

December 5, 2006

VIRGINIA S. HINSHAW

Provost and Executive Vice Chancellor

RE: Committee for Research Integrity FY 05/06 Report

Dear Virginia:

During the 2005/06 academic year, the Committee for Research Integrity met monthly to discuss current and emerging issues related to research compliance nationally and in particular at the University of California, Davis. The committee is charged with:

- Directing campus resources in multiple departments to efficiently and proactively address the highest priority challenges to research compliance and opportunities for strengthening compliance;
- Keep campus compliance policies and practices consistent with federal, state, and University of California policies;
- Provide for timely resolution of occurrences of non-compliance;
- Provide for development of training and education programs;
- Avoid duplication of effort among committees and task forces, as well as administrative and academic units;
- Avoid conflicts among policies.

NIH requires that organizations receiving NIH funds have in place a research compliance committee.

Among the areas discussed by the committee were the resources needed for various compliance units at UC Davis. Identified below are the resources that the committee identified during the past academic year as top priorities. Some of the priorities and requisite support and resources have been provided either on a stop-gap or temporary basis. This list represents compliance/regulatory areas that the UC Davis Committee for Research Integrity has determined are critical functions that will require additional resources to be fully functional and in full compliance with federal, state and UC policies and regulations.

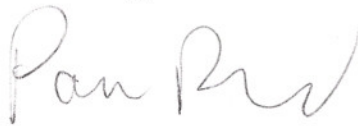
To respond to these needs, both the Office of Research and Office of Administration will require additional support. The resources needed to respond are listed in more detail in the attached document. In summary, the following areas were identified by the committee.

1. Faculty groups requested support for a Permitting Officer and a Good Laboratory Practices (GLP) Officer. These are service positions that also reflect federal and state policy requirements but do not carry the risk associated with the need for additional biosafety and other regulatory support. However, without this campus service, we are limited in some of the research that can be carried out on campus. Both the Permitting and GLP positions could easily be full-time positions; however, the committee recommended appointing half-time individuals to develop processes and assess specific resources that will be needed to fully respond to the faculty requests for support in these areas. Subsequently, and in response to faculty requests, EH&S has brought on an Assistant BioSafety Officer at 30% to begin supporting the Permitting issues. The School of Medicine has hired a nationally recognized faculty member, Dr. Gerhardt Bauer, to direct and design a Good Manufacturing Practices (GMP) laboratory. A GLP officer at 25 or 50% is still an identified need. Without these positions the burden rests on faculty to ensure appropriate licensing and oversight.
2. Boating Safety is a program in response to the Sea of Cortez boating incident and responds to Coast Guard recommendations. The Coast Guard released their report on the Sea of Cortez incident in the spring of 2006, and the report recommended developing both a boating safety program and a safety program. The Office of Research is currently supporting 1½ FTE for boating safety. The office does not have permanent funding for the 1 FTE position. If temporary resources are not renewed or made permanent, this program will not be continued. This is a risk mitigation decision.
3. Environmental Health and Safety (EH&S) staffing to support research activities has not kept pace with the growth and complexity of the research enterprise. Research funding has increased by almost 180% over an 8-year period while EH&S staffing has modestly increased by only 8%, and that increase was targeted to the animal care program to respond to AAALAC issues. Additionally, there have been significant new regulations enacted (e.g., Patriot Act, Public Health Safety and Bioterrorism Act) that further strain the available resources.
4. Currently, the Office of Research has one full-time Research Compliance and Integrity Officer and one full-time Research Compliance Analyst III. The Office of Research will cover for FY06-07 funds for both positions. Among many other responsibilities, this Analyst will be the primary point-of-contact for working with faculty to ensure that we are responsive to, and in compliance with, expanded Export Control and ITAR laws and regulations.

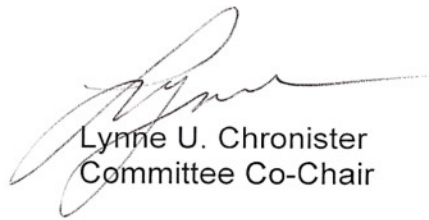
The Office of Administration has provided one-time funding for FY06-07 to cover the salary of an additional biosafety professional until permanent funding is identified. The Office of Administration request for additional Biosafety personnel, who will support area # 3, is considered by the Committee as the highest priority for the coming year. This individual will also provide assistance for limited faculty permitting activities. Thus the immediate request is \$109,000 support for a Biosafety Officer.

The Committee for Research Integrity is also recommending that over the next two to three years, support be provided for the additional EH&S regulatory positions and base funding be identified for the additional compliance staff, boating safety staff, a GLP officer, and a full-time Permitting Officer.

Sincerely,



Pam Ronald, PhD
Committee Co-Chair



Lynne U. Chronister
Committee Co-Chair

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Attachments

- c: Committee for Research Integrity (w/o attachments)
- Academic Senate Chair Linda Bisson (w/o attachments)
- Vice Provost Barbara Horwitz (w/o attachments)
- Vice Chancellor Barry Klein (w/o attachments)
- Vice Chancellor John Meyer (w/o attachments)
- Vice Chancellor Stan Nosek (w/o attachments)
- School, College, & Division Deans (w/o attachments)