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

June 27, 2005

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

Re: Draft Human Subject Injury Policy and Guidelines on Implementation

Dear M.R.C.:

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

Needed clarifications:

- The policy as written is vague about exactly who at each campus will be responsible for development of a mechanism for covering injury costs. This authority should be explicitly indicated and a deadline set for the establishment of that person or office (UCORP, Irvine, Riverside, San Diego)
- The definition of, mechanism for, establishing a timely claim of injury is inadequate. These are not addressed in the Policy and are incompletely detailed in the Guidelines (UCSD).
- The guidelines for insuring the welfare of victims for the cases not covered by government or for-profit organizations/companies are too vague and unstructured (Riverside).
- The draft refers (on page 3) to "each UC entity that funds human subject research." The referent here needs to be made explicit (Irvine).

- Would claims relating to psychiatric or mental problems be covered? The policy says pain and suffering would not be covered, but does not define the term (Irvine).
- Wording in Section VIII regarding insurance billing seems to conflict with what is stated in Section III. It would be clearer to outline which sponsored trials would be eligible (UCSF).
- The term “therapeutic intent” needs to be clarified in application to patient eligibility in certain trials (UCSF).

Costs to PIs / impact on research

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

Procedures and patient protection:

- The policy should state that patients on placebo arms of trials are equally protected (UCSD).
- The policy basically applies only to cancer patients and to those in Medicare. There are no specifics about other types of clinical subjects, of which there are obviously many (UCSD).
- Documentation of eligibility is probably impossible to obtain as suggested on page 9 and most likely not necessary, as prior required FDA review already provides what is needed (UCSD).
- Patient protection from unpaid bills remains scant. The issue of insurance companies paying for medical costs is, in fact, far from resolved (UCSD).

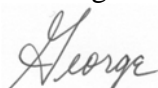
General follow up:

The changes may have a detrimental effect on research without any clear benefits (Irvine), and it is difficult to determine what the practical consequences of the policy as worded might be or what may be specific consequences of the adoption of the guidelines (Riverside). Because of this, it is recommended that a supplemental document be drafted stating current practices regarding contract wording, sources of funding for injuries, IRB statements on the issue, and rationales given for each proposed change. UCSF stresses the need for investigators to be made aware of the changes, and recommends that a revised policy or supplement include concrete examples of: 1) scenarios involving different types of trials and how they would be affected; 2) specific language that should be included in contracts with industry sponsors; and 3) specific language that should be added to consent forms.

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

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

Best regards,



George Blumenthal, Chair
Academic Council

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

Encl: 8

GB/hgf



UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP)
Max Neiman, Chair

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June 10, 2005

GEORGE BLUMENTHAL
ACADEMIC COUNCIL CHAIR

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

Dear George,

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

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

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

Respectfully submitted,

Max Neiman, Chair
UCORP

Copy: UCORP
Executive Directory Bertero-Barcelo



UNIVERSITY COMMITTEE ON PLANNING AND BUDGET (UCPB)
Michael Parrish, Chair
mparrish@ucsd.edu

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June 13, 2005

**GEORGE BLUMENTHAL, CHAIR
ACADEMIC COUNCIL**

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

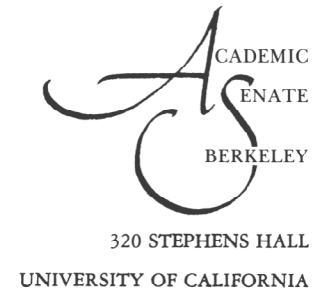
Dear George,

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

Respectfully submitted,

Michael E. Parrish, Chair
UCPB

cc: UCPB
Executive Director Bertero-Barcelo



May 31, 2005

GEORGE BLUMENTHAL
Chair, Academic Senate

Subject: University of California Draft Policy on Human Subject Injury

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

Sincerely,

A handwritten signature in cursive script that reads 'Robert C. Knapp'.

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

Cc: George Sensabaugh, Chair, Committee on Research
Diane Sprouse, Senate staff, Committee on Research



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June 3, 2005

George Blumenthal, Chair, Academic Council
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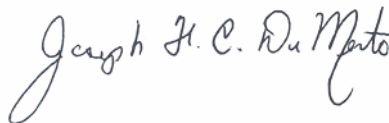
RE: Draft Policy and Implementation Guidelines on Human Subject Injury

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

- The paragraph on the responsibilities of investigators (page 2) states: “Investigators are responsible for making sure that a subject’s need for care stemming from a research injury is met, by either providing or arranging for medical care, or by coordinating with care providers to make sure that medical care is delivered.” This imposes an extremely unreasonable burden on the investigator, not only to arrange care but to make sure that the subject follows through. We suggest that the investigator be notified, but that the requirement for subject care is shifted onto the local Campus Authority designated to handle issues arising under the Human Subject Injury Policy. This will ensure proper care for the injured party, consistent treatment of all subjects, establishment of an appropriate paper trail, HIPAA compliance, etc.
- On page 3, “Each campus and each UC entity that funds human subject research...” It is not clear what is meant by a “UC entity.” Might this mean entities within each campus, such as ORUs? There should only be one entity responsible for human subjects’ injury issues on each campus. Is this what the proposal is recommending?
- It is unclear when claims regarding psychiatric or mental problems (e.g., depression) would be covered. Would such claims only be covered if the research involves a psychiatric drug or treatment? The policy indicates that pain and suffering would not be covered, but does not define this term.

- The policy and guidelines appear to be silent on residual injuries that are only learned about years later. For instance, if a subject who participated in a study using Vioxx developed cardiac problems stemming from the Vioxx and this was discovered several years after the end of the study, who would pay for the injured subject's ongoing cardiac treatment?
- Imposition of the financial burden for potential subject injury onto all for-profit corporations might limit the ability of small companies to sponsor research. This would have a negative impact in that it would diminish opportunities for UC researchers and the public would not benefit from the research results.
- Some felt it was unfair to give non-profit and government entities a loophole permitting them not to pay for subject injuries, but require all for-profit corporations to pay. It was felt that some for-profits (particularly small startups) might refuse to sponsor UC research for this reason, and that government and nonprofit groups might always invoke the loophole.
- Where would the pool of money come from to cover human subjects' injuries that UCI would be responsible for? Would overhead costs increase? What are historical fund sources, and have they been adequate? More fundamentally, are there cost or insurance implications for the University that might adversely affect researchers' ability to conduct studies involving human subjects?
- Is there a compelling need to change the current policy? Have problems arisen that have indicated a need for a change? In practice, are we already implementing some or most of these policies (e.g., in contract wording) and, if so, how have they worked out?
- Overall the policy changes might have a detrimental effect on research funding and administration, without any clear-cut benefits. We would like to see a supplemental document that clearly states current practices regarding contract wording, sources of funds for injuries, IRB statements regarding subject injuries, etc. along with each proposed change, rationale for the change, and likely implications (both pro and con).

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



Joseph F.C. DiMento, Senate Chair

Subject: human subjects comments from UCLA
Date: Mon, 13 Jun 2005 19:34:47 -0700

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From: "Komar, Kathleen" <komar@senate.ucla.edu>
To: "Maria Bertero-Barcelo" <Maria.Bertero-Barcelo@ucop.edu>,
"George Blumenthal" <George.Blumenthal@ucop.edu>

Dear George,

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

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

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

Thanks,
Kathy



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UCR

June 9, 2005

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

RE: University of California Draft Policy on Human Subject Injury and Draft Guidelines on Implementation.
(<http://www.universityofcalifornia.edu/senate/underreview/humansubjects.0405.pdf>)

Dear George:

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

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

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

Sincerely,

Manuela Martins-Green
Chair, Riverside Division



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June 10, 2005

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

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

Dear George:

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

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

The following specific comments were raised in committee reports:

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

As an aside, although UCSD's model is referenced in Provost Greenwood's letter as a possible funding mechanism model, various Council members expressed their opinion that the local model was less than ideal.

Professor George Blumenthal
June 10, 2005

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The issues surrounding funding for human subject injury are broad and sufficiently complex to require a systemwide, not campus by campus, approach. Concern was expressed that federal funding for clinical trials would decrease substantially, or even disappear, if a satisfactory policy is not in place. The Council expects to continue to work with the Administration on this issue and would welcome the opportunity to review the draft policy again.

Sincerely,

A handwritten signature in cursive script that reads "Don". The signature is written in black ink and is positioned above a horizontal line that serves as a separator between the signature and the typed name below.

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

cc: J.B. Minster
ChronFile

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

ACADEMIC SENATE



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Jean Olson, MD, Parliamentarian

George Blumenthal, PhD
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June 9, 2005

Dear Chair Blumenthal:

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

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

Sincerely,

A handwritten signature in cursive script, appearing to read "Len", is written below the word "Sincerely,".

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

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

cc: Maria Bertero-Barcelo, Executive Director, Academic Council
UCSF Academic Senate Task Force Reviewing University Of California Draft Policy On Human Subject Injury



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Jean Olson, MD, Parliamentarian

COMMUNICATION FROM THE TASK FORCE REVIEWING UNIVERSITY OF CALIFORNIA DRAFT POLICY ON HUMAN SUBJECT INJURY

V. Courtney Broaddus, MD, Chair

June 6, 2005

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

Re: Faculty Comments on Policy on Human Subject Injury

Dear Dr. Zegans:

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

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

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

that an industry initiated trial is eligible for the Medicare NCD or the Knox-Keene Act, the sponsor should be informed that the costs of subject injury may be billed to the subject's insurer or third party payor, consistent with this guidance." This allowance for payment seems to be in conflict with the section discussed above. Perhaps it would be clearer to outline which sponsored trials would be eligible.

- 3). **Research in Foreign Countries** Section V of the Policy (page 8) states that the responsibility for injury costs should be negotiated in advance. This may be difficult if not impossible in many countries; in developing countries, few if any financial resources exist for such payments. We agree, as stated in Section V that UCSF and UCSF investigators should not be held responsible for the costs of liability for such research, and this should be stated in any agreements and in the consent forms. However, the negotiated transfer of this liability to another entity may not be possible in many cases, and the requirement that this be accomplished prior to studies is likely to impede clinical research and care in countries that may need it most. We suggest that extra attention be paid to the special situations raised by research in foreign countries, particularly impoverished countries.
- 4) **Meaning of Therapeutic Intent** In the Guidelines, Section (III)(A)(1)(a)(page 6) states that qualifying trials under Medicare NCD must have a 'therapeutic intent'. Subsequently, Sections (III)(A)(1)(b) and (c) include categories such as 'diagnostic tests' and mention 'trials of diagnostic interventions'. We ask that the term 'therapeutic intent' be clarified. For example, are Phase I cancer treatment trials (which are not intended to demonstrate therapeutic benefit) or imaging trials of patients considered eligible? As noted in Section (III)(B)(2)(6), Phase I trials are specifically included as eligible under the Knox-Keene act.
- 5) **Implementation Concerns** Implementation of these policies will have far-reaching implications in the way research is conducted. It is critical that investigators be made aware of these changes. We suggest that the policy and/or guidelines provide concrete examples of:
 - a) scenarios involving different types of research trials and how they would be affected;
 - b) specific language that should be included in contracts with industry sponsors; and
 - c) specific language that should be added to consent forms.

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

Sincerely,

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

V. Courtney Broaddus, MD, Chair (Committee on Research)

John Kurhanewicz, PhD, Task Force Member (Committee on Research)

Susan Sniderman, MD, Task Force Member (Academic Planning and Budget)

William Seaman, MD, Task Force Member (Academic Planning and Budget)