

Health Care Compliance Institute

Issues in Academic Medical Compliance:

Bridging the Great Divide in Clinical Research – Office of Research, School of Medicine and Medical Center

Valerie M. Dixon, CCEP, CHC
Interim Chief Compliance & Privacy Officer – UC Irvine Health



UC Irvine Health

UC Irvine At a Glance

31,000+ students

MASCOT:
Peter the Anteater

92 majors

86 minors

#9 PUBLIC UNIVERSITY
in the U.S. by
U.S. News & World Report

#1 university
doing the most for the American
dream — *The New York Times*
College Access Index

TOP 10
"COOL SCHOOL"
by *Sierra* magazine
for eight years

28 NATIONAL TITLES
in nine sports

\$5 BILLION
annual economic impact
in Orange County

170,000+
Anteater alumni

Enrollment (fall 2016)

- ✓ 27,331 Undergraduates
- ✓ 6,136 Graduate students
 - ❖ General Campus – 4,817
 - ❖ Health sciences – 1,319

Workforce (fall 2016)

- ✓ Ladder-rank faculty – 1,232
- ✓ Campus staff – 5,461

UC Irvine Research

\$378 million in FY16-17

Research Administration is comprised of:

- Sponsored Projects Administration (SPA)
 - ✓ Contracts & Grants Administration
 - ✓ Electronic Research Administration
 - ✓ Clinical Trials
- Research Protections
 - ✓ Animal Care & Use (IACUC)
 - ✓ Human Research Protections (IRB)
 - ✓ Human Stem Cell Research (HSCRO)
 - ✓ Institutional Biosafety
- Research Engagement & Facilitation
 - ✓ Conflict of Interest
 - ✓ Export Controls
- Integrity in Research
 - ✓ Research Misconduct



UC Irvine School of Medicine

- Educates more than 400 medical students and trains more than 600 residents and fellows
- 560 full-time and 1,300 volunteer faculty
- 26 departments, ranging from basic science research to clinical medical and surgical specialties
- Ranked as one of the top 50 U.S. medical schools for research by *U.S. News & World Report*



UC Irvine Medical Center

- Principal clinical facility for UC Irvine Health and the UC Irvine School of Medicine
- UC Irvine Douglas Hospital located in Orange, CA
 - ✓ 417-bed acute care hospital
 - ✓ 19,243 admissions
 - ✓ 751,629 outpatient visits
 - ✓ 2,903 of providers
 - ✓ 4,973 non-physician employees
 - ✓ >\$3.8 billion total annual revenue
- Rated among the nation's best hospitals by *U.S. News & World Report* for 14 consecutive years, and is ranked No. 1 in Orange County, California
- Chao Family Comprehensive Cancer Center is one of only 41 in the nation, and the only one in Orange County designated for excellence by the National Cancer Institute
- Provides ambulatory, rehabilitation and mental health services, as well as the full spectrum of specialty care



5 UC Irvine Medical Center | April 15, 2018



UC Irvine Health Clinical Research Portfolio

- Over 3000 open human subject protocols
- Approximately 25-40 new protocols per month
- **\$70 million in industry-sponsored clinical trials**



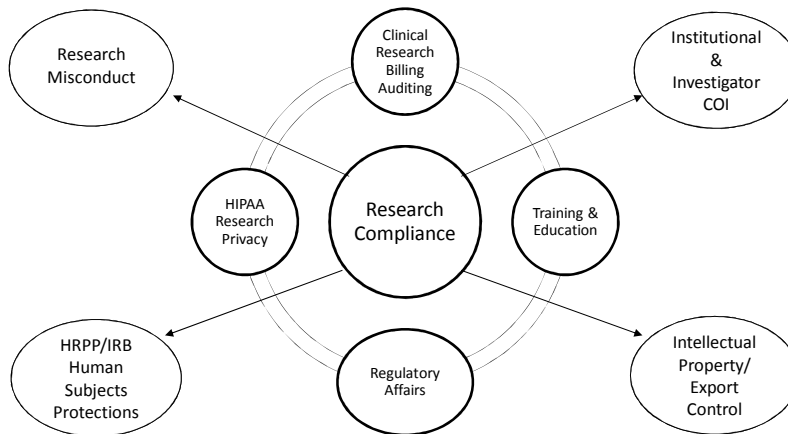
6 UC Irvine Health Clinical Research Portfolio | April 15, 2018



UC Irvine Health Corporate Compliance Office and Research Compliance Programs

- UC Irvine Health Corporate Compliance Office coordinates compliance activities as individual parts of an integrated institutional oversight program:
 - ✓ Revenue Cycle Compliance
 - ✓ Compliance Audit Program
 - ✓ Privacy Program
 - ✓ Research Compliance Program
- The Research Compliance Program is staffed by:
 - ✓ Research Compliance Officer
 - ✓ Research Regulatory Principal Analyst
 - ✓ Senior Clinical Research Billing Auditors (2)

UC Irvine Health Research Compliance Program Scope



**Clinical Research Infrastructure Discussion –
Roles/Responsibilities/Coordination
Office of Research - School of Medicine - Medical Center**

- What is your clinical research support infrastructure?
 - Who is responsible and how are the activities coordinated?
 - What tools and systems do you use?
 - How does Compliance support these activities?
-
- ✓ Study Initiation - identification of a trial through study activation
 - ❖ Protocol identification
 - ❖ Feasibility analysis
 - ❖ Coverage analysis
 - ❖ Budget Development
 - ❖ Contracting
 - ❖ Committee/IRB reviews
 - ❖ Start-up invoicing
 - ❖ Recruitment planning activities

**Clinical Research Infrastructure Discussion –
Roles/Responsibilities/Coordination
Office of Research - School of Medicine - Medical Center**

- What is your clinical research support infrastructure?
 - Who is responsible and how are the activities coordinated?
 - What tools and systems do you use?
 - How does Compliance support these activities?
-
- ✓ Study Management - subject screening through completion of protocol milestones
 - ❖ Subject registration
 - ❖ Milestone management
 - ❖ Charge reconciliation
 - ❖ Annual reviews
 - ❖ Amendments
 - ❖ Drug/device management
 - ❖ Invoicing
 - ❖ Charge reconciliation

Clinical Research Infrastructure Discussion – Roles/Responsibilities/Coordination Office of Research - School of Medicine - Medical Center

- What is your clinical research support infrastructure?
 - Who is responsible and how are the activities coordinated?
 - What tools and systems do you use?
 - How does Compliance support these activities?
- ✓ Study Close - financial, clinical, and administrative reconciliations through archiving
 - ❖ Notification process of study close
 - ❖ Drug/device return
 - ❖ Final AP/AR
 - ❖ Decommission charge account
 - ❖ On-site/off-site archiving

11 Clinical Research Infrastructure Discussion | April 15, 2018



Final Thoughts: How to Play Nice in the Sandbox

- It is important to define clinical research compliance in relation to the overall compliance structure
 - ✓ Interoperability of electronic systems
 - ✓ Cross-Functional teams with Compliance representation
 - ✓ Consistent education and training
- If the research compliance program is not campus wide:
 - ✓ Carefully determine the authority of the health system research compliance office and reporting mechanisms
 - ✓ Reduce interruptions to compliance activities resulting from internal politics and create transparencies that offer reassurance to researchers and study subjects



12 Final Thoughts | April 15, 2018



Questions?



Valerie M. Dixon, CCEP, CHC
Interim Chief Compliance & Privacy Officer
UC Irvine Health
714-456-8778
vdixon1@uci.edu
<http://www.ucirvinehealth.org/compliance>