

Enhancing Research Compliance & Funding Through Administrative Support

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Introduction

Over the past 6 years, the Department of Pediatrics responded to many internal and external needs, which led to the evaluation and redesign of its research administrative services.

For the clinical research aspect, a major driver stemmed from a School of Medicine (SOM) 2007 initiative to assure both scientific and financial integrity of human subjects research. Through this initiative department level clinical research units (CRUs) were established and charged with financial and scientific oversight. The framework for each of these units included:

- consistent organizational structure and roles/responsibilities (medical director, financial practice manager, research practice manager)
- scientific integrity key features including review of scientific feasibility, appropriate statistical plans, appropriately trained staff, secure data management plans, and compliance with Duke and federal regulations.
- financial integrity features, which included expectations for development and negotiations of budgets, tracking tools to monitor milestones and financial management

In addition, the Department consolidated multiple programmatic and divisional grants and contracts administration (GCA) into an overarching departmental hub. Through this organizational and governance change, the opportunity to integrate the GCA with the CRU as a single research administrative service was accomplished. Other key tactics were developed as well to achieve the major objectives as outlined in this project.

Objectives

In response to the Duke University School of Medicine (SOM) guiding principles to assure scientific and financial integrity of clinical research projects, the Department of Pediatrics has created infrastructure and implemented organizational changes with the specific goals to:

- Optimize compliance
- Increase funding of clinical and basic research
- Streamline grants and contracts administrative personnel to optimize customer service and recruitment/retention of grant and contract personnel

Method/Approach

Basic improvement science methodology and concepts were utilized to evaluate both aspects of Department CRU and GCA services. Internal current state analysis (internal Department review and SOM review) was performed to assess tasks and infrastructure (job descriptions, processes, tools, etc), and future state development and gap analysis showed key opportunities. These opportunities were then prioritized based on internal and external factors as well as alignment with the primary objectives desired by the Department and SOM.

Key Opportunities/Results

- **Ensure scientific approach of all protocols**
 - Scientific review of all protocols prior to submission to Institutional Review Board (IRB)
RESULT: 100% of all protocols have input from a biostatistician.
- **Increase Research Funding**
 - School of Medicine *Path to Independence* grant writing workshops for junior faculty
 - Dept of Pediatrics offers *Concept Review* of specific aims, which is an in-depth critique of scientific approach prior to writing
 - Editing/critique of grant applications (Blythe Devlin, PhD and Katie Misuraca, PhD)
RESULTS: see Figure 1a & 1b. Concept Review Results
- **Increase Positive Margin at Project Close-Out**
 - Developed spreadsheet to capture true cost of projects
RESULT: Capture 100% cost assessment
 - Improve negotiations with sponsors through SOM centralized training of negotiators
RESULT: Over dozens of untrained PIs and CRCs to 5 trained/approved negotiators
 - Developed clinical trial projection spreadsheets for anticipated expenses and a tracking spreadsheet for all trial invoiced items and receipts
RESULTS: see Figure 2. Collection Improvement
- **Optimize Regulatory Compliance with current Good Clinical Practice**
 - SOM mandatory annual training
RESULT: ~95% baseline; ~100% compliance (as of Nov. 2015)
 - Developed education program for Department CRCs
RESULT: Networking among CRCs; professional development of CRCs via presenting work; increase familiarity with institutional leaders and initiatives
 - Developed Internal review for GCP compliance
 - Streamlined grants and contracts administrative personnel/management
RESULT: see Figure 3. Grant Hub Improvements

Fig. 1A Concept Review Results

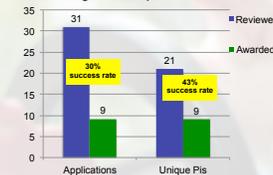


Fig. 1B Concept Review Results



Figure 2. Collection Improvement

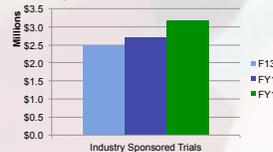
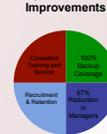


Fig. 3 Grant Hub Improvements



Conclusion

The next steps in the centralization of the GCA and CRU to create a more robust research administrative service for the Department include the following:

- Integrating these two offices by creating one shared office space so teams can have more interaction and direct face-to-face contact with each other
- Standardization of practices and processes within each group through Standard Operating Procedures.
- Coordination of activities and resources between the GCA and CRU (i.e. hybrid positions supporting both GCA and CRU)
- Improve financial management, financial research through reporting tools which are being optimized through the Department's use of web based financial reporting in Tableau.
- Optimize effort management in clinical research projects, in which revenues can fluctuate based on subject enrollment and participation.

Other initiatives include centralizing the reporting of clinical research staff to the CRU Research Practice Manager, with specific project activity oversight by the principal investigator. This structure, initiated by the School of Medicine, will facilitate standardization of training and job performance expectations. Review of all GCA positions and clinical research key personnel has been underway to standardize job descriptions and expectations and ensure appropriate research core competencies have been achieved.

In conclusion, the implementation of key administrative organizational and operational changes have led to

- positive changes in the support for scientific excellence,
- increased funding for junior faculty,
- improved financial management of both industry sponsored, federal, and foundation supported research.

Similarly, strategies to optimize regulatory compliance have created centralized and supportive environment for faculty and clinical research staff.

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