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A survey of clinical research education and perceptions among research staff within an urban hospital setting

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A Survey of Clinical Research Education and Perceptions Among Research Staff Within an Urban Hospital Setting

by

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Acknowledgments

I would like to dedicate this thesis to my friends and family that have supported and believed in me. I also dedicate my thesis to all the small-town dreamers who are on their journey to obtaining higher education. Your dreams are never too big or small to accomplish no matter how arduous the journey may be, keep climbing. A special thank you to Dr. Ding Wang, a member of my thesis committee who has always offered me support and guidance. I would like to acknowledge Grigoris Argeros as a resource provided by the Office of Graduate Studies and Research from Eastern Michigan University for help with my statistical analysis. Additionally, I would like to thank my professor and thesis committee Chair, Dr. Rowan, for all her support and guidance through the generation of this thesis. I am also grateful to the research professionals that took their time to participate in my survey and provide meaningful feedback in support of this thesis.

Abstract

Health centers are uniquely positioned to address the growing need for uniform clinical research training, which leads to scientific advances in improving overall population health outcomes. This study surveyed 44 clinical research professionals for their current baseline of research competency and perceptions, within a single medical campus in Michigan, to obtain the current baseline of education research competency for the suggested development and implementation of a future clinical research training curriculum. Clinical study coordinators and senior staff physicians accounted for 50% (22) of the survey respondents. Most of the participants 93% (41) reported that the primary source of their research education was from on-the-job training. A significant correlation was found between the self-reported level of understanding good clinical practice (GCP) and the number of clinical trials supported. A larger sample size is warranted to evaluate the impact of a formal research training program for clinical research professionals.

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Introduction

Clinical research education competency is integral to conducting clinical research that yields high-quality results. Medical practice and clinical research function in unison to drive therapeutic advances in treating medical conditions and delivering tomorrow's therapeutic breakthroughs. However, clinical research involves the use of investigational products that are not approved by the U.S. Food and Drug Administration and require researchers to follow a clinical investigational plan while complying with federal regulations and human subject protection laws. Commonly, research medical ethics training, such as good clinical practice (GCP) certification or human subject's protection training are heavily relied on at research institutions to encompass formal research training. Saleh et al. (2020) elaborate, "current GCP training for investigators often uses a 'one-size-fits all' approach and lacks the practical and pragmatic skills required to conduct clinical trials" (p.2). Clinical research coordinators typically receive on-the-job training and learn as they go through trial and error to become proficient in clinical research objectives (Behar- Horstein et al., 2018). In addition, these professionals assume critical responsibilities central to the success of research team according to Behar- Horstein et al. (2018). They go on to say, "the complexity of the research coordinator role requires essential professional qualifications. One barrier to professionalization, however, has been inconsistent, or absent, competency-based training" (p.2).

Sonstein and Jones (2018) state that the onboarding training of clinical research coordinators is very minimal and poorly organized overall. They acknowledge most research coordinators become skilled within their research role over time by gaining experience. Furthermore, the responsibilities of their roles are in a dynamic state of change with increasing technological or quality demands they add. Similarly, Sonstein and Jones (2018) note that as new career opportunities

arise clinical research professionals find themselves moving from the direction of proficient to novice repeatedly. As clinical research designs continue to increase in complexity, so does the support role of research professionals. However, Sonstein and Jones (2018) say that the lack of professional requirements and solid foundation of research education knowledge can lead to role dissatisfaction and personnel turnover as a costly by-product at health centers and impact the overall progress of ongoing clinical research investigations.

The need for formalized clinical research guidance and the development of tools to ascertain skills and competence is not limited to research coordinators. Physicians also struggle with obtaining experience to proficiently lead as a principal investigator (PI), who oversees the conduct of an entire clinical research protocol or participating as a sub-investigator and understanding the requirements that are needed for clinical research care vs. standard medical care for research patients (Saleh et al., 2020).

Residents and fellows are typically introduced to clinical research through direct mentorships with senior staff physicians. A clinical research training perspective from medical residents and fellows is warranted. Brubaker and Kenton (2011) state, and there is a research education requirement for most programs. They go on to say for their residency program in obstetrics and gynecology, many residents struggle with barriers to obtain effective clinical research exposure. According to Brubaker and Kenton (2011), barriers to clinical research include time conflicts for senior staff physicians, lack of desire to explore clinical research from residents, financial restrictions, and lack of relevant outcome measures. In addition, they say a common problem within research education is that residents are taught in a team format, leaving residents to work on their own projects, such as retrospective chart reviews or to collaboratively work on an existing project that is nearing completion. As a result, Brubaker

and Kenton (2011) say that by joining an existing team, the residents are not privy to the formulation of establishing a formal research hypothesis and study design. They go on to say that this may put residents at a future disadvantage for participating in clinical research or possibly provide a negative connotation with clinical research that may lead the residents not to participate in clinical research as a future clinician. Further development of formalized research education for residents and fellows may be beneficial for improved research participation and to have adequate knowledge on how to conduct future clinical research trials on his or her own.

Clinicians who have graduated from a fellowship program, may continue to obtain additional education within research through an MD-Ph.D. program, which train physician-scientists in the career field of clinical care and research, but a decreasing number of physicians are staying engaged in clinical research according to Sebastian et al. (2019). Mahmud et al. (2018) further elaborate, “Physicians are a key human resource in conducting clinical trials” (p.120). They go on to state, the engagement of physicians is paramount to ensuring the successful conduct, quality of data collected, and completion of clinical trials.

Sebastian et al. (2019) and Mahmud et al. (2018) both identified common challenges that physicians report in participating in clinical research, such as administrative burden of regulatory paperwork, administering complex informed consent discussions, and securing protected research time aside from their clinic schedule. Sebastian et al. (2019) suggest assessment tools that measure self-efficacy within clinical research competencies may be useful to evaluate the impact of research training programs to promote the development of clinical research skills in future and current physicians who focus and participate in clinical research.

Background

Refining existing training programs and developing new education and training opportunities are essential for the continued success and invigoration of the current clinical research work force according to Hornung et al. (2018). As evidenced by the guidance set forth by the World Medical Association (2018) in the 2013 revision of the Declaration of Helsinki, they go on to state, "Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training, and qualifications" (p.2). An additional element to clinical research competency Hornung et al. (2018) mention is the increasing complexity of clinical trial designs that are conducted in a real-world clinical environment often with non-clinical research staff and with physicians that may lack formal training in clinical research procedures.

As Hornung et al. (2019) elaborate, there is a critical need for tools to assess the quality of established clinical research education programs that prepare individuals to enter the clinical research profession and to measure continuing educational needs as clinical research professionals' careers evolve. However, until more recently, there was not an established consensus within the clinical research industry for an agreed upon core competency skillset in which, training requirements and continuing education for entry level candidates and seasoned professionals would be based. Sonstein and Jones (2018) state during the spring of 2013, the Joint Task Force (JTF) for Clinical Trial Competency and Clinical Research Professional Workforce Development was formed through the collaboration of key opinion leaders in the pharmaceutical industry, contract research organizations, academic institutions, clinical research sites, and clinical research professional organizations.

The JTF framework was developed to encompass a single global a set of professional standards to serve as framework to define 51 professional core competences for clinical research professionals (Sonstein & Jones 2018). There are eight domains within the JTF framework: "1.) scientific concepts and research design; 2.) ethical and participant safety considerations; 3.) medicines development and regulation; 4.) Clinical Trials Operations (GCPs); 5.) study and site management; 6.) data management and informatics; 7.) leadership and professionalism; 8.) communication and teamwork" (Hornung et al., 2018, p.47). According to Hornung et al. (2018), that in 2015, the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health expanded upon the JTF core competencies introducing Enhancing Clinical Research Professionals Training and Qualification (ECRPTQ). Behar-Horstein et al. (2018) remark that the goal of the ECRPTQ was to implement a standardized training process for translational clinical research leading to the advancement of training and qualification strategies that could be applied across research institutions in the setting of academic health centers in substitution of on-the-job training only.

Currently, about 40% of investigators are dropping out of clinical trial responsibilities while the number of clinical research investigators in North America are decreasing compared to the number of investigators in Europe (Saleh et al., 2020). As a result, Saleh et al. (2020) theorize that clinical research trials are being led by less investigators, which has the potential to impact the overall compliance and integrity of clinical trial outcomes. In addition, they found that failure to follow the clinical investigational plan was found to be the most common FDA audit deficiency in 51% of inspections in clinical trials from 2004 to 2011. To address the shortcomings of current investigator clinical research training, they developed a course for hands-on training called the Clinical Investigator Program (CITP). Moreover, Saleh et al. (2020) developed the CITP with the

hypothesis that, in order to increase quality and quantity of clinical research investigators it is essential to train junior faculty by providing clinical research education instruction to motivate them to become responsible investigators.

The curriculum of the CITP took the eight domains of clinical research competency created by the JTF into account for development of their clinical research training program for senior fellows and new junior faculty physicians (Saleh et al., 2020). As evidenced by the experience gained from clinical residency and fellowship training, a similar set-up was proposed for clinical research education through the mentorship of pairing of experienced physicians with new research investigators to gain insight into practical applications they mention.

According to Saleh et al. (2020), the CITP had the following goals: (a) to provide a general overview of the rationale of clinical research protocols and responsibilities of the PI, (b) introduce the concepts of the site activation process for clinical trials and clinical trial management, and (c) enlighten investigators to existing institutional support or research and mechanisms to benchmark the timeline of opening a clinical research trial. A pre-test and post-test were administered to participants to measure knowledge gained from the 2-month course. Positive feedback was generated from the CITP program; however, Saleh et al. (2020) convey there remains an unmet need for addressing practical aspects of clinical research education without prolonged time commitment away from physicians' clinical schedules to sufficiently prepare investigators for the role of a PI.

Purpose of the Study

This study aims to investigate emerging research professional education needs within an urban Michigan hospital by surveying research staff members regarding their current competency and perceptions of research education. The research questions were as follows:

Research Question 1: Does the self-reported knowledge of GCPs increase with the number of clinical research trials supported by clinical research staff?

Research Question 2: Is there a significant difference in the understanding of the necessary operational steps of clinical research when comparing the education level of clinical researchers with associate degrees vs. master's and doctoral degrees?

Methods

A survey was developed to determine the current research education needs at the urban hospital with input from senior staff physicians, coworkers, and an experienced advisor at Eastern Michigan University (EMU). The survey consisted of 22 questions. Furthermore, the questions were grouped into the domains of demographics, basic research experience, and self-perceived assessments of clinical research knowledge. A small group of colleagues volunteered to pilot test the survey as part of the survey development process to ensure the questions were clear and could be answered through the web based online survey platform SurveyMonkey. The experienced advisor and student researcher ensured that all items on the EMU survey development checklist were satisfied prior to distributing the survey to the participants.

The survey sample size of 50 respondents was approved by the institutional review board at the urban hospital under the Thesis Committee Member Ding Wang, MD, PhD, and the graduate student as a co-investigator (Appendices A and B). The health system approval letter has been de-identified to protect the confidentiality of the institution. The survey then was submitted along with the graduate school survey development checklist (Appendix C) and approved by the University Human Subjects Review Committee at EMU (Appendix D). The research was classified as exempted under research category 2(*i*) as anonymous survey research in which, no direct identifiers and no indirect identifiers, such as IP address were collected to ensure the identity of the survey participants could not be ascertained. The study was designed to evaluate the perception of current research education knowledge among research staff within an urban hospital setting.

After obtaining both human ethics committee approvals for this study, permission to use an internal email distribution listserv that represented the population was granted. The survey was distributed through Survey Monkey and emailed to clinical research staff members in

December 2020. To participate in this study, participants had to agree to the study terms listed in the de-identified informed consent script (Appendix E) by clicking “I agree” if participants did not agree to participate in the survey, a program algorithm was applied after a participant selected “I do not agree” to direct participants to a survey exit page.

Data Analysis

Data collected from the survey was downloaded from Survey Monkey into an Excel spreadsheet format. Questions of interest were uploaded to Statistical Package for Social Sciences (SPSS) Premium v27 and categorized into nominal data. Responses from select survey questions were grouped for correlative data analysis. The alpha level used for all tests of significance was $\alpha = 0.01$. Pearson’s two-tailed correlations were explored to determine if there was a relationship between the variables.

Results

The survey conducted included an analysis of 44 individuals that agreed to participate. The response rate of the survey was 88%. All 50 participants selected “I agree to participate”, but six did not continue to complete the rest survey questions for unknown reasons. According to this survey, 28 (63.6%) of the participants were female and 16 (36.4%) were males. Current job titles at the health system were reported as the following: 11 (25%) were senior staff physicians, 11 (25%) were clinical study coordinators, 7 (15.9%) clinical research nurses, 7 (15.9%), 4 (9.1%) research grant/contract specialists, 2 (4.6%) research managers, 1 (2.3%) fellow physician, and 1 (2.3%) research assistant. The most frequently reported highest degree level completed by the participants was a bachelor’s degree 15 (34.1%) followed by second highest reported degree level of a doctoral degree in medicine 11 (25%). Detailed results of the population demographics are presented in Table 1.

Table 1

Demographic Characteristics of Survey Participants

Gender	**Females** **Males**	*n* = 28 (63.6%) *n*= 16 (36.4%)
Current Job Title	**Senior staff physician** **Fellow physician** **Nurse manager** **Research manager** **Clinical research nurse** **Clinical study coordinator** **Research assistant** **Research grant/contract specialist** **Other:** **Data manager** **Physician assistant** **Medical lab assistant** **Nurse practitioner** **Clinical pharmacy specialist** **IRB/regulatory coordinator** **Medical office coordinator/Fibroscan**	*n* = 11 (25%) *n* = 1 (2.3%) *n* = 0 *n* = 2 (4.6%) *n* = 7 (15.9%) *n* = 11 (25%) *n* = 1 (2.3%) *n* = 4 (9.1%) *n* = 7 (15.9%) *n* = 1 *n* = 1 n = 1 n = 1 n = 1 *n* = 1 *n* = 1
Highest Degree Level Completed	**Associate's degree** **Bachelor's degree** **Master's degree** **Doctoral degree (MD)** **Doctoral degree (PhD)** **Doctoral degree (MD, PhD)** **Other:** **Medical assistant** **Doctor of Pharmacy (Pharm D)**	*n* = 4 (9.1%) *n* = 1 (34.1%) *n* = 9 (20.5) *n* = 11 (25%) *n* = 2 (4.6%) *n* = 1 (2.3%) *n* = 2 (4.5%) *n* = 1 *n* = 1

Of the 44 participants who responded to the question, 14 (31.8%) reported spending between 31 and 40 hours a week on average participating in clinical research. Likewise, 12 (27.3%) participants reported spending 41 hours or more per week supporting clinical research trials. If applicable to their job position, survey participants were asked how many clinical trials total did they enroll patients on within the last year: 8 (18.2%) of participants reported enrolling 15 or more patients on a clinical trial within the last year, and 18 (40.9%) reported it was not applicable to their clinical research role. A detailed summary of the additional survey responses to these questions are presented in Table 2.

Table 2

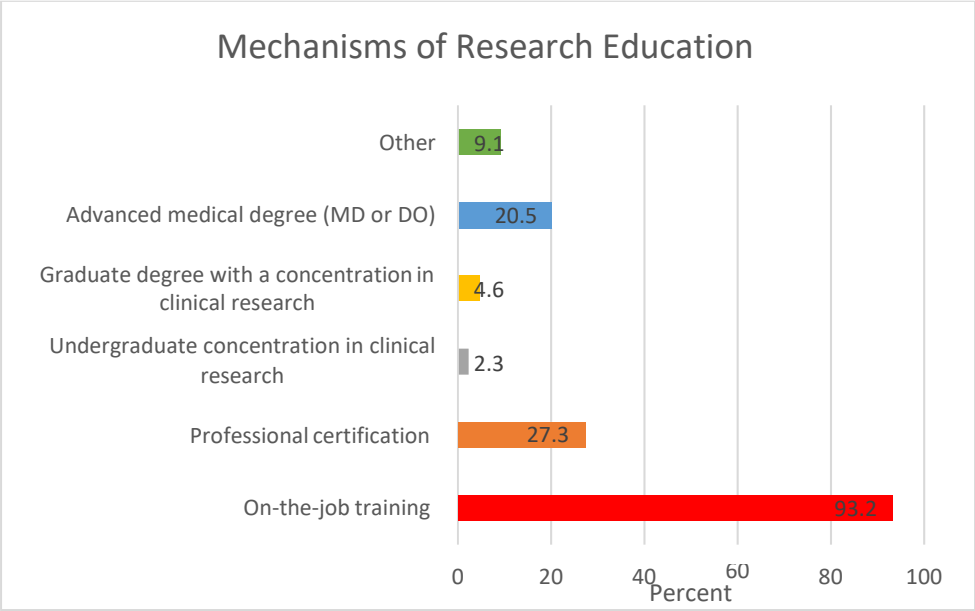
Survey Respondents Clinical Trial Participation

Average hours per week spent participating in clinical research	**1-10** **11-20** **21-30** **31-40** **41 or more**	*n* = 8 (18.2%) *n* = 6 (13.6%) *n* = 4 (9.1%) *n* = 14 (31.8%) *n* = 12 (27.3%)
Number of clinical trials supported	**Less than 5** **1-10** **11-20** **21-30** **31 or more**	*n* = 9 (18.2%) *n* = 5 (11.4%) *n* = 11 (25%) *n* = 4 (9.1%) *n* = 16 (36.4%)
Number of patients enrolled within the last year	**1-4** **5-9** **10-14** **15 or more** **Not applicable to my role**	*n* = 7 (15.9%) *n* = 7 (15.9%) *n* = 4 (9.1%) *n* = 8 (18.2%) *n* = 18 (40.9%)

Figure 1 details how survey participants obtained their current knowledge of research education. The majority of the survey respondents 93.2% (41) reported that they obtained their current knowledge of research education through on-the-job training (job shadowing, protocol specific training by research sponsors), or Collaborative Institutional Training Initiative (CITI) (GCP) training. An additional 27.3% (12) participants obtained their current clinical research education through professional certification, specifically Certified Clinical Research Professional (CCRP) or Association of Clinical Research Professionals (ACRP). Additional mechanisms of obtaining current clinical research education included an advanced medical degree (MD or DO) 20.5% (9), a graduate degree with a concentration in clinical research 4.6% (2), and 2.3% (1) held an undergraduate degree with a concentration in clinical research. Other options for obtaining current knowledge of clinical research education were selected by 9.1% (4) of the respondents and can be found in Appendix F.

Figure 1

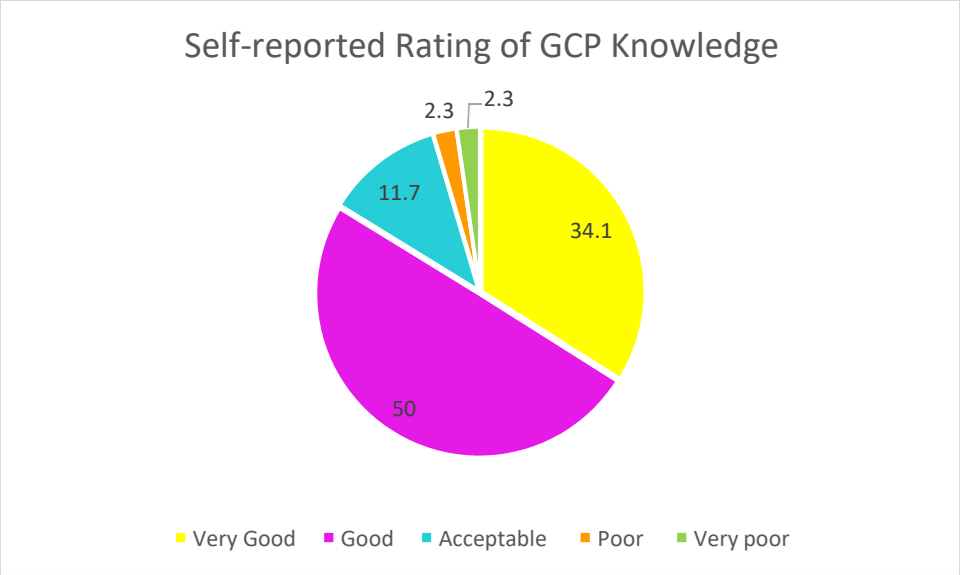
Self-reported Mechanisms for Obtaining Clinical Research Knowledge



Survey respondents were asked to rate their current knowledge of GCP. According to the World Health Organization (2002) International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, GCP is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials and serves to protect the rights, integrity, and confidentiality of human subjects. The survey found that 95% of the participants reported having an acceptable or better knowledge of GCPs. Specifically, 50% (22) of participants stated they had a "good" knowledge of GCPs, 34% (15) reported that they had a "very good" understanding, and 11.4% (5) said their knowledge was acceptable (Figure 2).

Figure 2

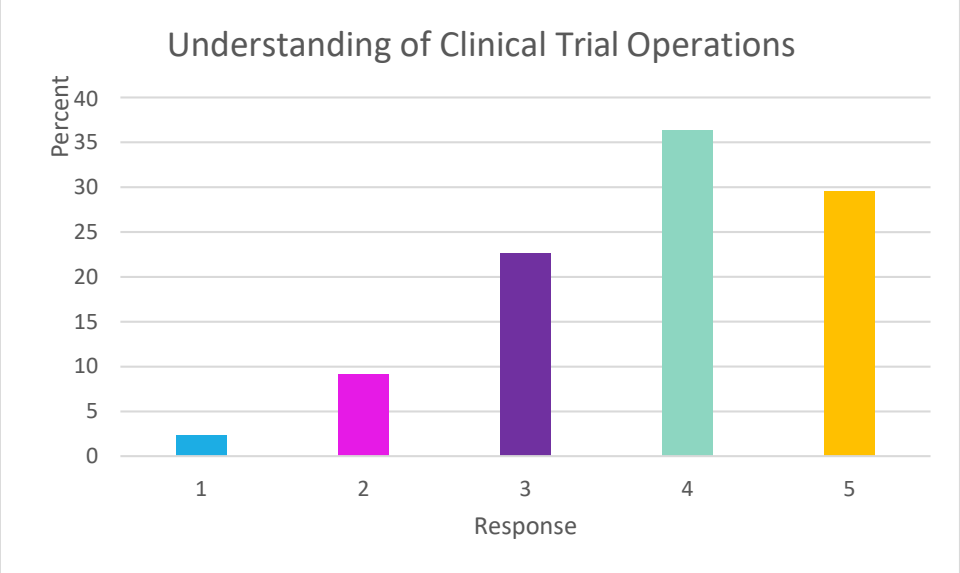
Participants Self-reported Knowledge of GCPs



Participants were asked to rate their current understanding of all the necessary steps that are required to be executed prior to opening a clinical research trial to patient enrollment (i.e., site selection, institutional review board (IRB) approval, finalized contact and budget, and site initiation visit). They were instructed to choose the option that best represented their knowledge on a scale from 1 = *very poor* to 5 = *very good*. Most participants (66.3%) rated their current understanding of clinical trial operations as being "good" or "very good" (Figure 3).

Figure 3

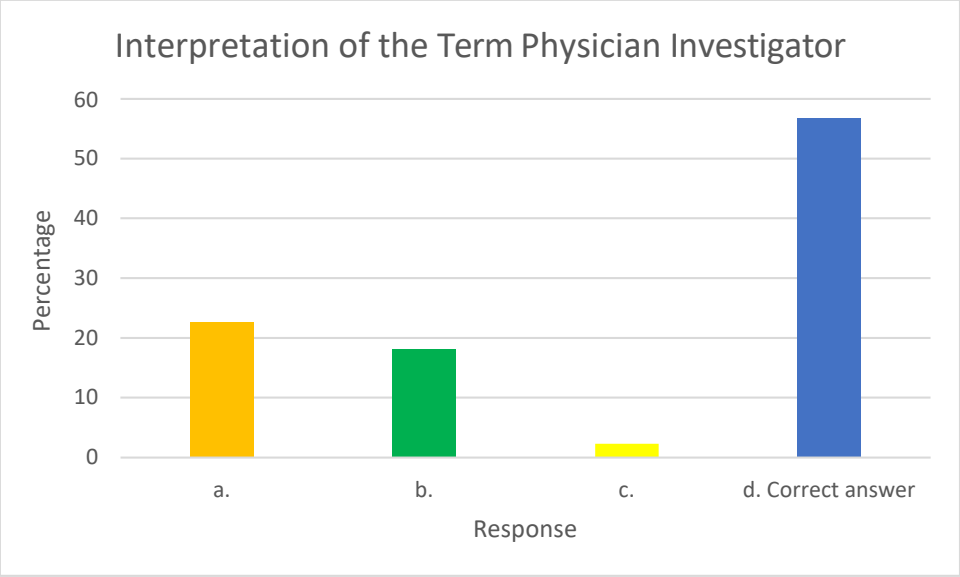
Survey Participant's Reported Understanding of Clinical Research Operations



The survey question "in your opinion, what is your interpretation of the term 'physician investigator' in which, a physician writes a protocol and conducts his or her own clinical research investigation?" was included as a comprehension question to see if respondents were aware of the correct U.S. Food and Drug Administration (FDA) definition. Over half of the of the participants 56.8% (25) selected the correct response (Option d. an individual who both initiates an investigation, and under whose direct supervision an investigational product is dispensed). The additional options for the question (Figure 4) included (a) writing a clinical trial protocol and designating research responsibilities as appropriate to clinical and administrative staff, (b) receiving U.S. Food and Drug Administration (FDA) or institutional review board (IRB) approval of a research protocol along with obtaining funding to execute the clinical research investigation, or (c) overseeing a clinical investigation that is financed by pharmaceutical company support.

Figure 4

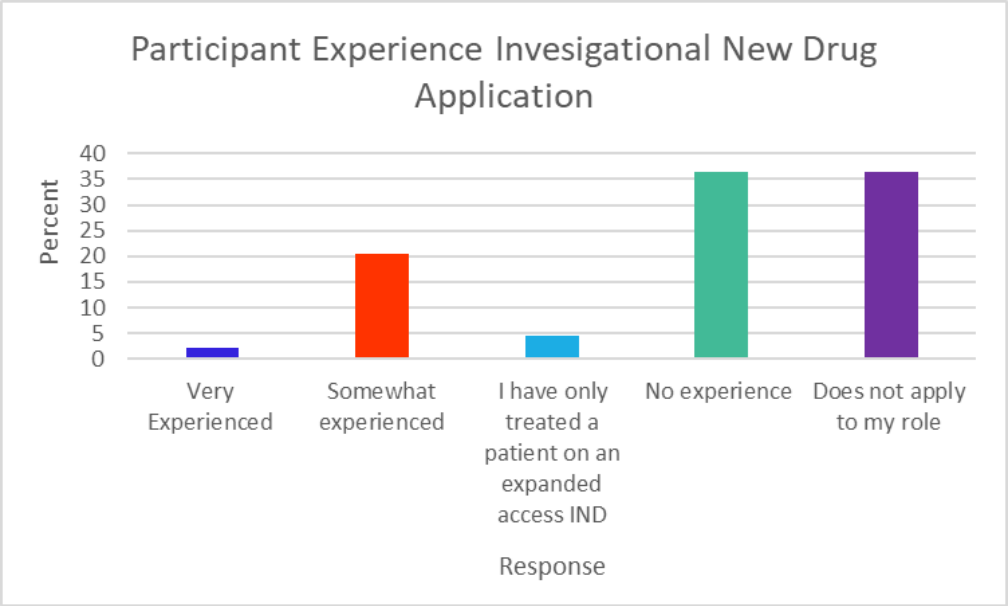
Reported Self-Reported Interpretation of the Term "Physician Investigator"



Participants were asked about their experience with the FDA Investigational New Drug (IND) application process. Most of the participants >75% reported they had no knowledge of the IND application process or that the process does not apply to their research role. Only 20.5% (9) of the participants reported being somewhat experienced from obtaining IND approval for one prior clinical trial (Figure 5).

Figure 5

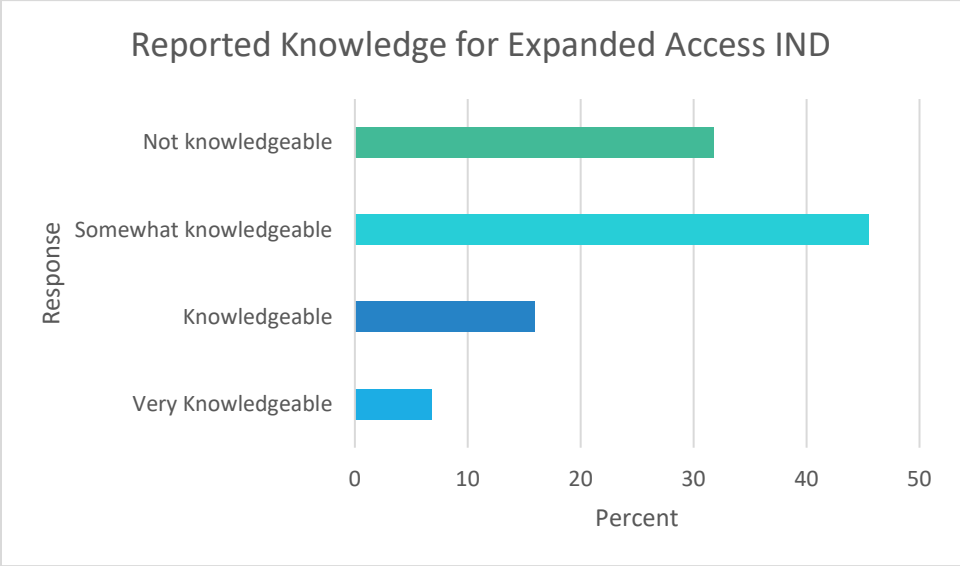
Reported Experience with the FDA IND Application Process



In addition, participants were asked to self-report how knowledgeable they considered themselves about the FDA's expanded access program. According to the U.S. FDA (2020) expanded access is a program in which, an IND is granted by the FDA as a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. More than half of the participants 60% (27) self-reported that they were "knowledgeable" or "somewhat knowledgeable" about the expanded IND access program while 31.8% (14) of respondent's reported that they did not consider themselves knowledgeable (Figure 6).

Figure 6

Participants-Reported Knowledge About the Expanded Access IND Process

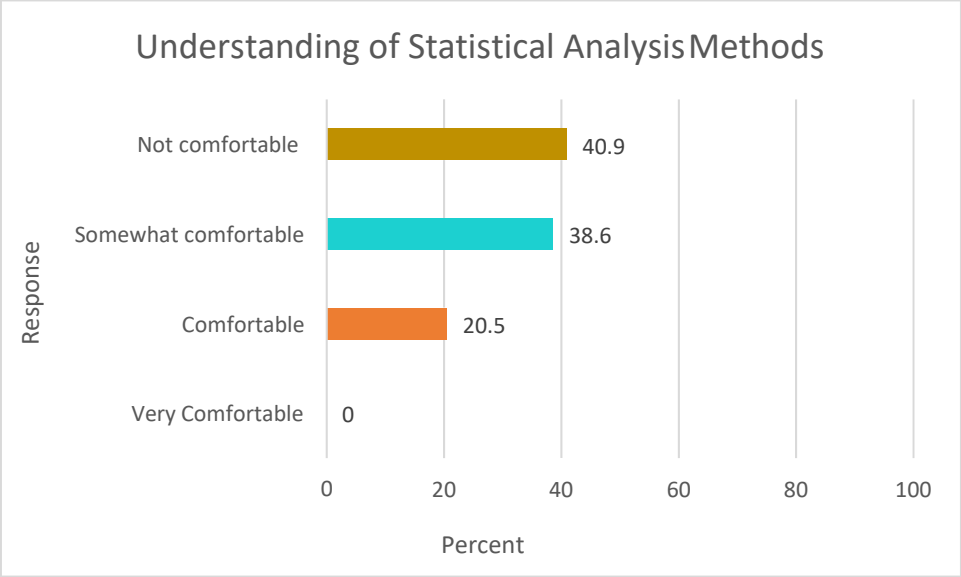


If applicable to their clinical research role, participants were asked if they had been previously granted approval for an expanded access IND, and if so, they were asked how many IND's total. A limited number of survey participants 15 (2.9%) responded that this question was applicable to his or her research role and they had received at least one approval for an expanded access IND. All survey responses to this question can be viewed in Appendix G.

Survey participants were asked to self-report how comfortable they felt regarding their knowledge of understanding of statistical methods, for clinical research design and analysis. The respondents 40.9% (18) reported they did not feel comfortable with their current understanding of statistical analysis methods and 38.6% (17) self-reported they were somewhat comfortable. Only 20.5% (9) of participants reported they were comfortable with their current understanding of statistical methods. None of the survey participants reported that they were very comfortable with their current level of understanding (Figure 7).

Figure 7

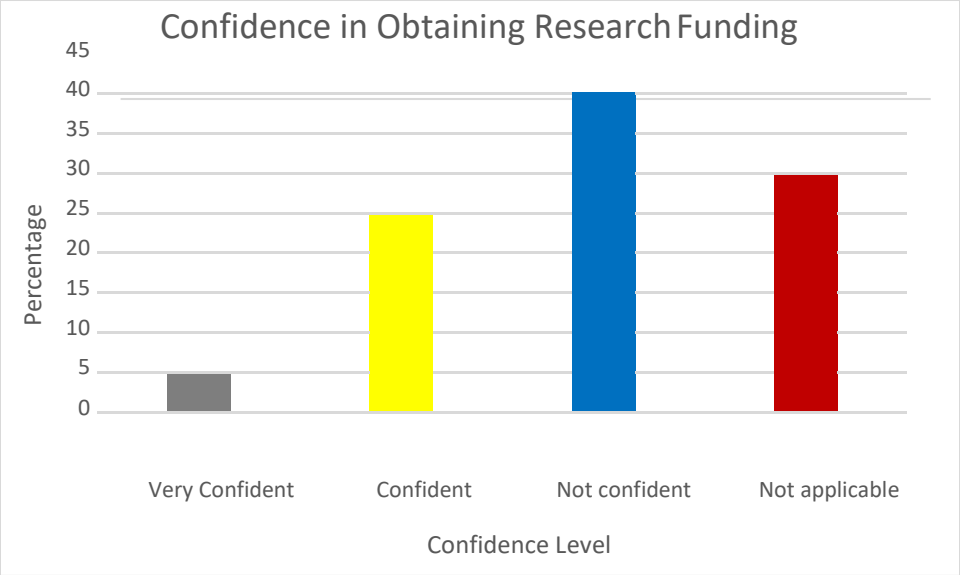
Participants Self-Reported Comfort Level for Understanding Statistical Analysis



Similarly, when participants were asked to self-report how confident they felt about their current understanding of resources to obtain clinical research funding if applicable to their research position, 40.9% (18) of the participants reported that they were not confident in their current understanding. Methods for obtaining research funding was not applicable to 29.6% (13) of the respondents. Only 4.6% (2) of the participants self-reported they were very confident in their understanding of research funding mechanisms and 25% (11) that rated themselves as confident (Figure 8).

Figure 8

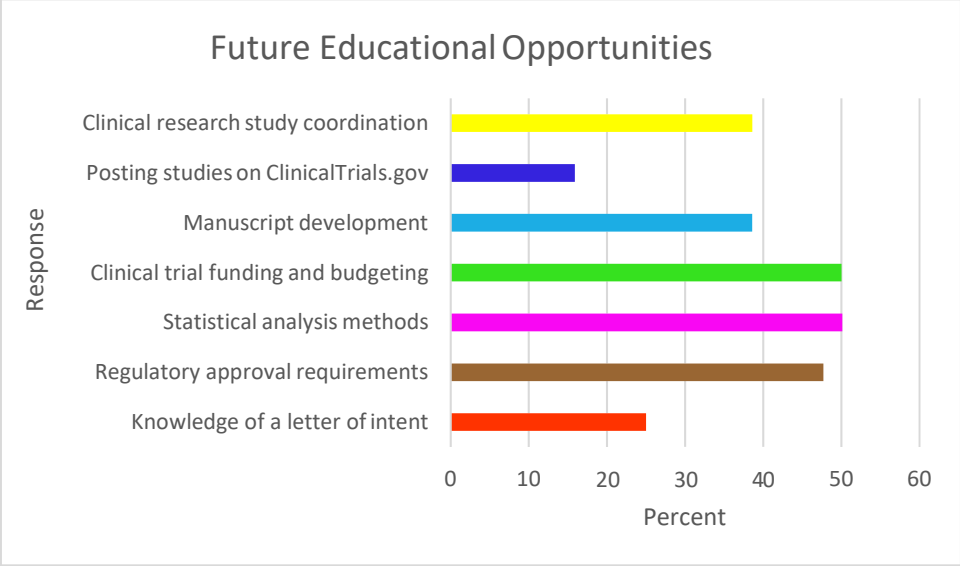
Participants Self-Reported Confidence for Obtaining Clinical Research Funding



Participants were asked to select all applicable clinical research aspects that they would like to improve their current overall understanding of. Of the survey respondents, 59.1% (26) indicated they would like to improve their understanding of statistical analysis methods for clinical research, and 50% (22) stated they would like to improve their understanding of clinical trial funding and budget development. In addition, 47.7% (21) of participants stated they would like to improve their overall understanding of U.S. FDA and IRB requirements for the regulatory approval of clinical research studies. Additional response options included 38.6% (17) manuscript development, 38.6% (17) clinical research study coordination, 25% (11) knowledge of a letter of intent, and 15.9% (7) requirements for posting studies on ClinicalTrials.gov (Figure 9).

Figure 9

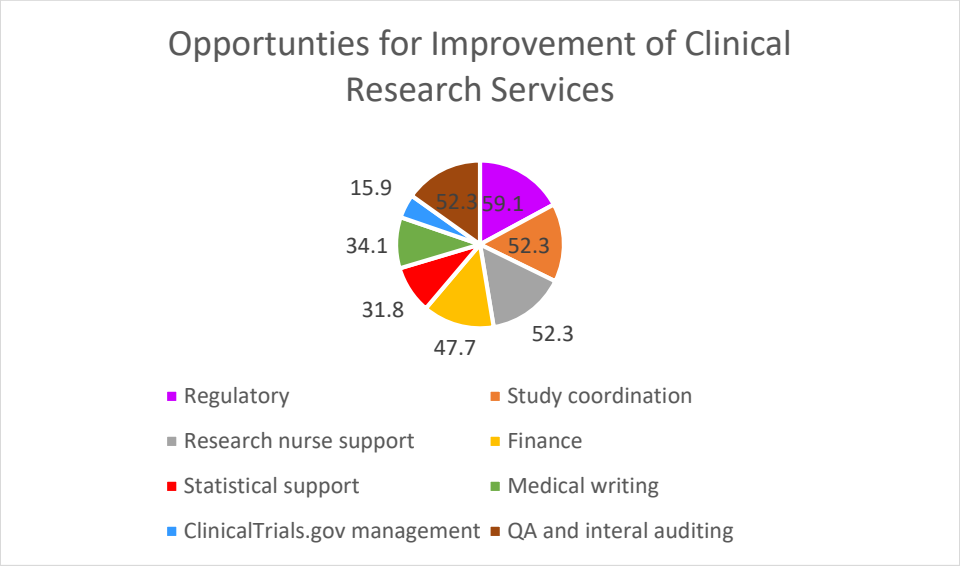
Participants Reported Interest for Future Clinical Research Education Opportunities



Survey participants were asked for feedback on research supportive services within the health system to facilitate future clinical trial opportunities. A large number of the participants 59.1% (26) indicated more regulatory support was needed for clinical trial opportunities. Interestingly, research nurse support, clinical study coordinator support, and quality assurance and internal auditing program were all equally tied with 57.3% (23) for each option respectively. Almost half of the participants 47.8% (21) believed finance and budgeting services were important to facilitate clinical trial opportunities. Medical writing services, 34.1% (15); statistical support services, 31.8% (14); and posting and managing studies on ClinicalTrials.gov, 15.9% (7), were viewed as less of a priority to support future research opportunities (Figure 10).

Figure 10

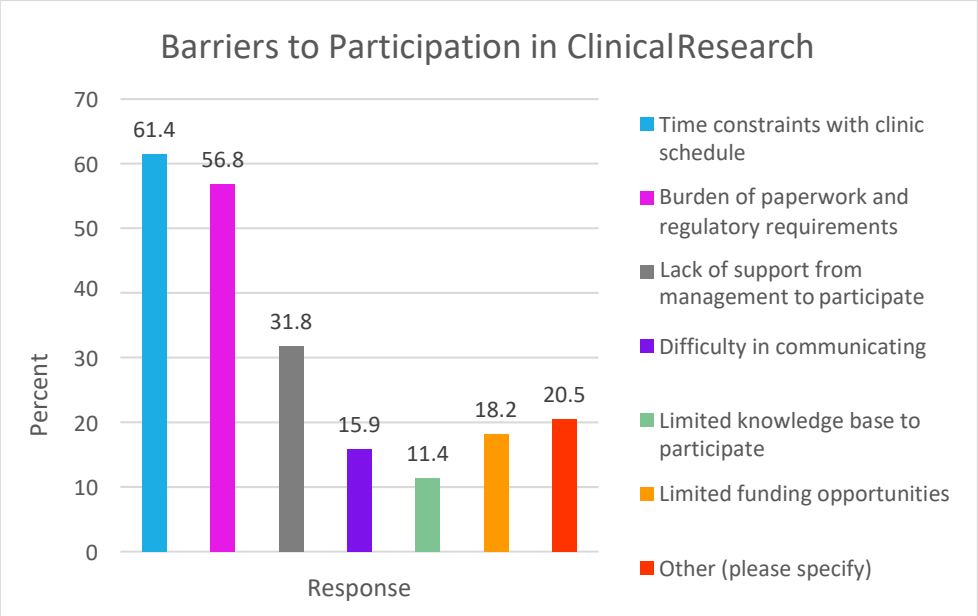
Opportunities for Improvement in Clinical Research Support Services



Participants were asked to select all options that applied regarding current barriers to their clinical trial participation and for others that performed a similar job to them. Time constraints with clinic schedule, 61.4% (27); burden of required clinical trial paperwork/administrative regulatory requirements, 56.8% (25); and lack of support from management for opportunities to participate in clinical research 31.8% (14) were the top three current barriers to clinical research participation. A complete summary of all responses can be seen in Figure 11. Responses recorded as "other please specify" can be found in Appendix H.

Figure 11

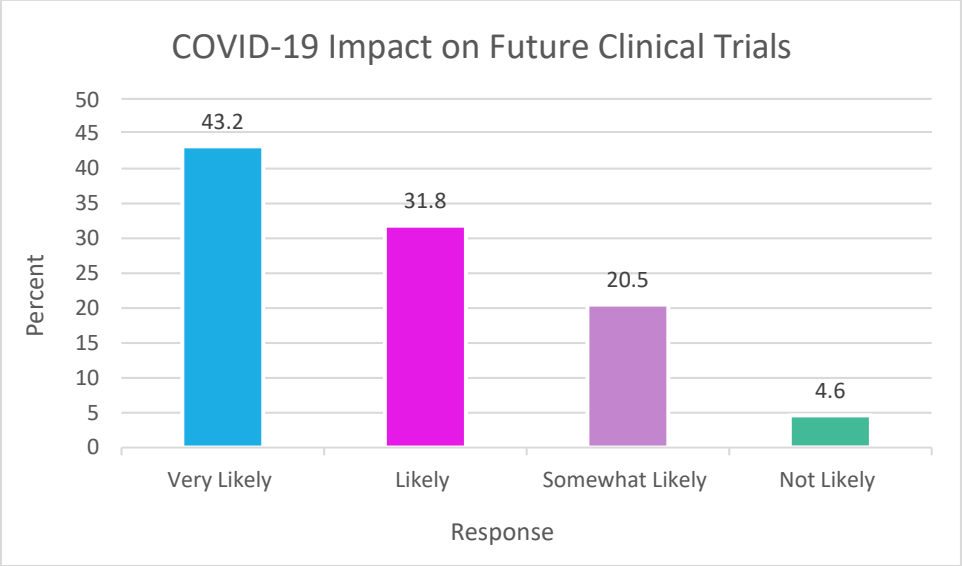
Current Barriers to Clinical Research Participation Within the Health System



Participants were asked how likely the current experience of the COVID-19 pandemic would challenge the future of clinical trial operations (i.e., continued use of remote site initiation visits, remote monitoring visits, telemedicine for research patient visits, and administrative research staff working remotely from home). Most of the participants 75% (33) believed it was "likely" or "very likely" that the COVID-19 pandemic would change the future of clinical trial operations while only 4.5% (2) believed it was not likely that future operations would be impacted (Figure 12).

Figure 12

Participants Response to the Experience of the Ongoing COVID-19 Pandemic



Survey respondents were asked to rank what clinical research career development resources they would be interested in, if offered by the health system, on a scale from 1 to 4 (1 = *most interested* and 4 = *least interested)*. A clinical research professional focused seminar series was the most requested career development resource that participants were interested in with 40.9% (18) of the responses. Participants equally ranked the following career development resources, respectively, with 36.4% (16) of responses for each option: formal clinical trials mentorship program, increase in the number of annual clinical trial workshops offered for physician investigators, and greater exposure to clinical research during fellowship programs (Figure 13).

Figure 13

Ranked Interest of Clinical Research Career Development Resources

The final survey question was optional and allowed for an open-ended response from participants to comment on additional clinical trial career resources that were not previously listed in Question 21. Twenty-three participants answered this question, and twenty-seven participants skipped this question. The recorded responses can be viewed in Appendix I.

Statistical Analysis

Research Question 1: Does the Self-reported Knowledge of GCPs Increase With the Number of Clinical Research Trials Supported by Clinical Research Staff?

A statistically significant correlation was found between the number of clinical trials supported by research staff and the self-reported knowledge of GCPs ($r = .428$, $p < 0.1$; Table 3).

Research Question 2: Is There a Significant Difference in the Understanding of the Necessary Operational Steps of Clinical Research, When Comparing the Education Level of Clinical Researchers With Associate Degrees vs. Master's and Doctoral Degrees?

No statistically significant relationships were found when comparing the education level (associate's, bachelor's, master's, or doctoral degree) and self-reported understanding of clinical trials operational steps (Table 4).

The correlation between the self-reported understanding of all required clinical trials operational steps and knowledge of GCPs was explored and revealed a statistically significant negative correlation *($r = -.395$, $p < 0.1$*; Table 5).

Table 3

Correlation Between Number of Clinical Trials Supported and GCP knowledge

		Good Clinical Practice (GCP) knowledge
Clinical trials supported	Pearson Correlation	.428**
	Sig. (1-tailed)	.004
	N	44

Table 4

Correlation Between Education Level and Understanding Clinical Trial Steps

		Associates degree	Bachelors degree
Understanding necessary steps	Pearson Correlation	.064	.145
	Sig. (1-tailed)	.340	.173
	N	44	44
		Masters Degree	Doctoral Degree
Understanding necessary steps	Pearson Correlation	-.009	-.055
	Sig. (1-tailed)	.477	.362
	N	44	44

Table 5

Correlation Between Understanding Necessary Clinical Trial Steps and GCP Knowledge

		Good Clinical Practice (GCP) knowledge
Understanding necessary steps	Pearson Correlation	-.395**
	Sig. (1-tailed)	.008
	N	44

Discussion

The purpose of this study was to identify emerging research education needs within clinical research staff in an urban hospital setting and to obtain a baseline of current research competency. The study results confirmed that a statistically significant (r = .428) relationship exists between self-reported knowledge of GCPs and number of clinical trials supported by the research staff. Meaning, as the number of clinical trials supported increases, the self-reported knowledge of GCPs also increases. These results confirm the primary endpoint of this study and indicates the survey participants gain further understanding of GCPs as they participate in more clinical trials. No significant relationship was found between the reported level of education of the survey participants and understanding all necessary operational steps of a clinical trial.

When the relationship between reported understanding of all the necessary clinical trial operation steps and knowledge of GCPs was explored, this revealed a statistically significant negative correlation. Only 36.6% (16) of participants responded that their knowledge of all operational aspects was “good.” However, when participants were asked to self-rate their knowledge of GCPs, 50% (22) of the survey population reported their knowledge as “good.” The self-reported scales for both questions were skewed in a positive direction and in addition, the sample size for this question was small leading to a negative correlation when the relationship between the variables was analyzed.

More female participants 63.6% (28) responded to the survey than male participants 36.4% (16). Clinical study coordinators and senior staff physicians accounted for 50% (22) of the survey respondents. The most frequently reported highest level of education was a bachelor’s degree 34.1% (15). Only 27.3% (12) of the participants reported that they had obtained a professional certification in clinical research.

Participants largely reported that the source of their research education was from "on the job training" or by obtaining a secondary professional certification in clinical research. Therefore, the primary reported source of research education is through informal job training. As Sonstein and Jones (2018) note, this has created research professionals to need experience to obtain a job and a professional certification, but employment is needed to obtain job experience and professional certification. However, it should be noted a clinical research professional certification program requires applicants to have at least two years, of previous research employment to be eligible for a certification examination, as it is assumed that experience equates with research education competence.

The results showed that 31.8% (14) researchers reported spending at least 40 hours per week on research and, in some cases, 27.2% (12) of the respondents reported they spend more than 40 hours per week on clinical research. Approximately, 36.6% (16) participants reported supporting 31 or more clinical trials. Enrolling patients was not applicable to most of the participants research role, and 40.9% (18) of the survey participants that did not have a direct clinical role. A question for future studies that may be investigated is how many years of experience a research professional may have as this variable was not measured in this study. Although a question was included within this survey regarding current years of research experience, there was an oversight in transposing this question into the Survey Monkey platform' therefore, this data was not collected.

The survey responses concluded 40.9% (18) of respondents reported they were not comfortable with their current knowledge of statistical methods for clinical research design. Similarly, over half of the survey of the survey population, 59% (26), responded that statistical analysis methods for clinical research was the top item that they would like to

improve their overall understanding of. In addition, 50% (22) of the survey respondents said they were not confident in their current understanding resources to obtain research funding or to develop a clinical research budget. Both items should be considered as content for future research education training workshops.

The survey results indicated that 47.7% (21) of respondents would like to improve their current understanding of FDA and IRB requirements for the approval of clinical research studies. These findings coincide with many of the respondents not having any experience with the FDA IND approval process 36.4% (16) or no previous knowledge about the FDA expanded access IND process 31.82% (14). There is a need for the future development of educational content regarding the regulatory requirements that need to be fulfilled in order to obtain FDA and IRB approval.

Respondents were asked what currently existing research services at the health system could be improved to facilitate clinical trial opportunities. The top-reported choice respondents felt could be improved was regulatory support services at 59.1% (26). The second highest reported supportive service in need of improvement were tied with 52.3% (23) for each option respectively: clinical study coordinator support, research nurse support, and quality assurance and internal auditing program. Participants may have chosen these two items as clinical trials are dependent upon the support of adequate research personnel to obtain regulatory approval and maintain study records. In addition, study coordinator support is critical for the enrollment and care of research patients. Quality assurance evaluates the performance of both clinical research professional roles. Perhaps the survey population thought there was an indirect relationship regarding the oversight of quality assurance feedback and productivity of study coordinator and

regulatory support services. Interestingly, participants did not feel that finance/budgeting services or statistical support services needed improvement.

The survey found the top three current barriers to participation within clinical research for participants were time constraints with clinic schedule, 61.4% (27); burden of required clinical trial paperwork/administrative regulatory requirements, 56.8% (25); and lack of support from management for opportunities to participate within clinical research, 31.8% (14). These findings are comparable to existing literature sources that have conducted similar survey studies of research professionals within a hospital setting. Caldwell et al. (2017) performed a study of 26 research participants to identify barriers to participation in research within a regional cancer center in the United Kingdom. They found that the respondents reported a lack of required knowledge, skills and training, support from managers, and a lack of time or opportunity to be involved in research. Hillyer et al. (2020) also found within their study that clinical trial paperwork was reported as barrier to clinical trial participation. In contrast, this study found difficulty in communicating complex information was only reported to be a barrier by 15.9% (7) of respondents, whereas Hillyer et al. (2020) found that 57.1% (56) found communication with patients to be a barrier to clinical research participation.

This study had some limitations. First, the sample size for this study was relatively small and limited conclusions can be drawn from the data generated. Second, most of the survey responses were obtained from study coordinators and senior staff physicians leading to interpretation of the results through the lens of a limited group of research professionals. Lastly, the survey population is only inclusive of responses from one medical campus in the state of Michigan; therefore, it is not representative of the general academic research staff population and their exposure to clinical research education.

However, the survey results of this study have identified the current baseline of clinical research education knowledge and self-reported levels of confidence within the urban hospital setting. In addition, respondents have offered insight into the preferred format of future educational opportunities, such as a formal clinical trials mentorship program, greater exposure to clinical research during fellowships, and a clinical research professional focused seminar series. Feedback has also been obtained for clinical research supportive services that the respondents feel could be improved at the health system outside of the immediate clinical research education

Conclusions

The study findings conclude that no relationship was found between the level of education completed and the reported self-assessment of understanding of all the necessary clinical trial steps that need to be completed in order to open a research study to patient enrollment, and there was a significant correlation between the level of self-reported GCP knowledge and the number of clinical trials supported. A larger sample size is needed to draw definitive conclusions.

Future development of a research education curriculum addressing the identified knowledge gaps as a result of this survey is warranted. This study found that participants desired to improve their understanding of statistical methods for clinical research design and analysis; mechanisms of obtaining clinical trial funding, including budgeting; and requirements for FDA and IRB approval. The research education needs identified in this study can be used as a baseline comparison for future research educational assessments of research professionals upon the implementation of a clinical research training program.

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APPENDICES

Appendix A: Health System Exempt IRB Approval Letter

[redacted] RESEARCH ADMINISTRATION

[redacted]

To: Ding Wang
IM Hematology/Oncology

From: [redacted]
IRB Chair

IRB No.: 14485

Title: A Survey of Clinical Research Education and Perceptions Among Research Staff within an Urban Hospital Setting.

APPROVAL PERIOD:	**November 16, 2020 – November 15, 2021**
DETERMINATION SENT:	**November 24, 2020**
Expedited Category	2

On November 11, 2020, the [redacted] IRB Conditionally Approved/Withheld the initial submission for this minimal risk study.

On November 16, 2020, the [redacted] Investigator's response, along with the revised and requested study documents provided, were reviewed and the IRB determined that the stipulations were met.

Criteria for IRB Approval of this research is met in accordance with 45 CFR 46.111 and if applicable, 21 CFR 56.111.

This study is approved for the review/enrollment of 50 subjects/medical records. An amendment via a Planned Change Form (PCF) must be submitted, reviewed, and approved prior to exceeding the number of approved subjects/medical records.

The IRB determined that this study is eligible for Continuing Review waiver pursuant to 45 CFR 46.109(f)(1). **Therefore, you are not required to submit a Continuation Report annually.** However, the IRB requires that you contact the IRB Administration office via email on an annual basis determined by the initial approval date to confirm if the study is still open for enrollment. In addition, a Final report is still mandatory at the conclusion of this study.

In addition, the IRB requires that any research study initially approved on or after January 21, 2019, that is subject to the Revised Common Rule, meets the definition of a clinical trial, and is supported or regulated by a Federal department or agency, must ensure that one IRB-approved informed consent form used to enroll subjects is posted on a publicly available FederalWeb site after the clinical trial is closed to recruitment, and no later than sixty (60) days after the last study visit by any subject, pursuant to 45 CFR 46.116(h).

Appendix B: Survey

Clinical Research Education and Perceptions Survey

1. What is your current job title?
a. Senior staff physician
b. Fellow physician
c. Clinical study coordinator
d. Research assistant
e. Research manager
f. Nurse manager
g. Clinical research nurse
h. Research grant/contract specialist
i. Other _____

2. What is the highest degree level that you have completed?
a. Associates degree
b. Bachelor degree
c. Master's degree
d. Doctoral degree (MD)
e. Doctoral degree (PhD)
f. Doctoral degree (MD/PhD)

3. What gender do you identify as?
a. Male
b. Female
c. Other
d. Prefer not to say

4. How many total years of clinical research experience do you have?
a. Less than one year
b. 1-5 years
c. 6-10 years
d. 11-15 years
e. 16-20 years
f. 21 or more

5. How many hours a week on average do you estimate that you participate in clinical research? Choose the option that best represents you.
a. 1-10 hours
b. 11-20 hours
c. 21-30 hours
d. 31-40 hours
e. 41 or more

6. How many clinical trials do you currently support? Please choose one option.
a. Less than 5
b. 1-10
c. 11-20
d. 21-30
e. 31 or more

7. Within the last year, how many clinical trials did you enroll patients on?
a. 1-4
b. 5-9
c. 10-14
d. 15 or more
e. Not applicable to my role

8. By what method, have you obtained your current knowledge of clinical research? Select all that apply.
a. "On the job" training (Job shadowing, protocol specific training by research sponsors, or CITI GCP training)
b. Professional certification (Certified Clinical Research Professional or Association of Clinical Research Professionals)
c. Undergraduate concentration in clinical research
d. Graduate degree with a concentration in clinical research
e. Medical advanced medical degree (MD or DO)
f. Other_____

9. How would you rate your current understanding of all the necessary steps that are required to be executed, prior to opening a clinical research trial to patient enrollment? (e.g. site selection, institutional review board (IRB) approval, finalized contract and budget, and site initiation visit).
Choose the option that best represents your knowledge.
(**1= Very poor, 5= Very good)**

a. 1
b. 2.
c. 3
d. 4
e. 5

10. In your opinion, what is your interpretation of the term "physician investigator" in which, a physician writes a protocol and conducts his or her own clinical research investigation? Please choose one option.

a. Writing a clinical trial protocol and designating research responsibilities as appropriate to clinical and administrative staff
b. Receiving U.S. Food and Drug Administration (FDA) or Institutional Review Board (IRB) approval of a research protocol along with obtaining funding to execute the clinical research investigation
c. Overseeing a clinical investigation that is financed by pharmaceutical company support
d. An individual who both initiates and conducts a clinical investigation, and under whose direct supervision an investigational product is administered or dispensed

11. Which, of the following clinical trial aspects would you like to improve your overall understanding of? Choose all that apply.

a. Knowledge of a letter of intent
b. FDA and Institutional Review board requirements for study approval
c. Statistical analysis methods for clinical research
d. Mechanisms for clinical trial funding and budget development
e. Manuscript development
f. Requirements for posting studies on ClinicalTrials.gov
g. Clinical research study coordination
h. Other_____

12. What is your experience with the FDA Investigational New Drug (IND) application process? Choose the best option that represents your experience.

a. Very experienced, I have been granted approval of an IND by the FDA three or more times
b. Somewhat experienced, I have obtained IND approval for at least one clinical research trial
c. I have only treated a patient on an expanded access (compassionate use) IND
d. I have no experience with the IND approval process
e. Does not apply to my research position

13. The FDA defines the term "expanded access" Investigational New Drug application (IND) as a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

How knowledgeable would you consider yourself about this process? Please choose one option.
a. Very knowledgeable
b. Knowledgeable
c. Somewhat knowledgeable
d. Not knowledgeable

14. If you have been previously granted approval for an expanded access IND, how many IND's total have you received approval for?
a._____
b. Not applicable

15. How comfortable are you overall in your understanding of statistical methods for clinical research design and analysis? Please choose one option.
a. Very comfortable
b. Comfortable
c. Somewhat comfortable
d. Not comfortable

16. How confident are you in your understanding of resources to obtain research funding? Please choose one option.

a. Very confident
b. Confident
c. Somewhat confident
d. Not confident
e. Not applicable

17. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. GCP also serves to protect the rights, integrity and confidentiality of human subjects.

In your opinion, how would you rate your current knowledge of GCPs? Please choose one option.

a. Very good
b. Good
c. Acceptable
d. Poor
e. Very poor

18. What research supportive services do you feel could be improved to facilitate clinical trial opportunities within the health system? Select all that apply.

a. Regulatory support services
b. Clinical study coordinator support
c. Research nurse support
d. Finance/budgeting services
e. Statistical support services
f. Medical writing services
g. Posting and managing studies on Clinicaltrials.gov
h. Quality assurance and internal auditing program

19. In your opinion, what are the current barriers to participation within clinical research for you and others that do a similar job to you? Select all that apply.

a. Time constraints with clinic schedule
b. Burden of required clinical trial paper work/administrative regulatory requirements
c. Lack of support from management for opportunities to participate in clinical research
d. Difficulty in communicating
e. Limited knowledge base to participate
f. Limited funding opportunities
g. Other_____

20. Will the experience of the COVID-19 pandemic will challenge the future of clinical trial operations? (e.g. remote site initiation visit, remote monitoring visits, and continued use of telemedicine for research patient visits, and research administrative staff working remotely from home). Please choose one option.

a. Very likely
b. Likely
c. Somewhat likely
d. Not likely

21. What clinical research career development resources would you be interested in, if offered by the health system? Please rank the options on a scale from 1 to 4 with **1** =being the **most** interested and **4**= being the **least** interested.

a. Formal clinical trials mentorship program
b. Greater exposure to clinical research during fellowship programs
c. Clinical research professional focused seminar series
d. An increase in the amount of annual clinical research workshops offered for physician investigators

22. Are there any other clinical trial career resources you would be interested in that not mentioned above? _____

Appendix C: EMU Survey/or Interview Development Checklist

Survey and/or Interview Development Checklist

This form is required for all student research involving surveys and interviews. Please attach this form, along with your survey or interview questions, with your human subject research application in Cayuse IRB.

The Office of Research Development and Administration provides research design and data analysis support for students. Email orda_stats@emich.edu for more information.

If you have any questions, contact Sonia Chawla at research_compliance@emich.edu or 734-487-3090.

Note: In the points below, *survey* also refers to interview questions.

Please check all that apply.

☒ My advisor and I have developed a research question and/or corresponding hypothesis. The research question is clearly stated in my thesis/dissertation/research proposal and is based on a review of existing literature.

☒ My advisor and I have determined the type of data we will need to collect to answer the research question and have developed a data analysis plan based on the type of data to be collected.

☒ I am using a previously validated survey AND/OR my advisor and I have developed survey questions that are clearly worded and designed to generate reliable and valid data that will answer my research question.

☒ Each of my survey questions has potential responses that are designed to provide me with the type of data I need based on my analysis plan.

☒ I have had at least one other person (another committee member, a statistician, etc.) read my survey questions and responses for clarity and pertinence to my research question.

☒ I have pilot-tested* my survey with at least 5 people to make sure that the questions are clear and can be answered. I have determined that my survey will generate the kind of data that I need for my analysis, including sufficient variability in responses for quantitative research and sufficient depth in responses for qualitative research.

I certify that I have completed all checked items above.

Francesca Picotta — 12/3/2020

Student Signature — Date

[redacted] — 4 December 2020

Advisor Signature — Date

* Pilot testing is a small-scale deployment of survey or interview questions for determining clarity, appropriateness of response options, and ease of completion. Pilot data are used for survey/interview improvement only and cannot be published or otherwise disseminated as research data.

Appendix D: Exempt Approval Letter EMU Human Subjects Review Committee

Dec 8, 2020 3:23:48 PM EST

Francesca Picotte
Eastern Michigan University, School of Health Sciences

Re: Exempt - Initial - UHSRC-FY20-21-122 A Survey of Clinical Research Education and Perceptions Among Research Staff within an Urban Hospital Setting

Dear Francesca Picotte:

The Eastern Michigan University Human Subjects Review Committee has rendered the decision below for A Survey of Clinical Research Education and Perceptions Among Research Staff within an Urban Hospital Setting. You may begin your research.

Decision: Exempt

Selected Category: Category 2.(i). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

Renewals: Exempt studies do not need to be renewed. When the project is completed, please contact human.subjects@emich.edu.
Modifications: Any plan to alter the study design or any study documents must be reviewed to determine if the Exempt decision

changes. You must submit a modification request application in Cayuse IRB and await a decision prior to implementation.
Problems: Any deviations from the study protocol, unanticipated problems, adverse events, subject complaints, or other problems that

may affect the risk to human subjects must be reported to the UHSRC. Complete an incident report in Cayuse IRB. Follow-up:
Please contact the UHSRC when your project is complete.
Please contact human.subjects@emich.edu with any questions or concerns.

Sincerely,
Eastern Michigan University Human Subjects Review Committee

Appendix E: Survey Monkey Consent Script

You are invited to participate in a research project entitled *"A Survey of Clinical Research Education and Perceptions Among Research Staff within an Urban Hospital Setting"* as you have been identified as actively being involved in clinical research within the health system. The research is being conducted as part of the thesis requirements for student investigator Francesca Picotte. Before taking part in this study, please read the informed consent form below and click the "I Agree" button at the bottom of the page if you understand the statements and freely consent to participate in the study.

The study is comprised of an anonymous web-based survey containing multiple-choice questions and ranking questions regarding knowledge and perceptions of clinical research education. It will take a research participant 10-15 minutes to complete the survey. The purpose of this study is to determine emerging research education needs within an urban Michigan hospital by surveying research staff members on their current research education competency. It is hoped the information learned will help provide insight into specific institutional research educational needs and assist with planning opportunities for future training content offerings for research staff and physicians. Your responses will be completely anonymous, so do not put your name anywhere on the form. The survey responses also cannot be linked back to your email address in any way. There are no known risks involved with this study. Participation is completely voluntary and there will be no penalty or loss of benefits if you chose not to participate in this study or withdraw. If you chose not to participate, you may discard the survey by clicking "I do not accept below". By proceeding in answering the SurveyMonkey questions and submitting this form, you are indicating your consent for use of the answers that you supply. If you have any questions about the study you may contact the Principle Investigator Ding Wang, MD, PhD [redacted] at or the student investigator Francesca Picotte at [redacted]

If you have any questions concerning your rights as a research participant, you may contact the [redacted] by phone at [redacted] or by email at [redacted] The IRB is a group of people who review the research to protect your rights.

By completing this survey and returning it you are also confirming that you are **18** years of age or older, understand the statements above, and freely consent to participate in the study, click on the "I Agree" button to begin the survey. If not, thank you for your time.

Please keep a copy of this page for your records, or if you would like a copy please email fpicotte@emich.edu.

Appendix F: Question 1---Other Responses for Obtaining Current Knowledge of Research Education

Response	**n**
MBBS from India	1
Academic Journals; Undergraduate nursing focusing in interpreting and implementing evidence-based practice.	1
Readings from professional publications, active clinical trial protocols and conferences	1
14 years as a clinical trials coordinator in a different department	1

Appendix G: Question 14---Other Responses

Total Reported Number of IND's Approved	**n**
Former job at KCI	1
1	1
15+	1
3	1
One, but I was on the upfront of the approval. Someone else managed the patient once they applied for access	1
4	1
2	1
2	1
1	1
3	1
2-5	1
1	1
1	1
2	1
1	1

Appendix H: Question 19---Other Barriers to Participation in Clinical Research

Other Response	**n**
Limited portfolio of available studies	1
My job is solely based in trials participation. I have no barriers, nor do my colleagues that hold the same role	1
In ability to get physicians to help find patients. Also, in in patient studies cooperation of those physicians to have time or make time to inform us if they have a patient that might fit one of the inpatient studies.	1
Workload	1
Fear of mistakes and resultant regulatory issues due to lack of personnel to support trials at Clinical Trial Office	1
For our department it is more of a lack of staff and our PIs wanting to take on everything and anything rather than what we can accommodate at the time	1
I feel that there is not a well-rounded understanding of clinical trials amongst all staff. They see what they do, and not the big picture of the office, or how it will affect someone 10-15 years down the road when a drug is FDA approved.	1
Staffing	1
Short staff	1

Appendix I: Question 22---Open-ended Responses for Career Resources

Response	**n**
None/No/Not applicable	18
A culture of clinical research needs to be developed by aligning incentives and facilitating the activity - research RVUs have been considered but difficult to deploy and value	1
I have been a member for SWOG, NRG Oncology, serving as physician investigator, attend group meetings, especially serving as committee member to support the inter-group clinical trial operations have help myself in clinical trials as continued learning/education, as well as clinical trials operation	1
Understanding and providing a physician compensation model that promotes clinical research	1
Formal on the job training	1
Free ACRP certification and paid membership fees by institution	1