



University of California, San Diego
Conflict of Interest Office

Conflict of Interest: Effective Management Across Silos

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Overview

- Definition
- Federal and State Regulations
- UC Guiding Principles
- UC San Diego Context
- Case Studies
 - Environmental Leadership
 - Health Sciences Designated Officials
 - Outside Professional Activities – Staff
- Essential Components of an Integrated Program
- Future Considerations
- Questions and Discussion

Definition – Conflict of Interest

- The term “*conflict of interest*” refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising an employee’s professional judgment in administration, management, teaching, research and other professional activities.
- **NOT** a statement of wrongdoing!

COI - Operational Framework

- Laws and Regulations
 - State (1974) – Political Reform Act w/Academic Decision Regulation
 - UC Conflict of Interest Code (1980)
 - Federal (1995) – NIH/NSF
- UC Policy – Disclosure/Review/Management
 - [Disclosure of Financial Interest in Private Sponsors of Research \(1984/2010\)](#)
 - [Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Research \(1995/1997/2009\)](#)
 - [UC Business and Finance Bulletin G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest \(Revised February 2010\)](#)

Guiding Principles & Institutional Responsibilities

- UC has comprehensive and interrelated policies and guidelines that address the conduct of employees, their interactions with private industry and conflict of interest.
- UC has long recognized the importance of research collaborations with industry and encouraged academics in private entrepreneurial ventures.
- However, such relationships may present an increased risk of potential or actual conflict between the interests of individuals and entities with which they are involved, and the public interest that federal and other sponsored funding should serve.
- To ensure the integrity of UC research results, guide interactions of employees in their partnerships with industry and in other university-related activities, the University has established a conflict of interest program to help employees eliminate, manage or reduce conflicts of interest.

Managing Conflict of Interest: The Balancing Act

- Balancing the desire to encourage innovation through research and commercialization with *emerging* best practices concerning disclosure, assessment and management of potential conflicts of interest.

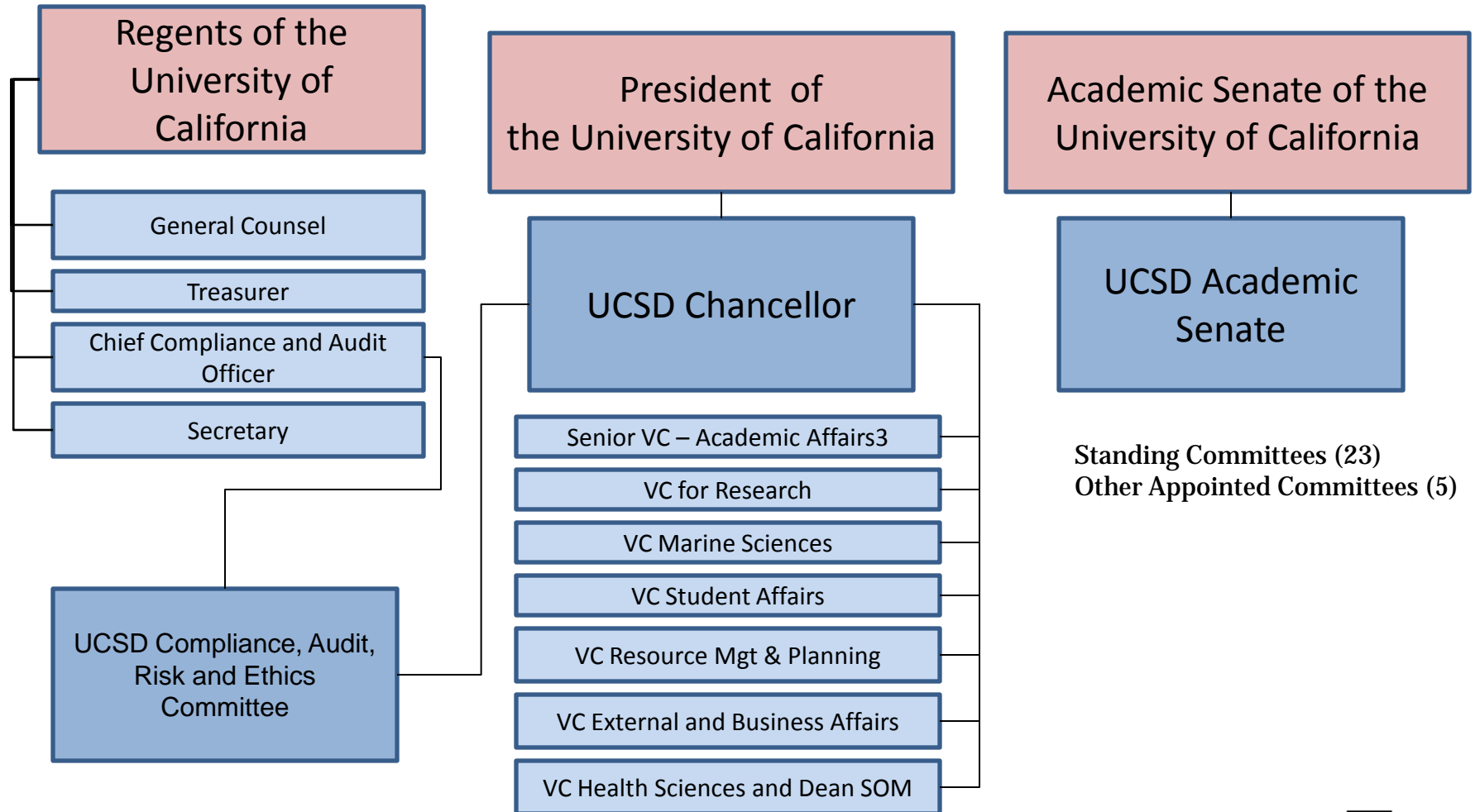


Types of Conflicts of Interest (COI)

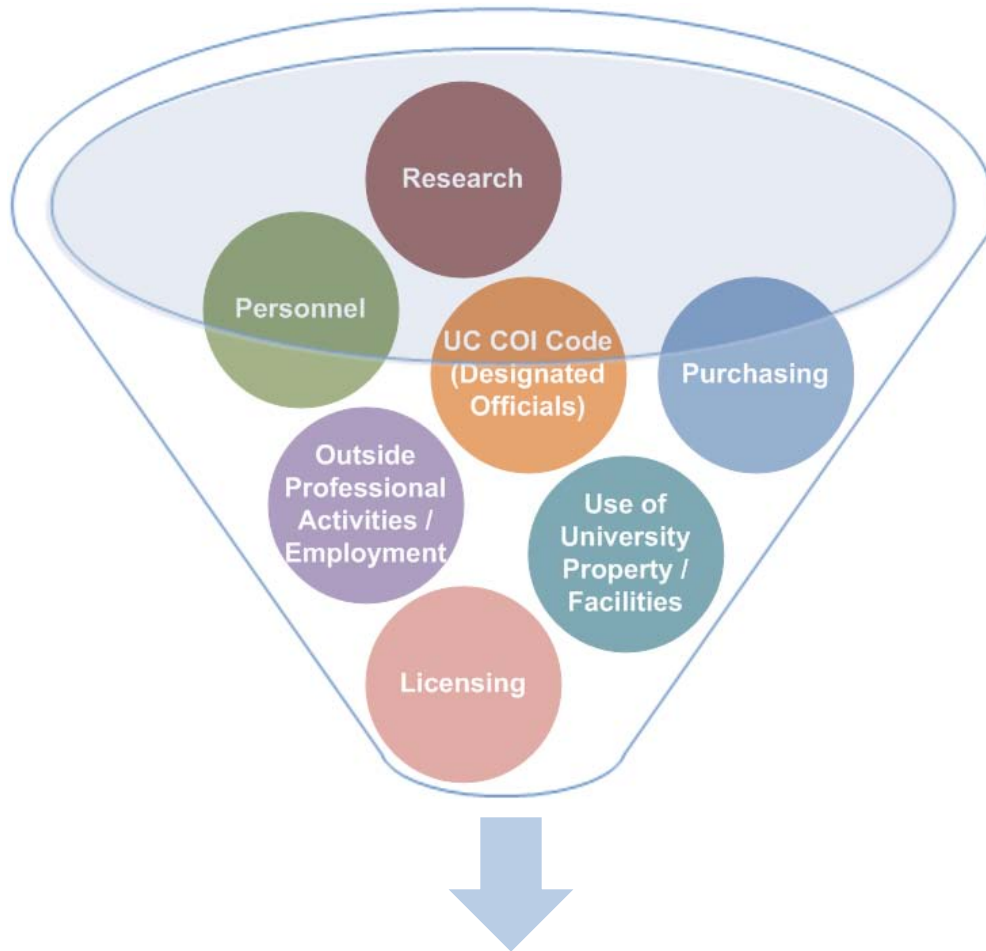
- **Individual**
 - All Employees - Anyone involved in procurement, licensing, contracting
- **Researchers** - A potential for COI exists if an individual:
 - Receives research support from, or evaluates therapies of a business in which he/she has an ownership interest (stock/options/deferred compensation)
 - Receives payments (consulting fees/honoraria-speaking fees/other) from an outside entity
 - Has a management position (Board of Directors, Chairman SAB, etc.)
 - Non-financial COI: Career advancement, personal advancement, scientific bias, glory...not easily identifiable or manageable
- **Institutional**
 - Financial & IP holdings of the University

UCSD Governance and Organizational Structure 2011

Shared Governance Responsibility



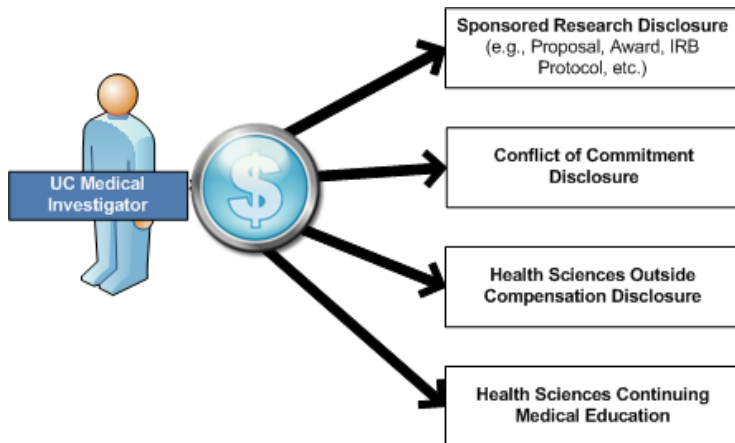
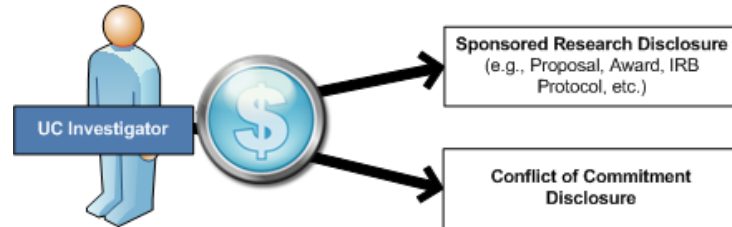
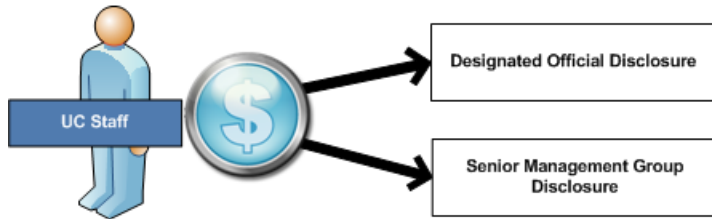
UCSD Model



UCSD COI Office

- Central office and resource to faculty, administrators, and staff:
 - General Campus
 - SIO
 - UCSD Medical Center
 - VASDHS/VMRF
- Assist employees in assessing circumstances under which their outside activities or interests may inappropriately conflict with their responsibilities to the University.

Current UC COI Challenges: Redundant and Laborious Disclosure Processes



Current UC COI Challenges: Inefficient Interdepartmental Communication



Current UC COI Challenges: Reporting, Risk and Resources

- Disparate collection of COI disclosures
 - Inaccurate and delayed data reporting
 - IntraCampus
 - InterCampus
 - Campus to UCOP
 - Unable to develop and implement **uniform** and **effective** of UC COI processes and procedures
 - Lack of compliance
 - Functional and IT Resources will be needed
 - COI offices have limited personnel and IT resources

COI Review Across Functional Areas

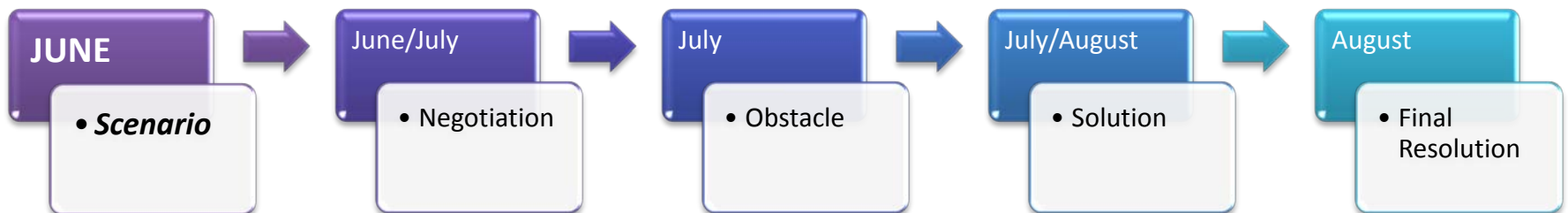
- Risks associated with conflict of interest in research lead to increased oversight of conflict of interest issues in other areas.
 - Assess compliance with regulations
 - Evaluate management procedures
 - Recommend changes to policies and procedures
 - Identify and implement best practices
 - Provide training

Case Study

Environmental Leadership

- **Scenario**

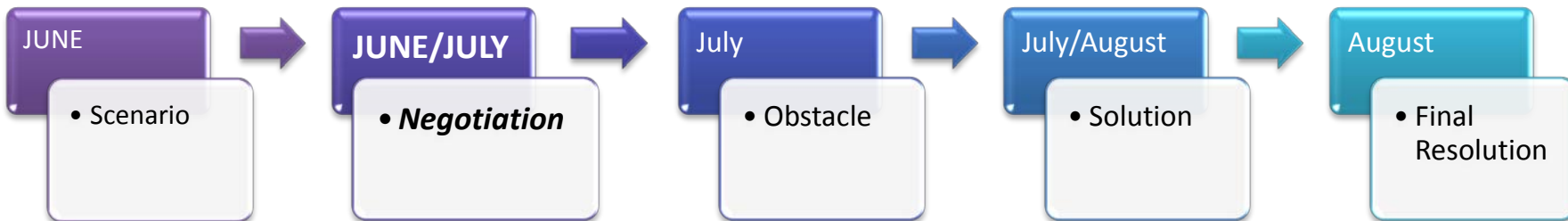
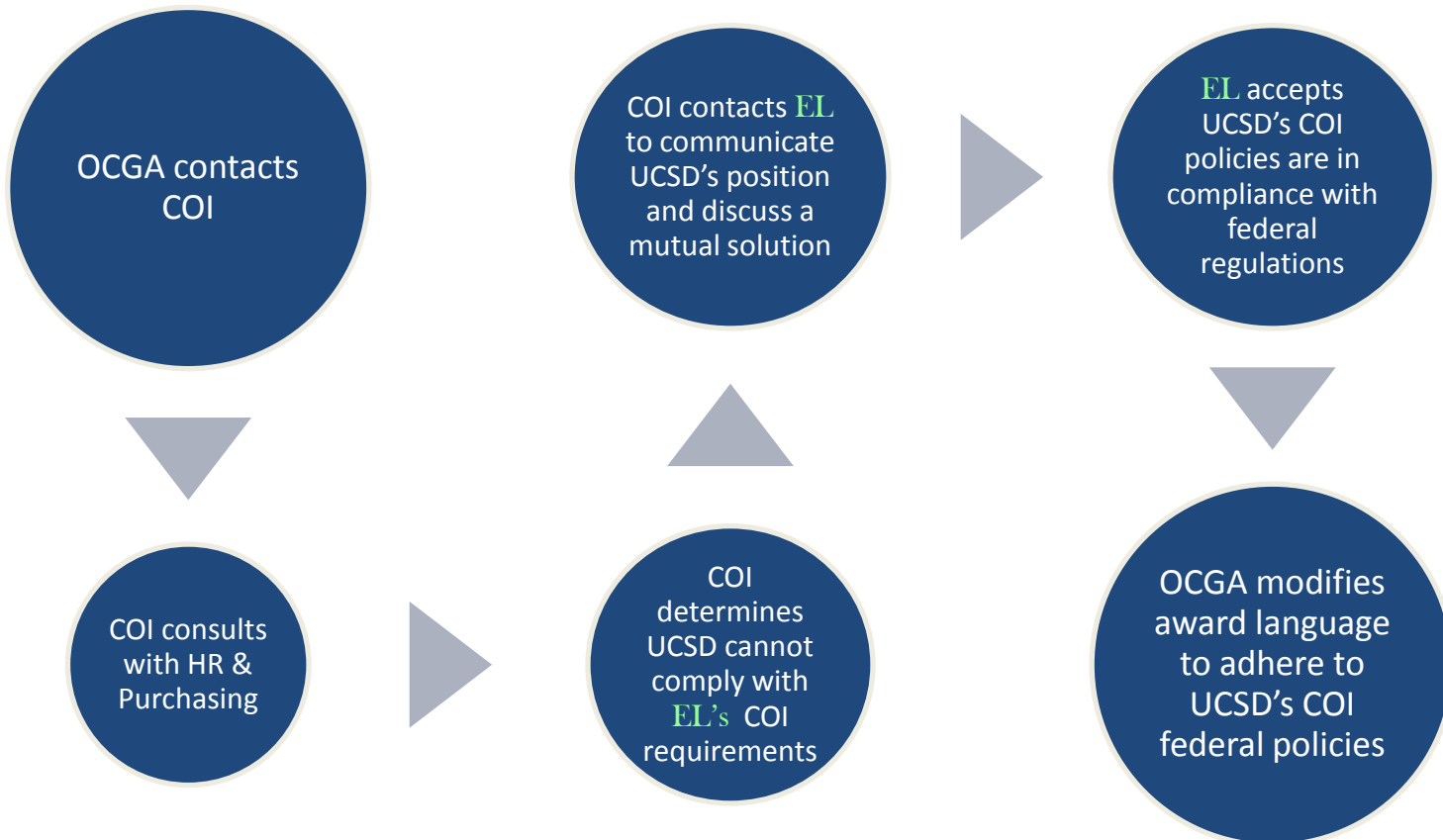
- \$60 million subaward awarded to UCSD from prime ARRA NSF awardee: **Environmental Leadership (EL)**
 - Mandates *“all UCSD personnel who have management/supervisory/ decision making authority, can influence decisions on technology selections/evaluations, and/or have inside knowledge on procurements”*
 - Sign **EL’s** COI disclosure forms
 - Agree to comply with any **EL** COI management plan developed



Case Study

Environmental Leadership

Negotiation



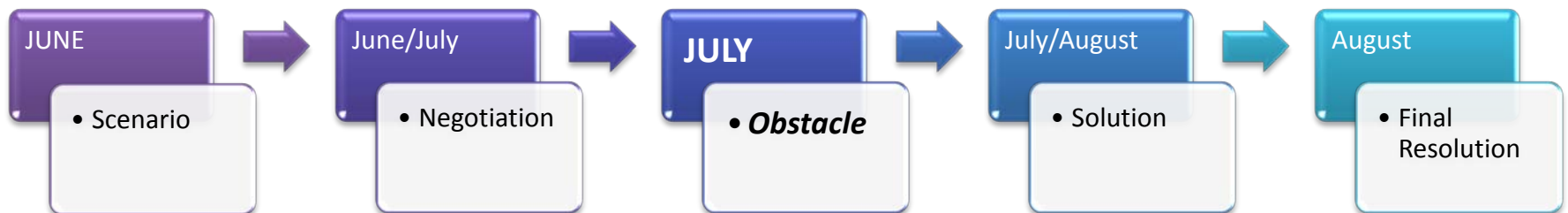
Case Study

Environmental Leadership

- **Obstacle**

- **EL's** Vice President does not agree with negotiated terms

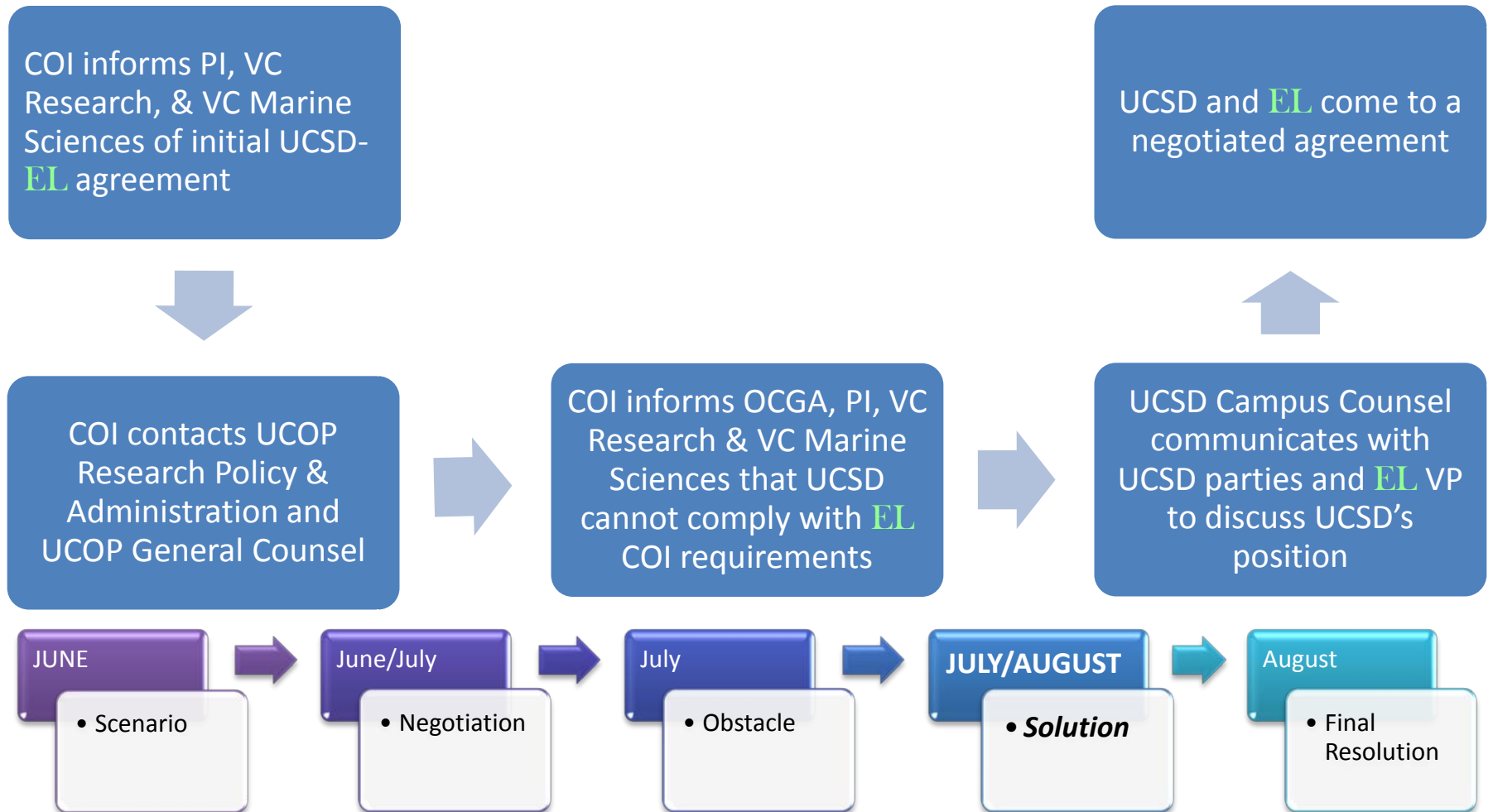
- Contacts UCSD VC Research and VC Marine Sciences
- Threatens to withhold releasing subaward funds until UCSD complies with EL COI terms.



Case Study

Environmental Leadership

• Solution

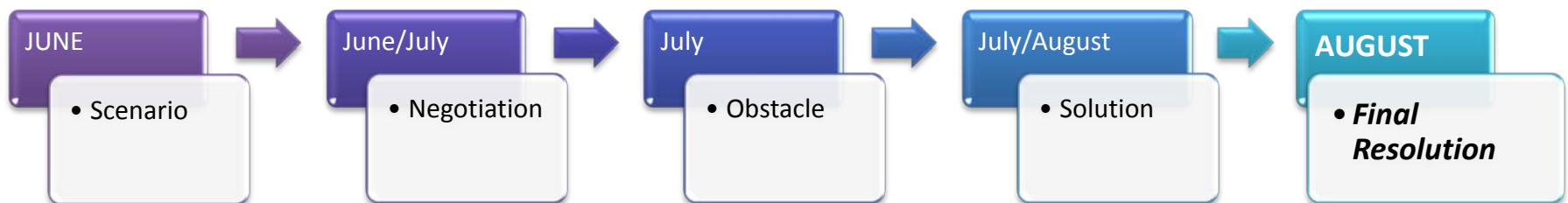


Case Study

Environmental Leadership

• Final Resolution

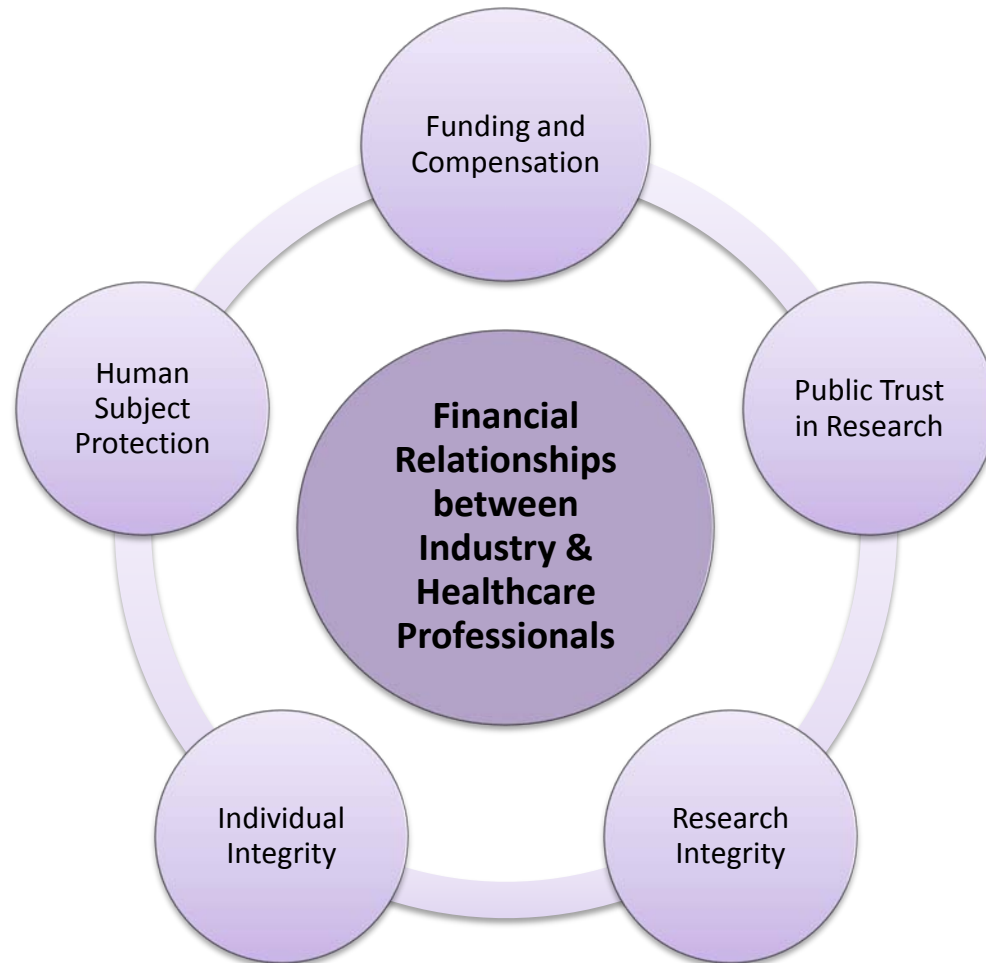
- OCGA agrees to modify the award language
 - New provision that any individual responsible for the design, conduct or reporting of research results must disclose using the UCSD disclosure form, be evaluated for potential COI using UCSD processes and report any potential COI to **EL**
- **EL** will send UCSD a separate letter stating
 - Reviewed UCSD's COI forms, policies and procedures and has determined that UCSD's forms, policies and procedures are at least equal in rigor to those of **EL**
 - UCSD may apply its forms, policies, and procedures in administering the contract.
- The PI will identify those UCSD personnel who need to sign a conflict of interest statement based on their having responsibility for the design, conduct and reporting of the research, as required by UCSD policy.



Case Study

Health Sciences Designated Officials

Intense focus from the Government, Media, Consumer Advocates, Scholarly Journals and Others



Case Study

Health Sciences Designated Officials

- AAMC and AAU Joint 2008 Report
 - Renewed focus on implementing compliance programs for conflict of interest
 - Recommended that all AAU and AAMC institutions develop institutional COI policy
 - Financial interests of the institution and of institutional officials in human subjects research
 - Deans
 - Department Chairs
 - Division Chiefs
 - Potential Institutional COI can exist for:
 - Institution
 - Institutional official



Case Study

Health Sciences Designated Officials

- Scenario
 - AAMC-AAU Joint 2008 recommends implementation of institutional COI policy
 - UC has no institutional COI policy
 - Other processes in place for disclosure and management of COI
 - How to integrate individual and institutional conflict of interest
 - Especially for Deans, Department Chairs and Division Chiefs

SCENARIO

Negotiation

Obstacle

Solution

Case Study

Health Sciences Designated Officials

- Negotiation
 - October 2008
 - UCOP Office of Research Policy drafts
 - UC Policy on Institutional COI (iCOI)
 - Draft guidance on Financial Interest Disclosure in the Informed Consent Form
 - May 2009
 - Draft iCOI Policy and Guidance is distributed to Administrative COI Coordinators
 - NIH issues an Advanced Notice of Proposed Rulemaking for COI
 - June 2009
 - VP Stobo requests to review the Conflict of Interest and Conflict of Commitment reporting/disclosure forms used by the 5 health campuses

Scenario

NEGOTIATION

Obstacle

Solution

Case Study

Health Sciences Designated Officials

- Negotiation
 - November 2009
 - UCSD, UCSF, UCLA and UCI receive HHS/OIG Survey on ICOI
 - UCSD COI Coordinator presents to the UCSD Compliance, Audit, Risk and Ethics (CARE) Committee on proposed changes in ICOI requirements
 - UCSD CARE Committee recommends additions of HS Department Chairs, Division Chiefs, Chief Administrative Officers to COI Code as Designated Officials
 - March 2010
 - UCSD COI Office receives endorsement from Health Sciences Compliance Advisory Group to add HS Department Chairs/Division Chiefs and Chief Administrative Officers be added to the COI Code as Designated Officials

Scenario

NEGOTIATION

Obstacle

Solution

Case Study

Health Sciences Designated Officials

- **Obstacle**
 - Health Sciences Department Chairs
 - Division Chiefs
 - Chief Administrative Officers
 - Concerned that broad reporting requirements will require new and significant efforts to report all financial interests.

Scenario

Negotiation

OBSTACLE

Solution

Case Study

Health Sciences Designated Officials

- Solution
 - June 2010
 - UCSD COI Office consults with UCOP General Counsel Conflict of Interest Coordinator
 - Add positions to the UC COI Code
 - August 2010
 - UCSD submits new positions for FPPC Approval
 - HS Department Chairs
 - HS Division Chiefs
 - HS Chief Administrative Officers (August 2010)
 - » Disclosure categories are very limited
 - Only financial interests in entities that have done business with the administrative unit or department
 - December 2010
 - FPPC adds new positions to the UC COI Code

Scenario

Negotiation

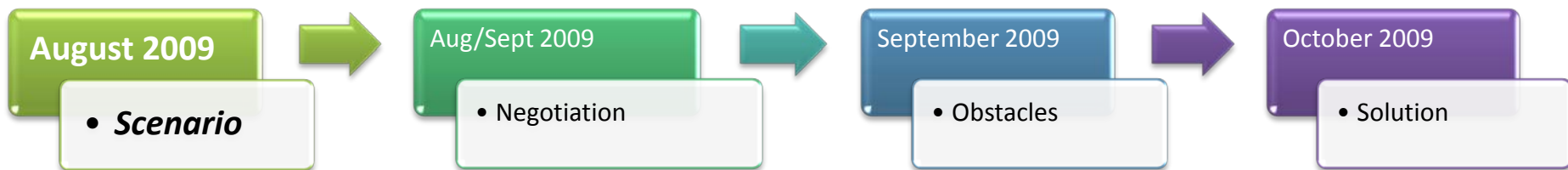
Obstacle

SOLUTION

Case Study

Outside Professional Activities-Staff

- Scenario
 - Furloughs and salary freezes
 - Numerous inquiries from UCSD staff and academic research personnel to engage in outside professional activities
 - No special provisions in the UC furlough plan to allow staff to engage in outside professional activities.
 - Faculty and SMG employees may consult under current UC Policy
 - APM-025 and the Policy for Outside Professional Activities for University Officers and Designated Staff
 - The University's Personnel Policy for Staff Members - Conflict of Interest
 - Employees shall not engage in any activities which create a conflict of interest between their assigned functions and any other interest or obligation.
 - Need to develop a standard process to address outside professional activities of staff



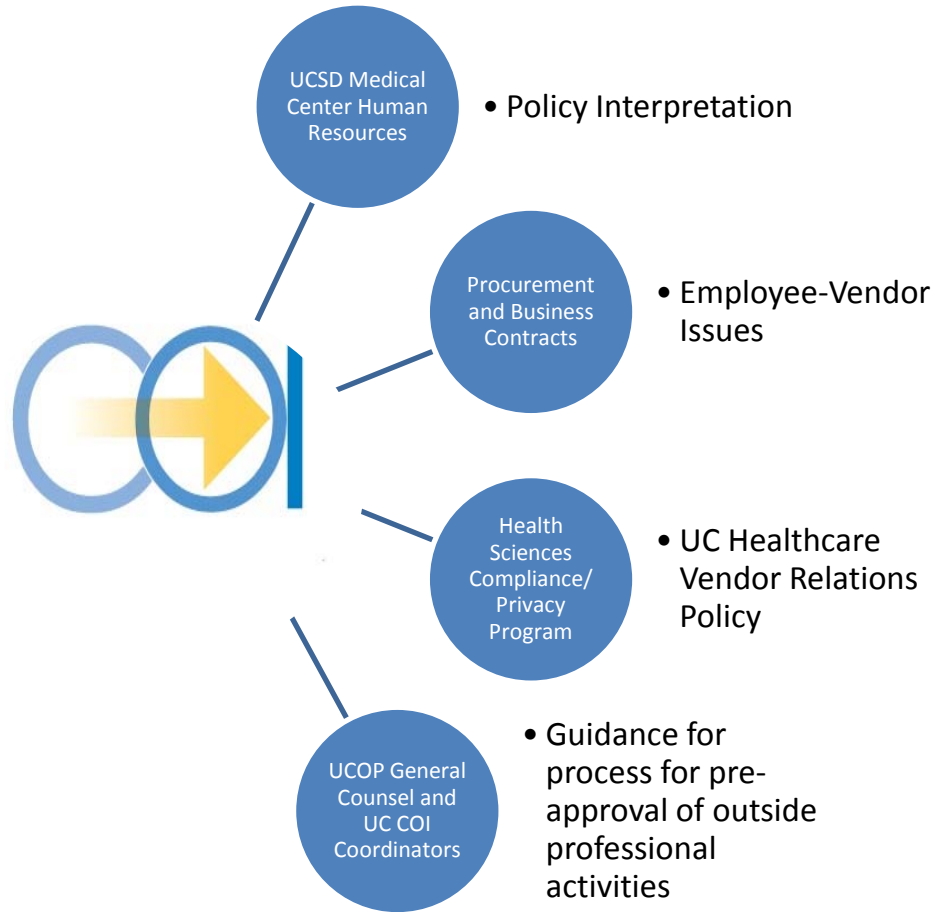
Case Study

Outside Professional Activities-Staff

Type of Employment	Regulation	Restrictions
All UCSD Employees	PPSM 82/Political Reform Act	Government (University) employees may not participate in decisions if they have a personal financial interest.
Designated Officials	Form 700 Annual Financial Disclosure	Requires certain officials to publicly disclose their private economic interest.
SMG Members	UC Policy on Outside Professional Activities for University Officers and Designated Staff	The immediate supervisor of a SMG employee is responsible for approving participation in outside professional activities in advance and in writing.
Faculty	APM-025 APM-670	Limits outside activities: (1) type of activity, (2) time allocation, (3) reporting. Places conditions on time spent and income earned from outside professional activities- HSCP Rules

Case Study

Outside Professional Activities-Staff



Case Study

Outside Professional Activities-Staff

- Obstacles (September 2009):
 - COI provides guidance, but must develop written procedures so that that staff can enter into consulting and other professional arrangements with private industry



Case Study

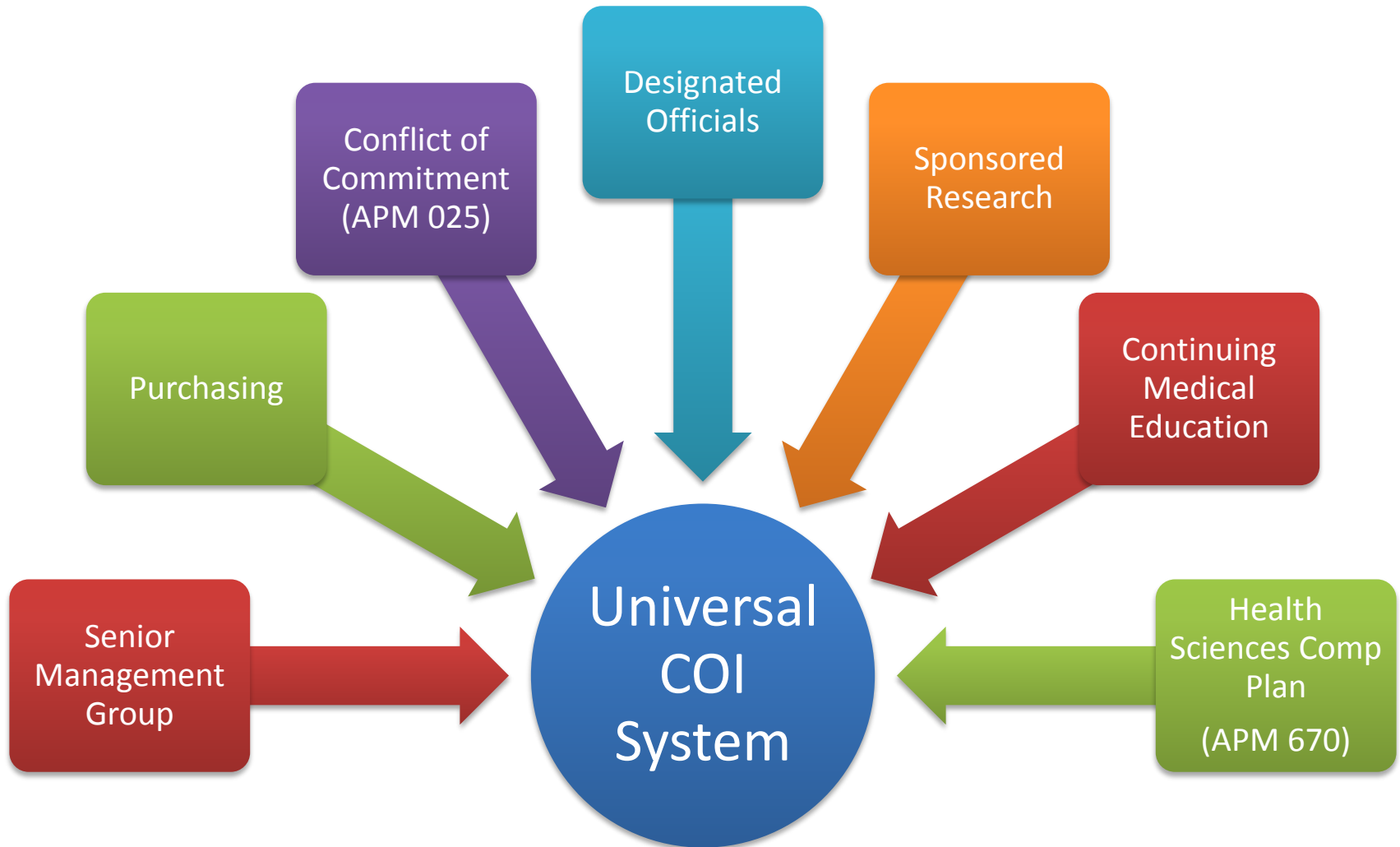
Outside Professional Activities-Staff

- Solution (October 2009):
 - Staff members must obtain prior approval, in writing, from their supervisor
 - Staff is required to use vacation time (or furlough days) for this activity
 - Outside professional activity would have to be disclosed to all departmental staff and if the activity interferes with the operational integrity of the unit, then the supervisor can deny the employee request to engage in the activity



The New COI Model:

Functional areas across UC that require financial reporting and COI monitoring



Essential Components of an Integrated COI Program

- Reporting
 - All financial interests must be reported
- Assessment
 - All interests must be assessed to determine if they are Conflicts of Interest
 - The assessment must follow pre-set criteria based upon policy and guidelines
- Management
 - Identified conflicts of interest must be reviewed to determine an effective management strategy
- Oversight
 - Must have systems to verify that the management strategy is implemented and remains sufficient to manage the conflict of interest.

Future Considerations

- **Self-regulation of University-Industry relationships is being threatened by increasing government regulations and oversight**
- Greater emphasis on reporting financial interests and disclosure to the public
 - How do we implement an integrated system to capture information, disseminate it as required and monitor compliance?
 - How can we reduce the administrative burden on researchers and better communicate changes in policies and regulations to facilitate compliance with disclosure requirements?
 - How do we assess our adherence to constantly changing regulations?
 - What processes are in place for continuous evaluation of COI management strategies?
 - Are training mechanisms adequate? Do all participants in the research enterprise understand their obligations?
 - How do we secure adequate resources to implement best practices?