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May 22, 2007

WYATT R. HUME
PROVOST AND EXECUTIVE VICE PRESIDENT-ACADEMIC & HEALTH AFFAIRS

Re: Academic Council Report on Institutional Review Boards at UC

Dear Rory,

At its April 25, 2007 meeting, the Academic Council unanimously endorsed the enclosed report, "Institutional Review Boards at UC: An Inquiry into IRB Operations and the Researcher's Experience," which was recently finalized by the University Committee on Research Policy (UCORP). I am pleased now to forward the report to you for consideration of its findings and recommendations.

The report suggests a number of measures that will work within the context of the University's ethical and legal responsibilities for the conduct of human subjects' research to improve interactions between IRBs and researchers, refine the review process, and generally increase awareness of the nature and function of IRBs. As you may know, 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, who, along with Senate committees and Divisions, provided feedback on an earlier iteration of the report. The enclosed final version reflects that broad discussion and includes a set of recommendations organized into three sections: 1) policy changes; 2) measures for improved IRB service; and 3) actions that can facilitate an engaged discussion of IRB issues both within the university and at the national level.

The Academic Council would like to see these recommendations in practice as soon as feasible, especially those (a) establishing electronic submission and tracking of protocols and (b) creating teaching mechanisms to increase faculty awareness of human subjects' protection issues and the IRB review process overall. Therefore, we respectfully request:

- 1) An outline of steps that will be taken to implement the recommendations, and an explanation, where applicable, of why any recommendations were not adopted; and
- 2) Plans for a follow-up review of IRB operations and implementation of the measures recommended in the report, to be conducted jointly with the Senate within three years of implementation.

On our part, UCORP and the Academic Council will assume the task of monitoring implementation and related developments through reports from our members. I am optimistic that the Senate's advice can lead to improved IRB operations as well as ease the review process for UC investigators whose research involves human-subject participation. I look forward to your response.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Oakley', is centered below the word 'Sincerely,'.

John B. Oakley, Chair
Academic Council

Copy: Academic Council
María Bertero-Barceló, Senate Executive Director

Enclosure: 1

JOBGP

INSTITUTIONAL REVIEW BOARDS AT UC:

IRB OPERATIONS AND THE RESEARCHER'S EXPERIENCE

REPORT OF THE UNIVERSITY COMMITTEE
ON RESEARCH POLICY
(UCORP)

Endorsed by the Academic Council
April 25, 2007

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**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

REVISED APRIL 2007

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 human subjects 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 call for IRB reform include: the formal Statement of the American Association of University Professors specific to IRBs and social science research⁵; 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 oversight⁸; a National Research Council report recommending guidelines to enhance the effectiveness of reviews commensurate with the level of risk⁹; 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 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 Chicago¹¹. Given these examples, IRBs regard part of their *raison d’être* 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 social science and humanities 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 social science and humanities 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 and social science and humanities 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. How the regulations are interpreted and how IRB staff (and board members) and researchers interact are fluid areas connecting these opposing demands.

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.

A 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 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 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 science and humanities 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 social science and humanities protocols is a central criticism in the published discourse on IRB reform.¹⁶ UC sources parallel this complaint. UC researchers in the social sciences and humanities 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 social science and humanities 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 social science and humanities 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

POLICY RECOMMENDATIONS FOR SYSTEMWIDE AND CAMPUS ADMINISTRATION

These measures respond to areas of critical need as identified in UCORP's findings and in the comments from Senate Committees and Divisions.

1. Create systemwide guidelines that directly address concerns with the IRB review process and related practices.

We recommend that the Office of the President, in consultation with appropriate systemwide and divisional Senate bodies:

1.1 Draft and oversee implementation of standard protocol application template(s) specifically tailored to methodologies commonly used in social science and humanities research. The template (s) should include:

- A full practical definition of informed consent, and full clarification of when informed consent is required;
- Clarification of the nature and needs of classroom and pedagogical research.

1.2 For those campuses that do not have a separate IRB for the review of social science and humanities protocols, ensure that IRB members and staff have relevant expertise in or thorough appreciation of research methodologies commonly in those disciplines or as applied by other disciplines.

1.3 Convene a panel to examine how academic departments can be allowed limited control over human subjects protection. The panel would consider development of a systemwide provision for agreements between IRBs and departments allowing preliminary determination of exempt, and in some cases, expedited status of protocols at the department level. We believe this streamlined review option would be especially appropriate for humanities and social science research and for graduate student proposals.

1.4 Review the university's policy that requires IRB approval of all human subjects research, including non-funded research and research funded by agencies other than the federal government. In reviewing its policy, UCOP should examine alternate policies developed by comparable institutions. According to a 2006 report of the AAUP, there are more than 160 institutions in the country that have opted not to apply OHRP regulations to non-federally funded research.

2. 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:

- 2.1 Establish a mechanism for Senate and administrative oversight to review IRB 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 local oversight bodies could liaise.
- 2.2 Consider the benefits of AAHRPP accreditation, which requires a feedback mechanism and an official way to express dissatisfaction with the IRB review process.
- 2.3 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. Evaluation metrics 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
- 2.4 Establish an independent process by which faculty can voice dissatisfaction regarding IRB operations with the expectation of a reasonable response.
- 2.5 Establish policy calling for an annual report on IRB operations to be developed through the Office of the Vice Chancellor of Research and submitted to both the Office of Research and an appropriate campus 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 #8.

3. 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. Because IRB review is a necessary component of the university's research mission, IRB service should receive appropriate recognition and compensation. By the same token, 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.

We recommend that:

- 3.1 IRB chairs and members be compensated commensurate to the workload and as appropriate to the campus context, e.g., partial teaching release.
- 3.2 Campus Academic Personnel Committees recognize service on IRBs as essential to the research mission of the University and reward it accordingly.

RECOMMENDATIONS FOR IMPROVED IRB SERVICE AND CONSISTENCY

- 4. 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:

- 4.1** Adequate resources be allocated for hiring and training of IRB staff in accordance with identified needs of each campus. Resource needs should be linked to assessment of IRB quality and service (see Recommendation #2).
- 4.2** Indirect cost recovery funds at the systemwide level be applied to systemwide training of IRB directors, members and staff.
- 4.3** Although recharging for protocol review is perhaps appropriate in the case of large multi-center studies, recharging investigators as a means of sustaining IRB operations should, in general, be avoided.
- 5. 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:

- 5.1** 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, coordination of reviews, informed consent, and the nature and function of classroom and pedagogical research.
 - 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 social science and humanities research protocol submissions.
 - Comparison of UC IRB review standards with those at other academic institutions.
 - Consideration of the advantages and disadvantages of obtaining accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP).
 - Cost/benefits analysis of outsourcing protocol reviews.
- 5.2** Continuation of the recently implemented one-year MOU for intercampus protocol review. Assuming no problems arise with the practice of intercampus protocol acceptance, we recommend extending the MOU for additional years to ensure ongoing coordination.

6. 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. Such a program would be similar to the tracking function of online submissions of journals and would enable the researcher to monitor the review timeline and be better informed of the review process. It should also serve as a means of tracking and providing baseline data for the assessment of IRB performance. The San Diego and Irvine campuses have electronic research protocol submission and are in the process of developing a tracking system.

We recommend that:

- 6.1** Campuses who have or will have electronic submissions and protocol tracking systems report on their operation to the Office of Research. This information should then be evaluated and shared with other campuses to encourage successful implementation on all campuses as soon as possible.

7. 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.

We recommend that:

- 7.1** UCOP 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.

RECOMMENDATIONS FOR PARTICIPATION IN POLICY DISCUSSION AT THE INSTITUTIONAL AND NATIONAL LEVELS

Human subjects protection is a significant element of the university research effort and warrants continual productive engagement with its surrounding issues.

8. Establish a Forum for Ongoing Discussion of Major Policy 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 sciences and humanities, 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. Participants would include faculty engaged 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 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 deficiency is recognized in one of the recommendations of the NRC report on human subjects.¹⁷

We recommend that:

8.1 The systemwide Office of Research establish an online IRB discussion forum as a cost-effective pilot program, which would be evaluated after one year of operation. This online discussion should be linked to campus IRB web pages to facilitate faculty input.

9. 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 social science and humanities 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, UC should also act to influence human subjects policy at the national level and shape its position by engaging with other academic institutions,

professional societies and other stakeholder groups.

We call on the Office of the President to:

- 9.1** Become a significant voice in the national discussion of human subject protection policy and bring related regulatory concerns to the fore, as appropriate, in UC's interactions with the federal government.

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/overvoll1.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, 2000 (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 Multicenter Survey 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.

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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

GB:gf



UNIVERSITY COMMITTEE ON ACADEMIC FREEDOM

PATRICK FOX, CHAIR

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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

2

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

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June 20, 2005

LARRY COLEMAN
VICE PROVOST - RESEARCH

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

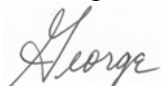
Dear Larry:

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:hgf

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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)

<u>Constitution of the committee</u>	
Does your campus have one or multiple IRBs? If the latter, how is the work subdivided?	<p>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.</p> <p>Berkeley IRB is also the official IRB for LBNL.</p>
What is the composition of the IRB?	<p>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.</p>
Is it accountable to your Senate, your administration, or both? If it is primarily an administrative group, what is its relationship to the Senate?	<p>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.</p> <p>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.</p>
How are members appointed?	<p>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.</p>
Is there adequate staff support?	<p>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.</p>

IRB Profile – Summary (rev. 7/19/06)

How are members and staff trained?	<p>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.</p> <p>Training for IRB staff is more formalized on most campuses, but at a range of levels. UCOP has regular meetings.</p>
Is the chair compensated? The members? If so, how?	<p>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.</p> <p>Members receive compensation for S&E, travel, at Davis; member's Dept. receives compensation at LA. Service on other campuses not compensated.</p>
To what extent is faculty commitment a problem?	<p>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.</p> <p>Faculty who serve take their service seriously.</p>
Does your campus contract reviews out? If not, is this option being contemplated?	<p>External IRB used (Davis) or contemplated (UCI, SF, LA, SD) for particular kinds of clinical trial protocols. Not contemplated for run of mill protocols.</p>
<u>Reviews</u>	
<p>1) What is the volume of protocols reviewed in a year?</p> <p>2) What is the distribution of exempt, expedited, and full board reviews?</p> <p>3) What is the turnaround time for each kind of review?</p> <p>4) Are there differences across disciplinary areas?</p>	<p>See attached spreadsheet for questions 1-3.</p> <p>Survey didn't distinguish between time from submission to 1st IRB response and time from submission to approval.</p> <p>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>i.e.</i>, multiple transactions.</p> <p>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, <i>e.g.</i>, and IRB email listserv and bi-monthly open forums.</p>

IRB Profile – Summary (rev. 7/19/06)

<p>When the research entails human subjects activities at multiple sites (<i>e.g.</i>, on different campuses), how do the IRBs at the different sites interact? To what degree are the reviews coordinated?</p>	<p>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.</p> <p>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.</p>
<p>What fraction of protocols submitted for review do not progress to approval?</p>	<p>Considerable variation – may reflect different interpretations of questions. See spreadsheet. More specific data is needed.</p>

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)
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Judith Aissen (Santa Cruz)
John Oakley, Academic Council Chair (ex officio)
Michael Brown, Academic Council Vice Chair (ex officio)
Brenda Foust, Policy Analyst