OPTIMIZING THE RESEARCH ADMINISTRATIVE INFRASTRUCTURE TO SUPPORT AN INCREASE OF CLINICAL TRIALS AT WAKE FOREST BAPTIST MEDICAL CENTER

by
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Abstract

In late 2017, Wake Forest Baptist Medical Center (WFBMC) created a Clinical Trials Task Force to identify ways of increasing their volume of industry-sponsored clinical trials. Increasing the number of industry-sponsored clinical trials provides many benefits, including: (1) offering more cutting-edge treatment options to its patients, (2) growing its research portfolio, (3) expanding the reach of its research across the entire WFBMC network, and (4) providing additional opportunities for revenue. The author is a member of this task force and capitalized on the opportunity to use this capstone project to help generate information and ideas that were presented to WFMBC leadership in March of 2018.

In order for WFBMC to build capacity to increase its volume of clinical trials, workflows must be improved in order to have a research infrastructure capable of facilitating clinical trial agreements (CTAs) in a timely manner. For this capstone project, the author examined a new improvement initiative, the 60-Day Challenge, and conducted a literature search to determine what other institutions consider best practices in this area. The author also conducted interviews with senior leadership to identify potential research infrastructure improvement strategies that could be implemented at WFBMC.

The research done for this capstone project led the author to make ten recommendations from the findings. These recommendations included continuing the 60-Day Challenge to allow for parallel submission and review of the budget, contract, and regulatory documents; incorporating previously approved contract language and master agreements whenever possible to help facilitate faster contract negotiations; and creating

a focused pool of dedicated CTA processing staff. These recommendations can help WFBMC become more efficient at processing CTAs and become more attractive to sponsors, which will promote and support an increase in clinical trials.

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Abbreviations

ACRP	Association of Clinical Research Professionals
AMC	Academic Medical Center
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
CTSI	Clinical and Translational Science Institute
eIRB	Electronic Institutional Review Board
GCP	Good Clinical Practice
IRB	Institutional Review Board for the Protection of Human Subjects
NCURA	National Council of University Research Administrators
OCR	Office of Clinical Research
OSP	Office of Sponsored Programs
PI	Principal Investigator
REDCap	Research Electronic Data Capture
SOCRA	Society of Clinical Research Associates
SOP	Standard Operating Procedure
WISER	Wake Integrated Solution for Enterprise Research
WFBMC	Wake Forest Baptist Medical Center

Chapter 1. Introduction

The aim of this capstone project was to examine the research administrative infrastructure at WFBMC and provide recommendations on process improvements to support an increase in industry-sponsored clinical trials conducted at WFBMC. Data from a survey administered by the Clinical and Translational Science Institute (CTSI) in May of 2017 was evaluated to support the need for better workflows. This survey was administered to all faculty and staff across the research enterprise and assessed the overall effectiveness and satisfaction with the Office of Sponsored Programs (OSP) Pre-Award, Post-Award, and Contracts Divisions.

This capstone project explored an initiative already underway at WFBMC, the 60-Day Challenge, to see how effective it has been at improving operational efficiencies and decreasing the amount of time it takes to execute an industry-sponsored CTA. This capstone project also examined current literature related to increasing efficiencies when working with industry-sponsored clinical research. It also examined infrastructure needs, industry-sponsored master CTAs, and how this information can be utilized at WFBMC. Interviews were also conducted with senior leadership in the CTSI to provide insight, assess the current environment, and discuss opportunities to optimize workflows in over thirty academic departments, centers, and institutes, as well as within central research administrative offices.

1.1 Background

WFBMC is an academic medical center (AMC) located in Winston Salem, North Carolina. It houses the CTSI, partially supported by a Clinical and Translational Science

Award funded by the National Center for Advancing Translational Sciences. The CTSI provides a unified research support mechanism and includes the central research infrastructure responsible for the initiation and ongoing review of clinical trials. This includes the following three primary offices as outlined in Table 1: Office of Sponsored Programs, Office of Clinical Research, and Institutional Review Board.

Table 1. CTSI offices, their function, and electronic system used

Office	Primary function	Electronic system used
Office of Sponsored Programs (OSP)	Manage all pre-and post-award functions, industry contracting, and reporting for all awards	InfoEd Global (InfoEd)
Office of Clinical Research (OCR)	Builds study calendars and budgets in WISER to manage study billing; Medicare Coverage Analysis; offers resources for study coordination, data and regulatory management; and conducts internal auditing	Forte's OnCore named Wake Integrated Solution for Enterprise Research (WISER)
Institutional Review Board for the Protection of Human Subjects (IRB)	Manages the review and approval of all human subjects research	Huron's Research Suite - an electronic IRB (eIRB)

These offices collaborate with over 1,200 faculty and staff who participate in research activities. In fiscal year 2017,[1] WFBMC received over $205 million in sponsored research funding with $10 million coming from industry–sponsored clinical research.

In the fall of 2017, WFBMC leadership created a Clinical Trials Task Force to develop strategies to increase clinical trial funding across the medical center, with an emphasis on industry-sponsored funding. According to WFBMC's Chief Science Officer

1. Academic Fiscal Year 2017 is July 1, 2016 through June 30, 2017.

and Senior Associate Dean for Research, "WFBMC is focusing on increasing industry-sponsored clinical trials as they offer benefits in these four areas:

1. Patient Perspective – Clinical trials provide patients with access to cutting-edge treatments and care. They allow patients to play a more active role in their care and help them understand more about their disease or condition.

2. Research Perspective – Industry-sponsored clinical trials address different questions than federally sponsored studies, so they help expand the range of WFBMC's research portfolio.

3. Clinician Perspective – Clinician involvement is required for most industry-sponsored clinical trials so this helps spread research across the entire WFBMC network.

4. Revenue – Since WFBMC is an AMC, it seeks to expand its funding portfolio and industry-sponsored clinical trials help bring diversification to its income statements. In addition, industry is considered the best third party payer for clinical ancillary services."[2]

In order to facilitate an increase in clinical trials, the research infrastructure at WFBMC needs to be able to build additional capacity to support growth in this key area. This capstone project focused on optimizing workflows and staffing recommendations to improve the industry-sponsored CTA process.

2. Gregory Burke, " Clinical Trial Task Force Charge" (presentation, WFBMC, Winston Salem, December 18, 2017).

1.2 Statement of the Problem and Needs Assessment

In May 2017, the CTSI administered an OSP Programs Assessment Survey (see Appendix 1 for complete survey). This survey was created and administered through Research Electronic Data Capture (REDCap), a web-based application used for building and managing online surveys and databases and was sent to 1,245 faculty and staff. 545 responses were received with an overall response rate of forty-four percent (281 responses from staff, 241 from faculty, and twenty-three from OSP staff). The comprehensive survey covered a number of topics, including: proposal review and submission, InfoEd (WFBMC's electronic research administration system used to submit grants and contracts), contract negotiation, sub-award negotiation, account setup, award management, effort reporting, award closeout, customer service, and overall effectiveness. For the purposes of this capstone project, the author focused on proposal review and submission, contract negotiation, customer service, and effectiveness.

As shown in Table 2, OSP is effective at facilitating proposals, mainly federally funded grants, but improvement is needed when it comes to facilitating industry-sponsored contracts and CTAs. OSP had a sixty-three percent positive score where faculty and staff felt OSP is very effective or effective at facilitating the overall proposal review, approval, and submission of grants while only ten percent surveyed felt OSP is ineffective or very ineffective. When compared to how effective OSP was at finalizing industry research contracts in terms of speed and timeliness of execution, the positive/effectiveness score dropped to thirty percent, while the negative/ineffective score rose to thirty-seven percent. This data shows that faculty and staff feel that OSP can be

more effective at reducing the turnaround time for executing industry contracts, have better customer service, and do more to reduce administrative burden. Administrative burden can include any barriers that exist including the paperwork needed to initiate the negotiations of a CTA as well as compliance and regulatory approvals.

Table 2. OSP assessment survey results

Survey Question	Positive*	Neutral*	Negative*
Indicate how effective OSP is at facilitating the overall proposal review, approval, and submission process.	63%	27%	10%
In terms of minimizing the administrative burden on investigators, how well does the overall proposal review, approval, and submission process meet expectations?	20%	56%	24%
Indicate how effective OSP is at finalizing industry research contracts in terms of speed/timeliness of execution.	30%	33%	37%
Indicate how effective OSP is at communicating the status of industry contracts.	34%	32%	34%
The individuals within the OSP Contracts Office have the right level of expertise and knowledge to perform their job duties and answer my questions.	56%	30%	14%
The OSP Contracts Office team members display a strong customer service attitude to my email and/or phone inquiries.	53%	28%	19%
Please rate your overall satisfaction with the response of the OSP Contracts Office to your questions, emails and/or phone inquiries.	50%	27%	23%

*Positive includes the following categories: Strongly Agree/Agree, Very Effective/Effective, Significantly Above Expectations/Above Expectations, Very Satisfied/Satisfied, Very User-Friendly/User-Friendly

*Neutral includes the following categories: Neither Agree nor Disagree, Somewhat Effective, Meets Expectations, Neither Satisfied nor Dissatisfied, Somewhat User-Friendly

*Negative incudes the following categories: Disagree/Strongly Disagree, Ineffective/Very Ineffective, Below Expectations/Significantly Below Expectations, Dissatisfied/Very Dissatisfied, Not User-Friendly/Not At All User-Friendly

*Responses of "Not Applicable" or "I don't know" were not included in the percentages above

WFBMC is not alone in thinking improvements can be made in order to increase efficiencies regarding the start-up of industry-sponsored projects. WFBMC metrics indicate the time from receipt of industry-sponsored regulatory documents to trial

activation was a median of 150 days.[3] When compared to other institutions, Vanderbilt-Ingram Cancer Center had a median of 171 days,[4] and median times from submission to opening a trial were 163 days for Washington University School of Medicine and 112.5 days for University of Torino.[5] These institutions also questioned what could be done to improve their internal processes in order to reduce the number of days it takes to initiate industry-sponsored clinical trials. This was a driving force behind a new initiative implemented in December of 2017 at WFBMC called the 60-Day Challenge. The 60-Day Challenge is a partnership between departments and the CTSI in which all parties commit to accelerating the submission and review of IRB applications, as well as budget and contract documents to help expedite the contracting and study start-up process. Preliminary data from the Challenge are reviewed and discussed as part of this capstone project.

1.3 Research Questions

This capstone project was designed to explore what can be done to improve the industry contracting process at the institutional level. The author acknowledges the industry sponsor and/or their contract research organization (CRO) plays a role in this process as well, but the author focused on what can be done internally to make process

3. Chris O'Byrne, interview with author, Winston Salem, December 8, 2017.

4. David Dilts and Alan Sandler, "Invisible Barriers to Clinical Trials: The Impact of Structural, Infrastructural, and Procedural Barriers to Opening Oncology Clinical Trials," *Journal of Clinical Oncology* 24, no. 28 (October 2006): 4550, accessed March 20, 2018, http://dx.doi.org/10.1200/JCO.2005.05.0104.

5. Andrea Wang-Gillam et al., "Time to Activate Lung Cancer Clinical Trials and Patient Enrollment: A Representative Comparison Study Between Two Academic Centers Across the Atlantic," *Journal of Clinical Oncology* 28, no. 24 (August 2010): 3804, accessed March 20, 2018, http://dx.doi.org/10.1200/JCO.2010.28.1824.

improvements. The following research questions were considered for this capstone project:

1. What improvements can be made within OSP to better facilitate CTAs?
2. What improvements can be made within departments to better facilitate CTAs?
3. What are other institutions doing to improve the industry contracting process?
4. Are the goals of the 60-Day Challenge being met and should it continue?

1.4 Research Objective

The objective of this capstone project was to provide recommendations to the CTSI leadership on process improvements to better facilitate CTAs. This will in turn help build capacity that will allow the institution to better position itself to grow in the number of industry-sponsored projects it participates in.

Chapter 2. Literature Review

Trying to reduce research administrative burden is not just an issue at WFBMC, it is a systemic problem as shown in the 2012 Federal Demonstration Partnership Survey. This survey showed principal investigators (PIs) spend, on average, forty-two percent of their time on administrative tasks related to conducting federally funded research.[6] While this survey focused on the administrative burden placed on university researchers who have been awarded federal grants, many of the same burdens exist for university researchers working on industry-sponsored research.

In order to assess best practices in facilitating industry-sponsored clinical trials at other research institutions, a literature search was conducted to evaluate best practices at other institutions and determine what could be implemented at WFMBC to help address the first three research questions:

1. What improvements can be made within OSP to better facilitate CTAs?

2. What improvements can be made within departments to better facilitate CTAs?

3. What are other institutions doing to improve the industry contracting process?

This chapter discusses literature related to the following areas: (a) increasing efficiencies in executing CTAs, (b) infrastructure needs to support an increase in clinical trials, and (c) the use of master CTAs.

6. Sandra Schneider, Kirsten Ness, Sara Rockwell, Kelly Shaver, Randy Brutkiewicz, "2012 Faculty Workload Survey Research Report," Federal Demonstration Partnership (FDP), April 2014, assessed January 30, 2018, http://sites.nationalacademies.org/cs/groups/pgasite/documents/ webpage/pga _087667.pdf.

2.1 Increasing Efficiencies in Executing Clinical Trial Agreements

There are a number of factors that can delay the start-up of clinical trials including contract negotiations, budget negotiations, and the IRB review and approval, with delays in contract negotiations being the most common. Rijswijk-Trompert suggests these delays are often tied to lack of clear processes, training, and communication of the staff who process CTAs.[7] This article suggests that, as often as possible, contracts offices should have well written contract templates that include language that has been previously approved.[8] Another recommendation was to set communication guidelines during training as communication is often seen as a barrier during contract negotiations.[9]

There are also processes unrelated to contract negotiations that can ultimately delay executing an industry contract, including IRB reviews, budget negotiations, finance office approval, and management of conflicts of interest. Baer et al. suggest that the establishment of processes that include a parallel review of the items listed above can reduce the time it takes to activate a clinical trial.[10] Baer et al. also suggest "Establishing a culture in which all members of the research team understand the importance of conducting their role in an efficient manner is imperative."[11] When all parties involved know their role, this can prevent avoidable mistakes and misses, and in turn reduce contract negotiation turnaround time. Internal deadlines should also be used to improve

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7. Myrthe Rijswijk-Trompert, "Clinical Trial Agreement Negotiations," *Applied Clinical Trials* 21, no. 6 (June 2012): accessed January 19, 2018, http://www.appliedclinicaltrialsonline.com/clinical-trial-agreement-negotiations.

8. Ibid.

9. Ibid.

10. Allison Baer et al., "Clinical Research Site Infrastructure and Efficiency," *Journal of Oncology Practice* 6, no. 5 (September 2010): 251, accessed February 15, 2018, http://dx.doi.org/10.1200/JOP .000109.

11. Ibid.

efficiency for the various stages of review and approval and reminders should be sent when these deadlines are due and when they are missed. One example is requiring a response to IRB concerns within seventy-two hours, which has been found to reduce the number of days it takes to receive IRB approval.[12]

In order to conserve staff time and resources for clinical trials that are most likely to be successful, it may be helpful to assess the feasibility of protocols prior to proceeding with IRB submission, contract review, and budget approval. Feasibility committee reviews can help determine whether or not a clinical trial should be implemented at the institution. These reviews can include evaluating the patient population to ensure the site has enough patients that can be enrolled in the trial and that the site has the capabilities for any specific imaging or specimen processing requirements.[13] Baer et al. recommend that the feasibility committee should be made aware of how many sites are already up and running and how many patients are available to enroll overall.[14] This will help ensure there will be enough time for the site to go through the contracting and startup process and still have time to enroll enough patients. If a clinical trial cannot enroll enough patients, it may result in not only a loss of potential revenue, but it can cost the institution thousands of dollars.[15]

12. Baer et al., "Clinical Research Site Infrastructure and Efficiency," 251.
13. Ibid.
14. Ibid.
15. Allison Baer, Cary Cohen, Dee Anna Smith, Robin Zon, "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," Journal of Oncology Practice 6, no. 6 (November 2010): 329, accessed February 18, 2018, http://dx.doi.org/10.1200/jop.2010.000156.

2.2 Infrastructure Needs to Support an Increase in Clinical Trials

In addition to exploring the use of a feasibility committee to review protocols prior to implementation, it is important that all faculty and staff participating in clinical trials are properly trained in Good Clinical Practice (GCP) so they better understand the rules and regulations associated with conducting human subjects research.[16] Additional education and training is also recommended and is available through organizations such as the National Council of University Research Administrators (NCURA), Society of Clinical Research Associates (SOCRA), and the Association of Clinical Research Professionals (ACRP).

Zon et al. recommends that an institution strive to maintain a high level of quality in its research programs.[17] They believe one way to achieve this is by implementing a quality assurance program to help identify strengths and weaknesses within any number of research programs. The authors suggest research programs utilize standard operating procedures (SOPs) and require routine review of these procedures.[18] This article also suggests that both physicians and non-physicians should be engaged in research across all disciplines as this will allow the site the opportunity to participate in more clinical trials that will in turn offer more diverse options for its patients.[19]

In addition to offering education, training, and requiring the periodic review of SOPs, AMCs should also provide a unified research support office that offers

16. Baer et al., "Implementing Clinical Trials," 330.

17. Robin Zon, Gary Cohen, Dee Anna Smith, Allison Baer, "Part 2: Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," *Journal of Oncology Practice* 7, no.1 (January 2011): 61, accessed February 18, 2018, http://dx.doi.org/10.1200/jop.2010.000185.

18. Ibid.

19. Ibid., 62.

harmonization of administrative support. The Duke University Office of Clinical Research formed in 2012 to help provide support to researchers and staff throughout the entire spectrum of conducting research by providing personnel to help reduce the administrative burden of investigators and study teams. The unified organizational structure at Duke provides personnel support from the following offices: Clinical Research Finance, Study Startup, Electronic Health Record Build and Support, Research Management Team, Training and Communication, and Outreach and Mentorship. This model has shown to increase efficiencies over time by decreasing the time from institutional approval to enrolling the first participant, increasing the overall number of clinical trials Duke participates in, and increasing the number of patients accrued into their studies.[20]

2.3 Use of Master Clinical Trial Agreements

When seeking to reduce the turnaround time of executing CTAs, institutions should use previous negotiated terms as much as possible to avoid recreating language already approved by the institution.[21] Researchers at the University of California, Biomedical Research, Acceleration, Integration, and Development found using a master CTA reduced the amount of time it took to finalize terms of a CTA by an average of thirty-four days, a forty-seven percent reduction in negotiation time.[22] In addition, industry sponsors with master CTAs took significantly fewer days to finalize terms with

20. Denise Snyder et al., "Retooling institutional support infrastructure for clinical research," *Contemporary Clinical Trials* 48 (May 2016): 139, accessed January 19, 2018, http://dx.doi.org/10.1016/j.cct.2016.04.010.

21. Rijswijk-Trompert.

22. Tam Tran et al., "Collaboration in Action: Measuring and Improving Contracting Performance in the University of California Contracting Network," *Research Management Review* 22, no. 1 (2017): 5, accessed January 19, 2018, https://files.eric.ed.gov/fulltext/EJ1134105.pdf.

their sites: forty-six days compared to seventy-six days for those who did not use master agreements.[23]

2.4. Methods Used in Literature Review for Best Practices

In order to help reduce the administrative burden of conducting industry-sponsored research, the author sought to review literature on how to increase efficiencies in executing CTAs, infrastructure needs to support an increase in clinical trials, and use of master CTAs. The goal of this literature review was to evaluate what other institutions are doing as best practices to provide recommendations to help WFMBC reduce administrative burdens related to industry-sponsored research.

The author used Google as the search engine and PubMed to find manuscripts and conducted searches using the following keywords:

- Research administrative infrastructure at a university
- Best practices within office of sponsored programs
- Use of master agreements for industry-sponsored research
- Attributes of exemplary clinical trial sites
- Increase efficiencies in executing clinical trial agreements

The articles chosen for the literature review section were selected based on their relevance to the research question “What are other institutions doing to improve the industry contracting process?”. These articles also helped the author understand what is being implemented at other institutions in order to provide recommendations on process improvements within OSP and departments to better facilitate industry research contracts.

23. Tran et al., 5.

Chapter 3. Project Description

This chapter provides a description of the capstone project and discusses why the author chose to write about increasing efficiencies in order to reduce the time it takes to start an industry-sponsored clinical trial. The aim of this project was to examine the research administrative infrastructure at WFBMC and provide recommendations on process improvements to support an increase in clinical trials conducted at WFBMC. The author, who leads a large study team at the department-level, is passionate about this topic and regularly interacts with the CTSI to facilitate sponsored projects. This capstone project came at the right time as the author was selected to participate on the Clinical Trials Task Force given her experience at WFBMC, as well as her increased skills and knowledge as a result of participating in the Johns Hopkins Master of Research Administration program.

The task force first implemented the 60-Day Challenge as a means of reducing the time it takes to facilitate a CTA. In addition, the task force wanted to see what else could be done to increase its volume of clinical trials. Since the author had first-hand knowledge of many of the inefficiencies and administrative burdens that prevent some researchers from participating in clinical trials, she wanted to explore what else could be done to help build a research infrastructure capable of handling an increase in industry-sponsored projects. As a result, the author chose to examine data from the 60-Day Challenge, conduct a literature review to explore best practices at other institutions, and interview key leaders within the CTSI. This information contributed to presentations on

recommended best practices for WFBMC leadership to consider, and was the basis for this capstone project.

Chapter 4. Methodology

This chapter discusses the methods used to gather data in order to provide recommendations on how workflows can be improved to build capacity for increasing clinical trials at WFBMC.

4.1 The 60-Day Challenge

Time is of the essence as sponsors and CROs are trying to finalize clinical sites to conduct clinical trials as quickly as possible and sites want the opportunity to enroll as many patients as possible to make sure the study will be fiscally feasible. As noted on the results of the OSP Assessment Survey, the majority of WFBMC faculty and staff were either neutral or dissatisfied with how well the institution minimalizes the administrative burden associated with the submission, review, and approvals of sponsored research.

The contracts office within OSP at WFBMC is tasked with negotiating contract terms and conditions of CTAs with the sponsor or CRO. Study teams have to work with both groups and there are numerous steps in the workflows that can impede the efficiency of the process. The current process at WFBMC is inefficient and causes industry-sponsored clinical trials to take a median of 150 calendar days from receipt of industry-sponsored regulatory documents to trial activation.[24] In an effort to improve the turnaround time of finalizing CTAs, the CTSI leadership implemented a new program in December 2017 called the 60-Day Challenge.

24. Chris O'Byrne, interview with author, Winston Salem, December 8, 2017.

There are two phases of the 60-Day Challenge. Phase I of the Challenge has study teams perform sequential targeted submissions and conducts parallel reviews in place of a process that has traditionally been haphazard with sequential reviews which caused delays at multiple points in the process as shown on top in Figure 1.[25] This workflow includes submitting the project to the IRB, submitting the budget to the OCR for review and approval through WISER, and submitting the draft contract to OSP through InfoEd, all within two weeks of each other so the reviews occur concurrently, as shown at the bottom of Figure 1.

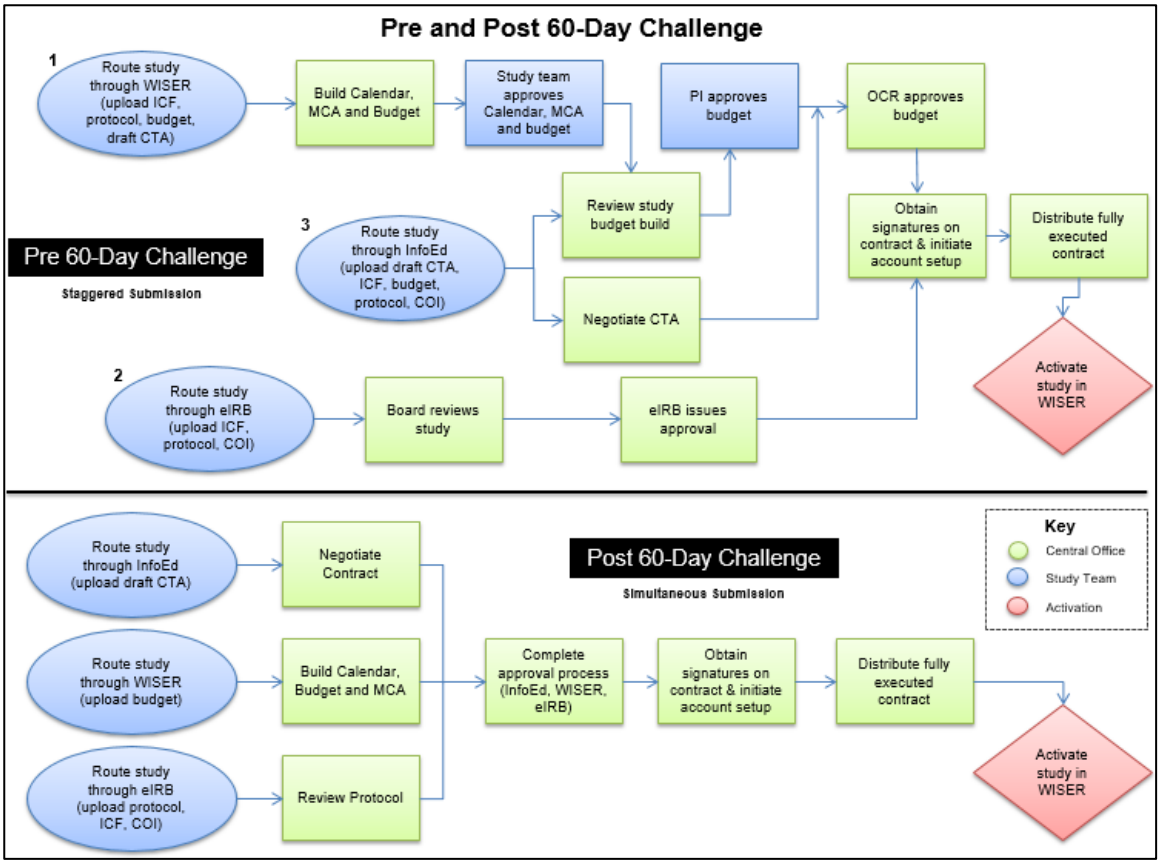

Figure 1. Pre and Post 60-Day Challenge workflows

25. Figure 1 adapted from Selvin Ohene, Director of the Office of Clinical Research, Unpublished 60-Day Challenge presentation slide, Winston Salem, 2017.

Phase II of the Challenge is to have all central office internal reviews and approvals for industry-sponsored clinical trials in sixty calendar days or less, which, if successful, will represent a sixty percent decrease in initiation time. This initiative requires a close partnership between WFBMC PIs, study teams, the OSP, the OCR, and the IRB to eliminate redundancy and improve workflows for trial initiation. The Challenge grew out of concern by CTSI leadership that clinical trials were being delayed, with consequences of fewer trials being initiated at WFBMC, patients not being offered potentially valuable treatments, and missed revenue opportunities. The Challenge aims to reduce the number of days to study activation by removing duplicative processes and creating a model of shared responsibility between departments and the central office.

Communication with the sponsor or CRO is also critical so that they are aware of how fast WFBMC can process the CTA. This quick response from WFBMC is designed to encourage more timely responses from the sponsor or CRO and to let the sponsors or CRO know that WFBMC is ready to enroll participants in the study. Because the Challenge requires a commitment by the department and allocation of additional resources to ensure timely submissions and responses, the Challenge is currently considered optional. Currently six distinct academic units have enrolled in the Challenge, including Neurology, Gerontology, Cardiovascular Medicine, Pulmonary, Anesthesiology, and Obstetrics and Gynecology.[26] This capstone project reviewed the preliminary data from this initiative to see if process improvements already in place are working in order to see if the Challenge should be expanded across the institution. Data

26. Departments participating as of April 13, 2018.

was examined to see if study teams achieved the goal of submitting all required documents within two weeks and to see if the time from receipt of industry-sponsored documents to trial activation had decreased.

4.2 Interviews with Senior Leadership

Data from faculty and staff at WFBMC showed a need for reducing administrative burden and increasing OSP efficiencies.[27] The author wanted to meet with CTSI leadership to get their perspective on how these issues can be addressed. In selecting whom to meet with, the author felt it was important to interview leaders in each of the key units involved in facilitating CTAs. This was done in order to get a better understanding of hindrances that could preclude process improvements. The units interviewed included overall research administration, the OSP, the OCR, and the IRB, all of which are located within the CTSI.

The author first met with the Vice President and Associate Dean for Research Administration and Operations.[28] This position is responsible for the oversight of all research infrastructure programs associated with the CTSI and includes Research Administration (where OSP is housed), Animal Research, Clinical Research (where IRB and OCR are housed), Research Education, Community Engagement, Biomedical Informatics, Technology, and Center and Core Administration. The interview started with the author presenting her capstone project idea to receive feedback on information that could be helpful to the institution and to the Clinical Trials Task Force. One concern the author had was the possibility OSP is inadequately staffed, but was assured staffing levels

27. Data from the Office of Sponsored Programs Assessment Survey shown on page 5.
28. Chris O'Byrne, interview by author, Winston Salem, December 8, 2017.

in the contracts office and the OCR were not the issue. Huron Consulting Group conducted a review of OSP in February of 2017, which showed that, when compared to peer institutions, benchmarks indicate that these areas within OSP are adequately staffed. This suggests that operational inefficiencies were driving the delays in clinical trial activation. This meeting was important for the author to obtain buy-in for the project and to get permission to access data from the OSP Assessment Survey and the 60-Day Challenge.

Since processing CTAs occurs mainly within the contracts office of the OSP, the author also met with the Interim Director of OSP and Associate Director of Contracts.[29] This person leads a team of eight staff and this team ensures CTAs, confidentiality agreements and material transfer agreements are negotiated in accordance with institutional standards and federal requirements. Since this person knows first-hand about the operational workflows involved in negotiating industry CTAs, the author conducted a semi-structured interview to gain insight on the current process improvement initiative, the 60-Day Challenge, and its progress to date. The author also asked questions about the following:

- results from the OSP assessment survey
- known best practices we could implement
- plan to increase the number of master agreements with industry sponsors
- ideas on process improvements in addition to the Challenge

The information gathered during this interview helped formulate the process improvement suggestions presented in the results and recommendations chapters.

29. Robyn Gore, interview by author, Winston Salem, February 16, 2018.

Much of the work done when initiating industry-sponsored clinical trials, outside of negotiating CTAs, is completed within the OCR. This office is led by the Director of the OCR. He serves as a resource for clinical trials and study management, as well as assisting with reviewing clinical trial budgets, entering budgets into WISER, promoting active participant management, and promoting accurate research billing. The author met with the Director of the OCR[30] and asked him questions related to the following:

- insight from previous institutions where he worked that would be valuable to implement or any other known best practices
- thoughts on an expanded OCR that could provide more services and support
- need for a Feasibility Committee
- what else can be done to increase the amount of clinical trials at WFBMC

The information discussed during this interview was used to formulate the process improvement suggestions presented in the results and recommendations chapters.

The WFBMC IRB is responsible for reviewing and approving all human subjects research conducted at the institution. Traditionally, WFBMC prefers to be the IRB of record for industry-sponsored clinical trials and has been reluctant to always allow the use of industry's selection of a central IRB, such as Copernicus, Schulman, or Western, as it takes some of the oversight away from the local WFBMC IRB. The author met with the Director of the IRB[31] and asked if the WFBMC IRB would start accepting the use of central IRBs more for industry-sponsored research since the National Institute of Health (NIH) is now requiring the use of single IRBs for multi-center human subjects research

30. Selvin Ohene, interview by author, Winston Salem, February 28, 2018.
31. Brian Moore, interview by author, Winston Salem, March 23, 2018.

protocols funded by the NIH.[32] The use of a central IRB is often preferred by sponsors or CROs as it helps expedite study-start up as it removes this process from the research site. This discussion is summarized in the results section.

32. "Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research," NIH Policy Notice Number: NOT-OD-16-094, accessed March 24, 2018, https://grants.nih.gov /grants/guide/notice-files/NOT-OD-16-094.html.

Chapter 5. Results

This chapter summarizes the preliminary data from the 60-Day Challenge, as well as the information learned from conducting literature reviews and interviews with senior leadership.

5.1 The 60-Day Challenge

The 60-Day Challenge was implemented in December 2017 with the goal of having all central office internal reviews and approvals for industry-sponsored clinical trials completed in sixty calendar days or less from the receipt of all three required components. This includes: (1) review and approval of the contract information within InfoEd, (2) review of the budget information, Medicare coverage analysis, and calendar build to set up the budget and research billing within WISER, and (3) the regulatory review within the eIRB. Since December, six units have opted in to the challenge including Neurology, Gerontology, Cardiovascular Medicine, Pulmonary, Anesthesiology, and Obstetrics and Gynecology.

To date,[33] a total of eleven projects from the participating units have begun phase I of the Challenge by submitting at least one component into eIRB, WISER, or InfoEd. The goal is to have all three submissions done in parallel.[34] Only one of these projects was been able to submit all three components within the recommended two weeks, with the complete submissions ranging from thirty-seven days to fifty-seven days. Four projects have submitted all three components and entered phase II which starts the

33. As of April 12, 2018.
34. Defined as all three components submitted within two weeks of each other.

official count of the number of days it takes to review and approve the project. Of these four projects, projects 1 and 2 have received full approval within sixty days and projects 3 and 4 are on track to receive full approval within sixty days (see Table 3).

Table 3. 60-Day Challenge data

Projects receiving full approval			
Project	Submission date	Approval date	Days to completion
1	1/23/2018	3/19/2018	55
2	2/6/2018	3/14/2018	36
Projects pending full approval			
Project	Submission date	Anticipated approval date	Days since submission
3	3/4/2018	5/3/2018	42
4	3/13/2018	5/12/2018	33

Of the seven remaining projects that do not have all three components submitted, notes from the system used to track this information indicate that the holdups are with the sponsor and the study team.[35] Once the study teams are able to submit the remaining components, the clock will start allowing these seven projects to begin phase II of the 60-Day Challenge.

5.2 Literature Review for Best Practices

A literature review was done to help provide insight on what other institutions are doing to see what information could help increase efficiencies in getting clinical trials initiated faster to help address research questions 1-3. A reoccurring theme throughout the literature review recommends that institutions use contract templates and previously

35. Results emailed from Robyn Gore included dates and notes in an excel file.

negotiated language as much as possible,[36] including the use of master agreements[37] as this can significantly reduce the time it takes to negotiate a CTA, thereby allowing the clinical trial to start-up quickly. This information is helpful as developing master agreements is a considerable amount of work, but data from Tran et al. show master agreements can be an excellent way of reducing the time it takes to finalize a CTA.[38]

The literature also suggests establishing processes that include a parallel submission and review of all items needed in order to execute an industry contract, including IRB reviews, budget negotiations, finance office approval, and management of conflicts of interest. This can decrease the time it takes to activate a clinical trial.[39] In addition, all parties involved should understand their role and be able to clearly define their duties as it relates to submitting and reviewing CTA documents.[40] Baer et al. also suggest having internal deadlines so all parties are aware of when documents or responses to concerns are due to avoid delays due to lack of timeliness.[41] The goal is to prevent avoidable delays so all components of the CTA can be reviewed and approved as soon as possible. In addition to everyone knowing their roles, staff should also have the proper education, training, and support to conduct their job.[42] The information learned from these articles suggest best practices that could be implemented at WFBMC to help facilitate CTA and reduce the time it takes to receive all necessary approvals.

36. Rijswijk-Trompert.
37. Tran et al., 5.
38. Ibid.
39. Baer et al., "Site Infrastructure and Efficiency," 251.
40. Ibid.
41. Ibid.
42. Baer et al., "Implementing Clinical Trials," 329.

Baer et al. suggest institutions who field a significant amount of clinical trials that either never enroll a patient or lose money should create a Feasibility Committee.[43] A Feasibility Committee would assess all potential clinical trials prior to starting contract and budget negotiations and the IRB submission to ensure the project is viable given the patient population and the timeframe left to enroll new patients. While creating a Feasibility Committee may save resources in the long run, it would also take a lot of resources to facilitate and should be further examined to see if the study team can evaluate a study's feasibility without having to involve a committee that may slow down the study start-up process.

The article from Denise Snyder et al. on the reorganization of Duke University's OCR suggests a unified research support office is beneficial to all involved in research as it has been shown to decrease the time it takes to enroll the first patient once a trial has been activated, increase the overall number of the clinical trials, and increase the number of their patients participating in these trials.[44] WFBMC has a unified research support office (the CTSI) and while it offers many of the same resources, there may be opportunities to expand in order to help accommodate an increase in industry-sponsored clinical trials.

5.3 Interviews with Senior Leadership

The author interviewed the following key leaders at WFBMC: the Vice President and Associate Dean, Research Administration and Operations; the Interim Director of the OSP and Associate Director of Contracts; the Director of the OCR; and the Director of

43. Baer et al., "Implementing Clinical Trials," 329.
44. Snyder et al., 139.

the IRB. These interviews were conducted to seek their buy-in for this project, access data, and determine what ideas they may have to optimize the research administrative infrastructure at WFBMC. During these interviews, all of the interviewees agreed that processes to submit and review documents related to a CTA could be further streamlined and a common theme emerged as everyone agreed there are “too many hands in the pot”.

One suggestion was made to reorganize duties within the contracts office so those who negotiate CTAs with sponsors and CROs focus their time on this function, with other duties, such as negotiating confidentiality agreements and material transfer agreements, being reassigned to others within the contracts office. CTAs are the most critical and if staff were not slowed by other tasks, it might improve the turnaround time for contract negotiations. Another suggestion involved those who prepare the submissions in WISER, InfoEd, and IRB as outlined in Figure 1. The submission of documents and information into these systems is currently the responsibility of departmental staff who have numerous other competing tasks associated with conducting research. A suggestion was made to take this responsibility out of the department and centralize these functions with support from the CTSI. The intent is to promote focused attention on these processes with limited distractions.

When asked about master agreements, the Associate Director of Contracts confirmed the ability to expedite contract negotiations since only an addendum is needed, but stated that even if the contract negotiations are complete, the IRB and WISER submissions can still hold up the process of activating a clinical trial. This could be

eliminated with parallel submissions of these components, as suggested by the 60-Day Challenge.

When asked about the how WFBMC can increase the number of clinical trials it participates in, the Director of the OCR felt the best way was to try and get repeat business from the sponsors and CROs with whom WFBMC already has a relationship. This would help expedite contracts, as much of the contract language would already be negotiated. In order to increase the likelihood of repeat business, he suggested creating a quarterly report card that allows sponsors to determine how well WFBMC is meeting their needs. This would help identify any problems early and maintain open communication between the site and the sponsor, which will allow the sponsor and/or CRO to understand the benefits of choosing WFBMC as a site for future trials.

The Director of the WFBMC IRB acknowledged that sponsors and CROs of most industry-sponsored clinical trials prefer the use of a for-profit central IRB as it helps expedite the study start up by preventing duplicative review and approval of the study protocol, advertisements, informed consent forms, study documents, etc. WFBMC has traditionally been hesitant in allowing the use of a for-profit central IRB and prefers the use of its own local IRB to review and approve industry-sponsored projects as it has more oversight and control. WFBMC IRB board members feel this is important since these projects tend to be clinical trials involving investigational medications or devices and can include more risk than other research projects. The Director of the IRB stated the WFBMC IRB plans to allow the use of a central IRB, like Copernicus, for more projects assuming the central IRB is accredited by the Association for the Accreditation of Human

Research Protection Programs and the study team is experienced and knowledgeable in managing industry-sponsored clinical trials. This change will allow researchers at WFBMC the opportunity to participate in clinical trials they may not have otherwise been able to participate in if the sponsor or CRO would require use of a for-profit central IRB.

Chapter 6. Recommendations and Conclusion

This chapter starts by offering recommendations to WFBMC leadership based on the literature review conducted, interviews with senior leadership, survey responses, and the preliminary data from the 60-Day Challenge. This chapter ends with a summary of the capstone project.

6.1 Recommendations

1. Recommendation: The 60-Day Challenge should continue to allow for parallel submission and review.

Given the limited data, it is difficult to say if the 60-Day Challenge is sustainable due to outside variables, mainly because of delays in sponsor feedback. However, it should continue as there is no harm in having expedited submissions to allow for parallel reviews as recommended by Baer et al.[45] Ideally, as this initiative moves from its current pilot phase, the workflows will become standard practice across the institution so this will no longer be considered a "challenge".

2. Recommendation: When working with a repeat industry sponsor, the institution should use standardized contract language that has been previously reviewed, limiting the administrative and review burden for all parties.

Conducting a search of previously negotiated contracts and finding the most recent or similar contract from the same sponsor will allow for easy implementation of this recommendation. When requesting changes, the contracts office can refer to

45. Baer et al., "Site Infrastructure and Efficiency," 251.

previously negotiated language in hopes the change is accepted without incident. This should help cut down on negotiations and improve turnaround time.

3. Recommendation: The institution should create master agreements with its most frequent industry sponsors.

As shown by Tran et al., master agreements can reduce the time it takes to negotiate a CTA by forty-seven percent.[46] Since contract negotiations often contribute to delays, anything that can be done to decrease CTA negotiation time should be done, especially if WFBMC works with the same sponsor for multiple projects. This is likely to encourage repeat business from the sponsor.

4. Recommendation: All persons involved in clinical research should be required by the institution to take a GCP training course.

Most sponsors require adherence to the principles of GCP in order to comply with Food and Drug Administration regulations regarding the conduct of human subject research. In addition, the NIH enacted a new policy where all NIH-funded investigators and staff should be trained in GCP.[47] Requiring this training will allow WFBMC investigators and staff to be compliant with these regulations and will not slow down the start-up process if someone has yet to complete this training.

46. Tran et al., 5.

47. "Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials," NIH Policy Notice Number: NOT-OD-16-148, accessed March 23, 2018, https://grants.nih.gov /grants/guide/notice-files/not-od-16-148.html.

5. Recommendation: All persons involved in clinical research should be encouraged to join NCURA, SOCRA, ACRP or like organization where they can access important information related to their job and gain professional knowledge.

Faculty and staff who are members of professional organizations are given professional development opportunities that extend beyond those offered at WFBMC. These organizations are a great way for researchers and staff to stay abreast of new rules and regulations, collaborate, and attend regional and national meetings to gain additional knowledge. This is critical when working with federal and industry sponsors and further engages individuals to build a solid foundation for WFBMC's research infrastructure.

6. Recommendation: All staff fielding a CTA should have a checklist, including required timelines for completion, that lays out each step in the process.

Having checklists provides an overview of all items needed to facilitate a CTA and can be helpful for new staff or those who do not process CTA frequently. Checklists that include timeframes can help staff stay on task and ensure nothing is missed so parallel submissions are completed which can help expedite the review and approval of all components related to a CTA.

7. Recommendation: WFBMC should develop SOPs to help study teams assess the feasibility of a new industry-sponsored clinical trial.

With a focus on pace and efficiency, SOPs can be used as an alternative to feasibility committees, which are often viewed as slow and obstructionist. SOPs will determine which studies to expect and outline the resources available within the CTSI,

and items to consider such as the budget, patient population, resources needed, and availability of the study team.

8. Recommendation: Expand services to include more staff who can process new CTAs and IRB submissions.

Since the institution already has a unified research administrative office (the CTSI) and provides many of the same services that Duke's OCR does, the author believes that more staff need to be trained in these areas in order to improve workflows and increase productivity. Based on the literature search and interviews with CTSI leadership, this could help build capacity for an increase in clinical trial activity. Providing additional staff capable of submitting contracts and budgets for review and completing IRB submissions will reduce the administrative burden on study teams, improving their ability to focus on conducting research. This would aid in parallel review and approval of the various components since these staff would not have other competing priorities.

9. Recommendation: Require that contracts staff that process CTAs should only process CTAs.

Those who negotiate CTAs will be able to focus on them and not be burdened by less urgent transactions like confidentiality agreements and material transfer agreements. This allows contracts officers to specialize on specific types of agreements, which is likely to help increase efficiencies and decrease the amount of time each agreement takes to be finalized.

10. Recommendation: Develop a report card that sponsors can use to provide feedback.

Having feedback from sponsors would allow WFBMC to track satisfaction with its services and support. This feedback could be useful in knowing where improvements should be made to improve the quality, time, and efficiency. Addressing any issues that may arise can help ensure sponsor satisfaction and may encourage the sponsor or CRO to engage WFBMC in future projects.

6.2 Conclusion

Process improvements are needed to build a research administrative infrastructure conducive to supporting an increase in CTAs and, in turn, an increase in the volume of clinical trials at WFBMC. The goal of this capstone project was to explore what can be done to improve the industry contracting process at the institutional level in order to streamline processes and provide better support for study teams and offices within the CTSI that process the submission, review, and approval of CTAs. Current improvement initiatives were examined and while the 60-Day Challenge is still relatively new, the streamlined processes and parallel reviews offer study teams who are willing to submit all required documents within two weeks of each other the opportunity to expedite the study start-up of new clinical trials. The author concludes that the Challenge should continue and once more data is available, the CTSI should determine if it is feasible for departments to be required to adhere to the Challenge guidelines to allow for a continued improvement in CTA turnaround times.

In conclusion, the information presented for this capstone project was intended to inform WFBMC of best practices from other institutions that could be implemented to better facilitate CTAs and to reduce the time it takes to activate a new clinical trial. This information along with continuing and expanding the 60-Day Challenge and the recommendations from senior leaders should be considered process improvements worthy of implementation. These recommendations will allow WFBMC to build a research administrative infrastructure that attracts industry sponsors and is capable of processing CTAs in a more timely and efficient way. This will put WFBMC in a position to rapidly open clinical trials to enrollment and give their patients opportunities to participate in clinical trials that they would not likely have access to in other parts of the nation.

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Appendix 1.

Office of Sponsored Programs Assessment

Please take a few minutes to provide feedback to the Office of Sponsored Programs (OSP).

Your responses to this survey, which are anonymous and confidential, will be used to shape our actions and act as a baseline that can be used for future assessments.

Please consider only your experiences in the last 12 months when answering the survey. Please skip or select "Not Applicable" for any questions that do not apply.

The survey should take about 10 minutes and covers the following topics:

Proposal Review and Submission InfoEd

Contract Negotiation

Subaward Negotiation

Account Setup

Award Management

Effort Reporting Award Closeout

Customer Service

General Information

How long have you been doing/involved in research/sponsored activity at WFUHS?

- ◯ 0-1 years
- ◯ 2-4 years
- ◯ 5-10 years
- ◯ 11-20 years
- ◯ greater than 20 years

How long have you been doing/involved in research/sponsored activity anywhere?

- ◯ 0-1 years
- ◯ 2-4 years
- ◯ 5-10 years
- ◯ 11-20 year
- ◯ greater than 20 years

Please describe your role in the research/sponsored activity community. What is your role?

- ◯ Faculty
- ◯ Staff
- ◯ Central Office

What category best describes the focus of your research? Check all that apply.

- ☐ Basic/Animal Science
- ☐ Clinical/Population Science
- ☐ Not Applicable

Which of the following research/sponsored activities are you involved in? Check all that apply.

- ☐ Preaward
- ☐ Postaward
- ☐ Contracts

Proposal Review and Submission

(Please consider only activity in the last 12 months in your responses.)

Indicate how effective OSP is at facilitating the overall proposal review, approval, and submission process.

- ◯ Very Effective
- ◯ Effective
- ◯ Somewhat Effective
- ◯ Ineffective
- ◯ Very Ineffective
- ◯ Not Applicable

In terms of minimizing the investigators Administrative burden, how well does the WFUHS overall proposal review, approval, and submission process meet expectations?

- ◯ Significantly Above Expectations
- ◯ Above Expectations
- ◯ Meets Expectations
- ◯ Below Expectations
- ◯ Significantly Below Expectations
- ◯ Not Applicable

Please rate your overall satisfaction with the changes which have been made to the proposal review, approval, and submission process.

- ◯ Very Satisfied
- ◯ Satisfied
- ◯ Neither Satisfied nor Dissatisfied
- ◯ Dissatisfied
- ◯ Very Dissatisfied
- ◯ Not aware changes had been made.
- ◯ Not Applicable

InfoEd

(Please consider only activity in the last 12 months in your responses.)

What is your overall satisfaction with the product InfoEd?

- ◯ Very Satisfied
- ◯ Satisfied
- ◯ Neither Satisfied nor Dissatisfied
- ◯ Dissatisfied
- ◯ Very Dissatisfied
- ◯ Not Applicable

What is your level of proficiency with the system?

- ◯ Beginner
- ◯ Intermediate
- ◯ Regular User
- ◯ Intermediate Seasonal User
- ◯ Expert
- ◯ Not Applicable

Contract Negotiation (Industry)

(Please consider only activity in the last 12 months in your responses.)

Indicate how effective OSP is at finalizing Industry research contracts in terms of speed/timeliness of execution (not including outgoing subcontracts).

- ◯ Very Effective
- ◯ Effective
- ◯ Somewhat Effective
- ◯ Ineffective
- ◯ Very Ineffective
- ◯ Not Applicable

Indicate how effective OSP is at communicating the status of industry contract negotiations.

- ◯ Very Effective
- ◯ Effective
- ◯ Somewhat Effective
- ◯ Ineffective
- ◯ Very Ineffective
- ◯ Not Applicable

Outgoing Subcontracts

(Please consider only activity in the last 12 months in your responses.)

In your estimation, how long does it take OSP to issue an outgoing agreement to a Subcontractor following receipt of the primary award to WFUHS?	◯	0-10 days
	◯	11-20 days
	◯	21-30 days
	◯	30-60 days
	◯	More than 60 days
	◯	I don't know
	◯	Not Applicable
Indicate how effective OSP is at facilitating the outgoing subcontracting process.	◯	Very Effective
	◯	Effective
	◯	Somewhat Effective
	◯	Ineffective
	◯	Very Ineffective
	◯	I don't know
	◯	Not Applicable
In the last year, we have added the option to be trained and use the Subaward Tool to initiate subawards at the department level. Please rate your overall satisfaction with the changes which have been made to the outgoing subcontract process.	◯	Very Satisfied
	◯	Satisfied
	◯	Neither Satisfied nor Dissatisfied
	◯	Dissatisfied
	◯	Very Dissatisfied
	◯	Not aware changes had been made.
	◯	Not Applicable
Have you used the Subaward Tool to initiate an agreement?	◯	Yes
	◯	No
Has your department used the Subaward Tool to initiate an agreement?	◯	Yes
	◯	No
	◯	I don't know
Do you believe the tool streamlines the outgoing subcontract process?	◯	Yes
	◯	No
Are you/your department interested in using The Tool?	◯	Yes
	◯	No

Account Setup

(Please consider only activity in the last 12 months in your responses.)

In your estimation, how long does it take for a fully executed award (externally funded) to be set up in the financial system (i.e. from the day the award arrives in OSP until the chartfield is ready for spending to occur)?	◯	0-5 days
	◯	6-10 days
	◯	11-15 days
	◯	15-20 days
	◯	More than 20 days
	◯	I don't know
	◯	Not Applicable

Indicate how effective OSP is at facilitating the chartfield setup process for externally sponsored projects.

- ◯ Very Effective
- ◯ Effective
- ◯ Somewhat Effective
- ◯ Ineffective
- ◯ Very Ineffective
- ◯ I don't know
- ◯ Not Applicable

In September 2016, we dedicated a person to the setup process. Please rate your overall satisfaction to the changes which have been made to the award setup process.

- ◯ Very Satisfied
- ◯ Satisfied
- ◯ Neither Satisfied nor Dissatisfied
- ◯ Dissatisfied
- ◯ Very Dissatisfied
- ◯ Not aware changes had been made.
- ◯ Not Applicable

Award Management

(Please consider only activity in the last 12 months in your responses.)

I have the tools that I need to understand the current financial state of my projects (for example access to fund balance report, monthly detailed statements, salary reports).

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

What types of information are you missing? _____

I have received adequate support from my Department administrator necessary to conduct my research/sponsored activity effectively and efficiently.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

Effort Reporting

(Please consider only activity in the last 12 months in your responses.)

I believe it would be most accurate if I reported My effort:

- ◯ Monthly
- ◯ Quarterly
- ◯ Bi-annually
- ◯ Annually
- ◯ Not Applicable

How user-friendly is the WFUHS effort reporting system?

- ◯ Very User-Friendly
- ◯ Moderately User-Friendly
- ◯ Somewhat User-Friendly
- ◯ Not User-Friendly
- ◯ Not At All User-Friendly
- ◯ Not Applicable

How user-friendly is the WFUHS effort reporting process?

- ◯ Very User-Friendly
- ◯ User-Friendly
- ◯ Somewhat User-Friendly
- ◯ Not User-Friendly
- ◯ Not At All User-Friendly
- ◯ Not Applicable

Award Closeout

(Please consider only activity in the last 12 months in your responses.)

OSP has a clear and consistent process for closing externally sponsored awards.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

In my opinion, OSP is very diligent in ensuring the final financial reports/invoices are submitted in a timely fashion.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

In the last year, we have been notifying Departments of upcoming NIH end dates and final report due dates. We have also dedicated a resource focusing on industry closeouts. Please rate your overall satisfaction with the changes made to the award closeout process.

- ◯ Very Satisfied
- ◯ Satisfied
- ◯ Neither Satisfied nor Dissatisfied
- ◯ Dissatisfied
- ◯ Very Dissatisfied
- ◯ I was not aware changes had been made.
- ◯ Not Applicable

Please answer the following questions regarding your experience with the Preaward Office in the past 12 months.

The individuals within the OSP Preaward Office have the right level of expertise and knowledge To perform their job duties and answer my questions.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

The OSP Preaward Office team members display a strong customer service attitude to my email and/or phone inquiries.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

Please rate your overall satisfaction with the response time of the OSP Preaward Office to your questions, emails and/or phone inquiries.

- ◯ Very Satisfied
- ◯ Satisfied
- ◯ Neither Satisfied nor Dissatisfied
- ◯ Dissatisfied
- ◯ Very Dissatisfied
- ◯ Not Applicable

Please answer the following questions regarding your experience with the Postaward Office in the past 12 months.

The individuals within the OSP Postaward Office have the right level of expertise and knowledge to perform their job duties and answer my questions.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

The OSP Postaward Office team members display a strong customer service attitude to my email and/or phone inquiries.

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

Please rate your overall satisfaction with the response time of the OSP Postaward Office.

- ◯ Very Satisfied
- ◯ Satisfied
- ◯ Neither Satisfied nor Dissatisfied
- ◯ Dissatisfied
- ◯ Very Dissatisfied
- ◯ Not Applicable

Please answer the following questions regarding your experience with the Contracts Office in the past 12 months.

The individuals within the OSP Contracts Have the right level of expertise and knowledge to perform their job duties and answer my questions.

- ◯ Strongly Agree Office
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Disagree
- ◯ Strongly Disagree
- ◯ Not Applicable

The OSP Contracts Office team members display a strong customer service attitude to my email and/or phone inquiries.	○	Strongly Agree
	○	Agree
	○	Neither Agree nor Disagree
	○	Disagree
	○	Strongly Disagree
	○	Not Applicable
Please rate your overall satisfaction with the response time of the OSP Contracts Office to your questions, emails and/or phone inquiries.	○	Very Satisfied
	○	Satisfied
	○	Neither Satisfied nor Dissatisfied
	○	Dissatisfied
	○	Very Dissatisfied
	○	Not Applicable

General Questions

Would you prefer to be copied on all email correspondence, rather than just your departmental administrator?	○	Yes
	○	No
Are you aware of the following OSP training program opportunities? Please select all that you are familiar with.	☐	Research Administration Certificate
	☐	RA Sessions
	☐	Periodic Webinars
	☐	InfoEd Training
	☐	Subaward Tool Training
How effective were the OSP trainings that you attended?	○	Very Effective
	○	Effective
	○	Somewhat Effective
	○	Ineffective
	○	Very Ineffective
	○	Not Applicable

Please provide any comments (strengths, weaknesses, opportunities) that were not covered in the survey.

Biography

Kimberly Kennedy was born in Honolulu Hawaii on August 20, 1979 and moved to North Carolina as a baby. She graduated from the University of North Carolina at Wilmington in 2001 and pursued a career in research at Wake Forest Baptist Medical Center. She has worked in the Department of Internal Medicine, Section on Gerontology and Geriatric Medicine since 2002 and is currently a Senior Clinical Research Manager. Mrs. Kennedy leads a large research team who works primarily on investigator-initiated research funded by the National Institutes of Health. Her duties include assisting with grant submissions, preparing regulatory documents for IRB review and approval, and managing a large team of project managers and clinical studies coordinators.