RECORD AND REVIEW OF RESEARCH PROTOCOL

Researcher: Harrison (Last) Christopher (First) C (Middle Initial)

Student ID: W 00331814

Research Advisor: Heather Horowitz

Academic Level

☒ 1. Doctoral Dissertation/Capstone

☐ 2. Master's Thesis/Capstone

☐ 3. Other Click here to enter text.

Forms Check List

☒ 1. Human Subjects Protocol

☒ 2. CITI Training Certificate*

* Check with your research advisor for training requirements
* Training certificate cannot be older than 3 years

☒ 3. Consent Forms or Invitations

☒ 4. Instrument(s)

☐ 5. Other Click here to enter text.

This section is to be completed by the HSR Committee

Archive Number: Click here to enter text.

Research Category: Choose an item.

Final Approval Date: Click here to enter a date.

Project Information

Title of study (12 to 15 words maximum):

Including LGBTQIA+ Healthcare Education in the Pre-Clinical Curriculum at Osteopathic Medical Schools

Research purpose or issue:

It is unknown if second-year, third-year, and fourth-year osteopathic medical students can confidently work with sexual and gender minority patients and are competent with LGBTQIA+ specific health concerns.

External Research

If the research will involve other organizations, it is necessary to obtain permission from these organizations prior to collecting data. Some organizations have Institutional Review Boards (IRBs), and it may be necessary to obtain formal approvals from these IRBs. In other cases, a document from an appropriate organizational executive specifically approving the research would be sufficient. The researcher is responsible for determining what type of approval is required and obtaining the approval.

In cases where approval from Wilmington University's HSRC is required as a precondition to obtaining approval from another organization, the HRSC's approval will be provisional, requiring the additional step of obtaining research approval documents from other organizations before receiving full approval from Wilmington University's HSRC.

If the research involves other organizations, please answer these questions.

	YES	NO
Do these organizations require approval by their IRBs?	☐	☒
Has IRB approval been obtained? If **YES**, please attach the approval to this submission	☐	☐
Have other permission documents been obtained? If **YES**, please attach the approvals to this submission.	☐	☐

Other relevant information or comments:

Click here to enter text.

Population Information

Population to be studied: Gender All Age Adult Race/ethnicity All

What is the anticipated sample size?

50

How will participants be recruited?

Email and Snowball Sampling

The researcher will reach out to research directors or diversity representatives at each osteopathic medical school ask if they would send the study invitation to current second-, third-, and fourth-year students. The invitation can be found in Appendix A.

Students may also forward the information to fellow students.

What inclusion criteria will be used to identify the sample's participants?

Current second-year, third-year, and fourth-year students in the osteopathic medicine programs in the United States who are 18 years old or older.

What criteria will be used to exclude participants from the sample?

Students under the age of 18 or who are not current second-year, third-year, or fourth-year students at an osteopathic medicine program in the United States.

How will participants be selected?

All eligible students who consent to participate will be allowed to participate.

What are the procedures that the participants will undergo in the proposed research project including the physical location and duration of participation? **Attach a copy of all research instruments, e.g., surveys, questionnaires, interview questions, etc.:**

Study invitation (Appendix A) will be dispersed via email by the appropriate party at osteopathic medical schools (Appendix A also includes the email being sent to those parties). This invitation will include a Qualtrics link (Appendix B) to the electronic consent form (text of the consent form can be found in Appendix C). All respondents, whether they're eligible or not, will receive a copy of the consent text upon submission of the consent document. All consent form responses will be kept in a secure Qualtrics account on a password protected computer. The consent form will ask for the participant's name and email address. This information will only be accessed by the researcher.

An email will be sent to all consenting, eligible participants, by the researcher, including the dates the online course will be open. Participants will receive a link to join the online course.

Pre-test links (Appendix B) will be distributed via email by the researcher to all eligible participants who have consented to participate two to five days before the workshop. Text of the pre-test can be found in Appendix D. Post-test links (Appendix B) will be included in the final module of the course. Text of the post-test can be found in Appendix D.

All pre-test and post-test responses will be kept in a secure Qualtrics account on a password protected computer. No responses will ask for identifying information and will not be able to be matched to the identifying information collected in the consent form.

The research will consist of an online, asynchronous course via Google Classrooms. It will take approximately eight to nine hours to complete. The course will be composed of seven modules including narrated PowerPoints for each module. An outline of the modules can be found in Appendix E. There are handouts and additional resources being provided to participants as well (Appendix F).

Participants will be asked to share their name and contact information when filling out the consent form. During the course, participants can use their name or a pseudonym. No portions of the course will be recorded. Any participant that needs to step away for self-care, for any reason, will be encouraged to pause the course and return when able. Participants will also be provided with contact information for free mental health support at the beginning of the workshop.

The pre-test and post-test will ask participants to identify the region of the United States in which their school is located. Participants will never have to identify their school by name.

Confidentiality and Security

Select **YES** to certify that:

	YES	N/A
Procedures have been taken to ensure that individuals cannot be identified via names, digital identifiers (e.g., email address, IP address), images or detailed demographic information.	☒	☐
Code to name association data/information is securely and separately stored. (Participants are given codes and the codes are securely stored separately from their answers.)	☐	☒

All data is maintained in encrypted and/or password protected digital/electronic files.	☒	☐
Individually identifiable information will be securely maintained for three years past the completion of the research, and then destroyed rendering the data unusable and unrecoverable.	☒	☐

Describe the procedures you are taking to maintain anonymity, confidentiality, or information security.

The pre-test and post-test are completely anonymous and taken and stored via a secure Qualtrics account. Participants will use a unique identifier on each test so the researcher can match their results. The unique identifier consists of the two-digit number of the day of their birth, the first two letters of the street they grew up on, and the last digit of their cellular phone number. Pre-test and post-test links can be found in Appendix B. Text of the pre-test and post-test can be found in Appendix D.

The participant consent form will ask for their name and email address, but it will not be connected to the pre-test or post-test in any way. The consent form link will be included in the email invitation sent by the appropriate party at each school. The consent forms will be held in a secure Qualtrics account. The consent form link can be found in Appendix B. Text of the consent form can be found in Appendix C.

No Qualtrics information will collect IP address or any other identifying information other than what is asked on the consent form. All data will be kept, securely, by the researcher, for three years and then destroyed.

Access to the consent information will only be held by the researcher. The researcher and two dissertation committee members will have access to raw data collected in the pre-test and post-test.

During the course, no audio or video recordings of any sessions will be taken. Participants may use their name or a pseudonym during the course.

Research Protocol

Does this research involve?

	YES	NO
Prisoners, probationers, pregnant women (if there is a medical procedure or special risk relating to pregnancy), fetuses, the seriously ill or mentally or cognitively compromised adults, or minors (under 18 years) as participants	☐	☒
The collection of information regarding sensitive aspects of the participants behavior (e.g., drug, or alcohol use, illegal conduct, sexual behavior)	☐	☒
The collection or recording of behavior which, if known outside the research, could place the participants at risk of criminal or civil liability or could be damaging to the participant's financial standing, employability, insurability, or reputation	☐	☒
Procedures to be employed that present more than minimal risk[1] to participants	☐	☒
Deception	☐	☒
Possible or perceived coercion (e.g., a concern in power relationships such as teacher/student, employer/employee, senior/subordinate)	☐	☒
Benefits or compensation to participants (beyond the general benefits of the knowledge to be gained or small gifts/lottery prizes)	☐	☒
A conflict of interest (e.g., the researcher's material or other interests may bias collection, interpretation, or use of data)	☐	☒

If you answered "**NO"** to all of the questions please proceed to the next page.

If you answered "**YES"** to any of the questions, provide evidence that you have taken the training module or modules that relate to this risk and discuss what you learned about reducing the risk from the training in the textbox below and/or by attaching the evidence to this document.

Click here to enter text.

[1] Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests

Consent Forms

	YES	NO
Is a consent form included with this study? If **YES**, attach a copy.	☒	☐
Are child assent forms included with this study? If **YES**, attach a copy.	☐	☒
Is implied consent being used? If **YES**, attach a copy of the invitation.	☐	☒

Minors must provide an affirmative consent to participate by signing a simplified form, unless the researcher can provide evidence that the minors are not capable of assenting because of age, maturity, psychological state, or other factors.

Please refer to the informed consent outline and checklist and the assent outline, which can be found in the Human Subjects Review Committee section of the Wilmington University website.

Implied consent – For some exempt or expedited research, it is not necessary to have a signed consent form. For example, a relatively short survey of competent adults which is anonymous and deals with noncontroversial topics could use a less formal means of providing information. In such cases, the person's voluntary participation indicates implied consent. Typically, the invitation to participate would be less legal in tone than a consent form but would provide information about the researcher, study purpose, voluntary participation, nature/duration of participation, and anonymity/confidentiality.

How is consent being obtained?

Informed consent will be obtained through an online Qualtrics survey link (Appendix B) included in the study invitation email. Text of the consent form can be found in Appendix C. Participants will be asked to read through the consent document and then have the option to consent to participation or not consent to participation. Participants will also need to verify they are 18 years of age or older, a current OMS-II, -III, or -IV, and attending an osteopathic medical school in the United States. If the answer to any of these questions is "no," then that respondent will not be able to participate in the research. No matter the answers, all respondents that submit the consent form will receive an email with the informed consent information for their records.

At the start of the course, the researcher will ask participants to review the consent form again.

The consent form will ask for identifying information, but this form will not be tied to pre-test or post-test information and only the researcher will have access to this information.

Additional Research Approval

	YES	NO
1. Are you a Wilmington University employee ***AND*** a current Wilmington University student conducting research that involves human subjects?	☐	☒
2. Are you a Wilmington University employee ***AND NOT*** a current Wilmington University student conducting research that involves human subjects?	☐	☒
3. Are you a Wilmington University employee ***AND*** a student at another school whose research involves collecting data from the University, its students, or employees?	☐	☒
4. Are you an outside researcher whose research involves collecting data from the University, its students, or employees?	☐	☒

If you answered "YES" to question 1, proceed to the next page.

* If you answered "**YES**" to question 2, 3, or 4, an appropriate Wilmington University dean or executive must sign this form, prior to HSRC submission.

The executive signing this form is responsible for conferring with institutional research or other parts of the university which would need to support the research.

Dean or Executive:

Print name: Click here to enter text.

Signature: _____ Date: Click here to enter a date.

Obligations of Researcher

Any substantive changes made to the research protocol must be reported to and reviewed by your college's HSRC representative(s) prior to implementation of such change. Any complications, adverse reactions, or changes in the original estimates of risks must be reported at once to the HRSC chairperson before continuing the project.

Select **YES** to certify that:

	YES
Research data, including signed consent form documents, will be retained for a minimum of three years past the completion of the research in accordance with federal regulations	☒
The researcher will submit document and form revisions and updates, as appropriate	☒
The researcher will submit a renewal petition if the data collection has not been completed within one year of the most recent HSRC approval*	☒

* **Note**: HSRC approval expires after one year, requiring renewal of the HSRC Protocol

The researcher's signature below certifies that the Researcher has (a) read and understands the obligations as a researcher, (b) research approval expires one year after the final approval date shown on page 1, and (c) that the information contained in and submitted with this HSRC protocol is accurate and complete.

Researcher:

Print name: Christopher Harrison

Signature: C Harrison Date: 11/6/2022

Obligations of the Research Advisor

The research advisor has two major obligations. First, the research advisor must ensure the researcher completes all relevant training courses. Second, the research advisor must ensure the researcher submits all document and form revisions and updates, as appropriate for the research.

The research advisor's signature below certifies that the advisor has (a) read and understands the obligations as an advisor and (b) that the information contained in and submitted with this HSRC protocol is accurate and complete.

Research Advisor:

Print name: Click here to enter text.Heather Horowitz

Signature: Date: 11.7.2022

WILMINGTON UNIVERSITY

WILMINGTON UNIVERSITY
HUMAN SUBJECTS REVIEW COMMITTEE (HSRC) HSRC-11

PROTOCOL REVIEW

This section is to be completed by the HSR Committee.

Researcher: Click here to enter text. Christopher Harrison

Date Submitted: Click here to enter a date. 11/17/2022

The protocol and attachments were reviewed:

The proposed research is approved as:

☑ Exempt ☐ Expedited ☐ Full Committee ☐ Provisional (see External Research section)

The proposed research was approved pending the following changes:

☐ See attached letter

☐ Resubmit changes to the HSRC chairperson

The proposed research was disapproved:

☐ See attached letter for more information.

	YES	N/A
The HSRC representative sent a copy of the HSRC Protocol to the VP of Academic Affairs for research requiring access to Wilmington University students, employees, or data.	☐	☐

HSRC Chair or Representative

Click here to enter text. Dr. Katherine Cottle
Printed Name

Dr. Katherine Cottle
Signature

Date Click here to enter a date. 12/5/2022

HSRC Chair or Representative

Click here to enter text. **Dr. Todd Hackett-Slimm**
Printed Name

Todd Hackett-Slimm
Signature

Date Click here to enter a date. **1/9/2023**