University Hospitals Case Medical Center

Evolution of Ethics & Compliance Training Programs

Carol Fedor
Clinical Research Manager, Office of Research Compliance & Education
Center for Clinical Research & Technology
University Hospitals Case Medical Center

Luanna Putney
Director of Research Compliance
Ethics, Compliance & Audit Services Office
University of California
Office of the President

University Hospitals Case Medical Center

Goals

- Discuss the value of building a quality improvement based research monitoring and education program
- Outline the key steps in the evolution and growth of a research compliance and education program
- Analyze the evolution of research compliance through quality improvement initiatives

University Hospitals Case Medical Center

Roadmap

- Part 1 - Integration of training into the day-to-day culture at University Hospitals Case Medical Center (UHCMC), from a single-site organizational perspective
- Part 2 – Training development at the University of California (UC), from a multi-campus corporate structure perspective

University Hospitals Case Medical Center

UHCMC/UC Comparison

- University Hospitals Case Medical Center
  - Main campus houses central research administration office; twenty-five clinical/academic departments
  - Ten satellite facilities conduct ongoing research; CTSC institutions
  - Research compliance oversight system-wide in parallel with Corporate Compliance
- University of California
  - Ten campuses, including five Academic Medical Centers, and one national lab
  - Each campus responsible for own research compliance training programs
  - System office provides support to help bolster research compliance training programs as needed

Part 1 -- University Hospitals Case Medical Center Organizational Structure

University Hospitals Case Medical Center

University Hospitals Case Medical Center -- Research Compliance & Education Program *Mission Statement*

Full AAHRPP Accreditation

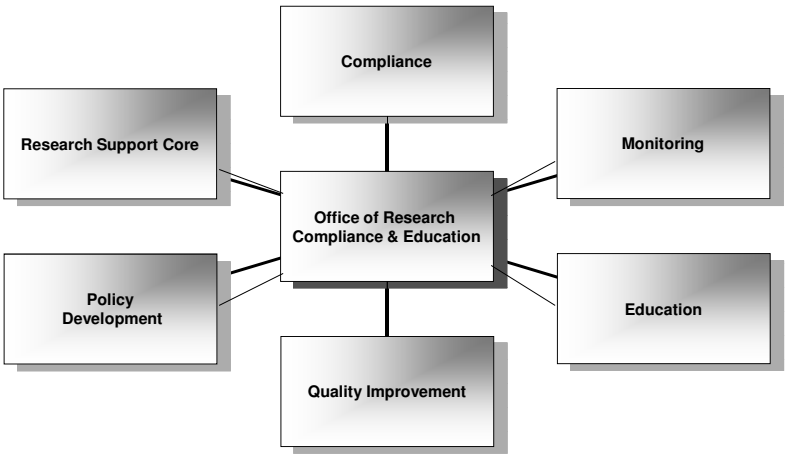
University Hospitals Case Medical Center

UHCMC
To Heal. To Teach. To Discover.

Research Compliance and Education Office
To promote research integrity while improving the protection of research participants through education, monitoring and regulatory guidance across the Human Research Protection Program (HRPP).

Continuous Quality Improvement

University Hospitals Case Medical Center



UHCMC Research Compliance & Education Program

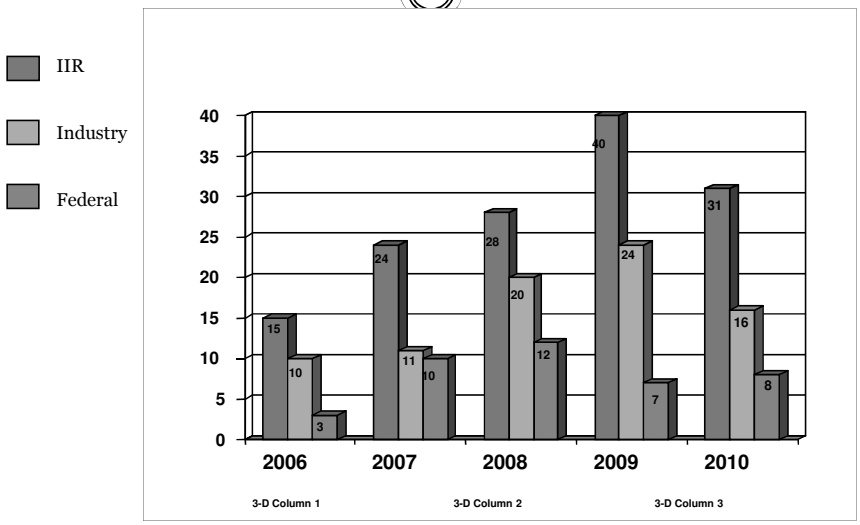
University Hospitals Case Medical Center

Responsible for:

- Prospective monitoring
- Directed monitoring
- Responsible Conduct of Research Education
- Quality Improvement
- Research Policies
- Research Support Core
- Additional monitoring: IRB, consent process, gra activity, research injury language

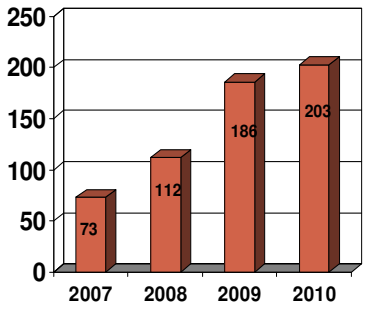
Protocol Monitoring by Category

University Hospitals Case Medical Center

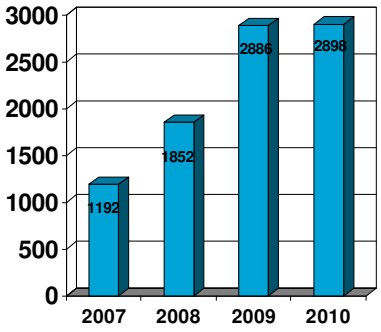


Clinical Research Education Program

University Hospitals Case Medical Center



Education Sessions



Attendees

Research Monitoring Process

University Hospitals Case Medical Center

Pre-monitoring	Monitoring	Post-Monitoring
Protocol selection	Monitoring review (regulatory binder, research records)	Review findings with research team
Notification letter	**Informed consent observation**	Written report
Schedule	**Grant/contract review**	Investigator response
File review (IRB)	**Investigational pharmacy**	**Review potential non-compliance with IRB**
Preparation	**Clinical research unit**	**Injury language**
Informed consent checklist	On-site education	**Conflict of interest**
Interview PI, staff	**Education**	**Education**

Human Research Protection Programs (HRPPs)

University Hospitals Case Medical Center

AAHRPP Standards

- The scope and purpose extends beyond the IRB and its corresponding administrative office and assesses many more components.

  Domain I. Organization
  Domain II. Institutional Review Board
  Domain III. Researcher and Research Staff

Human Research Protection Programs (HRPPs)

University Hospitals Case Medical Center

- Element I.5.B.
  - The Organization conducts audits or surveys or uses other methods to assess the **quality, efficiency, and effectiveness** of the Human Research Protection Program. The Organization identifies **strengths and weaknesses** of the Human Research Protection Program and **makes improvements**, when necessary, to increase the quality, efficiency, and effectiveness of the program.

Quality Improvement Process

University Hospitals Case Medical Center

- ☑ Review internal policies & procedures
- ☑ Evaluate performance targets and goals
- ☑ Establish benchmarking standards/metrics
- ☑ Analyze trends observed during monitoring visits → programmatic process improvement
- ☑ Continuous re-evaluation of CCRT operations and productivity
- ☑ Strategic Business Plan (5-year)

Education Development

University Hospitals Case Medical Center

Live Sessions

- **Clinical Research Curriculum (required)**
- Adverse Event Reporting
- Keys to a Successful IRB Submission
- Informed Consent
- Top 10 Common Non-Compliance Findings
- Regulatory Binder Compliance
- Research Ethics Series
- **Research Billing/Coverage Analysis (required)**
- **IND/IDE Education (required)**

Electronic newsletter
"*Collaboration Corner*"

Research Education Track Development

University Hospitals Case Medical Center

Education Topics	Track/Category
Clinical Research Curriculum (CRC) REQUIRED	Responsible Conduct of Research
Informed Consent Process	Responsible Conduct of Research
Event Reporting: Understanding Adverse Events, Unanticipated Problems, and Protocol Deviations	Research Compliance
Top 10 Compliance Findings	Research Compliance
Investigator Initiated Research: IND/IDE	Research Compliance
Research Ethics: Payment to Participants	Research Ethics
Research Ethics: Research with Children	Research Ethics
Research Ethics: Use of Placebo in Research	Research Ethics

Research Education Track Development

University Hospitals Case Medical Center

Education Topics	Track/Category
Research Billing (required)	Grants and Contracts
Labor Distribution	Grants and Contracts
Patient Reimbursement System	Grants and Contracts
Confidentiality Disclosure Agreements and Material Transfer Agreements; Intellectual Property Protection	Technology Management
Ask the IRB	IRB Topics
Chart Review and Discarded Tissue: Requirements for a Successful IRB Submission	IRB Topics
Enrollment of Subjects with Decisional Impairment in Research	IRB Topics
Mini-Course: Developing a Comprehensive Understanding of Regulations and Their Applications to IRB Submissions	IRB Topics

Value of Research Compliance

University Hospitals Case Medical Center

- Provides structure for continuous quality improvement
- Early identification and prevention of future compliance issues
- Provides real time insight to current issues
- Promote 'engagement' between research administration office and research community

Value of Research Compliance

University Hospitals Case Medical Center

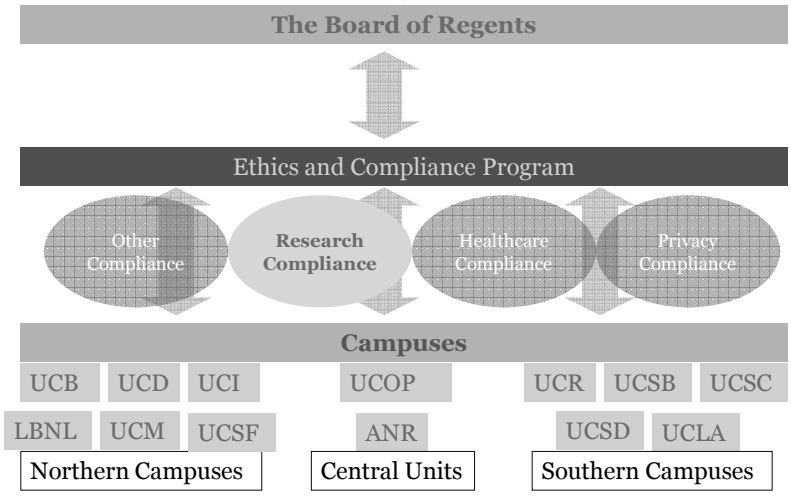
- Ongoing needs assessment for education
- Increase engagement in research community
- Consistent execution of protocols
- Efficient site performance; quality data
- Mitigate risk
- Professional mentorship and career development

Quality Management

University Hospitals Case Medical Center

- Measures impact of program
- Programmatic benchmarks
- Drives internal monitoring systems and compliance outcome
- Complement industry trends
- Prevent revenue loss: cost of data integrity, institutional reputation

Part 2 -- University of California Organizational Structure



21

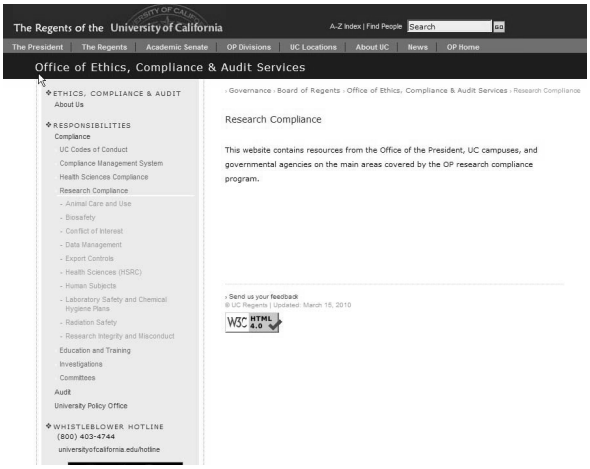
University of California Ethics and Compliance Program *Mission Statement*

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.

UC Research Compliance Program

Responsibilities:

- Support campus research compliance programs
- Promote mitigation of compliance risk in highest risk areas
- Focus on systemwide training and auditing/monitoring in highest risk areas
- Provide assurances to President and Regents that risk mitigation is occurring



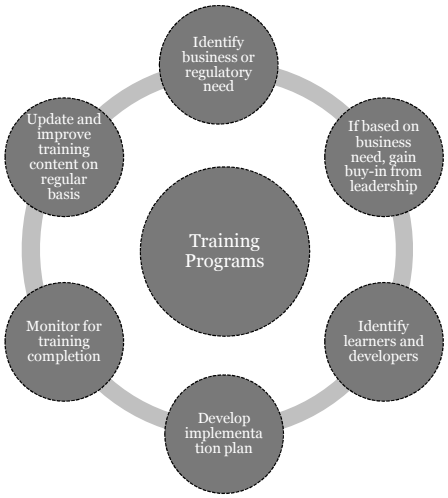
UC Research Compliance Program

Training as Internal Control

- "Generally speaking, the larger and more decentralized an institution is, the more important written institutional control standards, well documented policies and procedures, and formal training and communication will be…"

  Internal Controls: The Key to Accountability, PriceWaterhouseCoopers

University of California Training -- 360°



UC Research Compliance Program – Training Support to UC Campuses

- Focus on highest risk priorities
  - New regulations
  - High profile – national audit findings, media attention, etc.
  - Areas that campuses are not focusing on
- Support comes in all shapes and sizes
  - Content development
  - Implementation support
  - Financial support for training by consultants
  - Delivery management

Current Training Projects

- Conflict of Interest
- Clinical Research Billing
- Responsible Conduct of Research
- Effort Reporting

Conflict of Interest Training

- Approach
  - Mandated by systemwide Compliance Office
  - All researchers, postdocs and staff research associates must complete every 2 years
  - Online course (30 min) delivered through systemwide Learning Mangement System (LMS)
  - Rolled out to 15,341 UC employees in Fall 2009 for completion by Dec 31, 2010 (gave ~1 year to complete)
  - Completion rate 83%

Conflict of Interest Training

- New PHS Regulations – Need New Approach
  - Training will likely be mandated for all PHS-funded investigators (42% of UC's total research expenditures in FY10 came from PHS)
  - All researchers, postdocs and staff research associates must complete every 2 years, regardless of funding source (broadening of learners mandated by Compliance Office)
  - Update online course (30 min) delivered through systemwide Learning Mangement System (LMS)
  - Will train all of above employees at single point in time (giving 30-60 days for completion)
  - PHS proposed requirement that all researchers must be trained PRIOR to engaging in PHS-funded research; need control mechanisms to prevent charging of federal grants prior to taking training

Clinical Research Billing (CRB) Training

- Approach
  - Conducted privileged review at four UC AMCs to determine campus CRB processes and controls; identified need for training
  - Worked with expert consultant to provide training to campuses:
    - 4 week webinar series – 7 different (unique) CRB webinars; recorded for future use
    - 2 general CRB 1-day workshops (repeated in North and South)
    - 2 specific claims processing CRB 1-day workshops (repeated in North and South)
    - Campus-specific training as requested
  - Compliance Office support for workshops includes paying for consultant & food and registering participants
    - Campuses participants must pay nominal fee ($45/each) for workshops
    - Webinars are free to participants, fully organized and supported by Compliance Office

Responsible Conduct of Research (RCR) Training

- Approach
  - New regulation for NSF proposals submitted on or after January 4, 2010 that undergraduates, graduates and postdocs supported by NSF must be trained in RCR
    - Includes institutional certification requirement that training was completed
  - Compliance Office worked with campuses through systemwide calls to develop implementation plans
  - One campus agreed to develop online training (through faculty-led, research ethics-centered workgroup) for system
  - Compliance Office negotiated reduced systemwide license fee for use of a National Academies of Sciences publication to be incorporated into the training module
  - Compliance Office supported conversion of training module to the LMS format, and programming work needed to identify learners

Effort Reporting Training

- Approach
  - July 2009 request by UC President that the Provost lead a workgroup to determine if UC has adequate training for certifiers on federal awards
  - Compliance Office convened workgroup for Provost and facilitated workgroup activities
  - Workgroup recommended development of a systemwide training module
  - Compliance Office engaged consultant to develop training
  - Compliance Office vetted training content with stakeholders, including Academic Senate and revised accordingly
  - UC Provost will recommend training module and frequency (still to be decided) to campuses

Essentials In Decentralized Environment

- Engage Leadership
- Involve Faculty
- Engage End Users

Engaging Leadership

- Need leadership to support and drive training initiatives
  - Ownership of training initiatives should be with operations, not compliance
  - Credibility with faculty
  - Enforcement policies

Involving Faculty

- Faculty highly concerned about burden of non-essential training
- Engage Academic Senate Committees
  - systemwide assessment of mandatory training
- Important to involve faculty when developing content **and** approach for delivering training (i.e., faculty reps on workgroups)

Engaging End Users

- Key users should be involved in development of training content **and** delivery approach (i.e., part of workgroup)
- Training developers should consult with broad array of users for feedback prior to widespread release of training (i.e., pilot)
- New training should be open for comment period
- All training should provide learner mechanism for feedback related to content and delivery approach (including technical aspects of delivery)
- To be credible with end users, training developers must actually use feedback from learners to improve ongoing training

Engaging End Users

Follow us on **facebook** and **twitter**

University Hospitals Case Medical Center

Summary

- Even if your unit does not develop or conduct training, work closely with training unit to develop or offer appropriate compliance training as needed
- Use training as a tool to "sell" to stakeholders as a means of preventing untoward outcomes (i.e., mandatory HIPAA training)
- Ensure training is offered in high risk compliance areas; work toward mandatory training in highest risk areas
  - Benchmark practices of other institutions
  - Communicate benchmark data and federal/state settlements/enforcement actions against similar organizations

Remember: training is a key area in which metrics may be measured (% of workforce trained) to evaluate compliance with applicable regs/policies covered by training