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## **UCSF Clinical Enterprise Compliance Program (CECP) Description**

UCSF is committed to providing high quality health care, teaching, and research to achieve our institutional mission of advancing health worldwide. We can meet these responsibilities only when each member of the clinical enterprise understands and adheres to the UCSF Code of Conduct and its high standards of ethical conduct and integrity. The University expects each member of the clinical enterprise to act in accordance with these principles, using their best judgment to “do the right thing.” The UCSF Clinical Enterprise Compliance Program is intended to provide guidance and oversight of clinical enterprise programs as a means to ensure that ethical, compliant behavior is a standard and integral part of all UCSF clinical operations.

### **Why UCSF needs a Clinical Enterprise Compliance Program**

Health care delivery is complex. There are an increasing number of laws and regulations that apply to our operations, impacting how we deliver patient care, document clinical services, receive reimbursement for those services, engage with the health care industry, and identify opportunities to improve our systems and eliminate or manage organizational risks. Failure to meet these stringent regulatory mandates may cause harm to our patients, the financial integrity of the clinical enterprise, and the reputation of the organization.

An effective compliance program can increase the likelihood of preventing, identifying, and correcting problematic activities. The program provides a formal structure to identify potential areas of risk, manage identified issues, and mitigate potential financial loss and government penalties or sanctions for non-compliance. Not only does this program assist UCSF in fulfilling its institutional mission, but, in addition, compliance programs soon may be required under federal law for health care organizations like UCSF.

The UCSF Clinical Enterprise Compliance Program is described below and is a dynamic, progressive program that is intended to meet the changing regulatory landscape. The CECP will regularly review and modify the program to meet evolving compliance needs. Commitment and engagement of the entire organization are necessary for the objectives of the program to be effective.

### **Mission and Scope of the UCSF Clinical Enterprise Compliance Program**

The mission for the CECP is to reduce the risk of compliance violations that may impede UCSF’s core mission of promoting health worldwide through biomedical research, education in the life sciences and health professions, and high-quality patient care. Working in partnership with campus and clinical enterprise leadership, managers, and staff, we strive to promote a culture of compliance throughout the organization by aligning compliance activities with organizational strategies.

The specific objectives of the CECP are to:

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- Detect, deter, resolve and prevent potential violations of applicable laws and regulations, professional standards of practice, other applicable standards, and UCSF policies
- Promote a culture of compliance within and across clinical enterprise operations that empowers and expects individuals to address conduct that is inconsistent with these standards
- Establish, revise, clarify, and communicate applicable UCSF standards, policies and procedures
- Support the delivery of high quality, ethical patient care and clinical research, and the appropriate reimbursement for those services
- Maintain a review and monitoring process to identify and address potential or existing risk areas for the organization
- Establish and maintain mechanisms both for responsible parties to raise questions and concerns about potential compliance issues without fear of retaliation, and to ensure that those concerns are appropriately addressed
- Empower and encourage all employees and other responsible parties to report all suspected or known improper governmental activities
- Oversee implementation of corrective actions, including disclosures, follow up, financial refunds and potential disciplinary actions

The UCSF Clinical Enterprise Compliance Program has been endorsed by the Health Sciences Campus Compliance Program of the UC Board of Regents and by the UCSF Chancellor. The Clinical Enterprise Compliance Program covers all personnel and entities that are responsible for: direct patient care services, clinical support services, or ensuring that members of the clinical enterprise carry out their responsibilities in a legal manner (“covered personnel”). This list includes vendors, contractors, and UCSF representatives, such as administrative management and staff, faculty, clinical staff, house staff, and other health care personnel, including non-salaried faculty and volunteers.

To provide the means for ensuring that compliant, ethical behavior is an integral part of operations, the CECP’s role and operational infrastructure is based upon the required elements of the Federal Sentencing Guidelines for effective corporate compliance programs. These standards, which include review and development of policies and procedures to ensure compliance, also encourage and expect open, constructive dialog about areas of concern without risk of retaliation against any individual who, in good faith, has raised a question or reported suspicious activity or processes.

The key elements of the UCSF CECP are described below. Further information may be found on the [CECP web site](#).

## **1. Leadership and Structure**

The Director of the Clinical Enterprise Compliance Program has oversight over the development and operation of the CECP. The CECP is part of the UCSF Office of Ethics and Compliance, and the CECP Director reports to the Associate Vice Chancellor, Chief Ethics and Compliance Officer, who has a matrixed reporting relationship to the Senior Vice President and Chief Compliance Officer of

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the University of California (CCAO). The CCAO has a direct relationship to the UC Board of Regents Compliance and Audit Committee Chairperson and the University President. The Director is advised by the Clinical Enterprise Compliance Committee. This Committee is comprised of executive level clinical enterprise leadership and is responsible for assuring the effectiveness of the CECP. To promote objectivity and impartiality, the CECP Director and staff are independent of the activities they review.

## **2. Written standards**

The UCSF Code of Conduct outlines responsibilities of covered personnel. University personnel also must comply with the UC Statement of Ethical Values and Standards of Ethical Conduct. UCSF Medical Center personnel must adhere to the UCSF Medical Center Code of Conduct and Principles of Compliance, which provides more detailed descriptions of general clinical enterprise compliance objectives and practices. In addition, compliance policies and procedures are developed and refined on an ongoing basis to ensure that the compliance activities remain consistent with organizational goals as well as regulatory and other requirements.

In addition to the CECP objectives, which are designed to provide institutional oversight of clinical programs, individual units and programs are encouraged to develop and implement supporting policies and procedures specific to their clinical activities.

## **3. Education and Training**

A critical element of the CECP is education and training. The CECP is committed to implementing and supporting educational and training programs to effectively, and in a timely manner, communicate needed directives and guidance to covered personnel. New and existing personnel are expected to complete basic compliance training on a regular basis. The CECP will review and update its training programs periodically, as well as identify additional areas of training on an ongoing basis and by request. Information and resources can be found on the CECP website.

The CECP also encourages operational units to develop education and training programs specific to compliance risks in their areas. CECP staff are available to assist in developing content and responding to specific questions.

## **4. Internal Lines of Communication**

The opportunity to ask questions, clarify expectations, and raise concerns in a non-threatening environment is the cornerstone of an effective compliance program. Inquiries or reports can be made to a supervisor, manager, or directly to the CECP. The CECP maintains a variety of mechanisms for covered personnel to submit ad hoc questions or requests for consultation, including via phone, email, or on-line.

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UCSF employees are expected to promptly report suspected, planned or actual violations of regulations, or laws which govern UCSF clinical activities. Reports can be made to a supervisor, manager, or directly to the CECP Director. If these individuals are not available or if the reporter prefers to provide an anonymous report, including from outside the organization, reports may be made anonymously through the University Whistleblower Hotline: 800-403-4744 or at <http://whistleblower.ucsf.edu/>

Managers and supervisors are expected to review and, upon consultation with higher management or UCSF's Whistleblower Coordinator, report all known or suspected improper governmental activities that come to their attention in the ordinary course of performing their supervisory roles.

<http://policies.ucsf.edu/policy/150-23> (UCSF Administrative Policy 150-23 "Policy on Reporting Improper Governmental Activities and Protection against Retaliation")

Acts of retaliation or retribution against anyone, who in good faith reports a potential, suspected, planned, or actual violation to the CECP or Whistleblower Hotline will not be tolerated and will be handled according to University personnel policies in a timely manner. The action may include disciplinary actions, up to and including termination.

## **5. Review and Monitoring**

The CECP maintains a regular Review and Monitoring plan to identify potential or existing problem areas and will recommend corrective measures in an effort to prevent problems or put systems in place so they do not recur. The nature of the risk assessment, reviews, and other monitoring efforts, as well as the extent and frequency of this activity, is dependent on a number of factors. These include new regulatory requirements, government audit activities, Corrective Action Plan (CAP) validation, business practice changes, and other considerations. CECP strives to partner with and assist managers to integrate self-monitoring plans into their day-to-day activities. CECP Review and Monitoring reports are generated and shared with appropriate UCSF management and staff, as well as Compliance committees.

Certain business units not under the direct management of UCSF are responsible for periodically reporting their assessment, monitoring, and resolution of compliance issues to the CECP. Review of their operations also may be periodically incorporated into the CECP work plan.

## **6. Responding to Potential Violations**

The CECP shall oversee the review of non-compliance reports and determine whether further investigation is necessary. When deemed necessary, the CECP may conduct an investigation into potentially non-compliant activity to determine whether a compliance violation has occurred and may work with legal counsel. The CECP also works closely with the campus Investigations Group when allegations of potential Inappropriate Governmental Activities are involved.

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## **7. Corrective Action Procedures**

The CECP oversees the implementation of corrective measures in response to identified issues or review findings. Corrective measures take into account the nature of the findings; assessing whether enhancements should be made to policies, practices, training, or internal controls, to prevent future non-compliance. Corrective actions may include financial refunds and, consistent with UCSF personnel policies, appropriate and consistent disciplinary action, up to and including termination.

## **8. Exclusion Screening**

UCSF avoids employing or contracting with individuals or vendors who are excluded or debarred from participation in federally funded programs and government contract. The CECP oversees UCSF screening processes to prevent or detect relationships with these individuals and vendors.

### Resources

[UC Statement of Ethical Values and Standards of Ethical Conduct](#)

[Health Science Compliance Program Policy. University of California](#)

[UCSF Campus Code of Conduct](#)

UCSF Medical Center Administrative Policy 1.02.09: *Code of Conduct and Principles of Compliance*