Submission Type: Initial Date: 3-19-2024

IRB #: IRB-23-212
Title: Exploration of the interaction of gender identities, demographics, lifestyles, social determinants of health, and health access/utilization within the LGBTQ+ community.
Creation Date: 10-25-2023
Status: Review Complete
Principal Investigator: Tanya Cohn

Section 1 Getting started

About Cayuse IRB
Cayuse IRB is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all numbered sections may appear. You do not have to finish the application in one sitting. All information can be saved.

Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark in the top-right corner of each section.

Prior to starting your IRB application, please be sure you have read the IRB Manual: Instructions to Investigators and completed CITI Training.

For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the Cayuse IRB Procedures Manual.

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*required

I have read the information above and am ready to begin my submission

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✓ Yes

Getting Started

Throughout the submission, you will be required to provide the following, as applicable:

- Detailed Study Information
- Informed Consent Forms
- Study Recruitment Document(s)

Simmons University IRB

- You cannot begin data collection until a formal approval letter from the chair of the IRB has been received.
- Please submit the application as soon as possible.

Section 2 Investigator Information

*required

2.1 What is your status at Simmons University?

Student

✓ Faculty

Staff

*required

Principal Investigator

2.2 Name: Tanya Cohn

After entering the appropriate PI, please click "view" under "trainings." This will show completed CITI trainings. If you do not see any trainings listed, and this person has completed the required CITI training, please attach the certificate here.

Cohn CITI.pdf

Co-Investigator(s)

2.3

Your co-investigators will be required to certify this submission prior to review.

After entering the appropriate Co-PI(s), please click "view" under "trainings." This will show completed CITI trainings. If you do not see any trainings listed, and this person has completed the required CITI training, please attach the certificate here.

*required

Primary Contact

2.4 *Who should be contacted for questions or changes regarding this protocol? (Can be the same as Principal Investigator)*

Name: Tanya Cohn

Faculty Advisor

2.5

If you are a student, please select your faculty advisor for this project. Your faculty advisor is required to guide you through the submission process and sign off on your protocol.

After entering the faculty advisor, please click "view" under "trainings." This will show completed CITI trainings. If you do not see any trainings listed, and this person has completed the required CITI training, please attach the certificate here.

Other Personnel

2.6

Provide names of other personnel in this study who do not need access to this protocol (for example, student research assistants)

Personnel at other institutions

2.7

Personnel at collaborating institutions cannot have access to our Cayuse database. You may download a copy of your protocol as a PDF and share it with them that way. Please add their names and their roles below.

Please attach the CITI training (or equivalent) certificate(s) of personnel from other institutions who are involved in your study.

If you cannot find the appropriate Simmons contacts, please contact the IRB via irbprotocols@simmons.edu

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You may also share this form so that they may request a Cayuse account.

Section 3 Project Information

*required

3.1 Do you need assistance determining which type of application you should submit?

Projects include Human Subjects Research Project, Performance/Quality Improvement Project, or Classroom Project.

- Yes
- ✓ No

*required

3.2 Please select the type of project you are submitting.

- ✓ Human Subjects Research Project
- Classroom Project
- Performance Improvement Project

*required

3.3 Is this project being reviewed by another institution's review board?

- Yes
- ✓ No

*required

3.4 Is this project being submitted to a funding agency/organization?

Yes

✓ No

3.4.1 Is there any current funding for this project?

Yes

✓ No

*required

3.5 Start and End Dates of Project

Start Date

11-13-2023

End Date

11-18-2024

*required

Brief description of project

approximately 10 sentences or less

3.6 The LGBTQ+ community experiences significant health inequities and discrimination when seeking care resulting in poorer mental, emotional, and physical health outcomes. These inequities are further compounded by varying demographics and social determinants of health. Therefore, the aim of this study is to further explore on a greater national level, the interaction of gender identities, demographics, lifestyles, social determinants of health, and health access/utilization within the LGBTQ+ community. This will be accomplished using an exploratory approach using secondary

analysis of the *All of Us* Research cloud-based platform across a 5-year span. The anticipated outcomes seek to strengthen the identify of health inequities in order to provide national foundational evidence for provider education, policy reform, and patient care.

*required

Does your project involve any of the following populations?

3.7

Projects that involve any of the below "vulnerable" populations and involve greater than minimal risk may receive a full review.

Children under 8 years of age

Children 8-17 (under 18 years of age)

Prisoners

Economically disadvantaged

Educationally disadvantaged

Individuals with impaired decision-making ablity

✓ None of the above

*required

Does this project include secondary data analysis?

3.8 Secondary data analysis involves the re-use of data and specimens that were or will be collected for non research purposes or from research studies other than the proposed research study. The research materials generally will be publicly available materials, medical records or existing repositories of clinical specimens. Non contact between investigator and subject is allowed.

✓ Yes

3.8a The data is:

Publicly available

Identifiable

✓ Non-public data

Deidentified

No

3.9 If you will be utilizing any outside agencies to conduct your research, please attach the appropriate permission letters or emails from the agencies indicating their willingness to cooperate with your research.

About the Research Hub ? All of Us Research Hub.pdf

*required

Will you be recording identifiable, private information about individual subjects?

3.10 Private information is considered to be identifiable when it can be linked to specific individuals either directly or indirectly through a coding system. For example, collecting detailed demographic information or information on personal experiences qualifies the data collected as identifiable private information

Yes

✓ No

*required

3.11 Will you be utilizing audiotapes or videotapes in your research?

Yes

✓ No

*required

3.12 When you have completed your contact with the research participant, will there be a debriefing session?

Yes

✓ No

Section 4 Project Description

Please fill out the questions below for human subjects research and performance improvement projects.

If a question is not applicable to your study or project, which may occur in cases of secondary data analysis or performance improvement projects, you may write "not applicable." Sufficient detail should be provided so that the IRB may determine the level of risk and the purpose of the proposed study or project.

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*required

General Description. Briefly describe the overall goals of the proposed research and the general procedures you plan to use in conducting your research project.

4.1

The LGBTQ+ community experiences significant health inequities and discrimination when seeking care resulting in poorer mental, emotional, and physical health outcomes. These inequities are further compounded by varying demographics and social determinants of health. Therefore, the aim of this study is to further explore on a greater national level, the interaction of gender identities, demographics, lifestyles, social determinants of health, and health access/utilization within the LGBTQ+ community. This will be accomplished using an exploratory approach using secondary analysis of the *All of Us* Research cloud-based platform across a 5-year span. The anticipated outcomes seek to strengthen the identify of health inequities in order to provide national foundational evidence for provider education, policy reform, and patient care.

*required

Significance of the Study. Provide a brief theoretical and empirical rationale for why you believe this study is important. Include a concise review of literature including conceptual framework, and specific hypotheses to be tested and/or research questions to be addressed.

The LGBTQ+ community is more likely to experience mental health challenges which are often linked to anti-LGBTQ+ attitudes and compounded for those from racial and ethical minorities along living in poverty (Medina-Martinez et al., 2021). Furthermore, LGBTQ+ individuals fear disclosing their sexual and gender identities when seeking health care due to the anticipation that it will negatively impact the attitudes of their healthcare providers and thus quality of care (Alencar Albuquerque et al., 2016). In turn, homosexual women are less likely to seek out preventative gynecological care than their heterosexual counterparts (Alencar Albuquerque et al., 2016). This is also true for homosexual men who are found to show low demand for healthcare and when sought feel they are not met due to discrimination of healthcare professionals (Alencar Albuquerque et al., 2016). These same challenges are exemplified in the transgender and gender diverse communities who are more likely to report fair to poor mental and physical health along with significantly high levels of discrimination and denial of equal treatment in healthcare (Schiem et al., 2022).

4.2 Furthermore, lesbian/gay and bisexual women showed more significant economic health disparities compared to gay and bisexual males resulting in greater mental and physical disparities (Schuler et al., 2018). In addition, transgender adults are more likely to be uninsured, under educated, have poorer health, higher depression, and be members of other marginalized minors (Koma et al., 2020). Although there is data that has begun to identify the health inequities experienced by the LGBTQ+ community, there still exists a gap in various community and urban settings regarding the magnitude of social determinants of health for this vulnerable community. Therefore, this study seeks to further explore on a national level, the interaction of gender identities, demographics, lifestyles, social determinants of health, and health access/utilization within the LGBTQ+ community.

The purpose of this exploratory research study to further examine on a national level, the interaction of gender identities, demographics, social determinants of health, and health access/utilization within the LGBTQ+ community. Specifically, to look at protective and risk factors within the LGBTQ+ community in order to answer:

- 1.
  What are the interactions (relationships and differences) in demographics, social determinants of health and health access along with utilization among the LGBTQ+ community?
- 2.
  What are the interactions (relationships and differences) in overall health, lifestyles, demographics, and social determinants of health among the LGBTQ+ community?

*required

4.3 *Participant Population*. Describe the characteristics of the participant population, highlighting any potential vulnerabilities in this research project. If your participant population includes vulnerable populations, please express rational for including these populations in your study.

This study will include secondary analysis of existing data from *All of Us* Research. Demographically the inclusion criteria are members who identify as members of the LGBTQ+ community.

*required

Participant Recruitment. Describe plans and procedures for the recruitment of participants and the steps to obtain informed consent. Outline who will be recruited, by whom, from where, and how it will be accomplished. Include recruitment script and any recruitment materials in your attachments.

4.3a

This is a secondary analysis of cloud based workbench repository data available through *All of Us* Research. Simmons University is a member of the *All of Us* Research Registered Tier and has a Data Use and Registration Agreement with *All of Us* Research. Therefore, no participant recruitment will occur.

*required

Research Procedures and Sources of Research Material. Describe your research data collection procedures and identify the sources of research material obtained from individually identifiable living human participants in the form of specimens, records, or other data.

4.4

An exploratory research study will be conducted using a secondary analysis of existing data approach using the *All of Us* Research cloud-based platform across a 5 year span. The specific data to be explored are within the below *All of Us* Research databases:

1. The Basics
2. Overall Health
3. Lifestyles
4. Healthcare Access Utilization
5. Social Determinants of Health

Data will be explored and analyzed within the *All of Us* Research cloud-based platform, which is a requirement of *All of Us* Research, within the PI's password protected registered workbench.

Note that an Excel spreadsheet of all available data from All of Us Research has been uploaded under Survey Tools, however the above databases will be targeted for this project.

*required

4.5 *Risks*. It is very unusual for human participants research to have zero risk to them. Describe any potential risks (For example, confidentiality and privacy matters; physical, psychological and social well-being; legal and financial risks, etc.) and assess their likelihood and seriousness.

There is a potential risk to confidentiality, however all data will be explored and analyzed within the *All of Us* Research cloud-based platform, which is a requirement of *All of Us* Research, within the PI's password protected registered workbench.

*required

4.5a Technological and physical safeguards to protect data from inappropriate disclosure

Select all that apply

- ✓ Anonymizing data at point of collection (e.g. using Qualtrics to anonymize data)
- Locked room or space
- Behind a double lock (e.g. locked cabinet in a locked room)
- ✓ Restricted access to authorized research team members
- ✓ Password-protected computer or device
- ✓ Password-protected digital folder or online storage
- Encrypted file transfer
- Secure Simmons University Google Drive (or secure drive from affiliated hospital or institution)
- Destruction of source data immediately after processing
- Destruction of audio or visual data after transcription or after data analysis has been completed
- Modification of audio or visual data to eliminate identifiers
- Other (describe below in 4.5c)

*required

4.5b What will you do with data or specimens at the conclusion of the study?

Select all that apply

I am not collecting any identifiers. I will retain data for the required retention period (at least

✓ 3 years after completion of the research. (45 CFR 46.115(b)) and then destroy it.

I will de-identify data or specimen logs and erase or destroy any related codes. I will retain data for the required retention period (at least 3 years after completion of the research. (45 CFR 46.115(b)) and then destroy it.

I will keep identifiable data for the required retention period (at least 3 years after completion of the research. (45 CFR 46.115(b)) and then destroy it.

I will destroy any leftover specimens.

I will retain data and specimens for future use.

Other (describe below in 4.5c)

*required

4.5c *Protection Against Risks*. Elaborate on the procedures for protecting against or minimizing any potential risks in detail and assess their likely effectiveness. Where appropriate, describe provisions for secure storage of data.

There is a potential risk to confidentiality, however all data will be explored and analyzed within the *All of Us* Research cloud-based platform, which is a requirement of *All of Us* Research, within the PI's password protected registered workbench.

*required

4.6 *Benefits*. Discuss any direct, specific benefits *to participants*. (If none, please write "none")

None.

4.7 *Informed Consent*: Describe your consent process. (How and when you will distribute the informed consent document, when will it be collected, etc.)
If uploading consent form(s) please submit PDFs.

N/A

Attach your consent form(s)

Please submit as PDF

4.8 *Recruitment Materials*: Attach the materials (e.g. flyers, messages/emails, script(s)) that you will use to recruit participants.

4.9 *Study Tools*: Please attached any survey or interview questions, or other study tools relevant to your project.

All of Us Registered Tier Dataset v7 CDR Data Dictionary (R2022Q4R9).xlsx

Section 5 Important Info

Thank you for completing your protocol. Please be sure to click "complete submission" on the bottom of the blue navigation panel to the left.

Your protocol will not be submitted for review until you, your faculty advisor, if applicable, and co-PIs, have "certified" the submission. You will do this under Submission Details. This step must be completed every time you make changes to your submission for review because it acts as your signature. Please refer to the user manual if you have questions about this step.

Once you submit your protocol for review, please allow 10 business days for review and feedback.

If you have any questions please contact irbprotocols@simmons.edu.

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*required

✓ I have read the above information and understand that my protocol is not submitted for review until I certify the submission on the submission details page. If applicable, I understand that my co-PIs and/or faculty advisor will also have to complete this step in order for my submission to be reviewed.

Section 6 IRB Office Use Only

This page may be used by the IRB Office to summarize and communicate with the reviewers, if applicable.