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

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UC Irvine Health

UC Irvine At a Glance

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

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
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

- Research Misconduct
- Clinical Research Billing Auditing
- Institutional & Investigator COI
- HIPAA Research Privacy
- Training & Education
- Regulatory Affairs
- Intellectual Property/Export Control
- HRPP/IRB Human Subjects Protections

1 UC Irvine Health Corporate and Research Compliance Programs | April 15, 2018
2 UC Irvine Health Research Compliance Program Scope | April 15, 2018
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

✓ Study Management - subject screening through completion of protocol milestones
  ◆ Subject registration
  ◆ Milestone management
  ◆ Charge reconciliation
  ◆ Annual reviews
  ◆ Amendments
  ◆ Drug/device management
  ◆ Invoicing
  ◆ Charge reconciliation
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✓ 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

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
Questions?

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