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Design and Implementation of an Infrastructure Program to Support Clinical Research in Surgery

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ABSTRACT

Barriers to active participation in clinical research among academic surgeons include insufficient research training and mentorship, increased clinical demands, lack of protected research time, limited access to resources, complex regulatory requirements, and a highly competitive research funding environment. We describe the development and implementation of a novel clinical research infrastructure program designed to attenuate these barriers and increase clinical research engagement and productivity in a large academic surgery department. Interim outcomes show a high utilization of program services across all divisions within the department, a substantial increase in new clinical research protocols, more applications submitted to funding agencies, and a high level of user satisfaction. We discuss how a departmental infrastructure program can simultaneously address barriers faced by surgeon clinical researchers and foster continuation of the longstanding tradition of innovation and discovery in academic surgery.

Introduction

Surgeons have a longstanding tradition of discovering innovative treatments and technologies to improve the lives of surgical patients. Indeed, the advancement of new knowledge through scientific discovery is a cornerstone of academic departments of surgery. In recent years, however, it has become increasingly difficult for academic surgeons to establish independent, investigator-initiated clinical research programs. Barriers to active research engagement include insufficient research training and mentorship, increased clinical demands, lack of protected research time, limited access to resources, complex regulatory requirements, and a highly competitive research funding environment.[1-6]

Limited surgeon engagement in patient-centered research is problematic for academic departments and institutions alike because clinical science is at the nexus of optimal patient care. There has been a decline in both the number of research grant applications submitted by surgeons to the National Institutes of Health (NIH) and the NIH funding rates for surgeons.[7,8] Moreover, barriers to research engagement have important implications for career and professional development, as well as the academic advancement of surgeons, because scientific and scholarly accomplishments are integral to achieving meaningful impact in one's career, including recognition by peers, which is an important determinant of future leadership opportunities, as well as a significant metric for academic promotion.[9] Without an appropriate

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infrastructure program that targets barriers, surgeons may be discouraged from engaging in academic research. This has the potential to thwart innovative and groundbreaking ideas, their implementation and systematic evaluation, and the translation of positive findings into clinical practice.

To remove barriers to research engagement and to promote growth of scientific exploration, we developed a platform upon which clinical research could be cultivated, nourished, supported, and expanded. We report herein the conceptualization and implementation of this infrastructure initiative and present our initial experience with respect to relevant outcome metrics and user satisfaction. The intent is to provide sufficient information for other surgical departments to consider when contemplating or implementing a clinical research infrastructure program.

Method

Setting

Beth Israel Deaconess Medical Center (BIDMC), a teaching hospital of the Harvard Medical School, has an explicit mission to provide advanced surgical care of the very highest quality, improve health through innovation and discovery, and prepare future leaders in American surgery. The department is the primary academic home for approximately 80 full-time clinical surgeons. Clinical care and surgical education occur at BIDMC in Boston and at community hospitals in the BIDMC network throughout eastern Massachusetts.

Needs assessment

Separate vice chairs have been appointed with responsibility for clinical and basic and translational research, which establishes a leadership structure that is focused on faculty mentorship, resource allocation, and programmatic priorities unique to clinical or basic science research, respectively. In 2014, the Vice Chair for Clinical Research sought input from department leadership, faculty, and clinical research staff as to how best to support clinical research. Specifically, the Vice Chair requested time during division faculty meetings, held small group meetings with all existing clinical research staff, and met with approximately two dozen residents and fellows engaged in clinical research. In each context, two central questions were posed: (a) What are the barriers to engaging more actively in clinical research? (b) What resources would best facilitate clinical research for you and other members of the department? Subsequently, on the basis of these open-ended discussions, we surveyed faculty to assess their perceptions about clinical research interests, barriers, and needs. Collectively, this assessment identified nine commonly perceived barriers to clinical research: (1) limited time, in the context of competing clinical obligations; (2) labor-intensive nature of clinical research, including writing protocols, consenting patients, data collection; (3) complex human subjects research regulations and policies; (4) no, or limited, funding; (5) insufficient mentorship, particularly in the areas of study design and methodology, and grantsmanship; (6) lack of statistical support; (7) financial disincentives; (8) prominence of individual research silos, thus restricting collaboration across laboratories; and (9) weak research infrastructure, including limited availability to trained research coordinators and space.

Infrastructure development

Figure 1 presents the major stages and associated timelines for development and implementation of the Facilitating Innovative Research and Surgical Trials (FIRST) Program. Following the needs assessment, we consulted with directors of other, nonsurgical clinical research infrastructure programs to better understand achieved benefits, associated risks, budgetary considerations, and staffing demands. Next, several meetings were held with key stakeholders, including departmental leadership, research staff, and directors of the institutional review board (IRB), human subjects protection office, clinical trials office, cancer clinical trials office, clinical research center, sponsored programs, academic and research computing, and other institutional leadership, including the Vice President of Research Operations and Chief Academic Officer. The intent of these meetings was to solicit support for the eventual development of a department-level infrastructure program and, once implemented, to ensure a smooth integration into existing institutional research infrastructure so that these strengths could be fully leveraged and to establish a shared vision and close communication.

Subsequently, the Vice Chair developed an infrastructure program proposal to improve the efficiency, timeliness, and safety of clinical research, ensure compliance with federal regulatory requirements, enhance resident clinical research training, and strengthen the ability of faculty to compete successfully for extramural funding. This clinical research infrastructure program concept was presented to surgery leadership (chair, vice chairs, division chiefs, chief administrative officer), revised based on feedback, and subsequently approved by the Chair in June 2016 with three explicit objectives: (1) advance scientific discovery and foster the translation of research into clinical practice, (2) provide faculty and residents with robust and comprehensive clinical research support, and (3) consolidate clinical research resources and expertise. As an example, seven divisions supported 21 clinical research assistants, coordinators, and nurses, which were working with a small number of individual faculty members, without cross-coverage, mutual training, or shared best practices. The intent was to develop a collaborative model to ensure that these essential research personnel were integrated into a larger support system and, thereby, benefit from shared resources.

A preimplementation plan was then implemented, which included hiring a clinical research administrator, an experienced clinical trials specialist, a clinical research coordinator, and a data analyst. Along with the Vice Chair as its Director, this group formed the core staff at FIRST Program launch. The clinical research administrator was hired to help construct and manage the program's operational components, as well as supervise all research staff. This position was filled by a master's level epidemiologist and biostatistician with significant experience in surgery. In addition to existing relationships with faculty and residents in the department, the

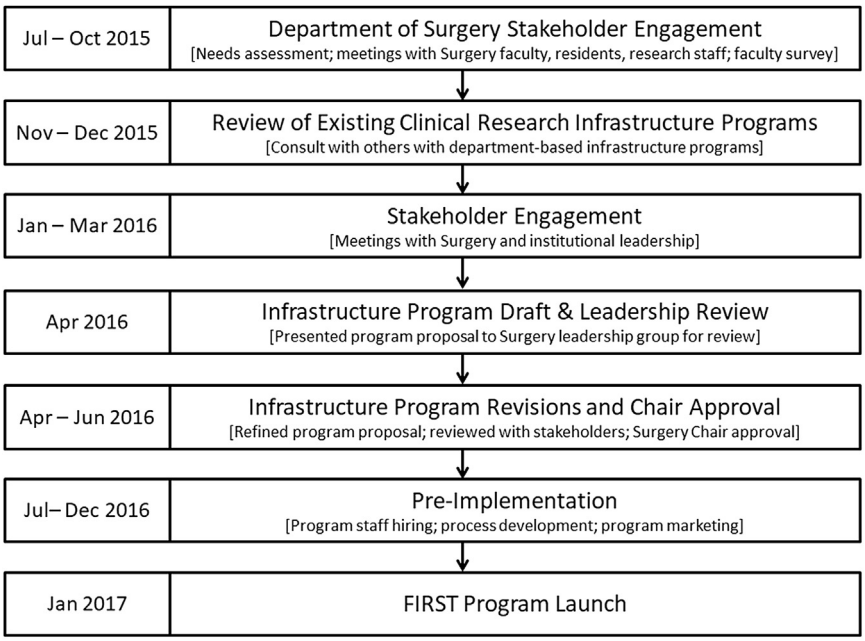

Fig. 1 – Major stages and associated timelines for development and implementation of the FIRST Program.

individual had preexisting relationships with other institutional entities including PhD-level biostatisticians, IRB leadership, research grant administrators, and the clinical trials office staff.

Calculated expenses to implement the clinical research infrastructure program initially included salary and fringe for new staff, research supplies and equipment, space renovation for new staff, regional and national database access fees, and travel. Faculty members integrated into the program as research mentors received no additional compensation.

Outcome metrics

Several process and outcomes metrics were identified *a priori* by the Vice Chair and surgery leadership to evaluate the effectiveness and impact of the program, including the number and types of service requests, supported clinical research projects, IRB submissions, IRB regulatory infractions, submitted clinical research abstracts, clinical research publications, submitted and funded extramural clinical research grant applications, industry-sponsored trials, and user satisfaction. We report descriptive statistics for these metrics. In, addition, t test was calculated to determine whether the number of service requests differed significantly between divisions with or without clinical research staff at the time of the FIRST Program implementation. Finally, chi-square statistic was calculated to determine whether the regulatory complexity of IRB protocol submissions changed significantly from preimplementation to postimplementation of the FIRST Program.

To assess user satisfaction, individuals who submitted one or more service requests were asked to complete an anonymous 17-item electronic survey. Respondents indicated their level of satisfaction (very dissatisfied, dissatisfied, satisfied, very satisfied) with 14 statements related to the quality of program services, and their level of agreement (strongly disagree, disagree, agree, strongly agree) with three statements related to achieving faculty goals, enhancing their ability to engage in clinical research and their ability to submit abstracts, manuscripts, and grant applications. We calculated and report the proportion of survey respondents who indicated they were either "satisfied" or "very satisfied" with each statement. On November 11, 2018, the BIDMC Committee on Clinical Investigations determined that the activities described herein do not meet the OHRP (45 CFR 46.102(f)) definition of human subjects research.

Results

Program implementation

On January 1, 2017, the Department of Surgery officially launched the FIRST Program to support faculty, fellows, residents, and research staff engaged in clinical trials, patient-reported outcomes research, health services research, prospective observational cohort studies, retrospective medical record reviews, prospective database creation and management, tissue research, surgical education research, and quality improvement initiatives. A website (http://bidmcfirst.com) was designed to provide information about the program and to serve as the primary entry portal for service users. Services offered by the FIRST program were phased in to ensure capacity and expertise to efficiently and effectively field requests.

Table lists services currently offered by the FIRST Program. Requests submitted by faculty, fellows, residents, or research staff are triaged by the clinical research administrator,

Table – Services offered by the Department of Surgery FIRST Program.

Targeted need	Service provided
Regulatory	IRB navigation and guidance
	IRB document preparation and submission
	IRB scientific review
	IRB audit preparedness (e.g., mock audits)
	Other regulatory guidance (e.g., FDA, data transfer agreements)
Research ethics	Human subjects protection training
	Regulatory on-boarding of new residents, fellows, and faculty
Data security	Database building
	REDCap education and training
	Data management and record retention
Mentorship	Individualized clinical research mentorship (research design, methodology, biostatistics)
	Oversight of clinical scholarship program for residents
Personnel	Recruit and hire research staff to meet project-specific needs
	Provide backup coverage for existing research staff
	Provide research nurse for studies requiring this level of engagement
Grant development	Identify funding opportunities
	Grant writing education and mentorship
	Grant writing assistance
	Presubmission grant application review program
	Industry outreach and communication
	Coordinate industry site visits
	Pilot research grant program
Project	Protocol development
	Survey development and validation
	Subject screening and recruitment
	Biostatistics consultation
	Data collection, coding, and validation
	Manuscript writing
	Sample processing and storage
	Lab website design and development

FDA = Food and Drug Administration; FIRST = Facilitating Innovative Research and Surgical Trials; IRB = institutional review board.

followed by a consultation with the director or clinical research administrator to clarify requests, assess project details, and determine the needs of the project. The project is assigned to one or more program staff for immediate engagement. Since initial launch, the FIRST Program has hired an experienced research nurse, an MPH-level Program Manager who oversees all cancer-related clinical research activity, and two clinical research assistants.

In addition to regulatory, data security, and project-specific services, the FIRST Program coordinates several programmatic activities to enhance clinical research activities and visibility. First, a biweekly clinical research seminar is held that serves as an interactive venue for clinical research sharing, learning, collaboration, and engagement. The goals of the seminar series are to learn about new innovations in clinical research, solicit feedback regarding projects in the early stages of development, foster new initiatives and collaborations, and share best practices in clinical research coordination and management. Second, a presubmission grant application review program allows investigators to request a review of their application from our internal Research Advisory Committee members and from a consultant hired by the department. The intent of this program is to conduct an NIH-style review and provide critical and timely feedback, thus allowing the investigator to revise and strengthen the application before formal submission to the funding agency. Third, we established an annual award for Excellence in Clinical Research Mentorship, which recognizes a faculty member in the department whose commitment to and investment in the clinical research development of students, residents, fellows, and junior faculty demonstrate excellence in mentoring. Nominations are solicited annually, and the award recipient is selected by the Research Advisory Committee. Fourth, the FIRST Program administers an annual request for applications to fund two pilot randomized controlled trials deemed to have substantial potential to generate preliminary feasibility and efficacy data for novel interventions that can be evaluated in a larger, extramurally funded trial. Finally, the department's Clinical Scholarship Program is administered by the FIRST Program. As described elsewhere,[10] the Clinical Scholarship Program is a structured clinical research rotation for first-year categorical general surgery residents, with a primary goal of providing an early foundation for effective engagement in scholarship.

The FIRST Program footprint consists of a 1900 sq ft open office suite with 42 work stations for staff and clinical research fellows mentored by department faculty, as well as a workstation with a high-performance computer dedicated for data analysis. Priority for allocating space for research fellows is given to faculty with extramural clinical research funding and junior faculty with high promise for future grant funding with FIRST Program support.

Interim outcomes

Data are presented for the 22-month period, January 1, 2017 through October 31, 2018. Figure 2 shows the number of unique monthly requests submitted to the FIRST Program (total = 227; mean per month = 10.3) and the associated number of services requested (total = 532; mean per month = 24.2). Ninety-seven unique individuals submitted requests to the FIRST Program (35 faculty, 34 fellows, 14 residents, and 14 staff). The most common types of service requests were for regulatory assistance (n = 255, 48%), biostatistics support and data management (n = 94, 18%), research mentorship and study development (n = 94, 18%), study management (n = 54, 10%), and research grant guidance (n = 35, 6%) (Fig. 3). Multiple requests were received from all divisions within the department. A substantially higher proportion of services requested were by divisions without

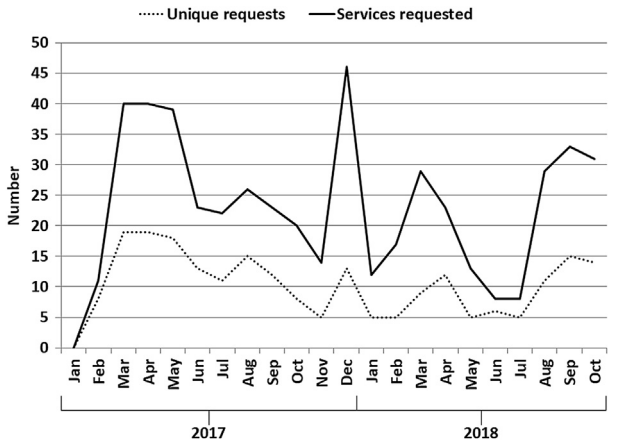

Fig. 2 – Number of unique requests submitted to the FIRST Program and the number of services requested, by month.

trained clinical research staff, compared to divisions with one or more coordinators before FIRST Program implementation ($n = 376$ or 71% vs. $n = 156$ or 29%, $P = 0.04$). Surgical oncology, plastic and reconstructive surgery, colon and rectal surgery, ophthalmology, podiatry, general surgery, and acute care surgery and trauma submitted the highest volume of service requests and accounted for two-thirds of all services requested ($n = 352$, 66%).

In the 24 months before FIRST Program implementation, faculty in the Department of Surgery were Principal Investigators on 192 open IRB protocols. In the 22 months since program implementation, the number of open IRB protocols increased 63% ($n = 313$). Faculty submitted 104 new IRB protocols since January 1, 2017, a 104% increase over the 51 new IRB protocols submitted in the 24 months before the FIRST Program (Fig. 4). Additionally, there was a significant increase in new IRB protocols requiring a higher level of regulatory complexity ($P = 0.002$). The proportion of new IRB protocols that required expedited or full board (versus exempt status) increased from 59% pre-FIRST Program implementation to 80% post-FIRST Program implementation. To assess whether the increase in new IRB protocols could be attributed solely to an increase in faculty in the department, we calculated a ratio by dividing the number of new IRB protocols by the number of faculty members in the department. Including only clinical surgeons without exclusively basic science laboratories, there were 75 in 2015, 77 in 2016, 78 in 2017, and 82 in 2018. The ratio of new IRB protocols per faculty member by year was as follows: 0.28 in 2015, 0.38 in 2016, 0.77 in 2017 (FIRST Program implementation), and 0.76 in 2018 (through October 31st). Additionally, 26 (48%) of the 54 faculty who had not submitted new IRB protocols in the 2 years before FIRST Program implementation submitted ≥1 new IRB protocol in the first 12 months after the infrastructure program was launched.

The FIRST Program facilitated the preparation and submission of more than half of the new IRB protocols and assumed responsibility for ongoing monitoring and IRB form preparation, including submission of adverse event reports, amendments, continuing reviews, and protocol terminations. We implemented a tracking system that ensures all regulatory deadlines are met and that there are no hand-off miscues or failures during the transition of residents and fellows. In addition to these IRB-approved protocols, the FIRST Program created and manages a number of prospective REDCap databases that capture treatment and outcomes data.

There has been a substantial increase in the number of new clinical research grant applications to federal agencies and national foundations since implementation of the FIRST Program (Fig. 5). The FIRST Program facilitated the submission of 10 new grant applications (3 foundation, 3 NIH RO1s, 1 NIH K08, 2 Health Resources and Services Administration, and 1 Patient-Centered Outcomes Research Institute); of which, seven were funded, one was not, and two is under review. Currently, 27% of FIRST Program staff effort is now funded on extramural grants or industry contracts.

Of the 97 individuals who submitted at least one service request, 58 (60%) returned completed surveys (27 faculty, 13 residents and fellows, 14 staff, 4 unknown). The majority of respondents were "satisfied" or "very satisfied" with all types of services: request form and process (100%), regulatory

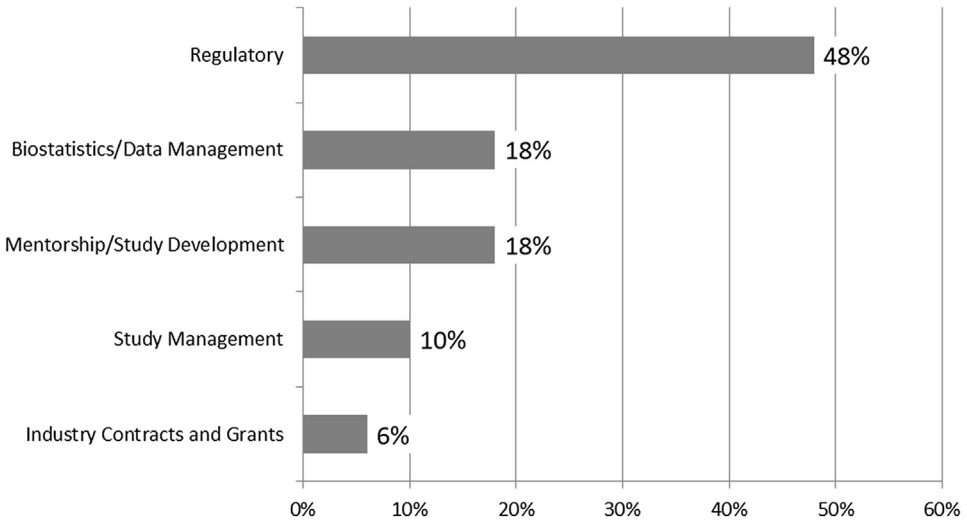

Fig. 3 – Types of service requests submitted to the FIRST Program.

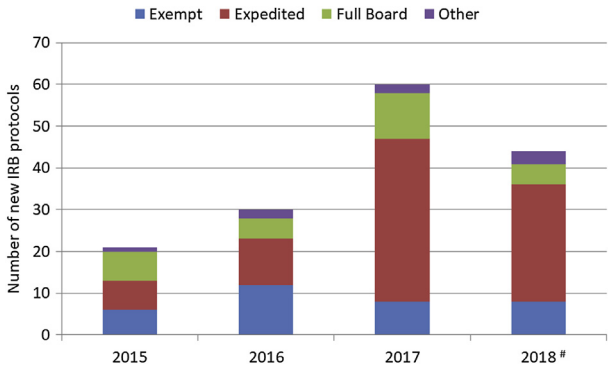

Fig. 4 – Number of new protocols submitted (and level of regulatory review) to the Institutional Review Board by Department of Surgery faculty in the 24 months before implementation (January 2015 to December 2016) and the 22 months after implementation (January 2017 to October 2018) of the FIRST Program. #Through October 31, 2018. IRB, institutional review board. (Color version of figure is available online.)

assistance (98%), timeliness (96%), responsiveness (98%), accessibility (98%), industry engagement (95%), knowledge about human subjects protections (95%), biostatistics consultation (97%), study design and methodology (95%), database creation (97%), data collection and entry (97%), mentorship (97%), and study coordination (97%). Ninety-six percent of respondents were satisfied or very satisfied with the overall quality of services provided and indicated that the FIRST Program met their expectations. Among faculty respondents, 96% reported that the FIRST Program enhanced their ability to engage in clinical research and facilitated their ability to disseminate their research and prepare grant applications.

The total upfront financial investment for the FIRST Program was approximately $375,000 USD, which included 3.5 FTE new staff positions (salary + fringe benefits), space renovation, and research expenses (e.g., supplies, statistical software, national databases).

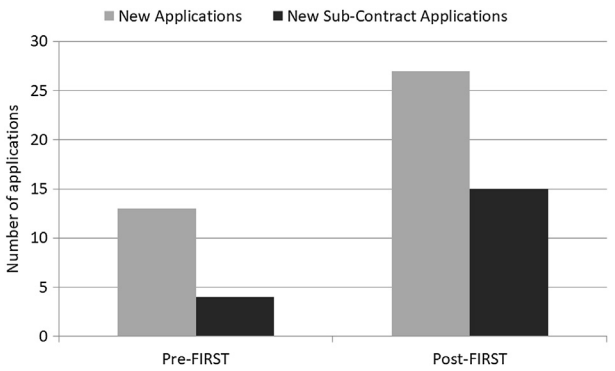

Fig. 5 – Number of new and subcontracted clinical research extramural grant applications submitted to federal agencies and private foundations in the 24 months before implementation (January 2015 to December 2016) and the 22 months after implementation (January 2017 to October 2018) of the FIRST Program.

Discussion

Our central finding is that implementation of a robust infrastructure program reduces barriers to clinical research engagement by surgical faculty. We demonstrated an increase in clinical research activity by providing faculty with a centralized hub for regulatory guidance, research mentorship, biostatistics support, database development and analysis, patient recruitment and enrollment, data collection capabilities, and grant development support. An increase in clinical research activity was reflected by an increase in IRB-approved protocols (standardized by number of faculty), especially those with a higher level of regulatory complexity, prospective clinical databases, industry-sponsored clinical trials, and extramural research grant applications. Sustained growth of clinical and translational research has also been reported by others who have implemented centralized clinical research infrastructure programs.[11,12]

The challenges to develop and lead a clinical research program are abundant and include clinical and financial pressures, administrative burdens, complex research regulations, limited funding, and insufficient mentorship. As highlighted by Hu et al7, these challenges have contributed to a decline in extramural funding. It is our experience that identifying novel and clinically meaningful scientific questions is not the primary barrier to research engagement; rather, it is gaining the expertise and identifying the time necessary to pursue these ideas. The failure to nourish innovation and engagement may delay academic promotion, limit career advancement, and reduce competitiveness for extramural funding required to recruit team members with expertise to address pressing clinical problems. The FIRST Program was established, in part, to improve the efficiency in executing clinical research ideas, recognizing that clinical revenue pressures and administrative demands for academic surgeons are not likely to abate in the short term. The desire among faculty to participate actively in clinical research is substantiated by the high volume and breadth of services requested from the FIRST Program since its inception. Additionally, 26 of the 27 (96%) faculty survey respondents reported that the FIRST Program enhanced their ability to engage in clinical research, thus providing preliminary support that our objective to attenuate the time demand was met. Indeed, among faculty who had not submitted new IRB protocols in the 2 years before FIRST Program implementation, nearly half submitted a Principal Investigator-led study to the IRB within 12 months of FIRST Program launch, another indicator of the renewed engagement by faculty in clinical research.

In addition to the benefits that accrue to individual faculty, fellows, and residents, a clinical research infrastructure program has many other notable benefits that are more difficult to objectively measure. For instance, the FIRST Program has been an important tool for the recruitment of faculty and research fellows, as it demonstrates the department's commitment to nurture and support research endeavors. The program has fostered a community of existing research staff,

including nurses, coordinators, and clinical trials specialists, facilitating interactions with other investigators and staff within the department. Integration into a larger research network promotes relationship building, sharing of best practices, mentorship of junior research assistants, consistency in implementation of training standards, and commitment to the broader scientific mission of the department. Finally, implementation of the program has allowed us to assess the relative strengths and weaknesses of individual faculty investigators to support their own development as clinician-investigators, the research training requirements of residents and research fellows, and the department's entire clinical research portfolio, thus allowing us to better identify opportunities and maximize potential.

Despite the early successes of the FIRST Program, there are many challenges that must be overcome to sustain a program of this nature. Some faculty members continue to have a strong bias against a centralized research infrastructure, preferring autonomy over their own research processes and the hiring of research staff. We made an *a priori* decision not to require faculty to use FIRST Program services if trained and experienced research coordinators were in place before program implementation. Nevertheless, we have worked diligently to build strong relationships with all clinical researchers and their staff, regardless of their level of engagement with the FIRST Program. We continually strive to maintain the proper mix of breadth and depth in experience and skill set in our cadre of research personnel. Recruitment and retention of research staff with both core expertise and the flexibility to support investigator and program needs, should they emerge, is essential to program success. Another challenge is maintaining awareness of and responding rapidly to changes in federal, state, and institutional policies or regulations governing clinical research to ensure ongoing investigator compliance. For example, the revision to the Common Rule, effective January 21, 2019,[13] impacts all clinical researchers and necessitates retraining of research staff and modifications to existing processes and policies.

There are noteworthy limitations in this assessment. The FIRST Program was implemented and evaluated at a single institution and may not generalize to other departments or institutions with a different administrative structure. At this initial phase, data regarding the program's impact on more traditional productivity metrics, including conference abstracts and published manuscripts are not yet available. It is possible that those who responded to the satisfaction survey were more pleased with services received, thus biasing responses toward higher favorability. Future assessments will also consider the impact of the FIRST Program on work-life balance since the provision of clinical research support services may reduce academic strain, which may mitigate burnout that is an increasing concern in all medical environments.

In conclusion, since its initial launch, the FIRST Program has contributed to a growth in both the quantity and complexity of clinical research with centralized regulatory services to ensure optimal compliance with institutional policies and federal regulations. The quality and range of services provided have been perceived favorably by residents, fellows, and faculty. We believe that every member of an academic center should own a question with each patient interaction viewed as an opportunity to improve the next. The FIRST Program represents a model that simultaneously addresses current barriers faced by surgeon-investigators while fostering the longstanding tradition of innovation and discovery in academic surgery.

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Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article. The authors have no conflicts of interest to disclose.

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