RIVERSIDE: AUDIT & ADVISORY SERVICES

June 13, 2012

To: Charles F. Louis, Vice Chancellor Office of Research

Subject: Internal Audit of Research Conflict of Interest

Ref: R2011-K

We have completed our audit of Research Conflict of Interest in accordance with the UC Riverside Audit Plan. Our report is attached for your review.

We will perform audit follow-up procedures in the future to review the status of management action. This follow-up may take the form of a discussion or perhaps a limited review. Audit R2011-K will remain open until we have evaluated the actions taken.

We appreciate the cooperation and assistance provided by your staff. Should you have any questions concerning the report, please do not hesitate to contact me.

> Michael R. Jenson Director

cc: Audit Committee Members Director Schmechel

UNIVERSITY OF CALIFORNIA AT RIVERSIDE AUDIT & ADVISORY SERVICES MEMBER OF ASSOCIATION OF COLLEGE & UNIVERSITY AUDITORS

INTERNAL AUDIT REPORT R2011-K

RESEARCH CONFLICT OF INTEREST

JUNE 2012

Approved by:

Noahn Montemayor Principal Auditor Michael R. Jenson Director

UC RIVERSIDE RESEARCH CONFLICT OF INTEREST INTERNAL AUDIT REPORT R2011-K JUNE 2012

I. <u>MANAGEMENT SUMMARY</u>

Based upon the results of work performed within the scope of the audit, it is our opinion that, overall, the system of internal controls over research conflict of interest is operating satisfactorily and is generally in compliance with University policies and procedures.

As the University initiates new research programs and encourages partnership with private industry; University and campus management, the Regents, and the public have become increasingly concerned about the adequacy of existing procedures and systems for addressing conflict of interest and conflict of commitment.

The Political Reform Act of 1974 (the Act) mandates the adoption of a conflict of interest code by each State agency, including the University, the filing of disclosure statements with the appropriate reviewing body, and the designation of a filing officer to monitor the disclosure statements.

Responsibilities associated with the Act are administered separately for academic and administrative personnel. Academic personnel with principal responsibility for a research project that is to be funded or supported in whole or in part by a contract, grant, or earmarked gift from a nongovernmental entity must file a financial interest disclosure statement. The academic researcher need not be disqualified from accepting the award and conducting the research if the financial interest disclosure statement and research decision are substantively reviewed by an independent committee within the institution prior to the granting of the award.

The UCR Office of Research is responsible for the review and regulatory oversight of campus research Centers and Organized Research Units. In addition, the Office of Research manages and assists the campus in complying with all mandated federal, state, and UC research compliance requirements.

Minor items that were not of a magnitude to warrant inclusion in the report were discussed verbally with management.

II. <u>INTRODUCTION</u>

A. <u>PURPOSE</u>

UC Riverside Audit & Advisory Services (A&AS), as part of its Audit Plan, performed a review of research conflict of interest to evaluate the adequacy and clarity of existing policies and procedures designed to identify and manage potential financial conflicts of interest of academic and research staff. A&AS also evaluated compliance with those policies and procedures, and the effectiveness of business practices to identify and manage potential conflicts.

B. <u>BACKGROUND</u>

University requirements for managing research Conflict of Interest (COI) are relatively complex and federal regulations in this area are changing and becoming more stringent. The appearance of a COI can undermine public trust, even in situations where mitigating factors are made known to the public.

The State of California and the Federal government have established different requirements for disclosure and review, and financial reporting thresholds for research COI disclosures. The California Fair Political Practices Commission requires that UC campuses use Form 700-U to obtain disclosure information from Principal Investigators (PI). A separate Federal disclosure form must be completed by the PI and any other individual responsible for the design, conduct or reporting of the results of work performed or to be performed under the sponsored project. If a positive disclosure is made on either form, additional evaluation is completed. At a minimum, a disclosure is typically required for each grant that a researcher submits.

The UCR Office of Research Integrity provides broad oversight, resources, and education for integrity and compliance issues – including COI – relating to the conduct of research at UCR. The Conflict of Interest Committee (COIC) is charged with reviewing all potential conflict of interest disclosures to determine whether there is or is not a conflict of interest. The COIC reviews financial disclosures for both privately and federally sponsored projects and situations where a potential, perceived, or real conflict of interest exists by virtue of financial interest. It establishes management strategies to eliminate, manage or reduce conflicts of interest, determines which strategies are appropriate, and ensures their implementation.

C. <u>SCOPE</u>

The scope of the review was limited to UCR Office of Research and Office of Research Integrity business processes to manage research COI. Procedures performed included studying University COI policy, requirements, and

applicable regulation as well as reviewing and evaluating Office of Research Integrity records and operating procedures to ensure policy compliance.

The period covered by the review is Fiscal Year (FY) 2010-2011. Office of Research Integrity records subjected to audit sampling and detail review are Forms 700-U, Federal disclosure forms, email, and related documents for sponsored awards active during FY 2010-2011.

We did not perform an exhaustive search for possible undisclosed or inadequately disclosed COI. The scope of audit procedures was limited to those deemed necessary to evaluate overall compliance with University policy and the effectiveness of business practices to manage potential conflicts related to sponsored research programs.

D. INTERNAL CONTROLS AND COMPLIANCE

As part of the review, internal controls were examined within the scope of the audit.

Internal control is a process designed to provide reasonable, but not absolute, assurance regarding the achievement of objectives in the following categories:

- * effectiveness and efficiency of operations
- * reliability of financial reporting
- * compliance with applicable laws and regulations

Substantive audit procedures were performed during November 2011 through April 2012. Accordingly, this evaluation of internal controls is based on our knowledge as of that time and should be read with that understanding.

III. <u>OBSERVATIONS</u>

We performed audit procedures to evaluate internal controls over research conflict of interest and compliance with University policies and procedures.

A total of 872 sponsored awards were active during FY 2010-2011. These awards were distributed among 59 campus departments. 480 awards were sponsored by Federal agencies, 117 by industry, and 275 by not-for-profit organizations.

Based on discussions with Office of Research management regarding research COI and the reasonable supposition that the risk of non-compliance with COI policy is higher in certain departments compared to others, the audit sampling population was limited to 366 awards in 9 departments: Bioengineering, CE-CERT, Chemical & Environmental Engineering, Chemistry, Computer Science & Engineering, Center for

Nanoscience & Engineering, Electrical Engineering, Entomology, and Mechanical Engineering.

Using both judgmental and systematic sampling methods, we selected 40 (11%) of 366 awards and reviewed all associated Forms 700-U, Federal disclosure forms, and other documents submitted by research personnel. We verified that COI disclosure statements were submitted in accordance with policy requirements and established campus procedure.

During FY 2010-2011, the Office of Research Integrity received 14 financial interest disclosure statements in which private investigators reported positive COI situations.

We reviewed all Forms 700U and Federal disclosure forms associated with positive COI declarations and ascertained that prescribed review and monitoring procedures were performed by the Office of Research Integrity and, as necessary, case evaluations and resolutions were completed by the COI Committee.