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.

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.

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)

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