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June 19, 2001

Roberto Peccei, Ph.D.
Vice Chancellor
2147 Murphy Hall
Los Angeles, CA 90095-1405

Dear Dr. Peccei,

The Task Force on Financial Conflicts of Interest in Clinical Research has met at least once a month, beginning in December 2000. In addition, considerable work has taken place between meetings. I am extremely grateful to the Task Force members for the dedication, commitment, and frank and open discussions that took place. A list of the members is appended (Attachment I).

The Task Force is aware that there are a number of ongoing initiatives in this area at other institutions, as well as at the American Association of Medical Colleges and the Institute of Medicine. We urge the University to follow these efforts closely, but not to delay moving forward with the Task Force recommendations in the interim. When the outcomes of the other initiatives are available, they should be reviewed and revisions to the UCLA program in this area can then be considered.

Some of the recommendations of the Task Force, particularly those related to the educational program, will require a significant allocation of resources to implement. We would strongly recommend that the necessary resources be defined and allocated as soon as possible to move this program forward. In this way, UCLA can serve a leadership role to other academic institutions in this difficult but critical area.

The Task Force agreed unanimously on the following recommendations:

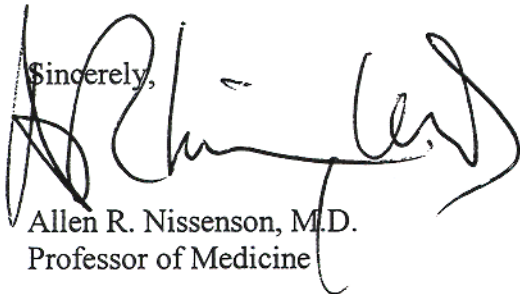
1. There should be a clear statement by the University of the principles regarding financial conflicts of interest in clinical research that articulates the views of the University and faculty. The Task Force has developed such a statement (Attachment II).

2. Clear guidelines for the faculty, useful to the ISRC, regarding specific types of financial conflicts of interest and how they are generally viewed by the institution should be distributed to the faculty. The Task Force has developed a set of such guidelines (Attachment III).
3. The faculty should have a clear understanding of the various ways that financial conflicts of interest are managed at UCLA. The Task Force has developed a description of management tools used at UCLA for this purpose (Attachment IV). In this document, the Task Force has also stated its opposition to one of the current policies of the ISRC in this regard (see last paragraph of Attachment IV).
4. The Task Force believes that disclosure of financial conflicts of interest needs to be required of key personnel engaged in clinical research, not just principal and co-investigators. There are several definitions of key personnel, but the Task Force recommends that the important component that should trigger the need for disclosure is that the individual has "responsibility" for design, conduct, data analysis, or reporting of the results of a clinical research project. Several definitions of "key personnel" that are currently used in various settings are provided in Attachment V, but the highlighted ones that emphasize "responsibility" are the ones the Task Force believes are most appropriate. The process for reviewing such disclosures needs to be developed, including the role of the principal investigator, the ISRC, or the need for an additional review committee for this purpose.
5. The Task Force, working with input from the ISRC, believes that there are additional areas of disclosure that should be captured, and proposes that supplemental questions be added to the State-mandated 730U form to capture additional information from all respondents. This includes information about intellectual property holdings, and potential or real royalty returns, even if those royalties are distributed by the University rather than an outside entity. Information should also be gathered about the planned involvement of students and trainees in the research.
6. The Task Force recommends that there be improved information sharing among various components of the clinical research enterprise, including the ISRC, IRBs, and other relevant groups. In particular, the sharing of information on financial conflicts of interest needs to be streamlined and made more efficient.
7. The Task Force recommends that a structured educational program on financial conflicts of interest in clinical research be developed, and successful completion of the program be required of all faculty and staff engaged in clinical research. Attachment VI provides further details about the Task Force recommendations in this area.

I have spoken with Professor John Edmond, incoming Chair of the Academic Senate, and made him aware of the work of the Task Force. The Task Force would like to stress the importance of ensuring that the appropriate Senate leadership have an opportunity to provide input regarding the way in which the recommendations can be openly discussed by the faculty prior to full implementation.

I would like to particularly thank the Ad Hoc members and support staff who worked with the Task Force for their participation and assistance in keeping the group on track, and helping develop the materials contained in this report.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Nissenson", written over the word "Sincerely,".

Allen R. Nissenson, M.D.
Professor of Medicine