PROFESSIONAL PROFILE: FACILITATING RESEARCH EDUCATION TO RESEARCH-NAÏVE, HEALTHCARE PROFESSIONALS.

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ABSTRACT

Having available research education for novice researchers and other healthcare professionals not currently in the field, allows them to gain knowledge of federal regulations and guidelines associated with conducting human subject research in a healthcare setting. Research education also provides optimal procedures to conduct a successful research study. Therefore, the purpose of facilitating the Clinical Research Coordinator (CRC) 101 training to research-naïve healthcare professionals is to further their exposure to the field and expand their knowledge on the foundation of research, theories, design, and methodologies that are used to conduct clinical and social behavioral research. Additionally, there is an end-of-training exam that allows the learner to demonstrate their knowledge on what they learned during the training, to ensure that each learner retains the knowledge given. As a result, the primary outcome to this activity is the knowledge gained by the learner.

STATEMENT OF RESPONSIBILITIES

As a research expert in my field, I hope to increase exposure and further the comprehension of conducting research studies among novice researchers, student interns, and other healthcare professionals by teaching this group the interaction of theory, foundation and history of research, methodologies used, and complexity involved in conducting clinical and social behavioral research.

I currently work as an adjunct faculty member and senior dissertation chair for a university where I teach the "Development of a Research Proposal" course. This course includes furthering the learners' knowledge regarding research design, theoretical foundation, and methodology. In my academic role, I serve as a mentor and guide to learners throughout their dissertation journey. In addition to my faculty position, I also work as the Associate Director of Research Education and Compliance for a large healthcare system within their Office of Clinical and Translational Research. In this role, one of my many responsibilities is to continue to develop

and facilitate learner research education. One of the most utilized training within the organization is the Clinical Research Coordinator (CRC101). This training was developed for and is facilitated to novice researchers, student interns, and other healthcare professionals interested in either clinical or social behavioral research fields.

Having experience in serving both academic and nonacademic roles, I believe the CRC101 scholarly activity fits into the overall agenda for scholarly engagement. This specific training allows me to utilize my disciplinary knowledge of research design, conduct, theoretical foundation, and methodologies when applied in a nonacademic setting to expose healthcare professionals and the community who have little to no research experience. Therefore, I am ultimately, offering knowledge on a topic, learners would have not been exposed to otherwise. Hence, utilizing my disciplinary knowledge outside of an academic setting gives me the opportunity to be the subject matter expert on the topic of research in various

organizations and healthcare settings. Therefore, when organizations need to develop training materials within the research arena, they call on me because I am proficient on the subject. Additionally, I guide other professionals in becoming more knowledgeable on the roles and responsibility of a clinical research coordinator and how this role can and will affect overall research being conducted within a healthcare setting.

BIOGRAPHICAL SKETCH

I currently develop and facilitate research education for an array of healthcare professionals who have little to no research experience and are interested in learning more about the field, whether the individuals are considering a career change, want professional development, or are simply curious about the research world. The development of each research education activity ranges in teaching times, depending on the nature of the research topic, as well as the platform in which the research education is delivered. Short research trainings I facilitate on a specific topic. such as learning how to obtain informed consent from a potential subject, are offered as 30-minute live webinar sessions, whereas trainings I facilitate that cover more in-depth information, such the CRC101 training, is offered as a seven-and-a-halfhour instructor-led session.

Due to the length of the CRC101 training, it is only offered quarterly and requires one to two facilitators to successfully disseminate the information to each class per session. This training is one of the most requested training by novice research healthcare professionals because it covers all aspects of research, which is taught in two parts. The first part covers the Good Clinical Practice aspect such as the history, federal regulations, basic and ongoing protections, research design, methods, data collection, theoretical foundation, and source documentation. The second part of the CRC101 covers the coordinator's role, such as describing the role and responsibility of a coordinator, organizational policies, standard operating procedures, Health Insurance Portability and Accountability (HIPAA) in clinical research, subject enrollment, FDA audits, and more. Consequently, novice healthcare professionals tend to gravitate to this training over others that are available. Hence, additional training sessions

may be added throughout the year depending on demand.

INTRODUCTION

Having available research education for novice researchers, student interns, and other healthcare professionals who are not currently in the field, allows them to gain knowledge of the federal regulations, guidelines, and policies that are associated with conducting research involving human subjects, in either the hospital or healthcare setting, as well as the proper procedures to conduct a successful research study. The knowledge gained can assist healthcare professionals with making decisions about the best care for their patients who may be involved in a research study, whether or not they would like to participate in research as a subject or conduct research themselves. Understanding the research field and what it entails allows each learner to utilize their new-found knowledge as part of their professional or personal growth.

GOALS

Due to the lack of research education and inadequate preparation, many healthcare professionals interested in research are unable to connect properly with patients, explain what research is to others in the community, or in some cases, properly design, execute, and present their own research (Supino & Borer, 2009). Therefore, the purpose of facilitating the CRC101 training to research-naïve healthcare professionals is to further their exposure to the field and expand their knowledge of the foundation of research, theories, design, and methodologies that are used to conduct clinical and social behavioral research.

Each educational session I facilitate provides a historical overview in which research was established, including the development of research regulations and human research protection guidelines to foster a firm foundation. Depending on interest, research-naïve healthcare professionals may also register for a range of additional research topics. However, the most popular training is the CRC101. The scope and objective of the CRC101 training is to provide an understanding of good clinical practice, provide clinical research requirements, and discuss the clinical research coordinator's role in the design, methods, planning, and implementation of a research study or clinical trial. Furthermore, the CRC101 training examines

the interaction of theory, research, clinical expertise, and the complexity involved in conducting clinical research. Lastly, this session provides a foundation that is necessary for finding and interpreting research evidence across all healthcare professions. Therefore, research education, such as CRC101 training, is deemed useful and necessary.

PREPARATION

My proficiency on the topic of research, generally comes from my education and work experience. I hold a Doctor of Education in Organizational Leadership with an Emphasis in Behavioral Health, and I have been in the clinical research sector of healthcare for over 14 years. Within the past 14 years, I have engaged in social behavioral research as a principle investigator, in an academic setting and in a clinical research setting as a research study coordinator, research compliance auditor/monitor, and educator, with various healthcare organizations. I also serve on several dissertation committees where I mentor doctoral-prepared learners through their dissertation journey and research study process.

During my clinical research tenure, I have collaborated with a college with a primary focus on nursing degrees to develop a new research certificate program for research-naïve nurses interested in going into the research field. During this process I developed several courses within the program, including the Good Clinical Practice Class created based off the CRC101 training, which focuses on the established ethical and scientific quality standards for the design, conduct, recording, and reporting of clinical research involving the participation of human subjects. Furthermore, I also developed and continue to maintain the Research Education Program for a large Healthcare System for the past seven years, which includes ensuring the compliance of the research program with federal agencies, local state laws, and company policies related to research. However, I started my journey prior to receiving my terminal degree. Based on my work experience, I was able to maintain and facilitate prescribed research training for the first nine years; however, once I attained my terminal degree, I understood the elements, such as research methodologies, with more ease and was better able to assist my learners. Hence, I then started to create my own training to facilitate verses just using the

prescribed research training that was available. The combination of academic and research experience allows me to apply disciplinary knowledge in a nonacademic organization to develop the current research education as a subject matter expert that learners and the healthcare system can rely on for proper research training in the field. Based on past literature, learners anticipate more outcomes from a subject matter expert. This is because the subject matter expert will inquire more on their knowledge towards the topic (Silk, Savage, Larsen, & Aisbett, 2018). The probing makes them well prepared ahead of time to be able to use the information gained in real life experiences (Silk et al., 2018; Ismail et al., 2015). Hence, as a subject matter expert, I am sought out by research-naïve healthcare professionals interested in learning more about or leveraging their unique expertise in research.

The dissemination of knowledge is a key factor in research because when results of high-quality studies reach a wide audience of peers, they provide an evidence base that can improve practice, guide patient care, and guide safety (Collins, Brannan, & Dogbey, 2015). Therefore, developing and facilitating the CRC101 training to research-naïve healthcare professionals enhances their knowledge of ethical and scientific quality standards for the design, conduct, recording, and reporting of clinical and social behavioral research involving the participation of human subjects and their Personal Healthcare Information (PHI). It also brings awareness to guidelines and regulations that affect how research can and cannot be conducted.

Not only is the CRC101 training important to the field of research but it is also known that efficient and effective training relevant to interest can play an essential role in overall career development for healthcare professionals who are interested in joining the research field (James Lind Institute, 2015). For example, in the clinical research arena, attaining relevant training and developing the right attitude is of immense importance since clinical research involves medical investigation performed on human subjects. As research-naïve healthcare professionals, they may encounter patients in their care that may be on a study, and it is beneficial for them to better understand how research plays a role in their care.

In addition, apart from knowledge, equal

importance is given to determine the different levels of training needed for various functional levels in research, which include a good working knowledge of International Council on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines (including design and method) and the applicable regulations issued by various regulatory authorities to perform research in an ethical way (Arnold, Boan, Lackland, & Sade, 2018; James Lind Institute, 2015). Hence, I touch on many important areas within the CRC101 training and provide an array of additional research education to healthcare professionals who otherwise would not have access to this type of education.

One practical issue involved in preparing for the CRC101 training and other research education that is disseminated to an audience of research-naïve healthcare professionals is developing material with the layperson in mind, since scientific ideas can be complicated, and communication of these ideas often becomes mired in discipline-specific jargon and terminology (Brownell, Price, & Steinman, 2013). Therefore, when developing and facilitating research education to a non-expert audience, I always consider the audience's technical knowledge and use of language the audience is familiar with. In doing so, I tend to avoid words or jargon typically used when training research experts in the field and use words and examples that could be understood by a layperson working in a healthcare setting.

METHODS

The CRC 101 is a comprehensive-training session on the development, foundation, conduct of research, as well as research methodology, which was designed for novice researchers, student interns, and other healthcare professionals working in a healthcare setting using a mix of instructor-led and online training, known as a blended method.

The instructor-led training continues to be the most popular method of training due to the face-to-face interaction, which allows learners to ask questions and receive answers in "real-time" (Ghafir et al., 2018; Silver, 2015). In addition, this method also allows me to use a variety of techniques, such as role-playing, exercises, and games to enhance the learning experience (Andrews, 2018; Business & Legal Resources, 2016). Using this method and techniques allows my learners to work in groups, collaborate with their peers, and share ideas, which can assist in understanding the key elements in

research. This method assists in teaching novice researchers, student interns, and other healthcare professionals working in healthcare, research skills through presentations, demonstrations, and discussions (Silver, 2015; Manktelow et al., 2018). Therefore, the CRC101 training using the instructor-led method is typically conducted in a conference room where it is delivered through a PowerPoint presentation and storytelling. Stories and situations are used as examples of right and wrong ways to perform skills, such as consenting subjects, with the outcome of each way described (Hennessey, 2017; Business & Legal Resources, 2016). Since this method is most effective with debriefing questions, I ask the following questions at each training to check for understanding of the material:

- How does this situation or story relate to the training?
- What is the proper way of handling the situation based on what you have just learned?
- Do you believe the character made the right choice? Why or why not?
- Based on what you have learned, what would you have done differently?

Instructor-led training is particularly beneficial for CRC101 research education, as the research material can be complex to comprehend for novice-research healthcare professionals. Therefore, having an instructor on-hand to answer questions and demonstrate concepts can significantly improve a novice's learning experience (Manktelow et al., 2018; Behar-Horenstein et al., 2017). Additionally, since this group is in a controlled space for a fixed period, I have the opportunity to train them without them being distracted by competing demands as they would, possibly, in an online-training environment.

However, sometimes online training is utilized to disseminate the CRC101 training. Online training is a term that covers E-learning, webinars, computer-based training, and virtual learning (Manktelow et al., 2018; Silver, 2015), and while the instructor-led training is the most popular, online training at times is the most convenient and can reach a boarder audience within a large healthcare system. To facilitate training to novice researchers, student interns, and other healthcare

professionals, I have used the synchronous form of online training, which involves the real-time exchange of information between individuals. This method is used because I work for a large healthcare system and traveling to a specific training site is not always feasible for a learner; therefore, they are able to remote-conference into the training using Skype, and still feel as though they are a part of the overall group (Risendal, Whitley, Valverde, & Kellar-Guentner, 2017). In addition, sometimes learners are looking for specific training such as consenting training. Therefore, instead of having them sit through a seven-and-a-half-hour session that discusses other elements in addition to consent. I offer an online training just on the specific topic. The material and content are taken from the instructor-led CRC101 training and broken into bit-size pieces for the learner to understand. For example, learners interested in learning more about research informed consent, registered for the short research training led by me on how to obtain informed consent from a potential subject via a "live webinar." During this type of training, learners have the opportunity to ask questions and have them answered by me in real time (Ghafir et al., 2018; Silver, 2015). In addition, I still incorporate techniques from my instructor-led sessions, such as role-play in this environment, and allow the learner to act as the consenting professional and me as the subject, for the learner to attain a hands-on feel to consenting subjects.

I use the blended method in order to benefit from the combination of face-to-face and online instruction. Instructor-led and online training should work in conjunction with one another, utilizing the strengths from each platform so that the combined instructional method is stronger than using one over the other (Business & Legal Resources, 2016). Hence, using both online training, combined with human support, such as interaction though live-training sessions, was the most effective way to meet the needs of each unique learner. As a result, the blended method was the most appropriate means to educate on the development, foundation, and conduct of research, as well as research methodology for noviceresearch healthcare professionals working in a large healthcare setting.

Furthermore, using a blended method is widely recognized in other healthcare and

educational settings. Dalto (2017) noted that the U.S. Department of Education found a significant learning advantage to courses using media blends compared to pure classroom-based or pure online learning. The blended method also provides new learning environments and strategies, promotes the development of new skills, such as basic research skills, and is good for measuring student satisfaction, learning effectiveness, and faculty satisfaction (Jesus, Gomes, & Cruz, 2017; Larson & Sung, 2009; Rosenbaum, Mikalsen, Lygre, Solheim, & Schjott, 2012). Therefore, the blended method is considered an accepted practice for disseminating CRC101 and other research education.

RESULTS

The purpose of facilitating the CRC101 training to research-naïve healthcare professionals is to further their exposure to the field and expand their knowledge on the foundation of research, theories, design, and methodologies used to conduct clinical and social behavioral research. As a result, the primary outcome to this activity is the knowledge gained by the learner. Since I facilitate training often and in a large healthcare system, the corporate compliance department will send out workplans and quarterly assessments to all healthcare professionals asking several questions including, "Is research being conducted at your facility?"; and understanding research is important. Therefore, there is an end-of-training exam that allows the learner to demonstrate their knowledge on research and what they learned during the training, to ensure that each learner retains the knowledge given. I also employ a separate end-of-training survey completed by the learner to assist me, as the facilitator and subject matter expert, to continuously improve the content for laypersons. This survey also asks questions regarding the delivery platform to ensure using a mix of instructor-led and online training, known as a blended method, is the most beneficial option to our learners.

By developing the CRC101 research education, facilitating, and demystifying the research process, methodologies, and outlining some of the basic research requirements, I was able to provide a venue or environment for healthcare professionals with little or no research experience to come and attain knowledge regarding the field. In doing so,

it allowed these individuals who would have not otherwise been exposed to the topic or field of research to consider the possibility of collaboration between healthcare professionals and researchers. Research collaboration throughout a healthcare system gives them the ability to offer the best treatment options for patients and to continue those advancements to target specific illnesses (Atrium Health, 2017). Hence, CRC101 research education plays an imperative role in the process.

PRESENTATION

The CRC101 research education is made public and open to all healthcare professionals within the healthcare system, surrounding universities, summer scholars, student interns, new residents, and fellows, primarily by posting research education material and registration notifications online via the hospital's intranet. However, the CRC101 research education is also made known through word-of-mouth within departments, general meetings, and through employee orientations at the system level. At any given time, there are approximately 50-75 people that hear about the training and register throughout the year. Therefore, in addition to healthcare professionals interested in taking one of the CRC101 training classes and registering online through the intranet, outside individuals can also contact me for registration who may not have access to the intranet. I will then send these individuals a link to sign up genius and have them register that way.

Below are screenshots (Table 1 and Table 2) supporting that research education is made public for all healthcare professionals.

Table 1: Research Education Online Registration Course List

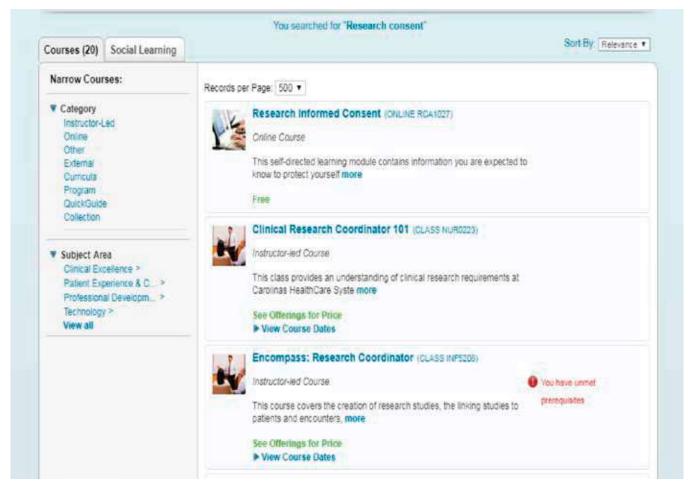
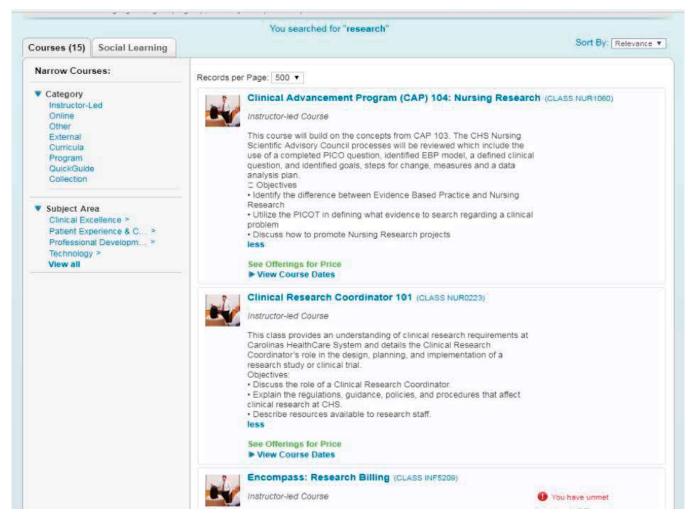


Table 2: Research Education Online Registration & Description



REFLECTIVE CRITIQUE

My colleagues and other professionals have been delighted to utilize the CRC101 training for their staff members, and I have also been invited to attend several learning and development meetings on the system level in order to shed light on the successful techniques and instructional design I used to develop research education. Due to the knowledge I have provided through the CRC101 training to teammates and staff members, leaders within the healthcare system look at me as the subject matter expert in my field and as a reliable resource.

In documenting the evidence of my scholarly activity, it has taught me the importance of knowing and understanding the responsibility of being a reliable resource to a large healthcare system, in addition to utilizing my academic knowledge in a non-academic setting. Therefore, creating a

professional profile has allowed me to demonstrate my qualifications, capability, and disciplinary knowledge regarding developing and facilitating research education and training for laypersons outside of an academic setting. In doing so, a professional profile better demystifies and aligns my academic and professional work experience. This profile also gives me a competitive edge when applying for tenure-track academic positions. However, the limitation in conducting this training is that it was only done in a healthcare setting. Yet, I believe demonstrating such skills can be beneficial to other faculty members and colleagues who are interested in developing and conducting seminars for laypersons on current disciplinary topics within a healthcare organization or other organizations outside of the academic arena.

Finally, creating a professional profile also had a positive influence on my decision-making skills regarding ways to better provide current CRC101 research education, which resulted in assisting me in the decision to potentially expand general research education to patients. This education would be beneficial knowledge to the patients, families, and healthcare systems in the future, leading to better healthcare outcomes.

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