OMB) Circular A-21*, Cost Principles for Educational Institutions
- *UCSF Accounting Website*

COMMITTEE ON ACADEMIC FREEDOM
Stuart Gansky, DrPH, Chair

Questions Regarding Policies and Practice for Extramural Grant Fund Overspending

1. When does overdraft shift from accidental / incidental to negligence? (e.g. does the PI "regularly" reviewing accounts and keeping records demonstrate fiduciary duty? is there a dollar amount/percentage or a certain amount of time with continued spending despite written warnings that indicates negligence?)

2. If the PI has been warned and continues to spend resulting in overdraft, is that an infraction for which disciplinary action be taken?

3. Can disciplinary action mean that a faculty member can be compelled to pay back the overdraft with personal funds?

4. What is the due process for such disciplinary action and what recourse does a PI have?

5. Is there a statute of limitations for a PI being presented with information about overdrafts and what appropriate documentation is needed?

Related Reference
300-19 Expenditures of Extramural Funds http://policies.ucsf.edu/300/30019.htm

Communication from the Task Force to Review the Draft Proposal on the Relationships between (Pharmaceutical) Vendors and Clinicians

Daniel Bikle, MD, PhD, Chair

March 15, 2007

RE: Faculty Response to Proposed UC (Pharmaceutical) Vendor Relations Policy

Dear Faculty Council Chair:

The University of California Office of the President (UCOP) has drafted a Proposal on the Relations Between (Pharmaceutical) Vendors and Clinicians (http://www.universityofcalifornia.edu/senate/underreview/Proposedpharmaceuticalpolicies.0107.pdf) and distributed it to the campuses for review and comment. The UCSF Academic Senate has convened a task force to draft the response. In an effort to represent your views on this matter, the task force would like your feedback regarding five key issues.

Please send your responses by **Tuesday March 27, 2007** to the Senate Analyst for this Task Force, Heather Alden (HAlden@senate.ucsf.edu) so they may be compiled and discussed at the next Task Force meeting.

ISSUE #1: DE MINIMIS (e.g. the magnitude of the gift)

DOCUMENT LANGUAGE:

Section IV. B. (lines 36-38) includes items such as pens, notepads, textbooks and meals in the definition of gifts to individuals. Section V. B. 1. (line 78) states, "Gifts from vendors to an individual are prohibited."

QUESTION #1 FOR FACULTY:

(Please indicate your pro or con opinion and any comment.)

Should the University determine an acceptable dollar amount for gifts (such as $5 or $10) for faculty for conferences on the UCSF premises (rather than banning individuals from accepting them altogether)? If not, should the individuals be allowed to accept similar items commonly distributed at meetings off site?

PRO/CON ARGUMENT:

PRO: Creating a de minimis amount for gifts would allow vendors to continue to provide low-dollar-value items for faculty, including food at conferences held on UCSF premises.

CON: Social science research (cited in the attached article from Brennan et al, JAMA 2006, p. 430-431 (http://www.universityofcalifornia.edu/senate/underreview/brennan.pdf) indicates that even small gifts can influence the behavior of individuals.

ISSUE #2: FOOD PROVIDED FOR GENERAL CONFERENCES

DOCUMENT LANGUAGE:

Section V. B. 2. (lines 79-89) states that vendors could, "replace the free food or payment for educational travel [by donating] funds to a unit of the University (e.g., department or division) to support meetings."

QUESTION #2 FOR FACULTY:

(Please indicate your pro or con opinion and any comment.)

Should free food be allowed at conferences and educational events on the UCSF premises? If so, should they be paid for using funds distributed by a department or division (which may have originally come from a vendor)?

PRO/CON ARGUMENT:

PRO: Eliminating food provided by vendors to faculty members would reduce vendors' presence at faculty education events. Channeling the distribution of funds through a campus unit such as a department or division could reduce the potential for a conflict of interest for individual faculty members.

CON: Eliminating vendor-funded food or channeling vendor food funding through departments could increase the demands on department resources, both monetary and personnel. Departments and/or individual faculty members would need to provide funds and/or manage the vendor funds for food for conferences and educational events. This would likely decrease food provided for many noon conferences and could undercut attendance.

ISSUE #3: VENDOR SAMPLES FOR PATIENTS

DOCUMENT LANGUAGE:

Section V. B. 3. (lines 90-101) states, "Sample donations are restricted to the amount necessary for evaluation or education, and are not intended to stock the University for patient care purposes on an ongoing basis."

TASK FORCE DISCUSSION:

Many clinics are eliminating samples because maintaining samples for distribution to patients (other than for evaluation or education purposes) conflict with existing State pharmacy laws.

QUESTION #3 FOR FACULTY:

(Please indicate your pro or con opinion and any comment.)

Should vendors be permitted to stock clinics with samples for patient care?

PRO/CON ARGUMENT:

PRO: In some cases, samples from vendors may be the only medication to which a patient with limited financial resources has access.

CON: The availability of samples in the clinic may influence physician decisions with regard to patient care.

ISSUE #4: TRAVEL AND LODGING REQUIRED FOR TRAINING ON EQUIPMENT

DOCUMENT LANGUAGE:

Section IV. B. 2. e. (lines 58-63) states that although individuals may accept "free admission, and refreshments and similar non-cash benefits" during a training session, individuals may not accept travel or lodging in association with training. Furthermore, the proposed policy states, "If free training is anticipated, it shall be referenced in the purchase contract for the vendor's product." Travel for the purpose of training on equipment at the vendor's expense can be considered a gift.

QUESTION #4 FOR FACULTY:

(Please indicate your pro or con opinion and any comment.)

Should vendors be allowed to provide travel and lodging for the purposes of training on equipment being purchased by faculty if such training cannot be readily performed on site? If travel and lodging for equipment training purposes are allowed, should it be written into the purchase contract?

PRO/CON ARGUMENT:

PRO: Vendors will bear the cost of travel and lodging for off-site training on equipment purchased by a faculty member. If included in the purchase contract, then the terms of the travel and lodging will be determined at the time of the purchase of the equipment and subject to conflict of interest review.

CON: The University and/or the faculty member will bear the cost of travel and lodging for off-site equipment training. Travel and lodging paid for by vendors under any circumstance is considered a gift to an individual.

ISSUE #5: PATIENT INFORMATION DOCUMENTS

DOCUMENT LANGUAGE:

The proposed policy does not address the issue of patient information documents provided by vendors.

QUESTION # FOR FACULTY:

(Please indicate your pro or con opinion and any comment.)

Should vendors be allowed to provide information documents for patients?

PRO/CON ARGUMENT:

PRO: Vendors are known to produce excellent documents. The cost and effort associated with reproducing those documents on campus or purchasing them from an outside source may reduce their availability for clinics.

CON: Documents provided by vendors will not provide a critical, unbiased view of their own products.

Should you have any questions, please do not hesitate to contact me (Daniel.Bikle@ucsf.edu) or Heather Alden (HAlden@senate.ucsf.edu).

Sincerely,

Daniel Bikle, MD, PhD, Task Force Chair

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

ACADEMIC SENATE www.ucsf.edu/senate

Communication from the Task Force to Review the Proposed Guidelines Regarding Vendor Relations

Daniel Bikle, MD, PhD, Chair

May 2, 2007

Deborah Greenspan, DSc, BDS
Chair, UCSF Academic Senate
Office of the Academic Senate, Box 0764

RE: Recommendations for Divisional Response to the Proposed Guidelines Regarding Vendor Relations

Dear Chair Greenspan:

The Task Force to Review and Recommend Divisional Response to the Proposed Guidelines Regarding Vendor Relations consists of 12 members, including one member from each School Faculty Council and one member from each of the following committees: Academic Freedom, Academic Planning and Budget, Clinical Affairs and Research. One member is from the Department of Medicine, one member is from the School of Dentistry and one member is the UCSF Conflict of Interest Officer. The Task Force met three times, on February 22, April 2, and April 30, 2007.

As requested by Chair John Oakley, the Task Force reviewed the proposed guidelines (Part I of this communication) as well as three additional proposed policies (Part II of this communication).

Part I – Review of the Proposed Guidelines Regarding Vendor Relations

At the first meeting, five issues emerged from the discussion as follows:

1. ***De minimis*, e.g. the magnitude of the gift,**
2. **Food provided for general conferences,**
3. **Samples for patients (other than samples undergoing evaluation),**
4. **Travel and lodging required for training on equipment, and**
5. **Patient information documents.**

The Task Force drafted and circulated questions regarding these issues to the Faculty Councils of the four Schools and the Clinical Affairs Committee. Using the feedback received in response to these questions, the Task Force discussed the issues further and formulated the following recommendations. Associate Dean Neal Cohen attended the April 2, 2007 meeting as an invited guest and provided a history of UCSF's efforts to draft a vendor relations policy which contributed to the Task Force's discussion.

Issue 1: *De minimis*, e.g. the magnitude of the gift

Proposed Guidelines Section IV. B. (lines 36-38)
The Task Force agreed with the proposed policy that there should not be a *de minimus*, that minor gifts from vendors to individual faculty should not be distributed on campus. Whether such gifts could be accepted by faculty members off campus was not in the purview of the Task Force.

Issue 2: Food provided for general conferences on campus
Proposed Guidelines Section V. B. 2. (lines 79-89)
The Task Force supported the proposed language that individual vendors should not directly provide food for recipients on campus. However, the Task Force recommends that vendors could provide funds to departments or divisions for educational events, and that vendors may be invited to provide information at events on campus, but may not do so unsolicited. The Task Force agreed that it was important that the proposed policy retain the statement "These funds (i.e., for food or meetings) will be managed in accordance with national continuing education accrediting body conflict of interest standards even when the meetings are not accredited continuing education programs" (lines 85 – 87).

Issue 3: Vendor samples for patients
Proposed Guidelines Section V. B. 3. (lines 90-101)
The Task Force agreed that the University should discourage the use of 'drug closets' in clinics for routine dispersal of samples to patients. The Task Force also noted that these "drug closets" are being eliminated because they are not in compliance with California state pharmacy laws. However, the Task Force supports that drugs and devices may be used for evaluation and education as stated in proposed policy. Further, the Task Force recommends setting a limit to the evaluation/education period. The majority of the Task Force agreed that a three-month evaluation period was appropriate. Should a provider or clinic need evaluation/education time beyond three months, the provider or providers in the clinic should develop a plan with the appropriate division or department to justify the extension of the evaluation and/or education period.

Issue 4: Travel and lodging for training on equipment
Proposed Guidelines Section IV. B. 2. e. (lines 58-63)
The Task Force accepted the proposed policy recommendation that free lodging, meals and travel for training purposes should be restricted to equipment that has already been purchased. The provision of the free travel, meals and lodging to the trainees should be written into the purchase contract. Prior to purchase all expenses involved with the evaluation of a piece of a equipment are the responsibility of the purchaser. For demonstrations or training sessions which do not require substantial travel or lodging the Task Force needed clarification on the limits for free admission, refreshments and similar non-cash benefits to be provided by the vendor for the training session. For example, free admission and light snacks at trade fairs with multiple vendors were considered appropriate, but dinners put on by a single vendor for the purpose of discussing a product prior to its purchase was considered problematic.

Issue 5: Patient information documents
Although not explicitly covered by the proposed policy, the majority of the Task Force agreed that providing patient information documents to patients in the clinics was acceptable as long as such documents were judged to be free of bias by the clinic chief or his/her designee. These documents should be accompanied by a disclaimer from the relevant department or school indicating that the information was not an endorsement of either the vendor or the specific products described in the document.

Other issues

1. The Proposed Guidelines did not explicitly identify who was covered by the policy. For example, the Task Force seeks clarification if they will apply to volunteer faculty during their service at UCSF.
2. The Task Force requests clarification on how the proposed policy will be enforced.
3. At its next meeting the Task Force will evaluate the three additional issues raised by the Brennan report that were not addressed explicitly by the current UCOP draft policy, and will provide its recommendations for those issues in a separate report.
4. The Task Force recognizes that UCSF does not have a consistent policy dealing with these issues across all schools, and recommends that such an effort be made, using the finalized version of the UCOP policy as a starting point.

Part II – Review of Three Additional Proposed Policies

The Task Force reviewed the three proposed policies and offers the following responses.

1. **Faculty may not publish articles or editorials that are ghostwritten by vendor employees.**
   The Task Force defines ghostwriting as writing an article but not appearing as a co-author on the article. We recommend that faculty be discouraged from this practice as we feel it is unethical. Furthermore we recommend that the authors of publications should have access to the complete, accurately reported data set, and their analysis for the papers on which they are authors.

2. **"No strings attached" grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants).**
   The Task Force recognizes and supports that gifts for research are an important part of University life. However, totally unrestricted gifts should be prohibited. Gifts to individual faculty members from vendors must come through University channels via gift administration and development departments.

3. **All consulting agreement and unconditional grants shall be publicly listed (e.g., on an internet web site.**
   The Task Force applauds the effort to increase transparency for University faculty with respect to consulting agreements. We believe that the compensation plan disclosure forms provide the ability for the departments to evaluate the activities of individual faculty members for potential conflicts of interest. Furthermore, we encourage all faculty members to disclose his or her relationship(s) with the vendor(s) in publications and public lectures.

   The Task Force is aware that not all consulting agreements are reviewed by the University, and we encourage the University to develop a mechanism for reviewing these for compliance with University policies.

   If the term "unconditional grants" means a "no-strings attached" grant, please see the Task Force response to number two above.

The Task Force hopes you will find these recommendations helpful in forming a response from the San Francisco Division to the Academic Council.

Signed,

The Task Force to Review and Recommend Divisional Response to the Proposed Guidelines Regarding Vendor Relations

Daniel Bikle, MD, PhD, Task Force Chair, School of Medicine Faculty Council Chair
Brian Alldredge, PharmD, Associate Dean, School of Pharmacy
Gary Armitage, DDS, MS, School of Dentistry Faculty Council
Lisa Bero, PhD, Committee on Research
H. Quinn Cheng, MD, Committee on Clinical Affairs, School of Medicine Faculty Council
Stuart Gansky, DrPH, Committee on Academic Freedom
Sharad Jain, MD, Department of Medicine
Susan Lee, DMD, School of Dentistry
Deanna Rutter, UCSF Conflict of Interest Officer
Jean Ann Seago, RN, PhD, Committee on Rules and Jurisdiction, School of Nursing Faculty Council
Norman Oppenheimer, PhD, Committee on Academic Planning and Budget

Communication from the Task Force Reviewing and Recommending Comment to the Proposed Policy on Open Access

David Teitel, MD, Chair

May 2, 2007

Deborah Greenspan, DSc, BDS
Chair, UCSF Academic Senate
Office of the Academic Senate, Box 0764

RE: Suggestions for Divisional Response to the System-wide Senate Review of the Proposed Policy on Open Access

Dear Chair Greenspan,

The Task Force Reviewing and Recommending Comment to the Proposed Policy on Open Access, consisting of two members from the Committee on Library (Chair), one Member of the Committee on Research, one Member of the Committee on Academic Freedom, one Member from the School of Medicine Faculty Council and one Member from the School of Dentistry Faculty Council, met on May 2, 2007 to review the proposed policy and to suggest a possible response from the San Francisco Division.

First, the Task Force would like to state its strong support for the open access policy. We concur that such a policy greatly improves the ability of researchers to share their findings, which advances their own research and education goals as well as those of the University. By not transferring all of the rights for use of their work to the commercial publisher, faculty authors will be able to publish their work on open-access, non-commercial repositories. This will result in increased dissemination of that work, as evidenced by increased citations of research freely available on such repositories. Moreover, such a policy assists changes in the economics of publishing faculty research, by providing an alternative to the excessive subscription rates charged by some of the commercial publishers who have near monopoly control of certain areas of scientific publication.

As we considered the various “opt out” policies put forward in the draft, we were torn between the incongruent goals of ensuring the rapid adoption of a real open access environment versus protecting the faculty member to advance his/her career. Options A and B are most in keeping with the former goal, whereas option C is most in keeping with the latter, as it only requires notification of opting out by the faculty member. We are in agreement that open access should be achieved rapidly, and thus we would like to support options A or B. However, we are concerned that the administrative structure is not currently in place to ensure that the faculty is adequately supported when the issue of opting out surfaces. New resources must be developed to educate faculty about open access and how to ensure its availability to their work, to provide a database of the open access practices of the various publishers,

and to respond to questions from the faculty as they arise. Such resources must be readily available to each faculty member, both via the web and via direct, personal contact. Currently, adequate resources to respond to calls for detailed assistance do not exist, and there is no clear commitment that adequate numbers of “open access agents” will be hired to assist the faculty in negotiating with the publisher. If either option A or B is adopted, it must be done with a clear commitment that it will be enforced only once adequate resources have been established, and that ongoing assessment of the impact of such a policy on the publication of faculty work be monitored and evaluated within the first years of its adoption.

Lastly, the roles of the various offices and Academic Senate committees in determining and implementing the open access policy should be defined at a University-wide level. Who will monitor that the administrative support of the faculty is adequate, and who can the faculty turn to if it is perceived to be inadequate? Who will police faculty compliance, and who will determine to what extent open access practice by a faculty member is considered in advancement?

Although important issues must be addressed prior to the implementation of an open access policy, we strongly support this initiative, and are delighted that the University of California is in the vanguard of this critically important step toward the advancement of faculty scholarship.

Sincerely,

The Task Force Reviewing and Recommending Comment to the Proposed Policy on Open Access
David Teitel, MD, Committee on Library, Chair
Richard Schneider, PhD, Committee on Library
Lisa Bero, PhD, Committee on Research
Sheila Brear, DDS, School of Dentistry Faculty Council
James Lightwood, PhD, Committee on Academic Freedom
Lawrence Pitts, MD, School of Medicine Faculty Council