AGENDA

All agenda items presented by Elizabeth Boyd  Associate Vice Chancellor, Ethics & Compliance

A. UCSF Industry Relations Statement of Principles

B. UCSF Workforce Sanctions for Patient Privacy Violations Policy

C. UCSF 2013/14 Compliance Risk Assessment and DRAFT Work Plan Areas
Attachments

A. UCSF Industry Relations Statement of Principles
Ethics and Compliance Board Meeting

Agenda Topic: UCSF Industry Relations Statement of Principles

Date of meeting: April 23, 2013

Draft Statement of Principles as basis for review of UCSF Industry Relations Policy (150-30)

UCSF INDUSTRY RELATIONS STATEMENT OF PRINCIPLES

Introduction

The University of California, San Francisco (UCSF) has a long and successful history of collaboration with industry, including, but not limited to, pharmaceutical, biotechnology and medical technology companies. These interactions have benefited patient care, educational programs, administrative initiatives, research, community well-being, and speedy transfer of our discoveries to societal benefit. However, industry collaborations may create conflicts of interest (COI) and/or commitment that must be acknowledged and addressed to protect the integrity of our mission, which is distinct from the mission of industry and private enterprise. UCSF is committed to ensuring an environment where all decisions regarding clinical care, research activities, administration, and educational content are unbiased, rooted in scientific evidence, and independent of industry influence and are made with the best interests of the public in mind. The following general principles are designed to guide policies defining relationships with industry and the interactions between all members of UCSF’s community and industry partners.

General Principles

- **University-Industry collaborations should support the mission of UCSF.** As employees of the University of California, all UCSF faculty and staff have a primary responsibility to advance the mission of the University.

- **UCSF practices should engender and maintain public trust.** UCSF is a public institution, and its integrity and transparency in dealing with industry and conflicts that arise in industry relations is central to ensuring confidence and trust in the institution. Disclosure and management of conflicts of interest also serve to maintain trust between and among all members of the UCSF community as well as with external partners.

- **Transparency.** As a public institution, transparency in dealing with industry is central to a healthy academic environment and to ensuring confidence and trust in UCSF.

- **University-industry collaborations should maintain academic freedom and the right to publish.** UCSF is committed to discovering and disseminating new knowledge through basic and applied research. Policies regarding university-industry collaborations should not restrict a UC investigator’s use of data, publication, discussion, or dissemination of research findings.

STP: CEC/ECB 04-23-2013 IR Statement of Principles. Page 1
• **UCSF practices should maintain objectivity and integrity.** Objectivity is fundamental to UCSF’s contribution to knowledge, to the well-being of patients and research subjects, and to the instruction of trainees. Instances wherein an institutional or individual COI introduces a question of objectivity and/or integrity of research, patient care, or teaching, must be appropriately and transparently managed or the COI must be eliminated.

• **University-industry COI should be managed through University governance.** Conflicts of interest must be managed or eliminated with a strategy that is appropriate to the perceived risks posed by the conflict, represents fairness and consistency of application across the university, and adheres to university policies and procedures.
Attachments

B. UCSF Workforce Sanctions for Patient Privacy Violations Policy
DRAFT CAMPUS POLICY REGARDING WORKFORCE SANCTIONS FOR PRIVACY VIOLATIONS

The Office for Civil Rights (OCR) requires Covered Entities to have a specific workforce Sanction Policy for privacy violations. To meet this requirement, the Privacy Office led a Multidisciplinary Task Group to develop the “Workforce Sanctions for Patient Privacy Violations” policy. The Multidisciplinary Task Group, included HR, Legal Affairs, Risk Management, Privacy, Academic Senate, Student Academic Affairs, GME, IT, Medical Staff, and Volunteer Services. The policy does not create new sanction processes; rather, it refers to the established policies governing that particular workforce member.

Purpose

Patients of the University of California, San Francisco (UCSF) have both a reasonable and legal right to the privacy and confidentiality of their personal health information. This policy describes the sanctions to be taken by UCSF when workforce members fail to comply with the patient privacy and confidentiality policies and procedures of the University of California and UCSF. This policy applies to any patient health information obtained and/or used inappropriately during the course and scope of work at UCSF. In addition to the corrective action defined in this policy, fines may be imposed by regulatory agencies, and civil actions by third parties outside of UCSF may be undertaken against UCSF workforce members.

The policy also includes language regarding a workforce member’s potential personal liability for direct and indirect costs associated with the investigation and legal defense processes, based on malicious intent or egregious disregard of University policies. (Section III. D.)

D. The University retains the right to pursue collection from the workforce member for the costs, direct or indirect, incurred by the University associated with the privacy breach investigation and legal defense processes (e.g., forensic scans, attorney fees), as well as fines and/or administrative penalties imposed against the University, for privacy violations caused by the workforce member. Factors for determining the workforce member’s liability for such costs include, but are not limited to, existence of malicious intent and/or whether the violation was a result of an egregious disregard for such policies and procedures.
I. Purpose

Patients of the University of California, San Francisco (UCSF) have both a reasonable and legal right to the privacy and confidentiality of their personal health information. This policy describes the sanctions to be taken by UCSF when workforce members fail to comply with the patient privacy and confidentiality policies and procedures of the University of California and UCSF. This policy applies to any patient health information obtained and/or used inappropriately during the course and scope of work at UCSF. In addition to the corrective action defined in this policy, fines may be imposed by regulatory agencies, and civil actions by third parties outside of UCSF may be undertaken against UCSF workforce members.

II. Definitions

**Business Associate:** A person or entity, not part of the workforce, who/that on behalf of a Covered Entity, creates, receives, maintains, or transmits Protected Health Information ("PHI") for a function or activity regulated by HIPAA.

**Protected Health Information (PHI):** As defined by the Health Insurance Portability and Accountability Act ("HIPAA"), an individual's health information or data collected from an individual that is created or received by a health care provider, plan or clearinghouse related to the past, present or future physical or mental health or condition of an individual, the provision of health care to the individual; identifies or could reasonably identify the individual; and is transmitted or maintained in electronic or any other form or medium.

**Workforce:** Employees, volunteers and other persons whose conduct, in the performance of their work for UCSF, is under the direct control of UCSF or The Regents of the University of California, whether or not UCSF pays them. The workforce includes faculty, non-faculty academics, staff, students, trainees, vendors and volunteers, and it includes those who are rotating through UCSF’s facilities from another institution, as well as those who are employed by an affiliated institution, who in the course of their duties need to access patient health information.

III. Policy

A. The University may initiate corrective action, up to and including termination or release during probation, when a workforce member has violated UCSF patient privacy or confidentiality policies and procedures. The initiation of any corrective action by the University does not preclude the University from seeking any other remedy available to it under law.

B. Should the University initiate any corrective action, it must do so in accordance with the applicable workforce policies and/or union contracts which may include, but are
not limited to, the Faculty Code of Conduct, University of California Policies Applying to Campus Activities, Organizations and Students, the Medical Staff Bylaws, Medical Staff Rules and Regulations, Graduate Medical Education (GME) policies and procedures, as well as any other existing and applicable policies for staff, collective bargaining agreements, University policies or practices, as applicable.

C. The corrective action imposed will depend on the nature, severity and frequency of the violation, as appropriate to the policies governing the workforce member.

D. The University retains the right to pursue collection from the workforce member for the costs, direct or indirect, incurred by the University associated with the privacy breach investigation and legal defense processes (e.g., forensic scans, attorney fees), as well as fines and/or administrative penalties imposed against the University, for privacy violations caused by the workforce member. Factors for determining the workforce member’s liability for such costs include, but are not limited to, existence of malicious intent and/or whether the violation was a result of an egregious disregard for such policies and procedures.

IV. Responsibilities and Procedures

A. UCSF may initiate disciplinary actions in cases of misconduct, repeated violations, or otherwise consistent with University policies.

B. Workforce members should review the policies listed in Section III.B for a comprehensive description of the disciplinary policies and procedures, including their rights under such circumstances.

C. The Privacy Office will investigate, in consultation with all applicable offices, all cases of alleged non-compliance with UCSF’s patient privacy and confidentiality policies. Cases for which sanctions may be appropriate will be referred to the applicable office for review as appropriate to the policies and procedures governing the workforce member. Relevant laws, regulations and UCSF’s policies and procedures will be considered.

D. For Business Associates and other vendors, the Privacy Office and Information Security Office (if electronic information resources are involved) will work with the appropriate UCSF department to implement any compliance corrective action or recommend appropriate sanctions.

E. Any sanctions that are applied will be documented by the appropriate governing body for the workforce member involved. Any appropriate sanctions for contractors and Business Associates will be documented by the Privacy Office and Information Security Office (if electronic information resources are involved).

V. Related Policies

UCSF Campus Administrative Policies

- Privacy Investigation Policy 200-30
- Information Security and Confidentiality 650-16 and Addendums
- HIPAA Business Associates 200-28
• Labor Relations 150-14
• Reporting Improper Governmental Activities and Protection Against Retaliation ("Whistleblowing") 150.23

UCSF Medical Center Administrative Policies (Requires Campus Login)
• Confidentiality, Access, Use and Disclosure of Protected Health Information and Patient Privacy 5.02.01
• Control of Access and Release of Information from UCSF Medical Center Information Systems for Research Purposes 5.01.06
• Information Security and Confidentiality 5.01.04
• Electronic Mail 5.01.02
• Code of Conduct and Principles of Compliance 1.02.09
• Facsimile Documents Containing PHI 5.01.25
• HIPAA Business Associates 1.02.15

VI. References

• Health Insurance and Portability Act (HIPAA) [Title 45 Code of Federal Regulations Part 160, 162 and 164]


• University of California Electronic Communications Policy (ECP), http://www.ucop.edu/ucophome/policies/ec/

• University of California Faculty Code of Conduct (APM-015) and University Policy on Faculty Conduct and the Administration of Discipline (APM-016), http://www.ucop.edu/acadpersonnel/apm/

• University of California Professional and Support Staff, Disciplinary & Separation Actions, Policies http://atyourservice.ucop.edu/employees/policies_employee_labor_relations/personnel_policies/index.html

• UCSF Campus Code of Conduct http://chancellor.ucsf.edu/UCSFCOC.pdf

• UCSF Medical Staff Bylaws http://www.ucsfmedicalcenter.org/medstaffoffice/Bylaws/UCSFBylaws.pdf

• UCSF Medical Staff Rules and Regulations http://www.ucsfmedicalcenter.org/medstaffoffice/Bylaws/UCSFRulesRegs.pdf

• University of California Policies Applying to Campus Activities, Organizations and Students
http://www.ucop.edu/ucophome/coordrev/ucpolicies/aos/toc.html

- University of California Policies Applying to Campus Activities, Organizations and Students, including UCSF Campus Supplement
  https://clubs.ucsf.edu/sites/clubs.ucsf.edu/files/PDF/PACAOS.pdf

- UCSF Interim Procedure for Investigation of Faculty Misconduct and the Administration of Discipline
  http://academicaffairs.ucsf.edu/academic-personnel/media/facinvestinterimproc.pdf

- Collective Bargaining Units and Agreements
  http://www.atyourservice.ucop.edu/employees/policies_employee_labor_relations/collective_bargaining_units/index.html

- UCSF Privacy and Confidentiality Website
  http://hipaa.ucsf.edu/

- UCSF Privacy and Confidentiality Handbook
  http://hipaa.ucsf.edu/Privacy%20Handbook.pdf

- ITS Security and Policy Website
  http://it.ucsf.edu/security
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C.  UCSF 2013/14 Compliance Risk Assessment and DRAFT Work Plan Areas
DISCUSSION OF COMPLIANCE RISK ASSESSMENT AND DRAFT WORK PLAN

Each year, UCOP requests that campuses complete a Risk Assessment and develop a Work Plan for the upcoming year. This year, UCSF collaborated with Risk Management and Audit Services to streamline the Risk Assessment process, and our final work plans will be combined into one campus plan. Clinical Compliance will produce its own detailed work plan, to be submitted to UCOP.

The Risk Assessment process consisted of a series of one-on-one interviews with senior leadership, including Deans and Vice Deans, Vice Chancellors, the Academic Senate leadership, Medical Center leadership, and key unit Directors, such as the Cancer Center. From these interviews, the following areas of risk were identified. Those highlighted in blue are on the Draft Work Plan for 2013/14.

- Conflict of Interest/Commitment: compliance with new PHS regulations and compliance with APM 670 – Outside activities policy
- Intellectual Property: compliance with UC IP and Patent policies
- Lab Safety: implementation of UCLA Lab Safety Settlement Terms/CalOSHA Title 8
- Export controls: identification of controlled items/data/research and process for monitoring
- International Students and Scholars: obtaining appropriate visas for international students, scholars, visiting professors, clinicians
- IT Security: encryption of mobile devices, including laptops, phones, iPads
- Privacy: clarification of policies and procedures regarding research records in the electronic medical record
- Consent: clarification of policies and language in consent forms regarding research records in the electronic medical record
- American Disabilities Act: compliance with regulations around electronic access for visually impaired and hearing impaired
- Child Abuse and Neglect Reporting Act: implementation of policies and procedures for identification of mandatory reporters and certification in employee file
• Professional Fee Billing: documentation issues in Apex

• Cleary Act: ensure compliance with Cleary Act

• Pre-employment screening: ensure appropriate policies and procedures for pre-employment screening for Denied Parties, debarred individuals, and other required categories

Other areas not on the Draft Work Plan for Compliance may be included in the Work Plans of Audit or Clinical Compliance.
Attachments

Minutes: Ethics & Compliance Board meeting 09.18.12
### Agenda Item

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<th>Agenda Item</th>
<th>Discussion</th>
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<td><strong>UCSF Privacy Compliance Annual Report for FY2012</strong></td>
<td>Deborah Yano-Fong, Chief Privacy Officer</td>
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**Highlights of Accomplishments**
- UCSF Medical Center privacy audit and follow up actions: Developed monitoring plan for disposal of PHI by clinical units
- Privacy Investigation policy finalized
- Privacy breach with more than 500 patients = 0
- Educational Programs: 62 -Educational activities during the past year.
- Collaborate on APeX optimization
- State Privacy work with Cal OHII

Risk areas include all printers, copiers, i.e., equipment with data storage; personal mobile devices carry big risk. For the period July 2011 – June 2012 the percentage of all privacy investigations related to electronic incidents was 31% with the remaining 69% related to non-electronic incidents. In this same period, the % of all breach notifications to individuals related to electronic incidents was 3% electronic versus 97% non. “Electronic” includes theft, loss, security, fraud or errors reported to Privacy Office which involved either electronic devices, networks or email errors containing ePHI.

Trends are similar to those of the last few years: human error, thefts and losses are up but all else is stable. Encryption helps greatly and overall compliance is on the rise. The IT Awareness Campaign / posters are helping quite a bit. Other potential risks included workforce turnover and technological innovations that electronically share information. Everyone should work with the Privacy Office to be sure all proper security is in place.

Detailed review of FY12 consults was provided and the discussion closed with a review of priorities for FY13, including:
- Readiness for OCR audit: Privacy risk assessment for OCR audit standards and readiness for OCR audit
- APEX Implementation and Access to PHI: Auditing and monitoring user access; Research records in APeX; Health Information Exchange
- New Federal Privacy Regulations pending publication
- Increased Mandatory Compliance Reporting Requirements: (Attorney General, UCOP, others)

Further detail in ppt presentation.

### Annual Threat Management Report

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<th>Annual Threat Management Report</th>
<th>Andrew Parker Manager, Faculty &amp; Staff Assistance Program</th>
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Reviewed Threat Management Team (TMT) membership. Criteria for consideration as a Threat Management Case is: 1. Violation of Zero Tolerance Policy, and 2. UCSF Community is in danger. The number of cases going to the full TMT has remained steady at approx. 2 per month; twice that number are screened out as not meeting the criteria stated above and are referred to labor relations (for employee issues), or student mental health / academic affairs (for student related issues). Employee: employee issues are handled by the Ombuds office. Historically, the predominance of cases were related to employee violence, however, currently most are related to 1. domestic violence, and 2. patients threatening staff (causes include but are not limited to issues around medicaitons, mental status, unrealistic expectations); this phenomena has been rising over the past four years and is typical as compared with other UC systems.
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<td>Developments: Susan Penny (Risk Management) will develop protocols for early identification, screening, and handling of patient issues. Campus &amp; Medical Center now have full/regular members on TMT (Susan Penny &amp; Bruce Flynn). Andrew Parker is now a member of the SFGH Critical Incident Response Team so UCSF personnel are represented at that site. A Students of Concern Committee has been formed; this a rising national trend &amp; not exclusive to UCSF; the chair of this committee will sit on the TMT.</td>
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| **Update on PHS Conflict of Interest Implementation** | **Elizabeth Boyd**, Associate Vice Chancellor, Ethics & Compliance  
On 8/24/12 the PHS changed regulations related to Conflict of Interest resulting in a huge shift in institutional responsibility; to meet the shift an online database system was implemented and UCSF met the all stated deadlines. However, workload in the Conflict of Interest office tripled due to the range & scope of disclosures required by the changed regulations. Although there was much preparation, the actual impact was unknown ahead of 8/24/12. Volume is being monitored and processes are being put in place. The new regulations resulted in a huge shift and set of responsibilities; perhaps input of the academic community would impact NIH expectations. |
## IN ATTENDANCE

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<th>Ethics &amp; Compliance Board Member Name</th>
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<tr>
<td>Jeffrey Bluestone</td>
<td>EVC/Provost</td>
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<td>Elizabeth Boyd, Chair</td>
<td>Associate Vice Chancellor, CECO</td>
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<tr>
<td>Marcia Canning</td>
<td>Chief Counsel</td>
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<td>Elizabeth Watkins</td>
<td>Dean, Graduate Division</td>
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<tr>
<td>David Vlahov</td>
<td>Dean, School of Nursing</td>
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<td>John Featherstone</td>
<td>Dean, School of Dentistry</td>
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<td>Sam Hawgood</td>
<td>Dean, School of Medicine</td>
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<tr>
<td>Joseph Guglielmo</td>
<td>Interim Dean, School of Pharmacy</td>
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<td>Mark Laret</td>
<td>Chief Executive Officer, Medical Center</td>
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<tr>
<td>Barbara French</td>
<td>Vice Chancellor, University Advancement &amp; Planning</td>
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### Members of Chancellor’s Executive Cabinet

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<th>Member Name</th>
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<tr>
<td>Susan Desmond-Hellmann</td>
<td>Chancellor</td>
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<tr>
<td>Regis Kelly</td>
<td>Director, California Institute for Quantitative Biosciences (QB3)</td>
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<td>John Plotts</td>
<td>Senior Vice Chancellor, Finance and Administration</td>
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<tr>
<td>Renee Navarro</td>
<td>Vice Chancellor, Diversity and Outreach</td>
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<td>Angelique Loscar</td>
<td>Assistant Chancellor, Chief of Staff</td>
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<tr>
<td>John Ford</td>
<td>Vice Chancellor, University Development &amp; Alumni Relations</td>
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<tr>
<td>Jaime Sepulveda</td>
<td>Executive Director, Global Health Sciences</td>
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<tr>
<td>Robert Newcomer</td>
<td>Chair, Academic Senate</td>
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### Guests

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<th>Member Name</th>
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<tbody>
<tr>
<td>Lynda Hilliard</td>
<td>Deputy Compliance Officer</td>
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<tr>
<td>Deborah Yano-Fong</td>
<td>Chief Privacy Officer, UCSF</td>
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<tr>
<td>Andrew Parker</td>
<td>Manager, Faculty &amp; Staff Assistance Program</td>
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### Ethics & Compliance Board Support

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<tr>
<td>Irene Broderick</td>
<td>Analyst/Special Assistant to AVC</td>
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