

ETHICS AND COMPLIANCE OVERSIGHT RESOURCES – long form

A shorter version of this document is available on the home page of the University of California, Irvine School of Medicine Academic Senate website under "Resources."

A. UC SYSTEMWIDE RESOURCES: REFERENCE MATERIAL

1. Faculty Code of Conduct (APM 015): Originally approved by the Academic Senate Assembly in 1971, and amended on multiple occasions, the code is supplemented by university policy on faculty conduct and the administration of discipline (APM 016), www.universityofcalifornia.edu/compaudit/codeofconduct.html.

2. History and context: In 2003, President Robert Dynes appointed a task force to review ethics in higher education nationally and in the University of California. This led to development of the University of California Statement of Ethical Values and the Standards of Ethical Conduct. In addition, in 2006 the UC Board of Regents requested the establishment of a compliance office and recruitment of a chief compliance and audit officer for the system, reporting directly to the regents. In 2007, President Dynes and Regent Gerald Parsky mandated ethics rollout teams for the following systemwide online tutorials: ethics briefings on all campuses, conflict of interest briefings for designated officials and regents, and conflict of interest briefings for researchers. Finally, in 2008 the Board of Regents hired a chief compliance and audit officer who established the systemwide Office of Ethics, Compliance, and Audit Services. As one of the components of the systemwide ethics and compliance program, each campus is required to have Campus Ethics and Compliance Risk Committees (CECRC), composed of high-level campus leadership representing functional areas that pose the greatest risks to the institution. The purpose of the CECRCs is to discuss compliance risks across all areas of the institution and to develop and implement strategies to mitigate these risks.

3. UC Ethics and Compliance Program: This program, approved by the Board of Regents in July 2008, is "designed to reinforce its commitment to ensure good stewardship of federal, state, and private resources and formally support the university's mission of teaching, research, and public service." This will maintain "both the public's trust and institutional and individual accountability." The program includes seven elements: (1) standards of conduct, (2) oversight by the regents' Committee on Compliance and Audit, (3) mandated education on topics such as sexual harassment prevention, conflicts of interest, ethics, and compliance, (4) reporting of potential and/or perceived compliance failures allowing the complainant to remain anonymous and free of retaliation, (5) compliance systems and controls, (6) disciplinary action for violations of university policies, procedures, or applicable legal requirements, and (7) assurance that management is taking appropriate corrective action and remedial measures when problems are identified in order to resolve and prevent recurrence of the problems www.universityofcalifornia.edu/compaudit. This website has links for tutorials on UC ethical values and conduct, conflicts of interest, an ethics glossary, and plans a link for current compliance policies. This resource primarily provides information but could be consulted if local resources were inadequate.

The UC Ethics and Compliance Program is responsible for coordinating, tracking, managing, and/or conducting investigations of complaints of improper governmental activity (IGAs) made under the university's whistleblower policy. The goal of the program is to ensure the university's compliance with federal and state whistleblower laws. Incidents may be reported confidentially either through the Whistleblower Hotline, 800.403.4744, or by submitting a secure web report through UC's systemwide vendor Ethics Point, www.universityofcalifornia.edu/hotline. One may also report complaints to the UC Irvine whistleblower-designated official or to one's supervisor.

B. UC IRVINE CAMPUS ETHICS AND COMPLIANCE OVERSIGHT RESOURCES

Go to the uci.edu website, search for "ethics" and click on UC Irvine ethics resources to obtain more than two pages of resources (officers, departments, services, etc.) with names of individuals and their telephone numbers to address questions such as: "Where can you go to report unethical behavior?" and "Where can you go for advice when an ethical issue presents itself?" In addition to the designated campus personnel listed, you may contact your supervisor/manager or the dean or chair of your department. Rather than include an exhaustive list, we have elected to provide a shorter list of what we consider to be the major ethics oversight resources, and rather than individual names and personal telephone numbers, we prefer to provide URLs and office phone numbers.

1. UC Irvine Campus Ethics and Compliance Risk Committee (CECRC) is chaired by the Vice Chancellor of Planning and Budget, 949.824.4923; 949.824.7023; 949.824.0576; www.pb.uci.edu, assisted by the Assistant to the Vice Chancellor, 949.824.7677, and by the Associate Vice Chancellor of Administrative and Business Services, 949.824.5108; www.abs.uci.edu. This committee oversees investigations of complaints of improper governmental activity and assures the university's compliance with federal and state whistleblower laws.

2. Research ethics: The UC Irvine Vice Chancellor for Research has appointed a Responsible Conduct of Research Task Force to meet the requirements of the National Science Foundation for training of undergraduates, graduate students, and postdoctoral researchers; the task force is chaired by the Director of Administration and Research Policy. Additional administrators are the Associate Vice Chancellor for Research and the Assistant Vice Chancellor for Research. Contact 949.824.4768. For research compliance and administration, call 949.824.5677; research integrity, 949.824.2898; research conflict of interest, 949.824.7218; human research protections, 949.824.1558; and clinical research and trials, 714.456.5153 or 8708. There are multiple Institutional Review Boards (IRBs) to protect human subjects of research, 949.824.5746; a Human Stem Cell Research Oversight Committee (HSCRO), www.research.uci.edu/ora/escro/index.htm; 949.824.7218; an Institutional Animal Care and Use Committee (IACUC), 949.824.8664, an Institutional Biosafety Committee (IBC); 949.824.6200, an Office of Public Records, 949.824.2312, which reports to the Office of Institutional Research, and an Office of Technology Alliances, 949.824.7186. An important website link for ethics resources at UC Irvine is www.icts.uci.edu/ethics1.cfm.

Campus conflict of interest committees work to ensure that researchers' personal interest in, or commitments to, entities outside the University do not compromise or appear to compromise their objectivity in performing research, in mentoring students involved in research, or in reporting a project's results. The UC Irvine Conflict of Interest Oversight Committee (COIOC, www.research.uci.edu/ora/coi/charter.htm, 949.827.7218) reviews university research relationships for potential conflicts of interest. "The COIOC is not a punitive body. Its purpose is not to discourage industry/university partnerships, personal investments, or consulting, but to protect the integrity of the research related to these activities."

3. Office of the Ombudsman: The purpose of this office is to provide or facilitate a confidential, impartial, informal resolution of problems, concerns, and complaints of students, faculty, staff, or administrators of the campus or the medical center. The office is private and independent, and all matters are confidential except for reporting of crimes, abuse, and potential harm to self or others and for systemic problems which, when identified, may be referred without disclosure of the specific circumstances or individuals for policy creation or change. Services of the ombudsperson include provision of information regarding policies, coaching how to deal with a problem of concern, and mediation of a dispute. Consultation does not obligate the client to pursue formal action. Discussion with the ombudsperson does not put the university on notice and is not a substitute for formal grievance, notice or investigation. The office does not investigate, make decisions, or enact policy, and it does not provide legal advice. Presently there are offices at the campus, 949.824.7256, and at the medical center, 714.456.5605. The ombudsman spends three days a week on campus, and two days a week at the medical center.

UC Irvine Healthcare Ombudsperson, 714.456.5605, is an informal, independent, impartial, confidential resource for faculty, staff, and students. The ombuds office is not an office of record or notice; no files are kept. The ombudsperson offers a safe place to voice complaints and concerns, assists in addressing or finding resolution of those complaints and concerns, advocates for equity and fairness, gathers information to share with decision makers, and establishes and develops relationships throughout the organization.

4. Office of Equal Opportunity and Diversity: The OEOD, www.oed.uci.edu, is a neutral office charged with coordinating the university's compliance with state and federal laws and university policies and procedures related to discrimination and sexual harassment. Services provided by OEOD include informal dispute resolution, formal investigation, and workshops on sexual harassment prevention, cultural awareness, nondiscrimination, and respect for diversity. Campus contact: 949.824.5594 or oed@uci.edu; medical center contact: 714.456.7469 or oed@uci.edu.

5. UC Irvine Campus Assault Resources and Education: CARE, www.care.uci.edu, provides consultation for issues related to sexual assault, relationship dynamics, and gender issues. It also provides individual and group counseling, training, workshops, and referrals to services on campus and in the community (such as the Student Health Center, OEOD, or a law enforcement agency). Call CARE, 949.824.7273, in the event of a sexual assault or for assistance in supporting another who has been sexually assaulted, or even because of concerns that a relationship may not be healthy.

6. Advance Program for Faculty Gender Equity and Diversity: The Advance Program, 949.824.2798, <http://advance.uci.edu> was originally funded by an NSF Institutional Transformation award. It is a commitment by UC Irvine to equity and diversity in the professoriate. One focus has been on strategies to diversify Science, Technology, Engineering, and Mathematics (STEM) faculty. Although the Advance Program is primarily a proactive resource to promote equity and diversity in recruitment, retention, advancement and leadership, the program not only provides advice, mentoring, and participation in recruitment but is also charged with proactively investigating inequities.

7. Internal Audit Services: The mission of Internal Audit Services (IAS) is to assist the regents and university management in the discharge of their oversight, management, and operating responsibilities through independent audits and consultations

designed to assist in the management of risk and evaluate and promote the system of internal controls, including effective and efficient operations. Internal Audit Services has unrestricted access to information, including records, computer files and property. IAS is free to review and evaluate all policies, procedures, and practices of any university activity, program, or function. To permit the rendering of impartial and unbiased judgment essential to the proper conduct of audits, internal auditors will be independent of the activities they audit. Auditors may talk directly to the chancellor, the university auditor, the president, or the regents regarding matters that they believe to be of sufficient magnitude and importance. The IAS office, 949.824.7543, is responsible for 3 activities: (1) auditing the business systems and processes of a department or service to mitigate risk, (2) advisory projects, providing consultation when requested by a department or service, and (3) investigations to ascertain whether whistleblower or other allegations (of fraud or policy violation) are substantiated. The director of IAS is responsible for the department. Three auditors report to the campus audit manager, two auditors to the health sciences audit manager, and there is a single information technology auditor for both the campus and the medical center. The IAS wishes to be helpful, not punitive, and is committed to assisting management in fulfilling its responsibilities, including risk management

8. Internal Controls: "Internal controls are the processes employed to help ensure that the University's business is carried out in accordance with standards [of ethical conduct], university policies and procedures, applicable laws and regulations and sound business practices." Internal controls "promote efficient operations, accurate financial reporting, protection of assets and responsible fiscal management. Internal controls are overseen by the university controller and the assistant vice chancellor for Accounting and Fiscal Services. All members of the university community are responsible for internal controls. Each business unit or department head is specifically responsible for ensuring that internal controls are established, properly documented and maintained for activities within their jurisdiction. Any individual entrusted with funds, including principal investigators, is responsible for ensuring that adequate internal controls exist over the use and accountability of such funds." The goal of internal control is to "help departments attain reasonable assurance that business risks are managed efficiently and effectively." Specific objectives include "accountability, effectiveness and efficiency of operations, reliability of financial reporting, and compliance with applicable laws and regulations." Known or suspected improper governmental activities should be reported under protection of the whistleblower retaliation policy. The internal controls office, 949.824.8987, receives reports from the Whistleblower Protection Program, but can also be contacted directly for concerns of embezzlement or financial impropriety such as claims of excessive travel expenses.

9. Conflicts of Interest: A conflict of interest exists when an individual's personal interests conflict with the interests of the university. The vice chancellor for planning and budget has overall responsibility for conflicts of interest. The administrative policies coordinator, 949.824.8713 in Administrative and Business Services, is responsible for recommendations for inclusion in the campuswide conflict of interest code and for informing employees at the time of hiring and at the time of leaving the university of state requirements for filing form 700 as required by the California Fair Political Practices Commission regarding reporting personal assets and income, limits on gifts, and bans on honoraria. The conflict of interest coordinator for the campus is the Office of Research Administration, 949.824.7218, which is responsible for conflicts of interest in research and for advice regarding the filing of form 700-U (required of UC employees with principal responsibility for a research project if the project is funded or supported by a non-governmental entity).

Conflicts of interest or commitment may include lectures, speaking engagements, and workshops, if promotional rather than educational in nature. Faculty should not be members of, or provide lectures for, industry speakers' bureaus, and should not permit review of lecture slides or handouts by industry prior to delivery to an audience.

10. Conflicts of Commitment: A conflict of commitment exists when UC Irvine faculty, staff, or students have outside activities that interfere with their primary obligations to, or responsibilities at, UC Irvine. Compensated and uncompensated outside professional and non-professional activities are addressed in Academic Policy Manual 025, a policy titled "Conflict of Commitment and Outside Activities of Faculty Members." Faculty members may pursue compensated outside professional activities "that advance or communicate knowledge through interaction with industry, the community, and the public and through counseling and professional opportunities." Indeed, "The university encourages outside faculty activities that contribute to their respective professions and to the community." However, compensated activities that raise the appearance of a conflict of commitment are classified in three categories "in terms of the extent to which they may raise conflicts of commitment issues." Some do not require prior approval and are not limited with regard to the amount of time spent by the faculty member. Some do not require prior approval but are limited, and some require both prior approval and are limited. Activities must be reported annually, and questions or concerns may be addressed to the department chair or dean.

11. Whistleblower Protection Program and Policy: "Members of the university community are strongly encouraged to report all known or suspected improper governmental activities (IGA's) under the provisions of the Whistleblower Policy. Managers and persons in supervisory roles are required to report allegations presented to them and to report suspected IGA's that come to their attention. Reporting parties, including managers and supervisors, will be protected from retaliation for

making such a report under the Whistleblower Retaliation Policy." To report concerns, one may contact his/her supervisor in writing or orally, or a variety of offices including Internal Audit, the UC Irvine Whistleblower office, www.evc.uci.edu/whistleblower, or may anonymously contact the university-wide Whistle blower Hotline, www.universityofcalifornia.edu/hotline, 800.403.4744. Reporting is encouraged for "corruption, malfeasance, bribery, theft, fraud, coercion, waste of money, gross misconduct, gross incompetence, or gross inefficiency as well as for activities that violate state or federal regulations." The UC Irvine Whistleblower Protection Program is overseen by the associate executive vice chancellor for academic affairs, who is the locally designated official for the whistleblower program. The office of the director of investigations is responsible for coordinating, tracking, managing, and/or conducting investigations at the office of the president and systemwide, www.universityofcalifornia.edu/compaudit/investigations. The office, headed by the director of investigations, maintains oversight of a comprehensive program for review and investigation of complaints of improper governmental activity. The goal of the program is to ensure the university's compliance with federal and state whistleblower laws. You may report suspected incidents anonymously, either through the Whistleblower Hotline, 800.403.4744 or online at www.universityofcalifornia.edu/hotline.

The university wants you to report improper activities, and will protect you from retaliation for whistleblowing. The university has a responsibility to conduct its affairs ethically and in compliance with the law. If you suspect that a UC employee is engaged in improper activities, you should know there are policies that can show you how to "blow the whistle" and can protect you from retaliation if the need arises.

What you can report: Any activity by UC or a UC employee that violates a state or federal law or regulation (e.g., corruption, malfeasance, bribery, theft or misuse of government property, fraud, coercion, or conversion); or wastes money, or involves gross misconduct, gross incompetence, or gross inefficiency.

Where to report: Make a report directly to the locally designated official, 949.824.5661 or to the UC Compliance Hotline at 800.403.4744 or [online, www.universityofcalifornia.edu/hotline](http://online.universityofcalifornia.edu/hotline). (The multi-lingual hotline is independently operated to help ensure confidentiality.)

How to report: In writing or orally with as much specific factual information possible. You may report anonymously, if preferred. Confidentiality will be maintained to the extent possible.

Protection from retaliation: If you believe you have been retaliated against for whistleblowing, immediately contact the locally designated official, or your respective human resources or academic personnel office, or your supervisor for information on how to file a grievance or complaint.

More information concerning Whistleblower and Whistleblower Retaliation policies can be found online at: <http://www.evc.uci.edu/whistleblower/>.

Administrative officials and supervisors reports of any known or suspected inappropriate activity, whether reported by their subordinates or discovered in the course of performing their duties, must be reported to the locally designated official when any of the following conditions occur: (1) the matter is the result of a significant internal control or policy deficiency that is likely to exist at other units within the institution or across the university system; (2) the matter involves the misuse of university resources or creates exposure to liability of potentially significant amounts; (3) the matter involves allegations or events that have a significant possibility of being the result of a criminal act (e.g., disappearance of cash); (4) the matter involves a significant threat to the health and safety of employees and/or the public; (5) the matter is judged to be significant or sensitive for other reasons; or (6) the matter is likely to receive media or other public attention.

The university has an experienced and diverse staff of investigators with backgrounds in investigation, forensic accounting, criminal justice, legal, compliance and research. The investigators utilize a strategic combination of these diverse fields of knowledge in many of the investigations to provide the university with the most complete, thorough, impartial, and accurate investigation possible. University investigators handle an array of allegations from theft of physical assets, discrimination, sexual harassment, fraud, research misconduct and violations of state and federal law. Typical elements of an investigation include collection and examination of written or recorded materials, interviews with parties and witnesses, and reporting conclusions and findings. When appropriate, outside experts are consulted.

12. Office of Technology Alliances (OTA): This office "exists to foster faculty/industry alliances and commercialization of UC Irvine technology for the broad public benefit." It deals with such matters as intellectual property, patenting, trademark, copyrights to increase research support from the private sector, faculty consultation with industry, conflicts of interest, material transfers, technology transfer and licensing, and startup companies. The OTA follows eight UC principles for partnering with industry (including open dissemination of research results, bringing innovations to practical application for public benefit, legal and ethical integrity). An assistant vice chancellor, 949.824.7186, oversees the Office of Technology

Alliances. The patent and licensing officer, biomedical engineering in the Office of Technology Alliances, comes to the medical center monthly to answer questions about intellectual property and the other matters dealt with by the OTA, 949.824.3104.

C. UC IRVINE SCHOOL OF MEDICINE ETHICS AND COMPLIANCE OVERSIGHT RESOURCES

1. Medical Student Mistreatment: Can consist of verbal or physical abuse; threats of physical abuse; discrimination based upon age, gender, race or ethnicity, religion, disability or sexual orientation; sexual harassment; requiring students to perform personal services not related to their education; requiring students to perform menial tasks that are belittling or humiliating. The most common form of mistreatment reported is verbal abuse. Other reported forms of mistreatment at UC Irvine include being required to perform personal tasks, discrimination based on gender, and sexual harassment (being subject to unwanted sexual advances). Clinical faculty and residents are reported to be the most frequent source of mistreatment, followed by fellow students.

The School of Medicine policy pertaining to mistreatment can be found in the student handbook under the teacher learner relationship and policies on sexual harassment sections. One can access the handbook by going to <https://intranet.ha.uci.edu/>, clicking on School of Medicine, clicking on students, clicking on current medical students, and clicking on student handbook. For help, after asking the person to stop, talk to the clerkship director, the associate dean for student affairs, or the health sciences ombudsperson, www.healthaffairs.uci.edu/ombuds/.

2. Corporate and Hospital Compliance and Privacy Offices: “Health-care compliance programs aim to maintain and enhance quality of care, comply with federal and state law and regulations, develop policies and procedures to enhance compliance, and empower healthcare professionals to prevent, detect, and resolve conduct that does not conform with laws, regulations, and policies. Compliance briefings on UC ethical values and conduct were mandated by the president and regents for annual training of faculty, staff, postdoctoral scholars and employed students to begin in 2010. Similar briefings including instruction on conflict of interest for researchers will be required of UC research employees (faculty, staff, and post doctoral scholars).” The corporate and hospital compliance officer for the school of medicine and the medical center worked in compliance at UCLA for five years (<http://compliance.uclahealth.org>), came to UC Irvine two years ago, and now has succeeded the compliance officer who developed the program at UC Irvine in 1969. Privacy violations or other concerns may be reported anonymously to the confidential reporting line at the Health System Compliance and Privacy Office, 888.456.7006. Online privacy and security training is offered, www.healthaffairs.uci.edu, left click, health affairs intranet; or log in with user name and password; left click, compliance and privacy; log in). The medical center Compliance and Privacy office number is 714.456.3674. There is also a confidential reporting line for the Health System Compliance and Privacy office, 888.456.7006, where privacy violations or other concerns may be reported anonymously.

D. UC IRVINE MEDICAL CENTER ETHICS AND COMPLIANCE OVERSIGHT RESOURCES:

1. Medical Ethics Committee: The Medical Ethics Committee's primary mission is to ensure optimal care of patients through education of the medical staff and other healthcare professionals, the development of hospital policies that address ethical issues, and consultation for attending physicians and healthcare professionals and for patients and their families. The committee exists to make communication easier and better among patients, their families, and healthcare providers. Where there are values conflicts, education, consultation, and mediation may be of benefit. Ethics consultation can be requested by the patient or surrogate (patient's representative), the patient's family, or any professional responsible for the care of the patient. Requests for consultation can be made to the Medical Staff Office, 714.456.5521.

2. Corporate and Hospital Compliance and Privacy Offices: Please refer to the paragraph on the same topic under the section on the UC Irvine School of Medicine Ethics Oversight Resources.

3. UC Irvine Healthcare Risk Management: The goal of risk management is to minimize liability of the medical center and of its professionals and employees within the constraints of providing optimal patient care. The director of risk management should be consulted, 714.456.5676 when there is question whether an issue is legal or ethical and when there is concern on the part of healthcare professionals or patients and their families. The Office of Risk Management & Regulatory Affairs provides the following non-patient care services in support of the medical center, medical school, staff and faculty: (1) liaison between the medical center and outside legal counsel for litigated claims in the areas of medical malpractice, general liability, and employment; (2) liaison between the medical center administration and patients/patient's families in a problem-resolution capacity; (3) provide risk management education and training to staff in order to reduce and/or prevent the risk of loss and to ensure quality patient care; (4) provide early investigation of serious risk events/occurrences; (5) act as consultant to faculty and staff on legal issues related to provision of patient care; (6) provide the regulatory and accreditation

oversight office for all federal and state regulatory agencies and the Joint Commission on Accreditation of Healthcare Organizations.

4. UC Irvine Healthcare Ombudsperson Office: Please refer to the section Office of the Ombudsman in the section on "UC Irvine Campus Ethics Oversight Resources."

5. UC Irvine Healthcare Patient Relations: The Patient Relations Service, 714.456.7004, has dedicated staff that daily reinforces the UC Irvine CARE standards (Understanding, Communication, Involvement, Commitment, Action, Respect, Environment) in an effort to elevate the medical center to the finest of healthcare systems. Patient Relations is involved in multiple projects that directly impact the overall patient experience and support those providing direct patient care. Patient Relations provides staff with customer service training and strives to bridge communications between the care providers, patients and families. We positively influence our colleagues and foster open attitudes toward change. Patient Relations listens to the patient experiences of both inpatients and outpatients at the medical center and uses that feedback to create a desirable healthcare environment. The patient's positive feedback is welcomed and used to reward and recognize staff as well as hardwire exceptional performance behaviors. When receiving feedback that is less than positive, Patient Relations sees it as an opportunity to resolve concerns and persists in uncovering root causes and finding the source of a problem. Patient Relations exists for the patients and offers continuous support to all those who care for them.