Specialized Consent Training in an Academic Biorepository

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Abstract

The Cooperative Human Tissue Network at Vanderbilt University Medical Center (CHTN-VUMC) is a federally-funded academic biorepository that is dedicated to providing high quality biospecimens and services to the research community. CHTN-VUMC aims to obtain broad informed consent from participants for a variety of research protocols. Participant samples may be utilized for multiple studies based on inclusion or exclusion criteria, thus making patient involvement critical to the biorepository's success. The academic biorepository, which serves various research projects, must have a precise training program that guarantees efficiency and patient participation. CHTN-VUMC has developed training protocols that boast a high consent success rate of 98%, cultivate a high-level understanding of patient privacy and protections, all while emphasizing the importance of institutional regulations. Due to the complexity and cross-departmental nature of the complete CHTN-VUMC consenting process, staff undergo a rigorous training program that highlights both the biological and the psychological aspects of disease. This training program utilizes situational and subject matter knowledge accompanied by the standard IRB training required of the institution with emphasis placed on the incorporation of disease-specific medical science in the consenting process. The CHTN-VUMC consent training includes: cancer biology, disease progression, treatment and outcome training in an effort to understand the patients' disease and psychology.

Introduction

Seeking informed consent for obtained biospecimens broadens the range of work for which they can be used. Many researchers opt for samples obtained with patients' consent due to the supplementary information that may be able to be provided alongside the samples with patients' permission. In order to effectively seek this permission, CHTN seeks consent staff who are proficient problem-solvers and able to adapt to different scenarios quickly. In the ever-changing world of biospecimen demand, CHTN recognizes the importance of the point for research to patient care interface, and how those single interactions shape the potential future of medical research, as well as that patient's likelihood of participating in more studies in the future. CHTN designed a one-week long intensive training program designed to prepare staff for consenting patients in the hospital.

CHTN staff, including those in consent, are required to obtain Yellow Belt Six Sigma Certification after 4-6 months on the job. Yellow Belt training introduces the concepts of time, cost, and quality in our service and product and provides staff with a better understanding of their role in ensuring that the biorepository is sustainable. Cross-training is an important aspect of the functionality of CHTN Western. Limiting factors such as lab funds and space put an upper limit on the number of CHTN staff. Cross-training allows the lab to maintain productivity, even when the expert in a certain field is gone.

Materials and Methods

CHTN-VUMC consent training was designed to take place over a span of five days, with each day being approximately 4 hours long. Training was designed to cover regulations, workflow, the consent documents themselves, and how to appropriately approach patients with an emphasis on both quality and efficiency.

In order to prepare for the new training methods, veteran staff members created a training manual to accompany the updated consent SOPs. The training manual included an outline of the 5-day supervised intensive training along with necessary documents and designated spaces for note-taking.

Day 1 of consent training heavily involved the legalities of the consent process. It begins with answering the question "Why is obtaining a patient's consent important?" then continues with an intensive session on The Belmont Report, Common Rule, and IRB regulations. HIPAA identifiers are next to be reviewed with the trainee, and examples of each identifier are given. Upon understanding of the legal and ethical importance of patient privacy, the trainee is required to sign VUMC and CHTN confidentiality agreements. Once the agreements are signed and the trainee is allowed access to patient information, they are allowed to track a sample through the entire CHTN process to get a better understanding of the overall lab workflow. By the end of Day 1, the trainee should understand why privacy laws have been nationally implemented and why it is important to abide by these laws. The trainee should also begin to gain a general understanding of the workflow in the lab.

Day 2 begins with a short examination over the material covered the previous day. Once understanding of the legal and regulations of consenting are in place, the trainee will then be introduced to the different types of consent forms currently in use at CHTN-VUMC. While studying these documents, the trainee will begin to formulate his/her consent speech that would be given to the patients when speaking with them. Close attention is paid to the differences between the forms, as consent staff may find that they will have to be able to outline those differences for patients while consenting for two different IRBs. The second day of training ends with the trainee beginning to practice the consent speech and also being assigned a handful of medical diseases and conditions to research that are often seen by CHTN-VUMC consent staff.

Day 3 starts with an examination over the consent forms and what makes each of them unique from one another. Following the test, the trainee is introduced to the various web-based applications that CHTN-VUMC has developed and utilize for efficient, streamlined workflow. The training staff also begin explaining VUMC's electronic medical record system, eStar, to those being trained. While the functional interface aspect of the system is new, the regulatory implications of HIPAA were already covered on Day 1, meaning that trainees already have a good idea of what they are looking for and what should not be opened. It is on this day that trainees are encouraged to begin consenting their fellow lab staff in order to get familiar with potential questions, as well as making sure they are comfortable and complete in their explanation of the consent documents.

On **Day 4**, the training staff will go through the entire consenting department's SOPs with the goal of consolidating the daily and weekly workflows in the mind of the trainee. At this point, the trainee should begin understanding the role of the web-based applications used by CHTN-VUMC and how they fit into the consent department's workflow specifically.

Materials and Methods (continued)

While going through the SOPs, the trainee will learn the other various tasks for which she is responsible for. The tasks include preparing patient mail, searching for normal blood donors, communicating with surgeons, etc. The trainee is now able to follow the training staff down to the holding room of the hospital to observe the actual consent process with real patients. This serves multiple purposes; first, the trainee gets to see the interaction that they are training for take place, the trainee gets to see the holding room and learn the geography of that area of the hospital, and lastly the trainee observes how research staff must be cognizant of their surroundings in order to not impede the day's true priority: the patient's scheduled surgery.

The final day of training, **Day 5**, was designed to be flexible in the sense that any suspected deficiencies could be addressed. Trainees are now able to perform the various smaller tasks outlined in consent staff's job outline with supervision. A veteran staff member will secondary check the trainee's work, and if a problem is found it will be handled as another opportunity to learn. This is also the day that the trainee will present on the medical conditions and diseases which they were assigned on Day 2 of training. Not only is it expected that the trainee will explain the physiological aspects of the assigned conditions, but CHTN-VUMC consent staff also must familiarize themselves with the outlook and treatment options for various diseases. This is done not only so that consent staff can be sharper when quickly looking at a case and understanding what samples can be reasonably expected from it, but also so that staff can have the emotional awareness to speak with patients whose first priority is not to be consented for biorepository donation, but instead to be treated for their illness.

Beyond the CHTN-VUMC training manual and SOPs, very few extraordinary materials were needed. The training manual itself was designed to have pages for note taking that prompted trainees to "fill-in-the-blank". During sessions where the electronic medical record systems and our web-based applications were highlighted, a computer with internet capabilities was used. Trainees were given copies of CHTN-VUMC's active consent documents that apply to different IRBs in order to properly familiarize themselves with those as well.

Observations

It was found that the consent training manual was very focused in only on the consent functions in the lab. It was determined after completion of training that a few hours spent with each of the departments within CHTN would give the trainee a more rounded idea of lab functionality. By allowing the trainee to really dive into the processes of each of the departments, he/she would learn how the consent process affects all the other departments within the lab.

Results

CHTN-VUMC found success with this training style. It was implemented unofficially in August of 2017, but the organized testing of this style described in this presentation occurred during January of 2018. Our trainee made it through the five day program without any problems, and was released to perform consent department tasks (not including the actual consent) without a trainer present the following week. The trainee consented actual patients with a trainer present for an additional week, this was a more conservative approach that CHTN-VUMC felt was necessary to take.

By mid-February of 2018 (about 4 weeks), the trainee was fully self-sufficient and was able to complete all the tasks outlined in the SOPs with only customary secondary checking that is outlined as standard.

Conclusion

Most often, especially in federal funding, the demand is for innovative wet bench research tools that will enhance, or increase, the usefulness of the biospecimen. Although this type of funding is vitally important, it is equally important for the funding agencies to understand and support the process of the biorepository itself. An advanced understanding of how systemic innovation can reduce the overall operational cost and institutional cost, while increasing the integrity of the sample and associated data keeps biorepositories on the forefront of relevance. Obtaining broad consent, informing the participants what their contribution means, and outlining how specimens can be used to advance medical knowledge is one of the most critical responsibilities of the operating repository.

Obtaining informed consent from research patients requires staff that are comfortable speaking with patients, working in a highly stressed environment, and being organized at a high level. Consent staff must also have advanced understanding of the processes, treatments and prognoses of the diseases that are affecting the patients with which they are talking. This not only allows staff to better understand the relevance of the samples, but also aids in problem solving in various situations and thinking about how best to handle each patient's unique situation. Finally, for a majority of patients, the CHTN consent staff are the only research staff they will interact with. Throughout all job function it is important to remember that being the one that explains the potential of donating samples to a patient is a privilege, and each consent is a step towards medical progress.

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