

**Thematic Analysis of Sexual and Gender Minority Enrollment in the All of Us
Pennsylvania Project: Implications for Public Health Research**

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Submitted to the Graduate Faculty of
the Department of Human Genetics
Graduate School of Public Health in partial fulfillment
of the requirements for the degree of
Master of Science

University of Pittsburgh

2019

UNIVERSITY OF PITTSBURGH
GRADUATE SCHOOL OF PUBLIC HEALTH

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Abstract

To date, large-scale population studies have failed to fully assess the health of sexual and gender minority (SGM) populations. With the implementation of individualized healthcare, comprehensive patient information—including gender identity and sexual orientation (GI/SO)—are gaining recognition as critically important to designing holistic treatment plans and engaging patients. Historically, SGMs have been described in the context of existing health disparities, most commonly substance abuse and HIV/AIDS. The All of Us National Precision Medicine research project is a historic effort to gather health information from one million Americans and has emphasized engaging with populations historically underserved and underrepresented in biomedical research, including SGM populations. To increase SGM representation, better understanding of the barriers and facilitators to enrollment in public health research is necessary. This study explored the attitudes, knowledge, and beliefs of 23 self-identified SGMs regarding public health research across six focus groups in Pittsburgh, PA. Participants who had previously enrolled in All of Us were also asked specifically about their enrollment experience. Discussions were audio-recorded and evaluated using thematic analysis. Five themes were identified: (1) explicit invitations and clear messaging, (2) factors that tip the scales, (3) variation of SGM research accessibility, (4) barriers and facilitators to disclosing identity, and (5) personalization of the research experience. Participants acknowledged numerous social ecological factors that may influence their decision to enroll in a study, including SGM-specific advertising, well-trained staff

who create a comfortable atmosphere, inclusive demographic questionnaires that allow for complete identity disclosure, and the ability to opt out of uncomfortable study components when possible. Based on participant recommendations, All of Us could consider adding same sex couples and gender non-binary individuals to advertising campaigns, clarifying the use of psychiatric records in medical records sharing, and engaging SGM community leaders in recruitment efforts. Beyond program-specific suggestions, the public health significance of this work is the reinforcement of the need for SGM-specific considerations in the design and implementation of research. Researchers can better engage SGMs through explicit invitations to participate, inclusive demographic questionnaires, and a trained staff who can engage with participants with a range of gender identities and sexual orientations.

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Acknowledgements

This work required the time and dedication of many individuals. I would first like to thank my thesis advisor Mylynda Massart, MD, PhD, who has matched my enthusiasm and excitement for this work from day one. Her involvement in All of Us has been invaluable in funding the focus groups and providing insight into the goals of this historic effort to increase participant diversity and inspire scientific discovery. To my program director, Robin Grubs, MS, PhD, LCGC, thank you for your constant support and accountability. I cannot thank you enough for encouraging me to pursue my project and helping me to connect it to my future career as a genetic counselor.

To my other thesis committee members, Martha Ann Terry, PhD and Sarah Krier, MPH, PhD, this document would not exist without your input and guidance. Martha Ann, your command of grammar and expertise in focus group design and implementation pushed me to be a better writer and qualitative researcher. Sarah, your work with sexual and gender minority populations and your excitement in my project has inspired me to continue this work.

The focus groups would never have materialized without the advertising help of Kerri Jackson and the Pitt+Me team as well as the IRB expertise of Shannon Valenti from CTSI. Thank you for helping me through the tedious processes of IRB application and recruitment.

Finally, I would be remiss if I did not thank all of the amazing friends and family who helped me through this process. Thank you for offering me space to write, support when the process felt overwhelming, and motivation when I felt stuck. Thank you for allowing me to cancel plans when time was short and not accepting a cancellation when you knew I needed a break. Your sacrifices never go unnoticed and I could not be more grateful.

Preface

Relevant qualitative terminology

Qualitative research is an amalgamation of science and art. Though data collection and analysis should be systematic and grounded in theory and direct observation, the synthesis and contextualization of human narratives and observations inherently introduces some level of subjective interpretation. Because of the potential for differences in interpretation of the data, clear explanation of the constructs and methods used to ground the research is vital. To aid in the interpretation of this work, several qualitative research concepts should be defined: *unit of analysis*, *meaning unit*, *condensation*, *abstraction*, and *barrier versus reservation*. The first four terms employed definitions introduced by Graneheim and Lundham, whereby *unit of analysis* refers to the level of data being considered an independent unit, such as a transcript; *a meaning unit* refers to a statement or thought related by a central meaning; *condensation* is the summary of narratives while retaining the core intent; and *abstraction* is the act grouping together codes or categories into higher themes while considering the larger context (Graneheim & Lundman, 2004). These concepts were used to analyze focus group transcripts for over-arching themes while preserving the original meaning of the narratives. These terms are further applied in the description of the methods, however the definitions provide some information about the underlying assumptions and approach to this work.

The final concept, *barrier versus reservation* arose during thematic analysis. When discussing why someone may not want to participate in research, participants offered two types of roadblocks: further questions or concerns that could be answered by the research team and issues that required some form of study modification to overcome. As an illustration, a participant may

have expressed wanting to know where a blood sample was being stored. This would be considered a reservation, as further information could encourage research participation. By contrast, if a participant described a lack of transportation or previous negative research experience, these were considered barriers. In such cases, the participant or researcher would need to address the issue specifically and consider adjusting the study protocol to minimize this barrier. Adjustments could include providing travel vouchers or building trust in the community by supporting a community advisory board. Essentially reservations require elucidation, while barriers require intentional modification. This distinction was required when considering interventions to increase sexual and gender minority enrollment: reservations would require clearer messaging and educational materials, while barriers may involve organizational changes and initiatives.

Considerations of researcher bias in qualitative research

Rather than try to completely eliminate the inherent bias introduced by a research team, qualitative research methodology encourages researchers to be transparent about potential sources of bias to give context to data analysis and reported results. As the principal investigator, my biases originate from my identity as a queer female and my personal experience with research, both as an investigator and a participant. Despite efforts to raise awareness and visibility of SGM health disparities, the field of SGM research remains in its infancy. For SGM communities to garner the attention, resources, and support required to address described and emerging disparities, SGM communities must first be counted and described in research. My hope is that the All of Us project is able to set the standard of how to thoughtfully engage with marginalized populations, like SGMs, in large scale studies and to model how research can include participants who are reflective of the

diversity in current society. By describing the health of SGMs on a population level, I believe research will be poised to address the unique health challenges faced by this diverse community.

I navigate the healthcare system as both a practitioner and a patient. I am often reminded of how infrequently gender identity and sexual orientation are included in demographic questions and how often heteronormative and cis-gender stereotypes impact my conversations with healthcare providers. My experiences as a queer female informed the design, execution, and analysis of these focus groups. Because I enrolled in the All of Us project, I began with some idea of the current practices and opportunities for improvement. Additionally, when considering how to divide groups and how to pose questions about the impact of gender identity and sexual orientation, I was able to draw on my experiences. Furthermore, I was better able to synthesize discussions across groups because of my knowledge of SGM culture.

Relevant abbreviations

AoU: All of Us National Precision Medicine research project

CDC: Centers for Disease Control and Prevention

GI/SO: Gender identity and sexual orientation

HHS: U.S. Department of Health and Human Services

LGBT+: Lesbian, gay, bisexual, transgender, and beyond

MSM: Men who have sex with men

NIH: National Institute of Health

SGM: Sexual and gender minority

1.0 Introduction

Sexual and gender minority (SGM) encompasses individuals who do not identify as cis-gender (identifying with the sex assigned at birth) or heterosexual. This diverse population includes but is not limited to lesbian, bisexual, gay, queer, transgender, gender non-conforming, gender non-binary, and those who do not identify with any labels. For decades, research has pointed to the range of health disparities experienced by SGMs. Beginning with the AIDS epidemic in the 1980s, the narrative of SGM health and pathology in the United States (U.S.) has largely been defined by the incidental discovery of a health disparities among SGM populations while looking at general population health (Krehely, 2009; Sanchez et al., 2006). As researchers studied the epidemiology of tobacco use, drug use, obesity, mental health and suicidal ideation in the general population, SGM populations were discovered to be overwhelmingly over-represented in this type of research (Gonzales & Henning-Smith, 2017; Simoni, Smith, Oost, Lehavot, & Fredriksen-Goldsen, 2017; Simoni et al., 2017).

Defining a population by a health disparity, rather than holistically analyzing the health of a population, creates interventions that are reactive and not population-specific (Alexander, Parker, & Schwetz, 2016; Bonvicini, 2017). This approach may also fail to identify health issues specific to a population. For example, during the HIV/AIDS epidemic, men who have sex with men (MSM) were quickly identified as a high-risk group. Interventions that focused on the distribution of condoms and encouraging safer sex practices were largely unsuccessful in preventing the transmission of HIV (Sullivan et al., 2012). Further research and engagement with MSM showed that messaging was ineffective, and a combination of biomedical intervention (such as treatment as prevention) and targeted messaging could have been (Sanchez et al., 2006). The focus on

solving a single issue ignores the larger context and interactions, such as socioeconomic status, health literacy, and social capital. In addition to social determinants of health, physiological interactions may also play a role, as research is beginning to consider the interactions of genes, environment, and lifestyle in an individual's overall health.

1.1 A new focus in research and medicine

In recent years, medicine has acknowledged that treating the patient holistically and engaging them as a stakeholder are more effective than the historically employed paternalistic approach. Known as patient-centered care, this framework includes considering factors important to the patient, like religion, cultural beliefs, and gender identity and sexual orientation, when designing a treatment plan *with*, rather than *for*, patients (Cliff, 2012). Precision medicine is the application of this concept. Moving beyond identifying variances in genes, environment, and lifestyle, precision medicine utilizes these differences to create the right treatment for the right patient at the right time (Abrahams, 2008). Biobanks are being created to store individual samples to better understand how each person's unique differences impact their overall health. These samples provide the basis for the emerging field of precision medicine research and its recommendations for patient care.

Unfortunately, reliable data do not exist for all patients (Konkel, 2015; Oh et al., 2015). Historically, marginalized populations have been exploited during the investigation and exploration of experimental treatments, while the affluent majority has reaped the benefits from biomedical research. Discussions of medical ethics often involve historic cases, such as the Tuskegee Study or the experimentation on prisoners at the Holmesburg Prison. These examples

are critical in understanding the apprehension of marginalized groups to engage with research. Moreover, even after the introduction of ethical principles and guidelines, like the Belmont Report, which serve to protect participants, medical research is far from being representative of the diversity in the general population. One striking example is the 5% representation of African Americans in medical research, while they account for 12% of the total population in the United States (Coakley et al., 2012). While no study to date has assessed the representation of sexual and gender minorities, research has shown this population faces unique health challenges and has been historically marginalized by society and the medical community. Because information to date focuses on SGM participation in disease-specific research, further investigation is necessary to determine factors impacting SGM enrollment in general health research, like AoU (Maril, 2016).

Currently, precision medicine is limited in application for underrepresented populations. Data supporting the use of certain treatments and therapies is limited to largely white male populations (König, Fuchs, Hansen, von Mutius, & Kopp, 2017; Konkel, 2015; Oh et al., 2015). Without the appropriate population sample, a therapeutic intervention cannot be appropriately applied to an individual, especially if they are from a population underrepresented in the collection and testing of that intervention. To combat this lack of diversity and propel medical discovery, President Obama introduced the Precision Medicine Initiative, currently known as the All of Us (AoU) Research Project. This study is an historic effort to collect health information from more than one million Americans across the U.S., with a particular focus to engage historically underrepresented and under-served populations, including SGMs (National Institutes of Health, 2019a). The information collected includes basic measurements, like height and weight, biological specimens, access to medical records, and on-going invitations to participate in future studies. Researchers will then be able to apply to access the biobank for further research, confident their

results will better translate to the diverse groups across the United States. SGM representation in AoU is paramount for inclusion in future medical studies and discoveries. Beyond ensuring that results are translatable to this unique population, gathering information from a larger population-based sample allows for the opportunity to assess the *health* of SGMs and better identify and characterize health needs and survey patients about their health goals.

Accounting for 4-10% of the general population, SGM are an underserved and understudied population (Gates, 2011). AoU is an opportunity to gather more information about the diverse SGM community and their health. In order to utilize this avenue, increased SGM participation is vital. The purpose of this study was to identify possible barriers and facilitators to SGM participation in public health research with the intent of improving current AoU recruitment practices. The information obtained from the study could also inform future public health research efforts.

To explore this aim, six focus groups, divided based AoU enrollment status, were conducted in the Pittsburgh area over a six-week period. Discussions were audio-recorded and transcribed verbatim using a combination of manual typing and transcription software. The transcripts were then analyzed using thematic analysis. To give context to the discussions, a secondary aim compared focus group demographic data to national AoU statistics. Results of this study offered insight in to current AoU recruitment practices and can be applied to larger SGM research settings.

2.0 Literature Review

Accurate and comprehensive health data does not exist for all populations. Historically, the scientific community has not engaged equitably with minority populations (Khubchandani, Balls-Berry, Price, & Webb, 2016; The Joint Commission, 2011b). Consequently some health data were based on skewed, biased results, gathered under false pretenses, or not representative of target populations (Aaron & Chesley, 2003; AHIMA Work Group, 2017; Krehely, 2009). To ensure diverse representation, focused efforts to engage underserved and underrepresented populations in an ethical culturally competent manner in research are paramount. Minority populations, as defined by Healthy People 2020, include race, ethnicity, age, physical and mental ability, as well as sexual orientation and gender identity. (U.S. Department of Health and Human Services, 2019b). Sexual and gender minorities were recently added to this list. To date, little research has been done on their overall health and funding for research about SGM populations is lacking. More national, population-based data are needed to accurately describe this population and their health. AoU offers a unique opportunity to build this data set. Therefore, informing SGM groups about and giving them the opportunity to enroll in the project are vital. This requires analysis of enrollment practices and the collection of demographic information, including gender identity and sexual orientation.

This literature review serves to define and describe the current health of gender and sexual minorities in the United States, as well as discuss the All of Us Precision Medicine initiative and its role in striving to achieve diverse representation in its own endeavors.

2.1 Defining the population

Sexual and gender minority (SGM) encompasses individuals who do not identify as cis-gender (identifying with the sex assigned at birth) or heterosexual. This diverse population includes but is not limited to lesbian, bisexual, gay, queer, transgender, gender non-conforming, gender non-binary, and those who do not identify with any labels. The SGM population is diverse and experiences unique health challenges (Krehely, 2009; Maril, 2016; Simoni et al., 2017). Describing and measuring such a diverse population can be challenging. Several organizations have created guidelines for collecting these data in the most exhaustive and culturally competent manner as possible, including considering the purpose of asking about GI/SO, having a predetermined method of grouping identities, and transparently communicating with participants about the intended use of the information (U.S. Department of Health and Human Services, 2019c).

2.1.1 Relevant vocabulary

Language around gender and sexuality is constantly evolving; therefore, choosing the appropriate term or definition can be challenging. How a researcher operationalizes gender identity and sexual orientation can impact the study population and the interpretation of the results. If the study does not clearly differentiate between identity, behavior, and attraction when asking about sexual orientation, participants may be unclear of how to answer and the data created may not have a clear interpretation. Acknowledging the ever-expanding vocabulary around gender identity and sexual orientation can give some insight into the difficulty researchers have had reliably measuring and reporting their findings.

2.1.1.1 Gender identity

Gender and sex are complicated concepts and often conflated by researchers, which can lead to challenges in defining and describing these populations. *Gender* is a societal construct that is often delineated into masculine and feminine categories based on biological sex (sex assigned at birth), psychological, and cultural factors (Kari, 2019). Gender identity is how someone views themselves (an internal attribute) while gender expression is how they present to society (an external attribute). Often, the presenting biological sex is used to determine someone's gender: babies with a penis are described using masculine pronouns and assigned male, babies with a vagina are described using feminine pronouns and assigned female. In Western culture, gender has historically been viewed as a binary dimension, though other cultures and current evidence suggest this is a gross over-simplification. Gender non-binary, genderqueer, and third gender are more recent adoptions supporting gender as a spectrum. Transgender or trans is someone whose sex assigned at birth is not congruent with their gender identity and/or expression. Gender affirmation is the act of reinforcing one's true gender identity through social recognition and support (Sevelius, 2013). Surgery or other medical intervention is assumed to be part of this process, though it can also include changing their name, their pronouns, or their physical appearance with different clothes or hairstyle. This does not need to involve a legal process, though some trans individuals have the resources and desire to solidify these changes on court documents, like a passport or driver's license. In 2014, 0.6% of the population identified as transgender, doubling the 2011 estimate (Gates, 2014). This estimate refers to identity, not necessarily how the individual has affirmed their identity, meaning not all people have undergone or even desire to undergo surgery or other medical intervention. The number of other gender minority populations, like gender nonbinary, has not been identified.

2.1.1.2 Sexual orientation

Sexual orientation is often described in terms of behavior, as in who someone has sex with or is in a romantic relationship with. The reality, however, is much more complex and includes dimensions of a person's identity, attraction, and behavior. Identity refers to how the person views themselves, as in they may identify as queer or as a lesbian. Attraction is the sex or gender of the person they are romantically or sexually interested in, which could be binary (man or woman) or anywhere along the gender spectrum. Someone may also be sexually attracted to someone regardless of their sex (pansexual) or no one (asexual). Finally, behavior considers the gender of the person with whom they are physically intimate —men who have sex with men, for example. These men may identify as straight but be attracted to and have sex with other men.

These distinctions are important when considering the wording of demographic questions for research purposes. Time is also an important concept, meaning how long a person has identified or attracted in a certain way. A man may identify as bisexual but have only had sex with women for the last 10 years. In such cases, the researcher should word the question to capture information most relevant to the research question. These nuances can drastically change population estimates: 3.5% of the population identifies as lesbian, gay, or bisexual, though 8.4% (19 million Americans) report same-sex behavior and 11% report same sex attraction (Gates, 2011). A sexual minority, broadly, is someone who is not only attracted to the opposite sex. While a transgender person may also identify as a sexual minority, this is not often the case.

2.1.1.3 Defining gender and sexual minorities

SGMs are largely defined as any group that differs from societal expectations of sexual orientation and gender identity, meaning attracted to and involved only with the opposite sex and identifying as cis-gender. SGM is considered more inclusive than LGBT, as the latter confines

the description to four identities: lesbian, gay, bisexual, and transgender. The full acronym is now 12 letters long: LGBTQQIP2SAA. Terms included are lesbian, gay, bisexual, transgender, questioning, queer, intersex, polysexual, two spirit, asexual, and allies. Even this list still does not capture all the variation in gender identity or sexual orientation. LGBT+ is often sometimes used, as the “+” denotes those who do not identify as the four named identities.

“Sexuality” can more broadly refer to how someone experiences themselves and others as a sexual being. This definition includes gender identity and sexual orientation (Dyer & das Nair, 2013). The distinction between gender identity and sexual orientation is important in SGM research, though the two are often conflated. Some researchers may ask about sexual orientation and include transgender, not appropriately separating gender identity and sexual orientation. Additionally, research regarding gender minorities is lacking even more than sexual minorities. Grouping the two terms could fail to capture valuable data for that population.

2.1.2 Measuring gender and sexual minorities in the general population

The many dimensions of gender identity and sexual orientation (GI/SO) create countless combinations for describing SGM populations. A recent review of 43 health surveys—regional, national, and international—analyzed the measures used to capture GI/SO information. Only 14% measured all three dimensions of sexual orientation—identity, behavior, and attraction (Patterson, Jabson, & Bowen, 2017). None of the studies reported measuring both sex assigned at birth and current gender identity as recommended by the Sexual Minority Assessment Research Team.

2.1.2.1 Current efforts to measure SGM

The Centers for Disease Control and Prevention (CDC) included a question to capture sexual orientation in the National Health Interview Survey in 2012. In 2014, survey questions on gender identity and sexual orientation were added to the Behavioral Risk Factor Surveillance System (BRFSS) after developing and testing the measure (Assistant Secretary for Health, 2015). Other government agencies have started collecting gender identity and sexual orientation information: the Substance Abuse and Mental Health Services Administration (SAMHSA) introduced it on the National Survey on Drug Use and Health in 2015 and the Health Resources and Services Administration (HRSA) included the measure on both the National Health Service Corps Patient Satisfaction Survey in 2013 and the NURSE Corps Participant Satisfaction Survey in 2014 (Assistant Secretary for Health, 2015).

2.1.2.2 Best practices for measuring SGM

Surveys usually begin with demographic questions as a way to identify and classify participants. Often, these items are considered “warm up” questions and little consideration is given to the wording or weight they may hold. For gender and sexual minorities, however, such questions are often a reminder of society’s narrow view of gender and sexuality and may not allow the participant to completely express their identity. Such oversimplifications may not only lead to inaccurate data but may also discourage participants from completing the rest of the survey or answering questions in an honest manner. The Human Rights Campaign challenges surveyors to consider *why* gender or sexual orientation is being asked in this particular form, how such a question may enhance the data being collected, and how the data will be reported and protected (Human Rights Campaign, 2016). If the organization determines that gender identity and/or sexual orientation data are essential, the Human Rights Campaign proposes a broad and specific way to

ask, which are outlined in Figure 1. While this example is not the only way to gather gender identity and sexual orientation in a culturally-informed manner, there are several components to highlight:

1. The depth of questioning depends on the purposes of the survey. There is no one way to ask about gender identity or sexual orientation; however, creators of the survey should consider how much detail is necessary. A broad question has the advantage of capturing a large range of identities and maintain some level of anonymity in a smaller data set, while specific questions may capture a more complete picture of one's identity.
2. In all scenarios, the questions are optional and an explanation of their purpose and use is outlined. This transparency provides a level of security and assurance to populations who may be wary to self-identify based on previous experience and discrimination.
3. As vocabulary describing gender identity and sexual orientation expands, creating an exhaustive list is nearly impossible and could complicate data analysis. By allowing several categories that are more widely used, and allowing for a write-in option, participants can describe as much of their identity as they feel comfortable, without a survey forcing them into a box.
4. The use of "prefer not to say" or "prefer to self-describe" is less abrasive than "other." These options keep self-identification optional and neutral, rather than imply someone who does not identify with the given categories is an outsider.

Broad Self-Identification as LGBT
 Our company does not discriminate on the basis of sexual orientation, gender identity or expression. In order to track the effectiveness of our recruiting efforts and ensure we consider the needs of all our employees, please consider the following optional question:

Do you consider yourself a member of the Lesbian, Gay, Bisexual and/or Transgender (LGBT) community?

Yes No No, but I identify as an Ally Prefer not to say

Specific: Gender & Transgender Status (ask together)
 Our company does not discriminate on the basis of gender identity or expression. In order to track the effectiveness of our recruiting efforts and ensure we consider the needs of all our employees, please consider the following optional question:

What is your gender?

Female Male Non-binary/ third gender Prefer to self-describe Prefer not to say

Transgender is an umbrella term that refers to people whose gender identity, expression or behavior is different from those typically associated with their assigned sex at birth. Our identities considered to fall under this umbrella can include non-binary, gender fluid, and genderqueer—as well as many more.

Do you identify as transgender?

Yes No Prefer not to say

Specific: Sexual Orientation
 Our company does not discriminate on the basis of sexual orientation, gender identity or expression. In order to track the effectiveness of our recruiting efforts and ensure we consider the needs of all our employees, please consider the following optional question.

What is your sexual orientation?

Straight/ Heterosexual Bisexual Prefer not to say

Gay or lesbian Prefer to self-describe

Figure 1 Options for gathering gender identity and sexual orientation as written by the Human Rights Campaign

2.1.2.3 Ethical considerations against exploitation

Working with SGM populations requires recognitions of past atrocities that have led to mistrust of current research and ethical considerations. Many of these “experiments” inflicted severe psychological and physical harm on participants. Such “research” includes hormone injections by Nazi physicians to eliminate homosexual behavior in male prisoners, use of shock

aversion therapy to alter same-sex attraction, and attempts to change sexual orientation through the use of behavioral modifications, electroconvulsive therapy, and medication (Tufford, Newman, Brennan, Craig, & Woodford, 2012). Research here must be applied in a loose sense, as many of these acts were employed at part of a clinical intervention. However the intention to investigate and cure the underlying causes of homosexuality in a planned manner could be placed under the umbrella of research.

While ethics documents like the Nuremberg Code and Belmont Report now require informed, voluntary participation in research that has been approved for human subjects, some religious and political extremists continue to promote sexual reorientation therapy, despite research contradicting its effectiveness and safety (Tufford et al., 2012). A qualitative study of 38 individuals who currently identify as gay or lesbian and had undergone a total of 113 episodes of reorientation therapy revealed experiences of shame and negative impact on mental health (Flentje, Heck, & Cochran, 2014). Participants later reported self-acceptance and sexual orientation not being a malleable trait for reason of accepting their identity. Even within mainstream science, homosexuality was not removed from the Diagnostic and Statistical Manual of Mental Disorders (DSM) until 1973, and gender identity disorder, which implied that transgender was a disorder, was not removed until 2013 (Drescher, 2015). Because of this enduring stigma researchers and research review boards must be cognizant of the reluctance of participants to disclose their sexual orientation or gender identity and the need for empathic and culturally-informed protocols.

2.2 Defining the problem

2.2.1 Health disparities

The United States Department of Health and Human Services defines a health disparity as “a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage” (Maril, 2016; U.S. Department of Health and Human Services, 2011). Healthy People 2020 expands this definition by explaining that “health disparities adversely affect groups of people who have systematically experienced greater obstacles to health” (U.S. Department of Health and Human Services, 2019b). These populations include those communities historically discriminated against based on gender, age, ancestry (race/ethnicity), socioeconomic status, physical ability, and sexual orientation. The Joint Center for Political and Economic Studies reported the “combined costs of health inequalities and premature death in the United States were \$1.24 trillion between 2003 and 2006” (2011).

2.2.2 Identified health disparities

Health disparities for SGM populations are most likely to emerge from public health data gathered from the general population, rather than a concerted effort to investigate SGM-specific health issues. Identified disparities include higher rates of obesity among lesbians, alcohol and drug use in men who have sex with men, and rates of mental illness and suicide across all group (Krehely, 2009; Maril, 2016; Simoni et al., 2017).

Considering the social determinants of health, SGM populations are also more likely to be affected, with higher rates of unemployment and housing insecurity and lower rates of health

insurance coverage. Overall, the health outcomes of SGM individuals are poorer than their hetero/cis counterparts (Krehely, 2009; U.S. Department of Health and Human Services, 2019c).

2.2.3 Current SGM disparity research efforts

A formal work group was first created in 2010 to examine published literature specific to LGBT health and research and proposed an LGBT health data collection objective to be included in the Health People 2020 (U.S. Department of Health and Human Services, 2019c). HRSA's Report on Women's Health, published in 2013, found that lesbian and bisexual women are at increased risk for adverse health outcomes, including overweight and obesity, poor mental health, substance abuse, violence, and barriers to optimal health care (U.S. Department of Health and Human Services, 2013). The National Institute of Health (NIH) established the Office of Sexual and Gender Minority Research in September 2015. This office aims to improve and increase evidence-based SGM research by increasing expertise, promoting advances in the field, and continuously evaluating the progress towards these goals (Assistant Secretary for Health, 2015). Despite these advances, funding for SGM health is lacking. A recent study found only 0.1% of National Institute of Health funding addressed LGBT health (Coulter, Kenst, Bowen, & Scout, 2014). Of those, 86.1% studied sexual minority men, 13.5% included sexual minority women and 6.8% studied transgender populations. The research topics also lacked diversity: 79.1% of projects focused on HIV/AIDS, 30.9% on drug use, 23.2% on mental health, 16.4% on sexual health matters and 12.9% on alcohol use. Nearly all the projects *described* a disparity, rather than introducing an intervention. This study shows a clear need for research that focuses on all SGM populations and looks beyond their sexual health.

2.2.4 Engaging with minority populations

While few data exist on the engagement of SGM populations in general research, the lack of diversity in research has been well described. Less than 2% of more than 10,000 National Cancer Institute funded trials included a measurable amount of racial and ethnic minority participants (Chen, Lara, Dang, Paterniti, & Kelly, 2014). This inequity can be seen across multiple disciplines, such as the under sampling of African American populations in diabetes and cardiovascular research, despite their higher risk of disease (Murthy, Krumholz, & Gross, 2004). The result is data that is largely based on white, male participants and may not be translatable to other populations (Oh et al., 2015). By sampling a more representative population, medicine can be more effective and efficient. These financial, medical, and ethical considerations underscore the importance of minority representation in clinical research (Oh et al., 2015).

Several studies have attempted to mobilize minority populations. A literature review conducted by the University of California San Francisco in 2000 found that women's participation in research can be linked to three factors: positive personal beliefs, a societal endorsement and reinforcement of their participation, and study design that maximizes benefits and minimizes risks (Brown, Long, Gould, Weitz, & Milliken, 2000). This study suggested by addressing issues of acceptance, awareness, and access, researchers could increase women participation and by accounting for intersecting factors, such as age or ancestry (race/ethnicity) they could engage with a more diverse pool of participants overall (Brown et al., 2000). Increasing awareness of the impact of research through education materials and advertising the value of minority representation in research with community leader endorsement both affect a woman's *desire* to participate; however, logistical barriers may prevent actual study enrollment. To that end, providing transportation and childcare may remove barriers, while offering compensation apart

from travel expenses and non-monetary compensation, like a cell phone, may encourage enrollment.

2.2.5 Lack of Data

One of the largest disparities remains the lack of knowledge and wellness among gender and sexual minorities. In 2011, the Institute of Medicine declared a dearth in research investigating gender identity and sexual orientation health disparities (Simoni et al., 2017). This deficiency remains and impacts current policy. Healthy People 2020 estimated that approximately 4% of the United States population identifies as lesbian, gay, bisexual, or transgender. This statistic is based on information collected in 2002 and is expected to be an under-estimation. Unfortunately, no probability-based sampling has been done on a high enough level to provide updated information. As such, objectives for Healthy People 2020 were based on decades-old reports and research. The paucity of up-to-date information does not represent some lapse in the Department of Health and Human Service's research, but rather highlights the lack of replication and evaluation studies conducted with SGM studies. Overwhelmingly, research is calling for current, larger national sample studies to identify disparities (Bilheimer & Klein, 2010).

2.3 Identifying the application

Accurately collecting gender identity and sexual orientation allow for data that can be applied directly to patient care. While some professional organizations have released standards

and guidelines for care, a stronger foundation of data could help inform more accurate and expansive recommendations.

2.3.1 Current professional guidelines

The Department of Health and Human Services encouraged the addition of LGBT cultural competency curricula to all healthcare training programs because “the lack of culturally competent providers is a significant barrier to quality health care for many LGBT people”(Maril, 2016). The American Psychological Association published the “Guidelines for Psychotherapy with Lesbian, Gay, and Bisexual Clients” in 2000. This document provides a framework for treating lesbian, gay and bisexual (LGB) individuals and suggestions for education, assessment and intervention with clients.

2.3.2 Competence and comfort of health care providers

Cultural competency training is currently ill-defined and rarely evaluated (Gallagher, Ward, & Gamma, 2015). The United States is not the only country with this problem. In the United Kingdom, a survey administered to nurses, doctors, physical therapists, and occupational therapists revealed that although 90% of health care professionals thought sexual issues should be considered in healthcare decisions, but only 6% frequently initiated the conversation with patients (Haboubi & Lincoln, 2003). Research has shown that barriers to these conversations occur at a number of levels. On the individual level, health care providers struggle with religious conflicts, homophobia, and embarrassment of discussing issues related to sexuality. Some studies have shown that physicians feel ill-equipped to address any issues that may surface should they initiate

a conversation. At the hospital system level, insufficient time and training to address sexuality further compounds physician discomfort (Haboubi & Lincoln, 2003; Stokes & Mears, 2000).

2.3.3 Patient provider relationship

Most providers do not identify as homophobic, but implicit bias towards heterosexuality can impact patient health outcomes. Perceived discomfort and negative attitudes may rise from feeling ill-prepared as most studies suggest physicians are more accepting of SGM than in previous years but consistently report not feeling adequately prepared or have large gaps in knowledge on surveys (Carr, 2018; The Joint Commission, 2011a).

Evidence suggests implicit bias affects health outcomes and previous studies have analyzed a range of healthcare providers (Nathan, Ormond, Dial, Gamma, & Lunn, 2019). Groups include social workers (Berkman and Zinberg 1997; Longie et al. 20017), psychologists (Hayes and Erkis 2000), psychiatric nurses (Smith 1993), physicians (Tellex et al. 1999), substance treatment providers (Chochran et al, 2007), first year medical students (Burke et al 2015), physicians, nurses, mental health care providers, and other non-diagnostic providers. Across all studies, heterosexuality was preferred to homosexuality and trans identity was not surveyed. These results indicate that while there may not be explicit discrimination, there is opportunity to better engage with SGM populations in their health and medical care.

2.3.4 Link to genetic counseling education and practice

The Accreditation Counsel for Genetic Counseling requires a competent genetic counselor to “apply genetic counseling skills in a culturally responsive and respectful manner to all clients”

(2013). Just as healthcare is for all and should be administered without discrimination or personal prejudice based on one's age, gender identity or expression, physical ability, or sexual orientation, so too should genetic counseling be practiced equitably and with cultural humility. To address this directive, genetic counselor training programs have implemented cultural competency content, though no standardized curricula exists.

Beyond generally providing a culturally-informed, patient-centered experience, introducing gender and sexual minority standards may hold special weight in genetic counseling. Though genetic counselors continue to work in diverse settings, oncology, pediatrics, and prenatal account for 96% of genetic counseling practice. Forty four percent of genetic counselor practice in cancer, 29% practice in prenatal, and 23% practice in pediatrics (National Society of Genetic Counselors, 2018). Each specialty involves a unique aspect of SGM life. In cancer, studies exploring the experience of trans patients receiving BRCA results have shown the importance of feeling comfortable addressing any issues related to trans identity that may surface. In prenatal, genetic counselors currently serve as consultants for SGM couples considering egg or sperm donation and surrogacy, helping with surrogacy referral, and preimplantation genetic screening (Speer, 2016).

2.4 Proposing a solution: Public health research

Large scale public health research efforts offer a unique opportunity to gather data on otherwise under-served populations. Oversampling of these populations is recommended in an effort to more fully describe any health disparity or difference in the population (Patterson et al., 2017).

AoU aims to recruit one million Americans across the United States. Considering the national population estimates, at least 100,000 SGM should participate to reach the national population estimate, with the hope that oversampling will result in even larger participant populations. As discussed previously, anticipated discrimination and negative previous healthcare experience may prevent SGM from enrolling in this study (Assistant Secretary for Health, 2015; Haboubi & Lincoln, 2003). To counteract this hesitancy, qualitative research may allow for further exploration of the motivations and reservations SGM have about participating in such research opportunities (Atieno, 2009; Maxwell, 2010). Methods such as focus groups and interviews have been used in other research with minority populations with positive results (LaVeist, Gaskin, & Richard, 2011; State of Connecticut Department of Mental Health & Addiction Services, 2009). Because research on SGM participation in public health research remains in its infancy, using a more flexible tool, such as thematic analysis may allow for the systematic consideration of new issues not previously described by the literature (Attride-Stirling, 2001; Braun & Clarke, 2006; Maguire & Delahunt, 2017).

2.5 Summary

Current SGM research has been unable to successfully capture the diverse health needs of this population; the majority of funding for this type of research is spent on describing the transmission of HIV/AIDs among MSM (Bonvicini, 2017; Cargill & Stone, 2005). Public health research as a whole often lacks diversity in its participants, resulting in data not necessarily translatable to under-represented groups (Betancourt, 2006; LaVeist et al., 2011). In order to better represent population diversity, public health research must make a concerted effort to engage

with minority populations. AoU allows the opportunity to gather population-level data on these underrepresented groups. Qualitative research, like focus groups, allows for further exploration of the barriers and facilitators to research participation. The results identified through this type of research can then serve as the basis for targeted interventions to increase SGM participation in future public health research efforts.

3.0 Manuscript

3.1 Background

3.1.1 Gender identity and sexual orientation

Sexual and gender minority (SGM) is an umbrella term that refers to someone whose sexual orientation, gender identity or expression, or reproductive development varies from the prevailing societal, cultural, or physiological norm (Alexander et al., 2016). SGM can also be referred to as LGBT—lesbian, gay, bisexual, transgender—although this is not a comprehensive list. As science and society’s understanding of gender and sexuality expands, so too have the definitions, resulting in more letters being added to the LGBT acronym. However, these discrete identities cannot fully capture the diversity of the population; thus SGM has emerged as a more all-encompassing term for anyone who is not heterosexual (attracted to the opposite sex) or cis-gender (their gender identity aligns with the sex assigned at birth).

Gender and sex are complicated and often conflated concepts, which could lead to challenges in defining and researching these populations. *Gender* is a societal construct that is often delineated into masculine and feminine categories based on biological sex (sex assigned at birth), psychological, and cultural factors (Kari, 2019). Most often, the presenting biological sex is used to determine someone’s gender: a baby with a penis is ascribed masculine pronouns and assigned male, while a baby with a vagina is ascribed feminine pronouns and assigned female. *Gender identity* is how someone views themselves (an internal attribute), while *gender expression* is how they present to society (an external attribute). In Western culture, this has historically been

viewed as binary, though this maybe a gross over-simplification. Gender non-binary, genderqueer, and third gender are more recent acknowledgements of gender being on a spectrum. Transgender or trans refers to someone whose sex assigned at birth is not congruent with their gender identity and/or expression. Gender affirmation is the act of reinforcing one's true gender identity through social recognition and support (Sevelius, 2013). Often, surgery or other medical intervention is assumed to be part of this process, though it can also include changing their name, their pronouns, or their physical appearance with different clothes or hairstyles. This need not be a legal process, though some trans individuals have the resources and desire to solidify these changes on court documents, like a passport or driver's license. In 2014, 0.6% of the population identified as transgender, doubling the 2011 estimate (Gates, 2014). This estimate refers to identity, not necessarily how the individual has affirmed their identity, meaning not all people have undergone or even desire to undergo surgery or other medical interventions. The size of other gender minority populations, like gender nonbinary, has not been determined.

Sexual orientation is often thought of in terms of behavior, meaning with whom the person is physically intimate. The reality, however, is more complex and includes dimensions of a person's identity, attraction, and behavior. For example, 3.5% of the U.S. population identify as lesbian, gay, or bisexual, though 8.4% (19 million Americans) report same-sex behavior and 11% report same-sex attraction (Gates, 2011). A sexual minority, broadly, is someone who is not only attracted to the opposite sex. While a transgender person may also identify as a sexual minority, this is often not the case.

Overall, current studies predict that SGM account for 4-10% of the total U.S. population, although this is likely to be an underestimation because of stigma, sampling error, and other factors (Gates, 2011).

3.1.2 SGM health disparities

Until 1973, homosexuality was listed by the American Psychiatric Association (APA) as a disorder in the DSM (Drescher, 2015). Prior to this change, science sought to cure homosexuality, or at least describe the pathology. Transsexual, a term once more widely used to describe transgender individuals, was removed from the World Health Organization's International Classification of Disease in 2018 (Fitzsimons, 2018). Perhaps, because of this stigma, much of the research to date has been centered around the risk of sexually transmitted disease, particularly among men who have sex with men (MSM) and their risk of HIV exposure. Other established risks include alcohol and drug abuse, tobacco use, and poorer mental health outcomes and suicidal ideation (Bonvicini, 2017; Krehely, 2009; Sullivan et al., 2012; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health, 2018). More recently, higher rates of obesity, body image disorders, heart disease, increased risk for certain cancers, lower rates of insurance and medical care, higher rates of sexual abuse, homelessness among SGM youth, and the social isolation of the aging SGM population have been described (Alexander et al., 2016; Bonvicini, 2017; Krehely, 2009; Mule et al., 2009; The Williams Institute, 2019). Healthy People 2020, a report produced by the U.S. Department of Health and Human Services (HHS), introduced two main objectives to increase the collection of SI/GO in public health surveys to better describe these disparities. These goals are the first time Healthy People 2020 has acknowledged that gender identity and sexual orientation are linked to health disparities and created specific aims to address the need for more research. Rather than address a specific disparity, these objectives aim to increase the use of standard questions to identify SGM populations in population-based data systems and state level surveys. While this may appear to

be a step backwards as an extensive list of disparities has been identified, these goals actually address the largest issue surrounding SGM health a wellness—a lack of data.

The many dimensions of gender identity and sexual orientation have made describing and defining these populations challenging (Wheeler, 2003). Much of SGM health research is based on behavior, like men who have sex with men, rather than distinguishing between gay or another sexual orientation. This has made determining the effect of identity and attraction on health difficult. This lack of standardization can cause confusion among the public and even among researchers studying the same topic. While some larger-scale surveys, like the National Health Interview Survey from the Centers for Disease Control and Prevention (CDC) and the Behavioral Risk Factor Surveillance System (BRFSS) include questions about sexual orientation and gender identity, data from these efforts are not collected in every state or comprehensive (Assistant Secretary for Health, 2015). Most questions allow the respondent to choose only from a limited list of terms and even then, not every state has adopted this new question set. Because sexual orientation cannot be fully described and are not collected consistently, these newly collected data are not considered fully representative of such a diverse population. No data set in existence in the United States is considered to have fully captured the SGM community from a population-based sample. The first step is addressing the current health disparities associated with this population to fully describe who within the population is affected and to what extent. A national survey of SGM is desperately needed.

3.1.3 Precision medicine: A public health initiative

AoU is an historic effort to gather health information from more than one million Americans (National Institutes of Health, 2018). This study aims to collect basic health

measurements, biological specimens, and access to participants' medical records to propel medical discovery by creating a national biobank. By looking at differences in individuals' genes, lifestyle, and environment, the National Institute of Health (NIH) wants to be able to deliver more personalized medical care through research on samples that are representative of our nation's diversity. As such, special attention has been paid to engage and oversample populations historically exploited and underserved by the medical community. Previous medical research in a range of disciplines has been primarily comprised of white male samples and may not be translatable to all patients (Coakley et al., 2012; U.S. Department of Health and Human Services, 2011).

Marketing campaigns for AoU have focused on diverse models and the messaging speaks to being part of this "one in a million" effort. This approach has been fairly successful. Nearly 80% of the 104,440 participants identify as being part of some minority group, including ancestral, ethnic, gender, and sexual minorities. Increasing SGM participation could be an opportunity to create a large scale, diverse population sample so desperately needed to further SGM research. To date, 0.38% of AoU participants identify as transgender, 0.61% identify as non-binary, and 9.4% identify as a sexual minority, which is on par with national statistics (U.S. Department of Health and Human Services, 2019a). Over-sampling this population will require more targeted recruitment methods and inclusive enrollment efforts.

3.1.4 Use of qualitative research and focus groups

Qualitative research allows for hypothesis generation and exploration. Studies exploring SGM participation in public health research are few. As such, asking the community directly about their research experiences is more appropriate at this time than testing through a quantitative

approach. For this reason, focus groups were conducted because they allowed direct community contact and feedback. In this study, participants were recruited through Pitt+ Me, which is an online portal connected more than 200,000 potential participants to research studies around the Pittsburgh area. This cohort is more likely to be invested in research and have strong opinion about the research than the general population.. Furthermore, focus groups allow for valuable discourse and validation among peers. In contrast, interviews allow participants to expand on their thoughts but do not provide the opportunity for group discourse regarding the SGM research experience. Additionally, focus groups allow for peer dialogue and social interaction which could help participants feel more comfortable discussing their opinions.

3.1.5 Focus group setting

Pennsylvania was one of the first states to pilot AoU and has enrolled 16,040 participants during the first two years (U.S. Department of Health and Human Services, 2019a). Its target enrollment is over 125,000 over five years. Gender identity and sexual orientation data are not available at the state level. However, considering previous surveys, Pennsylvania is not likely to have higher than the national average SGM representation, and thus SGM recruitment practices merit attention (A. R. Flores, Herman, Gates, & Brown, 2016; Gates, 2011). The majority of enrollment centers in PA are within 20 miles of Pittsburgh, a city with a rich history of SGM research.

Beginning with the Pitt Men's Study in 1984, which aimed to study the natural history of HIV/AIDS among MSM, the University of Pittsburgh and the city as a whole have been invested in research about the health of SGM (The Pitt Mens Study, 2010). The University of Pittsburgh has a Center for LGBT Health Research that has championed a number of research projects,

including healthy aging among MSM and a community-based intervention for LGBT youth of color called Project Silk (“Center for LGBT Health Research,” 2019). A number of LGBT resources, like the Pittsburgh Equality Center and the Persad Center are available for informed healthcare and referral, as well as offering a safe social space. This combination of community resources and history of research engagement has the potential to inform current AoU recruitment and enrollment practices to reach more SGM potential participants. Before this partnership can be realized, however, it is helpful to engage with the SGM community in Pittsburgh to discuss their opinions, beliefs, and knowledge about AoU, and public health research in general.

3.1.6 Purpose and specific aims

The primary aims of this study were to explore the barriers and facilitators to SGM enrollment in the All of Us Project and public health research. Both of these aims were explored through the use of focus groups. The purpose of this study was to improve current AoU recruitment and enrollment methods and provide some insight about improving SGM enrollment in other public health research.

3.2 Methods

3.2.1 Focus groups

Conducting focus groups was approved by the institutional review board (IRB) at the University of Pittsburgh as an exempt protocol in March 2019. Exemption was granted because

identifiable participant information would not be stored or shared as part of the study. Additionally, the use of focus groups is considered observation and low-risk. Approved documents included recruitment flyer, focus group guide, demographic questionnaire, screening and study introduction script, and reminder correspondence. These documents are available for further review in Appendices A through E.

3.2.1.1 Target population

The target population was SGM individuals in the Pittsburgh area who were eligible to enroll in AoU. Both persons currently enrolled and not enrolled in AoU were recruited because they offered unique perspectives. Enrolled individuals could possibly be able address the current AoU practices and factors that encouraged their participation. Those not enrolled could give insight to potential barriers to participation and untapped recruitment channels. Pittsburgh was chosen because ten of the 12 permanent AoU enrollment sites are within 20 miles of the city and research suggests SGM are more likely to live closer to urban areas. (University of Pittsburgh Clinical and Translational Sciences Institute, 2018a)

3.2.1.2 Participants

Study Eligibility Criteria: To be eligible for AoU Pennsylvania, potential participants must be over the age of 18. To fully participate in the study, a person must have had medical care in Pennsylvania (to access medical records) and be willing to give biological samples (blood and urine). For the purposes of our study, participants must also identify as a SGM and be willing to travel to one of the focus group locations in Pittsburgh. See Figure 2 for recruitment and enrollment protocols.

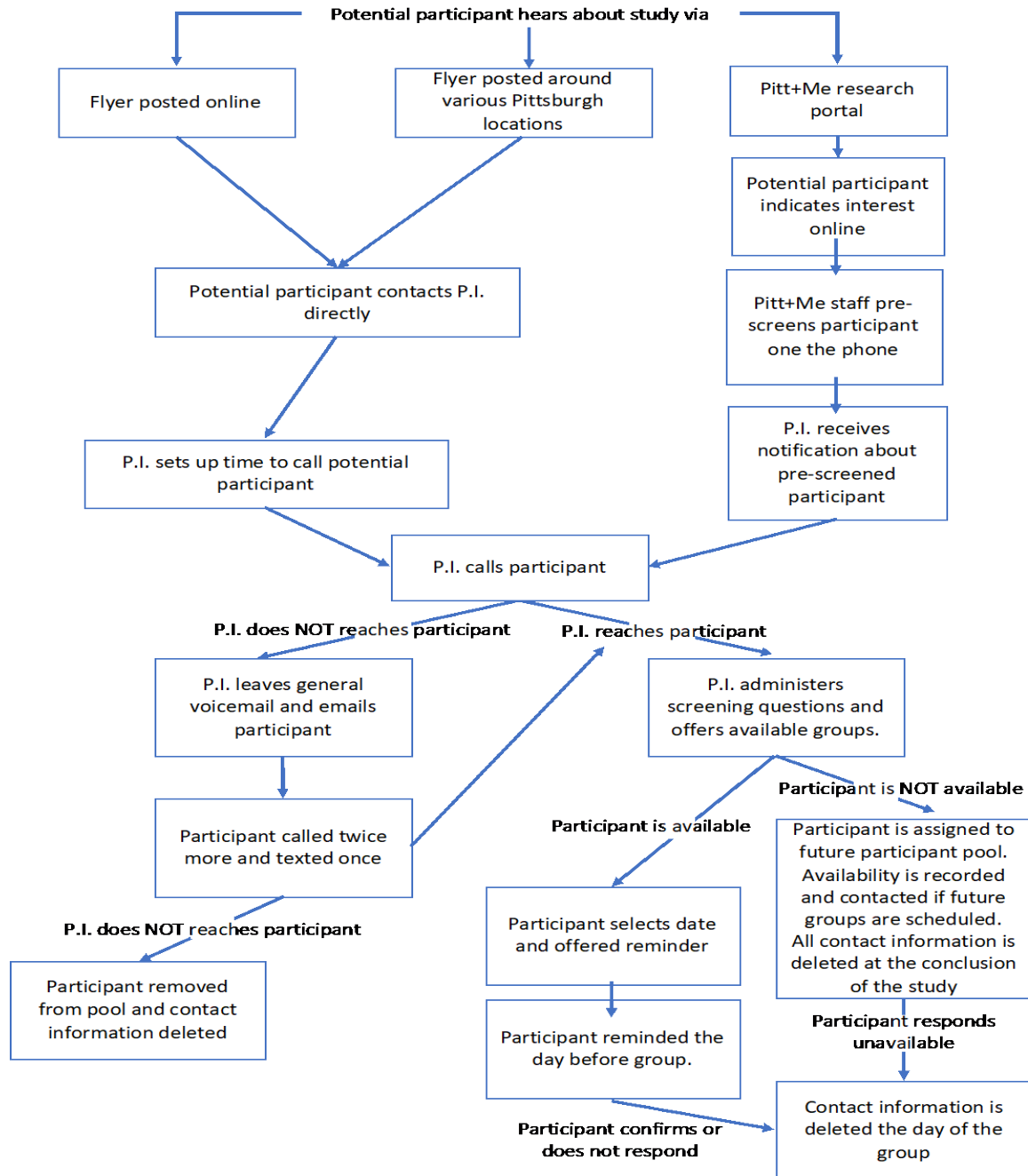


Figure 2 Focus group enrollment process utilizing diverse recruiting methods

Recruitment: A variety of recruitment methods were used to maximize SGM exposure to the study. Physical flyers were posted around Pittsburgh in areas known to have higher SGM traffic, like coffee shops, community centers, and libraries. LGBT+ community resources like Gay for Good, the Persad Center, LGBTQ Pittsburgh, TransPride Pittsburgh, and the Delta Foundation were provided with electronic flyers for further distribution. In-person presentations were also offered to organizations like the Pitt Queer Professionals affinity group. In addition to flyers, the Pitt+Me research portal was used to advertise the study. Pitt+Me, created by the University of Pittsburgh's Clinical and Translational Science Institute, is an online network of more than 200,000 participants and a dedicated staff who assist researchers in recruitment and screening (University of Pittsburgh Clinical and Translational Sciences Institute, 2018b). This platform creates advertisements, pre-screens participants, and sends out targeted advertising based on the expressed interests and demographic information. While this forum does not currently collect sexual orientation information, it does allow for members to identify as transgender. Pitt+Me has also been used extensively to recruit AoU participants and was likely to reach the same participant pool. In addition to placing an ad on the website, an email was sent to 15,000 participants who indicated they were interested in healthy aging or healthy volunteer studies. Finally, it has been demonstrated that social networks and word of mouth can be effective recruitment approaches, especially among SGM (Heckathorn, 1997; Martin, Johnson, & Hughes, 2015). Studies routinely use respondent-driven, snowballing, and purposive sampling methods to reach hidden populations (AHIMA Work Group, 2017; Wheeler, 2003). To leverage these social connections, the principal investigator circulated the flyer on her social media platforms, encouraged her social networks to do the same, shared the study information with classmates in

the University of Pittsburgh Graduate School of Public Health, and encouraged interested participants to share information in their social circles.

A total of 58 people indicated interest in the study; 44 were recruited from Pitt+Me. Of those who expressed interest, seven could not be reached for further screening and two were no longer interested in the study when contacted.

LGBT+ vs SGM language: “LGBT+” was chosen for recruitment and communication purposes as LGBT is the more colloquial term to refer to SGMs. The (+) was used to indicate individuals who identify as *any* gender or sexual minority, not only lesbian, gay, bisexual, or transgender.

Secure communication: Recruitment and enrollment involved several communication strategies, which required additional security considerations. To ensure that contact information was kept confidential, dedicated lines of communication were created specifically for this study. A Gmail account was used for following up with participants who could not be reached by phone, to confirm their enrollment, provide logistical information about the focus group, and remind them the day before the group. Additionally, a Flyp number was created to complete screening calls, send reminder texts or calls, and serve as a line of communication when participants had further questions or concerns. Flyp is a smart phone application that allows the user to create a local phone number that is disconnected when the subscription is ended.

Participants supplied their preferred method of communication during the initial screening phone call and could opt in for a reminder message the day before the group. This contact information was marked by first name only, stored on a secure, online Box account, and deleted

at the completion of the study. All communication through the email account and Flyp number was deleted at the completion of the study.

Screening and enrollment: Participants recruited from the Pitt+Me were pre-screened via telephone by Pitt+Me staff. This pre-screening reviewed the purposes of the study and the eligibility criteria and confirmed potential participants' continued interest. The principal investigator was notified of a participant's eligibility and reached out for further screening. Those who saw the flyers were invited to email, call, or text the study using dedicated lines of communication. After expressing interest, all individuals were contacted by telephone for further screening. Participants were asked if they (1) were at least 18 years of age, (2) identified as LGBT+, (3) were comfortable sharing in a mixed setting, meaning not everyone would share their identity but everyone would identify as being LGBT+, (4) received medical care in PA in the last decade (including emergency room visits), and (5) were able to attend a focus group in either the Oakland or Shadyside neighborhoods in Pittsburgh. For the purposes of group assignment, people were also asked if they were familiar with AoU and had completed enrollment. The participant was then given logistical information about the upcoming group, sent a confirmation email, and given a reminder, with permission, the day before the focus group. If a participant indicated they were unable to attend during the reminder correspondence, they were returned to the potential participant pool and contacted for future studies. The recruitment script and reminder communication can be reviewed in Appendix D.

3.2.1.3 Focus group design

Groups were divided between participants who had enrolled in AoU (referred to as enrolled) and those who had not completed the enrollment process (not enrolled). Four groups were initially scheduled, two for enrolled and two for not enrolled participants. Due to low

attendance, a third group of not enrolled participants was added. After conducting five focus groups, a sixth, open group was added to allow for any participants unable to attend previous groups. This group was open to those who had and had not enrolled in AoU (mixed). As previously discussed, not enrolled and enrolled participants have unique perspectives. The separate groups would allow the opportunity additional space to discuss current AoU practices with enrolled groups, as well as further discussion of reasons for not enrolling in AoU in the other group. The final mixed group was added to give interested participants the opportunity to voice their opinions, and to determine if not having the common experience of AoU enrollment would in fact stymie conversation.

Consideration was given to dividing groups based on sexual orientation and/or gender identity, but ultimately the concern for insufficient numbers, the difficulty defining subgroups, and the established similarities in the potential risk of discrimination based on identity, mixed groups were the most practical approach.

Instrumentation: The focus group guides can be found in Appendix C. Open-ended questions were created to explore previous research experience, factors that may impact one's decision to enroll in a study, whether gender identity and/or sexual orientation were considered a factor, and how researchers might better engage with LGBT+ populations. More specific questions pertaining to AoU were included to better understand current enrollment practices. Each group was asked approximately six questions, though the facilitator tailored the pacing and questions to the conversation.

Focus group setting: Focus groups were held at a local coffee shop in the Pittsburgh neighborhoods of Shadyside and Oakland. The neighborhoods were chosen because of proximity to bus lines and central location in the city. The coffee shops were selected because of public

access to private rooms, ability to cater the groups, and ample free on-site parking. While other locations, such as a library or local church, might offer an affordable public space, few allowed refreshments without a charge. The private rooms were equipped with small tables and chairs that could be arranged into a rectangle. This arrangement allowed all participants to easily see each other and minimize the appearance of a head of the table. The facilitator took care to sit in the middle of the table to establish equal seating arrangement. Refreshments were provided and participants were encouraged to help themselves throughout the group. The facilitator opened with an introduction about the goals of the study, the foreseeable risks and benefits of the study, and the expectation that everyone respect others' views and confidentiality. See the full script in Appendix D. Voluntary participation was assumed if participants remained at the table after the informed consent process. All of the aforementioned measures were used to foster a sense of safety and community, and to enhance participants' comfort sharing their thoughts. To further establish rapport, the first question in each focus group was designed as an icebreaker.

Focus group execution: Focus groups were conducted from March to April 2019. Each group was designed to last approximately 90 minutes and include six to 11 participants. However, conversations lasted 18-180 minutes. A total of 23 participants attended, 12 who had enrolled in AoU and 11 who were not enrolled. Group size ranged from two to six participants. Groups were audio-recorded for transcription. To maintain anonymity, participants used an alias during the group and original audio files were deleted upon completion of transcription analysis. A trained graduate student facilitated each session and the principal investigator took notes to give context to discussions. The facilitator encouraged equitable contributions by using targeted questioning, summarization, and silence to encourage cross-talk. The notetaker recorded the seating arrangement with aliases, as well as any relevant nonverbal cues that would be lost in transcription.

At the conclusion of the focus groups, each participant was given \$10 for travel expenses. A *Man on the Street* exemption was obtained through the IRB to use cash, rather than gift card, compensation. This exemption allowed the payment to be directly applied to travel cost, like bus fare, and avoided collecting identifying information required for gift card dissemination, which might affect responses and participation. The facilitator and notetaker debriefed after each group. These conversations were also audio-recorded and addressed immediate take-aways and thoughts on improving questions and flow for the next group.

3.2.2 Demographic analysis

3.2.2.1 Collection of focus group demographic data

Prior to each group, demographic questionnaires were distributed. Although the primary goal of this study was to assess participant attitudes, knowledge, and beliefs through qualitative analysis, demographic analysis allowed for contextualization of the response and general comparison to the national AoU participant pool. Completion was voluntary and anonymous. Questions asked participants' age, residence (both where they were born and where they currently live), ancestry, education, marital status, gender identity, sexual orientation, health care experience, and their experience with AoU. A total of 12 questions were asked, with a space for comments. To allow for more accurate identification, ancestry, gender identity, and sexual orientation questions were posed as "select all that apply" and allowed space to write in a response or indicate that none of the options fit. The complete questionnaire is included in Appendix E. To assess current AoU practices, ten of the 12 questions were taken from the AoU enrollment questionnaire and all groups were asked about their reaction to the subject and wording.

3.2.2.2 Analysis of focus group questionnaires

To de-identify surveys, participant IDs were created using age, sexual orientation, and gender identity. For example, a 29-year-old participant who identifies as gay, queer transfemale would be assigned 29GQTF. Group IDs were then assigned based on enrolled in AoU (enrolled, not enrolled, and mixed). Each question was assigned a variable name, type of data, description label, measure, and possible values explained. Data were entered into SPSS and analyzed using descriptive statistics to determine frequencies of characteristics.

To maintain anonymity within a small sample size, certain values were collapsed and recoded into different variables. For example, sexual orientation was re-coded to include gay, lesbian, bisexual, queer and other, no labels, and identifying with more than one label, rather than the original 14 categories. Ancestry was described as “white” and “non-white.” “Non-white” was used to describe American Indian, Alaskan Native, Asian, Black, African American, African, Hispanic, Latino, Spanish, Middle Eastern, Native Hawaiian, Pacific Islander, or if the participant chose more than one option. Age was separated by decade (e.g. 20-29, 30-39) to allow for a level of anonymity and comparison to national AoU data, which also reports age in decades. Several gender identity terms were collapsed as well. Transgender, female to male transgender, and male to female transgender were collapsed into a singular “transgender” category. “Gender non-conforming” was used as an umbrella term to encompass those who identified as genderqueer, genderfluid, gender variant, selected more than one gender identity, or preferred to self-describe their gender identity. “Queer and other” was used to describe those who identified as queer, polysexual, omnisexual, sapiosexual, pansexual, or two-spirit.

Data were delineated based on enrollment status to determine if there were any glaring differences between the groups. Differences were described but no statistical analysis was conducted. Results were summarized in a table format.

3.2.2.3 Comparison to national data

Although the small sample size of the focus groups prevented complete comparison to national AoU demographic characteristics a general comparison allows for some context. National data are published on the AoU Research Hub, which is open to the public and was used to gather age, ancestry, marital status, gender identity, and sexual orientation. To allow for a visual comparison, graphs were created in Microsoft Excel.

3.2.3 Qualitative research methodology

Briefly, focus group transcripts were analyzed using thematic analysis for overarching themes addressing SGM participation in research. The principal investigator considered the potential bias of the research team when analyzing the transcripts and used an inductive approach to allow the transcripts to suggest codes, rather than use a pre-determined framework to organize the data. Rather than analyze transcripts line by line, participant responses were broken into meaning units that were assigned categories. The considerations of researcher bias, as well use of meaning units for thematic analysis are further described below.

3.2.3.1 Considerations of researcher bias

Focus groups were conducted by a facilitator and note taker, both of whom were graduate students in the University of Pittsburgh Graduate School of Public health and had taken course

work specifically addressing focus group design and implementation. The facilitator was a white, cis-gender female who identified as straight. She had limited knowledge about SGM research and AoU prior to the study. Her lack of prior experience with the subject matter allowed her to better adhere to the provided focus group probes and ask participation more clarifying questions, rather than making assumptions based on personal experience. Prior to the group, she expected participants to discuss concerns regarding privacy and the storage of personal data, the basis of AoU. The notetaker was also responsible for focus group design and participant recruitment and enrollment. This research member was a white, cis gender female who identified as queer. Her personal experience in the SGM community helped her to identify responses potentially unique for SGM participants, rather than ideas shared by the general population. Prior to the group, she also expected privacy to be a concern, and anticipated that race and other intersecting identities may impact the participants' perception of their GI/SO in the research process.

3.2.3.2 Thematic Analysis

Thematic analysis, as described by Braun and Clarke, was applied to transcripts. (Braun & Clarke, 2006) This method was chosen because of the overall flexibility of the model while maintaining a structured framework to move from transcription to identifying and defining themes. This version of thematic analysis involves six phases: (1) becoming familiar with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining themes, and (6) producing the report (which comprises this work).

Becoming familiar with data. Audio files were transcribed verbatim using a combination of online transcription software, Otter, and manual audit by the principal investigator. Initial ideas and relationships were noted during the focus groups, during the transcription process, and through reading all transcripts in their entirety. Based on preliminary impressions, categories would need

to address a range of motivations and deterrents for research participation, specific considerations for the AoU, and a larger discussion of GI/SO implications in society

Generating initial codes: Because of the limited body of literature regarding SGM participation in public health research, inductive analysis of semantic content was used to create codes. This coding framework uses salient data points to create codes, rather than fitting data into theoretical constructs that had been previously established or assigning meaning present in the text. Transcripts were reviewed line by line and condensed into meaning units as described by Rennie (Rennie, 2005). Briefly, the participants response is broken into main ideas related to the overall theme of the transcript. The meaning units were assigned codes based on the identified main point and categorized to allow for comparisons across codes. Each meaning unit was reviewed and either grouped within an existing code or a new code was conceptualized. After the codes has been created, the transcript was reviewed with the list of codes to ensure each meaning unit was consistently assigned the same code and the list of codes exhaustively covered topics discussed in the transcripts.

Questions posed by the facilitator and the debrief following the focus groups were not coded, but rather reviewed as a whole for thematic considerations. The generated codes, descriptions, and illustrative quotes can be reviewed in Appendix G. Forty one codes relating to SGM involvement in public health research were created across the six focus groups. Codes addressed a range of topics, including specific AoU experiences, individual characteristics, and communication around gender identity and sexual orientation.

Searching for themes. Created codes were then abstracted and grouped to identify themes and create thematic networks (Attride-Stirling, 2001). Thematic networks, as described by Attride-Stirling, are visual representations to summarize the main themes of a study, as well as

their relationships. Based on the thematic network, overarching, candidate themes were identified. Many of the defined categories could be mapped to the Social-Ecological Model (SEM), which considers the complex interactions and pressures between individuals and their relationships with others and society as a whole (“The Social-Ecological Model,” 2019).

Reviewing themes. Illustrative quotes and meaning units for each code were then reviewed in the context of the assigned theme to ensure data were appropriately grouped under a theme. The full data set was then reviewed to ensure the candidate themes fully described the relevant points presented in the transcripts. At this point, additional identified relevant data were added to each theme.

Defining and naming themes. Identified themes were then refined and defined to create an overarching narrative. Subthemes were also identified during this refinement phase. Each identified theme is further discussed in the results.

3.3 Results

3.3.1 Participant demographics

Participant demographics are summarized in Table 1. While the age of participation ranged from 21 to 77, the sample skewed towards younger ages, with 47.8% of participants in their 20s (n=11) and only 13.0% 60 or older (n=3). Most participants were white (87%), born in the United States (91%) and grew up in the United States (96%). Few participants had ever been married (17%), some identified with more than one sexual orientation (26%), and most identified as cis-gendered (78%)

Table 1 SGM participant demographic information

		Enrolled (n=12)	Not Enrolled (n=11)	Overall (n=23)
Age	Mean	36.3	40.6	38.4
	Median	30.5	28	32
	Range	22-73	21-77	21-77
<hr/>				
Born in the United States	United States	92% (11)	91% (10)	91% (21)
	Other	8% (1)	9% (1)	9% (2)
<hr/>				
Grew up in the United States	United States	100% (12)	91% (10)	96% (22)
	Other	0% (0)	9% (1)	4% (1)
<hr/>				
Current residence	In Pittsburgh	58% (7)	100% (11)	78% (18)
	Within 10 miles of Pittsburgh	33% (4)	0% (0)	17% (4)
	More than 10 miles outside of Pittsburgh	8% (1)	0% (0)	4% (1)
<hr/>				
Ancestry	White	92% (11)	82% (9)	87% (20)
	Non-white	8% (1)	18% (2)	13% (3)
<hr/>				
Sex Assigned at Birth	Female	58% (7)	55% (6)	57% (13)
	Male	42% (5)	45% (5)	43% (10)
<hr/>				
Gender Identity	Man	33% (4)	45% (5)	39% (9)
	Woman	42% (5)	36% (4)	39% (9)
	Non-Binary	17% (2)	0% (0)	9% (2)
	Transgender	0% (0)	9% (1)	4% (1)
	Gender non-conforming	8% (1)	9% (1)	9% (2)

Table 1 Continued

		Enrolled (n=12)	Not Enrolled (n=11)	Overall (n=23)
Sexual Orientation	Gay	0% (0)	18% (2)	26% (6)
	Lesbian	17% (2)	0% (0)	13% (3)
	Bisexual	50% (6)	27% (3)	39% (9)
	Queer and other	17% (2)	9% (1)	17% (4)
	Do not identify with a label	0% (0)	9% (1)	4% (1)
	Selected >1 sexual orientation	17% (2)	36% (4)	26% (6)
Marital Status				
Marital Status	Married	17% (2)	9% (1)	13% (3)
	No longer married	0% (0)	9% (1)	4% (1)
	Never married	50% (6)	55% (6)	52% (12)
	Living With Partner	33% (4)	18% (2)	26% (6)
	No Answer	0% (0)	9% (1)	4% (1)
Highest Level of Education Completed				
Highest Level of Education Completed	Completed high school	17% (2)	9% (1)	13% (3)
	Completed undergraduate degree	25% (3)	36% (4)	30% (7)
	Completed some graduate school	25% (3)	9% (1)	17% (4)
	Completed Master's	17% (2)	45% (5)	30% (7)
	Completed Doctorate or professional degree	17% (2)	0% (0)	9% (2)
Healthcare Experience				
Healthcare Experience	I have never used healthcare	0% (0)	0% (0)	0% (0)
	I have only used medical care through the emergency room	0% (0)	0% (0)	0% (0)
	I had regular doctor's visits, but as an adult I only go in emergencies	17% (2)	27% (3)	22% (5)
	I see a doctor at least once every 3 years	25% (3)	9% (1)	17% (4)
	I see a doctor every year	42% (5)	9% (1)	26% (6)
	I see a doctor more than once a year	17% (2)	55% (6)	35% (8)

Table 1 Continued

		Enrolled (n=12)	Not Enrolled (n=11)	Overall (n=23)
Previous Research Experience	I have participated in at least one previous research study as a participant (apart from AoU).	100% (12)	83% (9)	91% (21)
	I have participated in at least one previous research study as a researcher or research staff.	42% (5)	45% (5)	43% (10)
Familiarity AoU	I have enrolled in AoU	100% (12)	N/A	52% (12)
	I have heard of the program and plan to enroll	N/A	45% (5)	22% (5)
	I have heard about the program but have some reservations about enrollment.	N/A	9% (1)	4% (1)
	I have heard about the program and will not be enrolling or have unenrolled.	N/A	27% (3)	13% (3)
	I have not heard about AoU but am interested in learning more	N/A	18% (2)	9% (2)
	I have not heard of the program and am not interested in learning more.	N/A	0%	0% (0)

Of note, 87% of participants had obtained at least a bachelor’s degree, 91% had participated in previous research studies, and 91% had heard or enrolled in AoU before the focus group. All participants had some healthcare experience and had routine healthcare during their childhood.

When comparing enrolled and not enrolled groups, several differences emerged. A higher number of not enrolled participants lived in the city of Pittsburgh (100%) and either see a doctor in case of emergencies (27%) or see several specialists more than once a year (55%) when

compared to the enrolled group. More not enrolled participants had completed their master's degree (45%) and see one doctor regularly, either within the last year (42%) or three years (25%) compared to enrolled participants. When compared to enrolled participants, a higher number of not enrolled participants identify with more than one sexual orientation (36%).

3.3.2 Comparison to National Enrollment Data

To date, 104,440 participants nationwide have completed the basic demographic questionnaire as part of their enrollment in the AoU project. Of those, Pennsylvania has enrolled 15,820, accounting for 10.75% of the national total, though no state-level data are currently available to the public (U.S. Department of Health and Human Services, 2019a). Considering the level of Pennsylvania representation in the national dataset, using national AoU data could be a reasonable proxy in the absence of state-level data. Figure 3 shows the comparisons between focus group and national AoU data for age, ancestry, marital status, education, gender identity, and sexual orientation. Enrolled and not enrolled participant data are reported separately to demonstrate no large demographic difference was found between the focus groups, but noticeable differences exist between the focus group and national samples.

Age. The median age of all participants, as shown in Table 1, is 32. When looking at age distributions across groups, the not enrolled group had more diversity in age groups, though nearly half of participants in both groups were under the age of 30. This differs from the national distribution, where 15% are under 30, and the median is between 50 and 59. Graph A in Figure 3 shows the age distribution across all groups. The national sample shows a more normal distribution, though fewer participants 70 or above than the other groups; 41% of national participants are 50-69.

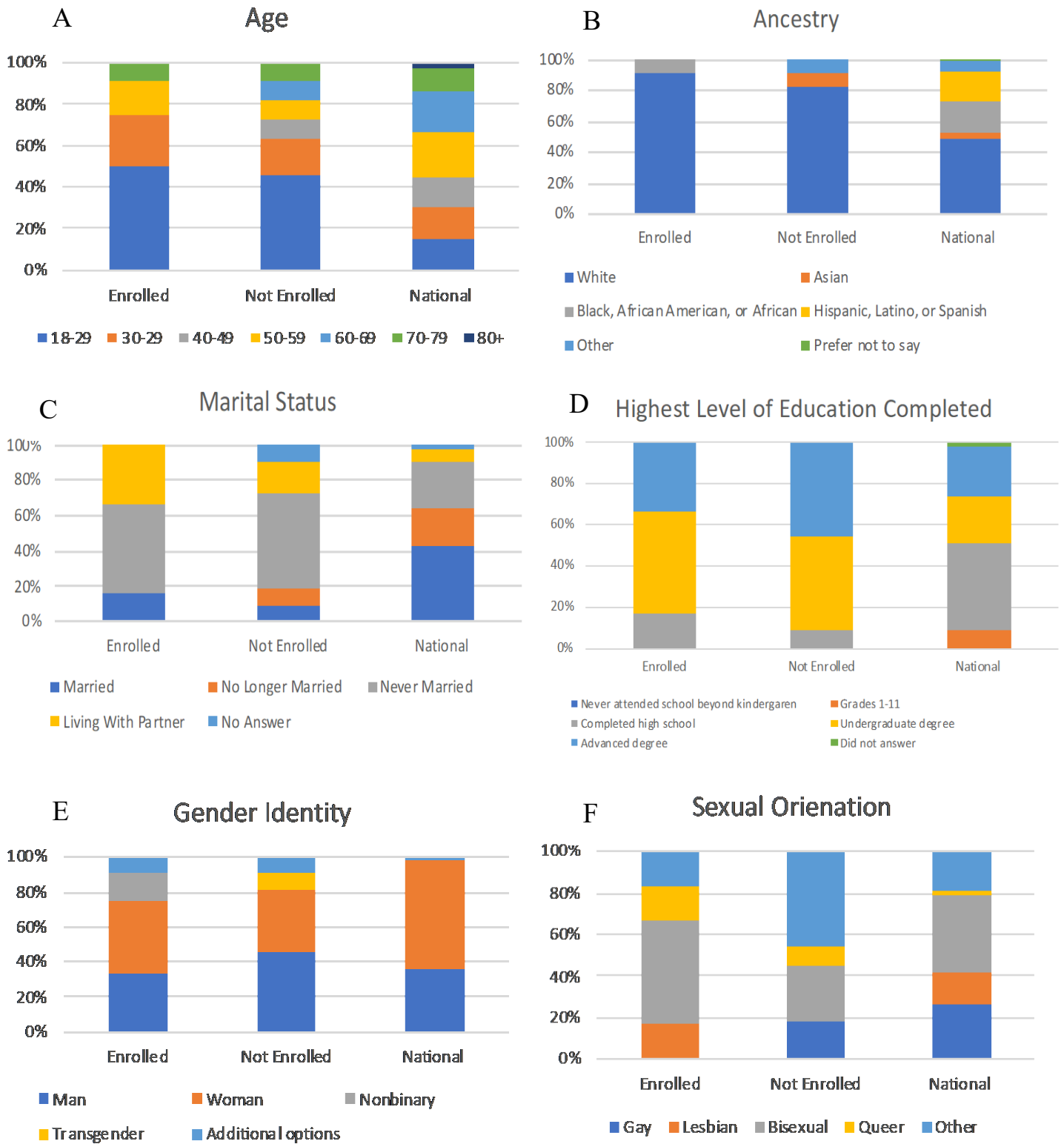


Figure 3 Pittsburgh focus group demographic data compared to national data

Ancestry. National AoU data show that 53% of participants identify as white, 23% identify as Black, African American or African, and 21% identify as Hispanic, Latino, or Spanish. The remaining identified as Asian (4%), other (7%) or preferred not to answer (1%). The other category included American Indian or Alaskan Native, Middle Eastern or North African, Native Hawaiian or other Pacific Islander, or “None of these describe me.” This differs from the focus group participants, where an overwhelming majority identified as white (92% of enrolled and 82% of not enrolled). The focus groups also lacked Hispanic, Latino, or Spanish representation (0%) or any of the ethnicities included in the “other” national category. There was also little Black, African American, or African or Asian representation, with 4% in each category. Data are presented in Graph B in Figure 3.

Marital Status. Nationally, most participants reported having been married at some point, either currently (42%) or previously (22%). Previous marriage included those that ended in separation, divorce, or loss of a partner (widowed). Twenty six percent reported never being married and 7% reported living with their partner. Compared with the national survey, 50% of enrolled participants and 55% of not enrolled) or live with their partner (33% and 18%). These comparisons can be seen in Graph C in Figure 3.

Education. The largest difference between the focus group population and the national sample is education attainment, shown in in Graph D in Figure 3. Approximately 50% nationally completed up to a high school diploma (42% earned their diploma or GED). In terms of educational attainment, 23% completed their bachelor’s and 24% completed an advanced degree. The focus groups reported higher levels of completed education. Ninety percent of not enrolled participants report a degree beyond high school, divided equally between undergraduate and

advanced degrees. Eighty three percent of enrolled participants completed programs beyond high school, with 50% earning a bachelor's and 33% earning an advanced degree.

Gender Identity. Nationally, 36% report identifying as a man, 62% report identifying as a woman. Additional categories include genderqueer, genderfluid, gender variant, questioning or unsure, or self-description, which account for 2% nationally when included with transgender and non-binary identities. Individuals in the focus groups represented a greater diversity of gender identities, with 22% identifying not male or female. Graph E in Figure 3 showed gender identity.

Sexual Orientation. Graph F in Figure 3 shows sexual orientation across groups. National data represent specific orientations reported by non-straight participants (less than 10% of the total population). "Other" is used to describe those who identified as asexual, being in the process of figuring out their sexuality, not using labels to identify themselves, two-spirit, polysexual, omnisexual, sapiosexual, pansexual, or self-describing. A greater number of enrolled participants identified as bisexual (50%) than not enrolled (27%) or national (37%) groups. More not enrolled participants identified as an identity described in "other" category compared to national (19%) or enrolled (17%) responses. Of note, no one identified as gay in the enrolled groups or lesbian in the not enrolled groups, though 27% identified as gay and 15% identified as lesbian nationally.

3.3.3 Qualitative thematic analysis

Five themes were ultimately identified through the analysis: (1) explicit invitations and clear messaging, (2) factors that tip the scales to participation, (3) variation of SGM research accessibility, (4) barriers and facilitators to disclosing identity, and (5) personalization of the research experience. The themes are outlined in Table 2 and are further delineated in the following sections.

Table 2 Summary of identified themes

	Definition	Contributing points
Explicit and clear messaging	In order for SGM to feel a personal obligation to participate based on GI/SO, advertising must be clear about the goals of the study and why SGM data are vital to the specific study	<ul style="list-style-type: none"> • Need for same sex-couple or non-binary advertisements • Appealing not only to personal benefit but the benefit to SGM community specifically • Clearly state the goals of the study to foster trust
Factors that tip the scales	Individual involvement in research is not limited to personal characteristics, but must be considered in the larger context of their identity within society, previous experience, and the characteristics of each study	<ul style="list-style-type: none"> • Those with same GI/SO may not make same enrollment decision • Participants have a personal set of standards to determine participation • Clear eligibility criteria may encourage enrollment and disclosure of identity
Variation of SGM research accessibility	Not all research studies offer the same level of access to SGM population. While some studies are explicitly designed to involve SGM populations, others have not considered how their eligibility criteria or enrollment protocols will impact SGM	<ul style="list-style-type: none"> • Some studies fail to address GI/SO or do so incompletely • Some studies have not considered how certain criteria (like medication use) will disproportionately impact SGM enrollment • Explaining <i>why</i> certain data are being collected, like GI/SO, allows SGM to see the value of their participation
Barriers and facilitators to disclosing identity	Disclosing GI/SO is a personal choice and requires some level of trust in the researcher. Most of this trust is built with subtle interactions, such as body language, and inclusive language that does not assume GI/SO	<ul style="list-style-type: none"> • Intake forms with inclusive language can signal acceptance of SGM identities • Participants did not report overt aggression from research staff but rather perceived discomfort when disclosing GI/SO • Past experiences can impact future decisions to disclose GI/SO
Personalization of the research experience	Participants appreciate having some control in what is shared and with who. This involves all steps of the research process, from allowing for accurate GI/SO disclosure to opting out of sharing certain medical information, like psychiatric records. When possible, participants prefer to give consent as part of an ongoing process, if the study were to change in any way	<ul style="list-style-type: none"> • Participants did not want to share psychiatric records when possible • Some participants were uncomfortable with the idea that enrollment meant ongoing access to all records • Participants said un-enrolling in certain studies was challenging and impacted future decisions to participate in similar studies

3.3.3.1 Theme: Explicit invitations and clear messaging

Explicit messaging appears to be vital to helping SGMs feel their participation is welcomed and desired. Beyond including sexual orientation and gender identity on eligibility questionnaires, many participants said transparency in general is important. If a researcher aims to sample larger SGM populations, for example, then recruitment materials can be targeted with photos of same-sex couples or non-binary individuals. By explicitly considering other genders and sexual orientations, SGMs are more inclined to participate.

The invitation can also appeal to their desire to benefit other members of the community. By presenting research as a way to help people, participants are more likely to feel their involvement is bigger than the compensation being offered. As a 27-year-old lesbian woman said:

I think there's a missed opportunity. When researchers say up front, like this is what you could do...And making it something where upfront, people can look at this and say, 'Oh I see this research project, but like 10 bucks. Yeah. But if they see, like, you know, research like this has solved these problems before, then they're like, okay so I can do this, and I can help other people.

Beyond altruistic reasons, some participants may view this as an opportunity for personal empowerment, as a 54-year-old queer, polyamorous, gay, transman shared:

I think presenting it as an opportunity for folks to participate in their own healthcare and having their voices heard would, you know, be effective because I think a lot of folks, especially marginalized groups feel left out of that conversation...I think that can be a source of empowerment.

Being clear about how research aligns with a person's values and beliefs will more likely create a situation that benefits both the researcher and the participant. In addition to appealing to their desire to do good, participants said that being clear about what the study will entail and how the information will be used can help to assuage some anxiety. A 24-year-old gay man stated:

I think, maybe if it were presented in a way that felt like, secure, like you know, the person...make each person, the person wouldn't feel that their information is like, at risk

of being stolen or something. So like a sense of security or like assurance, knowing that's not going to be stolen.

Many participants indicated that privacy and security is even more paramount when taking biological samples. They suggested that when a sample is taken, the research team should be clear about what testing will be done on the sample such as drug or pregnancy test, and who will have access to the information. Should a sample be destroyed, communication about this would also be appreciated.

3.3.3.2 Theme: Factors that tip the scales to participate

A common narrative woven through every group's conversations was the many considerations taken into account when deciding whether to participate in a study. Studies are specific about the criteria required to be eligible for participation, but the participants were just as specific about what motivated them to participate in the study. Each person seemed to have their own set of scales on which they weighed a number of factors. Some of these considerations were individual characteristics, like previous experience or their personal experience as researchers or research staff. Other factors moved beyond individual control to include how they communicate about research and health with other people in their lives, like healthcare providers, friends, and family. Some organizational factors were also considered, like how the researchers advertised the study or the eligibility criteria. All participants mentioned study-specific characteristics, like the risk of participation, the compensation being offered, the time commitment, or how well the study could ensure the information they shared would be confidential. Each participant had their personal set of scales on which they weighed these factors, and each person seemed to weigh the factors differently. Table 3 describes the participation profile of several focus group members,

Table 3 Participant profiles based on motivations and reservations for research participation

Participant: 65-year-old bisexual male, planning to enroll in AoU	
Previous Studies	Began participating in studies in the last year. Currently enrolled in four other studies, one of which is a healthy aging. No previous studies have addressed SGM issues. The majority of involvement has been completing surveys, no invasive procedures to date
Motivations	<u>Compensation</u> ; “I thought, why not just keep, just keep doing it. Like I said that to myself in this three-hour period. It’s like \$500 for three months...and it’s interesting. I find the money to be good.”
Reservations	<u>Risk and invasiveness</u> : “I have no intention of doing that.” Speaking about an investigational drug trial. “Like where there’s tons of blood draws. I’m not the person that really wants to do that.” Expressed apprehension about an MRI and potential sleep study

Profile: Motivated largely by compensation but enjoys the personal interaction. Prefers low risk studies that are well explained and research staff that is available to answer questions.

Participant: 22-year-old bisexual woman, enrolled in AoU	
Previous Studies	Has done “a lot of research studies,” including MRI, but no SGM-specific
Motivations	<u>Altruism</u> : “If I do other people’s projects then I’m going to get enough participants...seeing where I can help out.” “It was just like, why not?” <u>Ease of enrollment</u> : “It was really easy to do...they weren’t asking for much.”
Reservations	A blood draw is not a reservation, though she understands other people may have that consideration. Expressed that speaking to providers or researchers who assume aspects of identity and sexual orientation can be “tiring”

Profile: Motivated by adding to science because of previous research experience. Is willing to participate in a range of studies if the requirements are not too time consuming or risky. Very willing to give biological samples. Would be turned off to a study where staff was not properly trained to ask more sensitive questions.

Table 3 Continued

Participant: 27-year-old bisexual woman, chose to un-enroll in AoU	
Previous Studies	A few MRI studies, many other studies including ones that focused on mental health
Motivations	<u>Perceived value</u> : “I love to participate in things I think are important. <u>Offering a treatment</u> or new device/ therapy
Reservations	<u>Asking for a large investment</u> before the research has been more developed: “They’re taking a blood sample or biopsy or something... I...sort of weigh in my head sort of the value of the invasiveness and the value of the work. <u>Ambiguous recruitment material</u> : as a bisexual woman if a study is asking for gay women, she will assume she is not eligible

Profile: Motivated to contribute to science, with reasonable compensation. The study must be well-defined and clear about how samples will be used and how this will contribute to science. Was always trying to figure out what the goal of research was. Wanted to be the informed participant.

Participant: 57-year-old lesbian woman enrolled in AoU	
Previous Studies	Started “volunteering” in the 80s for insulin uptake and estrogen studies. Has also done lesbian women aging studies
Motivations	<u>Personal connection</u> : “I had a sister who died from ovarian cancer. So I’ve always looked for hormonal, especially estrogen and diabetes-related studies to participate in” “It’s like a personal quest.”
Reservations	<u>Security</u> : “What if the computer gets hacked, and they find out, this is me, and I just revealed all this about myself. <u>Being outed</u> : In the aging population, I know...the aging population is very reluctant to talk about identifying with the lesbian community because stigma...and in Pennsylvania, we still don’t have civil rights.”

Profile: Largely motivated to give back to the community, especially if the research aligns with her personal interest in cancer and endocrine research. Considers privacy and confidentiality, though she views those more as reservations than fully barriers.

Table 3 Continued

Participant: 37-year-old queer transman, starting the enrollment process	
Previous Studies	Has “participated in dozens over the last year and half” and has “done everything from just like reading things on a screen to learning languages. Long interventions...like a year long and lot of MRI studies.”
Motivations	<u>Compensation</u> : “I mean I do it for the money.” “It’s easy money.” <u>Being eligible</u> : “If I’m eligible—and I am for many of them—I sign up.”
Reservations	<u>Time</u> : “Sometimes I’ll wait to sign up because I’m busy.” <u>Very invasive procedures</u> : “the only study that I’ve said no to after hearing about they wanted to do a tube up the nose and down my throat.” <u>Being “outed”</u> : I’m always like anxious about participating in anything where they’re going to require [a urine sample] because I get worried about, I either have to out myself as trans or I have to, like, configure this and it’s pretty difficult.”

Profile: Motivated by compensation and much less likely to ask questions. Is willing to compromise certain reservations, like invasiveness or being “outed” if the compensation seems fair.

which illustrates the unique value system each participant brings to the study. Participants from each focus group who had previous research experience and represent a range of motivations and reservations expressed by other participants.

These unique profiles suggest that deciding to participate in research is a personal choice that is impacted by a combination of personal experience, risk to the participant, the perceived value of the study (whether personal gain or to “pay it forward”), and larger organizational and societal factors. The only common factor was compensation as a motivator. Most agreed that invasiveness may introduce a certain level of hesitancy. While some participants said this reservation could be overcome if the compensation was fair, others had strong opinions of which

procedures would be considered too invasive. Interestingly, having personal experience as a researcher was both a motivator and a reservation, as some cited wanting to help others, although other participants were more apprehensive about how the information might be used and how well-run the study was. Though not always explicitly stated, most participants considered themselves interested in research and appreciated studies that were clear about the goals and eligibility criteria, especially if they belonged to a community that was often ineligible or forced them to out themselves.

3.3.3.3 Theme: Variation of SGM acceptability in research

Participants stated that research environments vary with regards to the acceptability of SGM participation. While some studies were meant to be exclusively for SGM populations, like the nursing curriculum focus group one woman had participated in, others by default excluded some or all SGM. A 27-year-old bisexual woman reported her concern that many studies excluded anyone who takes psychiatric medication, regardless of its apparent relevance to the study itself. She speculated that perhaps researchers were trying to “control for all variables,” but should be more deliberate in their exclusion criteria. She said this could disproportionately affect SGM eligibility, as this population is at a higher risk for mental health conditions. Interestingly, rather than being fully excluded, participants reported the most unappealing studies as those for which eligibility was not clear. A 37-year-old transman illustrated the anxiety that can be induced by unclear criteria:

It’s more a of thing, like will I qualify? They don’t say anything about trans. And I don’t tell them unless they ask, but sometimes...sometimes I, they like point blank ask. And I lie. And then I get worried about being found out. Because I don’t want to be excluded from the study because I’m trans...And I’m suddenly afraid that I’ll be excluded...And so sometimes I’m like, ‘Oh I don’t know, the study looks like it might reveal that I’m trans.’

A study may try to be inclusive about asking about gender identity beyond the binary, however without explicitly stating *why* the question was being asked, the participant did not feel safe disclosing. A 27-year-old bisexual woman shared that researchers might not understand the significance of all the questions they ask:

I think there's a lot of problems and we don't, researcher, a lot of the time aren't, don't seem to be aware of this at the beginning and they don't make a decision on whether or not it's important, like what's important to you? Is gender identity important to you? Is, is sort of sex important to you? If sex is important to you, what do you mean by that? I think that's sort of the issue is that you don't know what they want from you when you're that. So you know, if somebody says, for example, like I don't know, if I would qualify for a study with, you know, gay women because I'm a bisexual woman. So what are you looking at? Are you looking at women who only have, you know relationships with other women? Or are you looking at women who have that sort of propensity? So, these are things that I think, especially something to go in a research pool, it's not clear what you're looking for, So, you know, I'm going to probably assume that I don't qualify if there's a question.

A number of participants indicated that more explicit criteria would be helpful. And beyond simply listing the criteria, explaining *why* certain features are being asked would allow them to self-select. Participants recognized that researchers cannot always share extensive information about the study in order to not skew the results. In such cases, sharing as much information as possible could be appreciated. As one participant said:

When I see something, even if it says it's inclusive, I don't feel it's inclusive, unless I actually see intention within it...If I see a poster of something recruiting from a diverse population, and they haven't included people who appear diverse. So yeah, so it does work on me when I see like something with a clearly gay or lesbian couple or I see somebody who's gender non-binary, you know or like I mean you never know people's gender but who appear gender non-binary. Then I feel like, 'Oh, they really do mean—they want—everybody.'

3.3.3.4 Theme: Facilitators and barriers to disclosing identity

Disclosing any personal information requires some sort of trust and relationship with the researcher. This trust may be even more important with marginalized populations who may have had negative previous experiences in the medical and/or research setting. Participants said this

rapport should start even before the researcher begins the study. Demographic questionnaires and inclusive language on study descriptions can signal to SGM that they will be treated competently and with respect. As a 29-year-old bisexual gender non-binary person stated:

If I'm set up at the beginning to know that this is a safe place to share, then it's like the rest, it kind of sets the mood for like the rest of the study or something like that. But I often feel if they don't include those chances to identify how I want to identify that I think pretty much okay, well they're not really capturing me, they're capturing what they...trying to only capture on what option I'm given. But they're not really capturing like my demographic because I'm not allowed to say what my demographic is.

Using inclusive language can subtly signal to participants that a researcher is comfortable with their identity and values their honesty. Ideally, building this rapport is an ongoing exchange, and often involves unspoken processes. A 25-year-old queer, genderqueer participant stressed the importance of body language and nonverbal cues:

Um, I think just some casual conversation where, like if I mention my female partner, or, you know being—if it's related to sexual activity—you know having sex with both men and women, then you can just tell that their body language changes, their reactions kind of change, or so it's never anything whereas I feel like super discriminated against, but then it's just kind of like, oh, like I don't know if I shared too much. And then I know sometimes it makes me less likely to disclose that information. And unless it's specifically asked, so I think even just like, people's comfortable...comfortability and talking about those issues, even if that's not what it's specifically about, helps.

Such rapport is needed when asking participants to share particularly sensitive information. Acknowledging and reinforcing a person's identity can facilitate developing a positive relationship with participants. A 54-year-old queer, polyamorous, gay, transman revealed:

I think as a transgender person, and because of my past experiences, I might be a little hesitant to give urine samples. It depends on how they're delivered. Sometimes they'll want a nurse to follow you into the bathroom...And then there's a lot of opportunity to be mis-gendered and to be, to be given a female nurse as a transgender man. And to be mis-gendered by medical staff, saying, 'That's not who you are. That's not what we mean. You have those parts; therefore we get, we get to determine which nurse gets to go into that stall or do that blood draw or help you with this stool sample.' So for me, that's a concern.

This participant was simply asking for the researcher to trust and respect his wishes. Occasionally, researchers make problematic assumptions, which can lead to a negative interaction. A negative previous experience may not just impact that one study but may leave a lasting impact that prevents the person from participating in future research studies. Several participants suggested that training could be helpful in ensuring research staff is comfortable addressing SGM-specific concerns and issues. A 27-year-old lesbian woman stated:

I think that difficult interactions arise from kind of fear on both sides.

This fear from either past experience or from lack of experience can color interactions on both sides. All participants agreed respecting the participant's identity and wishes is a valuable way to build rapport.

3.3.3.5 Theme: Personalization of the research experience

Some participants shared that they appreciated having some control in their research experience, such as how they identify. A 27-year-old lesbian woman stated:

I liked the number of gender identity options. That was nice. Normally, it's like men, women, and other, right? I'm like, who wants to be called 'other'?

Allowing participants to disclose as much as they feel comfortable sharing was discussed by a 27-year-old bisexual woman. She explained she would feel much more comfortable participating in certain research projects if she were given clear choices to "opt out" of sharing certain information:

But medical records is kind of a general question. Do medical records include psychiatric records? And if they do, is there some way to opt out?

Some participants also felt that acknowledging the diversity and perhaps potential utility of research for different SGM populations was a valuable strategy to recruit and allocate resources.

One participant said:

And I think for a long time, that community has been perceived as they are one size fits all, everyone needs the same sort of resources. And since there is such diversity, I think being included more in research really shows the commonalities, but also the differences.

Overall, participants acknowledged that while research requires a level of trust in the researcher and the process, being included in the decision making as much as possible and allowing options for the level of participation enhance building rapport and trust.

3.4 Discussion

This study identified five themes relating to gender and sexual minority participation in public health research. Synthesizing these main points reveals a complex interaction of individual beliefs with organizational goals in the context of societal norms and expectations, suggesting increasing SGM participation in research may require interventions on multiple levels. The implications of these results as well as the limitations and future areas of research are discussed below.

3.4.1 Thematic analysis

To ensure a participant understands, feels comfortable with, and adheres to research protocols, researchers must consider the target population at all stages of study design. The themes identified in this study can be applied across the entire research process to encourage meaningful SGM recruitment, enrollment, and data collection. The identified themes were (1) Explicit invitation and clear messaging, (2) Factors that tip the scale to participate, (3) Variation of SGM

research accessibility, (4) Barriers and facilitators to disclosing identity, and (5) Personalization of the research experience.

3.4.1.1 Explicit invitations and clear messaging

Participants indicated that having their community showcased and being explicitly invited to participate in a study would be more effective than general advertising. Like many minority populations, SGM individuals are often over-looked (Bonvicini, 2017; Maril, 2016). To combat this messaging, targeted advertising to SGM groups, can assure potential participants that their experience is not only welcome, but vital to the study. This visibility is particularly important to counteract assumptions by both potential participants and researchers. Studies about gay parenting and sexual minority women in the workforce suggest that society assumes individuals to be heterosexual and/or cis-gendered (Balsam, Molina, Beadnell, Simoni, & Walters, 2011; Lasio, Serri, Ibba, & Manuel De Oliveira, 2019; The Joint Commission, 2011a; Wilkerson, Rybicki, Barber, & Smolenski, 2011). The danger of such assumptions is that eventually, minority populations assume invitations to “all” apply only to *all* of the majority, rather than to everyone.

A focus group participant who was a transman described his girlfriend’s frustration participating in an oral contraceptive study. Researchers in this study assumed participants would be in a heterosexual relationship, thus her sexual experience with a man who did not have male genitalia could not be fully captured. His girlfriend felt her relationship and identity had not been considered in the study design. In such situations, SGM participants may feel as though their experiences are invalidated and not properly captured or respected. To avoid this potential participant frustration, researchers of the oral contraceptive study could have allowed space on demographic questionnaires to indicate the gender identity of their partner, or included a sentence welcoming all relationship and sexual histories in their recruitment and enrollment materials. This

would have not only improved the participant research experience but would have resulted in a more comprehensive and accurate data set.

Simply asking the GI/SO question, however, is not enough. Several participants said if GI/SO information was being collected, they would want to know why. Such explanations are supported by the literature. The Human Rights Campaign created sample GI/SO demographic questions that explain why the information is being collected and how it will be used (2016). Research on SGM attitudes about GI/SO questions has shown that asking is appropriate if done in a respectful and deliberate manner (Maragh-Bass et al., 2017; Robinson, McMichael, & Hernandez, 2017). These questions should avoid using “prefer not to disclose” as the only alternative to not identifying as a heterosexual or cis-gendered. Additionally, gender identity and sexual orientation should be presented as separate questions when possible to show participants researchers have considered the differences between these populations.

3.4.1.2 Factors that tip the scales to participate

SGM identity is considered in addition to factors affecting general research populations. Factors motivating research participation have been described in the general population, as well as some minority populations, such as racial and ethnic minorities and women (Brown et al., 2000; Coakley et al., 2012; Konkel, 2015). Certain aspects of participation, like the risk of being “outed” or being unsure if you qualify for a gay women study as a bisexual woman, are specific to SGM populations. The decision for SGM to participate in research is complex but can somewhat be visualized by the SGM Research Participation Decision Tree shown in Figure 4.

This model shows how an individual’s perceptions of SGM health and research involvement influence and are influenced by modifying factors such as personal variables, interpersonal relationships, study specific characteristics, and larger social and structural

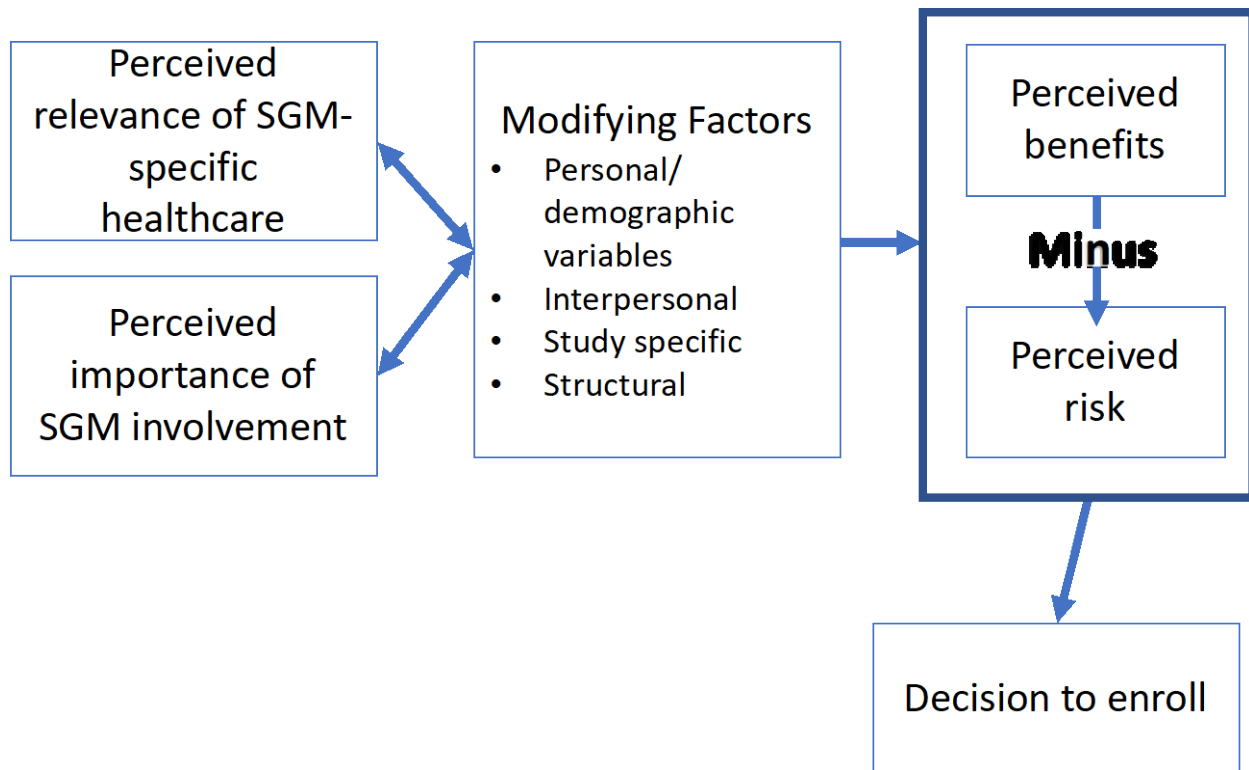


Figure 4 SGM Research Participation Decision Tree

considerations, like the current political climate. Together these perceptions and experiences influence an individual’s perceptions of the risks and benefits of participation. If these benefits outweigh the risks, the potential participant may choose to enroll. If the risks are too great, they may not enroll.

Understanding this model is best done through example. For the purposes of this illustration, consider the 37-year-old transman considering AoU enrollment described in the results section. He perceived SGM populations to have specific health care needs and that their involvement in research was important in studies that could clearly justify GI/SO importance in research. This could be impacted by his identity as a transman or his communication with his girlfriend about her involvement in research. Add to SGM health knowledge was a benefit for him. He saw the gift card offered at enrolment as a benefit, but the urine collection as a risk to be

mis-gendered. Because of the current political climate, he often avoids situations where he may be found out or discriminated against based on his gender identity. Ultimately, he decided the risk of being found out was not greater than the benefits of compensation and enrolled. Another 22-year-old bisexual woman chose not to enroll because while she thought SGM representation was important in research and had given biological sample previously, the risk having her health information stolen from such a large database was too great. This could be based on her previous experience as a researcher and the breaches she had heard about through her job. In both examples, individuals perceived SGM representation to be important in research but divergent modifying factors ultimately resulted in different outcomes.

The identified them can also be mapped onto this model. For example, *Explicit invitations and clear messaging* can be considered in the study-specific factors and may encourage participants to see the benefits of enrolling in the study. *Variations of SGM accessibility in research* can be considered with study specific factors, as well as personal factors as gender minorities and sexual minorities described differences in considering eligibility criteria. *Facilitators and barriers to disclosing identity* can be described as a combination of how important the individual feels SGM representation is in research and previous experience with communicating about their GI/SO. Finally, *Personalization of the research experience* takes into account the competing factors and proposes that by allowing participants to share the level of information they feel comfortable disclosing, researchers are able to minimize the perceived risks of being out and discriminated against.

While this visualization can be helpful to ground a discussion of SGM deliberations about research enrollment, it is important to note that this is likely an over-simplification and more complicated than a simple decision-making tree. This figure is unable to account for the magnitude

of influence on certain aspects of an individual's identity or previous experience. Some participants may be unlikely to ever disclose their identity because of past social rejection, regardless of the benefits of participating. The final decision for each individual to enroll is highly complex

3.4.1.3 Variation of SGM accessibility in research

For research to be fully accessible for SGM participations, eligibility criteria must explicitly address their eligibility and be prepared to capture their SI/GO respectfully and completely. Participants discussed the range of acceptance they felt when interacting with researchers. The language on intake forms can signal how comfortable and prepared the researcher is to discuss sexual orientation or gender identity. For example, incorrectly using transgender as a sexual orientation may show a participant the researcher doesn't understand the difference between sexual orientation and gender identity. Conversely, listing more specific terms such "two-spirit" or demisexual to describe sexual orientation may show the researcher has done some previous research with this population and views each identity as distinct.

Perhaps because some research studies have medical elements, like providing a blood sample or describing sexual history, many participants discussed experiences in the health care setting as well. While no current studies have assessed SGM perceptions about demographic questionnaires in research studies, some research has looked at the use of demographic information, like GI/SO, in the medical setting. In one study, focus groups with health care providers and SGM patients found that intake forms can potentially be problematic, especially for trans patients, as gender is asked more often than sexual orientation (Wilkerson et al., 2011). This study suggested adding LGBT-relevant electronic medical record (EMR) templates will "institutionalize LGBT healthcare" (Wilkerson et al.). While studies often do not use an EMR

system, adding LGBT-relevant questions with an explanation of *why* participants are being asked may serve a similar objective.

Participants spoke mostly about non-verbal cues, stating that a researcher had never explicitly indicated they were uncomfortable or shut down a conversation about SGM-specific concerns, but their body language would change. Examples included avoiding eye contact, shifting in a chair, and generally becoming more rigid. These cues often prevented trust in the researcher and could impact the information shared by the participant. Wilkerson et al. found a similar roadblock to building trust, especially for trans patients who felt pushed to disclose, especially if they were early in a physical transition. Because that study surveyed patients in a clinical setting, being “found out” may be more of a concern, than in a research setting where a singular interaction during the enrollment process may not require the participant to disclose their identity.

Interestingly, no group discussed visual cues, like a sticker in a window or a poster, as a way to make SGM groups feel more comfortable in a space. The Wilkerson et al. study, reported stickers and other visual cues were one of the most discussed structural themes in the healthcare setting. (2011). The current study did not ask specifically about an inclusive *physical* environment, but the consensus that ads should include visual cues such as same sex couples suggests that the groups consider visual signs of representation to be important for recruitment, but not to complete the enrollment. The research setting and clinical setting offer very different physical spaces: a patient is likely to spend more time in the doctor’s office or exam room than a participant is to spend at an enrollment site, which may account for the differences in importance.

Participants spoke extensively about the efficiency of the AoU enrollment process; by their report, the entire interaction took about half an hour and the majority of time was spent completing

questionnaires online. The physical space used is often temporary, meaning the research staff may have little control or investment in hanging anything during the short time they occupy the space. One participant mentioned that her biological sample was taken in a difficult-to-find room in the dental school and the nurse reporting they would be moving to a new location soon. Conversely, many clinical settings are well established and have a patient flow involving several different physical areas—the waiting room, the exam room, and maybe a separate room for taking vital signs. Waiting in each space provides an opportunity to reinforce inclusion, while participants are schedule at a specific time to meet with a single person and perform a specific task.

3.4.1.4 Facilitators and barriers to disclosing identity

Across groups, participants felt that trust in the research staff was vital when deciding when and how much to disclose. Training and experience working with SGM populations were both identified as bridges to encouraging full disclosure. When the researcher appeared to have previously discussed topics related to gender identity or sexual orientation, participants felt more comfortable continuing the conversation and being open about other personal questions in future conversations. Not providing the opportunity to disclose and appearing uncomfortable when the participant did share information about their sexual history or gender identity were barriers to that relationship. These findings are supported by other studies regarding LGBT disclosure under various conditions, including professional and medical settings. An integrative review of 21 studies describing patients' perceptions of being asked about their gender identity or sexual orientation also found that the majority of participants thought these topics were important for their healthcare but were deterred by homophobia and discrimination (Bjarnadottir, Bockting, & Dowding, 2017). Another study assessing transgender patient perspectives on sexual orientation

and healthcare identified the importance of provider training before asking such questions (Maragh-Bass et al., 2017). Such training is further supported by the results of this study.

3.4.1.5 Personalization of the research experience

Participants expressed wanting to opt out of certain sections of a study and to consent to future data sharing. The majority of discomfort was around the use of psychiatric records. Allowing participant input at the level of data collection is not well described; however, population-informed methods, such as community-based participatory research, are gaining support in public health research (Horowitz, Mimsie Robinson, & Seifer, 2009). Involving community stakeholders in the design and implementation of a project improves participation and diminishes researcher bias and stigmatization of a population (Damon et al., 2017). Such input would be even more pertinent for marginalized populations, where individuals are already at an increased risk of discrimination and harassment based on identity alone. Allowing the community to define what information is being collected and how it is shared adds a layer of engagement and would likely increase participation as individuals feel included and in control of their health information. Allowing participants some control over the level of information they share can make analysis and interpretation challenging but can also be used as an analysis itself: if a large number of people are opting out, then further investigation can explore what and how certain information is being collected. This could lead to adjustments to the study that result in better quality data and improved participant perceptions of the study.

3.4.2 Implications

Focus groups were designed to gather the opinions about SGM participation in AoU, as well as public health research. Implications for AoU centered on considering SGM populations during all parts of the enrollment process, especially when creating and displaying advertisements and when asking about demographic information. While participants were able to speak specifically about AoU, most were unable to distinguish between public health research and other types of research, and thus spoke on their experiences as participants in all research. As such the larger implications are not limited to public health research, but any research involving SGM participants.

3.4.2.1 Implications for All of Us

Then current demographic questionnaire is inclusive and comprehensive: Participants overwhelmingly appreciated the option of selecting multiple gender identities and sexual orientations. Additionally, the range of listed options in addition to the self-describe option allowed participants to accurately report their full identity. Giving options for disclosing identity is well supported by the literature and was well-received by this cohort. (Robinson et al., 2017; The Joint Commission, 2011a; Wilkerson et al., 2011) The one suggestion was to add polygamy to marital status, as the current options do not capture that experience.

SGM-specific advertising would appeal to several SGM populations: While current advertising efforts show representation of multiple ancestries, ethnicities, physical ability, and genders, advertisements showcasing, rather than just including, these groups can underscore the value of their contribution. Suggestions included featuring same sex couples, gender non-binary actors, and alternative relationship compositions and gender expressions. In addition to

photographs, the content should be geared to the importance of LGBT participation specifically. Text could include information about the lack of *health* information, how similar studies have impacted LGBT health (with specific examples), examples of some of the studies that would use the data, linking this research to possible grant funding for LGBT studies in the future, or just simply explaining *why* asking about gender identity and sexual orientation are important.

Explicit explanations of the use and distribution of medical records is important: Several participants identified privacy as a concern, especially in regard to psychiatric records. While the current AoU informed consent videos describe how and when medical files will be used, addressing psychiatric records directly is recommended. Additionally, allowing participants to opt out of certain aspects of the research protocol may increase enrollment and overall satisfaction in the process. In addition, several participants mentioned concerns related to privacy and who would access their research files. While not every research partnership may be known presently, providing a list of the partnered organizations as well as a websites or other references to allow for further research would increase transparency. Additionally, participants could re-consent after a fixed period of time with updates of partners could help them feel more involved and empowered with their research information. Finally, being clear about what each sample is used for would be advised. Participants expressed some anxiety about the urine test being used as a drug or pregnancy test, while others were not sure what genetic information was being studied. Clearly stating the intended use would help to assuage that anxiety.

Community partnerships and advocates could help to reach new populations: Many of the places suggested for advertising were community centers or online groups. Mobilizing community partners will be instrumental in recruiting from such locations, as merely placing flyers is unlikely to gather much response, as evidenced by the low response rate from non Pitt+Me participants for

this study. Community partners likely have insights into social networks and dynamics to help recruit potential participants. Using respondent-driven sampling could also be considered at these locations. Word of mouth was referenced as a way to hear about research studies. With a population more apprehensive to trust the medical system, this approach to recruitment be particularly helpful, as personal recruitment can help reassure that the experience will be positive (Heckathorn, 1997) Placing “seeds” at strategic locations can help to diversify the respondents. “Seeds” are strategically chosen community members with access to a social network to recruit more participants from a particular demographic(Heckathorn, 1997). Additionally, while AoU currently uses community advocates, none of the participants had heard of this program. Contacting currently enrolled SGM participants and the opportunity to serve as an ambassador foster community buy-in. Moving forward, offering information to participants at the point of enrollment about the ambassador program may be helpful. Furthermore, recruiting community leaders encourage enrollment of certain sub-populations. Non-traditional, influential members of the community can appeal to hidden populations, such as house mothers from the ball scene, drag queens and kings in the area, DJs, and LGBT social influencers. AoU could offer to provide informational sessions at more informal locations, like a coffee shop or at a cookout. A more relaxed atmosphere could encourage more discussion and allow an opportunity for community members to share their thoughts about current recruitment and enrollment practices.

Focus groups could be a valuable tool with other minority populations: Other minority samples are also largely underrepresented in research. While AoU has been able to sample African Americans and Latinx populations, more needs to be done in terms of engaging Native American populations, as well as other minority populations not currently being described, such as those with physical disabilities (Oh et al., 2015). Implementing focus groups to determine better ways

to partner with these communities can help build rapport and produce concrete recommendations for next steps, as this study has done.

Participants appreciate giving feedback: Though not explicitly stated, participants in this study seemed to appreciate sharing their opinions. Several indicated they had chosen to participate in the focus group to have their opinion heard. A couple of participants enrolled in AoU over a year ago and could not remember specific feedback. At the completion of the AoU enrollment demographic questionnaire, leaving a space for participants to leave their input and suggestions may be a way to gather information from an already invested population, and may be less expensive and time-consuming than running focus groups. Data collected from this feedback could be used to inform future focus group conversations and ensure suggestions are representative of the views of the group.

3.4.2.2 Implications for research with SGM populations

Respondent-driven sampling could diversify focus group participation: While targeted advertising was able to bring in motivated participants, this group was not diverse in several key areas, such as ancestry, rurality, gender identity, and educational attainment. As suggested previously, the use of community partners may enhance the diversity of research participants. Though selecting optimal seeds can require extensive time and resources, this model has allowed researchers to access hidden sections of the SGM population for other studies and could be useful to add to the information gathered in this study (G. Flores et al., 2017; Heckathorn, 1997; Martin et al., 2015).

Evaluation should be an ongoing process: Program evaluation and assessment are two of the least funded areas of public health research, though evidence-based interventions are considered the gold standard of implementation and require ongoing assessment (Brownson,

Fielding, & Maylahn, 2009). Most studies that develop interventions do a final analysis at the end of the study to determine the impact of the intervention. While this information is vital for future research, it offers little insight into ongoing changes that could have affected outcomes. Several public health frameworks, like the Active Implementation Frameworks, require research teams to continuously assess the progress of the intervention and suggest small changes to improve the overall outcome (Hattie, 2009). AoU will recruit participants for at least ten years. In order to ensure that resources and recruitment efforts are effective, on-going assessment like this study are vital. On-going assessment and evaluation serve as quality assurance measure and have the potential to positively affect health outcomes, as researchers are able to adjust strategies based on information provided from the target population themselves.

3.4.3 Limitations

3.4.3.1 Recruitment methods

The majority of participants (44 of 58) were recruited through the Pitt+Me portal. While this means of recruitment did allow for a larger number of participants, the opinions, beliefs, and experiences expressed in the focus groups are fairly specific. Pitt+Me is designed to match potential participants with studies and is largely advertised to Pitt students and faculty. As such, most of the 200,000 participants on this site have an expressed interest in research. Nearly all of the focus group participants (91%) had participated in previous research, which is not representative of the general population. As such, these individuals had already overcome some barriers to enrollment and may not be able to identify barriers other SGM populations face. Most of the barriers identified were around lack of time or interest, rather than lack of resources or ability to attend an enrollment appointment. Participants unable to sign up for Pitt+Me or

disinterested in research would likely have other considerations and factors relevant to their enrollment. Identifying these barriers is extremely important for future research, as AoU, and other research, aims to enroll a diverse participant population, including those not previously interested in or available for research.

3.4.3.2 Focus Group Composition

Considering outcomes specific to this study, the responses collected, and themes identified may not be generalizable to the larger SGM participant pool nationally, and even across Pennsylvania. This sampling bias is acknowledged with focus groups in general, as the thoughts and opinions of a small subgroup cannot be taken as representative of the views of the entire target population. Additionally, this study encountered some unique challenges.

Across focus groups there was a lack of representation of certain demographics; the majority of participants were white and cis-gender. Transgender populations are currently underrepresented, even in SGM studies, and this study only had two transgender participants. Additionally, 87.0% of participants identified as white. Without ancestral and ethnic diversity, the results cannot represent the views of those with multiple minority identities. Intersectionality is a crucial consideration in disparity research, as health risks are often not proportional, but compounded (Hsieh & Ruther, 2016). For example, non-white bisexual women are significantly more likely to be obese than white bisexual women, and white gay men are much more likely to report being moderate to heavy drinkers compared to non-white gay men (Hsieh & Ruther, 2016). In the case of alcohol use among gay men, other public health research has shown men who are racial or ethnic minorities have higher rates of alcohol-related injuries and health consequences (Witbrodt, Mulia, Zemore, & Kerr, 2014). Sexual orientation, then, must be a compounding factor, and could be an independent determinant of health, along with ancestry. Without studies

specifically focused on this intersectionality, researchers are likely to miss interactions and implications of having membership to multiple minority groups, whether such association is negative (as is the case of obesity among bisexual women) or positive (as in alcohol use among gay men). This focus group study recruited mostly white sexual minorities rather than other SGM subpopulations and as such does not capture crucial aspects of intersectionality.

The other consideration is the over representation of certain populations. While there is a paucity of information for SGM participation in research as few LGBT-specific studies are funded and other minority groups are less likely to participate in health research, the actual percentages are likely to be quite low. (Coulter et al., 2014; Crider, Reefhuis, Woomert, & Honein, 2006; Konkel, 2015; Oh et al., 2015) In this study, however, 91% of participants had prior research experience. This may indicate they have overcome barriers to SGM participation in other studies, whether AoU or other research. They were able to give insights into facilitators—compensation, a family legacy, personal connection to research, positive past experiences—but identifying barriers was more difficult to ascertain all the groups.

Additionally, 87% of participants had earned at least a bachelor's degree. In the United States, 33% of the general population and 40% of SGM have earned at least an undergraduate degree. (Schmidt, 2018) In Pennsylvania, 40% of SGM of have at least a bachelor's, just slightly above the 40% of SGM nationally. (Gates, 2011) Such high education and research participation rates are not representative of the general population, as historically those with lower education levels are less likely to engage in routine care and presumably research as well (Arfken & Balon, 2011; Murthy et al., 2004). Several respondents worked in the field of research and therefore could be more likely to have opinions regarding the process than the general population. Trends and recommendations are most applicable to higher socioeconomic groups.

3.4.3.3 Data Analysis

Some approaches to qualitative research use a consensus among several researchers as part of the analysis (Atieno, 2009; Maguire & Delahunt, 2017; Maxwell, 2010). At each step of the process, researchers can work collaboratively to confirm their findings or offer alternative interpretations. In some cases, researchers may have collaborators apply the codes they have generated to the transcript as a quality assurance measure. The involvement of others can help decrease researcher bias and adds to the study's rigor. Because this study was undertaken as an independent thesis project, no other researcher re-coded sections or confirmed the coding line by line. To counter this, the principal investigator did read, code, identify themes and return to each step several times to ensure categories were defined and applied consistently. She also shared transcripts as well as reported findings with a committee member with expertise in qualitative analysis. Future directions could include the reanalysis of the transcripts by a second party, as they were typed verbatim; however, current analysis and interpretation are limited largely to a single view.

3.4.4 Future directions

The current study addresses a gap in the literature around factors contributing to SGM participation in research. Research to date focuses largely on describing SGM populations and associated health disparities, rather than explore their participation in general research. The implications and limitations of this study can illuminate future considerations for research about SGM research participation in public health research, as well as other research with SGM participants.

3.4.4.1 Considerations for this study

As mentioned previously, addressing the lack of diversity in the recruitment methods and focus group composition would help to contextualize the results of this study. As previously presented, the majority of participants were recruited from Pitt+Me. Future studies could focus on various recruitment strategies. For example, researchers could identify several LGBT-friendly businesses or organizations around Pittsburgh and host a focus group at each of those locations. The Persad Center, 5801 Video Lounge, and before OUTrageous Bingo at Rodef Shalom could be locations to conduct focus groups with different SGM populations. AoU could also offer to hold community forums as part of LGBT events, such as the ReelQ Film Festival or Pride events. Partnering with LGBT events already scheduled would allow for interested participants to give their opinions on the same day, rather than finding time for a separate meeting.

The focus group composition was also a limitation of the study. Future research could create focus groups for specific subpopulations. Based on the demographic analysis, people of color, trans individuals, and SGM who have not yet participated in a research study should especially be considered for further research. As with recruiting non Pitt+Me participants, future studies must be deliberate about the location and the timing of advertisements. Asking local community organizations, such as SisTers PGH that works with trans/non-binary individuals experiencing homelessness, about how to sensitively speak with certain populations should be the next step.

Finally, the study could be continued using the current protocols to add to participant responses. Even though the focus groups lacked certain diversity, every group offered new ideas. Focus groups can be continued until no new ideas are being discussed. Although six groups were conducted, many identified factors did not overlap across groups. Conducting more focus groups

could give more information about which themes might be more considered or produce factors that have not yet been discussed.

3.4.4.2 Extending research on SGM participation in public health research

The results of this study have implications not just for AoU but should be further explored in other research relating to public health. Personal connection to the research topic and study requirements were motivating factors for several participants. Further research could use focus groups of SGM participants in specific types of research, such as the MRI studies or reproductive health studies mentioned during the focus groups, to determine if the identified themes appear in other research as well.

Furthermore, surveys could be considered to more quantitatively describe factors in SGM participation. Qualitative research like this study often serves to generate hypotheses. The current study served to identify potential barriers and facilitators to SGM enrollment. Online surveys could be distributed through online LGBT groups and further describe to what extent the identified factors might impact an individual's decision to participate. The survey should also allow participants to list unaddressed factors, as this study has not yet been reproduced and has likely not yet identified all barriers and facilitators. The AoU project could include such a survey among the SGM participants in the national cohort.

3.4.4.3 Larger considerations for SGM participation research

Future research could focus on further description and application of the “SGM Research Participation Decision Tree” presented in Figure 4 and create a standardized GI/SO data collection method. Figure 4 outlines several potential relationships between perceptions and personal experience that could impact the decision to enroll among SGM. While this focus group study

was designed to discuss SGM views on public health research specifically, results have shown that most participants do not distinguish based on the category of research. As described previously, when asked about the role GI/SO might play in the decision to participate in research, participants described a wide range of scenarios, including medical research and even medical treatment. Because of this conflation, the themes identified, and the relationships proposed are likely to apply to other areas of SGM research and care. Future studies could apply the “SGM Research Participation Decision Tree” to other types of research to further explore these relationships. Potential applications could include research already focused on SGM health disparities, like substance use or social connection among the elderly, and more general research, like studies assessing memory or political science research. By applying the model across a range of disciplines, future research could begin to determine to what extent GI/SO are considered in a participant’s decision to enroll in a study and if this consideration varies with the types of research.

Beyond describing the translatability of this model across types of research, further application of this model could help to identify potential interventions. If the relationships between these factors are solidified, researchers are better able to propose interventions to increase enrollment by addressing concerns at each level of decision making. In certain research, the perceived importance of SGM involvement may have the biggest impact and interventions can focus on education about the value of SGM-specific data or creating a concrete plan to disseminate the data and reinforce participation. In other types of research, adjusting study requirements or increasing compensation may be the biggest facilitators.

While encouraging SGM enrollment is crucial in diversity efforts; deliberate, informed questioning is also needed. As many participants in this study described, asking the question is not enough. Participants want to know why the question is being asked and to be asked in a

respectful, well-informed way. Currently several organizations have suggested various ways to collect GI/SO, including the Human Rights Campaign. While most agree that asking gender identity and sexual orientation should be separate, there is no standard list or categorization for GI/SO labels. For example, while AoU has 15 categories of sexual orientation, most surveys include gay, lesbian, bisexual. These types of differences make comparisons across studies difficult. Furthermore, when researchers allow participants to write in their identities, there is no standard way to interpret or group the responses. As such, while wildly different, these identities are likely to be grouped as “other.” Participants in the focus groups appreciated having such a range of choices, but this can be difficult for data analysis on the back end. A future study could examine which methods of collections (multiple choice, select all that apply, write in) are best for collecting this information and which identities can be grouped together appropriately for further analysis. This standardization would ensure a common language to discuss SGM research and could ultimately result in more targeted and appropriate interventions.

Because this study has not yet been replicated, considerations for its larger research implications are currently limited to SGM participation in research, rather than expanding to other minority populations.

3.5 Conclusion

Public health research consistently reports that gender and sexual minorities are disproportionately affected by a number of conditions, including obesity, certain types of cancer, alcohol and drug abuse, and mental health illness. (AHIMA Work Group, 2017; Alexander et al., 2016; Krehely, 2009) This study aimed to address the gap in literature regarding SGM health by

identifying barriers and facilitators to SGM enrollment in public health research. By determining factors impacting SGM enrollment, this study will help future studies focus on interventions designed to leverage identified facilitators and minimize barriers.

3.5.1 Importance

This study was the first known exploration of barriers and facilitators to SGM enrollment in public health research. While the demographics of the focus group may not be representative of SGM populations across the country, the extensive research participation experience of this cohort offered a unique perspective about the engagement of minority populations. In focus group discussions, participants were able to establish many factors that could influence a person's decision to participate in research, ranging from individual to societal. The tipping point for enrolling in research varies between individuals, but inclusive messaging and positive relationships with providers and research staff can positively impact enrollment. Additionally, fostering an environment that allows people to comfortably share their full identity not only produces more accurate data, but can serve as a rapport-building strategy. While majority groups may not be impacted by these additional questions or options, the effort and range of choices will signal to minority groups that they are heard, they are respected, and their involvement is valued.

3.5.1.1 Key Findings

In addition to previously described general barriers and facilitators to public health research participation, this study identified SGM-specific motivations and reservations which can be applied specifically to AoU practices or adapted to other research studies (Arfken & Balon, 2011; Chen et al., 2014; Murthy et al., 2004; Shirk et al., 2012). Overall, SGM participation in public

health research is dependent on messaging in recruitment materials, language used on enrollment forms, and the perceived acceptance of their identity. In order to increase SGM enrollment, studies could consider targeting recruitment, explaining why SI/GO information is important to the study and the interpretation of results, and ensuring enrollment protocols consider SGM inclusive language and explain the rationale for biological specimen collections.

3.5.2 Further implications

These findings have a direct and immediate application for the enrollment of SGM in research. One of the clearest applications is for research, medical, and professional intake forms to ensure that the demographic questions are posed deliberately and in a way that allows participants to disclose as much as they feel comfortable, which has been supported by other studies of SGM in medical settings. More generally, community input can be invaluable to design enrollment practices that are representative of the target population. Suggestions of targeted advertising and allowing parts of the studies to be “opt out” can also be reasonably applied to other minority groups.

Engaging minority populations, like SGM communities, in public health research creates data that are more representative of the true diversity in the general population and provides a unique opportunity to more accurately describe the overall health of an underserved population. Results from future population-based samples can be used to identify resiliencies in the population and may reveal more accurate predictions of the prevalence and impact of identified health disparities. Participants in this study were able to supply concrete next steps for recruitment efforts and illuminate general motivations to be leveraged and challenges to be overcome.

4.0 Significance for Public Health and Genetic Counseling Practice

The AoU project is a historic effort to amass a diverse biobank to fuel future research efforts. (National Institutes of Health, 2018) As such its significance cannot be overstated. Rather than focusing on a specific disease, this project takes a broader view of health. Goals of this research include creating and updating risk models, identifying individual differences, and developing new disease classifications and relationships. (National Institutes of Health, 2019b) The participants of this study will serve as study populations for an array of health research for years to come. This focus on health, rather than a specific pathology, could fill current gaps in SGM research. The study identified several ways to meaningfully engage with SGM populations. The application of information gleaned from this project can be applied both public health and genetic counseling practice.

4.1 Public Health Significance

Public health centers on monitoring and improving the health of whole populations. While the AoU project is focused on the population of the United States as a whole, its expressed interest to oversample minority communities will allow for a closer analysis of subpopulation-specific health, including gender and sexual minorities. AoU has asked about gender identity and sexual orientation separately and with more inclusive language than past population-based surveys. These data, therefore, have the potential to identify factors that impact the health of

SGM, as well as identifying relationships between certain health conditions and gender identity or sexual orientation that have not been previously described.

Discussing factors impacting enrollment is the first step in increasing SGM-specific data in future studies and falls under several of the functions of public health. Public health aims to assess and define community health problems (assessment), develop policy to support individual and community health efforts (policy development), and insure the public is connected to health services that are routinely monitored (assurance). This research addresses both assessment and policy development. Assessment in public health involves identifying and describing a public health problem. The end goal of this focus group research is to increase SGM enrollment in a program that will be assessing the health status of several populations. Based on themes identified in the focus groups, policy development can be undertaken on several levels. The desire to have inclusive identities could be shared with SGM community stakeholders: SGMs, community health center staff and administration, and healthcare providers. The community partners could then advocate for better demographic intake surveys. More specifically for AoU and Pitt +Me, research staff can ensure that future studies are inclusive of SGM populations by requiring associated research projects to address both gender identity and sexual orientation, acknowledging a broad range of experiences.

The advertisement suggestions, such as including same-sex couples and gender non-binary models, can be used to educate and empower SGMs to participate in this effort for their health and the health of their community. Additionally, one of the aims of this study was to explore barriers and facilitators to public health research. Participant response suggests that AoU has a competent workforce, as participants felt the process of enrollment was fairly straightforward and staff were able to answer questions. Future directions could assess

demographic data of Pennsylvania participants, as well as national efforts and compare these results with population statistics. This piece could serve as an assurance that suggested changes to recruitment and messaging have translated to increased enrollment.

More broadly, the results of this study can be used to inform policy and empower community members with the larger goal of assessing population health. Future evaluation could assess the effectiveness of implementing the suggested changes.

4.2 Genetic Counseling Significance

This study informs genetic counseling practice and education in several ways. In terms of patient care, genetic counselors must consider how they will approach sessions with SGM clients differently. Ninety percent of genetic counselors (90.1%) reported having worked with LGBT-identifying patients and 87.5% reported not approaching these sessions any differently.(Glessner, VandenLangenberg, Veach, & LeRoy, 2012) While the intent may be to not draw attention to the client's differences, research as well as participant feedback suggest that we should be knowledgeable about issues specific to SGM care and be comfortable discussing options with patients. Care should not be approached as "one size fit fits all," as the one participant shared. Counselors should customize sessions to meet the needs of patients.

Currently the majority of genetic counselors support additional training in LGBT health issues.(Glessner et al., 2012). This study serves to underscore the importance of adding SGM health and wellness issues to educational standards for genetic counseling training programs. Results from recent curriculum pilot program introduced at in the Sarah Lawrence College Genetic Counseling Program showed students comfort level and base education were improved with SGM

additions to the curriculum through a combination of lectures, class discussion, panels, and personal reflection (Gallagher et al., 2015). Furthermore, information gathered from this study, and ultimately the AoU project will highlight health considerations and other information specific to SGM populations. Being able to competently and empathically care for patients requires knowledge of the special needs of their unique identity. The results of this study support more explicit acceptance of SGM patients. Previous studies point to approaches such as displaying LGBT symbols demonstrate acceptance, however the results of this study suggest more educational opportunities, like continuing education credits, may be more effective for practicing genetic counselors. (Mayer et al., 2008) Beyond expressing LGBT acceptance, by learning more about the specific needs of this population, genetic counselors will be better equipped to build rapport and personalize sessions.

Appendix A IRB Approval

University of Pittsburgh Institutional Review Board

Human Research Protection Office
3500 Fifth Avenue, Suite 106
Pittsburgh, PA 15213
Tel (412) 383-1480
www.hrpo@pitt.edu

APPROVAL OF SUBMISSION (Exempt)

IRB:	STUDY19010217
PI:	Kelsey Bohnert
Title:	Barriers and Facilitators to Sexual and Gender Minority Enrollment in Public Health Research: A Case Study with the All of Us Pennsylvania Project
Funding:	None
Date:	March 1, 2019

On 3/1/2019, the Institutional Review Board reviewed and approved the above referenced application through the administrative review process. The study may begin as outlined in the University of Pittsburgh approved application and documents.

Approval Documentation

Review type:	Initial Study
Approval Date:	3/1/2019

Exempt Category:	(2)(ii) Tests, surveys, interviews, or observation (low risk), (2)(i) Tests, surveys, interviews, or observation (non-identifiable)
Approved Documents:	<ul style="list-style-type: none"> • Recruitment Flyer • Focus Group Guide • Demographic Questionnaire • Focus Group Exempt Application • IRB Clarification Responses • Screening and Study Introduction Script • Reminder Correspondence • References for IRB Background and Sig

As the Principal Investigator, you are responsible for the conduct of the research and to ensure accurate documentation, protocol compliance, reporting of possibly study-related adverse events and unanticipated problems involving risk to participants or others. The HRPO Reportable Events policy, Chapter 17, is available at <http://www.hrpo.pitt.edu/>.

Research being conducted in an UPMC facility cannot begin until fiscal approval is received from the UPMC Office of Sponsored Programs and Research Support (OSPARS). Contact OSPARS@upmc.edu with questions.

If you have any questions, please contact the University of Pittsburgh IRB Coordinator, [Teresa McKaveney](#).

Please take a moment to complete our [Satisfaction Survey](#) as we appreciate your feedback.

Appendix B Man on the Street Exemption



University of Pittsburgh Institutional Review Board

Office: 3500 Fifth Avenue
Pittsburgh, PA 15213
Phone: 412.383.1480
Fax: 412.383.1508

Approval of Vincent™ Exception Request: “Man on the Street” Payment Option

Date: March 8, 2019
IRB Number: STUDY19010217
Investigator: Kelsey Bohnert
IRB Protocol Title: Barriers and Facilitators to GSM Enrollment in Public Health Research

Thank you for submitting a request to make payments using the “Man on the Street” option and for an exception to the requirement to collect social security numbers for subjects receiving payments for participating in the above referenced research study. I have carefully reviewed all of the materials provided to me about this project and on that basis, approve your requests. Both exceptions are applicable to this research study only.

Please note that we are granting exceptions as part of a feasibility study that examines the extent to which subjects participate in multiple research studies over the course of a calendar year and obtain \$600 or more in incentive payments. The \$600 limit is the IRS threshold that requires the paying organization to report this other income to both the taxpayer and the IRS on Form 1099-MISC. Should we subsequently discover that subjects in this ‘exception’ program have reached that IRS reporting threshold, we may modify or disband this program. If that happens, you will be notified in a timely manner.

You have also requested permission to use the “Man on the Street” payment option. Based on the small payment and the subject population and nature of the study, I am also happy to approve that request for this research study only.

The PI or designate will obtain funds through a Vincent™ card issued in their name for distribution to study subjects. A separate record must be maintained in sufficient detail to account for all payments (e.g., a subject receipt log initialed by the recipient of the payment) should be prepared and maintained by the PI as necessary for audit purposes.

The University of Pittsburgh’s Office of Finance can answer detailed questions about the Vincent™ system.

If you have any other questions, please don’t hesitate to contact the IRB Office.

Dana DiVirgilio
Research Review Analyst
University of Pittsburgh | Human Research Protections Office
3500 Fifth Avenue, Hieber Building, Suite 106 Pittsburgh, PA 15213
www.hrpo.pitt.edu | askirb@pitt.edu

Appendix C Approved Recruitment, Enrollment and Communication Materials

C.1 Recruitment flyer



Let's Talk.

Sexual orientation and gender identity matter in health care and research. We want to hear from you.

For more information or to enroll in the focus group, call or text Kelsey: 412-448-0800

To find out more about All of Us, visit <https://joinallofuspa.org/>

As part of a research project through the University of Pittsburgh Graduate School of Public Health in partnership with the All of Us Pennsylvania Research Program, **we want to hear from LGBT individuals, both those who have and have not enrolled in the All of Us project.**

We are looking for LGBT+ individuals, 18 and older, to participate in a 1.5 hour focus group in Pittsburgh.

Focus groups will discuss motivations and experiences with scientific research, as well as current All of Us enrollment strategies in Pennsylvania.

The All of Us Research Program is a national effort to collect health information on a diverse set of one million Americans in an effort to fast-track medical research and discovery.

We will provide food during the discussion and you will be given \$10 to pay for travel.

We want to hear from you!



C.2 Pitt+Me Recruitment Advertisement

Public Health Research: LGBT+ Focus Group

Study Basics

We know our health is impacted by many factors, including our identity. Gender identity and sexual orientation are two pieces of that puzzle. Our study aims to explore the thoughts and experiences LGBT+ individuals have around medical research. We are interested in speaking with people who have enrolled in the All of Us research project, and those who have not. Participation involves one, 1.5 hour focus group. Compensation provided.

Study Purpose

We aim to explore LGBT+ experience in enrolling and participating in research. The All of Us Research Program is aimed at recruiting a diverse set of one million Americans to gather medical information in an effort to fast-track medical discovery. In an effort to ensure participation reflects the diversity in our country, All of Us has made reaching previously under-served and under-represented populations a priority. The LGBT+ community is one example. We know our gender identity and sexual orientation impact how we experience healthcare, health research, and our world.

This study is interested in exploring the experiences of those who have enrolled in the All of Us project, but also to hear from those who have not. We want to know if you felt your gender identity or sexual orientation impacted your participation in All of Us. If you have not enrolled, we are interested any previous research experience, or just your thoughts about health research in general.

Could This Study Be Right For You

- Ages 18+

- Identify as LGBT+
- Received any form of health care, including emergency room visits, in Pennsylvania in the last ten years
- Willing to participate in a single focus group located around the city of Pittsburgh

What Participants Can Expect

Participation involves 1 focus group:

- Groups of 6-12 participants will meet for 1.5 hours to discuss their thoughts and experiences around public health research. Groups will be divided between those who have already enrolled in the All of Us project, and those who have not. Conversations will be audio recorded and de-identified to protect your privacy. During the focus group, you will be asked several questions about any previous research experience, and if you felt your gender identity or sexual orientation played a role in your experience. Refreshments will be provided during the event and each participant will receive \$10 for travel costs.

Age

- 18+

Location

Groups will be conducted in a private room at Panera Bread. Two locations will be used:

- Boulevard of the Allies in Oakland
- Centre Ave in Shadyside

Both locations have on-site parking and are reachable via several bus lines.

Compensation

- \$10 cash for travel expenses
- Refreshments during the discussion

C.3 Enrollment Guide

Study Introduction

Thank you for calling to find out more about our focus group research study. OR I am returning your call to provide more information about our focus group research study.

My name is Kelsey Bohnert, and I am a student researcher at the University of Pittsburgh. The purpose of our research study to explore the attitudes, knowledge, and beliefs people hold about participating in public health research. We are interested to find out if gender identity or sexual orientation play a role in that decision making and are therefore asking people who identify as being part of the LGBT+ community to participate. Our research study is especially interested in discussing how all of this play into the *All of Us* research project. Have you heard about *All of Us*?

IF YES: Great, what do you know about it? (*then adjust the No script as necessary*)

IF NO: Sure. So the *All of Us* research project is an initiative set forth by President Obama to gather health information on at least one million Americans. This information includes basic things like height, weight, blood pressure, and also some more involved things like blood sample and urine collection. The study also asks to look at your medical records for as long as you give them permission. The goal of all this data collection is to study how genes, lifestyle, and environment play a role in our health. Using all that information to make personalized medical decisions is called precision medicine. By gathering information on such a large group of people, the hope of the study is to be able to advance precision medicine. For the information to be accurate, *All of Us* is trying to make sure they collect from all different types of people across the whole country. Pennsylvania is responsible for 125,000 of that one million. To make sure the data represent our nation's diversity, the project is interested in hearing from populations that have historically be underserved by medicine, like the LGBT+ community.

We are asking people to attend a 1.5 hour focus group at a local Panera to share their thoughts around public health research with 5-11 other participants. We will also ask you to complete a brief anonymous questionnaire at the beginning of the focus group. We will be audio

recording the sessions but your responses will be de-identified. It will just require the one visit and you will receive \$10 to cover travel expenses and food during the focus group.

Do you have any questions or concerns? Now that you have a basic understanding of the study, do you think you might be interested in participating?

IF NO: Thank you very much for calling [end call]

If Caller is Interested

IF YES: Great, but before enrolling you in this study, we need to determine if you are eligible to participate. Would it be okay if I asked you a few demographic questions? It should take no more than 5 minutes.

I will keep all the information I receive from you by phone, including your name and other identifying information confidential. At the end of the call I will collect your first name, phone number, and email for scheduling purposes only. This will allow me to send you a reminder before the group and update you if for some reason the group is cancelled. This information will not be linked to your actual comments during the focus group and will be deleted when the focus groups have finished.

Remember, answering these questions is voluntary, and if at any point you do not wish to answer, just say “skip.” If you have any questions or concerns along the way, please feel free to stop me.

Do I have your permission to ask you these questions?

Screening Questions

1. Are you at least 18 years old?
2. Do you identify as LGBT+?
3. Have you received any medical care in Pennsylvania in the last 10 years, including emergency room visits?

4. Do you have access to transportation to attend the focus group?
5. Are you comfortable sharing your ideas in a mixed group, meaning not all people in the group have the same identify as yourself?
6. Have you ever needed to give a blood or urine sample for medical care?
 - a. If no, ask: Would you be willing to give a sample if your doctor asked for it?

If they answer yes to the previous questions, they are eligible for the study. (If they answer yes for 6a, the question is scored as a “yes” response). The next question is to determine group assignment.

The next question is multiple choice

7. What is your experience with the *All of Us* Research Program?
 - a. I have enrolled in the All of Us Research Program
 - b. I have heard of the program and plan to enroll
 - c. I have heard about the program and have reservations about enrollment
 - d. I have heard of the program and plan not to enroll
 - e. I have not heard about All of Us, but am interested in learning about research participations
 - f. I am not interested in participating in All of Us or other research participation.

If Eligible

Based on your answers to the questions, it appears you may be eligible to participate in the research study.

Currently, we have focus groups scheduled for [give dates that correspond to their *All of Us* enrollment status].

Could I get your first name, email, and phone number for communication about the group? In addition, would you like a reminder the day before the group? How would you prefer us to communicate—call, text, or email? [obtain the information]

If Not Eligible

Unfortunately, based on your responses, you are not eligible to participate in the research study.

Study Team Contact Information

Thank you for taking the time to talk with me today. If you have any questions or concerns, please feel free to contact me. My name is Kelsey and I can be reached at 412-448-0800. Please let us know if your plans change and you'll be running late or unable to make the group.

C.4 Reminder Correspondence

Hello, [first name of participant]. This is Kelsey from the focus group research study. This is a reminder about the focus group meeting tomorrow, [insert date and time] at [specific Panera location]. As we spoke about previously, the session will last about an hour and a half and you will be asked to share your thoughts about enrollment in public health research with 5-11 other LGBT+ participants. We will provide refreshments during the group and you will be given \$10 at the conclusion of our meeting for travel expenses. If you have any questions or concerns, or if you are unable to make it, please call or text 412-448-0800. Thank you again for agreeing to participate in this research study and we look forward to speaking with you tomorrow!

If the person asked for a reminder email, instead of a call or text, they will also be given the option to “reply to this email” if they have questions or concerns, or will be unable to attend.

Appendix D Focus Group Guide

D.1 Introduction

Hello and thank you for being here this today/ this evening. My name is Sam; I'm an Master's of Public Health student at the University of Pittsburgh. We're here today as part of a research study to discuss topics relevant to the *All of Us* Research Program – an effort to gather demographic and health information, including height, weight, and biological samples, from at least one million people living in the United States. *All of Us* considers individual differences in lifestyle, environment, and biology, with the goal of accelerating health research and medical breakthroughs and enabling individualized medical care. One of the main objectives of the *All of Us* Program is to collect a data set representative of the diversity across our country. As members of the LGBT+ community, your input is crucial to this effort. We have invited individuals who identify as LGBT+ around the Pittsburgh area to participate.

Because this is a research study, there are some specific points to be addressed. First, participation in this study is voluntary. You may leave at any time. Secondly, while there are no foreseeable risks associated with your participation, there are also no direct benefits. You will, however, receive \$10 for transportation expenses, which will be given at the end of the focus group. Your confidentiality is very important to us. We have taken several measures to protect that confidentiality. First, we ask that you use aliases during today's session. We have provided name cards for you to write them on, and would also like you to indicate which pronouns you use. As you can see, I am recording the audio of our conversation, however your responses will not be identifiable in any way, as we will create anonymous transcripts and destroy the original

files. De-identified data may be shared with the All of Us Research Program and/or other researchers interested in this project, but the original audio files will not be shared. We also ask that you respect each other's confidentiality by not discussing other's participation or responses outside of the group. We will be keeping this confidentiality but recognize that we cannot control what is said by other members of the group.

My role here is to ensure that each of your voices are heard on a range of topics over the next hour and half. I encourage each of you to share and discuss your opinions, beliefs, and knowledge, and I ask that you be respectful of opinions and beliefs that you disagree with. Furthermore, you should choose an alias to write on your name tag for the purposes of our conversation. I will also ask that you write what pronouns you use, I use she/her pronouns. If you need to leave at any point, if you need to answer or make a phone call, or use the restrooms (specify location), please feel free to step out without asking. Also, please feel free to help yourself to food or beverages at any time. Finally, Kelsey will be taking notes this evening. She will not be participating in the discussion but will be capturing your aliases and take notes in order to give context to the transcripts we review later. She is also the student conducting the study and can be reached at 412-448-0800.

D.2 Sample Questions for Not Enrolled Groups

1. First, I'd like each of you to state your name you are using for today's session, what pronouns you use, and give a suggestion. It could be a concept, a restaurant, a book, a movie... literally anything.
2. What research studies have you heard of, or are most familiar with?

3. Have you ever participated in a research study before?
 - Can you tell me more about that?
4. Why might people want to participate in a research study?
5. Why might people not want to participate in research?
 - Do you think gender identity or sexual orientation could play a role in the decision?
6. In the introduction, I mentioned the All of Us Project, which is an effort to collect medical information from one million Americans. This information involves height and weight measurement, blood and urine specimens, access to medical records, and ongoing invitations to complete questionnaires. Have you heard anything about this?
 - The All of Us Project stresses diversity and inclusion in its recruitment and enrollment practices. How might the project make sure LGBT populations are included?
 - Are there better ways to be advertising?
 - The enrollment process requires a physical and urine and blood collection. Are there any things staff should be aware of?
7. **Optional:** The demographic questionnaire you completed when you came in today was taken from the All of Us Project enrollment survey. What were your reactions to these questions?

D.3 Sample Questions for Enrolled Groups

1. First, I'd like each of you to state your name you are using for today's session, what pronouns you use, and give a suggestion. It could be a concept, a restaurant, a book, a movie... literally anything.
2. Other than the All of Us Project, have you participated in any other research projects?
 - a. Can you tell me more about that?

- b. Have any of those studies focused on gender identity or sexual orientation?
- 3. How did you hear about the All of Us project?
- 4. What is your understanding of what the All of Us Project?
 - a. Why did you participate?
 - b. Did you have any reservations about participating?
- 5. What was your experience going through the enrollment process for All of Us?
 - a. Were you comfortable during the process?
 - b. Was there anything you wish would have been handled differently during the recruitment, sign up, enrollment, or in-person visit?
- 6. The demographic questionnaire you filled out at the beginning of the group is similar to the one you filled out for the All of Us project. Did you have any reactions to any of the questions?

Appendix E Demographic Questionnaire

Demographic Questionnaire

Please complete the following questionnaire. Do not write your name on this piece of paper.

1. How **old** are you? _____
2. In what **country** were you **born**? _____
 - a. Have you grown up in the same country? Y / N
 - b. If not, in which country have you spent the majority of your life? _____
3. Where do you **live now**?
 - a. In Pittsburgh
 - b. Within 10 miles of the city
 - c. More than 10 miles outside of the city
4. What category or categories best describe you (circle all that apply)
 - a. American Indian or Alaska Native
 - b. Asian
 - c. Black, African American or African
 - d. Hispanic, Latino, or Spanish
 - e. Middle Eastern or North African
 - f. Native Hawaiian or other Pacific Islander
 - g. White
 - h. None of these describe me: _____
 - i. Prefer not to answer
5. What was your biological **sex assigned at birth**?
 - a. Female
 - b. Male
 - c. Intersex
 - d. None of these describe
6. What terms best express how you describe your **gender identity**? (Circle all that apply)
 - a. Man
 - b. Woman
 - c. Non-binary
 - d. Transgender
 - e. Transman/Transgender Man/ FTM
 - f. Transgender Woman/ MTF
 - g. Genderqueer
 - h. Genderfluid
 - i. Gender variant
 - j. Questioning or unsure
 - k. None of these describe me: _____
 - l. Prefer not to answer

7. Which of the following best represents **how you think of your self?** (Circle all that apply)
- a. Gay
 - b. Lesbian
 - c. Straight: that is, not gay or lesbian, etc
 - d. Bisexual
 - e. Queer
 - f. Polysexual, omnisexual, sapiosexual or pansexual
 - g. Asexual
 - h. Two-spirit
 - i. Have not figured out or are in the process of figuring out your sexuality
 - j. Mostly straight, but sometimes attracted to people of your own sex
 - k. Do not think of yourself as having a sexuality
 - l. Do not use labels to identify yourself
 - m. Don't know the answer
 - n. None of these describe me: _____

8. What is your current **marital status?**
- a. Married
 - b. Divorced
 - c. Widowed
 - d. Separated
 - e. Never married
 - f. Living with partner
 - g. Prefer not to answer

9. What is the highest grade or **year of school** you completed? _____

10. Which best describes your **healthcare experience?**
- a. I have never used any healthcare
 - b. I have only used medical care through the emergency room
 - c. I had regular doctor's visits, but as an adult I only go in emergencies
 - d. I see a doctor at least once every 3 years
 - e. I see a doctor every year
 - f. I follow with several specialist, so I see the doctor more than once a year
 - g. None of these describe me: _____

11. What is your experience with the **All of Us Research Program?**
- a. I have enrolled in the All of Us Research Program
 - b. I have heard of the program and plan to enroll
 - c. I have heard about the program and have reservations about enrollment
 - d. I have heard of the program and plan not to enroll
 - e. I have not heard about All of Us, but am interested in learning about research participations
 - f. I am not interested in participating in All of Us or other research participation

12. All of Us requires a blood and urine sample during enrollment. How willing are you to provide a these samples for a research study?

(not at all) 1 2 3 4 5 (no problem)

Feel free to explain your response: _____

Appendix F Codes Mapped to the Social-Ecological Model

The defined codes addressed factors a number of levels that could be mapped onto the Social-Ecological Model, as shown in Figure 5.

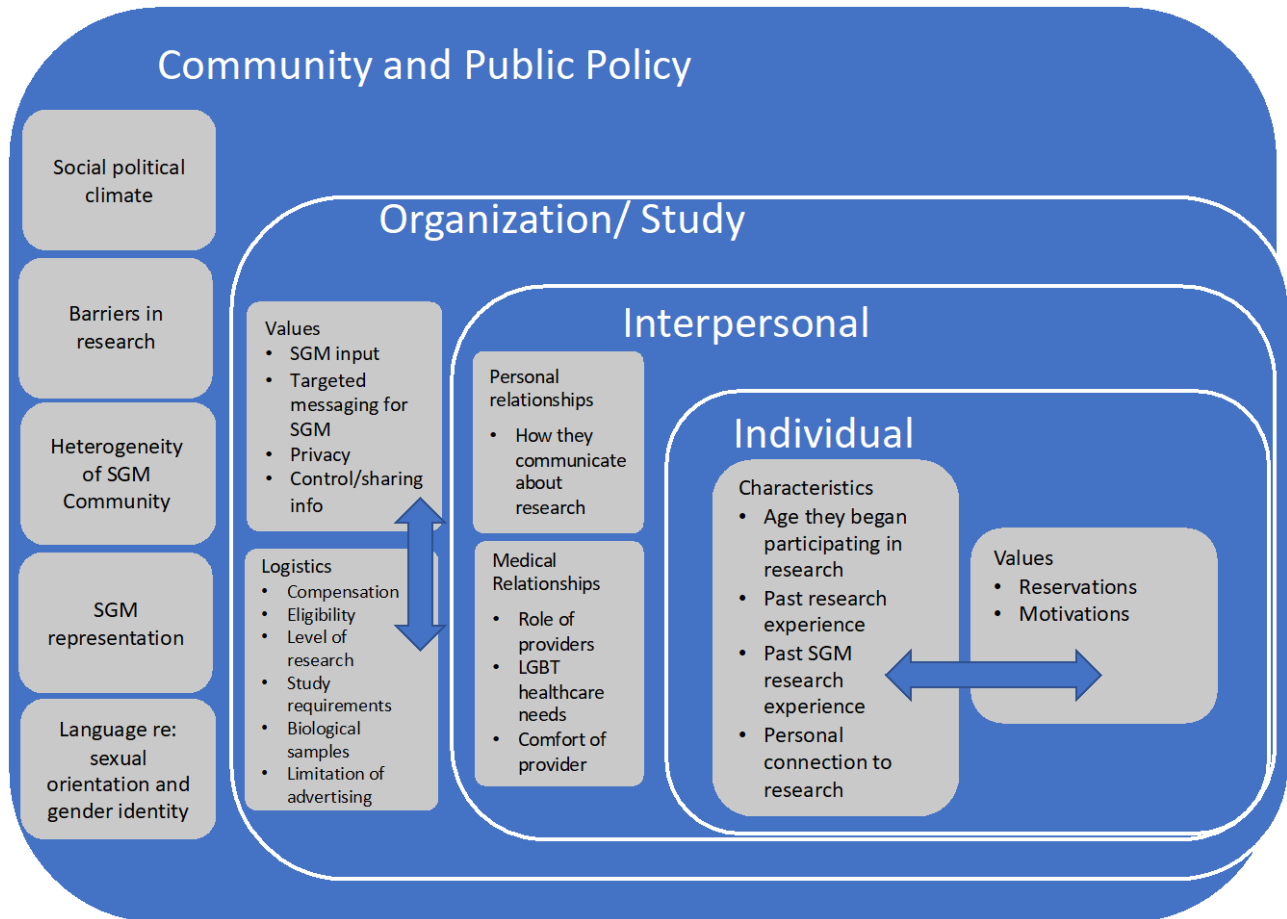


Figure 5 Motivation interactions as illustrated in the Social Ecological Model

At the individual level, characteristics like past research experience and personal connection to the research influenced and were influenced by reservations and motivation to participate in research as a whole. The interpersonal level addressed how the participant communicated about research and GI/SO in their personal relationships and medical providers.

The role of healthcare providers in the decision to enroll was unexpected, however nearly all participants discussed their relationship with a health care provider as impacting their comfort discussing their GI/SO with research staff. The organizational/ study level included logistics of the study, such as the time commitment or compensation, as well as the identified values a research team would apply during the study design and execution. For example, if the research team highly valued SGM input, they may create eligibility criteria more explicitly inviting SGM participation. Finally, at the community and public policy level, factors such as the heterogeneity of the SGM community and how society at large defines gender identity and sexual orientation and views and individual based on their identity may impact how the SGM participant views their role in research.

These levels affect the perception and experience of the individual, as well as influence the factors identified above and below that level. The way a participant discusses research and GI/SO with their healthcare provider may be influenced by their previous research experience and could influence how the participant considers the risks and benefits of the study at the organizational study level. If a participant perceives the patient/provider relationship to be supportive, they may be more likely to engage in conversation about their reservation and clarify some of the study logistics, like what biological samples will be used for. All of the interactions between participants and researchers, however, must be considered in the context of the community and public policy. Even if a researcher considers SGMs in the study design and actively seeks their enrollment, if the language describing SGM in the community is derogatory or the current political climate creates a hostile environment toward SGMs, potential participants may consider disclosing GI/SO to be too great a risk.

Overall, this model allows researchers to consider the complexities of SGM enrollment and look beyond addressing individual behavior to the effect of the environment in which the research is being conducted.

Appendix G Codebook for Transcript Analysis

This codebook contains code abbreviations, descriptions, and illustrative quotes. To give context to the quotations, some demographic information is included about the speaker.

Abbreviations:

AOU: All of US

PPM: Pitt+Me

HCP: Healthcare Professional

Code	Category (Sub category)	Description	Example
ADLIMIT	Modifying factors (structural)	Participants describe difficulty and limitations of advertising for research.	<p>“That’s difficult to say, because there's already so much advertisement for everything everywhere, that your observation just kind of shifts it to the background naturally. So it's kind of hard to get noticed.” (NE)</p> <p>“So we basically all saw it on Pitt+Me. So like, I mean, that's good, targeted advertising to people who already do research. I've seen, I work at Magee, so I've seen tables where people can go to sign up, but like, we have to approach it.” (E)</p> <p>“My other thought to is, is they're trying to get a million people across the country, reaching people in rural areas that, you know, don't have good bus service or just don't have that density of people—” (E)</p>
AGE	Modifying factors (individual)	Participants describe the age or life stage they became involved in research	<p>“I have participated in another study. I did, I’ve done Harvard, Growing Up Today Study. GUTS. And so I started filling out surveys, I think I was eight.” (E)</p> <p>“I actually started volunteering for Pitt programs in the 80s when I was in an endocrine study on insulin uptake, and estrogen models.” (NE)</p> <p>"I participated in dozens [of studies] in the last year and a half, since I got to Pittsburgh." (NE)</p>

AOU_HEAR	Modifying factor (study-specific)	Participants describe how they heard about AoU	<p>“It goes on the Pitt+Me website. I'm pretty sure that's where I saw it.” (E)</p> <p>“I think we got a postcard about it too...I saw it up on a poster at the, at like UPMC urgent care.” (E)</p> <p>“But I also work here and I think there was an article. Even the Pitt names are like on my homepage or something back when they first announced the study.” (NE)</p> <p>“My doctor's office, like merged with UPMC. So then like now there's, there's like flyers taped on doors and stuff. But like, it's not like talked about, like, nobody says anything. I was like, Oh, let me check that out.” (E)</p>
AOU_BARRIERS	Modifying factors (study-specific)	Participants describe barriers to enrolling in AoU	<p>“I think I thought I'd signed up for it. And I didn't know about the---I'd somehow I got stopped between the processes. You know I really rely on, when I'm doing studies, the researchers to prompt me about things...for them to reach out to make the appointment and for them to remind me about the appointment...And so it just never happened.” (NE)</p> <p>“Opting out was not intuitive, and did not—regardless of what—like I said I trust that it was completed, and they'll do</p>

			what they said. But there was very little sort of follow up...even a confirmation screen.” (NE)
AOU_COMM		Participants describe ongoing communication with AoU.	“I wish that they would, I guess. And just for your original question, I wish that they were a little bit more clear about I know that they kind of say that we will get like results back and things like that. I do wish that they had a timeline for that. Because it is, I think the experience that we've had is just kind of like I know, for me, it's like it's been two years. And I get emails asking about doing different surveys, but not really anything about kind of like, what is going on. And when they would like kind of have something that is more like, some information for me so.” (E)
AOU_COMP	Modifying factors (study-specific)	Participants describe their understanding of the purpose of AoU	<p>“I think originally it was you had to go in for one visit where they took your blood and your...urine. And then it was like you had the option to participate continually, but they would have continuing ability to pull your medical records for like 25 years.” (NE)</p> <p>“It's a it's kind of a historic effort to get data from 1 million people across the United States, and it's to make medicine more individualized for people. So it...Yeah, so it was just they kind of, like they said it was more of a registry, kind of like it's about different conditions, but not really focusing on any condition.” (E)</p>

			<p>“What was explained to me was that it was longitudinal, but it was now across the U.S. and, you know, an attempt to gather enough data in order to parse it in a more intelligent way around groups that may be small enough that they’re difficult to treat or understand without that larger view.” (E)</p>
AOU_ENROL	Modifying factors (study-specific)	Participants describe their AoU enrollment experience	<p>“I remember, the questionnaires as being long.” (E)</p> <p>“Yeah, it was pretty straightforward. Like I can't really remember anything about it because it was so straightforward.” (E)</p> <p>“I just had one visit, that was it.” (E)</p> <p>“Well, we basically had to fill out a lot of forms, then they gave you an appointment, you know, to come to a certain area that was open, and they took blood, they drew blood, I think they took blood pressure.” (E)</p>
AOU_FAC	Modifying factors (study-specific)	Participants describe features that made AoU enrollment possible, i.e. why they ultimately decided to enroll	<p>“It was really easy to do, it took like half an hour. They weren’t asking for much.” (E)</p> <p>was easy enough. And then they were even just filling out the in questionnaire is—they were giving you their money for your time for that as well. And then it wasn't really super labor intensive. close to campus. So you just walk down, you know, for the initial one, then they, they're not really doing much after that, besides,</p>

			know, like you were saying following up and checking in on yo So it's not like yet they keep coming back for a month at a time to the facility basically. So it's not too labor intensive.” (E)
AOU_MOTIVT	Perceived benefits	Participants describe their motivations for enrolling in AoU specifically.	<p>“It's not taking much time. And then also it can be very helpful. You know, moving into the future. Making sure people get adequate health care without having to fight tooth and nail for it essentially.” (E)</p> <p>“I think with all research studies. Overall, I think we're all just trying to, like do our part in society, because we know, like, we can't make major changes, but by doing research studies, like maybe we can help someone who's sick some day or thing.” (E)</p>
AOU_RES	Perceived risks	Participants describe any reservation they personally hold or any they have heard about joining the AoU Project	<p>"Some people are like, oh I don't want my information out there kind of thing.“ (E)</p> <p>But I didn't have any reservations about that." (E) "I chose to unenroll. I just don't trust big data right now." (NE)</p>
BIO	Modifying factors (study-specific)	Participants describe their knowledge, attitudes, and beliefs about the collection of biological samples (urine and/or blood) for scientific research	<p>“Like where there's tons of blood draws. I'm not a person that really wants to do that.” (E)</p> <p>“They're religious minorities that will not give you blood.” (E)</p>

			<p>“If we’re told ‘Your blood and urine will be used for this study in this study only and it won’t be used any other study and then it will be destroyed after the study is over.’ There’s a part of me that says, “Okay, that’s kind of a waste.” (E)</p> <p>“I sort of agree, just being direct about exactly what the samples are used for. And like upfront about, that it involves that because they might be interested or like in a little bit deeper into it, and then realize they don’t want to give those samples.” (E)</p> <p>“I mean, the main issue I can think of is that, obviously, is the blood ban on men who have sex with men. And I mean, I know it’s probably not a major point between, but it’s probably something worth keeping in mind. Saying that it’s perfectly alright to give a blood sample.” (NE)</p> <p>“Like people are literally taking parts of my body and walking off with it, which is sort of a weird thing.” (E)</p>
CLIMATE	Modifying factors (structural)	Participants discuss gender identity and sexual orientation in the context of current political and social climate.	<p>“Well, especially this administration. I mean it’s undeniable. They made their position very clear.” (NE)</p> <p>“I have family that relates to---that are not—they’re sympathetic to my experience and who I am as part of their—but they’re not sympathetic to the trans community.” (NE)</p>

CONNECT	Modifying factors (individual)	Participants describe personal connection or experience in conducting research.	<p>“I really like that you had, you don’t think of yourself as having a sexuality and do not use labels to identify yourself. You know I think it’s easier. I didn’t choose either of those because I think it’s easy. It’s—but that was honestly more of because it’s easier for you guys to know sort of what box they fit in.” (NE)</p> <p>“I think to some degree, it takes privacy the next level, right, because now this is not only data that your doctor has, but is available in a database. And people that are researchers understand how data is handled and all that. But if you're a lay man or a lay woman, you're less familiar with it, you may be more anxious about it.” (E)</p> <p>“I've done maybe a lot of research studies. I work in research. So I'm kind of like research karma. If I do other people's projects then I'm going to get enough participants.” (E)</p>
DEBRIEF	Modifying factors (study-specific)	Participants describe the role of debriefing the participant in research.	<p>“At the end of the study, they weren’t telling her what they were looking for. So yeah, she stopped doing them.” (NE)</p> <p>“I have been not been debriefed and been debriefed, and I was...I show up for the money, so it doesn’t matter, doesn’t make a difference to me.” (NE)</p> <p>“But it’s really cool to go back and go on their website and look at like the masses of papers that they’ve been able to get out this data set.” (E)</p>

<p>DEMO</p>	<p>Modifying factors (study-specific)</p>	<p>Participants describe their thoughts, opinions, and recommendations for the demographic questionnaire</p>	<p>“I would say for relationship status, it might be nice to have an option for non monogamy or have a place to put that because I think that there's a lot of people who might not necessarily be monogamous.” (E)</p> <p>“You might not want to put sapiosexual, and polysexual, and omnisexual, and pansexual...in the communities that I've known, sapiosexual is very controversial term and I think...I wouldn't want to circle the same thing.” (E)</p> <p>“I'm, I'm kind of happy that a few of these questions are circle all that apply, rather than just just the one. I mean, for me, personally, like I identify as gay, but technically on pansexual. So if someone asks me, like, what are you it's like, ‘Okay, well, how detailed of response do you want?’” (NE)</p>
<p>ELIG_GEN</p>	<p>Modifying factors (study-specific)</p>	<p>Participants describe general eligibility criteria for research studies.</p>	<p>“If you pre-screen that you might be eligible to participate in particular study, they'll call you back. And they're real good about that. And then they'll really screen you and to say, are, you know, here's the qualifications, you are or are not eligible? Some I am some I'm not.” (E)</p> <p>"There's a lot of studies that...count out people who take certain psychiatric drugs for any actual, sort of like academic reason...I think a lot of times, you know, you find yourself ineligible for something sort of surprisingly ineligible." (NE)</p>

ELIG_SGM	Modifying factors (study-specific)	Participants describe how gender and sexual identity impact eligibility to participate in research studies	“Will I qualify? They don’t say anything about trans. And I don’t tell them unless they ask, but sometimes, it sometimes I, they like point blank, ask. And I lie...And I’m suddenly afraid that I’ll be excluded.” (NE)
GEN_BARRIERS	Perceived risks	Participants describe why they ultimately don't participate in research or why someone else may not participate	<p>"It can be something vain, like 'Oh I don't want to take my earrings out [for an MRI]." (NE)</p> <p>“Maybe people would have like, prior commitments or responsibilities, that they may not want to get involved with research. So like, they don't have the time for it.” (NE)</p> <p>“Probably, also, if they're worried, or it could be harmful to them? Like if there are harmful side effects? Or perhaps they don't have the time or they feel, they're not compensated enough?” (NE)</p> <p>“I think a big factor can also be many people have, like an uncertain relationship with doctors, with dentist, with sort of the health field. And so they may be afraid to participate, because, like what if they shame me in that I haven’t seen the doctor? Or what if they tell me, you know, what if I’m forced to confront this great big thing I’m uncomfortable with?” (E)</p>
GEN_MOTIVAT	Perceived benefits	Participants describe general motivation or	"I want to find a cure. So that when I get to be that age, hopefully we will have hope to create a knowledge base that

		reasons for participating in any research	<p>can cure disease." "I also by my nature...one of my core values is knowledge and curiosity." "It's easy money for me." (NE)</p> <p>"But more importantly, especially look at the queer community in general the necessity to help it inform healthcare policy." (NE)</p> <p>"It was mostly a sense of curiosity for my part." (NE)</p> <p>"I mean, they're all nice people you're dealing with, there's no health risks or anything like that." (E)</p> <p>"I guess to like contribute to field they care about or like further, something that they're interested in." (NE)</p>
GEN_PAY	Modifying factors (study-specific)	Participant describe compensation or benefits they have received in past study participation.	<p>"And I was, like, typical, here's, like, we'll pay you \$40, just for pre-screening." (E)</p> <p>"And so, you're participating in the study, but then they also have some sort of support too." (NE)</p>
GEN_RES	Perceived risks	Participants describe general reservations or considerations when deciding to participate in research.	<p>"Okay, so I have a different perspective on it from from a Native American viewpoint. We don't tend to like to participate in these kinds of studies because of genocide, because medical information has been used against us in blood quantum and disenrolling native people. And because of, you know, the, the previous history of the government and</p>

			<p>the medical community, inoculating Native American folks with smallpox and other sorts of diseases to kind of commit that genocide, very few Native American people feel comfortable doing medical research studies, or providing blood, or anything like that, because of that history.” (NE)</p> <p>“I guess if they’re private? Like if people are private? And they don,t wanna..” (NE)</p> <p>”If you have an identity that isn't well understood, getting out there, you might find it difficult already, just to live your life, and having to explain yourself over and over again, it becomes burdensome.” NE)</p>
HCP_COMFORT	Modifying factors (interpersonal)	<p>Participants describe the comfort level of health care providers working with SGM patients and the role that may play in research participation and health outcomes. This include research staff for health research.</p>	<p>“I believe it’s based on the individual, you know, that you're dealing with? I mean, you know, you can I can sense like Lindsey said, you know, if they're uncomfortable saying something, you know, something's going to change in them. And I mean, you could see, I mean, you can tell like, it's like day and night. I mean, say, Oh, this guy's uncomfortable, or this woman's uncomfortable talking with me, and it puts you on edge I mean puts you like, ‘What should I tell them?’” (E)</p> <p>“like Bill was saying, with the body language changing and everything, it's even helpful, if you can kind of not pick up that this might be the first time that they're talking about something related to sexual or gender identity, like, you can very easily tell if a researcher has has had experience talking</p>

			<p>about these things. And so those conversations are just much easier to facilitate. But as soon as you can kind of like see it, or like, you know, kind of tense to then it's like, oh, so I think body language and just kind of ease the conversation has a lot to do with it.” (E)</p> <p>“And especially among the sample collectors, and it's like the doctor sick, too, right? Are they open? Are they trained of how to handle different situations? Do they feel comfortable? Or are they going to like clam up with the first trans person they see? And like not not don't know how to give the like, urinary collection? You know, like that would, that would, I think people will just walk out in some cases with that. And so representation would be nice.” (E)</p> <p>“Because basically, it boils down to trust, okay, I think, you know, if you're talking to somebody you want it, you know, you would like to know, that you're going to trust them. And if somebody is, you know, on edge, or, you know, kinda like, disoriented or, you know, don't know when it's gonna be, it's gonna be hard to put trust in them. Because they're, you know, no fault of their own, maybe it's the first time it did or whatever. But it's going to be hard.” (E)</p>
HCP_ROLE	Modifying factors (interpersonal)	Participants describe the role health care providers play in patient participation in research	“The provider can try to, like, maybe well they'll probably just like, advertise it to everybody. But if they work specifically with the LGBT community that they can definitely, like, advertise it.” (E)

			<p>“And someone who knows how to interact with LGBT individuals like my, I remember specifically my, I believe he was a nurse, helping me with this project was very comfortable and talking about it, not that we went into great detail about it, but that definitely makes me more like prepared to open up and be comfortable sharing other details.” (E)</p>
INFOSHARE	Perceived risks	Participants describe their thoughts, opinions, and desires regarding the sharing of their health information.	<p>“I guess usually, I'm pretty open about talking about my individual health like currently and what's been in the past, but never so much so where, like, my individual medical records were then, like, given access to.” (E)</p> <p>“I don't want everyone to have access to my medical records. I will choose who has access to it. And they, well it's too much of a threat.” (NE)</p>
PPM_COMP	Modifying factors (study-specific)	Participants describe their understanding of purpose and use of Pitt+Me	<p>“Oh, it explains what the study's about. And then as links to other studies.” (E)</p> <p>“Pitt+Me? Yeah, it's a website. Yeah, it's a website that gives, it gives a list of studies. Basically, there's about 230, 240, and which ones you qualify for, you can register for.” (E)</p>
PPM_HEAR	Modifying factors (study-specific)	Participants describe how they heard about Pitt+Me	<p>“You know, recently, I went to a doctor's appointment. And like when doing the online check in it queued me like, would you be interested in research through Pitt+Me.” (E)</p>

PRIVACY	Perceived risks	Participants describe thoughts, beliefs, and concerns about privacy in research.	<p>“If, if that's since that's the requirement, you might want to have some sort of upfront message about if there's going to be sort of drug screening? And if that would like adversely impact enrollment? Or who might very sure that information would remain confidential and not turned over to authorities?” (NE)</p> <p>“Sorry, like when I studied the genetic information, non discriminatory act it was passed in 2008. And so um jobs and workplace I mean, this is for your job, of course. So they can't discriminate against you not give you insurance based on your genetics and that sort of thing. But that doesn't cover like life into like long term insurance--like life insurance that kind of thing. But yeah, so there's GINA for some things, but there's a lot of holes in GINA.” (E)</p> <p>“Well, like for instance, I used to suffer from major depression and like the might say you can't discriminate. But that doesn't mean they [insurance companies] can't hack in and discriminate.” (E)</p> <p>I think to some degree, it takes privacy the next level, right, because now this is not only data that your doctor has but is available in a database. (E)</p>
PRONOUNS	Modifying factors (individual)	Participants share preferred pronouns	She/her, they/them, he/his

REASSOC	Modifying factors (individual)	Participants describe words or concepts they associate with research	"I Think it usually means something important is happening and we can try to participate." (NE)
REQ	Modifying factors (study-specific)	Participants describe requirements for participation in other research studies.	<p>"Some involve, like one involved just a small blood draw one.. there's a couple that involve an MRI as part of it, and they do a pre-screen, like they do a pre intervention, uh, discussion, and post intervention discussion." (NE)</p> <p>"But the intake, the initial, is basically social work and doctor...interviews. And then we, they take some biological samples." (NE)</p> <p>"I think the only study that I've said no to after hearing about, they wanted to do a tube up the nose and down the throat." (NE)</p>
RESEXP_GEN	Modifying factors (individual)	Participants describe previous research experience or research experience in general	<p>"I'm currently involved in 1,2,3,4 others. Yeah, four there's one that led me to this was through Carnegie Mellon. It's healthy aging study." (E)</p> <p>"So I guess I've been doing a lot of volunteer for any of the estrogen studies...I had a sister who died from ovarian cancer. So I've always looked for hormonal, especially estrogen, and diabetes-related studies to participate in" (NE)</p>

			<p>"I am doing some Alzheimer's disease research participation with my mother." (NE)</p> <p>"I've taken MRI studies for that. I use that Pitt plus me, that website. I whatever studies I qualify for bigger, you know, I get compensated in and helps, you know, for the research. I believe I over 167 studies." (E)</p> <p>"I've participated in a lot of mental health studies also through Pitt+Me." (E)</p>
RESEXP_SGM	Modifying factors (individual)	Participants describe any experience participating in LGBT-specific research.	<p>"The research I'm involved in for the LGBT community, uh youth studies is... as I said with Dr. XX. And he's like studying, basically, how school climate affects whether LGBT youth attend like a particular school, or if they feel comfortable." (E)</p> <p>"I did...well, ongoing part of the PittMen's study...it is for HIV positive and negative men and you meet twice a year." (NE)</p> <p>"I've only done one that was related to LGBTQ people, it was a focus group. It was looking to see how nursing curriculum could be more inclusive of the gender and sexual minorities." (E)</p>
RTIER	Modifying factors (study-specific)	Participants describe how the level of research (how	"Sort of weighing in my head sort of the value of the invasiveness and the value of their work they're doing...I'm

		evolved) contributes to their participation	like, 'Oh well for that level of what you're trying to do right now, I'm not comfortable giving that of myself.' (NE)
SGM_HC	Perceived relevance	Participants describe SGM-specific healthcare needs to discuss with providers	<p>“I mean, like, like, someone's reason for going to the doctor who has a different sexual orientation, you may want to bring up different health topics that you wouldn't bring up for other populations. So like, when I first went to the OB GYN, she was like, well, like, I was talking about birth control. And she was like, "Well, at least you're not pregnant. " And like, you know, as someone who does not a risk of getting pregnant, like that was not something that she should have brought up. So perhaps going to the doctor, like, if you're a man, then they should maybe say like, "Hey, like, what do you thinking about PrEP? Or you're trans? Like how is that going? How are the hormones balancing. Like, there's so many different things that are specific to the population.” (E)</p> <p>“It's like it is a population that is at risk for certain things. And so you want to make sure that you're getting the best data that as soon as that is like being so associated with those people, I can be useful for those people.” (E)</p>
SGM_HET	Perceived relevance	Participants describe the diversity and heterogeneity within the SGM population.	“But I think word of mouth, if you're looking for, like specific type, like, if you're looking for a target population of older lesbians, they're not going to be out in public all that much as like younger lesbians.” (NE)

			<p>“I think that there's I guess, I just want to add, I think the LGBT plus individuals are there's a lot of different types of people. So even within that group, it's a lot of diversity. And I think having that as a marker, in addition to everything else, and kind of indicating kind of that is important for seeing the differences and similarities within that group.” (E)</p>
SGM_INPUT	Perceived importance	Participants describe the role of SGM input in research design and implementation.	<p>“I don't know how realistic this would be, but having members of that community be be part of the team. So so you can at least talk to someone who can relate to you somewhat.. for the most of the process, but particularly probably for this, particularly in terms of design. (NE)</p> <p>“I would say that I think it does matter to have a diverse and very group of sample collectors” (E)</p>
SGM_LANG	Modifying factors (structural)	Participants describe the role and possible confusion around gender identity and sexual orientation terms.	<p>“I know that, like, you can't have always twenty options, but like having even other category you can write in or something like, just being given that opportunity to have the voice and identify how you would identify.” (E)</p> <p>“I think, you know, the reproductive like the the studies at Magee who have a really good thing where it's like, assigned female at birth assigned male at birth. So that's like a good, that's a good language to use.” (E)</p>

			<p>“I don’t even know what the Q is in LGBTQ anymore.” (NE)</p> <p>“It’s a norm within the society...that gender identity and sexuality are linked, they are not obviously, that was something I only learned...within the last five or six years.” (NE)</p> <p>“Researchers a lot of the time aren’t, don’t seem aware of this at the beginning and they don’t make a decision on whether it’s important, like what’s important to you? Is gender identity important to you? Is, is sort of sex important to you? If sex is important what do you mean by that?” (NE)</p>
SGM_REACH	Modifying factors (study-specific)	Participants describe how they would target and engage with SGM populations to recruit for research.	<p>“I don't know if you're doing if you would try to do something in person, like have people outside strategic locations, and just like, ‘Hey, here, so pamphlet, you know, do you know about us? Here's what we're trying to do.’ I don’t know how long this is going on. But I’m sure it’d great to have something set up at the pride festival in June.” (NE)</p> <p>“I think specific targeting to on advertisements would be good. I know that sometimes like the title All of Us. I think some people who may not be used to being included in research may not think that that <i>All</i> includes them.” (E)</p>
SGM_REP	Perceived importance	Participants describe why SGM representation in research may be important.	

			<p>“I mean, they can't study white guys forever... Like, if you're going to say this is the population then like, you gotta represent the population.” (E)</p> <p>“Yeah, I think it's absolutely critical that LGBT q people are given a voice definitely research, like Don was saying, population is vulnerable to too many things. But if the data is not out there, then it's impossible to see what can be done to improve it.” (E)</p> <p>“When you look at the medical treatment that people who identify as trans are and you know, like, all the misunderstanding about sexual relationships with non cis gender couples, and you know, all those pieces, it just...it’s like that much sharper when you’re one of these minority populations, and so becomes even more of a push of like ‘Oh I can help myself, I can help the people who come after, I think it’s even stronger for those communities.” (E)</p>
SPEAK	Modifying factors (interpersonal)	Participants describe the role speaking/ communication with friends and family impacted their participation in research.	<p>"[My mother] was a psychology major and... she was hugely involved in research studies. I think she passed that in to me." (NE)</p> <p>"I've done Harvard, Growing Up Today Study. GUTS...My parents told me to do it or whatever." (E)</p> <p>“That I know a friend of ours recruited us for that, because they were looking for older lesbians at the time.” (E)</p>

			<p>“So I’m in XX, and a lot of people work there because it’s kind of like this precision medicine thing. So I have a lot of friends that work there. And it’s like a big initiative. So I was like, “Oh, sure. Like ,I’ll sign up, of course.” (E)</p>
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