Central Connecticut State University
-Institutional Review Board-

INITIAL PROTOCOL SUBMISSION FORM

SUBMISSION INSTRUCTIONS – The Initial Protocol Submission Form (IPSF) is now a fill-in form. The fill-in format is designed to facilitate preparation of the IPSF and review by the IRB. As this is a new format there are likely to be periodic updates.

Each item on the IPSF has a text field (Click or tap here to enter text), a check box (☐) or a date menu (Click or tap to enter a date) to enter information about the proposed research. Text fields will expand as information is entered. Click on the check box to place x. To initiate the IRB review process, submit the completed IPSF and supplemental materials to irb@ccsu.edu. Attach supplemental materials as either a Word or PDF document.

Please provide the information requested. If an item is not applicable enter N/A. If information is not available, enter "Info not available" with explanation. If there is information about the research that is not requested on the IPSF please enter the information in Section VIII, Additional Information.

Principal Investigators are to submit the completed IPSF and supplemental materials to the IRB. PIs as faculty advisors are to review the Lead Investigator's IPSF for completeness and includes all relevant supplemental materials. The PI will then forward the IPSF to the IRB on behalf of the LI under their supervision. Submissions to the IRB by student researchers will be returned to the student's faculty advisor.

SECTION I – General Information

1. **PROTOCOL TITLE:** How Are Athletic Training Student Learner's Skill Development Ratings in the Clinical Learning Courses Related to their Ultimate Proficiency

2. **RESEARCH TEAM:** Principal Investigator (PI) is the designation for faculty conducting research and/or is a faculty advisor. The PI designation is also for a CCSU staff member named as PI on a grant.

   Lead Investigator (LI) is a designation for student researchers. "Other Researcher" is for an individual who is part of the research team and will have direct involvement with research subjects, but is not a PI, Co-PI, LI, or Co-LI.

	NAME	CCSU ID	INSTITUTION/ DEPARTMENT	PHONE/EMAIL
Principal Investigator / Faculty Advisor	Dr. Xxxxx Xxxxx	XXXXXXXX	Central Connecticut State University/Educational Leadership	860-832-xxxx xxxxx@ccsu.edu
Co-Principal Investigator	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Lead Investigator	Xxxxx Xxxxx	XXXXXXXX	Central Connecticut State University/Educational Leadership	860-832-xxxx xxxxxx@ccsu.edu
Co-Lead Investigator	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Other Researcher	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Other Researcher	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

3. HUMAN SUBJECT PROTECTION EDUCATION: Enter requested information in appropriate space.

	NAME	EDUCATION (CITI)	DATE COMPLETED	CERTIFICATE INCLUDED W/APPLICATION?
Principal Investigator/Faculty Advisor	Dr. Xxxxx Xxxxx	CITI	6/9/2019	YES
Co-Principal Investigator	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.	Click or tap here to enter text.
Lead Investigator	Xxxxx Xxxxx	CITI	6/22/2020	Yes
Co-Lead Investigator	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.	Click or tap here to enter text.
Other Researcher	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.	Click or tap here to enter text.
Other Researcher	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.	Click or tap here to enter text.

4. RESEARCH PURPOSE: Check the appropriate box in the column left of research purpose options. If the option checked is Undergraduate, Graduate or Other describe the course, project and department in the space to the right.

☐	Faculty Research	☐	Undergraduate Course/Project	Click or tap here to enter text.
☒	Dissertation	☐	Graduate Course/Project	Click or tap here to enter text.
☐	Master's Thesis/Project	☐	Other	Click or tap here to enter text.

5. FUNDING SOURCES: Check the appropriate box in the column to the left of the funding options. If research has funding enter funding source information in the space to the right of the funding option.

☒	Research not funded	Click or tap here to enter text.
☐	Funded by Federal agency or department	Click or tap here to enter text.
☐	Funded by Connecticut State agency or department	Click or tap here to enter text.
☐	Funded by CCSU center, department, school or other	Click or tap here to enter text.
☐	Funded by private organization	Click or tap here to enter text.
☐	Funded by other entity	Click or tap here to enter text.

SECTION II – Research Overview

Please provide the information requested. If an item is not applicable or information is not available, enter N/A.

1. Proposed start date of research activities: 8/15/2020

2. In 250 to 500 words please provide a brief summary of the proposed research, including study hypothesis or research question, objectives, and rationale. Also cite relevant published research and articles to support the hypothesis or research question for the proposed research.

   Athletic training student learners must demonstrate evidence of clinical growth during respective clinical courses and clinical assignments. Clinical growth is inclusive of: safe application of clinical procedures; a level of skill that demonstrates expedience and confidence; and the eventual achievement of independence from the clinical preceptor during direct patient care delivery. The CAATE *2020 Standards for Accreditation of Professional Athletic Training Programs* noted that the student learner's clinical experiences should be logically

progressive, increasing in complexity, and inclusive of experiences that provide autonomous patient care. The NATA *Athletic Training Education Competencies,* noted that "students must demonstrate competency in a particular task before using on it on a patient" (2011, p. 4). Competency is an expected outcome that demonstrates knowledge and skill acquisition. Walker, Weidner, and Armstrong (2008) conducted a study determining that approximately eighty-three percent of the athletic training education programs did not monitor for real-time patient care opportunities. Additionally, only 16 percent of the responding program director acknowledged having a method for tracking all the various assessments that during the student learner's growth towards clinical proficiency. The purpose of the study will be to discover evidence of comprehensive bench mark patterns of clinical skill growth towards entry level proficiency during the undergraduate AT student learner's assigned clinical courses and clinical experiences. The findings from this study will be used to explain patterns of clinical skill growth of AT student learners towards ultimate proficiency during respective clinical courses and clinical assignments. Phan et al.(2012) discussed as a barrier to clinical education was the inability for standardizing the extent of the knowledge and skills to be acquired by the student learner's clinical experience. The study acknowledged the lack of firm guidance from professional standards documents that leaves accountability for assessment of the student learner's progress open to interpretation.

This study will address the following three research questions: Is there any statistically significant growth for student's clinical skill development toward proficiency during the respective clinical rotation with real-time patient care? Is there statistically significant relationship between preceptor's assessment and the student's self-assessment of clinical skills during the respective clinical rotation with real-time patient care? Is there statistically significant relationship between preceptor's assessment and the student's self-assessment of clinical skills during the respective clinical rotation with real-time patient care?

H01: There will be no statistically significant growth for student's clinical skill development toward proficiency during the respective clinical rotation with real-time patient care. H02: There will be no statistically significant relationship between preceptor's assessment and the student's self-assessment of clinical skills during the respective clinical rotation with real-time patient care. H03: There will be no statistically significant relationship between Comprehensive Objective Standardized Practical Exams results and preceptor's assessment of real-time patient care.

A longitudinal quantitative study will be used to investigate how athletic training student learner's skill ratings in the clinical courses relate to their ultimate proficiency. The research will be designed to also explore the relationship between the preceptor's assessment and the student's self-assessment of clinical skills during respective clinical course with real-time patient care. Lastly, this research study will establish if a statistically significant relationship exists between the comprehensive standardized practical exam results and preceptor's assessment of the student learner during real-time patient care.

3. Describe the subject population demographic which is specific to the objectives of the proposed research stating age range, gender, ethnicity/race or whether subjects will be children, prisoners, students, employees, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

   The subject population will be CCSU athletic training students who were enrolled in AT clinical courses from 2014 - 2019. The population will consist of up to 30 CCSU athletic training students who were assessed during four distinct clinical learning courses identified as: EXS 315 Practicum I, EXS 316 Practicum II, EXS 319 Practicum III, and EXS 445 Internship.

SECTION III – Sponsors, Affiliates, and Collaborators

4. Describe any arrangements with an agency, organization, or institution that is a collaborator for this research. Include a name of the collaborator official with contact details and a gatekeeper letter. If the gatekeeper letter is not available indicate the status for procuring the letter.

The athletic training students clinical assessment portfolios are maintained and stored by the Athletic Training Education program which is housed in the Department of Physical Education & Human Performance. The student's assessment portfolios were created to collect program evaluation data for CCSU's ATEP; for generating annual CAATE accreditation reports; and for providing AT students with their respective clinical education assessment/feedback. Arrangement for permission to gain access to the CCSU athletic training student's clinical for this research study was obtained from Dr. Xxxxx Xxxxx. Dr. Xxxxx, has agreed to serve as the gatekeeper for this study and has provided a gatekeeper letter of support this research study. The Lead Investigator has a dual role as a researcher, serving as xxxxxxxxxx in the ATEP program.

5. Describe the status of the collaborator IRB for this proposed research. If the collaborator IRB has approved this research include a copy of the approval. If the collaborator does not have an IRB enter N/A.

   Dr. Xxxxx Xxxxx has approved the use of secondary data from the ATEP that is to be de-identified and then analyzed. Dr. Xxxxx, has approved this research proposal, understands the purpose of the data for analysis and also serves as a member of the Lead Investigator 's dissertation committee.

6. Describe any plans to recruit subjects or to obtain data from an agency, school, organization or institution other than CCSU.
   No plans for recruiting subject – use of secondary data from CCSU's Athletic Training Education Program.

SECTION IV – Human Subjects

7. Describe the expected demographics for the proposed research sample if known.

   CCSU Athletic Training Students enrolled in clinical courses from 2014-2019 consists of up to19 males and 11 females. All participants match the typical demographics of undergraduate students in the age range of 18-22 year olds.

   The categories below indicate populations that are considered vulnerable to coercion or undue influence. Check each category that is applicable to this proposed research. If none enter N/A.

   N/A to all categories listed below in the table.

☐	Children
☐	Individuals with impaired decision making capacity
☐	Economically or educationally disadvantaged persons
☐	Prisoners
☐	Probationers or parolees
☐	Veterans

8. Describe any relationship that members of the research team might have with the prospective subjects.

   The Lead Investigator has a dual role as a researcher and xxxxxx in the ATEP. The Lead Investigator served as xxxxxxxx to the AT student participants of this research study during their enrollment in the ATEP. The Lead Instructor's role in the ATEP included xxxxxxxxxx….

9. Do you plan to recruit CCSU students through a class that you or one of your faculty collaborators instruct?
   ☐ Yes (Answer 9a) ☒ No (Go to #10)

9a. Please explain why this population is necessary to the study and indicate what precautions will be taken to minimize potential undue influence or coercion.
Click or tap here to enter text.

10. Describe recruitment procedures and attach recruitment materials.
No Recruitment – use of secondary data.

11. Describe criteria for subject inclusion and screening procedures of prospective subjects. If any inclusion/exclusion criteria are based on gender or ethnicity/race explain rationale.

Inclusion criteria will be CCSU undergraduate athletic training students who were enrolled in AT clinical courses from 2014 – 2019. Secondary data analysis will NOT be based on gender, race, or ethnicity as an inclusion or exclusion criteria.

12. Describe the minimum number of eligible subjects needed for the proposed research or the anticipated number that will participate.
Secondary Data analysis of up to 32 participants is anticipated.

13. Describe any compensation of subjects or indicate if there is no compensation. SONA credits are considered compensation. If subjects are compensated explain details should the subject not complete or withdraws from the research activity.
No compensation – use of secondary data.

14. Describe research procedures. Procedures include interviews, self-administered surveys or questionnaires, focus groups, psychometric or educational testing, follow-up for longitudinal studies. Procedures can also include web-based data collection, analyzing data obtained from institutional records or secondary data sources both publically available or with limited access. Attach a copy of the materials that will be used for collecting data.

CCSU's ATEP collects data for program evaluation and for annul reporting as required by the accrediting agency (CAATE). The secondary data that is being proposed for analysis by the Lead Investigator was collected for the purpose of assessing student's clinical skills during respective clinical courses and for the ATEP's program evaluation, including annual accreditation reporting. The procedure consists of the Lead Investigator accessing the AT student's clinical assessments portfolios in their current form as paper files, as well as any clinical assessments/practical examinations within the student's electronic files which are held within the ATEP department files secured on CCSU's One Drive. The Lead Investigator will ensure that removal of personal identifiable information for the purpose of creating a research related electronic data set for this research study would be performed by the process of anonymization.

15. Describe who will administer the proposed research procedures, where and when procedures will take place, and the frequency and duration of visits /sessions for the research.

The Lead Investigator will administer to the proposed research procedures. The Lead Investigator will access the athletic training student clinical portfolios, which are stored in a locked filing cabinet within a locked closet in the athletic training facility. The student participant's Comprehensive Clinical Assessment and their Standardized Objective file exists electronically as a secured file within the ATEP's Program Evaluation File in Microsoft team. De-identified data will be entered into the anonymized research data set. Removing the student participants name and assigning a random number from 1-30 will code the paper and electronic assessments within the anonymized research data set. The student's paper and electronic files will be reviewed in the Lead Investigator 's office at CCSU and/or within the Athletic Training Conference room, which is also located within the athletic training facility. All files will be return in their original format to their original secured location immediately after being de-identified, review, and the data electronically entered into the anonymized research data set. An

estimated timeline for access to the secondary data is anticipated to be from mid-August 2020 and may extend to mid- December 2020 during the Lead Investigators permitted on-campus COVID-19 assigned days.
As a contingency plan for a COVID-19 closure of the campus, the student's paper files may be transported to the home of the Lead Investigator for review, de-identifying, and electronic entering of the data set. In addition, electronic files may be viewed from home on CCSU's one drive. The home office of the Lead Investigator has a lockable filing cabinet for storage of the student's paper files. The anonymized research data set will be stored electronically on Lead Investigator's CCSU One Drive which is password protected and additionally secured by Two Factor Authentication.

16. If applicable, describe any audio or video recording that will occur and the purpose.

    There will be no audio or video recordings utilized. – N/A

17. If applicable, describe if any deception or incomplete disclosure of informed consent will take place and explain the rationale.

    There will be no deception or incomplete disclose of informed consent- N/A

18. Describe all potential risks and discomforts associated with participation whether physical, psychological, economic or social (e.g., pain, stress, invasion of privacy, embarrassment, breach of confidentiality).

    The use of de-identified secondary data minimizes any associated risks and discomforts to the participants as above noted above.

19. Describe measures that will be implemented to minimize risks and discomforts to subjects.

    The anonymization process minimizes the risk of the identifiers tracing back to an individual. All the data will be reported as groups of participants from 2014-2019, thereby eliminating any reporting in an individualized manner.

20. Describe any potential benefits to the individual subjects, group of subjects, and/or society. If there is no direct benefit to subjects it should be stated. NOTE: Compensation/payment for participation is not considered a benefit.

    The benefits of this research study may include enhancing the preparation of CCSU athletic training students for entry-level professional practice. This in turn may also improve the quality of patient care provided by graduates of CCSU's ATEP.

21. Describe what identifiable data will be obtained from the subjects. Audio, photo, and video recordings are generally considered identifiable unless distinguishing features are masked.

    The anonymized research data set that will be created will have the following as variables that cannot be traced back to an individual participant. All the data will be reported as groups for the participants from 2014-2019, thereby eliminating any reporting in an individualized manner. Collected from the de-identified secondary data will be the following 23 variables:
    1. Student's Comprehensive Clinical Assessment Rating Score- Practicum 1
    2. Student's Comprehensive Clinical Assessment Rating Score- Practicum 2
    3. Student's Comprehensive Clinical Assessment Rating Score- Practicum 3
    4. End of Semester Student Clinical Assessment Rating Score – Internship
    5. End of Semester Student Self- Assessment Rating Score – Practicum 1
    6. End of Semester Student Self- Assessment Rating Score – Practicum 2
    7. End of Semester Student Self- Assessment Rating Score – Practicum 3
    8. End of Semester Student Self- Assessment Rating Score – Internship

9. Clinical Integrated Proficiency Rating Scores – Practicum 1
10. Clinical Integrated Proficiency Rating Scores – Practicum 2
11. Clinical Integrated Proficiency Rating Scores – Practicum 3
12. Clinical Integrated Proficiency Rating Scores – Internship
13. Comprehensive Standardized Objective Practical Score - Practicum 1
14. Comprehensive Standardized Objective Practical Score - Practicum 2
15. Comprehensive Standardized Objective Practical Score - Practicum 3
16. Clinical Course Final Written Exam Score – Practicum 1
17. Clinical Course Final Written Exam Score – Practicum 2
18. Clinical Course Final Written Exam Score – Practicum 3
19. Clinical Course Grade – Practicum 1
20. Clinical Course Grade – Practicum 2
21. Clinical Course Grade – Practicum 3
22. Clinical Course Grade – Internship
23. BOC Pass/Fail Score

22. Describe how confidentiality of subject information will be maintained and how long research data will be kept. Maintaining confidentiality of subject information can be managed by limiting access to research records, securing records on password protected computer, saving data in encrypted files, storing information in a locked cabinet, etc.

    Once created, the de-identifiable electronic anonymized research data set will be secured and stored electronically on the Lead Investigator's CCSU One Drive which is password protected and additionally secured by Two Factor Authentication. Only the Lead Investigator will have access to the de-identified anonymized research data set. The student's electronic comprehensive assessment/ practical test files will remain within the ATEP File on CCSU's One drive for de-identification and gathering of data for entering into the electronic anonymized research data set. Paper files will be returned to their original locked filing cabinet within the athletic training facility. The de-identified electronic anonymized research data set used for this research study will be kept electronically secured on the Lead Investigator's One Drive pending need for future research. Limiting the created electronic anonymized research data set access to solely the Lead Investigator will further insure confidentiality is preserved.

SECTION V – Informed Consent Process

23. Check the space next to the informed consent process option for this proposed research and attach a copy of the consent form, script, or statement for the option. If not applicable enter N/A – Not Applicable

☐	1. Subjects will be given the standard consent form to read, sign, and return to researcher(s).
☐	2. Subjects will be given an information sheet to read.
☐	3. Subjects will be briefed orally by the researcher and given an information sheet.
☐	4. Subjects will only be briefed orally.
☐	5. Subjects will be given an online survey consent statement to read and acknowledge.
☐	6. Subjects will be given a short form consent with a witness to the oral presentation.
☐	7. Request to waive informed consent.

24. If requesting a waiver for documentation of informed consent for options 2, 3, 4, 5, and 6 above, check the space next to the appropriate condition below to justify the waiver. If not applicable enter N/A

Not Applicable

☐	The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
☐	The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

25. Describe the process for obtaining parental/guardian permission and assent from a child for research involving children. Attach copy of parental/guardian permission form and child assent form.

    Not Applicable

SECTION VI – Investigator Certifications

1. **Potential Conflicts of Interest:** Potential conflicts of interest exist when there is a divergence between an individual's private interests and his or her professional obligations to CCSU such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

   Each investigator will disclose all significant financial interests: (I) that would reasonably appear to be affected by the research, educational, or service activities or proposed for funding, by an external sponsor; or (II) in entities whose financial interests would reasonably appear to be affected by such activities.

   I certify that I am aware of this policy and have no conflicts to disclose.

   Date and LI initials: 7/25/2020 XXX **Date and PI initials:** 7/27/2020 XXX

2. **Scientific Misconduct Statement**: CCSU does not tolerate scientific misconduct as defined by the Public Health Service (PHS): "Misconduct in science is defined as (1) plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting or reporting research; or (2) material failure to comply with federal requirements that uniquely relate to the conduct of research." I certify that I am aware of CCSU's policy on scientific misconduct, and that everything I have reported on this form is accurate and true to the best of my knowledge. I also understand that deception on this form may result in the rejection of my application and/or the revocation of IRB approval for this project.

   Date and LI initials: 7/25/2020 XXX **Date and PI initials:** 7/27/2020 XXX

3. **Faculty Advisor Responsibilities**: If applicable, the PI as a faculty advisor must certify that he or she has reviewed the student's proposed research application and assures that the application is complete and the information contained accurate, confirms the integrity of the student's proposed research design, and that rights and welfare of the research subjects are protected at all times.

   Date and LI initials: 7/25/2020 XXX **Date and PI initials:** 7/27/2020 XXX

SECTION VII – IPSF Checklist of submission materials.

Check each appropriate box before sending submission materials.

☐ The relevant sections of the IPSF are complete.

☐ Attached is a copy of each informed consent document, parent permission form, and assent or oral consent script if applicable.

☐ Attached are all required gatekeeper letters and/or external IRB information and documentation for any planned external collaborations.

☐ Attached are copies of all measures, survey instruments, interview guides/questions, and questionnaires, etc.

☐ Attached are copies of all of all recruitment materials including oral scripts, email notices, web postings, flyers, etc., survey instruments, interview guides/questions, and questionnaires, etc.

☐ Attached is a copy of an ethics tutorial completion certificate for each member of the research team (e.g.; CITI).

Date and LI initials: 7/25/2020 XXX **Date and PI initials:** 7/27/2020 XXX

SECTION VIII – Additional Information

Re-consenting for this study from athletic training students participant from 2014- 2019 for the viewing of their ATEP assessment portfolio would be very difficult at this time as they are all have since graduated from the university.

Department of Physical Education and Human Performance
Central Connecticut State University
1615 Stanley Street ▪ New Britain, CT 06050

December 1, 2020

Re: Gatekeeper Letter

Dear CCSU Institutional Review Board:

XXXXX XXXXX is a xxxxxxx in Central Connecticut State University's Athletic Training Education Program (ATEP) housed in the Department of Physical Education and Human Performance and a doctoral student in CCSU's Educational Leadership Program. Xxxxxx is proposing to conduct a dissertation on "How Are Athletic Training Student Learner's Skill Development Ratings in the Clinical Learning Courses Related to their Ultimate Proficiency" during the 2020-21 academic year.

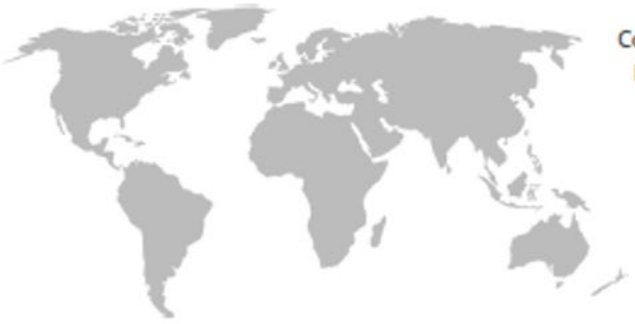
I fully support XXXXX's dissertation proposal and approve of the need to have access to athletic training student participant's assessment portfolios from 2014 – 2019. I am familiar with the methodology that is being proposed in this research study and support the use of the secondary data from CCSU's ATEP. I give permission for XXXXX to review the clinical assessment tools within the AT students' clinical paper and electronic portfolios maintained by CCSU's ATEP.

I understand that the XXXXX, as the Lead Investigator, will de-identify personal identifiable data in creating an anonymized electronic research data. The de-identification of the athletic training student participants in this study will be completed to safeguard that data cannot be traced to a particular participant.

XXXXX's role as xxxxxx in the ATEP includes similar review of athletic training student's portfolios for the purpose of program evaluation and annual accreditation reports. Therefore, I am confident in Xxxx's ability to maintain the confidentiality needed for conducting this study, as well as for proper security of the student's assessment portfolios and the research data set.

Sincerely,

CITI PROGRAM



Completion Date 22-Jun-2020
Expiration Date 22-Jun-2023
Record ID 36878077

This is to certify that:

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

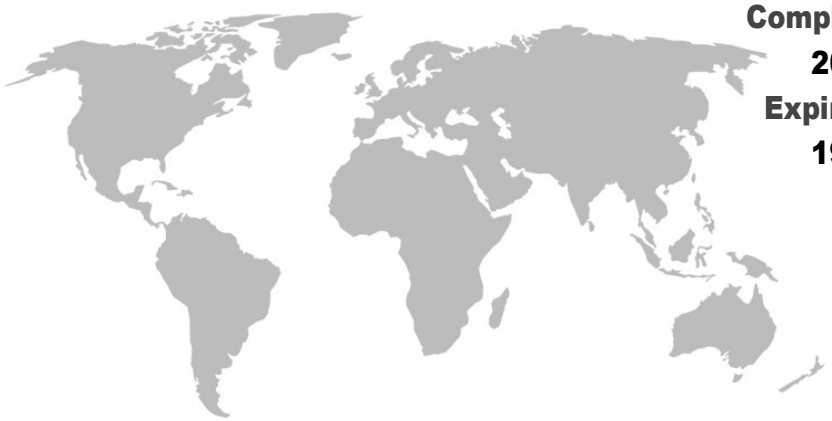
Human Subjects Research (Curriculum Group)
Group 2: Faculty/Graduate Students - Human Subjects Research (Course Learner Group)
1 - Basic (Stage)

Under requirements set by:

Central Connecticut State University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wc8f29d9a-6841-4c76-8b23-c0be74f3a561-36878077



Completion Date
20-Jun-2019
Expiration Date
19-Jun-2022
Record ID
32
107591

This is to certify that:

Has completed the following CITI Program course:

Human Subjects Research

(Curriculum Group) Group 2: Faculty/Graduate Students - Human Subjects Research **(Course Learner Group)** 1 - Basic

(Stage)

Under requirements set by:

Central Connecticut State University

Verify at www.citiprogram.org/verify/?w8ed30662-7a21-4dbc-83ea-25822fdc4993-32107591