UNIVERSITY of DENVER

OFFICE OF RESEARCH & SPONSORED PROGRAMS
Research Integrity & Education

DATE:	December 4, 2019
TO:	Emma Porter, M.A.
FROM:	University of Denver (DU) IRB
PROJECT TITLE:	[1507231-1] Psychological Factors that Impact White Counseling Trainees' Responses to Cultural Ruptures
SUBMISSION TYPE:	**EXPEDITED NEW PROJECT**
APPROVAL DATE:	December 4, 2019
NEXT REPORT DATE:	December 4, 2020
RISK LEVEL:	Minimal Risk
REVIEW TYPE:	Expedited Review
ACTION:	**APPROVED**
REVIEW CATEGORY:	Expedited Category # 6 & 7 **Category 6:** *Collection of a data from voice, video, digital, or image recordings made for research purposes.* **Category 7:** *Research on group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.*

Thank you for your submission of the **New Project** materials for this project. The University of Denver Institutional Review Board (IRB) has granted Full Approval for your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission. The IRB determined that the criteria for IRB approval of research, per 45 CFR 46.111, has been met.

This submission has received an Expedited Review based on applicable federal regulations. This project has been determined to be a Minimal Risk project. Please note that the following documents were included in the review and approval of this study:

- Advertisement - Recruitment Email for Professors_Emma Porter.docx (UPDATED: 12/3/2019)
- Advertisement - Recruitment Email_Emma Porter.docx (UPDATED: 12/3/2019)
- Application Form - Qualtrics Informed Consent_Pdf DOWNLOAD.pdf (UPDATED: 12/3/2019)
- Application Form - Qualtrics Informed Consent_Screen shots.pdf (UPDATED: 12/3/2019)
- Application Form - irb-appendix_n.docx (UPDATED: 12/3/2019)
- Application Form - irb-appendix_a_Emma Porter.docx (UPDATED: 12/3/2019)
- Application Form - Informed Consent_Porter.docx (UPDATED: 12/3/2019)
- Application Form - Citi_Alhabib.pdf (UPDATED: 11/11/2019)

- Application Form - Citi_Devin Kelly.pdf (UPDATED: 11/6/2019)
- Application Form - Citi_Dallas Vallar.pdf (UPDATED: 11/6/2019)
- Application Form - Citi_Anna Hangge.pdf (UPDATED: 11/6/2019)
- Application Form - Citi_Sabina Musliu.pdf (UPDATED: 11/6/2019)
- Application Form - Citi_Sree Sinha.pdf (UPDATED: 11/6/2019)
- Application Form - Citi_Anna Edelman.pdf (UPDATED: 11/6/2019)
- Application Form - Citi_Paulina Dzik.pdf (UPDATED: 11/6/2019)
- Application Form - Citi_Jasmine Davis.pdf (UPDATED: 11/6/2019)
- Application Form - irb_part_one_Emma Porter.docx (UPDATED: 11/6/2019)
- Application Form - CITI COI 2019_Owen.pdf (UPDATED: 10/8/2019)
- Application Form - citiCompletionReport6528937_Emma Porter.pdf (UPDATED: 10/3/2019)
- DU - IRB Application Form - DU - IRB Application Form (UPDATED: 11/14/2019)

Informed Consent Process

Please remember that informed consent is a process beginning with a description of the project and assurance of participants understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant.

A **Waiver of Written Documentation of Informed Consent**, per 45 CFR 46.117(b), has been granted by the IRB, as the following information was provided to document the consent procedure:

1. That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

However, the IRB requires the investigator to provide subjects with a written statement regarding the research. This type of consent process includes obtaining implied consent that may be used in conducting an online research study.

Implementation of Changes to Previously Approved Research

Prior to the implementation of any changes in the approved research, the investigator must submit any modifications to the IRB through completing an amendment form and await approval before implementing the changes, unless the change is being made to ensure the safety and welfare of the subjects enrolled in the research. If such occurs, a Reportable New Information (RNI) Form should be submitted, via the IRBNet system, within five days of the occurrence indicating what safety measures were taken and provide an updated protocol and/or consent, if applicable.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)

Any incident, experience or outcome which has been associated with an unexpected event(s), related or possibly related to participation in the research, and suggests that the research places subjects or others at a greater risk of harm than was previously known or suspected must be reported to the IRB. UPIRTSOs may or may not require suspension of the research. Each incident is evaluated on a case by case basis to make this determination. The IRB may require remedial action or education as deemed necessary for the investigator or any other key personnel. The investigator is responsible for reporting UPIRTSOs to the IRB within 5 working days after becoming aware of the unexpected event. Use the Reportable New Information (RNI) form within the IRBNet system to report any UPIRTSOs. All NON-COMPLIANCE issues or COMPLAINTS regarding this project must also be reported.

Continuation Review Requirements

Based on the current regulatory requirements, this expedited project does **not** require continuing review. However, this project has been assigned a **one-year review period** requiring communication to the IRB at the end of this review period to either close the study or request an extension for another year. The one-year review period will be posted in the Next Report Due section on the Submission Details page in IRBNet. During this one-year period, a staff member from the Office of Research Integrity and Education (ORIE) may also conduct a Post Approval Monitoring visit to evaluate the progress of this research project.

PLEASE NOTE: This project will be administratively closed at the end of a one-year period unless a request is received from the Principal Investigator to extend the project. Please contact the DU HRPP/IRB if the study is completed before the one-year time period or if you are no longer affiliated with the University of Denver through submitting a Final Report to the DU IRB via the IRBNet system. If you are no longer affiliated with DU and wish to transfer your project to another institution please contact the DU IRB for assistance.

Study Completion and Final Report

A Final Report must be submitted to the IRB, via the IRBNet system, when this study has been completed or if you are no longer affiliated with the University of Denver. The DU HRPP/IRB will retain a copy of the project document within our records for three years after the closure of the study. The Principal Investigator is also responsible for retaining all study documents associated with this study for at least three years after the project is completed.

If you have any questions, please contact the Institutional Review Board at (303) 871-2121 or through IRBAdmin@du.edu. Please include your project title and IRBNet number in all correspondence with the IRB.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Denver (DU) IRB's records.