



Developing a Centralized Ethics and Compliance Program in a Decentralized and Defunded Environment

SCCE Conference on Effective Compliance Systems in Higher Education – June, 2009

Presenters

Lynda Hilliard, MBA, RN, CHC, CCEP

Deputy Compliance Officer

Ethics and Compliance Department

University of California

Luanna Putney, Ph.D., CHC, CCEP

Director of Research Compliance

Ethics and Compliance Department

University of California

Presentation Outline

- Establishment of a Systemwide Compliance Program
- Decentralized Compliance Roles
- Tying it Together: the Communication Plan
 - For Example: Research, Privacy and Healthcare Compliance

Presentation Goals

- Identify important elements of an effective systemwide compliance program in the decentralized model
- Learn how to leverage decentralized activities to improve compliance program efficiencies

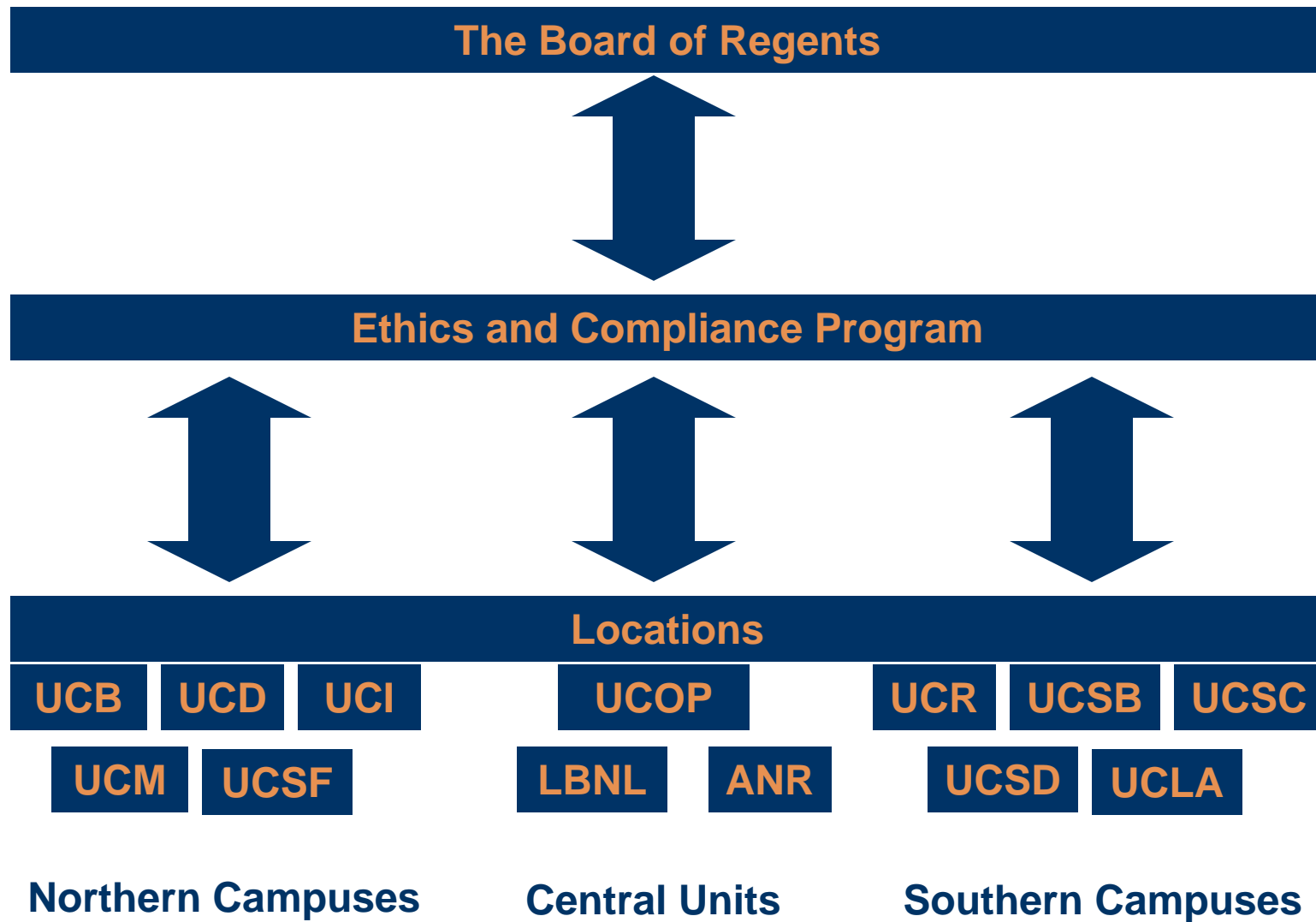
Establishment of the Systemwide UC Ethics and Compliance Program

- Why?
 - Good business practice
 - Required by Federal Acquisition Regulation (FAR 52.203-13)
 - Provides efficiencies in processes and communication
 - Reduces/prevents civil/criminal enforcement by regulatory agencies
 - Enhances public trust
 - Meets expectations of external constituents and The Regents
- When?
 - Program was approved by The Regents July 2008

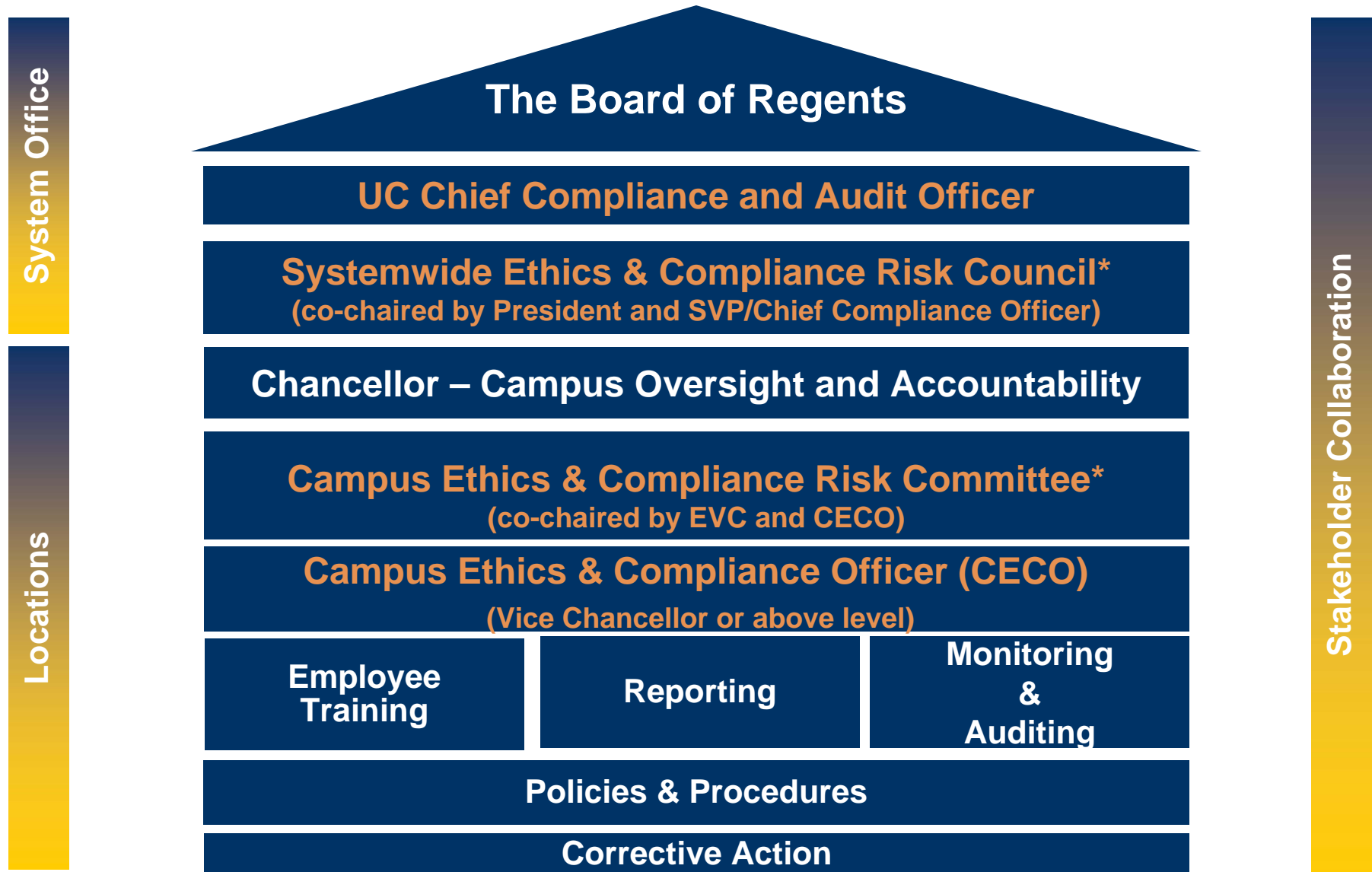
Systemwide Program: Getting Started

- Determine scope of Ethics and Compliance Program (“Program”)
 - ✓ Reduce compliance “silos”
 - ✓ Model from the Federal Sentencing Guidelines
- Identify and understand compliance risks within organization
 - Determine scope of services provided
 - Identify applicable rules and regulations governing the operations of the business, i.e., research, health care, education, financial aid, sports (NCAA), title IX, ADA, etc.
 - Outline and understand the business processes and their inter-campus relationships
- Gain leadership commitment for a Program based on strong “tone from the top”

Defining the Communication Plan



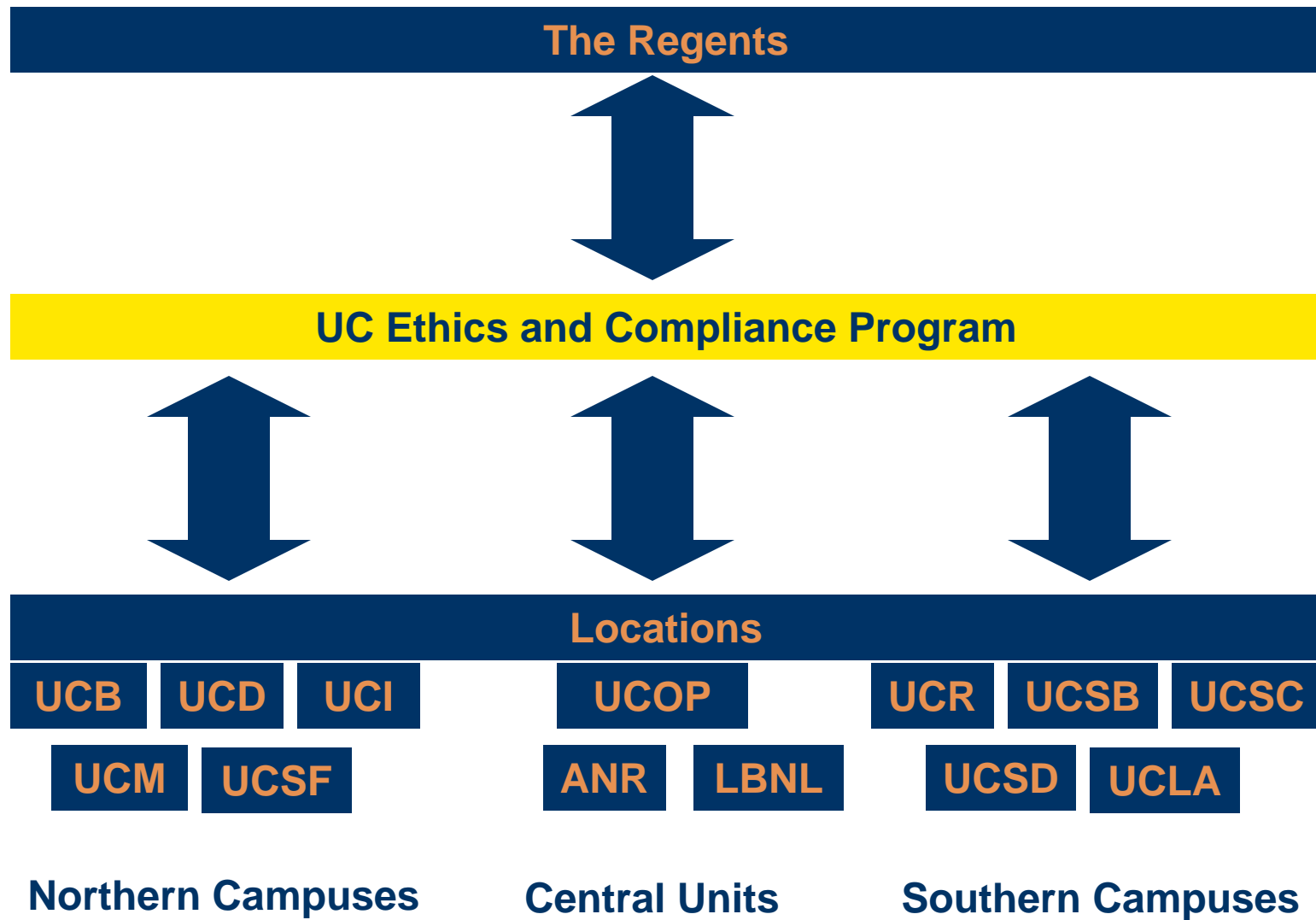
Building the Structure



*Membership to include representation from academic senate and administrative leaders of compliance risk areas; “campus” refers to UC locations including LBNL, UCOP and ANR

*Academic Medical Centers are included in “campus” definition

Systemwide Program: Mission and Roles



Mission Statement

The UC Ethics and Compliance Program **enhances** the University's duty to perform its public responsibilities in an ethics and compliance-based environment where applicable legal, regulatory, Regental and UC Policy are followed and in which the public trust is maintained.

Sample of Compliance Obligations including but not limited to the below				
<ul style="list-style-type: none">▪ Anti-kickback/ Sponsorship Laws▪ Anti-trust/ Competition Laws▪ Pricing & Reimbursement▪ Promotional Activities	<ul style="list-style-type: none">▪ Equal Employment Opportunity▪ Affirmative Action▪ Sexual Harassment▪ Benefits Fiduciary Obligations▪ NCAA	<ul style="list-style-type: none">▪ Grants and Contracts Rules▪ Animal Research▪ Environmental Health & Safety▪ Import/Export Controls	<ul style="list-style-type: none">▪ Human Subjects Protection▪ HIPAA Privacy▪ Good Clinical/Lab Practices (GCP)▪ Licensure	<ul style="list-style-type: none">▪ Conflicts of Interest▪ Compensation & Tax (IRS)▪ Information Security

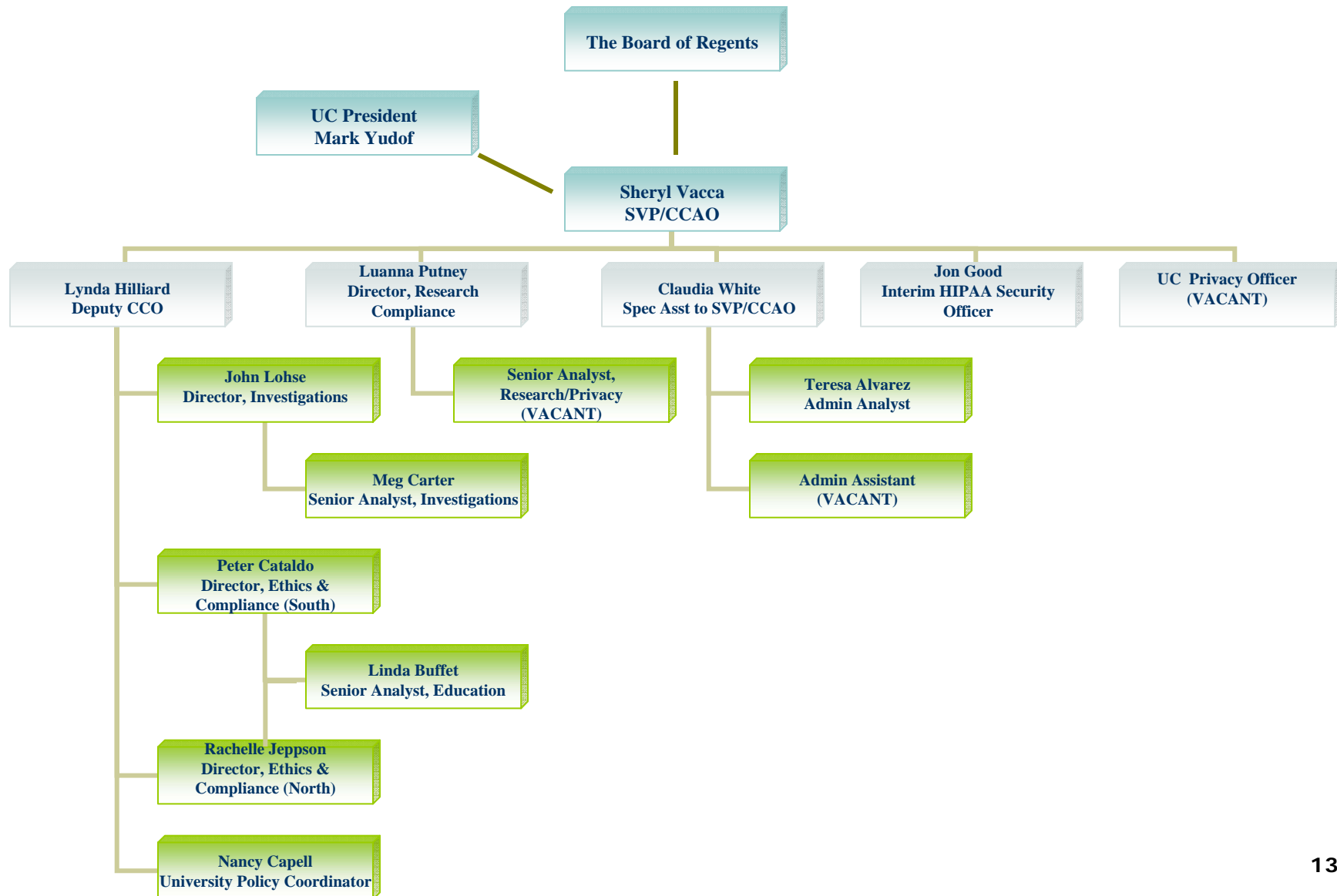
Tenets of a Systemwide Program

- Demand individual accountability and responsibility as key tenets of an effective Program
- Educate key stakeholders on the role of compliance as differentiated from legal and/or risk management and outline the benefits of having a strong Program
- Gain consensus from key stakeholders from both the administrative and academic functions
- Develop a Program that is efficient and leverages current policies/procedures, internal controls, training and education, human resource protocols and audit/monitoring activities that meet regulatory requirements

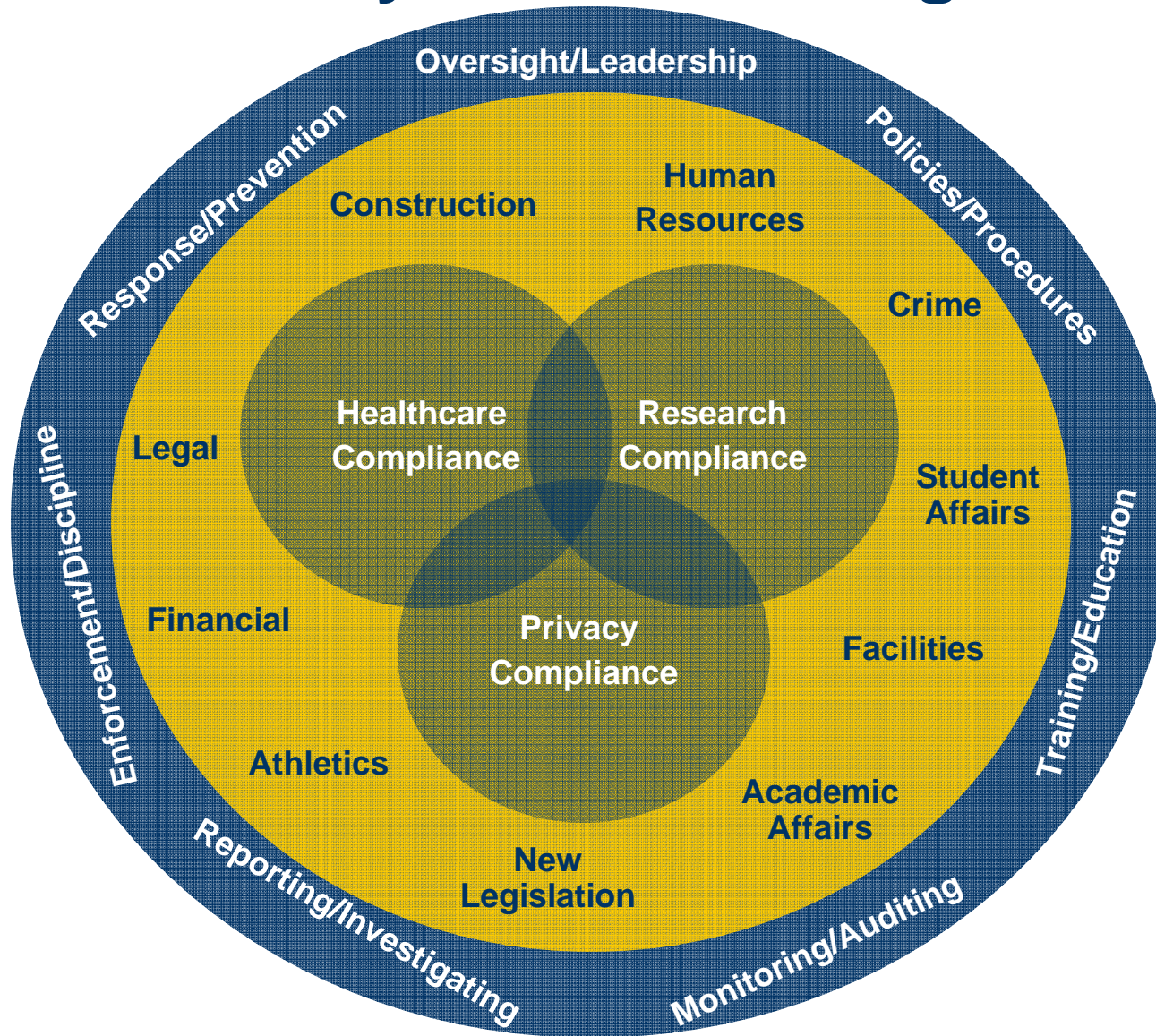
Tenets of a Systemwide Program (cont)

- Identify informal and formal communication structures and key stakeholders in the organization
- Establish Program communication plan that includes frequent updates and status reports on Program development, activities, etc. to key stakeholder communities
- Solicit feedback from stakeholders on process questions, i.e., communication methodologies to other constituencies within the organization
- Establish trust by following through on tasks, etc in a timely manner.

Structure of the Systemwide Program



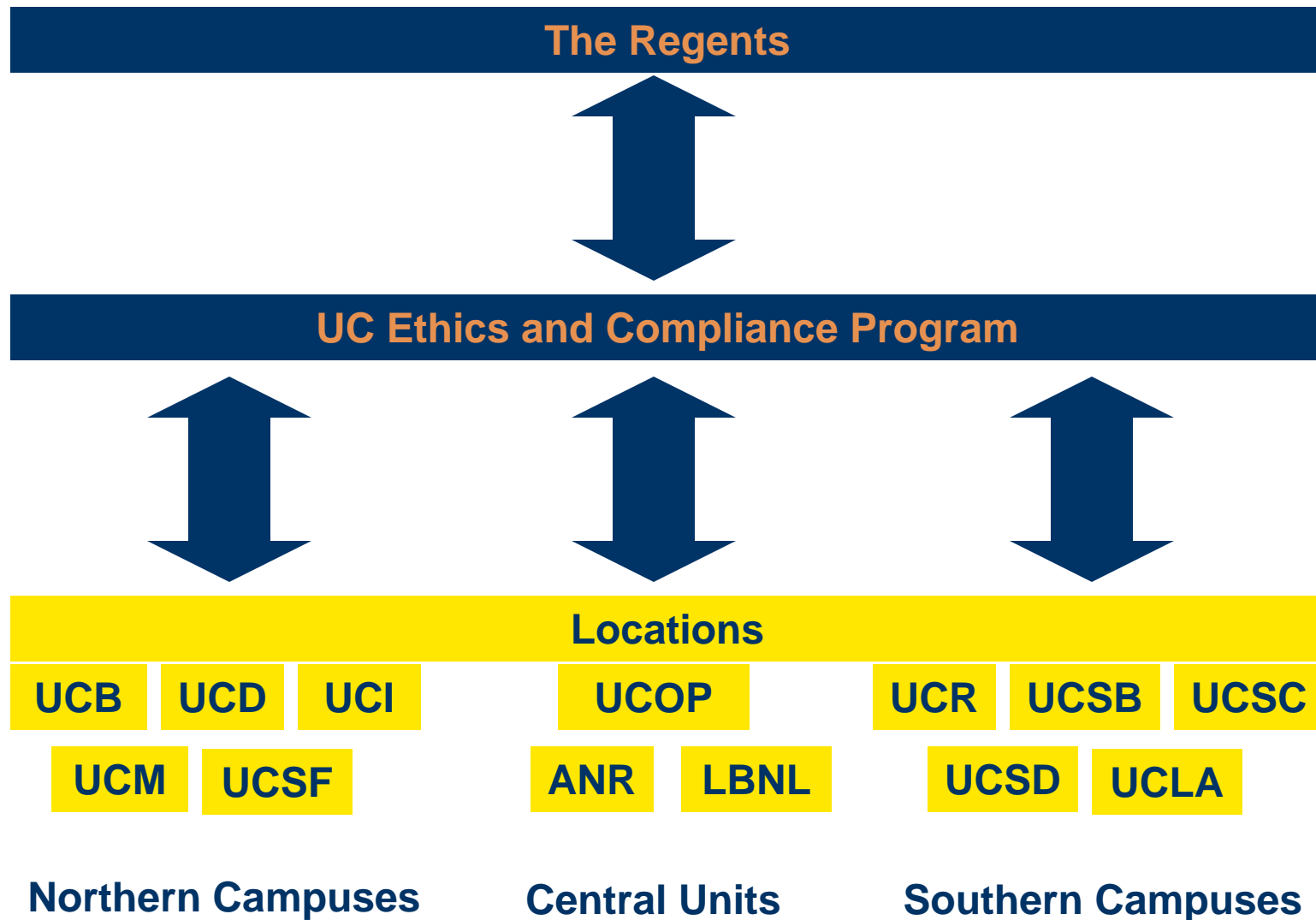
Priority Functional Areas of the Systemwide Program



Roles of the Systemwide Office

- Responsible for coordinating and reporting overall activities and performance metrics to the Compliance and Audit Committee of the Board of Regents
- Assist locations in establishing effective Ethics and Compliance Risk Committees, i.e., provide tools, performance metrics, benchmarking, etc.
- Coordinate/collaborate with locations on identification of compliance risks and mitigation efforts
- Develop mandatory training (i.e., Sexual Harassment, Compliance/COI Briefings, HIPAA)
- Facilitate accountability through development of central policy statements (i.e., enforcement policies)

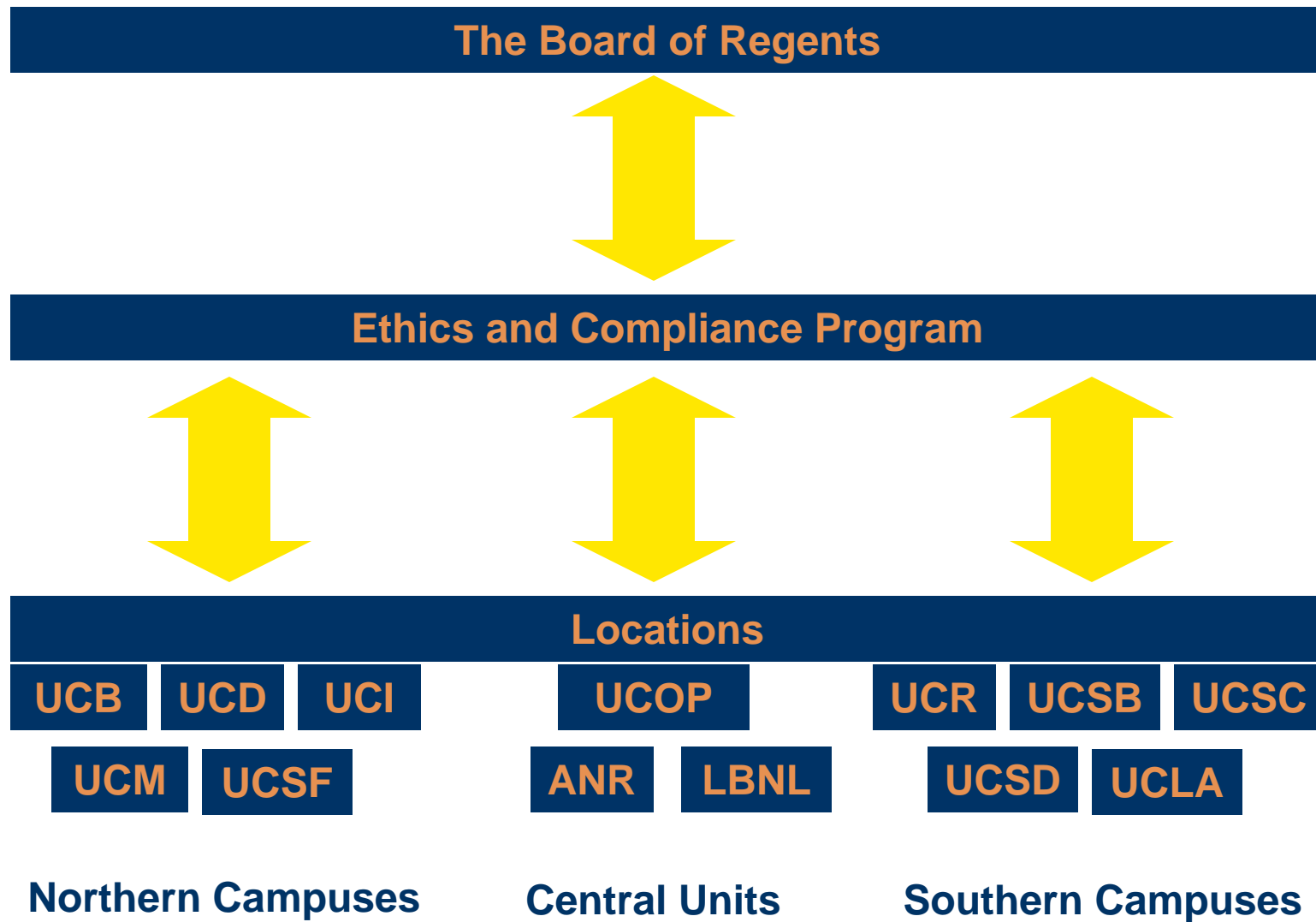
Decentralized Program: Roles of the Locations



Roles of the Locations

- Chancellor accountable for compliance on campus and appointment of EVC as CECC Chairperson
- Designate location Campus Ethics and Compliance Officer as liaison to Systemwide Ethics and Compliance Program
- Identify, address and mitigate high risk compliance areas at specific location
- Ensure completion of location-specific mandatory compliance training (100% compliance)
- Facilitate accountability through development of applicable local policies/procedures (i.e., enforcement policies)
- Report overall location-specific activities and performance metrics to the Systemwide Ethics and Compliance Program

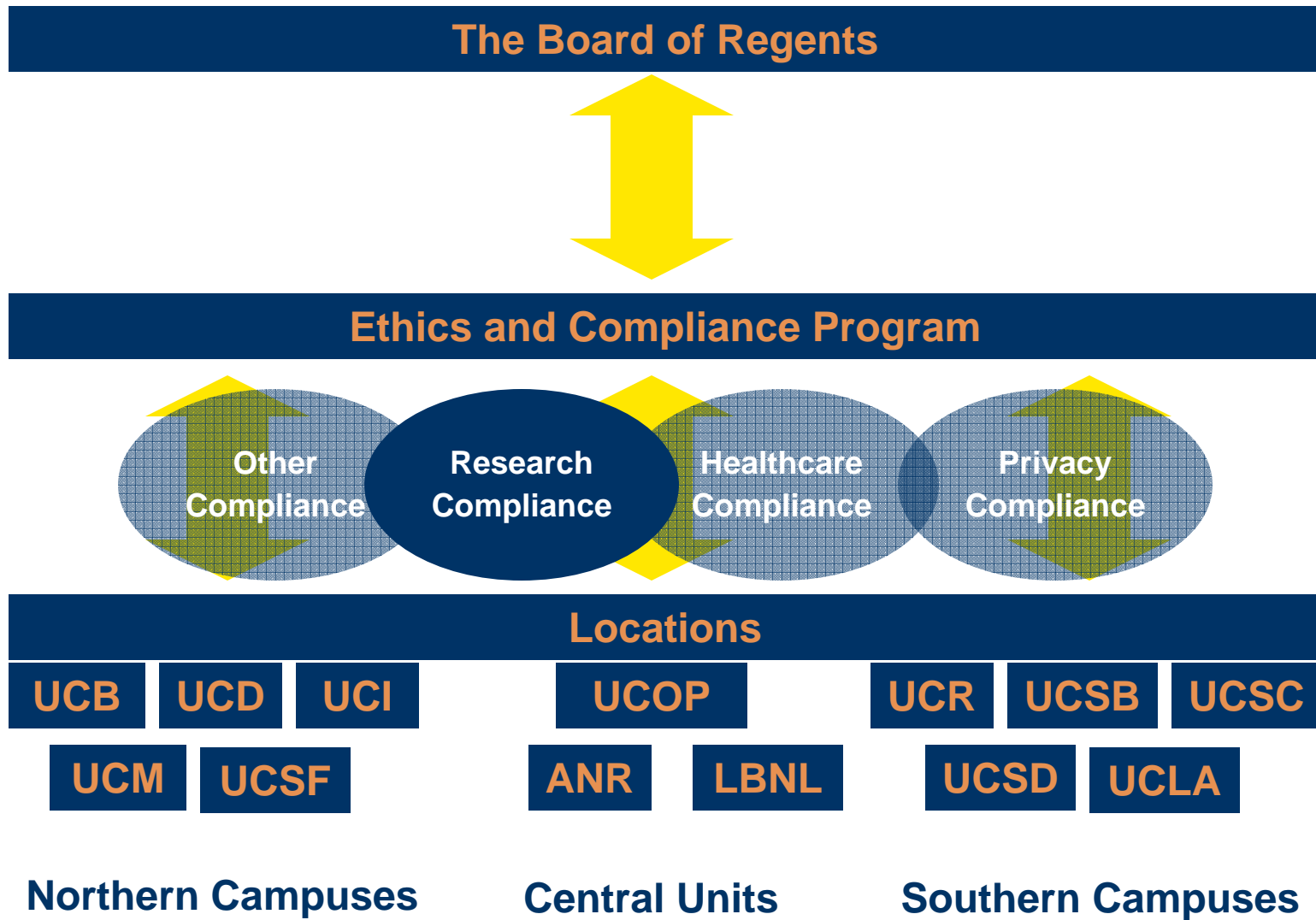
Tying it Together: The Communication Plan



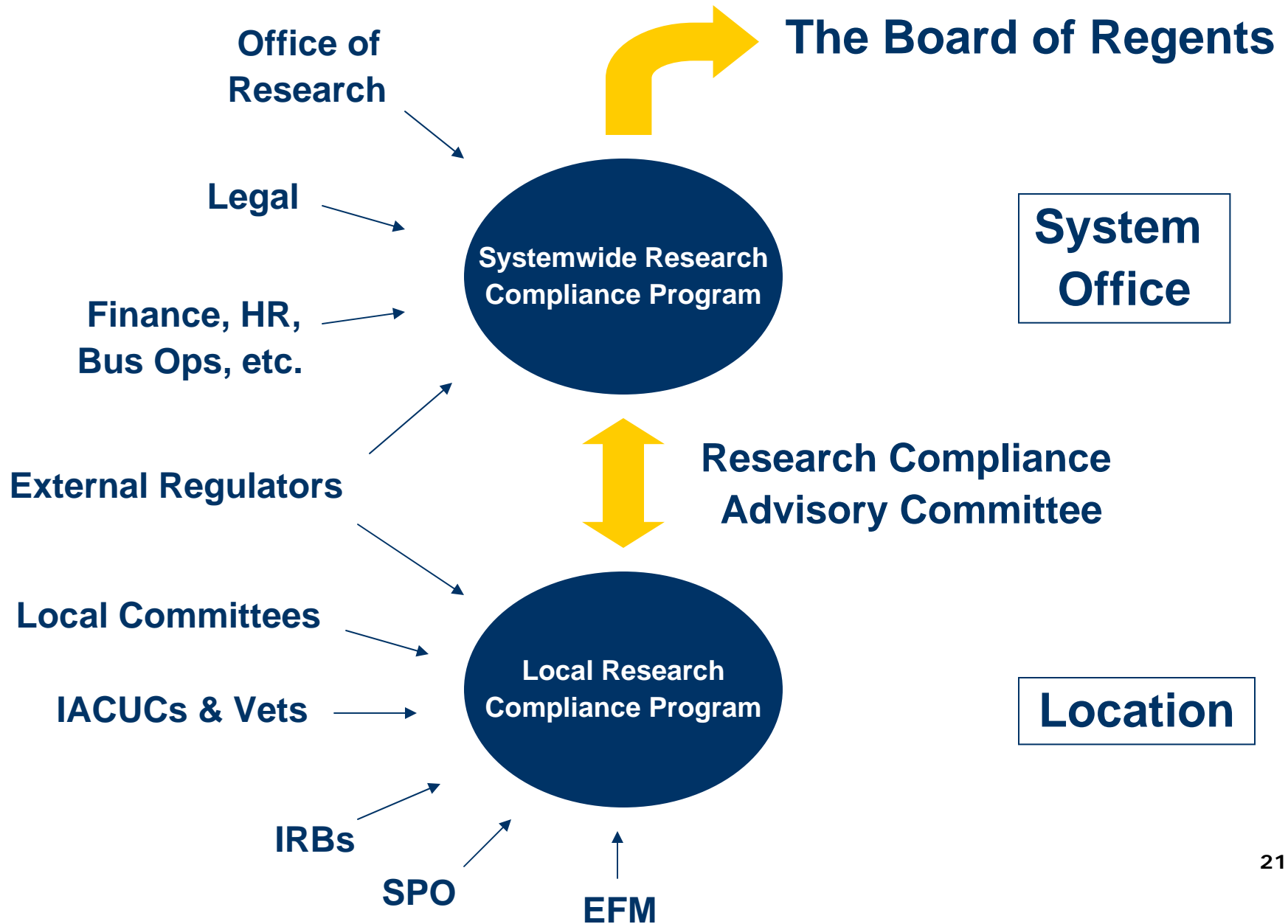
Communication is Key

- Participation by Chief Compliance and Audit Officer (CCAO)
 - CCAO participates in location committee meetings
 - CCAO conveys first-hand information from The Board of Regents and UC President directly to location leadership
- Integration of full-time Systemwide Directors of Ethics and Compliance in location committees
 - Directors provide written and verbal systemwide updates at each location committee meeting, and report information from locations back to Systemwide Program leadership
 - One Director for Northern locations and one for Southern locations
 - Fluid communication between Northern and Southern Directors to ensure consistency in messaging
- Systemwide Program Office facilitates frequent meetings and standing calls to discuss and mitigate specific high risk priority areas among location stakeholders and leadership

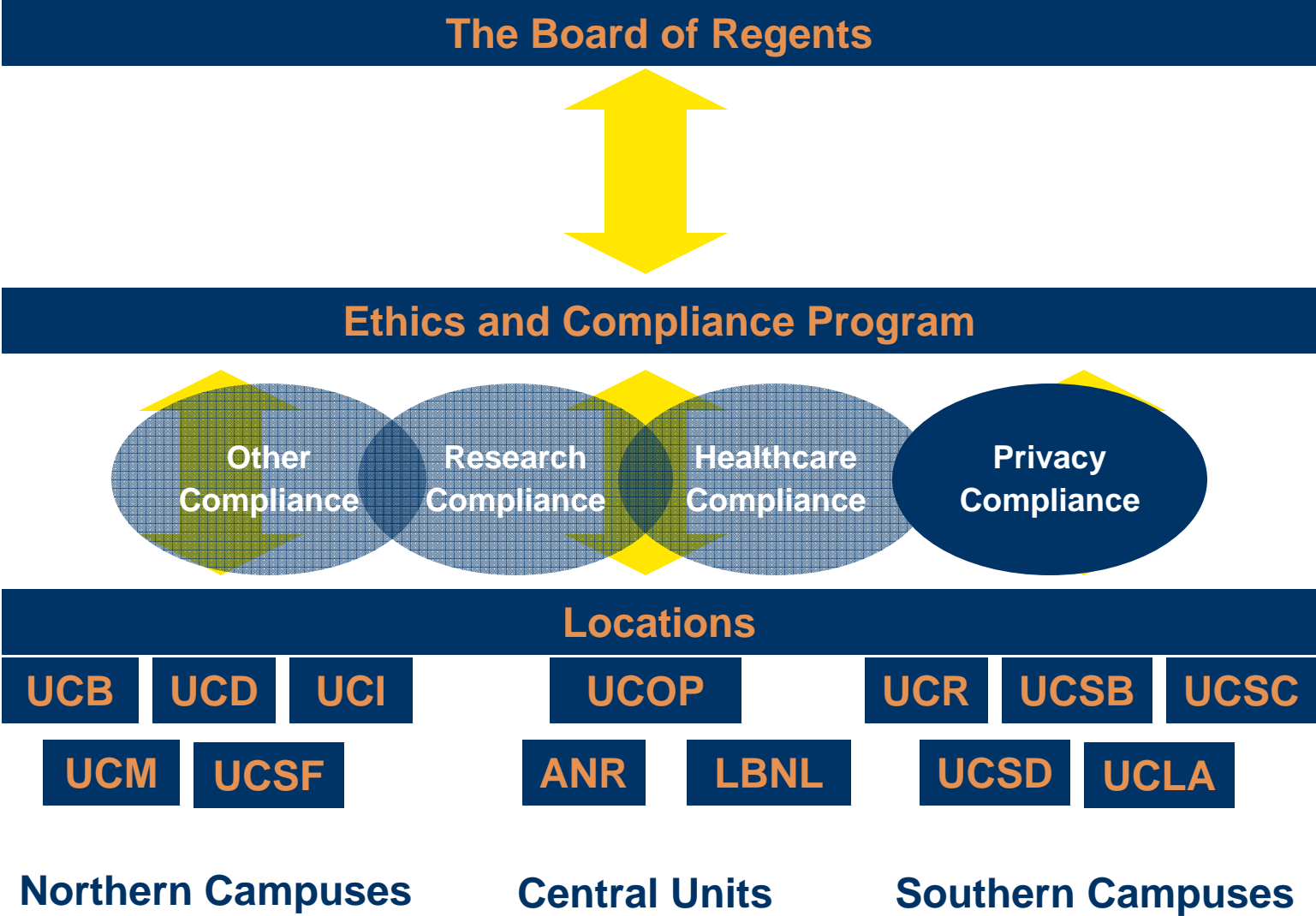
The Communication Plan: Research Compliance Example



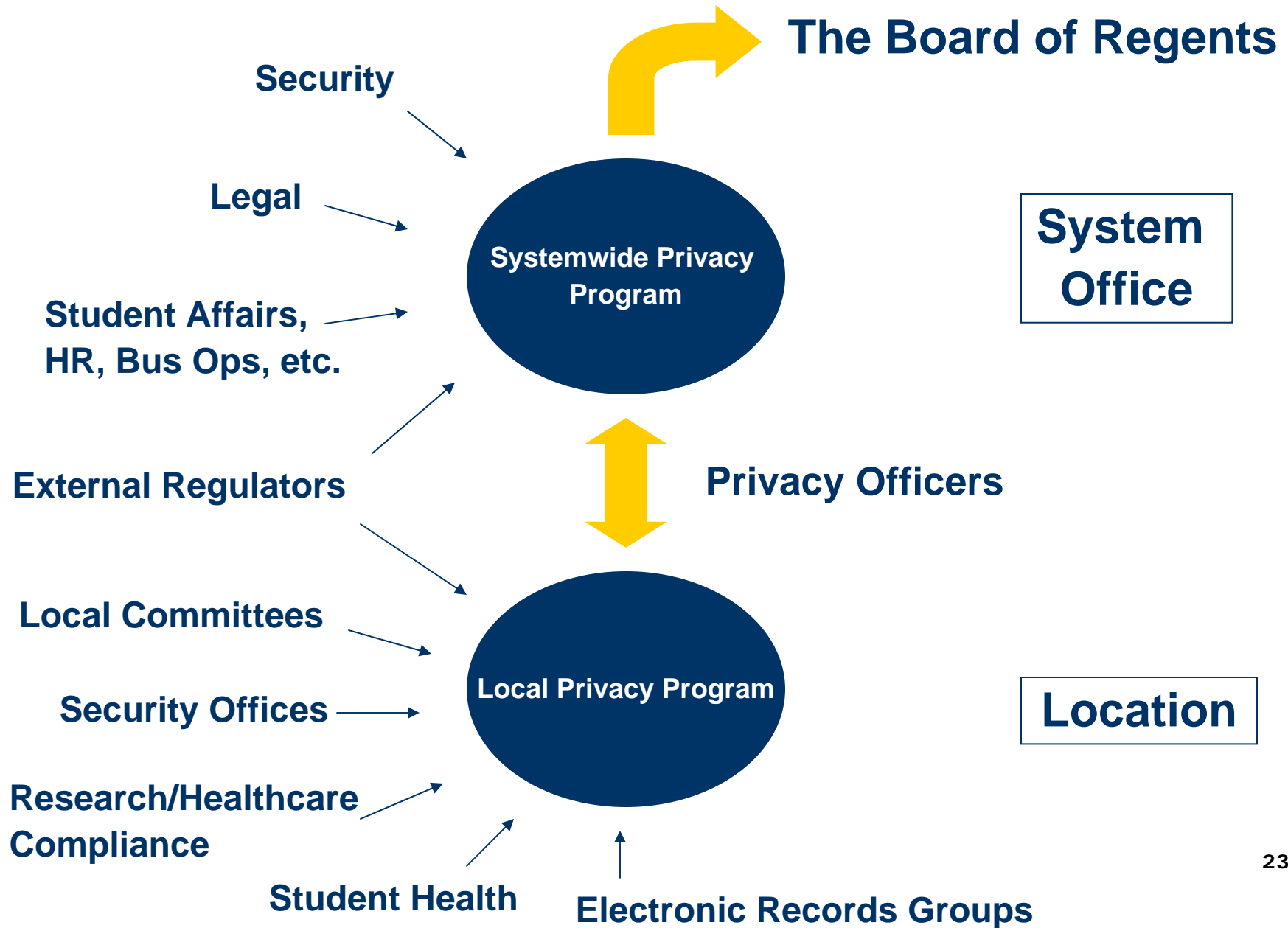
Research Compliance Communication



The Communication Plan: Privacy Compliance Example



Privacy Compliance Communication



Adding Value in Decentralized and Defunded Environment

- **Leverage locations' existing organizational structure, training, policies/procedures and monitoring efforts already in place/being conducted**
 - Mandatory training pushed out centrally could be incorporated into location-specific training already being offered
 - If dispersed compliance leadership/committee activity already exists in area, suggest locations pull together outcomes/status of those efforts for reporting
- **Provide centralized assistance to bring locations together and facilitate communication**
 - Offer to do the leg-work and/or fund (if office has \$\$) information gathering and workgroup formation (i.e., scheduling, hosting meetings, etc.) to focus on high risk systemwide compliance issues
 - Provide infrastructure support for value-added compliance training (i.e., webinars, listservs for education sharing, hosting in-person training, etc.)
- **Provide personnel to participate in location meetings and campus workgroups**
 - Personnel act as information gatherers—saving time and effort on part of location leadership
 - Personnel provide direct, timely and accurate information to location leadership about systemwide compliance risks

Thank You!!

Lynda Hilliard, MBA, RN, CHC, CCEP

lynda.hilliard@ucop.edu

510-987-0851

Luanna Putney, Ph.D., CHC, CCEP

luanna.putney@ucop.edu

510-987-0028