

IRB New Project Proposal Form



Academic Affairs

Approved

Date: Wed, Mar 22, 2023 7:28 PM

By: Christine Helfrich

Primary Investigator Information

Principle Investigator Name



Principle Investigator Department/Program/Division



PI Level:

Faculty

PI AIC Email Address:



PI Phone:



Where did you complete Human Subjects Research Protection Training?

CITI

PI Research Ethics Training Certificate Number:



PI Research Ethics Training Certificate Expiration Date:

(Note: If your certificate does not include an expiration date, indicate the date 3 years from your training date)



Are you working on this study as part of a project that has been approved by an IRB at another institution?

No

Are there additional co-investigators, research staff, or student assistants involved in the project?

If you are a student, you MUST include your faculty advisor as an investigator.

Yes

Additional Investigators

Investigator Name

[REDACTED]

Investigator Department/Program/Division

Physical Therapy

Investigator Level

Faculty

Investigator Email

[REDACTED]

Investigator Phone Number

[REDACTED]

Where did you complete your Human Subjects Protection Training?

CITI

Investigator Research Ethics Training Certificate Number:

[REDACTED]

Investigator Research Ethics Training Expiration Date:

[REDACTED]

Are there additional co-investigators, research staff, or student assistants involved in the project?

Additional investigators are involved in the project.

If there are additional investigators, please upload one file that includes the above information for all additional investigators here. Please note student assistant information will be entered on a separate page.



DOWNLOAD FILE

Conflict of Interest

Does a potential conflict of interest exist for the Principal Investigator or any of the research team members with this study?

Yes (Please list each person and explain) [REDACTED] PI is also an instructor.

Section II: Proposal Submission Information

Date of Form Submission

[REDACTED]

Research Project Title

The Effectiveness of the Creighton Competency Evaluation Instrument (CCEI) in the assessment of physical therapy students' learning during clinical simulation.

Please indicate which of the following criteria apply to your proposed research:

The research is conducted in established or commonly accepted educational settings involving normal educational practices

The research involves educational tests, survey procedures, interview procedures, or observation of public behavior.

The research involves benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information being collected.

Participation in the research poses no more than minimal risk to the subjects.

Submission Type and Rationale: (Please visit *Human Subjects Regulations Decision Chart* (<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2>) before checking box.

Exempt Review - The simulations conducted are an academic activity part of the course, however, are voluntary for student participation and are not graded. The study is to analyze student evaluation forms used in the class. Consent will be waived and all forms will be de-identified.

Exempt/Expedited Confirmation

The research has been approved by another institution's IRB. Please upload a copy of the IRB approval form which must include the Institution name, dates of approval and approval number.

n/a

Please describe the possible risks associated with participation in this study.

There are no more than minimal risks. There is minimal risk to the participants, of emotional stress and anxiety during a simulated patient experience. To minimize these risks, prebriefing of the students for the scenario, and a blended debriefing approach with emphasis on positive interactions will be conducted. Risk is limited to breach of confidentiality of survey data. All forms will be de-identified.

Indicate which of the following apply to your study (Please select all that apply):

The information will be recorded in a way that subjects cannot be readily identified.

Any disclosure of identifiable information outside of the research setting would not place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation.

The research does not include children.

Recruitment Process

How many total subjects will be recruited for the study? *Please remember that posting a recruitment statement on Social Media IS recruiting.*

26

Where will subjects be recruited from? Check ALL that apply!

AIC campus announcements

Educational settings

Subjects will not be recruited as the data is part of regular educational activities or is a secondary data set. Please describe. - The simulations conducted are an academic activity part of the course, however, are voluntary for student participation and are not graded. The study is to analyze student evaluation forms used in the class.

Describe what subjects will be told during recruitment. You must also attach copies of all consent forms, assent forms, information scripts, and scripts for oral consent with this application.

Second-year students will be completing neurological and cardiopulmonary coursework in the DPT curriculum; they will be offered the opportunity to perform in a hands-on simulation coinciding with their current coursework. An announcement to offer participation will be done in person and via email to the second-year cohort. Once students agree to participate, they will be contacted to schedule a simulation date and time. Student participation will be voluntary, including the self-evaluation process. Participation in this study will have no impact on the student's grade.

Describe your inclusion and exclusion criteria for the study and how subjects will be selected. Include rationale for any excluded groups of participants (age, gender, race, ethnicity, abilities).

The simulation will reflect an acute care hospital setting. Second-year students will be completing neurological and cardiopulmonary coursework in the DPT curriculum; they will be offered the opportunity to perform in a hands-on simulation coinciding with their current coursework. Once students agree to participate, they will be contacted to schedule a simulation date and time. Student participation will be voluntary, including the self-evaluation process. Participation in this study will have no impact on the student's grade.

Are additional permissions required to recruit your sample? (*This includes, but is not limited to, permissions to post a recruitment blurb on a website, social media page or to conduct secondary data analysis*).

No

Will participants be paid or otherwise compensated for research participation?

No

Research Project Procedures

Provide a brief **Brief Summary** and non-technical description of the study using everyday vocabulary.

(**LIMIT 150 words**)

Clinical experiences are crucial for many healthcare fields, and physical therapy is no exception. With growing enrollments and limited placements, increased burden on practitioners and clinical sites and the restrictions to clinical participation due to the COVID pandemic, it has become increasingly difficult finding appropriate clinical experiences to satisfy program accreditation requirements. This is particularly true for Integrated Clinical Experiences (ICE). While CAPTE does not specify the number of hours for part-time clinical experiences, they remain a requirement for accreditation. Such clinical exposure can be fulfilled in a number of ways – in-person clinical experiences which are commensurate with the educational curriculum, virtual visits and simulation activities. Simulation activities may be via computer, video, or in person. Much of the current literature discusses the potential benefits of simulation-based learning to improve physical therapy student clinical decision making, confidence, efficacy and competence prior to engaging in inpatient acute care clinical work.^{1, 2} However, the access to the simulation lab in physical therapy programs across the country is limited due to requirements to share with students in other health professional programs (i.e., nursing, PA, MD), a limited number of resources due to high cost, as well as scheduling and time logistics for both students and faculty alike. Previous research has highlighted many different assessment tools in clinical simulation (OSAD, DASH, etc.). Patient assessment, communication, safety, and clinical judgement are important clinical skills for training physical therapists. These are assessed in the classroom interactions and in the Clinical Performance Instrument (CPI) during full time clinical placements. These areas are assessed with the Creighton Competency Evaluation Instrument (CCEI). The CCEI has been validated and used in the assessment of nursing students during hands-on simulation, however, it has yet to be used with doctor of physical therapy students.^{3,4,5,6,7} Integrating clinical simulation can assist in the learning and preparation of physical therapy students by providing the ability to critically think and garner confidence for clinical work in a safe controlled environment, particularly for the acute inpatient setting.² Logistics such as scheduling, limited resources and staff restrict the opportunity for multiple experiences in the simulation lab. However, it is thought that even one experience in hands-on simulation based learning may increase student self-efficacy and confidence for the inpatient setting.

Purpose and Rationale

Provide a brief summary of the background information, state the research question(s), and tell why the study is needed. (**LIMIT 300 words**)

The purpose of this project is to determine the effectiveness of the Creighton Competency Evaluation Instrument (CCEI) as an assessment tool for evaluation of clinical skills of physical therapy students during a hands-on simulation experience. • 1: To analyze the student evaluation forms used in the simulation activity. a. To validate the CCEI as an assessment tool for developing physical therapy student skills b. To determine if limited hands on simulation based learning improves confidence and self efficacy in physical therapy students using the student simulation survey.

Describe the research study methods and procedures. Be sure to provide sequential description of what subjects will be asked to do, how data are to be collected (e.g., questionnaire, interview, focus group, etc.), and who will collect data. Indicate the number and duration of contacts with each subject and follow-up procedures.

Limit:300 words *Hint: Put this information in a numbered list for clarity!*

Copies of all materials (e.g., questionnaires, surveys, measures, tests, interview questions) to be used with participants must be included with the project submission. If a specific item cannot be included with the submission, it must be thoroughly described. Items may be attached at the end of this document.

Students will be recruited from the second-year cohort as it is commensurate with the coursework associated with inpatient and acute care setting. Students will participate in pairs, in an inpatient/acute care clinical simulation. Each student will receive prebriefing (cases are given to the student prior to the simulation, a few days in advance to allow for research and preparation). The cases will be uncomplicated cardiac or pulmonary case scenarios(MI or COPD); the case presented is dependent on the day of simulation. Upon arrival at the sim lab, students will complete a short survey to determine their perceptions of the acute care/inpatient setting. Students will complete the simulation. Two faculty (one nursing and one physical therapy) will evaluate student performance using the CCEI. Following the simulation students will debrief with both faculty and their peer, and then complete the post-

simulation survey. Mother's birthdate will be used as an identifier to match the pre and post-simulation surveys. Upon completion of the simulation and survey, no other contact or follow-up is needed at this time.

Describe the study sample. Include age range, gender, race, ethnicity. (Be specific, if you are doing secondary analysis or studying regular educational procedures, your sample consists of your de-identified data).

A maximum of 26 second-year graduate AIC DPT students (cohort of 2024), ranging from 22-60, of varying gender, race, and ethnicity. Consent will be waived and all forms will be de-identified.

Data Monitoring and Analysis: Describe how the qualitative and/or quantitative data will be analyzed. Describe the provisions for monitoring the data to ensure the safety of participants (eg Codes/pseudonyms/etc.).

The CCEI has 23 items for assessment of the student during simulation. Each item is scored 0 (not competent), 1 (competent), and N/A for not applicable. There are areas available for comments for each item and for the overall simulation. Simulation Survey: The survey is a 10 item survey used to assess students' perceptions on their preparedness for the inpatient setting. Each item is rated on a 5 point likert scale (SCALE: (1) Strongly disagree; (2) Disagree; (3) Neutral; (4) Agree; (5) Strongly agree). Student participants will also be given an area for comments. Quantitative and qualitative data will be obtained from the CCEI scoring, the simulation survey (5-point Likert scale), and the debriefing interaction. The quantitative data will be analyzed through statistical analysis (T-tests, ANOVA, etc.), and the qualitative data will be examined for themes and comments resulting from the simulation regarding the students' perceptions of their preparedness for the acute care setting. Both the CCEI and Simulation survey data will be aggregated in a spreadsheet. Quantitative data will be analyzed for statistical significance (i.e., t-tests, ANOVA, etc.). The qualitative data will be analyzed and compared for common themes and comments after all simulations are completed. The survey results and participant information will be kept confidential to ensure the safety of participants.

Data Monitoring and Safety - Please be specific!

Where will data be stored - Surveys will be distributed on paper and will be kept in a locked drawer in the PI locked office, with access limited to the primary investigator and co-investigators.

How will data be protected (Passwords/encryption/locked cabinets) - Locked cabinets and locked office.

How will audio or video data be protected - Simulations may be recorded for use in the debriefing and stored on the simulation computer. Access is limited to Nursing Clinical Resource Laboratory Coordinator.

How and when will data be destroyed - Data will be disposed of in confidential documents (locked) disposal for shredding once the research is completed. Any video recordings will be deleted after the completion of the study.

Investigator's Assurances

I certify that the information provided in this application is correct to the best of my knowledge, and that all persons directly involved in this project agree to follow the applicable policies and procedures regarding the protection of human subjects. I agree to inform the Human Subjects Review Committee of any substantive changes made after this project is approved. **This form will not be accepted or approved without signatures and dates.**

By placing a check next to my role and typing in my **Full Name and Date**, I am providing my electronic signature.

Principle Investigator [Redacted]

Additional Investigator [Redacted]

Student Assistant [Redacted]

Faculty Advisor [Redacted]

Please upload an additional page to include any additional assurances. Every person involved must sign an assurance.

n/a

Attachments

Please upload all Human Subjects Protection Training Certificates here:

 DOWNLOAD FILE

Please upload your Consent form here. Upload consent language if conducting an anonymous survey.

n/a

Please upload your Assent Form here

Note: Assent forms are used for Minors under age 18.

n/a

Please upload your Information Sheet here.

Note: Information sheets are ONLY required in cases where consent is being waived.

 DOWNLOAD FILE

Please upload your Recruitment materials or script here:

 DOWNLOAD FILE

Please upload any Permission Letters here

n/a

If you need permission from another IRB, please upload that documentation here

n/a

Please upload any additional documents here:

Possible items here include: Survey or data collection tools, additional IRB certificates. etc.

 DOWNLOAD FILE

Discussion

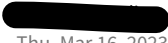
C Christine Helfrich

Write a message

 Add an Attachment

CANCEL

POST

M 
Thu, Mar 16, 2023 6:29 PM



[Reply](#)

Your Review

C Christine Helfrich
Your Vote: None



Reviewers



Voting Reviewers

C

Christine Helfrich

Level 1

Association - Form

Non-Voting Reviewers

A

Anne Stuart

Level 2

Association - Form

K

Kate Barlow

Level 2

Association - Form

L

Linette Wilson

Level 2

Association - Form

Z

Zane Pfefferle

Level 2

Association - Form