DATE: June 9, 2021

TO: C. Riley Hostetter, MSW
FROM: University of Denver (DU) IRB

PROJECT TITLE: [1770840-1] Social Connection and Stability Among Nonbinary People: The Impact of COVID-19

SUBMISSION TYPE: New Project

ACTION: EXEMPTION GRANTED

DECISION DATE: June 9, 2021

NEXT REPORT DUE: June 9, 2022

RISK LEVEL: Minimal Risk

REVIEW CATEGORY: Exemption category #2

Exemption 2: Educational Tests, Surveys, Interviews, or Observations

Research in this category is allowed as long as one of the three criteria is met:

1. Information obtained is not identifiable
2. Disclosure outside of the research would not put subjects at risk of harm
3. Information obtained can be identifiable and a limited IRB review has been conducted which relates to there being adequate provisions for protecting privacy and maintaining confidentiality.

This exemption does not apply to research in the following instances:

• When the research is subject to Subpart D and includes children, Category 2 still does not allow:
  ○ Surveys
  ○ Interviews
  ○ Investigator participating in the activities being observed (public behavior observation without intervention is permitted)
  ○ Survey cannot be combined or paired with the collection of biospecimens or interventions, as those additional activities would disqualify the research from this category.

Thank you for your submission of Exemption Request materials for this project. The University of Denver IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations. This exemption was granted based on appropriate criteria for granting an exemption and a study design wherein the risks have been minimized.

Please note that maintaining exempt status requires that (a) risks of the study remain minimal; (b) that anonymity or confidentiality of participants, or protection of participants against any increased risk due
to the internal knowledge or disclosure of identity by the researcher, is maintained as described in the application; (c) that no deception is introduced, such as reducing the accuracy or specificity of information about the research protocol that is given to prospective participants; (d) the research purpose, sponsor, and recruited study population remain as described; and (e) the principal investigator (PI) continues and is not replaced.

If changes occur in any of the features of the study as described, this may affect one or more of the conditions of exemption and may warrant a reclassification of the research protocol from exempt and require additional IRB review. For the duration of your research study, any changes in the proposed study must be reviewed by the University of Denver IRB before implementation of those changes.

Informed Consent Process

Informed consent is an important process when conducting human subject research beginning with providing potential subjects with a description of the project and assurance of a participants understanding. The DU IRB has granted this project exempt status with the use of an Exempt Information Letter. Informed consent must continue throughout the project via the use of the approved Exempt Information Letter. If requested, each participant is entitled to receive a copy of the Exempt Information Letter.

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 exempt 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.

Study Completion and Final Report

A Final Report must be submitted to the IRB, via the IRBNet system, when this study has been completed. 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.

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.
If you have any questions, please contact the DU Institutional Review Board (IRB) at (303) 871-2121 or at 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.