University of California
2019 Ethics, Compliance and Audit Symposium
REACHING NEW HEIGHTS

Navigating Clinical Research Operations and Compliance

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UC's Mission

The University's fundamental missions are teaching, research and public service.

We teach — educating students at all levels, from undergraduate to the most advanced graduate level. Undergraduate programs are available to all eligible California high-school graduates and community college transfer students who wish to attend the University of California.

We do research — by some of the world's best researchers and brightest students in hundreds of disciplines at its campuses, national laboratories, medical centers and other research facilities around the state. UC provides a unique environment in which leading scholars and promising students strive together to expand fundamental knowledge of human nature, society, and the natural world.

We provide public service — which dates back to UC's origins as a land grant institution in the 1860s. Today, through its public service programs and industry partnerships, UC disseminates research results and translates scientific discoveries into practical knowledge and technological innovations that benefit California and the nation.

Each UC campus that performs clinical research strives to…

- Advance therapeutics, medical devices/diagnostics and digital-health technologies by bridging the gap between academic research and industry/venture capital interests.
- Become a Research Center of Excellence by investing in our infrastructure, education, and improving internal workflows and processes.
- From a patient-centered perspective, provide access to leading-edge and high quality treatments for our patient communities.
- Ensure optimal protection of intellectual property, research data, and patient confidentiality.
- Create an efficient clinical research study start-up and management model, thereby increasing patient's access to novel therapies and improving study participation.

How is Clinical Research Compliance defined?

- Informed Consent - Ensure that patients are adequately and appropriately informed of the risks and benefits related to study participation.
- Protocol Adherence and Data Integrity
  - Ensure that Protocol inclusion/exclusion criteria and enrollment Standard Operating Procedures are followed to allow the patient to safely participate in research studies.
  - Ensure that all protocol-required procedures and services are completed.
  - Ensure that protocol-required corresponding data is entered in a timely manner.
- Ensure that adverse events are documented and reported.

How do we manage Clinical Research Billing Compliance Risks?

- Ensure that:
  - Relevant portions of study documents are harmonized in accordance with applicable regulations and billing rules.
  - Clinical research services that can or cannot be billed to third-party payors are clearly designated.
  - Processes are in place to bill to sponsors and third-party payors in compliance with study budgets and billing rules.
  - Study participants are not billed for items/services that are covered by the study sponsor and vice versa.
- Serve as an internal consultant to multiple clinical research stakeholders regarding all aspects of clinical research.
- Monitor and oversee institutional systems and workflows, to optimally achieve the operational and financial goals of the research enterprise.

Clinical Research Stakeholders

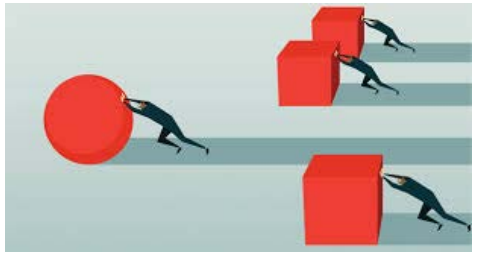
Communication among Clinical Research Stakeholders is Critical

Consider:

- Who is planning workflow changes?
- Who is impacted by workflow changes?
- What do they need to know? (Who decides what is needed?)
- Who is responsible for communicating?
- How should the communication be initiated?

There is NO one right way, find what works!!

Operational Challenges



- Stakeholders have varying backgrounds, skills, and knowledge.
- Low retention of key research staff.
- Dynamic and demanding work environment.
- Insufficient guidance and engagement from Principal Investigators.
- Training/onboarding is not mandatory or consistent between departments – employees are expected to hit the ground running.
- Compliance expected to be the "heavy" when challenges arise pre-award (e.g. budget and contract language negotiations, coverage analysis decisions) or post-award (e.g. investigator non-compliance, privacy breaches, incorrect billing).
- Communication regarding system or workflow changes between centralized operational units and research community is not clear or consistent.

Research Billing Compliance Challenges - Examples

- No billing calendar/grid for reference in research charge direction or compliance audit.
- Insufficient billing calendar/grid detail, resulting in potentially high-dollar risk.
- Unclear information related to investigational drugs or devices.
- Insufficient budgets created for complex protocol-required procedures.
- Study-related charges generated do not correspond to services listed in the certified budget.
- Unclear how to bill expenses related to a study-related Adverse Events.
- Unclear billing guidelines regarding off-label use of drug or device.
- Unclear billing guidelines regarding compassionate use and expanded access protocols (Right-To-Try?).
- Reconciliation of research charges and payments; management of surplus or deficit.

Clinical Research – Common Best Practices

- Education, Education, and MORE Education
  - Create and provide fundamental and advanced education modules that standardize and enhance stakeholder knowledge in clinical research systems, operations, policies and regulations.
- Stakeholder engagement
  - Create opportunities and forums for the research community to engage in problem-solving beyond their own areas of expertise and comfort.
- Revenue cycle infrastructure and processes
  - Build revenue cycle infrastructure, processes, and tools that encourage active communications within and between stakeholder teams.

Clinical Research – Common Improvement Opportunities

- Streamline the study activation workflow
  - Continually seek ways to simplify workflows, while still actively engaging stakeholders in decision-making.
- Communication and relationship-building
  - Invest time and attention in working with leaders and stakeholders at all levels and with varying priorities, especially in difficult conversations.
- Device management and study activation
  - Engage multiple stakeholders (Purchasing, CDM, Engineering, Research Application Team, Coverage Analysis, Ancillaries, study teams) in assigning clear accountabilities and communication mechanisms.

Suggestions?

Self-Reflection

- How does your institution manage the clinical research business line?
- Does your institution address its clinical research education needs effectively?
- How does your institution handle risk related to clinical research activities?
- Do you seek counsel on clinical research topics? (If so, from whom?)

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