Clinical Trials Offices: What's New In Research Administration?

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Little uniformity exists in structure or functions; models needed for future

Academic health centers continue to assess, change, and improve clinical research administration to advance science and better serve patients nationwide. In recent years, clinical trials offices (CTOs) have emerged within the academic health center research infrastructure to consolidate administrative activities related to clinical trials—from protocol development to billing compliance—and thus enhance institutional research capabilities. Management of clinical trial operations, viewed as critical to the sustainability and growth of the research enterprise, is among the challenging tasks for academic health center administrators because of the multitude of regulatory requirements and administrative procedures that must be addressed before, during, and after a clinical trial takes place.

To learn about the nature and scope of CTO operations, and as part of its ongoing analysis of clinical trials administration[1,2,3,4], the Association of Academic Health Centers (AAHC) profiled eight member institutions in late 2008.

Institutions were selected based on responses to the AAHC Census[5], an AAHC survey of organization, governance, and operations at member institutions. Six institutions with a CTO and two without a designated office were selected. Of these eight institutions, four were public universities and four private, with 2007 research expenditures ranging from $10 million to more than $300 million.

AAHC staff conducted telephone interviews with seven chief compliance officers and one vice president of research to gather information on the development, organization, structure, and activities of the CTO, as well as leadership involvement and future plans.

FINDINGS

The examination of clinical trials offices (CTOs) reveals that academic health center leaders are proactively developing and organizing research

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administration infrastructure to support clinical research and related compliance activities. The AAHC findings highlight strategies and initiatives intended to create systems and optimize resources and thus transform the research enterprise for the future. In addition to infrastructure and operational issues, the findings provide important insights on institutional cultural change and the challenges that academic health center leaders must face to ensure the research enterprise evolves to address new scientific developments, translational research, and interdisciplinary, multisite research.

LEADERSHIP

It has been recognized that change within academic health centers is greatly facilitated when CEOs and other senior academic health center administrators are directly involved in an initiative, or signal that particular issues or projects are a high priority. These individuals can be, and often are, the most critical forces of change within an academic health center.

The AAHC findings show that academic health center leaders were instrumental in developing and establishing the CTOs, which often emerged from institutional strategic planning efforts spearheaded by the academic health center CEO and/or the highest level research administrator. Top leaders are often perceived as the only individuals capable of ensuring a systems approach to change. A variety of factors motivated strategic planning efforts, including the need to provide a focal point for clinical trials compliance or educational activities, standardize institutional policies, address clinical trials billing, or improve financial management of clinical trials.

Key leaders established and participated in major working committees on clinical research at the various institutions and often played leading roles in developing relationships with new clinical partners.

However, even as academic health center leaders worked to align organizational commitment to operational change, and provided funding for the establishment of CTOs, they sometimes appeared unable or unwilling to mandate an entirely new set of operational requirements across the institution.

ORGANIZATION, STRUCTURE, ACTIVITIES

The Landscape for Research Administration

The current administrative landscape for clinical trials is exceedingly complex. Many interdependent functions are spread across the research enterprise, which often results in the establishment of administrative structures and small bureaucracies operating as separate, unconnected silos that lack policies or formal procedures for communications and interaction.

In addition, the life cycle of a clinical research project involves stakeholders from different realms of academic health center administration who possess various skills and knowledge about clinical research or business functions. Significant stakeholders include members of institutional review boards, contract negotiators, sponsored project officers, legal counsel, research administrators, investigators, study coordinators, compliance officers, clinicians, patient schedulers, IT managers, grants accountants, medical records staff, revenue cycle managers, facility and professional fee billing staff, internal auditors, and budget analysts.

The emergence of CTOs is a sign of a growing recognition that stakeholders need to be formally linked together, and interrelated disparate functions identified and brought together. Operations need to be harmonized in a rationale and effective infrastructure.

Some institutions viewed the development of the CTOs as the means to connect many stakeholder groups by merging related operations. The CTO designation implied a central point of

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management. It was assumed that CTOs would be integrated one-stop shops that had consolidated the various scientific review, contracting, budgeting, compliance, and education and training activities related to clinical trials, with staff connected by established communications channels.

Varied Structures: Dual Systems

Contrary to expectations, the AAHC found that CTOs exhibited varied characteristics and combined some, but not all, of the processes associated with clinical trials administration and management. Most significant, CTOs did not serve all of the researchers and operated in parallel with existing infrastructure in many of the profiled institutions.

While all the established offices were "dedicated to clinical trials," little uniformity was noted in the organization, structure, or services offered. At least 14 activities were noted in the six offices, including contract negotiations, sponsor recruitment, protocol development, budget development and approval, developing billing grids, costs analysis, defining standard of care, patient recruitment and scheduling, approving charges, education and training, and compliance.

Some similarity was evident: five offices approved and managed study budgets, with financial analysts performing cost and reimbursement analysis to ensure regulatory compliance; six offices assisted researchers in budget development; five offices had formal policies to guide investigators through the budget development process; three offices managed pre-award services, including contract negotiations, sponsor recruitment, and protocol development. When CTOs did not exist, these services were handled by the office of sponsored research or spread throughout several offices.

Only one CTO had responsibilities for patient management services, including patient recruitment and patient scheduling. The principal investigators (PIs) or study coordinators were responsible for these patient activities within the other institutions.

All CTOs had education and training responsibilities although the scope varied widely, with education programs related to human subject protections and the health insurance portability and accountability act (HIPAA) to conflict of interest and billing compliance. In institutions without a CTO, education and training was administered by a number of offices, including compliance, human subjects protection, and the institutional review board.

Building on Existing Infrastructure

Some institutions made a decision to build upon existing administrative offices and entities when establishing the CTO as a means to gain acceptance of the CTO, particularly among faculty using existing administrative support services within their departments. Some leaders envisioned that the new CTO would offer more benefits and services and thus outperform existing entities. Over time, CTO performance would cause researchers to migrate to the CTO, ending the need for existing, redundant infrastructure. While this approach appeared to be working in some institutions, it could be argued that the CTO is placed in a competitive, and perhaps, defensive position. Without any mandates for use of the CTO or timeframes for phasing out overlapping infrastructure and transitioning to full use of the CTO, the long-term benefits of the CTO to the institution were not clear.

Resources

Operating budgets for CTOs ranged from $400 thousand to over $4 million; five of the six CTOs had budgets of $400-$700 thousand. Funding for the CTOs came from the office of the vice president for research, clinical revenues, and/or funding for clinical translational science awards (CTSAs). Recruitment and retention of CTO personnel, including study coordinators, biostatisticians, financial analysts, and auditors, emerged as a concern for some institutions.

Compliance

A range of compliance responsibilities is under the CTOs, with education and training very prominent. Compliance offices often conduct regulatory and safety monitoring and internal audits. The function is fiscally based. Some offices do not do compliance reviews — that is, ensuring that accurate billing to the correct payer is taking place. Such reviews are not always the responsibility of the CTOs, which results in billing and compliance functions fragmented and spread throughout the academic health center. Where management consolidation is occurring, there is increased melding of the billing and compliance functions with contracting and sponsored research. Interactions between the CTO and the compliance function appeared to be based on good, established working relationships, rather than established policy.

CONCLUSION

A trend toward consolidation or centralization of administrative functions associated with clinical trials has been noted for several years. Improved management of and assistance with clinical trials budgeting and billing processes, one of the most complex and problematic aspects of clinical trials, has been a driving force of change to address increased research activity, mounting regulatory requirements, and escalating costs.

A review of clinical trial offices (CTOs) at eight academic health centers reveals that consolidation is far from accomplished. Similar to findings in 2007, there was little uniformity in the structure or functions designated to the CTOs. While they were hubs for clinical trial operations, some were control points and gatekeepers on all budgeting and billing, while others provided educational or liaison services. Some provided financial expertise to clinical investigators; others did not. Some had monitoring and auditing responsibilities for compliance; others did not.

Institutions are still stressed and challenged by the lack of a clearly defined organizational and governance structure for clinical trial administration. Most notable are:

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- The lack of mandates for use of CTOs where they do exist;
- CTO operations existing in parallel with infrastructure in departments or centers where departmental rather than institutional priorities prevail;
- Lack of timelines for transitioning to a single organizational model for clinical trials administration;
- Lack of institution-wide policies for clinical trial administration; and
- Turnover and/or lack of skilled technical workforce.

The current economic crisis provides a new window of opportunity to address some of these challenges as institutions look to create increased efficiencies and effectiveness while conserving resources.

To identify a select number of CTO models that are appropriate to academic health center operations and can be easily adopted by academic health center leaders, stronger collective action may be needed. The Forum on Regulation of the Association of Academic Health Centers, which brings together the chief compliance officers from academic health centers nationwide, is an appropriate group to act on this issue.

Academic health center leaders should examine the organization and structure for clinical trials administration within their respective institutions and determine what, if any, changes are needed to consolidate the infrastructure and provide:

- A focal point for all billing and compliance activities;
- Increased communication and coordination of activities and policies;
- Consolidated education and training function;
- Decreased redundancy and costs for staffing and infrastructure; and
- Increased access to information for university and academic health center leadership.

INSTITUTION 1

PUBLIC: CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES: $80+ MILLION

A CTO was established as part of a strategic research plan designed to transform the conduct of research within the university.

LEADERSHIP

Top research administrators recognized that today's new research paradigm which promotes multidisciplinary and inter-institutional research would benefit from an integrated administrative infrastructure. To build such an infrastructure would require consolidating activities related to clinical trials, increasing the number of clinical trials, standardizing policies, and improving operations.

The executive vice president for research and staff from an existing clinical research outcomes office developed the CTO with support from university leaders, including the university president, the executive vice president for health affairs, and members of the board of trustees.

## ORGANIZATION, STRUCTURE, ACTIVITIES

The CTO opened in fall 2008. Named the office of clinical research services & support, it built upon the clinical research outcomes office that provided some support for clinical investigators, including retrospective analyses on completed projects.

Coordinated Approach: One-Stop-Shop under the Executive Vice President for Research

Before the establishment of the CTO, administrative and management functions for clinical trials were spread throughout the academic health center and a number of clinical sites.

Researchers in departments throughout the university's affiliated hospitals recruited patients for clinical trials with little communication with university compliance offices. Very few policies governed communications about clinical trial-related regulations, such as amendments of trial procedures, protocol violations, or serious adverse events.

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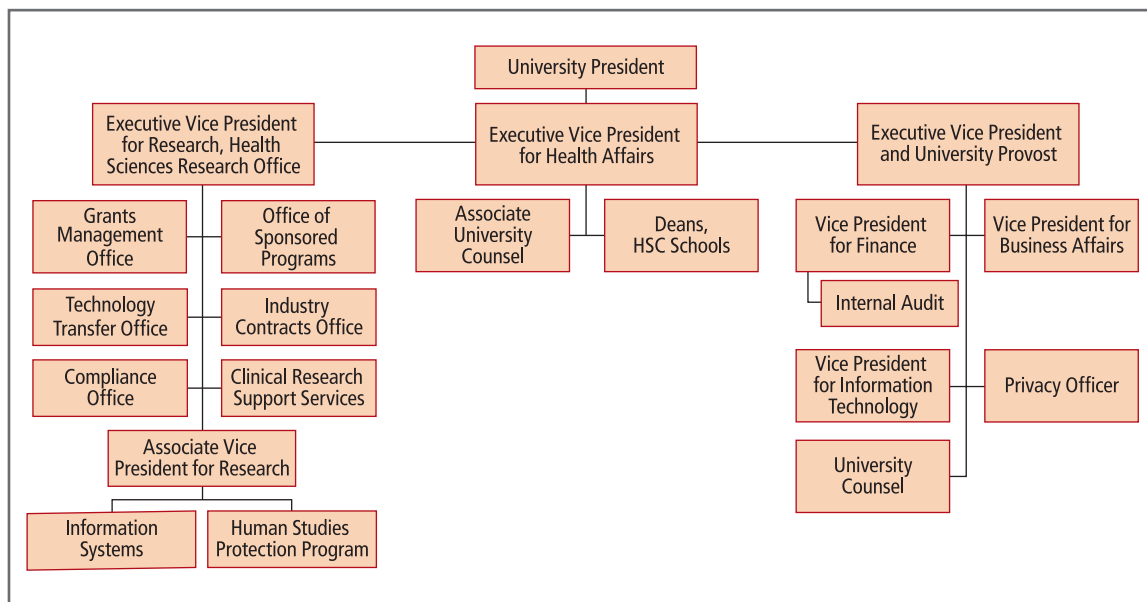
The CTO created a one-stop-shop for clinical trials administration (i.e., pre-award to study close-out). The CTO is under the office of the executive vice president for research, a university-wide research office that also includes the offices of grants management, sponsored programs, technology transfer, industry contracts, and compliance.

Institutional leaders believed that consolidation of functions in the CTO could help investigators to manage studies and submissions to the institutional review boards (IRBs), as well as shorten times for contract negotiations and IRB approvals, and improve coordination and communication with clinical sites. In 2009 an inter-hospital committee was established to review all clinical trials and examine the potential to increase integration of services.

CTO: Providing Services and Expertise

The CTO provides administrative support for clinical departments lacking resources. Services currently offered by the CTO include contract negotiations, patient recruitment, budgeting, scheduling, and reviewing and approving clinical trials charges. The CTO also has personnel with expertise in finance to help researchers develop a business plan, perform a cost analysis, create billing grids, define the standard of care, and conduct a prospective reimbursement analysis.

Use of CTO

Use of the CTO is strictly voluntary. However, research administrators have been successful in working to get buy-in from departments with investigators who conduct large numbers of clinical trials. One of the largest departments with a significant clinical trial portfolio mandated that its researchers use the CTO. It is anticipated that many divisions will follow this lead.

To expand use of the CTO, staff spends a great deal of time raising awareness about the office and educating research personnel about CTO services. CTO staff meets regularly with department heads and division chiefs to highlight how CTO resources and expertise

can communicate research findings to major audiences, in addition to assisting investigators. Daily news emails and other communications are sent regularly to the research community. The CTO director is developing performance metrics based upon clinical outcomes, quality, and patient recruitment and retention to measure the office's success.

Services: Industry Point of Contact

The CTO is the point of contact for industry partners. The CTO reviews all solicitations and identifies the most appropriate and interested investigator for the research, thus ensuring that the investigators with the appropriate patient pools are receiving trial opportunities for their patients.

Education and Training

The CTO offers education and training programs on research compliance on an ad hoc basis. There are very few required courses for research personnel, aside from those related to human subjects research. The CTO is developing a comprehensive course for study coordinators on basic clinical research compliance, protocol and study design, data collection and management, budget development, billing grids, advanced budgeting and negotiation, billing compliance, conflict of interest, research ethics, and effort reporting. This new educational offering will be administered through one-on-one instruction, workshops, and lectures. The hope is that this comprehensive module will become the model for further course development. Research administrators anticipate making the course a requirement for all research personnel in the near future.

Resources

The CTO has an operating budget in the range of $700,000. One-third of the budget is allocated from the office of the executive vice president for research; clinical revenues provide the remainder of the budget.

The office has eight full-time employees, including certified research coordinators, bio-

statisticians, medical editors, information technologists, and administrative support staff.

It is envisioned that study coordinators in the hospital departments will at some time become part of the office and be employed by the CTO.

Policies

The CTO is currently establishing policies and procedures (e.g., negotiating charge masters) to increase effectiveness in university-hospital interactions.

The administration is addressing policy development for the treatment of patients at affiliated hospitals by establishing processes that guide interactions with external stakeholders, as well as strengthening relationships with management and governing boards at the hospitals.

COMPLIANCE

The CTO works closely with the university-wide committee on compliance under the university provost. The compliance office is the enforcement arm, conducting regulatory and safety monitoring related to specific clinical trials. The university's associate general counsel works closely with and advises the CTO on an ad hoc basis. This individual is also the director of the industry contracts office, which is located near the CTO.

The institution plans to conduct internal audits of the CTO's fiscal operations; there are also plans for an external financial audit.

SUMMARY

This CTO was an outgrowth of strategic planning designed to transform the research infrastructure within the university. Established as a vehicle to help break down silos and highlight how consolidated resources could expand services and improve operations, the CTO has increased collaboration between disciplines and been a catalyst for promoting a comprehensive approach to clinical research administration. Strong leadership involvement and institutional commitment were evident. Leaders took account of existing administrative research units when considering the organization and structure of the CTO.

At present, two parallel administrative structures—departmental and CTO—coexist for clinical trials administration, with the CTO gaining ground as a central management center. The CTO is particularly effective in marketing its services, which appear particularly strong in education and training. Without a requirement for researchers to use the CTO or a timeline for transitioning to mandatory use of the office, it is difficult to fully gauge its success or the impact on the institution's research mission at this time.

INSTITUTION 2

PRIVATE: CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES: $300+ MILLION

This CTO, called the Office for Clinical Research (OCR), was established within an academic health center to provide administrative support and guidance for the conduct of clinical research. The office has five teams with the following responsibilities: Pre-Award, Post-Award, Invoicing, Information Technology and Process Engineering, and Education and Training. The CTO is primarily responsible for research billing compliance and is charged with providing centralized support related to the administrative aspects, and billing, for clinical trials and other clinical research studies with billable items and services. This includes budget development and negotiation, creation of a prospective reimbursement analysis (PRA) followed by post-award bill review, as well as training for principal investigators and coordinators to ensure research billing compliance. These functions are supported by ongoing IT process improvement, education and training for researchers on research billing compliance, and a process for tracking "services provided" and invoicing for owed revenue.

LEADERSHIP

In 2005, senior academic health center leaders identified gaps, risks, and weaknesses in clinical research operations and supported further development of an existing OCR. Prior to this time, administrative and financial aspects of clinical research were decentralized and managed by principal investigators, clinical research coordinators, and departmental administration.

As the CTO evolved, the administrative and financial activities were centralized to improve consistency, accuracy, and process development. Members of a series of committees charged with oversight of clinical trial operations initially made decisions on the growth, centralization, and processes managed by the CTO. Now, one committee makes decisions on issues regarding clinical research functions at the university.

This committee meets monthly to discuss clinical research issues and their resolution. Its membership includes vice presidents for research administration, health affairs and health affairs research, the chief medical officer for the hospital, the medical director, and the executive director of the CTO. In addition, the CTO executive director works very closely with general counsel, the research compliance officer, and the healthcare compliance officer. They meet on an ad hoc basis as issues arise.

ORGANIZATION, STRUCTURE, ACTIVITIES

As the CTO consolidated all financial activities related to clinical research, accountabilities and controls were developed to ensure billing uniformity for all clinical research studies with billable items and services, as well as research billing compliance throughout the institution. According to a decision tree, applicable studies with billable items and services must be processed through the CTO for prospective reimbursement analysis (PRA), budget development, and budget negotiation. In addition, the CTO Post-Award team is charged with review of billing issues and process development for the billing aspects of the study.

The CTO was designed to have direct links to the Office of Research Administration, with the CTO executive director reporting to the vice president for research administration within the university and the associate dean for clinical and translational research in the school of medicine. The CTO works closely with the Office of Research Compliance (ORC), a unit within the Office of Research Administration.

Services

Five teams within the CTO provide the following services:

- **Pre-Award:** Staff work with investigators and research coordinators to develop a PRA and study budget that complies with applicable Medicare regulations for all clinical research studies with billable items and services. Study budgets are created and negotiated prior to fully executing the clinical trial agreement.
- **Post-Award:** Staff perform an Initial Post-Award Consultation (IPAC) with the clinical research coordinator after receipt of the notice of award in order to review the study documents for consistency, verify the CPT/CDM codes for the billing forms, and review the billing process and timing requirements. A bill hold is performed for at least the first patient/first visit on each protocol to review the charges against the PRA to assure research billing compliance.
- **Invoicing:** In 2009 CTO staff offered their services for study invoicing, accounts receivable, and accounts payable to interested investigators. This service offering is expected to grow in the near future.
- **Education and Training:** A team of three research services consultants is charged with identifying training needs and developing training programs for research personnel. In addition to monitoring an e-mail system through which researchers ask questions and receive support, this team provides the following:
  - Intensive two-day trainings on clinical trials administration, which is open to all personnel involved in clinical trials. The program, which is a series of lectures offered by the CTO, IRB and ORC offices, is a collaborative effort that includes instruction on study design, IRB submission, federal requirements for human subject research, reportable events, conflict of interest regulations, patient screening and recruitment, patient registration, patient billing, research billing compliance, and effort reporting.
  - Training for Research Billing Compliance, which is a 4-hour class dedicated to research billing compliance, with institution-specific information for navigating the existing billing systems.
  - Monthly Lunch-and-Learn sessions on clinical research topics of interest (e.g., SiteMinder Training on the web-based software tool for budget development and research billing compliance and tracking).
  - One-on-One Training to provide support and guidance to the university research community.
- **Information Technology and Process Engineering:** The IT and Process Engineering team is charged with identifying and developing improvements to enhance operational efficiencies, providing the CTO with needed IT support, and creating IT solutions for complex interdependencies wherever possible. This team works to develop mechanisms to identify clinical trial participants in the medical record, provide metrics for administration on clinical research activity, investigate potential interfaces or bridging technology within existing legacy systems, and research creative solutions to labor-intensive processes.
  - Of note, the team has evaluated existing business processes related to research billing compliance. Process improvements have been implemented and a new Research Management System is being developed to support the newly-established processes. The system will be built in several phases and will facilitate compliance and operational efficiencies.

Resources

The OCR has an operating budget of more than $4.4 million, with funding from the school of medicine, the healthcare system, and fees charged for administrative services. The office has approximately 41.2 full-time equivalents.

COMPLIANCE, AUDITING, LEGAL

The Office of Research Compliance (ORC) works closely with CTO staff to ensure compliance with local, state, and federal regulations pertaining to clinical trials billing with human subjects research, drugs, and devices, as well as investigating any potential research misconduct.

The ORC conducts regulatory monitoring and analysis, performs compliance reviews, and administers mandatory training on the Health Insurance Portability and Accountability Act (HIPAA) along with other educational and training programs.

Responsibility for both legal and auditing functions rests with the university. The university's associate general counsel representing the health sciences division assists with institutional policy development and advises on legal matters. Clinical trials billing is audited by the university's internal auditing division for the health sciences.

FUTURE

The institution plans improvements in its overall research process by creating automated efficiencies to replace manual systems and eliminate redundancies. The goal is to consolidate the IT system for research billing and eventually link the university, hospital, and other clinical sites on all aspects of clinical trials.

Presently, the institution relies on communication between investigators, study coordinators, and billing personnel to identify patients enrolled in clinical trials and input information into web-based billing forms at the study and patient visit levels where charges can be reviewed to verify correct billing. The hope is to continue to move to a comprehensive IT solution related to clinical research operations, as well as to create a research portal for researchers to obtain data about the status of their protocol submissions across disparate systems.

INSTITUTION 3

PUBLIC: NO CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES: $300+ MILLION

This institution is developing a clinical trials office (CTO). Currently, the institution has a decentralized administrative infrastructure for clinical trials, with some consolidation evident in a cancer center.

LEADERSHIP

Concerns about variations in clinical trial budgeting policies and practices across components of the academic health center were a catalyst for establishing a CTO. A Clinical Trials Working Group, comprising representatives from all affiliated hospitals, practice plans, research centers, and the pediatric clinical trials office of the children's hospital, has been established to standardize policies for clinical research and develop the CTO. The working group is examining other consolidations (e.g., office of regulatory compliance) in considering models for structuring the CTO.

ORGANIZATION, STRUCTURE, ACTIVITIES

The CTO, expected to open in 2010, will provide opportunities to achieve efficiencies in clinical trial operations. Activities are currently spread throughout all clinical departments. Plans are to house the CTO in a translational sciences institute, with the CTO director reporting to the institute director, who reports to both the vice chancellor for research and the vice chancellor for health affairs.

Currently, investigators are responsible for budget development, with some departments and centers providing assistance. The hospital, which is not owned by the university, requires that investigators submit a business plan for approval before a study can begin.

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Investigators will be encouraged to take advantage of the services offered by the CTO, but there are no plans to mandate use of the office. The working group is now defining operational logistics, determining services to be offered, and considering funding for the office.

Metrics, Personnel

The working group is developing performance metrics for the CTO to assist in the creation of standard policies and processes for clinical trials administration. For example, effectiveness of CTO operations would be judged against measures related to cycle times, as well as patient recruitment, enrollment, and retention.

The group will address the recruitment and retention of study coordinators. It is envisioned that study coordinators could eventually be employed by the CTO rather than departments within the hospital.

Resources

A portion of the funding for the CTO will come from the Clinical and Translational Science Award awarded to the institution from the National Institutes of Health.

Education and Training

A variety of offices across the academic health center offer education and training. Multiple institutional review boards (IRBs) also administer required educational programs on human subjects research protections.

A plan is being developed to consolidate training resources within the CTO, which would then become the primary source for all education and training modules. Training will also be coordinated with the translational sciences institute and the regulatory compliance divisions. The working group is developing processes for education and training to ensure standardization in curricula and administration.

Training modules in use throughout the institution often target specific personnel (e.g., principal investigator, study coordinator, billing personnel) and examine specific types of studies (e.g., phase I, device, retrospective). For example, a comprehensive clinical trials training program, designed for investigators and study coordinators, is administered by the Office of Regulatory Compliance. This intensive 24-hour program

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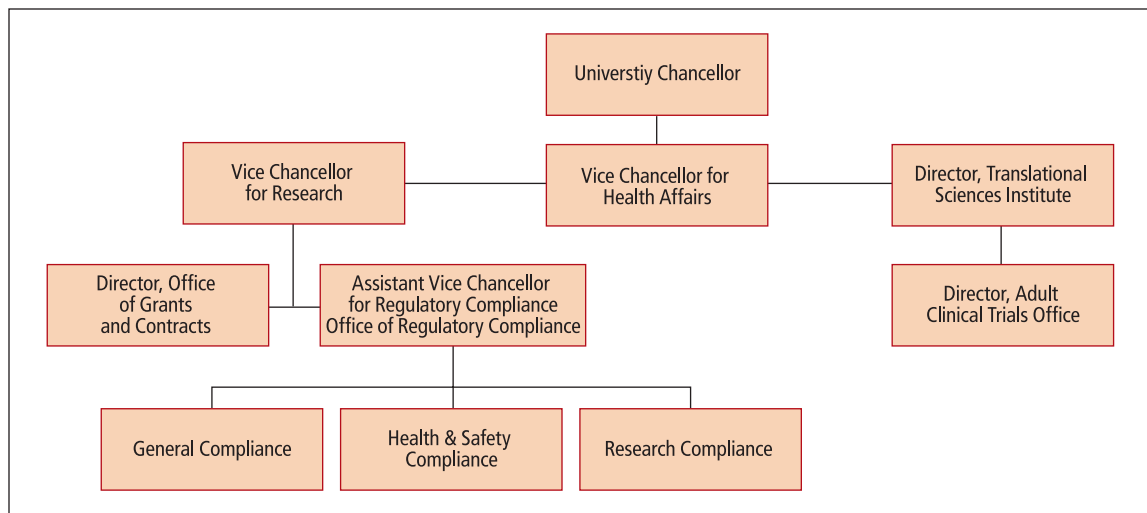
INSTITUTIONAL PROFILES

covers a range of topics, including good clinical practice, FDA audits, budget development, clinical trials billing compliance, and recruitment. The program, conducted through lectures, workshops, and on-line, is open to all research personnel. Completion of the program is not required by all departments.

COMPLIANCE

In recent years, a number of compliance activities were merged into the office of regulatory compliance. The director of the office of regulatory compliance reports directly to the vice chancellor for research and has responsibilities for regulatory monitoring and enforcement for general compliance (e.g., fiscal, HIPAA, human resources), health and safety compliance (e.g., campus security, environmental health, and safety), and research compliance (e.g., animal welfare, conflict of interest, export controls, protection of human subjects, research ethics). The working group is also developing the formal compliance mechanisms as the translational sciences institute comes online this year.

The office of regulatory compliance works closely with the office of the general counsel and the office of internal auditing, both of which are university system responsibilities. The university system conducts financial audits on a regular basis. In addition, quality assurance audit units operate out of the office of regulatory compliance, the cancer center, and the hospital.

SUMMARY

This CTO will be established to consolidate the financial and compliance functions related to clinical trials, thus helping to strengthen the research infrastructure and further promote and facilitate the translation of science to patient care through a translational sciences institute. Leadership has been key to the development of the CTO; both administrators and researchers are enthusiastic about the CTO and its potential to improve efficiencies and operations.

Education and training on clinical trials activities will be a primary function of the office. Use of the office will not be mandatory, thus creating the potential for continued duplication of effort or redundancies throughout the institution.

INSTITUTION 4

PRIVATE: NO CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES: $10+ MILLION

The institution does not have a clinical trials office (CTO). Decentralization characterizes clinical research administration although consolidation of some activities has occurred. The institution conducts a relativity small amount of clinical research.

LEADERSHIP

University administrators are trying to increase the consolidation of activities related to clinical research compliance. However, the lack of integrated governance and aligned priorities across the academic health center is a barrier to implementation. No one person, board, or committee has total authority over policy, finances, or operations. The university, hospital, and faculty practice plan are each separate legal entities with some shared governance.

The institution recently created a number of working groups to address issues related to clinical research. The working groups, comprising leaders from the university, hospital, and practice plan, are currently addressing issues related to the Health Insurance Portability and Accountability Act (HIPAA), the development of centralized databases, clinical trials billing compliance, and audits.

Changing the research infrastructure is challenging given a department-centric institutional culture and little staff turnover in the departments that conduct 80 percent of the institution's clinical research.

ORGANIZATION, STRUCTURE, ACTIVITIES

Clinical research is managed and administered through a variety of offices located across the university, hospital, and practice plan. Department

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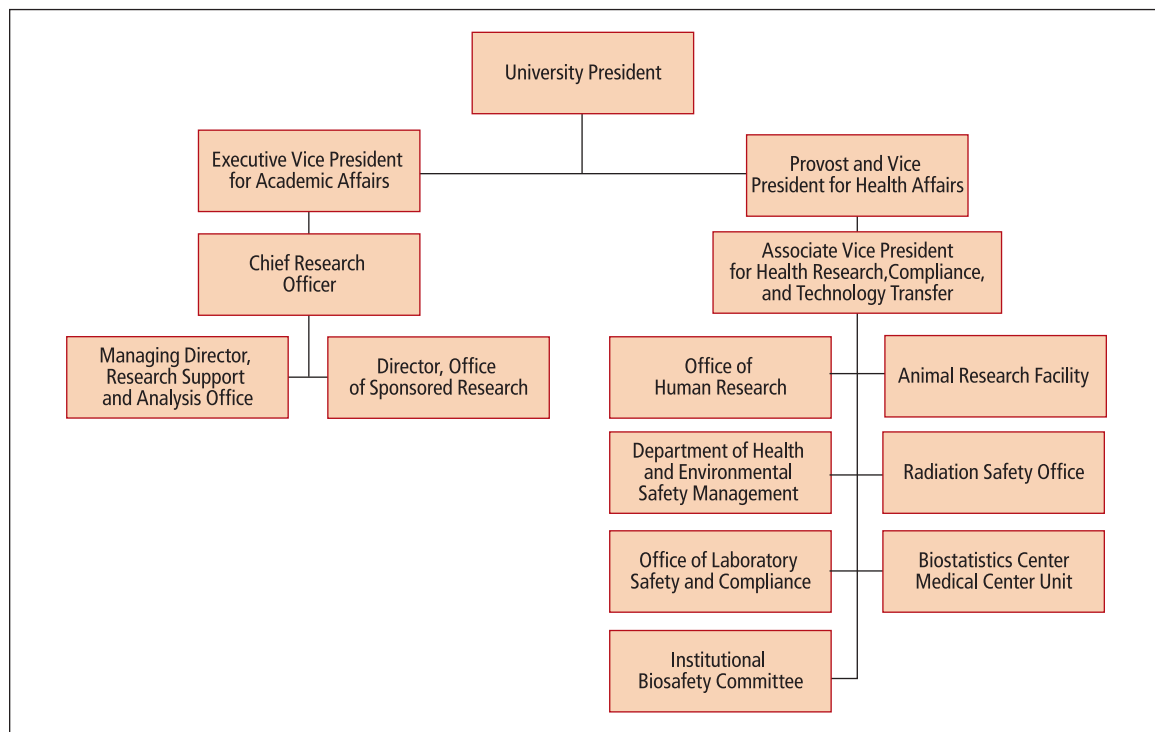
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chairs are responsible for monitoring sponsored projects conducted by investigators in their respective departments.

Contracts with industry sponsors are managed through the university. Clinical research contracts are managed through the medical center's office of sponsored research, which assists investigators in negotiating and managing contracts. Investigators and their research staff are responsible for developing study budgets. The hospital, however, requires investigators to submit a breakdown of study costs that indicates where each charge will be billed.

Education and Training

The office of human research, which reports to the associate vice president for health research, compliance, and technology transfer, is responsible for administering and managing the institution's institutional review board (IRB) and related education and training on human subjects research.

Most of the education and training programs are for study coordinators. The Collaborative Institutional Training Initiative (CITI) online training program is used as a primary mechanism for ensuring familiarity with the ethical principles of human subjects research for research personnel. Study coordinators are required to complete the following modules: history and ethical principles; basic IRB regulations and review processes; informed consent; records-based research; research with vulnerable subjects; and FDA regulation research. A number of additional topics are covered in optional modules, including international research, human subjects research at the Veterans Administration, and research involving minors.

The office of human research also offers monthly workshops on biomedical research topics, "office hours" conducted at various sites across the academic health center, and weekly introductory sessions for new researchers. Intensive one-on-one training for investigators and study coordinators is also available.

It is not clear to what extent education and training programs will be incorporated into any new structure.

COMPLIANCE

The health research, compliance, and technology transfer office manages and coordinates compliance activities across the academic health center but it is difficult to determine the degree of interaction with departments on clinical trials administration.

SUMMARY

While no CTO exists, many of the elements needed to establish and develop a strong clinical research infrastructure are evident. Institutional leaders are taking a strategic approach to compliance with the formation of a workgroup that includes key decision makers from all components of the academic health center. Leaders are involved in the process and committed to consolidation. Some consolidation of the compliance function already exists, laying the foundation for building an integrated administrative structure, if desired.

However, aligning priorities across various academic health center entities has been noted as being a slow and difficult process. Each entity has a vested interest in a different element of research compliance, complicating any move towards consolidation and consensus in policy changes. Firm agreement on the part of leadership on the options for the future will be needed to ensure that appropriate resources are dedicated to build and enhance the research infrastructure for clinical trials.

INSTITUTION 5

PRIVATE: CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES: $35+ MILLION

A clinical trials office (CTO), established in the late 1990s to assist in the recruitment and management of industry-sponsored research, evolved to become a management center and provide researchers and departments with administrative infrastructure that did not exist. The institution has a split infrastructure for clinical trial management with a CTO and departments operating in parallel and providing many of the same services.

LEADERSHIP

Senior administrators are highly engaged in addressing planning and policy related to clinical trial administration; policies and procedures are reviewed annually.

ORGANIZATION, STRUCTURE, ACTIVITIES

The CTO was designed to improve clinical research capabilities for clinical departments conducting clinical trials, increase the number of clinical trials, and improve support for departments and researchers not involved in clinical research. At its start, several departments with large research portfolios and well established administrative infrastructure elected to remain outside the scope of the CTO.

The CTO is located in the office of research services for the health sciences; the director reports to the vice president of health sciences research of the university medical center, who is also senior associate dean of research, school of medicine research office.

CTO services include contacting and recruiting industry sponsors and contract research organizations, IRB submissions through electronic application processes, budget preparation and

Institution 5
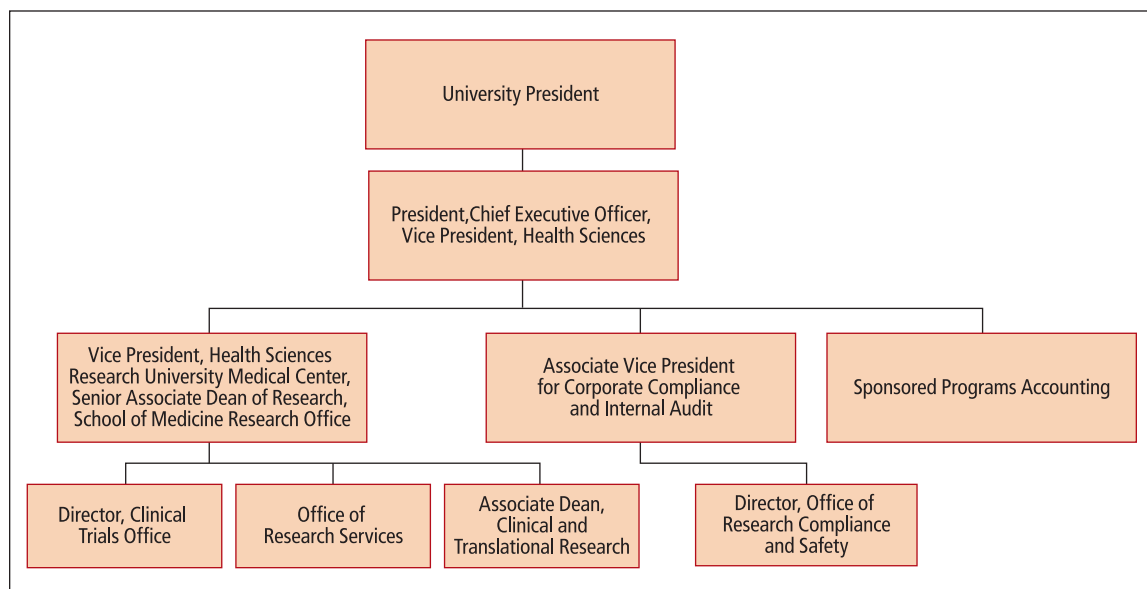
negotiation, screening of potential patients for clinical trials, coordination of the clinical trials, maintaining regulatory documents, and education and training. Investigators are responsible for recruiting study patients.

The CTO manages the financial aspects of a clinical trial through an account set up in the sponsored programs accounting office. A researcher can bring a protocol to the CTO, where a study coordinator then manages all the administrative activities related to the study. Researchers can also contact the CTO for particular services, such as searching for funding possibilities and/or open studies on a particular topic.

All clinical trials contracts and budgets are approved through the office of research services, where study budgets are also reviewed against the original protocol to see if the funding provided by the sponsor covers all services identified as sponsor charges. The office of research services then approves the budget.

Resources

The CTO has an operating budget of approximately $700,000, primarily from fees charged to investigators for services, including protocol review, and study management. Because the director of the CTO has additional responsibilities unrelated to the office, the school of medicine's office of research services subsidizes 80 percent of this salary. The operating budget, reviewed on an annual basis, is determined by current levels of clinical research. Four full-time employees staff the CTO. Additional, study coordinators are employed as needed, depending on the workload.

No Mandated Use of Services

Use of the CTO is on a voluntary basis. Currently, 35 percent of the institution's investigators use the office; 65 percent of investigators manage clinical trials through their respective departments. The majority of the institution's clinical trials are conducted by three large departments with resources to employ study coordinators.

Research administrators are working to encourage clinicians who have not previously been involved in research to use the CTO. CTO staff conduct seminars and disseminate information to highlight CTO services and thus increase the number of investigators conducting clinical trials through the office. Research administrators say word-of-mouth among clinicians is the most significant factor related to increased use of the office.

Education and Training

Education and training is administered through three separate offices within the academic health center — the CTO, the research compliance office, and the office of research services. The vice president for health sciences research is currently working to integrate the three programs.

All investigators and study coordinators are required to complete training on human subjects protection through the institutional review board (IRB) office. The office of research services conducts in-depth training on IRB processes. The research compliance office is currently developing a mandatory training program for investigators and study coordinators. The program, which began in 2009, includes modules on billing, compliance, and IT use.

COMPLIANCE

The director of research and compliance safety conducts random billing audits of clinical trials, monitors human subjects compliance, and reviews informed consent forms for both activities. The research compliance office works closely with the CTO and the office of research services. The administration anticipates an increase in staff in the compliance office, which will include an auditor position funded jointly by the medical school and health system. At present, there are no plans to relocate any of the compliance functions.

SUMMARY

The CTO was originally established to provide administrative and management support for departments and researchers lacking services necessary to engage in clinical research. The CTO provides a range of services, including protocol development and cost analysis. Use of the office is voluntary.

The CTO operates in parallel to an existing departmental administrative support system that still accommodates approximately 65 percent of the institution's investigators. Nevertheless, the CTO has proven successful, reengineering the administrative model over the years, setting an institutional standard for the conduct of clinical trials, and serving as a model to facilitate outreach and expansion of clinical trials in the community.

INSTITUTION 6

PUBLIC: CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES: $220+ MILLION

The clinical trials office (CTO), called the clinical trials compliance office, resulted from an institutional strategic plan for enlarging the research enterprise, developing a sustainable research administration infrastructure, and creating an integrated approach to billing for clinical trials. The CTO, originally modeled as a consultant service, has evolved to be a central management office performing proposal review, compliance review, contract negotiation and signature, education, and compliance auditing.

LEADERSHIP

The vice president for health sciences, dean of the school of medicine, and associate vice president for research created an advisory executive committee for clinical trials compliance in 2007 to oversee improvements in clinical trials billing operations. The committee included the assistant vice president of research, the clinical trials compliance director, the physician practice vice president, the director for billing and receivables, the director for physician billing compliance, and advisors from the general counsel's office.

This group performed a gap analysis of operations to identify risks and weaknesses associated with clinical research billing. Based on the findings, senior leaders from across the academic health center designed a CTO to be a centralized contact point for information related to clinical trials billing. A consultant model was selected as the best mode for operations. Recognizing the need to streamline administrative processes and also thread compliance through all research policies and operations, the CTO also would have capabilities and resources to educate and train personnel and monitor fiscal compliance.

INSTITUTIONAL PROFILES

Institution 6
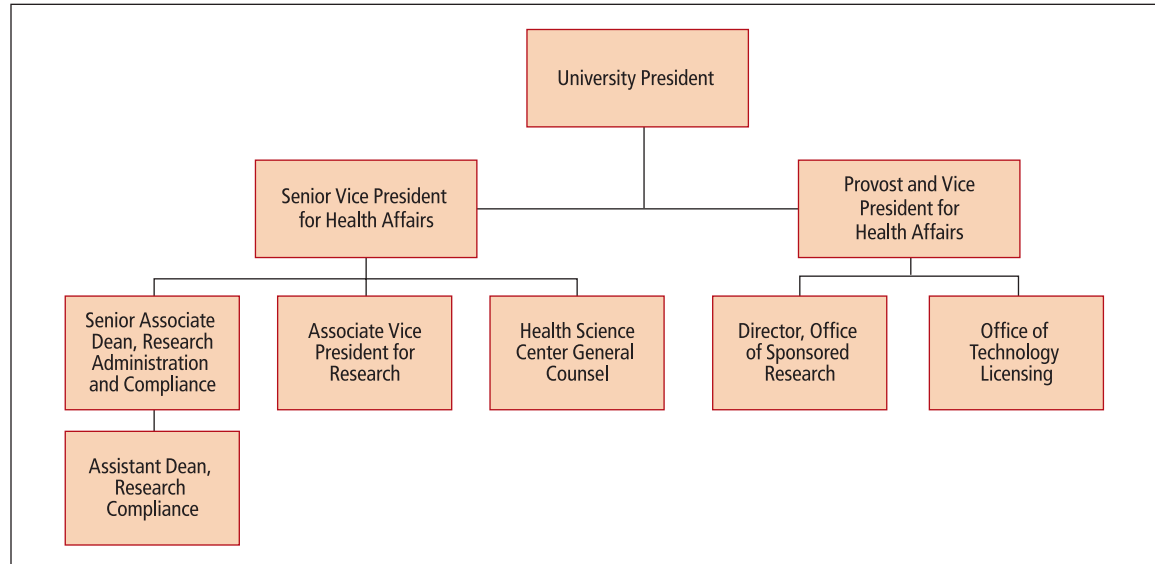
ORGANIZATION, STRUCTURE, ACTIVITIES

The CTO was established in 2007 and charged with providing services on a range of financial, management, and compliance issues related to clinical trials across the university. The CTO was needed because established offices, including the office of sponsored research, did not include individuals with expertise and understanding of clinical trial compliance issues. In early 2008, the administration decided to merge the CTO into the office of research administration, also located in the school of medicine.

Institutional leaders allocated money and staff to combine the two offices, resulting in increased efficiencies for the institution. The CTO provides end-to-end support services for clinical trials on industry-sponsored, government, or foundation sponsored research projects along with education and training on issues ranging from developing policies to monitoring compliance reviews and internal audits. The combined office does proposal review, compliance review, contract negotiation and signature, education, and compliance auditing.

One person from the office of sponsored research now works in the merged office. All clinical trials with external funding must flow through the office. Contract negotiations and signing activities are now in the CTO. The goal is to add the processing of investigator-initiated studies to the work of the CTO.

Investigators are responsible for the development of study budgets, which are then examined by the CTO. The CTO can assist investigators in budget development; classes and one-on-one training is offered to investigators.

Clinical trial proposals are submitted to the CTO for review and approval. The review includes Medicare coverage analysis and budget assessments to ensure all required protocol services have an identified payer. Grant specialists review pre-award proposals and work with investigators to ensure financial accountability of all protocol driven services; document coordinators ensure harmonization of protocol, contract, and consent language; auditors monitor compliance and audit clinical trials billings processes; and, an education coordinator provides in-person training and education.

INSTITUTIONAL PROFILES

A study registration system and a study participant identification system are in place. Administrators would like to have a centralized database in the future. A more automated system for communication and information exchange on registration and participant identification between hospital billing personnel and research departments would be desirable.

Resources

The CTO has an operating budget of approximately $500,000. The funding is allocated from the indirect cost of clinical trials. Five full-time staff and three part-time staff from the office of research administration and compliance staff the CTO.

Education and Training

The CTO conducts various training/educational activities for study coordinators, investigators, and other research personnel. The current training courses are:

- Introduction to compliance: describes the national climate of clinical research and provides participants with a summary of institutional policies, processes, and resources;
- Budgeting: focuses on designing study budgets;
- Billing and Medicare Coverage: provides an in-depth look at Medicare coverage and the National Coverage Decision;
- Registering Studies for Services: provides a comprehensive review of end-to-end billing compliance processes and communication with the hospital and group practice;
- Tracking Services: reviews how research teams can ensure that billing plans are followed and services paid correctly; and
- Device trials: under development.

In addition to classes, the CTO holds monthly workshops and forums on various topics related to clinical research; one-on-one training is available upon request.

The education coordinator, in collaboration with other senior leaders, has developed a required comprehensive training course that incorporates elements from the six existing courses for research billing compliance. The class is offered online with testing sections included in the offering. It was launched in early 2009.

INTEGRATION WITH COMPLIANCE

The CTO performs compliance review, coordinating all activities related to clinical trial compliance, pre-award processes, fiscal integrity, and conflicts of interest.

SUMMARY

This CTO was designed and established with key institutional leaders involved throughout all stages of development. A merger with an existing research administration office turned the office into a management center for all clinical trials, thus consolidating functions, eliminating duplication of work effort, and improving efficiencies in research administration. By building on an existing structure, the institution increased buy-in from a broad array of faculty and staff.

This CTO provides services to the researcher, facilitates operations, manages all phases of clinical trial compliance matters, and develops policy for conducting clinical research. The CTO also has developed a system for compliance auditing. A strong education/training program is part of the office.

INSTITUTION 7

PUBLIC: CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES:
APPROXIMATELY $20 MILLION

This clinical trials office (CTO) was established as part of the institution's strategic plan to increase clinical research capacity and to encourage and facilitate clinical and translational research, generate new knowledge, and improve the human condition. The institution had a relatively integrated infrastructure for research administration.

LEADERSHIP

The CTO, called the center for clinical research, was established with the help of a policy committee, comprising representatives from across the academic health center. Policies and procedures governing the CTO were vetted through a number of heads of departments and division directors before final reviews and evaluations were made by top institutional leaders.

ORGANIZATION, STRUCTURE, ACTIVITIES

The CTO manages and administers all clinical trials, and provides support for investigators conducting research. The CTO does contracting, budget development, and education and training. Industry-sponsored contracts are negotiated and approved through the CTO.

The CTO has expanded education, training, and career development opportunities in clinical research while also promoting internal and external collaborations across disciplines.

Institution 7
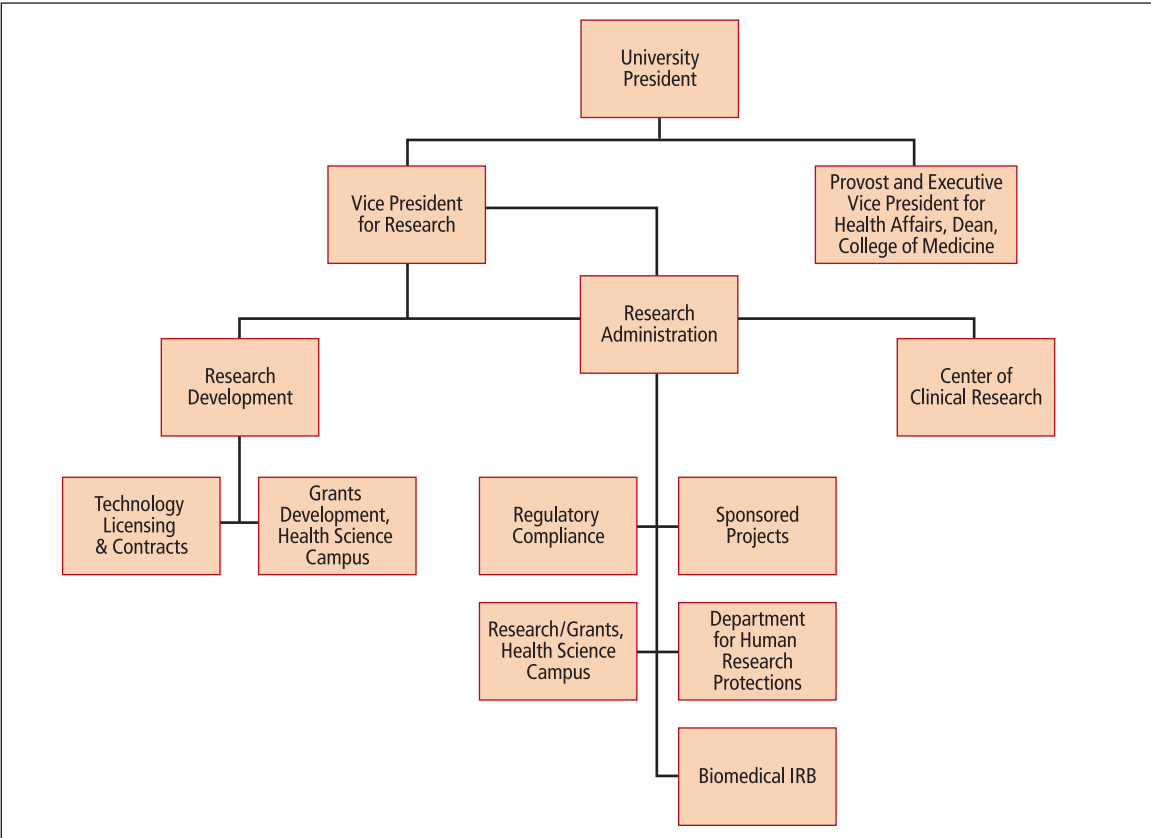
Investigators have the primary responsibility for developing study budgets, which are then submitted to the CTO. CTO staff review each protocol, perform cost and prospective reimbursement analyses, and assist investigators in defining the standard of care. Study coordinators review charges for accuracy before they are billed. The CTO holds an open forum once a month for study coordinators and other research personnel to discuss the current state of operations.

The CTO is located in the department of research of the university medical center. The director of the CTO reports to the vice president for research, as well as the provost, executive vice president of health affairs, and dean of the college of medicine.

Resources

The CTO has an operating budget in the range of $500,000 and approximately 20 full-time employees. The workload has increased exponentially in recent years. Some major changes in research administration are underway which could impact the resources for the office.

Education and Training

Education and training on research compliance is spread throughout the institution. The CTO administers a required program that certifies all study coordinators. The program includes workshops and presentations on effort reporting, research and the Health Insurance Portability and Accountability Act (HIPAA), budgeting, and billing compliance.

The office of regulatory compliance in the department of human protection conducts mandatory training for all researchers, study coordinators, and other research personnel engaged in human subjects research. The CTO is developing an educational program on institutional conflicts of interest, which will be required for all clinical research personnel. The timeline for completion is not yet known.

INTEGRATION WITH COMPLIANCE

Compliance is a university function located within the office of the legal counsel for the university. Research compliance is monitored through the medical center's office of research administration. Two compliance officers monitor human subjects research, HIPAA, animal care in research, bio-safety, research integrity and misconduct, conflict of interest, and export control regulations. The institution's internal auditing conducts financial reviews of research billing operations on a regular basis.

SUMMARY

This CTO results from a strong organizational commitment to creating the sustainable infrastructure necessary to expand the research enterprise. With support from the research community and senior leadership, the CTO will continue to expand and grow. A collaborative approach to policy development appears to have helped to enhance CTO operations and activities. The office serves as a centralized mechanism for many of the management functions concerning clinical trials, including contracting, budget development, and education and training.

The administration is continually developing new ways to address the rapidly increasing work load of the CTO, including new policies and adoption of new IT systems (e.g., outpatient billing and registration). IT continues to be one of the institution's greatest challenges.

INSTITUTION 8

PRIVATE: CLINICAL TRIALS OFFICE
RESEARCH EXPENDITURES: $95+ MILLION

The clinical trials office (CTO) was established in 2000 to centralize financial management of clinical trials and to create standard policies, practices, and operations. Since then, the institution has seen a significant increase in research dollars, a trend that institutional administrators believe will continue.

LEADERSHIP

Academic health center leaders made clinical research a priority and played key roles in establishing a framework for the development of the office.

ORGANIZATION, STRUCTURE, ACTIVITIES

The institution does not own a hospital but conducts clinical trials through a number of affiliated hospitals and clinical sites. The CTO is located in the medical center office of regulatory affairs; the CTO director reports to the associate vice president of regulatory affairs who, in turn, reports to the executive vice president for health affairs.

The CTO and the office of sponsored research are responsible for the financial administration and management of clinical trials. The office of sponsored research is responsible for reviewing, negotiating, and approving clinical trials contracts. Budget development is the responsibility of the CTO, which also performs a cost analysis of the study protocol, develops billing grids to reflect payers for protocol-driven services, and works with the investigator to define the standard of care.

Institution 8
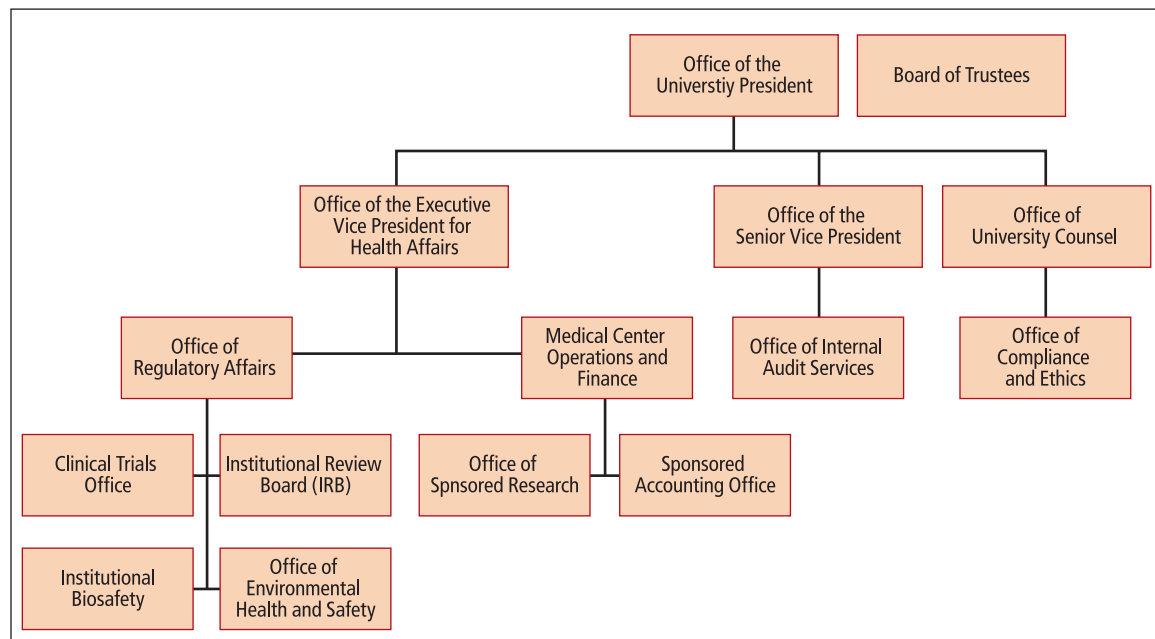
INSTITUTIONAL PROFILES

All issues related to compensation for clinical trial participants are handled through the CTO. Creating standard policies for budgeting and billing has been the most challenging aspect of the CTO. Currently, the study budget is approved by the CTO and a research account is then created for the flow of funds through the sponsored accounting office. Personnel at the hospital or other clinical sites use the budget documentation developed by the CTO to review the protocol and perform a reimbursement analysis.

In addition to pre-award and billing of clinical trials, the CTO monitors the internal flow of funds to ensure that services are billed and paid correctly, tracks research activities, and acts as a liaison between investigators and clinical service departments.

Resources

The CTO has an operating budget of more than $400,000 allocated through the office of regulatory affairs. The CTO employs four full-time staff, three of whom are analysts dedicated to clinical trials budget development activities and one auditor who performs financial audits of office operations. Study coordinators also work in the office on an ad hoc basis for an hourly rate. The administration believes that the staffing level will increase as the amount of external funding to the institution grows, and has approved additional CTO staff positions.

Education and Training

Education and training is a joint effort of the CTO and the institutional review board (IRB). All investigators, study coordinators, and research personnel are required to complete an online course in human subjects protection and the Health Insurance Portability and Accountability Act (HIPAA), which is administered by the IRB.

The CTO organizes monthly lectures and workshops on a variety of clinical research topics, including regulations of the Food and Drug Administration and clinical trial audits. Workshops are open to all investigators, study coordinators, and other research personnel.

COMPLIANCE

Compliance is a centralized function of the university under the office of ethics and compliance in the office of the university counsel. Responsibilities for monitoring and enforcement of regulations are divided by area and have been assigned to a number of offices located across the academic health center. The institution created compliance accountability charts that provide information about various compliance areas and assignments for monitoring and reporting. For example, the office of regulatory affairs is responsible for monitoring issues pertaining to human subjects protection, as well as the design, conduct and reporting of research, the use of hazardous materials, conflicts of interest, and research misconduct.

SUMMARY

This CTO was established out of the need to standardize budgeting and billing activities for clinical trials. The institution standardized policies for clinical trials financial activities that can be monitored and enforced through both the CTO and office of sponsored research, and created processes that have helped to increase the number of clinical trials.

References:

[1] Rubin ER, Lazar D, Gaich N, Haray D. *The Clinical Trials Landscape: Limitations, Strengths, and Promise.* Association of Academic Health Centers. Washington, DC: 2007.

[2] Association of Academic Health Centers. *Investing in Clinical Trial Compliance.* Washington, DC: 2007.

[3] Rubin ER, Lazar D, Gaich N, Haray D. *The Clinical Trials Functional Process Map: A Guide to a High-Performing Research Enterprise.* Association of Academic Health Centers. Washington, DC: 2008.

[4] Steinberg MJ, Rubin ER. *Research Compliance Education and Training Programs: Responding to a New Regulatory World.* Association of Academic Health Centers. Washington, DC: 2009.

[5] Association of Academic Health Centers. *2007-2008 Academic Health Center Census.* Washington, DC: 2008.

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