January 8, 2007

Professor John Oakley
Chair of the Academic Council
1111 Franklin Street, 12th Floor
Oakland, CA 94607

In Re: Institutional Review Boards (IRB) at UC: IRB Operations and Research Experience

Dear John:

The UCLA Academic Senate was pleased to receive the report “Institutional Review Boards at UC: IRB Operations and Experience.” Upon receipt of the request for review, I invited all standing committees of the Academic Senate to opine. Additionally, I specifically requested that the following Senate Committees opine: Council on Research, Academic Freedom, Graduate Council, and the Executive Board. There is wide agreement that IRB are in need of reform. Generally, the responses to the report were positive and UCLA is prepared to endorse the report inasmuch as it seeks to address the IRB related problems at a Systemwide level. To make the report more relevant to our Division, we offer certain suggestions.

The concerns outlined in the Report are indeed representative of issues being raised nationally through various media pertaining to the regulation of human subjects research. The list of recommendations generally are reasonable and provide a framework for: (1) better understanding of the policies and procedures that govern human research; (2) promoting ways to increase efficiencies in the review process; and (3) improving customer service.

However, each of the ten UC campuses confronts its own individual set of challenges when it comes to IRBs. As our Graduate Council recognized, “within the UC System the volume of IRB workload differs considerably across campuses, as does the level of staff support provided to deal with the workload. For example, according to the UCORP-IRB Workload Summaries, UCLA IRBs had a total volume of over 6400 research protocols to process in comparison to other UC campuses like Irvine, San Diego, Davis, or Berkeley that had ½ to ¼ the volume of UCLA.” The sheer volume and specificity of the protocols handled by the UCLA IRB raise a set of issues that need to be addressed both internally as well as by its respective campus administration.

UCLA is prepared to endorse the report with the following insights:

- The UC should significantly expand the means whereby faculty may outsource their proposals for review by the regional ethics organizations (REOs) such as the Western Regional IRB. (Executive Board)
• Increase and provide sufficient IRB administrative infrastructure to properly serve the research community. With a sufficient number of highly trained administrative staff, OPRS IRB staff would be able to provide guidance and education on the front end before the Board reviews applications. With additional administrative IRB staffing, the work of the Board could be done in a timelier manner, which would significantly decrease delays in responses and approvals back to investigators. (Graduate Council)

• Provide sufficient resources for education and training at each individual campus because training needs differ from campus to campus. (Executive Board and Graduate Council)

• UCLA does not have a functional tracking system. The system in place cannot be enhanced and has not been changed since 1996. A viable, user-friendly, robust system is necessary for program accountability and to better facilitate the research enterprise of the University. *Priority should be given to create a system that can accommodate the workload as well as serve the research community.* (Executive Board and Graduate Council)

• Departments should be called upon to nominate senior, highly respected faculty to serve on the IRBs as representatives of their disciplines. Departments could also develop a pre-review process prior to submission of protocols to the IRB. (Graduate Council)

• Recognition and encouragement to serve on an IRB should come from the Chancellor of the University. It should then be endorsed and followed through by Department Chairs and Division Chiefs, nominating their best faculty to represent their disciplines. Service on IRBs should be given commensurate consideration during review of dossiers. (Graduate Council and Executive Board)

• Distinct, discipline-specific procedural guidelines for IRBs be developed that recognize, for example, the difference in risks to human subjects (e.g., medical research vs. sociological interviews) and that such protocols be developed in conjunction with experts in the various disciplines. (Executive Board and Academic Freedom).

I have attached the various responses from the committees at UCLA. Please do not hesitate to contact me, should you have any questions.

Sincerely,

Vivek Shetty
Chair, UCLA Academic Senate

Cc: Maria Bertero-Barcelo, Executive Director of the Systemwide Senate
Jaime R. Balboa, Chief Administrative Officer of the UCLA Academic Senate
DATE: December 8, 2006
TO: Vivek Shetty, Chair, Academic Senate
FROM: Council on Research Meeting November 3, 2006
RE: System-Wide Review of the Universitywide Committee on Research (UCORP) IRB at UC: IRB Operation and the Researcher’s Experience

UCLA’s Council on Research (COR) discussed the above-entitled action item during their November 3, 2006 meeting. This review was requested by UCORP in coordination with the University Committee on Academic Freedom, the Coordinating Committee on Graduate Affairs and the Office on Research to inquire into the operations of UC-based IRBs. UCORP held discussions with UCOP Office of Research, local IRB offices, and PIs and other faculty. Concerns have been raised by faculty that there is interference with faculty research, “being overzealous” and “creating an unreasonable level of difficulty with the IRB approval process”.

One major concern raised was the absence of formal procedures to challenge an IRB decision. In fact, IRB decisions cannot be overturned by any other institutional authority. IRBs are answerable to the Vice Chancellor for Research with regarding to operations but not to decisions.

In addition, concerns were raised about inconsistent interpretations of regulations, uncertainty of scope of IRB oversight, and their intrusion on research activity of faculty. Faculty members at UCLA in particular have expressed strong concerns that the IRB interferes in their research methodology beyond their main charge of human safety.

UCOP Findings:

Research complaints centered around dissatisfaction with IRB customer service, slow turnaround time, excessive paperwork, staff unresponsiveness, rudeness and/or obstructionism. Staff thought, as well, that some faculty were abusive, do not respond to request in a timely manner and expect staff to “kowtow” to their authority.

Survey responses revealed:
1) Marked variation among UC campuses in level of IRB funding and in the degree of professional training;
2) Lack of coordination between campus IRBs in protocol review and approval;
3) Differences among IRBs in interpretation of federal regulations;
4) Frustration of faculty; reported process 1 – to longer than 6 months;
5) Lost or misplaced files;
6) Poor communication; can negatively impact one’s research funding;
7) Lack of channels to voice dissatisfaction. This was a major concern in most campuses. Berkeley Academic Senate stepped in to appoint the IRB chair and oversee operations;
8) Social and behavioral scientists are upset by inappropriate use of medical model for ensuring protection of human subjects, as their research is mostly administration of questionnaires and surveys and not invasive procedures

University of California, Irvine has a good model to view regarding delivery of information and advice.

**Recommendations of the Committee**

1) Increase funding for staff augmentation and training. All campuses were in need of increased support for training. Indirect funds at the systemwide level be applied to systemwide training of IRB directors, members and staff;
2) Facilitate systemwide coordination in training – avoid interpretation differences;
3) Establish a forum for the systemwide discussion of major issues in human subjects research and system-wide policy guidelines that should be followed in all the UC campuses;
4) Evaluate electronic submissions and review tracking systems – not knowing the progress – similar to online journals. Emphasis on web-based application submission and tracking system should be a priority and should be implemented as soon as possible;
5) Establish mechanisms for local campus oversight of IRB operations – local Academic Senates should have a voice in the evaluation of IRBs:
   - Monitor level of faculty satisfaction
   - Consider AAHRPP which requires feedback mechanism
   - Set performance standards regarding on-time performance, reasons for failed protocols, number of transactions per protocol, differences among disciplines
   - Establish an independent process by which faculty can voice dissatisfaction
   - Establish policy through campus Vice Chancellor for Research calling for annual report
6) Cultivate greater faculty familiarity with Human Subjects Protocol issues;
7) Encourage faculty recruitment and recognition of service; compensation, merit recognition and dept chair vested interest;
8) Social sciences and humanities IRB process should be revisited especially projects that are dealing with administration of questionnaires and surveys only, maybe consider exemption category as opposed to expedited or full review process.

The Council on Research endorses these recommendations.

Sincerely,

[Signature]

Ajit K. Mal, PhD
Chair, UCLA Council on Research
November 29, 2006

To: Vivek Shetty, Chair
   Executive Board, UCLA Academic Senate

From: Hossein Ziai, Chair
   UCLA Committee on Academic Freedom


The Committee on Academic Freedom reviewed the July 2006 Report of the University Committee on Research Policy (UCORP). We have the following reactions and recommendations:

While recognizing the importance of keeping all research on human subjects within legal and ethical bounds, we believe there is a significant concern about IRBs infringing on the academic freedom of faculty and graduate students. IRBs were originally designed to protect the health, welfare and privacy of patients subjected to medical research where there is a real risk of physical harm. The extension of this model of supervision to the humanities and social sciences, along with the inevitable ‘mission creep’ of any bureaucratic institution has meant that researchers outside of the natural sciences can be subjected to inappropriate restrictions and unnecessary requirements to justify what are normal research methods. Beyond the delay and bother these cause (which are certainly important issues, but not within our jurisdiction), we feel that there is both a real loss and a chilling effect with respect to academic freedom as a result. While it is not within our capacity to quantify how far this has occurred within the UC system, the anecdotal evidence that it has occurred here and at other institutions nationwide is sufficient for us conclude that some remedy is needed.

In general, we feel that research that involves observation of public behavior, surveys or conversations with competent adults (and which therefore resembles the work that journalists or polling firms do constantly without any IRB-like supervision) does not present a risk of a recognizable harm to its subjects that is in any respect similar to what occurs in a medical setting. Risks of offense or hurt feelings are something that exist in any human interaction and autonomous adults can be presumed able to manage these risks for themselves. (When
those being studied are children or those otherwise deemed mentally incompetent, of course, the situation is different.)

The division of UCLA’s IRBs into north- and south-campus groups is a step in the right direction. However, from what we have been able to gather, the procedures of the north-campus IRBs are little different from the south-campus ones.

We recognize, of course, that there are federal regulations and legal concerns which have guided the development of the IRBs to this point and that any reform of the process will have to take these into account. We feel, however, that the search for legal safe-harbor has been undertaken without sufficient concern for the effects of the sweeping authority of IRBs on academic freedom. Our recommendations are intended to redress this imbalance.

- The committee recommends that there be a separate set of IRB procedural guidelines for the social sciences and humanities different from that in the life-sciences – the IRB process and protocol need to be field-appropriate. We do not offer specific recommendations in this regard but suggest instead that the IRBs reconsider their protocols from the ground up in consultation with representatives from the various fields to be governed or that a special ad hoc multi-disciplinary committee be formed to examine this question.

- The committee, furthermore, strongly endorses proposed AAUP language from a report published October 2006 stating that “research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review...”. If legal constraints prevent the full implementation of this language, we recommend the exploration of a ‘notification-only’ status where researchers that employ such methods would notify the IRB of their work but not be required to obtain approval.
December 8, 2006

TO: Vivek Shetty, Chair, Academic Senate

FROM: Roger Savage, Chair, Graduate Council

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

At its meeting of December 8, 2006, the Graduate Council discussed the UCORP Report on Institutional Review Boards (IRBs) at the UC. The lead reviewers, Professors Grijalva and Franke, have prepared an excellent summary report outlining the issues of Institutional Review Boards and their processes at UCLA. Moreover, the subcommittee met with Judith Brookshire, Director, UCLA office for the Protection of Research Subjects (OPRS) to discuss the Report and the list of recommendations as they are related to UCLA.

When a motion was called, the Graduate Council unanimously endorsed the report. If you have any questions related to the report, please do not hesitate to contact me at Rsavage@ucla.edu.

Cc: Jaime Balboa, CAO, Academic Senate Office
    Graduate Council Members and Student Representatives