The Effect of Immediate Versus Delayed Debriefing on Basic Life Support Competence In Undergraduate Nursing Students.

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October 5, 2023

Instructions:

1. Complete **all** sections of the protocol template. By clicking on headers in the Table of Contents below, the form will navigate you directly to that section.
2. If a section does not apply, list Not Applicable as advised.
3. Refer to documents, templates, checklists, SOPs, and worksheets as advised throughout the protocol in **Blue**. Each document referred to in blue contains a hyperlink to the RAP library to obtain the documents (CONTROL + CLICK)
4. Please ensure that your RAP Profile is up to date with your correct email address, phone number, and a current CV/Resume.
5. Upload this completed document into a New Study Submission in RAP (https://rap.irb.uc.edu/irb), on the Basic Information Page under "Protocol".

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STUDY SUMMARY:

PROTOCOL TITLE:	The Effect of Hot and Cold Debriefing on Basic life Support Competence And Reflection In Undergraduate Nursing Students.
PRINCIPAL INVESTIGATOR:	FAHAD ALANEZI, BSN, MSc
VERSION NUMBER/DATE:	Version 3 07/19/2023
SHORT TITLE:	The Effect of Hot and Cold Debriefing on Undergraduate Nursing Students.
RESEARCH INTERVENTION(S)/ INVESTIGATIONAL AGENT(S):	Debriefing intervention
IND/IDE #:	N/A

STUDY SPECIFIC ABBREVIATIONS/ DEFINITIONS:

PI: Principal Investigator

BLS: Basic Life Support

CPR: Cardiopulmonary Resuscitation

AHA: American Heart Association

CITI: Cincinnati Collaborative Institutional Training Initiative

CON: University of Cincinnati College of Nursing

CATER: Center for Academic Technology & Educational Resources

CCTST:Center for Clinical and Translational Science and Training

REDCap: Research Electronic Data Capture.

RCT: Randomized Controlled Trial

PEARLS: Promoting Excellence and Reflective Learning in Simulation

DES: The Debriefing Experience Scale

QR: Quick Response

BSN: Bachelor of Science in Nursing

IRB: QR Institutional Review Board

FUNDING SOURCE	The PI plans to apply for an internal fund soon. If the fund is not approved, the PI will self-fund the study.	
FUNDING LOCATION	☐	**Funds are held in Sponsored Research Services for a Grant or Contract (funds are held internally at UC)**
	☐	**Funds are from a department account (held internally at UC)**
	☐	**Funds held in a corporate account from a Contract (funds held externally from UC)**
	☒	**No funding**

PROTOCOL:

1.0 OBJECTIVES	**1.1 Describe the purpose, specific aims, or objectives.** For phase 1, quantitative part: Specific aim 1: Identify the efficacy of cold versus hot debriefing in (Basic Life Support) BLS training for undergraduate nursing students' BLS competence. Specific aim 2: Assess the impact of hot and cold debriefing on senior or third year nursing students' debriefing experience. For phase 2 qualitative part: Specific aim 3: Explore the experiences of undergraduate nursing students who used the cold and hot debriefing style in BLS training. Specific aim 4: To identify the similarities and differences in reflective thinking between undergraduate nursing students who used hot and cold debriefing.
	1.2 Describe the hypotheses to be tested. Hypothesis 1a: In both cold and hot debriefing groups, there is a significant difference in the BLS competence of undergraduate nursing students between pre-intervention and post-intervention. Hypothesis 1b: Undergraduate nursing students who have cold debriefing will show greater BLS competence than those who receive hot debriefing. Hypothesis 2: There is a significant difference in debriefing experience scores of undergraduate nursing students between hot and cold debriefing.
2.0 BACKGROUND	**2.1 Describe the relevant prior experience and gaps in the current knowledge.** Cardiac arrest is one of the leading causes of death globally; the number of out-of-hospital cardiac arrests in the U.S. exceeds 356,000 per year. Nearly 90% of them are fatal (Tsao et al., 2022). Over the years, cardiopulmonary resuscitation (CPR) has been proven to be associated with patient survival (Oermann et al., 2020). The American Heart Association (AHA) and European Resuscitation Council recommend high-quality CPR following a cardiac arrest to improve patient outcomes and survival rates (Cheng et al., 2018; Wolfe et al., 2014). Basic Life Support (BLS) is an essential element in simulation for nursing students. The primary goal of BLS is to enable nurses to provide resuscitation to individuals experiencing cardiac or pulmonary arrests (The Association for the Advancement of Sustainability, 2019). According to the literature, even if undergraduate nursing students are BLS certified, they frequently lack the comprehensive knowledge and competence of BLS (Oermann et al., 2020). This lack of knowledge and competence can be

affected by the type and effectiveness of the debriefing provided to the students after the BLS simulation session (Couper & Perkins, 2013).

Debriefing is an essential component of simulation-based learning to achieve desired learning outcomes through student self-reflection and constructive discussion with instructors or peers. (Cheng et al., 2015; Kim & De Gagne, 2018; Sawyer et al., 2016; Sweberg et al., 2018). Yun and Kang (2022) conducted an integrative review where they highlighted various types of debriefing, and its effect on nursing education, except for the effectiveness of hot and cold debriefing. Results of the review by Yun and Kang (2022) could not conclude whether hot or cold debriefing is better than the other due to the scarcity of the paper investigating this concept. In the literature, "hot" debriefings occur within minutes to hours of the simulation, whereas "cold" debriefings occur within days to weeks (Couper & Perkins, 2013). Hot debriefing could identify and address several reported care errors, including delays in treatment defibrillation, airway insertion, drug administration, equipment issues, and suboptimal leadership (Couper & Perkins, 2013). However, without the instant availability of a CPR code summary, hot debriefing is unlikely to have a significant influence on CPR quality (Couper & Perkins, 2013). Furthermore, an inadequate emotional preparedness of learners to debrief might be a disadvantage with hot debriefing (Kessler et al., 2015). Nevertheless, cold debriefing provides some significant advantages to hot debriefing. Firstly, because meetings take place many days after the resuscitation attempt, performance data can be gathered, analyzed, and integrated into the debrief (Couper & Perkins, 2013; Kessler et al., 2015). Therefore, this gap enables learners to reflect on their performance during the resuscitation event. Another advantage of cold debriefing is that the debriefing data is available for all of the learners, and they can learn from each other's experiences (Couper & Perkins, 2013; Kessler et al., 2015). In addition, the data of cold debriefing can be gathered by video recording, performance summary, and defibrillator downloads (Couper & Perkins, 2013; Kessler et al., 2015). Yet, cold debriefing has limitations that include the necessity to schedule additional time and space for debriefing, the requirement to assemble students who participated in the simulation to debrief, and the risk of forgetting simulation events (Kessler et al., 2015).

2.2 Describe any relevant preliminary data.

Not Applicable

2.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge.

Nurses must be knowledgeable and skilled in BLS to provide positive outcomes in terms of patient survival after cardiopulmonary arrest (Pareek et al., 2018). Not only is the BLS training a vital subject for nurses but also it is required for practicing nurses. A study conducted by Pareek et al. (2018) aimed to identify the efficacy of BLS training for nurses on the mortality rate and discovered that the percentage of return of spontaneous circulation increased from 19.7% pre-intervention to 30.1% post-intervention (P = 0.003).

	In order to have a well-structured simulation experience, debriefing plays an essential role in the learning process. It improves the performance of individuals, teams, and systems (Abulebda et al., 2022). In simulation training, debriefing is one of the essential tools recommended following cardiopulmonary arrest events (Abulebda et al., 2022). Yet, more than 70% of participants who witnessed CPR did not debrief post-CPR events (Khpal & Coxwell Matthewman, 2016). Additionally, although AHA recommends debriefing for BLS, debriefing is still delivered in hot format or not delivered at all (Couper & Perkins, 2013). Thus, this proposed study will shed light on the importance of debriefing by comparing the efficacy of hot and cold debriefing on undergraduate nursing students' BLS competence and which debriefing method appears to be more advantageous from students' perspectives of their learning experience. Even though other studies investigated the significance of cold debriefing (Wolfe et al., 2020), none of the studies recruited nursing students**.** Moreover, novice learners lack context compared to proficient staff who have the context (Persky & Robinson, 2017). It is anticipated that results from this study will determine the efficacy of hot and cold debriefing styles on novice learners, the significance of debriefing to the simulation experience, and assist in improving the way we debrief in nursing education. Hence, conducting larger scale studies to further test the efficacy of hot and cold debriefing will be recommended. Moreover, the study will identify vital themes that will emerge from nurses in the qualitative part. Qualitative findings will enable us to explore the experiences and differences in the reflective thinking of undergraduate nursing students who used the cold versus hot debriefing style in BLS training. The outcomes of this study will advance nursing education in the way we teach undergraduate students about BLS. Thus, having competent nurses will positively impact patient outcomes (Pareek et al., 2018).
3.0 RESOURCES AVAILABLE	**3.1 Describe the resources available to conduct the research. Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period, e.g. how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?**
	There are a total of 183 senior undergraduate nursing students and 204 third year undergraduate nursing studets. Based on G*Power 3.1, the recommended sample size will be 26 participants in each group. Still, because there is a possibility that participants may withdraw from the study, the total number will be 30 participants in each group.
	3.2 Describe the time that you will devote to conducting and completing the research, i.e. percent effort.
	The PI will devote 100 percent of his time to this study.
	3.3 Describe the availability of medical of psychological resources that subjects might need as a result of an anticipated consequences of the human research.
	The potential participants will not be expected to expose more than what they might face in a simulation experience that they are familiar with. In case they feel uncomfortable or distressed in the study, they can stop, take a break, and re-join. If they want to withdraw

at any time, they can. In case of persistent stress or discomfort, the students' wellbeing center is ready to help them.

3.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

All members of the study team will be required to complete the web-based University of Cincinnati Collaborative Institutional Training Initiative (CITI) program. Additionally, the study team will be informed about the study protocol, the research procedures, and personnel's respective duties and functions. The study team will meet at least once bi-weekly to discuss the study progress. The study team will sign a conflict-of-interest form and provide their current CITI certification

3.5 Describe the facilities you have access to that will allow you to conduct the research.

The setting of the study will be held in the simulation Lab at the University of Cincinnati (UC) College of Nursing (CON). The CON has a large skills lab comprised of three rooms located on the 1st floor and a simulation collaboratory located on the 3rd floor.

The PI has a private office at the CON with telephones for subject enrollment and laptop computers using Microsoft Office Software and JMP statistical software. The laptops are connected to the UC Academic Health Center Server and is internet accessible. The PI has access to a secure computer research server for data storage. There is convenient access to facsimile transmission, e-mail, and photocopying equipment. Administrative assistance is also available.

Center for Academic Technology & Educational Resources (CATER), which provides a variety of communication and technology services to faculty, staff and students. CATER includes a staff of 9 full-time individuals (instructional designers and information technology specialists). The CON has received national recognition as an Apple Distinguished Program. CATER provides services including but not limited to desktop support, help desk support, server administration, eLearning, instructional design, classroom technology, web design/administration, group and one-to-one training, technology seminars and workshops, and continuing education training. The CON has a separate, secured research server for the storage of all research data which is administered by CATER according to University of Cincinnati policies and procedures.

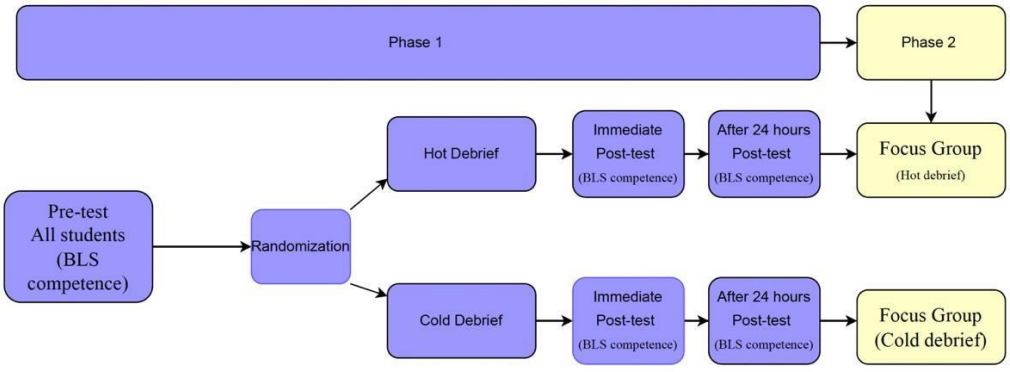
Center for Clinical and Translational Science and Training (CCTST) at the University of Cincinnati:
• Data management tools, including REDCap
University of Cincinnati Libraries
• Off campus access to electronic resources
• Interlibrary loan and document delivery

	• Collections of books, journals, audiovisuals, and electronic publications
4.0 INVESTIGATOR EXPERIENCE	**4.1 Detail the investigators' experience as it pertains to the study.** PI: Fahad Alanezi is a PhD Candidate at the University of Cincinnati College of Nursing. He has previous experience in the cardiology field, particularly in cardiac ICU nursing. With a master's degree in Critical Care, Mr. Alanezi has honed his research skills, which he demonstrated in a published systematized review that required extensive literature review, critical appraisal, and data synthesis. Mr. Alanezi is skilled in teaching in the cardiac ICU setting and has a keen interest in nursing education. To improve his research skills, Mr. Alanezi has taken various courses, including philosophy, theory construction, statistics, qualitative, quantitative, and experimental courses. He has also worked as a research assistant with Dr. Miller and Dr. Weber, who are both working on funded grant studies. Collaborators: Dr. Elaine Miller is a professor at the University of Cincinnati College of Nursing. Dr. Robin Wagner is an Associate Professor Educator at the University of Cincinnati College of Nursing. Dr. Caroline Morrison is an assistant professor at the University of Cincinnati College of Nursing. Dr. Benjamin Kelcey is a professor at the University of Cincinnati College of Educational Studies. My Dissertation Chair is Dr. Elaine Miller. Dr. Miller is a Fellow in both the American Academy of Nursing and the American Heart Association. She is certified in rehabilitation nursing and gerontological nursing. At the University of Cincinnati, College of Nursing, Dr. Miller is a professor and teaches primarily PhD and master students, has extensive experience teaching online courses, and creating effective simulated learning experiences. She has experience in simulation study designs and has guided several students previously who worked on their projects related to simulation. Therefore, she will be a valuable and experienced collaborator in my study. Dissertation committee member is Robin Wagner. She has extensive experience in simulation pedagogy. She will be a vital collaborator based on her expertise in simulation pedagogy. If I want to design a simulation intervention, Dr. Wagner can create a simulation intervention based on the simulation standards. Dissertation committee member is Dr. Caroline Morrison. Phase 2 of the study will be the qualitative part, and Dr. Morrison has extensive experience in qualitative methodology. Therefore, Dr. Morrison will supervise and guide the PI on the qualitative aspect in terms of qualitative design, data collection, and analysis.

	Dissertation committee member is Dr. Benjamin Kelcey. Dr. Kelcy is a statistician and a professor of quantitative research methodologies. Dr. Kelcy will supervise and guide the quantitative part regarding study design, power calculation, and statistical analysis.
5.0 STUDY ENDPOINTS	**5.1 Describe any primary and secondary study endpoints.**
	Primary endpoint is the completion of phase 1 (quantitative part) Aim 1: Identify the efficacy of cold versus hot debriefing in BLS training for undergraduate nursing students' BLS competence. Aim 2: Assess the impact of hot and cold debriefing on senior or third year nursing students' debriefing experience. Secondary endpoint is completion of phase 2 (qualitative part) Aim 3: Explore the experiences of undergraduate nursing students who used the cold and hot debriefing style in BLS training. Aim 4: To identify the similarities and differences in reflective thinking between undergraduate nursing students who used hot and cold debriefing.
	5.2 Describe any primary and secondary safety endpoints.
	Not Applicable.
6.0 PROCEDURES INVOLVED	**6.1 Thoroughly describe the study design.**
	This study consists of two phases. Phase 1 will be a randomized controlled trial (RCT). Having a controlled group is the gold standard to measure the efficacy of an intervention (Polit & Beck, 2021). RCTs provide the most persuasive evidence on whether one variable has a causal influence on another. RCTs' main strength is the certainty with which causal links may be determined. Kolb's learning theory serves as the underpinning for this study (Kolb & Kolb, 2009; Kolb, 1984). Manipulation: The researcher will do a cold debriefing (after one-day post-simulation) for undergraduate nursing students in the intervention group. Control: The control group will do a hot debriefing (immediately after the simulation). Randomization: The researcher will assign the participants to a control or experimental based on number generator. Once participants complete Phase 1, we will record their progress on REDCap. If they chose to only participate in Phase 1, we will mark their status as "completed" on REDCap. If they expressed interest in Phase 2, we will randomly select 16 participants from the pool based on a number generator and update their status on REDCap for Phase 2. Outcome: The study outcome is BLS competence level. The competence level will be measured AHA (2020) BLS competency Checklist. First, the control and experiment groups will complete a pre-test on BLS competence. Both groups will do a pre-test. After finishing

the pre-test, we will do the randomization process. Then the intervention group will receive (cold debriefing); the control group will have the (hot debriefing). Both groups will do the post-test immediately after the debriefing session and another post-test after 24 hours of the first post-test.

For phase 2, we will do a qualitative descriptive design with focus groups interview. Themes relating to hot and cold debriefing will be generated using a focused qualitative interview technique. Focused interviews are loosely structured interviews in which the interviewer guides the participant through a set of questions (Polit & Beck, 2021). Throughout the guide, participants are encouraged to share their own experiences and discuss all topics freely. Researchers can obtain all necessary information utilizing this technique, and participants will have the capability to provide illustrations and explanations (Polit & Beck, 2021).



6.2 Detail the procedures being performed, specifically the interaction or intervention with human subjects and/or their identifiable information. Please be clear and concise and provide information relevant to the current study. For example, please be sure that what will be done for this research is explained and differentiated from activities that have already taken place or will be submitted for future review. Please note that details about recruitment and consent are asked in later questions.

Potential participants will access the REDCap link to answer the eligibility questions (1) if they are above 18 years of age and (2) if they are senior or third year undergraduate nursing students. If they are eligible, they will enter their demographic on REDCap. After that, The PI will assign the participants to a hot or cold debriefing group based on a number generator. Participants will do a baseline BLS competence where they will do a simulation experience related to the competence of BLS, which is conducted as part of the study design. There will be a scenario about a nurse taking care of their client at a hospital, and when the nurse enters the client's room to check on their client, they find that their client is unresponsive. Nursing students are expected to start the process of Basic Life support. Nursing students are expected in the simulation to check the client's

responsiveness, activate the cardiopulmonary arrest code, begin cardiopulmonary resuscitation, and give 30 compressions and 2 breaths. They will attach an automated external defibrillator and follow the instruction of the machine. The total scenario will last up to 5 minutes.

Another interaction with participants will be the debriefing experiences, where students will do a group debriefing. Afterward, participants in the hot debrief group will do their post-test immediately after their debrief on the same day as the simulation, and another post-test after 24 hours of the first post-test. And then, the cold debrief participants will do the simulation, wait 24 hours, have the debrief, and will do an immediate post-test, and another post-test after 24 hours of the first post-test. The simulation will be conducted in order to complete the BLS assessment checklist at baseline, post-test, and second post-test. The same simulation and BLS Assessment checklist will be conducted at baseline, post-test, and second post-test. The BLS competence and DES will be administered online via REDCap. During the qualitative phase, participants will engage in a focus group which will be the final interaction. Random sampling will be used to select subsamples from both hot and cold groups for the focus group..

6.3 Describe procedures being performed to monitor subjects for safety or minimize risks.

The study carries minimal risk. Potential participants will not be expected to expose more than what they might face in a simulation experience that they are familiar with. Participants will be informed that they can choose to participate or not and can withdraw at any time. They can also decline to answer any questions that make them uncomfortable. The PI will receive training from the Co-PI/Faculty Advisor to monitor participants for any psychological stress during study phases. The PI and Co-PI/Faculty Advisor will meet weekly to discuss interactions with participants and ensure that the procedures for managing data protect confidentiality.

6.5 Where applicable, list and describe the data collection tools such as surveys, data collection forms, etc. All tools described should be uploaded in the RAP Smart Form on the Local Site Documents page unless they are standardized, validated tools.

For Phase 1

(A) Demographic

(B) BLS Competence Checklist

The baseline BLS Competence level will be measured via the AHA (2020) BLS competency checklist. The BLS Competence assessment will be conducted by the primary investigator and/or Dr. Wagner (Co-PI). All of the tests (Baseline, post-test, and second post-test) will be measured by the same tool of the AHA (2020) BLS competency checklist. The simulation will be conducted in order to complete the BLS assessment checklist at baseline, post-test, and second post-test. The same simulation and BLS Assessment checklist will be conducted at baseline, post-test, and second post-test.

(C) Debriefing Tool

(D) The Debriefing Experience Scale

Phase 1

Construct	Measure name	Minutes to complete	Baseline	Debriefing	Immediate Post test	24-hours post-test
(A) Demographics	Demographic (6 items) age, gender, Race, ethnicity, Finished credits hours, GPA, BLS certificate.	5 minutes	X			
(B) BLS Competence level	AHA (2020) BLS competency Checklist. there are 15 items, for each item 0 (not done or done incorrectly) and 1 (done correctly).	5 minutes	X		X	X
(C) Debriefing Tool	The PEARLS Healthcare Debriefing Tool The tool has five domains (Bajaj et al., 2018) : (1) Setting the Scene, (2) Reactions, (3) Description, (4) Analysis, and (5) Application/Summary	10 minutes		X		

	(D) Debriefing Experience Scale	The Debriefing Experience Scale (DES) (Reed, 2009, 2012) 20 items in total and was split into four subscales: (1) Analyzing Thoughts and Feelings; (2) Learning and Making Connections; (3) Facilitator Skill in Conducting the Debriefing; and (4) Appropriate Facilitator Guidance (Reed, 2009, 2012). The items on the scale were rated in two different areas: the "experience" for the student and the "importance" of the simulation experience (Reed, 2009). The 20 items were scored on a Likert scale of 1 (strongly disagree) to 5 (strongly agree) (Reed, 2009).	10 minutes		X		
	Total minutes	Total data collection minutes each visit	30	10	20	5	5
	Phase 2						
	The data collection will use a Semi-structured interview, the most common sort of interview used in this methodology, and it is the primary method of data collection (DeJonckheere & Vaughn, 2019). It will be included open-ended questions related to the participants' overall experience in terms of emotions, feelings, challenges, and learning. All the interviews will be conducted in a private place, and the PI will do all the interviews so the participants' interactions and questions will be consistent. The general initial questions will be the same for the hot and cold debriefing group are: (1) Tell me about your experience with simulation and what that's looked like for you? (2) Tell me about your experience in debriefing?						

(3) What did you like in debriefing?

(4) How did debriefing help you to reflect on your simulation experiences?

(5) Did you face any challenges during your experience?

(6) What did you not like with debriefing?

(7) How has debriefing impacted your ability to learn concepts or attain competency in you nursing skills.

(8) How did debriefing impact your confidence in performing at the bedside?

(9) Do you have any advice for educators who are designing simulation scenarios?

(10) Is there anything else you would like to share?

6.6 Describe all data that will be accessed and collected during the study and how that data will be obtained (how it will be accessed).

All data that will be accessed and collected during the study is described in Section 6.5 above.

The PI will ask permission from the student affairs office of the undergraduate nursing student to send an email to potential participants. Potential participants will be contacted via the UC email, and we will post flyers in the simulation lab at the CON. Potential participants will access the REDCap link or scan the QR code to answer the eligibility questions (1) if they are above 18 years of age and (2) if they are senior or third year undergraduate nursing students. The potential participant will also indicate in REDCap if they want to participate in phase 2 (focus group). In case there are over 16 participants who want to participate in phase 2, we will randomly choose 8 participants from the hot debriefing group and another 8 participants from the cold debriefing group. If they are eligible, they will enter their contact details, such as their name, email, and phone number(s) on REDCap. Alternatively, they may also contact the PI via email or phone. Once a potential participant's response is received, the PI will contact them to verify their eligibility and contact information.

For phase 1:

The quantitative data will be stored electronically in the University of Cincinnati's server using REDCap, which offers several features, including a user-friendly interface for validated data entry, audit trails to track data manipulation and user activity, automated export procedures for seamless data downloads while maintaining confidentiality, and importing data from external sources. REDCap will be used to securely manage the electronic data collected during the study, and only authorized personnel will be given access. The university backs up REDCap nightly. To ensure confidentiality, study ID numbers will be generated for data analysis to protect the participants' identity in the final data set. REDCap will be used to efficiently export de-identified data to statistical software packages.

For phase 2:

Audio recordings will be captured through an audio recording device - EVIDA V618 portable digital voice recorder. After that, audio recordings will be saved to an encrypted drive that is password protected and

	backed up daily. All electronic devices will be secured and have anti-virus software. All the paper notes will be scanned and saved as digital files. After scanning the papers, they will be destroyed by shredding immediately. Audio recordings will be transcribed by an independent transcriptionist who will de-identify the transcripts. We will not collect any private identifiable information from participants (other than audio transcripts).
	6.7 If there is a long-term follow-up plan (once all research related procedures are completed), what data will be collected during this period.
	This section is not applicable
7.0 DATA AND SPECIMEN BANKING	**7.1 If data or specimens will be banked for future use, describe where the data or specimens will be stored, how the data or specimens will be accessed, and who will have access to the data or specimens.**
	All data will be deleted after the study concludes as the UC data retention policy allows.
	7.2 If specimens are being stored, list the data to be stored or associated with each specimen.
	Not Applicable
	7.3 Describe the procedures to release data or specimens, including: (the process to request a data/specimen release, approvals required for release, who can obtain data or specimens, and the data to be provided with the specimens.
	Not Applicable
8.0 SHARING OF RESULTS WITH SUBJECTS	**8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe the process for sharing. If you do not intend to share any results, please state that here.**
	Results will be available to participants and the community. All data and results will be de-identified and in aggregate format.
9.0 STUDY TIMELINES	**9.1 Describe the duration of an individual subject's participation in the study. List the number of study visits or frequency of study visits.**
	Phase 1: The participants will be asked to fill in the demographic data (5 minutes). Baseline BLS Competence level (5 minutes). After that, PEARLS Healthcare Debriefing Tool will (10 minutes). After debriefing, students will complete a survey about their debriefing experience (10 minutes). Finally, a post-test BLS Competence level (5 minutes) and another post-test BLS Competence level after 24 hours for both groups (5 minutes).

	Phase 2: 45-60 minutes of focus group interview.
	9.2 Describe the timeline allotted for the enrollment of subjects.
	From 08/24/23 to 11/01/23
	9.3 Describe the estimated date for the investigators to complete this study (complete primary analysis).
	We estimate that data analysis will be completed by May 1, 2024.
10.0 INCLUSION AND EXCLUSION CRITERIA & VULNERABLE POPULATIONS	**10.1 Describe how subjects will be screened for eligibility.**
	The PI will ask permission from the student affairs office of the undergraduate nursing student to send an email to potential participants. Potential participants will be contacted via the UC email, and we will post flyers in the simulation lab at the CON. Potential participants will access the REDCap link or scan the QR code to answer the eligibility questions (1) if they are above 18 years of age and (2) if they are senior or third year undergraduate nursing students. The potential participant will also indicate in REDCap if they want to participate in phase 2 (focus group). In case there are over 16 participants who want to participate in phase 2, we will randomly choose 8 participants from the hot debriefing group and another 8 participants from the cold debriefing group. If they are eligible, they will enter their contact details, such as their name, email, and phone number(s) on REDCap. Alternatively, they may also contact the PI via email or phone. Once a potential participant's response is received, the PI will contact them to verify their eligibility and contact information.
	10.2 Describe/list the inclusion/exclusion criteria for the study.
	Senior or Third Year Undergraduate Nursing students who are above 18 years old.
	10.3 Indicate specifically whether you will include each of the following vulnerable populations. Check all that apply. (You may not include members of the below populations as subjects in your research unless you indicate this in your inclusion criteria and are approved by the IRB to include them in your research) The member checklists are for reference only to ensure you provide appropriate safeguards and justification. The checklists do not need to be completed.
	☐ **Adults unable to consent (cognitively impaired individuals)** (**HRP-417 – MEMBER CHECKLIST Cognitively Impaired**)
	☐ **Individuals who are not yet adults (infants, children, teenagers)** (**HRP-416 – MEMBER CHECKLIST Children**)
	☐ **Individuals who are not yet adults and are, or may become, wards of the state.**
	☐ **Pregnant women (a woman shall be assumed pregnant if she exhibits and of the presumptive signs of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.)** (**HRP-412 MEMBER CHECKLIST Pregnant Women**)
	☐ **Non-Viable Neonates (HRP-413 – MEMBER CHECKLIST Non-Viable Neonates)**
	☐ **Uncertain Viability Neonates (HRP-414 – MEMBER CHECKLIST Uncertain Viability Neonates)**

	☐ **Prisoners (HRP-415 – MEMBER CHECKLIST Prisoners)**
	10.4 If the research involves individuals listed in 10.3 or other individuals who are vulnerable to coercion or undue influence, please justify based on the applicable checklist and describe additional safeguards included to protect their rights and welfare.
	Not Applicable.
	10.5 If the research involves or may involve individuals who are students or employees where the research is taking place, please describe additional safeguards included to protect their rights and welfare.
	The academic performance will not be impacted if they choose not to participate. The primary PI is not a faculty member at UC-CON and has no direct relationship with participants. They will not be expected to expose more than what you might face in a simulation experience that they are familiar with. In case they feel uncomfortable or distressed in the study, they can stop, take a break, and re-join. If they want to withdraw at any time, they can. In case of persistent stress or discomfort, the students' wellbeing center is ready to help them.
11.0 NUMBER OF SUBJECTS	**11.1 Indicate the total number of subjects to be accrued.**
	The total number of subjects to be accrued is 60 senior or third year undergraduate students.
	11.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures.
	We will over-recruit and enroll (60 potential participants) to account for 15% attrition.
12.0 RECRUITMENT METHODS	**12.1 Describe when, where, and how potential subjects will be recruited.**
	On 08/24/23, the PI will ask permission from the student affairs office of the undergraduate nursing student to send an email to potential participants. Potential participants will be contacted via the UC email, and we will post flyers in the simulation lab at the CON. Potential participants will access the REDCap link or scan the QR code to answer the eligibility questions (1) if they are above 18 years of age and (2) if they are senior or third year undergraduate nursing students. The potential participant will also indicate in REDCap if they want to participate in phase 2 (focus group). In case there are over 16 participants who want to participate in phase 2, we will randomly choose 8 participants from the hot debriefing group and another 8 participants from the cold debriefing group. If they are eligible, they will enter their contact details, such as their name, email, and phone number(s) on REDCap. Alternatively, they may also contact the PI via email or phone. Once a potential participant's response is received, the PI will contact them to verify their eligibility and contact information. We will track participants' participation on REDCap. Participants who do not want to participate in phase two will indicate that on REDCap. Participants who want to participate in phase 2 will indicate that in REDCap. In case there are over 16 participants who want to participate in phase 2, we will randomly choose 8 participants from the hot debriefing group and another 8 participants from the cold debriefing group.

	12.2 Describe the source of the subjects.
	The PI will ask permission to post on the UC-CON BSN Canvas site and have interested students who are at the senior or third year level contact them. Also, the PI will post flyers in the simulation center at the CON.
	12.3 Describe the materials that will be used to recruit subjects. (Attach copies of these documents in the Recruitment section on the local site documents page in RAP. For advertisements, attach the final copy of printed advertisements (avoid making copies until approved in case modifications are required). When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape)
	To recruit participants, various materials will be employed, including flyers with multiple response options such as QR codes, REDCap links, and direct contact information of the PI mentioned on the flyers. The flyers will consist of the study's title, objectives, eligibility criteria, PI's name, and contact details such as email and phone number. Additionally, a QR code will also be provided on the flyer.
13.0 COMPENSATION FOR SUBJECTS	**13.1 Describe the amount, method, and timing of payments to subjects.**
	Phase 1: -Hot Debriefing Participants: Day One (Baseline, Immediate Debriefing, Post-Test): $25 Amazon gift card will be sent via email after completing baseline. Second Post-Test (after 24 hours of the first post-test): $20 Amazon gift card will be sent via email after completing second post-test. -Cold Debriefing Participants: Day One (Baseline): $25 Amazon gift card will be sent via email after completing baseline. Following Day (Debrief and Post-Test): $25 Amazon gift card will be sent via email after completing debrief and post-test. Second Post-Test (after 24 hours of the first post-test): $20 Amazon gift card will be sent via email after completing second post-test. -Phase 2 (Qualitative Phase): $25 Amazon gift card will be sent via email after completing the qualitative interview. Participants who choose to withdraw at anytime during the qualitative study will also receive a $25 Amazon gift card will be sent via email. Total for hot debriefing in phase 1 ($45) Total for cold debriefing in phase 1 ($70) Total of hot debriefing in phases 1 and 2 ($70) Total of cold debriefing in phases 1 and 2 ($95)

	The cold debriefing group will need 3 days to complete phase 1, while hot debriefing will need only 2 days to complete phase 1. Both the hot and cold debriefing groups have the same time for participation; however, the cold group will need to arrive 24 hours after the simulation experience. Participants in the cold group will require additional time for transportation and scheduling a different day for the research activity. Therefore, the PI will give an additional $25 Amazon giftcard to compensate.
14.0 WITHDRAWAL OF SUBJECTS	**14.1 Describe the anticipated circumstances under which subjects will be withdrawn by the study team from the research without their consent.**
	Because this study presents a minimal risk, it is not anticipated that any potential participants will be withdrawn from the study. In case they feel uncomfortable or distressed in the study, they can stop, take a break, and re-join. Participants have the right to withdraw themselves from the study at any time and will never be persuaded to participate in research activities that they refuse. If participants refuse any part of the study, that data will be considered missing. Study participants will be withdrawn by the study team without their consent if the study team cannot contact them to complete phase 1 of the study. Participating to phase 2 is optional, if a participant completes Phase 1 but cannot be contacted to complete Phase, their Phase 1 data will not be deleted.
	14.2 Describe any procedures for orderly termination.
	The participants have the liberty to withdraw from the study at any point, and the study team can also withdraw them if they cannot be contacted. Participants can inform the PI of their decision to withdraw verbally, via voicemail, or email. If the study team is unable to contact a participant, they may receive a voicemail stating that they have been withdrawn from the study due to non-contactability.
	14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection, withdrawal of previously collected data upon request, etc.
	Potential participants have the right to withdraw themselves from the study at any time, and will never be persuaded to participate in research activities that they refuse. If potential participants refuse any part of the study, further data collection will be stopped, and that data will be considered missing. Previously collected data will be withdrawn upon request.

15.0 RISKS TO SUBJECTS	**15.1 Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. It may be useful to include: a description of the probability, magnitude, duration, and reversibility of the risks. Consider the physical, psychological, social, legal, and economic risks.**
	Their academic performance will not be impacted if they choose not to participate. The primary PI is not a faculty member at UC-CON and has no direct relationship with participants. They will not be expected to expose more than what they might face in a simulation experience that you are familiar with. In case they feel uncomfortable or distressed in the study, they can stop, take a break, and re-join. If they want to withdraw at any time, they can. In case of persistent stress or discomfort, the students' wellbeing center is ready to help them.
	15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
	Not Applicable
	15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject or the subject's partner be or become pregnant.
	Not Applicable
	15.4 If applicable, describe risks to those who are not subjects.
	Not Applicable
	15.5 Describe the procedures and actions taken to mitigate the risks to subjects and others.
	Their academic performance will not be impacted if they choose not to participate. The primary PI is not a faculty member at UC-CON and has no direct relationship with participants. They will not be expected to expose more than what they might face in a simulation experience that you are familiar with. In case they feel uncomfortable or distressed in the study, they can stop, take a break, and re-join. If they want to withdraw at any time, they can. In case of persistent stress or discomfort, the students' wellbeing center is ready to help them. To maintain confidentiality, a study ID number will be used instead of actual names on all research forms. All data will be kept on password-protected secure REDCap and OneDrive at the University of Cincinnati. The contact details of the participant will be stored within REDCap and Microsoft Outlook for UC. After verifying the accuracy of the transcripts, PI will proceed to destroy all digital recordings. After the analysis and distribution of data, the study will be finalized, and any identifiable information will be removed. The remaining data will be stored on a secure, password-protected research OneDrive, which only the PI and faculty advisor can access. All research data will be de-identified. Investigators' usernames and passwords are required to access the data in REDCap. The audio recordings will be held at a private place in the UC College of Nursing or in a secure virtual room. The audio recordings of a qualitative focus group will take place in a secure virtual room, only if the participants choose to conduct the interview in that setting. If the participants prefer an in-person focus group, then a secure virtual room may not be necessary. The audio recordings will be stored on password-protected secure REDCap and UC OneDrive. The transcribed interviews will be stored by the PI (in a de-identified form) on his UC OneDrive as per the as the UC data retention policy allows. Agents

	of the University of Cincinnati may inspect study records for audit or quality assurance purposes. The data from this research study may be published; but participants will not be identified by name.
16.0 POTENTIAL BENEFITS TO SUBJECTS	**16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. It may be useful to include: the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit to subjects. Do not include benefits to society or to others.**
	They will probably not get any benefit from taking part in this study. But being in this study may improve the debriefing experience at the UC-CON.

17.0 DATA MANAGEMENT AND CONFIDENTIALITY

17.1 Describe the data analysis plan, including any statistical procedures or power analyses.

For quantitative phase 1, Statistical power G*Power 3.1 was used to determine sample size based on a 2-tailed, two-way repeated measure ANOVA for the design, a type I error of 0.05, a statistical power of 80% (type II error), and a large effect size of eta square .25-.99 (Faul et al., 2007). Based on the literature, a large effect size is appropriate for the use of simulation (Padilha et al., 2019; Pauly-O'Neill, 2009). Based on G*Power 3.1, the recommended sample size will be 26 participants in each group. Still, because there is a possibility that participants may withdraw from the study, the total number will be 30 participants in each group. There is a total of 183 eligible participants.

Statistical Plan

The statistical analysis will be used by JMP Pro 16 software. The descriptive analysis for students' demographics will be computed to describe means, standard deviations, and frequencies. For hypothesis 1a, the appropriate statistical analysis test will be the repeated measure ANOVA to find the difference between the experimental and control group in pre and post-intervention. For hypothesis 1b, an independent t-test will be used to find the differences between the two groups in the BLS competence level. The p-value of <0.05 will be considered statistically significant, and the confidence interval will be set at 95%. If the p-value is less than 0.05, we will reject the null hypothesis; If the p-value is more than 0.05, we will fail to reject the null hypothesis. For hypothesis 2, an independent t-test will be used to compare means between hot debriefing and cold debriefing groups. DES with P-values <0.05 will be considered statistically significant.

For Qualitative phase 2 , thematic analysis will be used because it is applicable to the aim of our study (Doyle et al., 2020). All transcripts will be transcribed by a transcriptionist. All transcripts will be uploaded to MAXQDA 2020, a qualitative analysis software. Two researchers will examine each interview transcript thoroughly on their own to ensure that the data is complete. The researchers then read and reread each interview individually, looking for keywords or phrases that defined participants' experiences and views of debriefing methods. We will use line-by-line coding, writing 1 or 2 words that will indicate what was stated (Creswell & Poth, 2018). Data will be coded according to their meaning and focuses on categorizing participant experiences and perceptions. Frequently recurring codes with the same content will be classified and compared consistently across transcripts. We will combine comparable and overlapping categories into a single category (theme) (Creswell & Poth, 2018).This classifying procedure will record participants' overall views of their experiences.

17.2 Describe the steps that will be taken to secure the data.

To ensure the security of data, any paper forms containing research data will be kept in a file cabinet that is locked in a locked office. The data will be entered into either a password-protected computer, a password-protected secure REDCap database, or a password-protected secure OneDrive at the University of Cincinnati. After three years of the study's completion, all research data will be de-identified, and any contact information or links to study ID numbers will be destroyed by shredding paper documents and deleting electronic files. The identity and information about the participants will be kept confidential, except in cases where authorities need to be notified about abuse or immediate harm that may come to the participants or others. Agents of the University of Cincinnati may review study records for audit or quality assurance purposes. The research data may be published, but the participants will not be identified by their names.

To capture qualitative data, audio recordings of participant interviews will be made and stored on the University of Cincinnati's secure online course management system. Additionally, a backup recording using an encrypted audio recorder will be saved in the University's HIPAA-secure OneDrive folder. After de-identification, the transcriptions of the interviews will be uploaded to the study's secure online OneDrive folder.

17.3 Describe any procedures that will be used for quality control of data collection.

For quantitative data, access to REDCap will be restricted to the study team only. Any modifications made to the database, or the data stored in it will be documented in the comment section provided by the database. The REDCap database will automatically generate a code book that is specific to the research study. The Principal Investigator and the study team will review the initial data sets to ensure that the data collection and analysis are not affected by any issues with the instruments used. The team will hold weekly meetings to discuss and monitor the confidentiality of participant data. The study team will use REDCap to track data manipulation and user activity.

To capture qualitative data, audio recordings of participant interviews will be made and stored on the University of Cincinnati's secure online course management system. Additionally, a backup recording using an encrypted audio recorder will be saved in the University's HIPAA-secure OneDrive folder. After de-identification, the transcriptions of the interviews will be uploaded to the study's secure online OneDrive folder.

17.4 Describe how data or specimens will be handled study wide as outlined below.

17.5 What information will be included in the data or associated with the specimens?

For Phase 1:
(A) Demographic
(B) BLS Competence Checklist
(C) Debriefing Tool
(D) The Debriefing Experience Scale

For Phase 2:
The data collection will use a Semi-structured interview, the most common sort of interview used in this methodology, and it is the primary method of data collection (DeJonckheere & Vaughn, 2019). It will be included open-ended questions related to the participants' overall experience in terms of emotions, feelings, challenges, and learning. All the interviews will be conducted in a private place, and the PI will do all the interviews so the participants' interactions and questions will be consistent.
The general initial questions for the hot debriefing group are:
(1) Tell me about your experience with simulation and what that’s looked like for you?
(2) Tell me about your experience in debriefing?
(3) What did you like in debriefing?
(4) How did debriefing help you to reflect on your simulation experiences?
(5) Did you face any challenges during your experience?
(6) What did you not like with debriefing?
(7) How has debriefing impacted your ability to learn concepts or attain competency in you nursing skills.

	(8) How did debriefing impact your confidence in performing at the bedside? (9) Do you have any advice for educators who are designing simulation scenarios? (10) Is there anything else you would like to share?
	17.6 Who will have access to the data or specimens?
	Only the study PI and IRB approved study team members will have access to the data.
	17.7 Where and how data or specimens will be stored?
	To ensure the security of data, any paper forms containing research data will be kept in a file cabinet that is locked in a locked office. The data will be entered into either a password-protected computer, a password-protected secure REDCap database, or a password-protected secure OneDrive at the University of Cincinnati. After three years of the study's completion, all research data will be de-identified, and any contact information or links to study ID numbers will be destroyed by shredding paper documents and deleting electronic files. The identity and information about the participants will be kept confidential, except in cases where authorities need to be notified about abuse or immediate harm that may come to the participants or others. Agents of the University of Cincinnati may review study records for audit or quality assurance purposes. The research data may be published, but the participants will not be identified by their names. To capture qualitative data, audio recordings of participant interviews will be made and stored on the University of Cincinnati's secure online course management system. Additionally, a backup recording using an encrypted audio recorder will be saved in the University's HIPAA-secure OneDrive folder. After de-identification, the transcriptions of the interviews will be uploaded to the study's secure online OneDrive folder.
	17.8 How long the data or specimens will be stored?
	After the study has ended, the research data will be de-identified within three years. The de-identified data will be kept indefinitely for analysis purposes.
	17.9 If applicable, how data or specimens will be transported?
	Not Applicable.
	17.10 Who is responsible for receipt or transmission of the data or specimens?
	Fahad Alanezi (Principle Investigator)
18.0 PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS	**18.1 For more than minimal risk research, describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether the subjects remain safe.**
	Not Applicable: the research involves no more than minimal risk to subjects.
	18.2 What data are reviewed, including safety data, untoward events, and efficacy data?
	Not Applicable: the research involves no more than minimal risk to subjects.
	18.3 How will the safety information will be collected?
	Not Applicable: the research involves no more than minimal risk to subjects.
	18.4 The frequency or periodicity of review of cumulative data.
	Not Applicable: the research involves no more than minimal risk to subjects.
	18.5 Who will review the data?

	Not Applicable: the research involves no more than minimal risk to subjects.
	18.6 The statistical tests for analyzing the safety data to determine whether harm is occurring.
	Not Applicable: the research involves no more than minimal risk to subjects.
	18.7 Any conditions that trigger an immediate suspension of research.
	Not Applicable: the research involves no more than minimal risk to subjects.
19.0 PARTICIPANT PRIVACY	**19.1 Describe the provisions to protect participants' privacy and to minimize the intrusiveness of the study questions or procedures.**
	The study will be conducted in a simulation lab. We will put a sign on the simulation lab door indicating this place is private during the whole study duration. The qualitative interview will be conducted in a private place. The principal investigator will hold bi-weekly research team meetings where the topic of privacy will be discussed and carefully monitored.
20.0 COMPENSATION FOR RESEARCH RELATED INJURY	**20.1 For more than minimal risk research, describe the available compensation in the event of research-related injury.**
	Not Applicable.
	20.2 Provide a copy of contract language relevant to compensation for research-related injury.
	Not Applicable.
21.0 ECONOMIC BURDEN TO SUBJECTS	**21.1 Describe any costs that subjects may be responsible for because of participation in the research.**
	There are no costs that subjects may be responsible for because of participation in the research.

22.0 CONSENT	**22.1 Obtaining consent – Check applicable and complete the corresponding section(s). Please note, sections 23-28 each apply under different circumstances. Please complete the correct sections as checked in this section (e.g. if you do not request a waiver of documentation of consent, do not complete section 24)**	
	☐	**The research team will obtain written consent from all subjects. (Complete section 23) (HRP-502M TEMPLATE Medical Informed Consent or HRP-502S TEMPLATE SBER Informed Consent or HRP-502V TEMPLATE VA Informed Consent)**
	☒	**The research team will obtain consent from all subjects but is requesting a waiver of documentation (signature) of consent. (Complete sections 23 and 24) (HRP-502I TEMPLATE Information Sheet)**
	☐	**The research team is requesting a waiver or alteration of the consent process. (Complete section 25)**
	☐	**The research team is requesting Exception from Informed Consent for emergency research. (Please complete the EFIC supplement document and upload under number 3 on the local site documents page in RAP)**
	☐	**The research team will enroll Non-English-speaking subjects and obtain consent (written or otherwise). (Complete sections 23 and 26)**
	☐	**The research team will enroll subjects who are not yet adults (infants, children, teenagers) and will obtain written consent from the subject's parent(s) or guardian(s). (Complete sections 22 and 27) (Parent Permission Template)**
	☐	**The research team will enroll adult subjects unable to provide consent (cognitively impaired individuals) and will obtain written consent from the subject's Legally Authorized Representative. (Complete sections 23 and 28)**

23.0 CONSENT PROCESS	**23.1 Where will the consent process take place?**
	The study information sheet will be provided to potential participants either by email or on REDCap. The principal investigator will explain the contents of the information sheet to the potential participants in-person at a private place or in a secure virtual room and obtain their verbal informed consent. The information sheet will be provided before participants complete the baseline BLS activity. For the qualitative phase, we will reconfirm consent by verbal question.
	23.2 Is there a waiting period available between informing the prospective subject and obtaining the consent?
	Potential participants will receive the study information sheet with sufficient time to review and consider their participation.
	23.3 Describe: • **The role of the individuals listed in the application as being involved in the consent process.** • **The time that will be devoted to the consent discussion.** • **Steps that will be taken to ensure the subjects' understanding.** • **Steps that will be taken to minimize the possibility of coercion or undue influence.**
	Address each bullet point. Refer to SOP: **HRP 090 Informed Consent Process for Research** for responsibilities, policies and procedures around consent. In the consent process, the principal investigator, Fahad Alanezi, will be responsible for screening potential participants, obtaining their consent, and documenting it. The consent discussion will take about 5 to 10 minutes, during which the PI will review the study information sheet and answer any questions to ensure the participants' understanding. The principal investigator will explain all aspects of the information sheet and encourage questions from the participants, which will be answered clearly. Participants who are both eligible and willing to take part in the study will provide their consent verbally. The PI will not use any form of pressure or undue influence to obtain participants' agreement to participate. The study is voluntary, and participants may withdraw at any time without any penalty or impact on their academic performance.
	23.4 Describe how consent of the subject will be documented in writing.
	Description. Refer to SOP: **HRP 090 Informed Consent Process for Research** for responsibilities, policies and procedures around consent. All procedures and processes of obtaining informed consent will be recorded in the appropriate REDCap flowsheet, which adheres to the SOP: HRP 090 Informed Consent Process for Research. This SOP outlines the policies, procedures, and responsibilities involved in the informed consent process.

	23.5 Describe the conditions under which you believe it would be appropriate to obtain ongoing consent from the subjects.
	Participants' ongoing consent will be ensured by addressing any questions or concerns that may arise during the course of the study. The participants will be reminded that their participation is entirely voluntary and that they have the right to withdraw from the study at any time, or decline to answer any questions that they are uncomfortable with.

24.0 WAIVER OF DOCUMENTATION OF CONSENT	**24.1 Justification for waiver of consent documentation. Check all that apply and provide rationale for all checked items. Please note that certain combinations of the selections below may justify a waiver of documentation. Please refer to HRP-411 – MEMBER CHECKLIST Waiver of IC Documentation to determine if your study qualifies for a waiver of documentation, and which boxes to check to justify the waiver.**	
	☐	**N/A not requesting a waiver of documentation of consent.**
	☒	**The research presents no more than minimal risk to subjects.** The study is minimal risk. Participants will not be expected to expose more than what they might face in a simulation experience that they are familiar with. In case they feel uncomfortable or distressed in the study, they can stop, take a break, and re-join. If they want to withdraw at any time, they can. In case of persistent stress or discomfort, the students' wellbeing center is ready to help them.
	☒	**Written information describing the research is to be provided to the subject, subject parent(s) or guardian(s), or subject Legally Authorized Representative.** All study participants will receive a study information sheet containing information about the research.
	☐	**Written information describing the research does not need to be provided to the subject, subject parent(s) or guardian(s), or subject Legally Authorized Representative.**
	☒	**The research involves no procedures for which written consent is normally required outside of the research context.** Participants will not do any procedure outside the research context, which will be explained in the information sheet. Participants may refuse to answer any questions. Participants will not be expected to expose more than what they might face in a simulation experience that they are familiar with.
	☐	**The only record linking the subject and the research would be the consent documentation.** Rationale/Explanation
	☐	**The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.** Rationale/Explanation
	☐	**The subjects are members of a distinct cultural group or community in which signing forms is not the norm.** Rationale/Explanation
	☐	**There is an appropriate alternative mechanism for documenting that informed consent was obtained.** Rationale/Explanation
	☒	**The research is not FDA-Regulated.** The research does not involved any FDA-Regulated procedures, drugs, or devices.
	☒	**The written script of the information to be provided orally, electronically, or on paper (information sheet) includes all required and appropriate additional elements of consent disclosure. When requesting a waiver of documentation, an information sheet is**

		required. This box should always be checked for a waiver of documentation. (Follow HRP-502I TEMPLATE Information Sheet) Participants' consent will be obtained verbally in-person before conducting the study. The study information sheet and consent discussion will include details about the study's purpose, the specific involvement required of the participants, the potential risks and benefits, the voluntary nature of the study, the confidentiality measures in place, and contact information for the investigator. The principal investigator will explain the participants' involvement in the study. Participants will be informed that they have the right to withdraw at any time or choose not to answer any questions that they find uncomfortable. The participants' academic performance will not be impacted if they choose to participate or withdraw at any time in the study. For the qualitative phase, potential participants' verbal consent will be obtained in a secure virtual room or in-person. During phase II, a qualitative focus group will take place in a secure virtual room, only if the participants choose to conduct the interview in that setting. If the participants prefer an in-person focus group, then a secure virtual room may not be necessary.
	☐	**Other Describe** any other reasons/explanations for request of waiver/alteration
25.0 WAIVER OR ALTERATION OF CONSENT PROCESS	**25.1 Justification for waiver or alteration of the consent process. Check all that apply and provide a rationale/explanation for all checked statements. Please note that certain combinations of the selections below may justify a waiver of or alteration of consent. Refer to HRP-410 – MEMBER CHECKLIST Waiver of IC Process to determine if your study qualifies for a waiver or alteration of consent, and which boxes to check to justify the waiver or alteration.**	
	☒	**N/A Not requesting a waiver or alteration of consent process.** Rationale/Explanation
	☐	**The research does NOT involve non-viable neonates.** Rationale/Explanation
	☐	**The research involves no more than Minimal Risk to subjects.** Rationale/Explanation
	☐	**The research could NOT practicably be carried out without the waiver or alteration.** Rationale/Explanation
	☐	**The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.** Rationale/Explanation
	☐	**Whenever appropriate, the subjects will be provided with additional pertinent information after participation.** Rationale/Explanation
	☐	**The research is NOT FDA regulated.** Rationale/Explanation
	☐	**Other** Describe any other reasons/explanations for request of waiver/alteration

26.0 CONSENT OF NON-ENGLISH-SPEAKING SUBJECTS	**26.1 Indicate what language(s) other than English are understood by prospective subjects or representatives. (Please note that if non-English speaking subjects will be consented, translated consent forms must be uploaded into the consent section of the RAP Smart Form. For Greater than minimal risk studies, a third-party translation certificate is also required. For minimal risk studies, the consent must be translated by someone independent of the study team and their credentials should be provided.)**
	Not Applicable
	26.2 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate that language that will be used by those obtaining consent.
	Not Applicable
27.0 CONSENT OF SUBJECTS WHO ARE NOT YET ADULTS (infants, children, adolescents)	**27.1 Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g. individuals under the age of 18 years (Ohio))**
	The potential participants will be senior or third year undergraduate nursing students who are above 18 years old.
	27.2 Describe whether parental permission will be obtained. (Parent Permission Template)
	• Not Applicable.
	27.3 Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.
	Not Applicable.
	27.4 Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. (HRP-502Y Youth Assent or Medical Assent Template)
	Not Applicable.
	27.5 When assent is obtained, describe whether, and how, it will be documented.
	Not Applicable.

28.0 CONSENT/ASSENT OF COGNITIVELY IMPAIRED ADULTS	**28.1 For potentially cognitively impaired adults, describe the process to determine whether an individual is capable of consent.**		
	Not Applicable.		
	28.2 List the individuals from whom permission will be obtained in order of priority. (Please note that the consent form will require revision to add a signature line for LAR and authority of LAR).		
	Not Applicable.		
	28.3 Describe the process for assent of the subjects. Indicate whether assent will be required for all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.		
	Not Applicable.		
	28.4 If assent will not be obtained from some or all subjects, explain why.		
	Not Applicable.		
	28.5 Describe whether assent of the subjects will be documented and the process to document assent.		
	Not Applicable.		
29.0 HIPAA	**29.1 If you will use hospital or other healthcare provider records, data from a research data repository or any other information maintained by a hospital, academic medical center, or another healthcare entity, how will you gain access to the information? (check all that apply, i.e. if you will request a waiver for screening and obtain a signed authorization upon enrollment, check both).**		
	☒	**Not using HIPAA-protected information for any research activities**	
	☐	**Through a HIPAA Authorization signed by the participant (or their legally authorized representative).**	
	☐	**Requesting that the IRB approve a waiver of authorization in this application. Submit HRP-209 – FORM – UC Waiver of HIPAA Authorization**	
	☐	**As a limited data set under a data use agreement.**	
30.0 STUDY INTERVENTION/ INVESTIGATIONAL AGENT	**30.1 FDA – Select all that apply.**		
	☐	**Drugs/Biologics**	**The proposed research involves the administration of an article (e.g. drug, biologic, herbal preparation, dietary supplement, etc.) to a human where the article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or is intended to affect the structure or any function of the body. For both FDA and non-FDA approved article. Include HRP-306 – WORKSHEET Drugs and Biologics in the submission in RAP.**
	☐	**Devices**	**Any research that involves the use of a device (medical or other devices, approved or investigational) to test the safety or effectiveness of the device or the device is the focus of the research. Note: This includes research that**

			will use human samples to test the safety or effectiveness of a device. Include HRP-307 – WORKSHEET Devices in the submission in RAP.
	☐	**Data Collection**	**Any research that involves the collection of data or other results from individuals that will be submitted to, OR held for inspection by, the FDA. In general, this would include research that involves any data that will be provided (in any form) to a pharmaceutical, medical device or biotech company.**
	☐	**Specimens**	**Any research activity where specimens (of any type) from individuals, regardless of whether the specimens are identifiable, are used to test the safety or effectiveness of any device (medical or other devices, approved or investigational) and the information will be submitted to, or held for inspection by, the FDA.**
	☒	**Not Applicable**	**None of the above describes my research.**
	30.2 Describe the study intervention and/or investigational agent (e.g. drug, device) that is being evaluated.		
	List and describe, or, if Not Applicable was checked in section 16.1, Not Applicable		
	30.3 Drug/Device Handling: Describe plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.		
	Not Applicable.		
	30.4 If the drug is investigational and has an IND or if the device has an IDE, or claim of an abbreviated IDE (non-significant risk device) include the information below: • **Identify the holder of the IND/IDE/Abbreviated IDE** • **Explain the procedures followed to comply with the sponsor requirements for FDA regulated research (as applicable, 21 CFR 11, 21 CFR 54, 21 CFR 210, 21 CFR 211, 21 CFR 312, 21 CFR 812, 21 CFR 820)** • **If the PI holds the IND/IDE, please include the FDA Application and the FDA Letter of Acknowledgement on the Drugs/Devices page of the RAP Smart Form. Please also note that a Safety Monitoring Plan will be required if the PI holds the IND/IDE.**		
	Not Applicable.		
31.0 ADDITIONAL REVIEWS AND CONSIDERATIONS	**31.1 Check all that apply.**		
	☐	**The proposed research meets the definition of a clinical trial, is regulated by HHS, and requires that the consent form is posted to a federal website within 60 days of completion** **Clinical Trial: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health-related or behavioral outcomes.**	
	☐	**The proposed research involves embryonic stem cells or xenotransplantation.**	

	☐	**The PI is responsible for registration of this study on www.clinicaltrials.gov. (Please contact the Human Research Protection Program with questions about clinicaltrials.gov)**
	☐	**The proposed research requires review by the Institutional Biosafety Committee (IBC). IBC review is required for research that will utilize infectious agents, select agents, recombinant DNA or viral gene transfer vectors, toxins for human gene transfer or genetically modified agent.**
	☐	**The proposed research requires Radiation Safety Committee (RSC) review. RSC review is required if the research involves participants being exposed to radiation for research purposes or an increase in frequency or duration of radiological imaging procedures.**
	☒	**UC Student is serving as Principal Investigator (Add the Faculty Advisor to the Study Team Members page in the RAP Smart Form and ensure that their CV is included in their RAP profile.)**
	☐	**UC study team members will be conducting research activities at international location(s).**
		If the research involves international locations, describe additional safeguards included to protect the rights and welfare of subjects recruited in these locations. Refer to HRP-399 – MEMBER WORKSHEET International Research for more information on the information required for review for international studies.
		Description, e.g. information about local research oversight, local context, etc.
	☐	**Collection of information that may include incriminating activities (e.g. illicit drug use, illicit sexual behaviors, fraudulent behaviors, theft, abortion or other related activities that may be illegal in some states, assault)**
	☐	**Review of UC Student records without obtaining consent. If so, a FERPA waiver is required. (Please reach out to Lorre Ratley with UC Office of General Counsel.)**
	☐	**Sharing of genomic information generated from NIH-funded research**
	☐	**UC Health services will be utilized (check applicable).**
		☐ **Investigational Drug Services** ☐ **Imaging Services** ☐ **Lab Services**
	☐	**CCHMC Services will be utilized (check applicable).**
		☐ **CICRL** ☐ **IRC** ☐ **SRC**
	☐	**Acute Care Research (Research that occurs within 24 hours of a visit to an emergency department or unscheduled admission, or within 24 hours of identification of a new or worsening condition – characterized by sudden onset requiring immediate care)**
	☐	**The research team will send data FROM the United States TO another country:** if so, list the country or countries here
	☐	**The research team will send data FROM another country TO the United States:** if so, list the country or countries here

32.0 REGULATORY OVERSIGHT	**32.1 Check the applicable federal oversite and/or funding.**			
	☐	**Environmental Protections Agency**	☐	**Department of Energy**
	☐	**Tribal Law**	☐	**Department of Defense**
	☐	**Department of Justice**	☐	**Department of Education**
	☐	**Food and Drug Administration**	☐	**Health and Human Services (NIH)**
	☐	**Office of Civil Rights**	☐	**National Science Foundation**
	☐	**Veterans Affairs *See Below**	☐	**Other Federal Agency**
	☐	***Check if you will enroll non-veterans**	☐	**ICH-GCP (E6)**
	☐	**Specify other federal agency/oversight** Name		
33.0 SETTING	**33.1 Where will research activities take place, including where data will be stored/accessed (check all that apply).**			
	☐	**Barrett Cancer Center**	☐	**Infectious Disease Clinic (Holmes-UC Health)**
	☐	**Blue Ash Campus**	☐	**Kettering Laboratory**
	☐	**Cincinnati State Technical and Community College**	☐	**Linder Center of Hope**
	☐	**Clermont College**	☐	**Liver Transplant Clinic (Medical Arts Building)**
	☐	**College of Allied Health Sciences**	☐	**Medical Sciences Building**
	☐	**College of Arts & Sciences**	☐	**Shriners Hospital**
	☐	**College of Business**	☐	**Talbert House**
	☐	**College Conservatory of Music**	☐	**UC Gardner Neuroscience Institute**
	☐	**College of Design, Art, Architecture & Planning**	☐	**UCMC (Emergency Department, Inpatient and Outpatient Units)**
	☐	**College of Education**	☐	**UCMC NICU**
	☒	**College of Nursing**	☐	**University of Cincinnati Physicians (UCP)**
	☐	**College of Pharmacy**	☐	**University Pointe Surgical Hospital**
	☐	**Crossroads Center**	☐	**VA – Cincinnati Medical Center**
	☐	**Drake Center**	☐	**VA – Chillicothe Medical Center**
	☐	**Genome Research Institute (Reading Campus)**	☐	**VA – Columbus Medical Center**
	☐	**Hoxworth: Inpatient Unit**	☐	**West Chester Hospital**
	☐	**Hoxworth: Outpatient Clinics**	☐	**Other UC/UC Health Affiliated location/clinic:** list location/clinic

34.0 EXTERNAL LOCATIONS	**34.1 List any external locations to UC or its affiliates.**
	Not Applicable..

	35.1 List any references sited throughout the protocol below.

35.0 REFERENCE LIST

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