

ABSTRACT OF CAPSTONE

Jasmin Berrios

The Graduate School
Morehead State University

April 24, 2018

USING A SIMULATION TO TEACH THE INFORMED CONSENT PROCESS

Abstract of Capstone

A capstone submitted in partial fulfillment of the
Requirements for the degree of Doctor of Education in the
College of Education
At Morehead State University

By

Jasmin Berrios

Houston, Texas

Committee Chair: Jeannie Justice, Assistant Professor

Morehead, Kentucky

April 24, 2018

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USING A SIMULATION TO TEACH THE INFORMED CONSENT PROCESS

This capstone focuses on the research, design and development of a performance-based training in clinical research, more specifically in the clinical research informed consent process, using a simulation. The informed consent process is an integral procedure of a clinical research study.

The informed consent simulation game was designed to teach the clinical research informed consent process to clinical research professionals. Simulation supports learning by enhancing a learner's knowledge, providing a controlled and safe practice environment and shapes the acquisition of new skills. The simulation allowed the replication of necessary aspects of the informed consent process. The methodology used to design the informed consent simulation was andragogy and the ADDIE model. As a result, it is anticipated that clinical research professionals will be able to perform the informed consent process appropriately with actual clinical research participants; as well as increase ethical research practices.

KEYWORDS: Simulation, informed consent, clinical research, research training, simulation design

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USING A SIMULATION TO TEACH THE INFORMED CONSENT PROCESS

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DEDICATION

I dedicate this accomplishment to...

- My parents, Delmy and Guadalupe Berrios, for instilling in me at a young age the belief that I could accomplish anything in life. Your sacrifices have paid off and it has made me the person I am today.
- My husband, Efrain Lazo, for standing by my side and happily supporting me throughout all my adventures.
- My grandma, MaLucia, who was like a second mother to me and great role model. You are so missed.
- Lastly, to my children, Christian and Cataleya Lazo, anything is possible.

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Executive Summary

What is the core of the capstone?

The purpose of the capstone was to design an informed consent simulation game to teach the clinical research informed consent process to novice clinical research professionals. It was hypothesized that designing an informed consent simulation game would increase ethical research practices and increase learner knowledge of the informed content process. Simulation is an educational technique that imitates the realities encompassing healthcare without putting actual patients at risk. The aim of the informed consent simulation game was to replicate necessary aspects of the informed consent process in a safe and secure computer-based environment. As a result, clinical research professionals would be capable of performing the informed consent process appropriately with actual clinical research patients. The informed consent simulation game served as the “bridge between classroom learning and real-life clinical experience” (Ssih.org, n.d.).

While training is required for all clinical research professionals before conducting any clinical research procedure at MD Anderson Cancer Center (MDACC), the trainings do not thoroughly focus on implementation of the informed consent procedure but rather provide a general overview of the informed consent policy. Despite efforts to allocate more time for teaching the informed consent procedure, it is practically untenable to teach each individual how to conduct the informed consent process. There is a limited number of experts and simulation

centers available to teach a large group of clinical research professionals. This is a limitation faced by many other institutions (Messenger & Carroll, 2008).

Currently, each department is responsible for teaching its novice clinical research professionals the informed consent procedure. While it might seem ideal to teach the informed consent procedure based on assigned clinical trials, each trial has different components. For the most part, the clinical research professionals are responsible for managing multiple clinical trials simultaneously. Teaching all clinical research professionals a standard method of conducting the informed consent process possesses the benefit of uniformity across the institution. Audit findings demonstrated through evaluation of clinical research conducted at MDACC that the current method of teaching the informed consent procedure is inefficient and ineffective. At some point in time research teams have failed to conduct some aspects of the informed consent procedure. One way to address this issue is to use technology that would be able to reach the masses and place the learner in a controlled and safe environment while conducting the informed consent process. An instructional method that can accomplish this goal is simulation.

Simulation can be defined as “the technique of imitating the behavior of some situation or process . . . by means of a suitably analogous situation or apparatus, especially for the purpose of study or personnel training” (Bradley, 2006, p. 254). The simulation designed has the capacity to reach the masses due to its availability online. Additionally, it provides a safe environment to practice the informed consent procedure, and, most importantly, provides immediate explanatory feedback.

Who is your capstone meant to impact?

The informed consent process is an integral procedure of a research protocol. Informed consent safeguards trust and the relationship between human subjects and researchers. The Principal Investigator is responsible for all aspects of a clinical research study. They may delegate tasks to clinical research professionals. Informed consent is an important responsibility for clinical research professionals. It is of utmost importance that clinical research professionals are properly trained given the risk associated with poorly executing the informed consent process in a clinical trial. For minimal risk trials, a person must be qualified by experience, education, and training to be able to obtain consent from research participants.

This capstone is intended to impact all clinical research professionals who conduct the informed consent process in minimal risk trials at MDACC. The informed consent simulation is designed to serve as a training tool for clinical research professionals to learn and practice the informed consent process. At the cancer institution, all clinical research professionals are required to complete two trainings- Human Subjects Protection Training (HSPT) and Clinical Research Training (CRT)- prior to partaking in any research procedure. Obtaining consent from clinical research participants requires high-level communication skills. Clinical research professionals that obtain consent from clinical research participants are qualified by experience, education, and training.

The capstone is geared towards novice clinical research professionals. Novice clinical research professionals are individuals who have 6 months or less of MDACC clinical research experience. They have little to no experience with a topic, task, and/or career in MDACC clinical research. These types of learners need to learn in an environment where situational experience is a non-factor. Novices have no professional frames to perform in a manner where intuition and experience are also guiding factors. Therefore, rules guide their performance. Also, these learners have not developed the ability to use discretionary judgment when performing tasks that form their job responsibilities (Benner, 1984). Summaries of the common roles, responsibilities, and requirements of novice clinical research professionals can be found in Appendix A. There is a possibility that a clinical research professional may have learned the general guidelines for conducting the informed consent process at another research institution. However, some institutions have additional requirements. It is for this reason, clinical research professionals who do not have more than 6 months of clinical research experience at MDACC are considered to be novice clinical research professionals.

It was anticipated that the informed consent simulation would also impact clinical research participants. Research has shown that many clinical research participants are not fully aware of all aspects of their participation in clinical trials (Hereu, Pérez, Fuentes, Vidal, Suñé, & Arnau, 2010). Providing adequate training on obtaining consent would ultimately help clinical research professionals explain all the required information to clinical research participants. Additionally, clinical research

professionals would be able to communicate all elements of the informed consent document and assess the research participant's understanding of the clinical trial.

Ultimately, both the clinical research professionals and the clinical research participant would be impacted by the creation of the informed consent simulation. For the clinical research professionals, the simulation would provide better training and a safe environment to practice their skills before performing the procedure with actual clinical research participants. As a result of the informed consent simulation, clinical research professionals would be able to provide all the necessary information in a clear manner to the clinical research participant. Therefore, increasing the clinical research participant's understanding of the clinical research study and allowing them to make an informed decision about their participation in the clinical research study.

How was the capstone project implemented?

The e-learning authoring software, Articulate Storyline, was used to design and develop the simulation. The software offered the ability to create a standalone simulation and compatibility across many learning management systems. The simulation, therefore, can be published in any of the learning management systems offered by the institution. Furthermore, the compatibility of the e-learning authoring software with the institution's multiple learning management systems increases the accessibility and availability of the simulation to all clinical research professionals.

The simulation was based on federal, state and the institution's clinical research policies regarding informed consent and clinical protocols conducted at the

institution. Literature has shown that adults are most interested and internally motivated in learning subjects that have immediate relevance and impact on their job and/or personal life (Knowles, 1970, 1984). The simulation was designed using clinical protocols conducted at the institution. Once clinical protocols were identified, selected clinical protocols were converted into case studies. The case studies were administered to clinical research professionals who took CRT in the last six months, as well as experienced clinical research professionals. The implementation was primarily for:

- content validity
- relevancy
- degree of authenticity/realism
- troubleshooting any unforeseen issue
- flow and timing

The case study education program was updated and appropriate changes were made throughout the formative implementation of the education simulation. No learner data was collected in the pilot phase. The following opportunities for improvement and recommendations were evaluated and remedied:

- clinical protocols with lengthy verbal cases did not present well in the simulation. Too much reading minimizes the planned interactivity of the simulation.

- for multiple response questions, it was difficult to distinguish between selected and unselected responses
- absence of audio could be a treat to learner engagement
- learner feedback should consist of the exact section within the informed consent policy that is applicable when appropriate.

Why were this capstone and related strategies selected?

The idea of incorporating simulated encounters in the healthcare field is not a new breakthrough (Aggarwal & Darzi, 2011; Alon Farfel, Daniel Hardoff, Arnon Afek, & Amitai Ziv, 2010; Argani, Eichelberger, Deering, & Satin, 2012; Baile & Blatner, 2014; Dickinson, 2011; Lane & Rollnick, 2007). Its rise can be attributed to the Institute of Medicine's publication, *To Err Is Human: Building a Safer Health System*. This publication revealed that approximately 98,000 patients die each year from preventable medical errors in the United States (Kohn, Corrigan, & Donaldson, 2000). While it is not a breakthrough in healthcare, its similar counterpart, clinical research, shows there is limited research on the topic (Brindley & Dunn, 2009; Dickinson, 2011; Sinz & Taekman, 2008). With the increase of clinical trials (Clinicaltrials.gov, 2016), the need to adequately train clinical research professionals on clinical research procedures, more specifically the informed consent process, is important for the continued existence of clinical research studies (Cassileth, Lusk, Miller, & Hurwitz, 1982; Erlen, 2010; Jenkins, Fallowfield, Souhami, & Sawtell,

1999; Llewellyn-Thomas, McGreal, Thiel, Fine, & Erlichman, 1991; Sutherland, Lockwood, & Till, 1990). There are various ethical guidelines that must be followed when conducting research procedures. Most importantly, in the informed consent process. The use of simulations was found to be a worthwhile tool in mitigating ethical dilemmas that are encountered in the informed consent process (Ziv et al., 2006).

History of Informed Consent

Throughout history there has been notable occurrences of unethical clinical research conducted on human subjects. The first document to establish ethical regulations in human experimentation based on informed consent is known as The Nuremberg Code (Vollmann & Winau, 1996). The Nuremberg Code was developed following the trial of Nazi war crimes of World War II (Nuremberg Code, 1949). A few years later, in 1964, the Declaration on Helsinki established a set of ethical principles regarding human experimentation to be applied worldwide. The Declaration of Helsinki addresses the rights of the human subject and the responsibilities the investigator holds (World Medical Association, 2000). Other developments that justified the need for informed consent guidelines included the Jewish Chronic Disease Hospital Case (Katz, 1972) and the Tuskegee Syphilis Study (Brandt, 1978; Thomas & Quinn, 1991). Both studies conducted research procedures without prior consent from the human subjects and, in some cases, the subjects were unaware that they were research subjects.

A federal regulation that has also shaped ethical guidelines in clinical research, particularly the informed consent process, is The Belmont Report. The Belmont Report gave rise to three basic ethical principles of research: respect of persons, beneficence and justice (Department of Health, Education, and Welfare, 2014).

Most recently, the Department of Health and Human Services (DHHS) issued The Common Rule (Clayton, 2005). The Common Rule lists regulations for federally funded clinical research and identifies the eight elements of clinical research trial information that must be provided to the human subject or its legal representative. See Appendix B for the informed consent required elements. The Common Rule also states that optional elements of the informed consent should be described when appropriate. See Appendix C for informed consent optional elements.

The Common Rule established that the informed consent process be documented in writing (U.S. Department of Health & Human Services, 2009). After the Common Rule, the 1996 International Conference on Harmonization (ICH) proposed guidelines for Good Clinical Practice to be used by clinical researchers enrolling human subjects (Guideline, 2001).

The guidelines regarding informed consent have become widely accepted over time. Clinical research professionals must comply with informed consent requirements set forth by respective regulatory agencies (Clayton, 2005; Department of Health, Education, and Welfare, 2014; Guideline, 2001; Nuremberg Code, 1949;

U.S. Department of Health & Human Services, 2009; World Medical Association, 2000).

Informed Consent Process

The informed consent process is central to clinical research. Its purpose is to provide human subjects with sufficient information so that he/she fully understands and can make an informed decision about their participation in the clinical trial. The goal cannot be achieved solely on the informed consent specification set forth by regulatory agencies (Appelbaum, Lidz, & Meisel, 1987; Department of Health, Education, and Welfare, 2014; Nuremberg Code, 1949; World Medical Association, 2000), rather, it will require that the clinical research professionals conduct a thorough informed consent encounter that meets all requirements. The basic elements and requirements of informed consent must be defined prior to assessing the integrity of informed consent processes (Flory & Emanuel, 2004).

The informed consent process in clinical research can be defined as providing information about the clinical trial followed by the human subject signing the informed consent document. Although a signature is obtained to affirm a decision, a signature is not sufficient enough to ensure that the process was conducted in an ethical manner. In order to ethically perform the informed consent process, the encounter must go beyond presenting information and obtaining a signature. It should be a process that extends before and after documentation of the human subject's willingness to participate. In other words, the informed consent is not a one-time

event and/or contract; rather, a continuous partnership between the clinical research professional and the clinical research subject (Hoover-Regan, Becker, Williams, & Shenker, 2013). Research has found that the most effective way to increase understanding of the clinical trial is by having the clinical research professional or person obtaining consent talk with the subject one-on-one (Flory & Emanuel, 2004; Hoover-Regan et al., 2013; Jensen, Madsen, Andersen, & Rose, 1993; Mattson, Curb, & McArdle, 1985; Nealon, Blumberg, & Brown, 1985).

Many studies attribute deficiency in the informed consent process to the human subject's poor understanding (Guarino, Lamping, Elbourne, Carpenter, & Peduzzi, 2006; Hoover-Regan et al., 2013; Howard, DeMets, & BHAT Research Group, 1981; Nuremberg Code, 1949; Simes, Tattersall, Coates, Raghavan, Solomon, & Smartt, 1986; Sutherland et al., 1990). In some cases human subjects may not be aware that they are participating in research (Nuremberg Code, 1949). An important, but not often examined, influence on a human subject's understanding is the quality of information communicated to prospective human subjects during the consent process (Hoover-Regan et al., 2013; Jensen et al., 1993; Mattson et al., 1985; Nealon et al., 1985). In order to provide adequate information to prospective human subjects, clinical research professionals or the person obtaining consent should be adequately trained.

Simulations for Training

The use of simulations for training and evaluation has long existed in an array of fields (Bradley, 2006). Most recently, it has made its way into the healthcare field. Simulations take on many faces, including the use of devices, trained persons, role playing, and virtual environments that mimic various environments (Brock, Abu-Rish, Chiu, Hammer, Wilson, Vorvick, & Zierler, 2013; Dickinson, 2011; Hubal & Day, 2006; Issenberg, McGaghie, Petrusa, Gordon, & Scalese, 2005; Lane & Rollnick, 2007; Link et al., 2006; McAllister et al., 2013; Sinz & Taekman, 2008; Wright, Taekman, Barber, Hobbs, Newman, & Stafford-Smith, 2005). Although it is currently used, simulated encounters to teach the informed consent process to clinical research professionals conducting clinical research studies is an endeavor that has been approached sparsely (Brindley & Dunn, 2009; Wright et al., 2005).

One of the primary uses of simulations in the healthcare field is to enhance learner's knowledge, provide controlled and safe practice environments, and shape the acquisition of new clinical skills (Hubal & Day, 2006; Issenberg et al., 2005; Salas, Wilson, Lazzara, King, Augenstein, Robinson, & Birnbach, 2008). Simulation-based training can provide benefits to educators, learners and patients. Educators can use simulations to evaluate a learner's acquired knowledge by providing standardized experiences which would yield reliable outcome measures (Kneebone, Kidd, Nestel, Asvall, Paraskeva, & Darzi, 2002; Link et al., 2006; Peddle, 2011). Learners benefit from simulations by being immersed into various events and conditions (Brindley & Dunn, 2009; Dickinson, 2011; Peddle, 2011). Patient safety and satisfaction is one of the most important benefits that results from simulations (Aggarwal & Darzi, 2011;

Argani et al., 2012; Brock et al., 2013; Green, Tariq, & Green, 2016; Kohn et al., 2000; Patel, Glaiberman, & Gould, 2007; Salas et al., 2008). Another effective feature that simulation brings to both educators and learners is the ability to give and/or receive feedback after a simulated scenario (Dayal, Fisher, Magrane, Goffman, Bernstein, & Katz, 2009; Issenberg et al., 2005; Patel et al., 2007; Salas et al., 2008; Takayesu, Farrell, Evans, Sullivan, Pawlowski, & Gordon, 2006). Although a simulation has lots of benefits, it is not a substitute for clinical practice in a “real” clinical setting (Barach, Satish, Streufert, 2001; Link et al., 2006).

Providing solely didactic-based education is not enough to influence proper performance; instead, the didactic-based education should be complemented with simulation-based training (Gibber et al., 2009; Ziv et al., 2006). The responsibility of educators to provide learners with effective training and constructive learning experience should be viewed as a moral commitment (Crosby, 2000). Learners are responsible for ethically conducting many aspects of the clinical trial. As a requirement to conduct human subjects research, all clinical research professionals are required to have some form of human subjects protections training, which covers general aspects of the informed consent process (Shalala, 2000). It can be assumed that clinical research professionals, at a minimum, receive education about the informed consent process, but the same cannot be said about the actual performance of the informed consent process. As stated earlier, solely relying on didactic-based education is not enough, learners must be presented with the information needed to perform successfully in their work environments, given the opportunity to practice a

variety of scenarios in a simulated environment that provides actual operational conditions, and provided with constructive feedback on their overall performance in meeting the education goals (Dayal et al., 2009; Salas et al., 2008; Takayesu et al., 2006). Providing these types of instructional techniques will lead to further knowledge and proficiency in the informed consent process. More importantly, it will reduce unethical research conduct occurrences as it relates to the informed consent process.

Informed Consent Simulation Conceptual Framework: Andragogy

Simulation creates a practical context in which skills can be learned, applied, and mastered (Dede, 1996). In simulations, many learning theories can be applied due to the wide variety and complexity of the clinical research situations that can be presented. Nevertheless, knowing the target audience and understanding how they learn helps tailor the simulation. The informed consent simulation is targeted to adult learners. Adult learners have the need to perform real life job skills as part of their learning experience. They want their learning experiences to have immediate relevance and impact on their jobs.

Based on the target audience and the skills needed to perform informed consent sessions, the informed consent simulation was designed using the adult learning theory, andragogy. Andragogy is defined as “the art and science of helping adult’s learn” (Knowles, 1970, pg. 43). Knowles (1970 and 1984) developed andragogy based on the following assumptions about adult learners characteristics:

1. Self-directed/ Self-Concept
2. Experience
3. Readiness
4. Orientation
5. Motivation

Self-directed/ Self-Concept

The assumption is based on the process of maturation, where a person moves from total dependency to being self-directed. Adults have a mature concept of self that promotes self-directed learning. The informed consent simulation will not be a required training for clinical research professionals; hence, it is the learner who chooses to pursue the learning experience. After completing the education offering, the learner holds him/herself accountable for following through with implementing what they have learned in their clinical environment experience to its completion.

Experience

The assumption is that as a person matures, they expand their reservoir of experience. The learner's reservoir of experience is then used as a base to relate new knowledge. Adults bring their work and life experiences with them to the classroom which make them valuable instructional resources in the learning environment. As part of the institution's requirement, all clinical research professionals cannot partake in any clinical research procedure until they have completed HSPT and CRT. In these

trainings, policies, rules and regulations governing clinical research procedures are discussed. Prior to participating in the informed consent simulation, clinical research professionals must complete the two trainings, HSPT and CRT. The knowledge acquired in HSPT and CRT will serve as the foundation to the practical aspect of the informed consent process.

Readiness

The assumption is that an individual becomes ready to learn when they experience a need to learn. Readiness to learn for adults is dependent on situational needs related to work performance or societal roles. Learning needs can be related to their changes in the work environment, such as a new job or job responsibilities. The informed consent simulation was designed to target clinical research professionals who are novices in the clinical research field. Even though they are novices, clinical research professionals are responsible for performing informed consent sessions with clinical research participants. While they may struggle with managing complex consent-based situations, they must be capable of meeting the minimum standards of this role. The simulation supports achieving this workplace goal.

Orientation

The assumption is that adult learners have a performance-centered orientation to learning. Adults' orientation to learning focuses on problem-solving. The focus is on applying new knowledge and skills to their routine responsibilities. The informed

consent simulation allows for clinical research professionals to apply their knowledge immediately. Without the use of the informed consent simulation, clinical research professionals have to wait to have a chance to practice with a real clinical research participant. This method increases institutional risk where many things can go wrong. In alignment with the orientation assumption, the informed consent simulation was designed to be a performance centered-training. It will complement the HSPT and CRT required trainings.

Motivation

The assumption is that as a person matures, they respond to internal motivators rather than external motivators. Motivation to learn is more internal than external. Based on the assumption, the clinical research professional's motivation to participate in the informed consent simulation would be attributed to their desire to learn a necessary job skill. The simulation is designed to appeal to the learners' internal drive to acquire necessary job skills to perform successfully in their new role. The newly acquired skill would allow clinical research professionals to perform their job responsibilities well and thus, receive high evaluation marks. The clinical research professionals would be able to facilitate obtaining an informed decision from the clinical research participant to participate in the research study.

Instructional Design Theory: ADDIE

The instructional design model chosen to design the informed consent simulation is the ADDIE model. The ADDIE model is an acronym that stands for analysis, design, development, implementation, and evaluation. The ADDIE model outlines a systematic process that produces evident and sustained results in instruction (Gustafson & Branch, 2002). This model serves as a useful tool for educational and practice performance improvement. It provides a useful framework for guiding the development of learner-centric content, which has the potential to better prepare novice clinical research professionals for clinical research procedures, in this case informed consent sessions.

Phase 1: Analysis

A needs analysis was conducted using data collected in research audit findings and focus groups. Research audits are conducted by an internal research audit group. The team reviews the overall conduct of clinical trials and makes findings based on the following categories:

- Informed consent
- Eligibility
- Protocol compliance
- General data quality
- Essential documents

It is important to note that internal auditors are independent from clinical research educators. Audits examine the overall conduct of clinical trials and have no vested interest in the design and development of the informed consent simulation. Although the internal auditors are independent from the clinical research educators, auditors work collaboratively with clinical research educators by providing access to the audit findings summaries and allowing clinical research educators to observe audit findings meetings. Face-to-face audit findings meetings are where clinical research professionals have the opportunity to explain the reason for their actions with the auditors. Observing audit findings meetings have been found to be very useful. It allows both the auditor and the clinical research educator to obtain the clinical research professionals' perspective as it relates to their job performance. On many occasions, it has been found that clinical research professionals are unaware that they are implementing a research procedure incorrectly and/or conducting procedures based on an incorrect interpretation of the clinical research policy.

For the purpose of the informed consent simulation, only the data from the informed consent category was used to design the informed consent simulation. Also, only audit findings from the last 5 years were selected for use. A five-year compilation of data was selected for use because prior to 5 years ago, there was no formal CRT training for the target learners. As mentioned previously, CRT is a required training that provides an overview of research policies that govern clinical trials. Informed consent policies and procedures are reviewed in the training.

Analysis of the data helped determine the learner's knowledge and learning motivation. Based on the analysis, it was found that there is no institution-wide standard operating procedure for conducting the informed consent process. While there are a few clinical research teams that have standard operating procedures for the informed consent process, many did not have any formal written standard operating procedures. Therefore, clinical research professionals' performance of the informed consent process varied substantially across all areas. Besides the lack of standard operating procedures, analysis revealed that many clinical research professionals were unaware that they were conducting the informed consent procedure incorrectly. The analysis was found to be very beneficial in defining the gaps in knowledge.

Phase 2 and 3: Design and Development

The informed consent simulation will be used to enhance the informed consent workshop. The needs analysis conducted previously was used as a guide to develop goals and objectives for the workshop and simulation. The goals and objectives of the simulation and the workshop complement each other as it relates to presentation of didactic content and the implementation of the content in a computer based simulated environment.

Scenarios

Scenarios were chosen as the methodology used to examine judgments and decision-making processes (Evans, Roberts, Keeley, Blossom, Amaro, Garcia, &

Reed, 2015). Scenarios are short descriptions of a clinical research situation. Each simulated scenario allows clinical research professionals to apply and demonstrate their clinical research knowledge and technical and/or nontechnical skills (Lunza, 1990). Scenarios provide a cost-effective training method to gather information about how a clinical research professional might perform in situations that are difficult to effectively observe on a daily basis (Polit and Beck, 2012). Additionally, scenarios are a practical method that allows for the ability to manipulate variables and to control extraneous variables since all clinical research professionals are responding to the same stimuli (Gould, 1996).

The simulation, as with the workshop, was constructed as a series of scenarios where the learners can systematically reflect on their performance, reorganize their thinking and ultimately form new knowledge. Following the scaffolding framework, the simulation was designed as a series of scenarios that progressively become more complex. This was intentional because of the complex interpersonal nature of the informed consent process. The design is as follows:

Level 1: Preparation for IC process

Challenge: Learners will identify the appropriate documents and processes that are needed to be obtained prior to conducting the informed consent process. Various scenarios will be used that range from basic consent scenarios to complex scenarios.

Level 1 is illustrated in Figure 1.



Figure 1. Informed Consent Simulation Level 1

Level 2: Identification of IC elements

Challenge: Learners will read through informed consents and identify the required elements of the informed consent document. In general, the required elements have no set order in which it should be presented in the informed consent document. The only expectation is that institutions have the required elements within the informed consent document. Level 2 is illustrated in Figure 2.



Figure 2. Informed Consent Level 2

Level 3: Meeting with participants

Challenge: The learner will meet a virtual participant and conduct the informed consent session. As the learner is progressing through the informed consent document, the virtual participant will randomly ask questions about the informed consent document. Level 3 is illustrated in Figure 3.

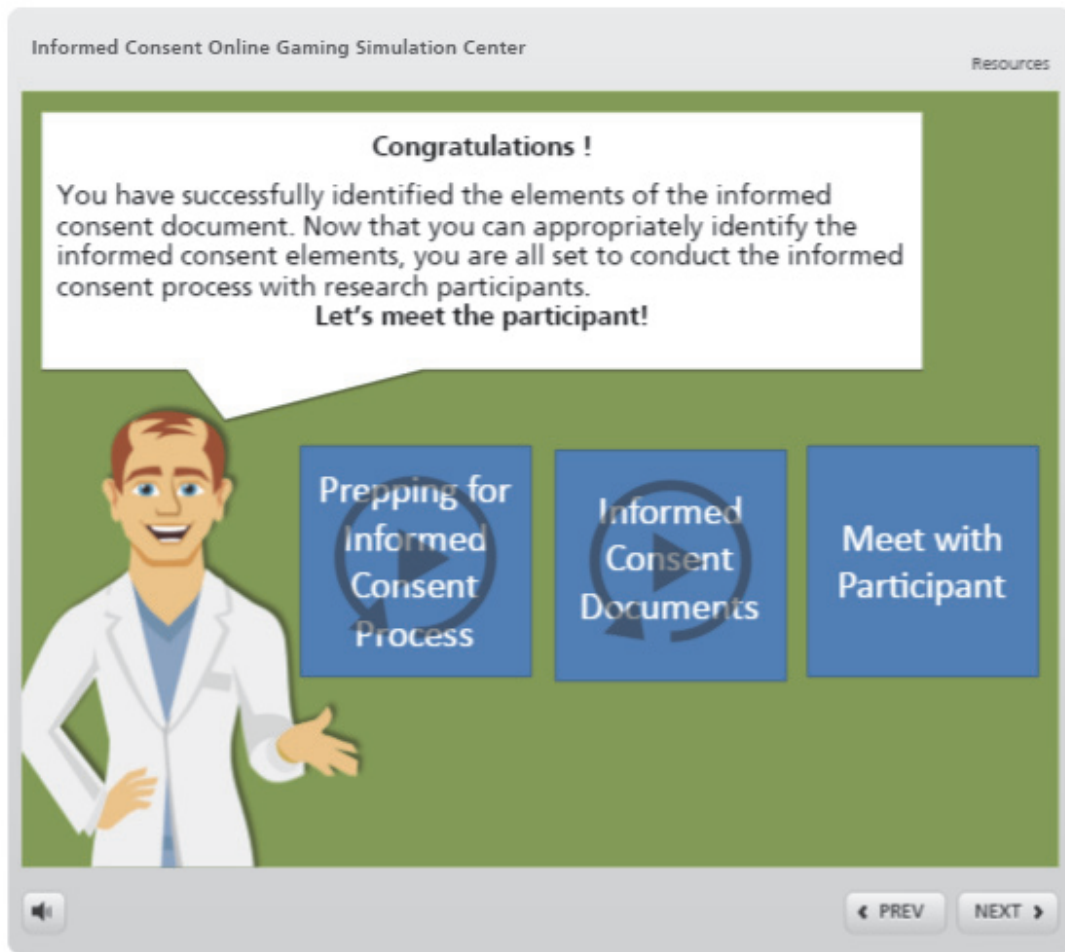


Figure 3. Informed Consent Simulation Level 3

Phase 3: Development

Simulation Software

The platform chosen to develop the informed consent simulation was Articulate 360, more specifically articulate storyline. Articulate 360 is an e-learning course development software. Articulate is one of the most widely used platforms throughout the institution for its compatibility with the institution's learning

management system. Also, the software allows for the informed consent simulation to be properly displayed in various devices. Illustrations of the informed consent simulation display in the various devices are seen in Figures 4 through 6.



Figure 4. Desktop display

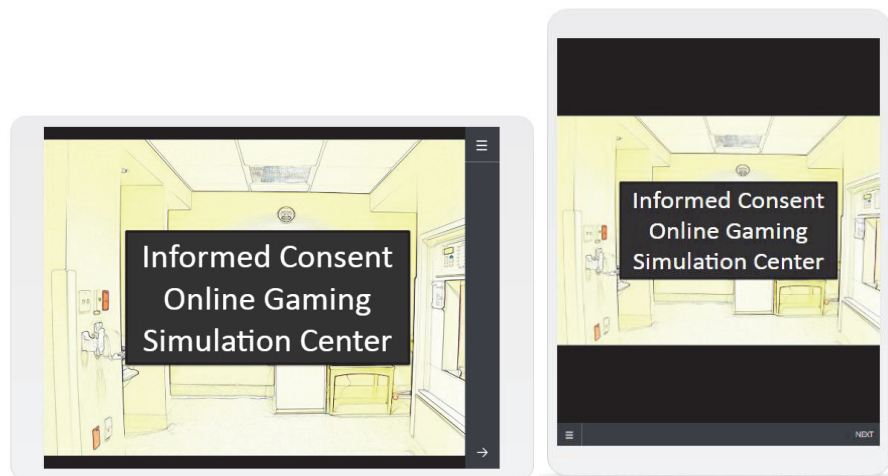


Figure 5. Tablet display - landscape and portrait



Figure 6. Phone display - landscape and portrait

Visual Design

The visual design of the simulation was based on the branding guidelines set forth by the institution. The institution has its own branding requirements. Branding requirements consist of design rules that must be adhered to when developing materials that will be used internally and externally. Branding encompasses color schemes, system fonts, illustrations/images and logos.

In adherence to the institutions branding requirements, the colors used in the development of the simulation are seen in Figure 7.

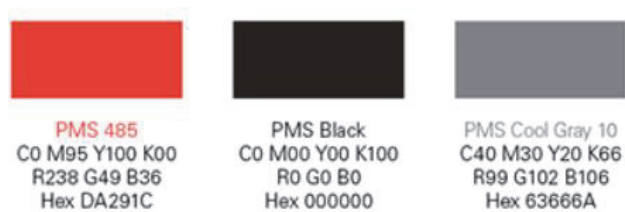


Figure 7. Primary palette

Branding guidelines state that PMS 485 is a red that should be used sparingly to help it retain importance and impact. PMS 485 should not be overused as it will appear common. PMS Cool Gray 10 and PMS Black can be used more liberally.

According to branding guidelines, the secondary palette is designed to work with the primary palette. The purpose of these colors is to add interest to supporting collateral and marketing materials. The secondary colors should not be overused. They are intended to complement rather than compete with primary colors. When appropriate, it is acceptable to use tints (screens) of the secondary palette. Figure 8 shows an illustration of the secondary palette.



Figure 8. Secondary palette

The neutral palette consists of light, neutral hues designed for use behind elements such as typography and photographs. These colors can be used to fill a page or as accents to highlight specific information. The neutral palette is intended to support and enhance the other design elements. When appropriate, it is acceptable to

use tints (screens) of the neutral palette. Figure 9 shows an illustration of the neutral palette.



Figure 9. Neutral palette

The illustrations used to represent the patients will be those provided within the Articulate Storyline software. The characters available through Articulate Storyline have been approved to be used in educational material. Figures 10 through 12 show examples of illustrations that were used in the informed consent simulation:

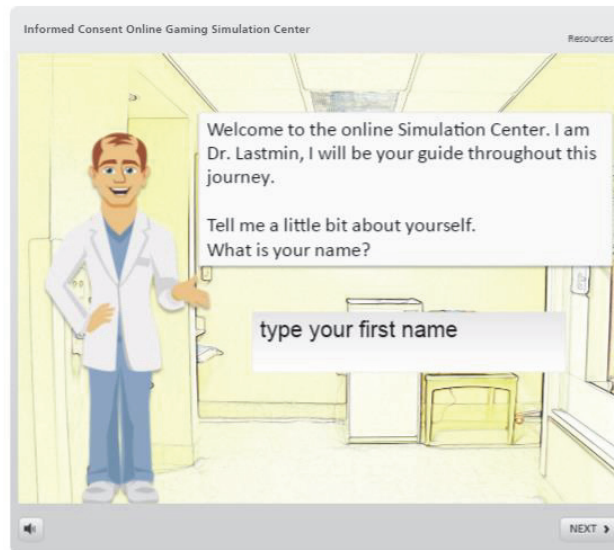


Figure 10. Principal Investigator/Trainer

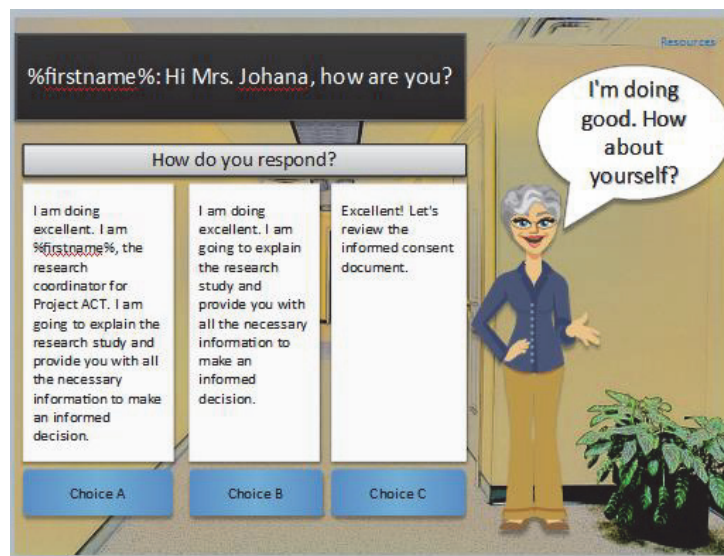


Figure 11. Developer view of encounter with clinical research participant includes multiple choice question

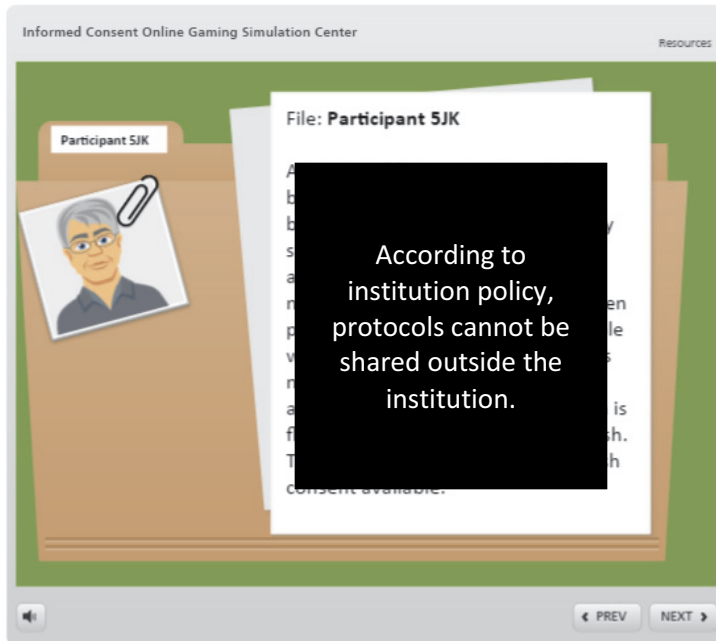


Figure 12. Scenario from Level 2

Phase 4: Implementation

The capstone focused on the design of the informed consent simulation. A small-scale pilot-test of the informed consent simulation was conducted. The pilot-test focused on clarity, usefulness, and relevancy of the informed consent simulation. Currently, the informed consent simulation is not available for public use. Once the informed consent simulation has been fully developed, it will be implemented with an appropriate representation of target learners to provide adequate feedback on the simulation performance.

Phase 5: Evaluation

Formative Evaluation

A formative evaluation was conducted using a small group of pilot-testers. The formative evaluation focused on three aspects:

1. Clarity: is the content presented in the informed consent simulation clear and understandable?

Results: Users found the informed consent simulation clear and understandable. The feedback component of the informed consent simulation provided user with a clear understanding of their decisions/selection- whether they responded correctly or incorrectly.

2. Usefulness: is the informed consent simulation achieving the goals/objectives that were set? Are learners finding the informed consent simulation useful and helping them enhance their skills?

Results: Users found the informed consent simulation useful and valuable. The feedback component helped users identify the areas in which they were workplace deficiencies. It allowed learners to focus and hone their skills in deficient areas.

3. Relevancy: is the informed consent simulation relevant to the learner?

Relevant to clinical research practice? Are they able to correlate the content covered in the informed consent simulation with their job responsibilities?

Results: All users felt there was relevancy between their job responsibilities and the informed consent simulation. Also, users stated that the skills

acquired through the informed consent simulation could directly be used in their everyday role.

Summative Evaluation

Kirkpatrick's four levels of training evaluation was chosen to determine the effectiveness of the informed consent simulation. Kirkpatrick's four levels of training evaluation (1998) are as follows:

1. Reaction: measures learner's reaction to the training.
2. Learning: measures how much a learner's knowledge has increased as a result of the training.
3. Behavior: measures a learner's change of behavior based on the training received; more focused on application of the skills learned.
4. Results: measures overall success of the training; aligns/links to the overall organizational performance goal

The informed consent simulation is focused on skill-based learning. In other words, it is assumed that after practicing the skill using the informed consent simulation, clinical research professionals will be able to transfer those skills to their actual practice. The transfer of skills to practice is recognized as being one of the highest level of the Kirkpatrick evaluation model- behavior level (McGaghie, Issenberg, Petrusa, & Scalese, 2010). Ultimately, it is expected that clinical research professionals will transfer the skills to practice, resulting in an increase in patient safety and satisfaction (Level 4: Results).

When was the capstone implemented?

The design and development of the beta version of the informed consent simulation was completed on February 2018. This version was published on the institution's learning management system testing site, Education Center. Once the simulation was published, the application was tested for basic technical issues.

The implementation of the Informed Consent simulation will be considered after the simulation is further pilot tested. At the completion of the pilot-test phase, the simulation will be ready for public use. Public use refers to MDACC employees and its formal collaborative network institutions. It is anticipated that the informed consent simulation will be implemented in a workshop focused on the informed consent process, known as Informed Consent in Minimal Risk Trials Workshop. The workshop is of a hybrid nature. Hybrid trainings consist of in-person and online components. It is 5 weeks long and limited to 20 individuals. Clinical research professionals must have completed Human Subjects Protection Training (HSPT) and Clinical Research Training (CRT). Completed HSPT and CRT are needed prior to enrolling in the workshop because both trainings cover informed consent research policies and guidelines. The workshop will briefly cover informed consent policies. The focus will be on the procedural aspects of the informed consent process.

Impact of the capstone

The Informed Consent simulation is currently in its initial implementation phase, the impact of the simulation is currently minimal. The overall impact of the

simulation will be assessed more accurately after the simulation is released to the public. The simulation is currently live on the learning management system's testing site for beta testing purposes. A small group of individuals were given access to test the beta version.

In assessing the impact that the capstone had on the small group of beta testers, the responses received were favorable. The Informed Consent simulation was viewed as a valuable tool that would help remedy issues such as providing an institution-wide standard operating procedure for the informed consent procedure. Also, users believed the informed consent simulation will accommodate a wide range of learners due to the scaffolding learning approach used in the development of the simulation.

Users commended the accessibility of the Informed Consent Simulation. Many stated that the simulation would allow for clinical research professionals to practice in a safe environment as many times as possible. This method was preferred rather than practicing as patients came into the clinic. The simulation was viewed as an effective way to train clinical research professionals that are stationed at locations outside the main campus as well. Locations outside main campus include the regional centers, collaborating hospitals and health systems within Texas, outside of Texas, and in other countries.

A few technical issues arose that were quickly remedied during the pilot. The display and resolution setting on users' computers made reading the content very difficult. This issue was corrected by reducing the text on the screen. Also, it was

discovered that some of the visuals issues were only encountered using Internet Explorer. Issues with the browser were found to be unrelated to the Informed Consent Simulation, rather a communication issue between the learning management system and the browser. Visuals were not affected when using Google Chrome; therefore, users were instructed to use Google Chrome for beta testing.

The small-scale beta testing proved to be very beneficial. Overall, users felt the informed consent simulation provided a safe environment to make mistakes and learn from their mistakes. They found the feedback component to be very beneficial in assessing their deficiencies and commended the accessibility of the simulation. They appreciated that the simulation can be accessed by all clinical research professionals regardless of time and location.

Limitations of the study

There are some limitations to the informed consent simulation and its impact. The informed consent simulation is limited in the number of scenarios. All clinical trials are diverse, it would be impractical to include every single type of clinical trial seen at MDACC. While not all clinical trials can be included in the informed consent simulation, the theme of the scenarios are reflective of the various types of clinical trials conducted at MDACC.

Simulation was chosen as the most desirable method of teaching and assessing the ability to perform the informed consent procedures. However, there are limitations to the method. The informed consent simulation is a low fidelity computer-based simulation. For the purpose of the capstone, fidelity refers to the

degree of realism or authenticity; more specifically, the fidelity continuum ranges from a completely artificial environment to an actual real-life situation. While every effort was made to replicate the environment, such as illustration of consult rooms and clinical research participants, the simulation was through a computer interface with limited animations of the virtual clinical research participant.

The informed consent simulation is designed using scenarios of varying complexities, followed by multiple choice questions. This form of simulation is more focused on the application of knowledge. Therefore, assessment of the transfer of skills to practice is limited. Further refinement of the informed consent simulation will be made after the simulation is tested at a larger scale. Through continued improvement of the informed consent simulation a number of limitations will be remedied.

Lastly, the simulation was designed based on the clinical trials conducted at MDACC. Therefore, generalizability of the informed consent simulation is limited to MDACC. While the informed consent required elements (see Appendix B) are federal standards that all clinical research institutions must abide by, the informed consent simulation was designed to also include MDACC policies regarding the informed consent process.

Reflections

There is so much that can be said about my doctoral capstone journey. I stepped into the journey somewhat afraid and a bit naïve about the whole journey. Most of my experience has been in research. Coming into this journey, I had

a difficult time trying to get out of the frame of clinical research I had been accustomed to conducting to acquire these new skills. The capstone showed me a different perspective on research. This capstone project gave me the opportunity to incorporate my creativity into a topic often viewed as dull and tedious.

My passion for the use of simulation as a teaching methodology for clinical research began when I entered my Ed.D. program. However, I became fully immersed in the idea as I started my capstone journey. I started the capstone with no experience in designing and developing simulations; therefore, I can attest to the struggles and moments of uncertainty that come with learning a new skill. Often times, I found myself frustrated and searching for resources on how to code the triggers within the software. Other times reading up on more theories and principles related to simulation. The time invested was well worth it. It led to an increase in personal and professional growth.

The development of the simulation is groundbreaking, and hopefully, change the culture of the institution as it relates to education. At my workplace, education has long been seen as a form of remediation and used only to assist underperformers to meet job related requirements. This is a reason why learners may view education/trainings as an extra thing to “check off the list”. Many of the current trainings consist of face-to-face lectures and/or PowerPoints transformed into online slideshows. I am very confident that instituting other teaching methodologies (i.e., simulation), providing performance-based trainings, and focusing on the learner will have a positive impact on the institution and will help bring an appreciation to

education as a whole (i.e., culture change). Therefore, the design and development of the informed consent simulation is a sound capstone for the completion of my doctoral journey.

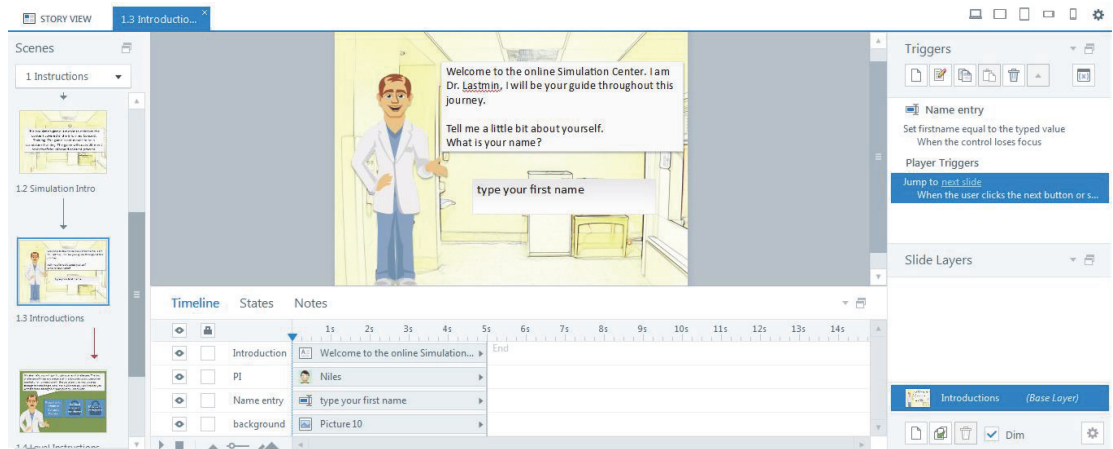
Capstone Project

In compliance with the institution's rules and regulations, clinical research that has been conducted, is currently being conducted or is in the works of being conducted cannot be shared outside the institution. Therefore, an image-based walkthrough of the application's core scenes is below.

- Developer's view Introduction Scene- Title of Simulation



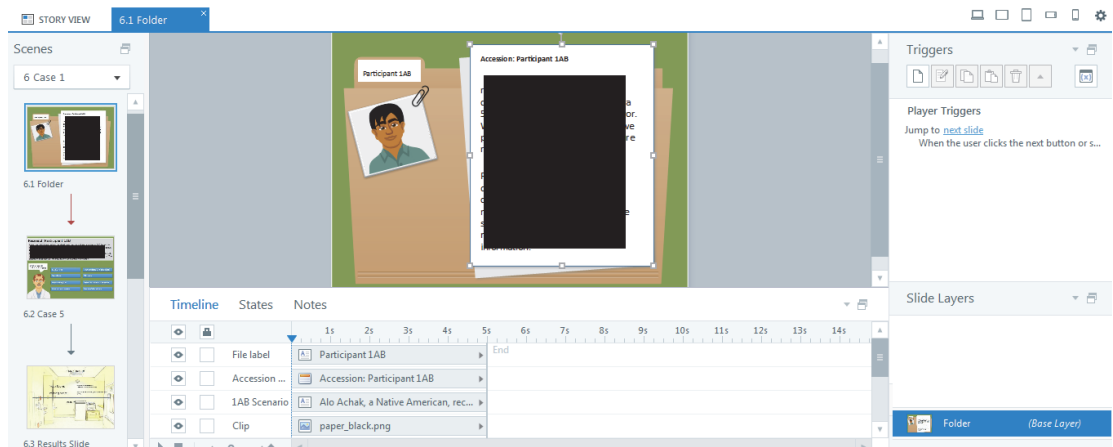
- Developer's view Introduction Scene- Player Name



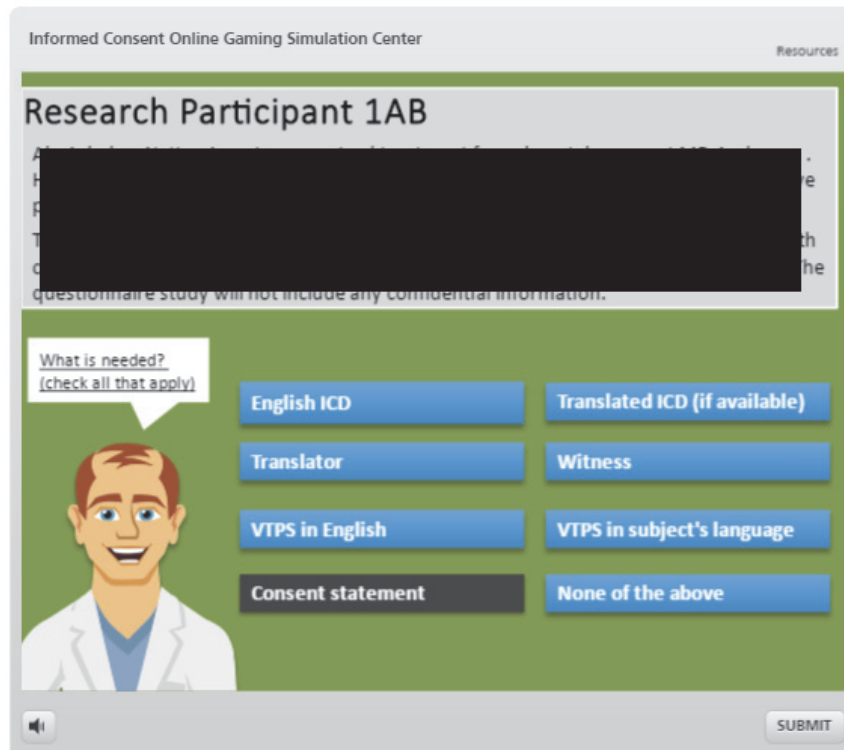
- Learner's view Introduction Scene- simulation levels



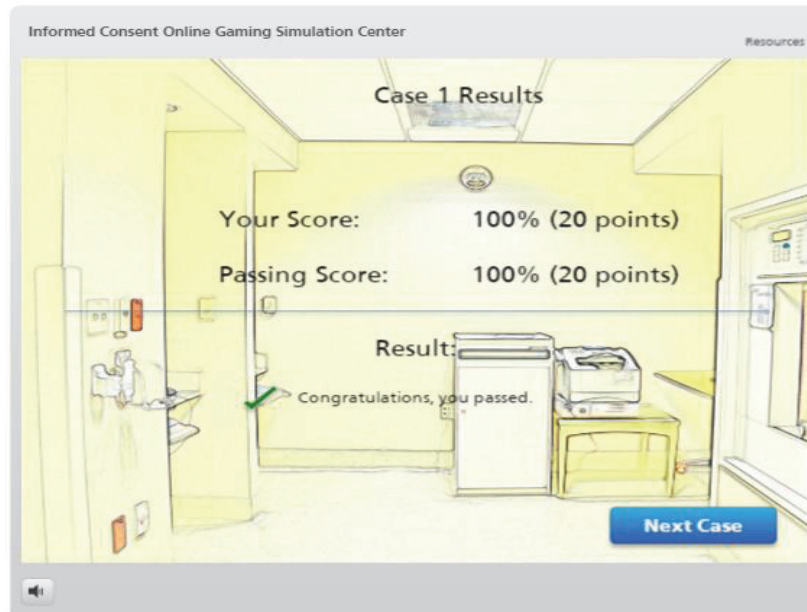
- Developer's view Level 1: Case study



- Learner's view Level 1: Case study with question and selected response



- Learner's view Level 1: Case study results page



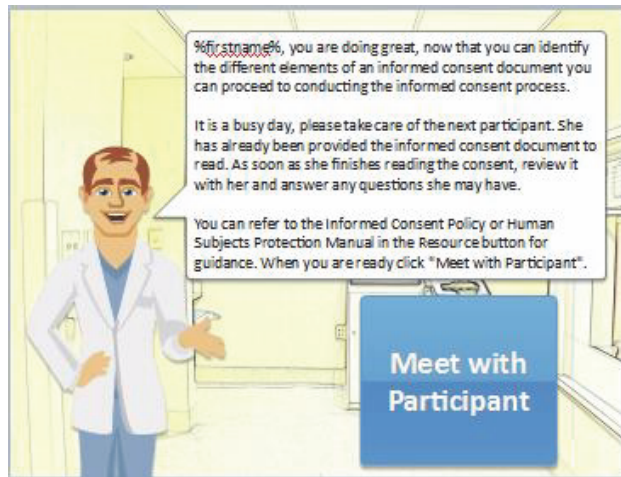
- Developer's view Level 2: Menu to start next level



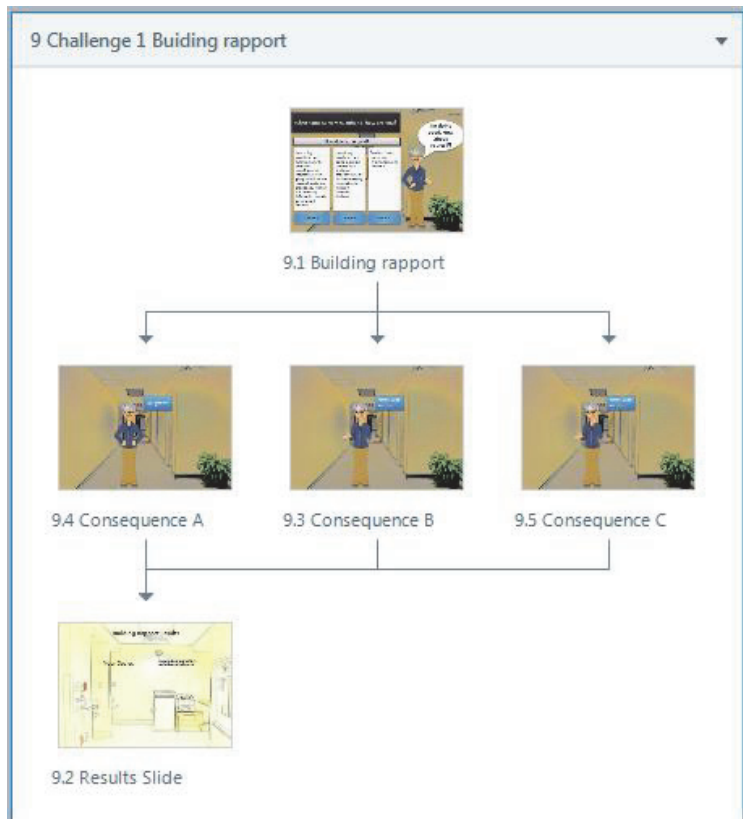
- Developer's view Level 3: Menu to start next level



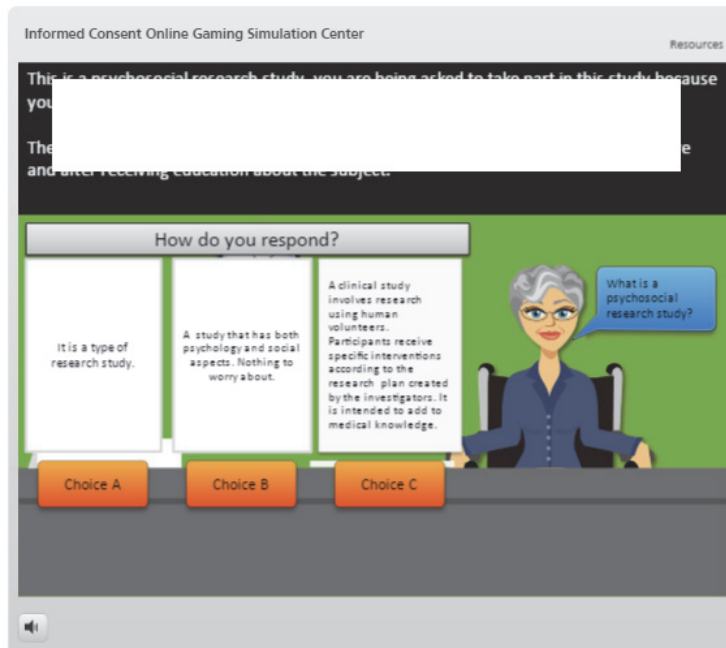
- Developer's view Level 3: Meet with participant



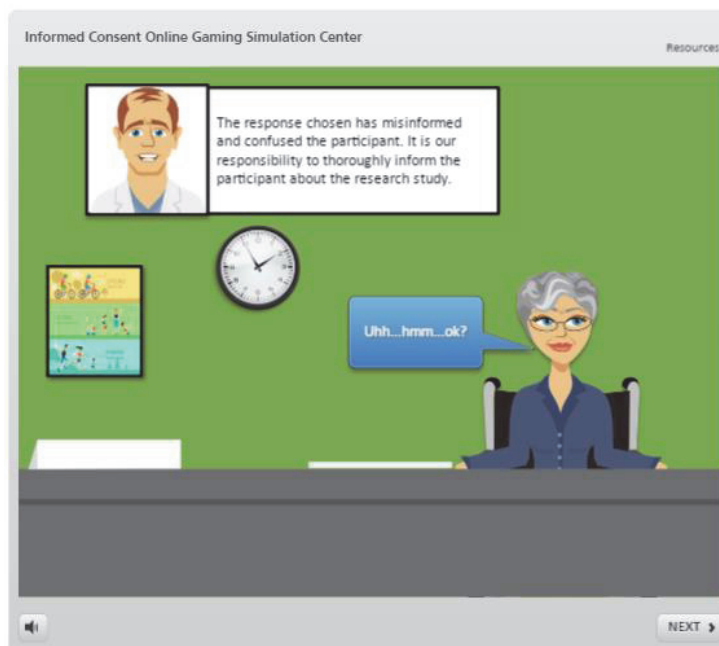
- Developer's view Level 3: Story view Building Rapport



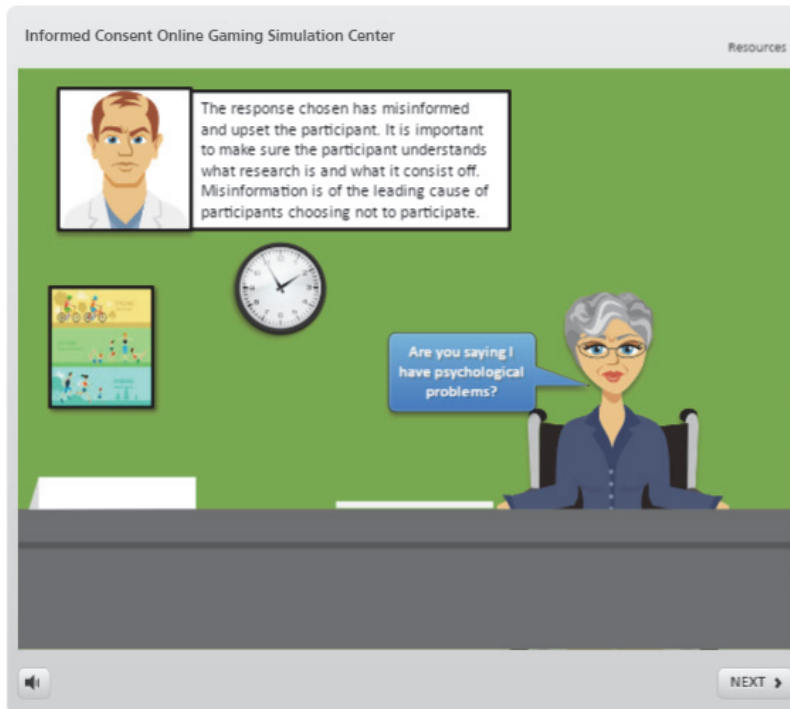
- Learner's view Level 3: Purpose and description of clinical research study with questions



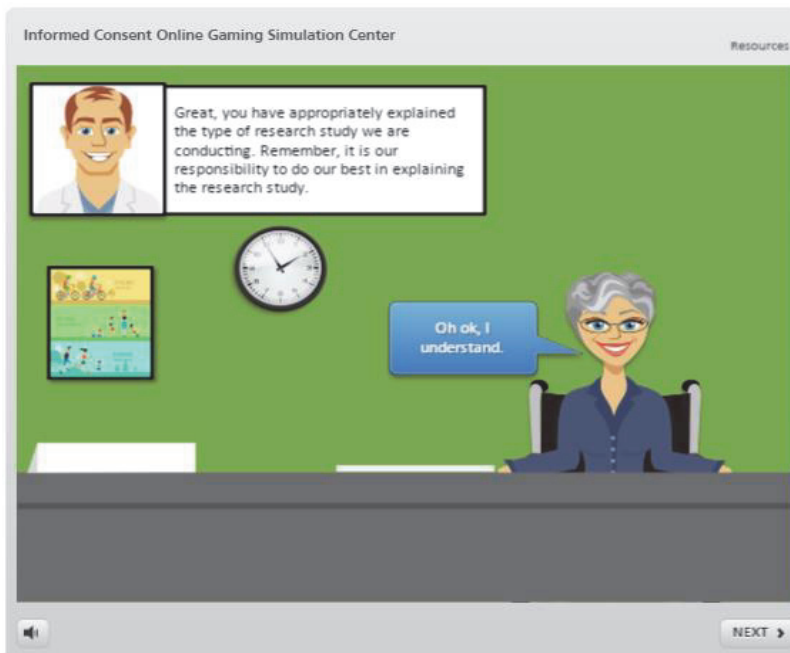
- Learner's view Level 3: Choice A result feedback



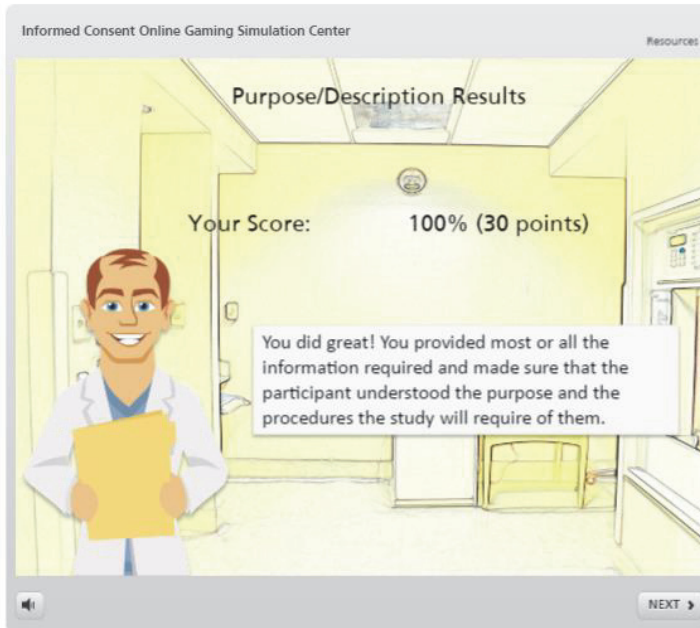
- Learner's view Level 3: Choice B result feedback



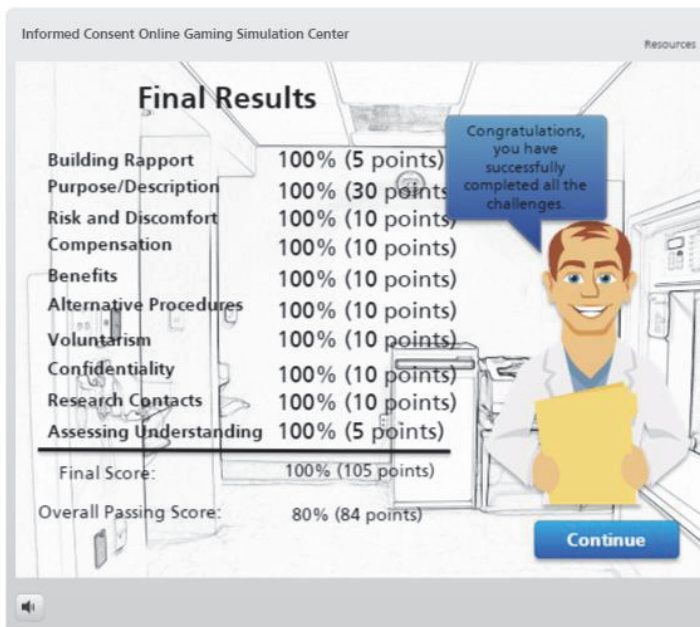
- Learner's view Level 3: Choice C result feedback



- Learner's view Level 3: Result page of required element- purpose and description



- Learner's view Level 3: Result page of ALL required elements



- Developer’s view Level 3: Result page of ALL required elements- triggers

The screenshot displays the 'Developer's view' of a simulation slide titled '19.1 Results Slide'. The main content area shows a slide with the following text:

Final Results

- Building Rapport
- Purpose/Description
- Risk and Discomfort
- Compensation
- Benefits
- Alternative Procedures
- Voluntarism
- Confidentiality
- Research Contacts
- Assessing Understanding
- Final Score:
- Overall Passing Score:

To the right of the text is a character illustration of a man in a white lab coat holding a yellow folder. The interface includes several panels:

- Scenes:** A list of slides including '19 Summary', '19.1 Results Slide', '19.2 Untitled Slide', and '19.3 Untitled Slide'.
- Timeline:** A horizontal axis from 1s to 14s with a table below it:

Character	Notes
Character 1	Niles
Text Box 28	%Results15.ScorePercent%% (%R...>
Text Box 27	Assessing Understanding
Text Box 26	%Results13.ScorePercent%% (%R...>
- Slide Layers:** Shows 'Failure' and 'Success' layers, with 'Results Slide (Base Layer)' selected.
- Triggers:** Contains icons for various actions like 'Show layer', 'When the timeline starts', and 'Submit results'.
- Slide Triggers:**
 - Show layer **Success** When the timeline starts If Results14.ScoreP...is Greater than or equal to Results14.PassPoints
 - Show layer **Failure** When the timeline starts If Results14.ScoreP...is Less than Results14.PassPoints
 - Submit results **19.1 Results Slide** When the timeline starts

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Appendix A

Clinical Research Professional Job Descriptions

Job Title	Job Description/Functions	Education Requirements
Behavioral Science Research Assistant	Performs basic level-specific activities related to research projects and studies. Assists with research projects within behavioral science. Registers study participants. Schedules and monitors study participation and attendance. Answers questions and corresponds with study participants. Conducts participant interviews and administers questionnaires. Handles biological specimens. Performs library research, data entry and coding.	Bachelor's degree in related field. No experience
Behavioral Science Research Coordinator	Performs intermediate level-specific activities in support of research projects and studies. Registers, schedules and monitors study participation and attendance. Schedules and conducts interviews with study participants and administers questionnaires. Conducts group or individual interventions with supervision. Performs basic data entry and coding. Assists with preparation of presentations. Prepares records and maintains reports. Formats protocols and coordinates project logistics. Handles biological specimens.	Bachelor's degree Two years of related experience
Epidemiology Research Coordinator	Provides administrative or managerial support in carrying out various research projects. Obtains and documents appropriate releases for medical research. Conducts patient interviews, including scheduling, performance and follow-up. Carries out research projects within Epidemiology. Manages and files study materials and data collection instruments. Coordinates schedule of multiple research interviewers. Manages participant relations, including eligibility determination, requests for participation and assistance with questions concerning studies. Records and evaluates data in accordance with methods requested.	Bachelor's degree with major course work in one of the basic or behavioral sciences Two years of related experience
Clinical Studies Coordinator	Provides administrative and patient care services for the coordination of clinical trials. Provides all study related coordination including writing, submission and maintenance of protocols. Develops and maintains a processing and tracking system for all protocol related paperwork. Develops patient care methodology for protocols, including criteria for patient participation. Coordinates FDA submissions and supervises clinical trial audits. Reviews patient eligibility of potential study cases and assists in obtaining consents. Follows patients on studies and maintains knowledge of adverse events. Submits information on adverse events to IRB and revises consents. Tracks protocol related labs, responses and research tests. Compiles protocol data for manuscript submission. Enters data into case report forms. Maintains necessary data for audits. Schedules patient tests, keeps patients informed about test results and studies. Collaborates with physicians, mid-level practitioners, research nurses, and data managers to document patient care. Trains other support staff in study coordination. Effectively conducts assigned operations of research protocols. Coordinates, evaluates and follows patient participation in clinical trials. Assists in the collection and evaluation of data. Under supervision of the medical staff and research nurse staff, performs protocol-specific tasks including screening, ordering tests, collecting specimens and study documentation of patient reported responses.	Bachelor's degree in Public Health, healthcare Administration or related scientific field Three years' experience in area of research study or direct patient care obtained nursing, data gathering or other related experience

Appendix B

Informed Consent Required Elements

Required Element	Description
Purpose and description of trial	A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
Risk, side effects and discomforts	A description of any reasonably foreseeable risks or discomforts to the subject.
Potential benefits	A description of any benefits to the subject or to others which may reasonably be expected from the research.
Alternative procedures/treatment	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
Confidentiality	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
Forms of compensation	For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
Research contacts	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
Voluntary/Right to refuse	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(U.S. Department of Health & Human Services, 2009)

Appendix C

Informed Consent Optional Elements

Optional Element	Description
Unforeseeable risk for special situations	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
Termination by investigator	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
Cost incurred, if applicable	Any additional costs to the subject that may result from participation in the research.
Consequence for withdrawal	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
New findings related to subject's participation	A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
Number of enrolled subjects	The approximate number of subjects involved in the study.

(U.S. Department of Health & Human Services, 2009)

VITA

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EDUCATION

May 2010	Bachelor of Science Prairie View A&M University Prairie View, Texas
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PROFESSIONAL EXPERIENCES

11/2017 - Current	Program Manager MD Anderson Cancer Center Houston, Texas
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07/2010 - 03/2012	Behavioral Science Research Assistant MD Anderson Cancer Center Houston, Texas

PUBLICATIONS

Berrios, J. (2016). Game On: Creatively using gaming to teach the informed consent process to clinical research professionals. *Proceedings of the Annual Meeting of the Association for Educational Communications and Technology*, 39(2): 173-176.