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Institute for Sexual  
and Gender Minority  
Health and Wellbeing

# Evidence-based recommendations for ethical research practices with sexual and gender minority adolescents

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A White Paper from the Northwestern University Institute  
for Sexual and Gender Minority Health and Wellbeing



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and Gender Minority  
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Authors:

**Brian Mustanski**  
**Kathryn Macapagal**  
**Margaret Matson**  
**Rana Saber**

The Institute for Sexual and Gender Minority Health and Wellbeing (ISGMH) was founded in 2015 and is the first university-wide institute in the country focused exclusively on research to improve the health of the sexual and gender minority (SGM) community. As a university-wide institute, our mission is to connect scholars from numerous disciplines with the SGM community to forge collaborations and stimulate innovative research to improve SGM health and wellbeing.

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## Purpose

A significant barrier to sexual and gender minority (SGM) adolescents' participation in sexual health research has been institutional review boards' (IRBs) failure to apply federal regulations permitting adolescents to self-consent to research without parental involvement (Mustanski & Fisher, 2016). Studies have shown that IRBs often overestimate risk on sensitive topics and behavioral research and express concerns that participants may experience psychological distress in sexual behavior surveys or engage in unsafe sexual activity (Petrie et al., 2013; Pritchard, 2011). In addition, attitudes have generally been conservative, assuming adolescents are incapable of making mature and well-considered decisions about research participation and in need of protection by their parents/guardians and other responsible adults (Chenneville et al., 2010). While well-intentioned, these assumptions delay or discourage necessary research and function to systematically exclude an entire population of adolescents who may benefit from participation in research without considering that many have the capacity to provide informed consent and make decisions that impact their sexual health and wellbeing (Mustanski & Fisher, 2016). To better inform IRB decision-making, we collected data from SGM adolescents and parents on their perspectives toward participating in sexual health research and parental permission requirements. We frequently receive questions from other investigators about conducting sexual health research with SGM adolescents and navigating conversations with IRBs about this type of research. The purpose of this white paper is to summarize our studies' findings and share a guide for researchers based on lessons learned.

## Definitions

### Sexual Health

The World Health Organization (2006) (WHO) defines “Sexual health is a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled.” The WHO describes sexual health-related issues as wide-ranging and encompassing sexual orientation and gender identity, sexual expression, relationships, pleasure, conditions or consequences (e.g., HIV, sexually transmitted infection (STIs)s, reproductive tract infections) and outcomes (e.g., cancer and infertility), unintended pregnancy and abortion, sexual dysfunction, sexual violence, and harmful practices (e.g., female genital mutilation, FGM) (World Health Organization, 2022). In this paper, sexual health research refers to studies focused on a subset of sexual health-related issues, specifically sexual orientation, gender identity, sexual expression, relationships, HIV, and STIs.

# Sexual and Gender Minority

Sexual and gender minority (SGM) adolescents, including members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities and those who engage in same-sex behaviors, are underrepresented in sexual health research.

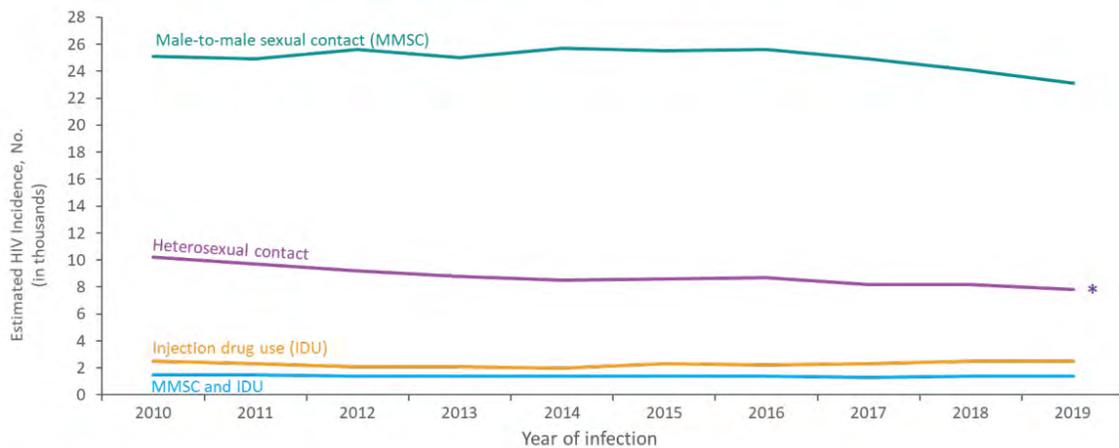
## Background

### Need for Sexual Health Research with SGM Adolescents

In the United States (U.S.), the burden of HIV has been significant and HIV infection rates have been escalating among youth, especially among sexual and racial/ethnic minority populations (Koenig et al., 2016; Mustanski & Fisher, 2016). At the end of 2019, an estimated 1,189,700 people aged 13 and older were living with HIV in the U.S. including 13.3% living with HIV undiagnosed (CDC, 2021). In 2019 66% of HIV infections were among men who have sex with men (MSM) (ages > 13) (see Figure 1) (CDC, 2019). Young gay and bisexual men accounted for 84% (5,161) of all new HIV diagnoses in people aged 13 to 24 in 2020 (CDC, 2022). This scenario highlights the urgency of addressing primary prevention and HIV health outcomes in this population.

**Figure 1.** Figure reproduced from slide 10 of PowerPoint presentation (CDC, 2019)

#### Estimated HIV Incidence among Persons Aged ≥13 Years, by Transmission Category 2010–2019—United States



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Heterosexual contact is with a person known to have, or with a risk factor for, HIV infection. \* Difference from the 2010 estimate was deemed statistically significant (P < .05).

SGM adolescents are underrepresented in or excluded from scientific research studies that have the potential to reduce health disparities among their population. Parental permission requirements create barriers to SGM adolescents' participation in sexual health research, but IRBs fail to apply federal regulations permitting adolescents to self-consent to research without parental involvement (Mustanski & Fisher, 2016). This calls for greater inclusion of youth's voices in different aspects of the research process from regulatory, scholarly, and advocacy standpoints. Studies focused on SGM adolescents' perspectives toward participating in sexual health research can enable us to promote inclusion and responsiveness to SGM adolescents' needs and inform decision-making about ethical and regulatory issues impacting enrollment of SGM adolescents in research (Fisher & Mustanski, 2014).

This report summarizes over a decade of our research on ethical aspects of SGM adolescents' involvement in sexual health research, focusing on SGM adolescents' and their parents' perspectives toward SGM adolescent participation in different types of sexual health studies. We also share takeaways from our work with SGM adolescents, how it shaped our research, and recommendations for other researchers. Studies included in this report collected data between 2007 and 2018 and recruited participants in the U.S. through multiple sources including paid advertisements on social media, participant registries, cards and flyers distributed in LGBT-identified neighborhoods and events, and incentivized peer recruitment.

## Study Findings

### Takeaways: A Summary of our Findings in Ethics Research

- 1 SGM adolescents perceive adolescent sexual health research procedures to be low-risk and high-benefit.
- 2 SGM adolescents under 18 can make reasonable, informed, and voluntary decisions about participation in sexual health research.
- 3 Parents' attitudes toward parent/guardian permission waivers were aligned with federal regulations regarding adolescent self-consent to research, which recognize adolescents' autonomy over their sexual healthcare under most state laws .
- 4 Parental permission waivers are critical to conducting sexual health research that is inclusive of and representative of SGM adolescents.

# What do we know about SGM adolescents' experiences in sexual health research?

1

SGM adolescents are comfortable participating in research on sexual and behavioral health

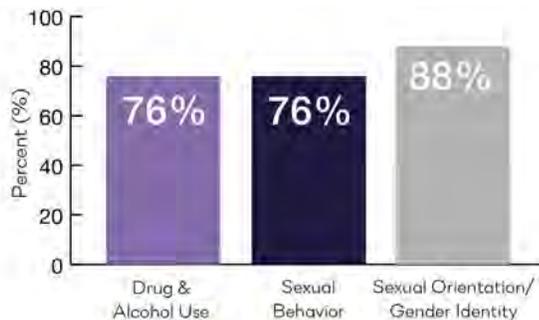
## Majority of Chicago-Area SGM Youth Were Comfortable with Survey Questions About:



(Mustanski, 2011)

Mustanski (2011) reported that the majority of racially/ethnically diverse SGM adolescents and young adults (n = 181, ages 16-20) living in the Chicago area were “comfortable” or “very comfortable” answering study questions about mental health and suicide (88.4%), sexual behavior (89%), and alcohol and drug use (90.6%). In addition, more than half (54%) were more comfortable answering study questions than visiting their physician, doctor, psychologist, or counselor (Mustanski, 2011).

## Most SGM Adolescents Were Comfortable with Survey Questions About:



(Macapagal et al., 2017)

In an online survey, a majority of SGM adolescents (N = 74, ages 14-17) indicated they felt “very comfortable,” “somewhat comfortable,” or “neither uncomfortable nor comfortable” answering questions about drug and alcohol use (75.6%), sexual behavior (75.6%), and sexual orientation or gender identity (87.7%) (Macapagal et al., 2017).

These studies utilized questions with different scales to assess comfort with answering survey questions. In addition, sample age differences may account for slight variations in comfort with answering survey questions about sexual behavior and alcohol/drug use. For example, adolescents may have additional privacy/confidentiality concerns related to parents/guardians seeing their survey responses and/or being inadvertently outed than SGM young adults (ages 18-20) who may not live with parents/guardians.

Macapagal et al. (2019) assessed comfort with sexual health, HIV prevention, and risk behavior research procedures relative to everyday events and routine care among 616 SGM adolescents (ages 14-17) across the U.S. in an online survey.

Macapagal et al. (2019) reported that SGM adolescents are equally or more comfortable with various HIV and sexual health research procedures compared to everyday life experiences. Examples of HIV and sexual health research procedures included in the assessment were HIV testing, urine drug screening, talking to a researcher about sexual behavior, and talking about sexual behavior in a focus group with other teenagers (Table 1). The few HIV and sexual health research procedures rated as more uncomfortable than everyday life events included asking for parental permission to participate in research and more invasive procedures such as a rectal swab to test for STIs. Notably, greater parental acceptance of SGM identity and outness to parents predicted increased comfort with HIV/sexual health research procedures. Findings indicate that common sexual health research procedures may meet minimal risk criteria among SGM adolescent populations and provide further support for waivers of parental/guardian permission to reduce barriers to inclusion of SGM adolescents who are not out to parents.

**Table 1.** Means and Standard Deviations of all items on the Measure of Adolescent Comfort with Clinical, Research, and Everyday Experiences (MACCREE) in an online survey of 616 SGM adolescents (ages 14-17; mean age = 15.7 years). Appended from Table 1 in Macapagal et al. (2019) published in Journal of Adolescent Health

<b>QUESTION:</b> Please indicate how uncomfortable or comfortable you would be with each event on a scale from extremely uncomfortable (1) to extremely comfortable (7).	<b>N</b>	<b>MEAN</b>	<b>SD</b>
Routine Medical and Psychological Tests (M = 4.43, SD = 0.92)			
Having your vision checked at the doctor's office	616	5.59	1.32
A doctor asking you about the types of foods you usually eat and drink	616	5.43	1.52

<b>QUESTION:</b> Please indicate how uncomfortable or comfortable you would be with each event on a scale from extremely uncomfortable (1) to extremely comfortable (7).	<b>N</b>	<b>MEAN</b>	<b>SD</b>
Answering a questionnaire about your future career or job interests at your school counselor's or psychotherapist's office	615	5.40	1.59
Getting an X-ray to check your bones at the doctor's office	616	5.38	1.40
A doctor asking you about your alcohol and drug use	614	4.79	1.84
Providing a urine sample at the doctor's office to be tested for sexually transmitted infections.	614	4.79	1.63
Answering a questionnaire about your mood at your school counselor's or psychotherapist's office	615	4.25	1.74
Having your blood drawn at the doctor's office	615	3.99	1.94
A doctor asking you about your sexual behavior	616	3.50	1.68
Having a doctor do a full-body skin exam for spots that could be cancerous	616	2.92	1.69
Providing a sample of your poop at the doctor's office	614	2.66	1.55
<b>Everyday Events for Adolescents (M = 3.49, SD = 0.58)</b>			
Sending a text message to your friend	616	6.30	1.09
Talking to your classmates about an after-school activity	616	6.18	1.13
Posting a picture on social media	616	5.27	1.55
Getting drug tested at school to participate in a sport or extracurricular activity	612	4.75	1.94
Getting caught in the rain	615	4.69	1.63
Taking a test at school	616	4.63	1.64
Having the principal of your school observe your class	615	4.37	1.63
Doing homework	615	4.11	1.61
Getting called on in class	616	3.82	1.89

<b>QUESTION:</b> Please indicate how uncomfortable or comfortable you would be with each event on a scale from extremely uncomfortable (1) to extremely comfortable (7).	<b>N</b>	<b>MEAN</b>	<b>SD</b>
Being asked to donate money or sign a petition on the street	616	3.76	1.62
Standing in a long line at a store	616	3.47	1.37
Being grounded for something you did	616	2.98	1.35
Picking up dog poop	614	2.85	1.47
Forgetting to do your homework	616	2.69	1.52
Getting a detention	615	2.52	1.37
Getting into an argument with a friend	615	2.34	1.07
Finding out a friend was talking about you behind your back	616	1.98	1.03
Sending an embarrassing text message to the wrong person	615	1.95	1.10
Having your partner break up with you	604	1.65	0.90
Having someone read your private blog or journal who was not supposed to see it	614	1.64	0.93
Having your cell phone stolen	615	1.25	0.59
<b>SGM Identity and Sexual Health (M = 3.57, SD = 1.08)</b>			
Talking about sex with your friends	615	5.37	1.67
Discussing sexual issues in a health class	615	4.33	1.71
Talking about sex with your parent or guardian	616	2.44	1.47
Coming out to a parent or guardian	615	2.13	1.47
<b>HIV/Sexual Health Research Procedures (M = 4.19, SD = 0.94)</b>			
Filling out survey questions about your sexual orientation or gender identity for a research study	616	6.02	1.23

<b>QUESTION:</b> Please indicate how uncomfortable or comfortable you would be with each event on a scale from extremely uncomfortable (1) to extremely comfortable (7).	<b>N</b>	<b>MEAN</b>	<b>SD</b>
Having the inside of your mouth swabbed with a Q-tip to test your saliva for HIV during a research study	615	5.34	1.47
Filling out survey questions about your sexual behavior for a research study	615	5.14	1.52
Talking to a researcher about your alcohol or drug use	613	4.97	1.63
Taking a pill that can help you prevent HIV every day for a year-long research study	616	4.84	1.70
Getting your urine tested for STIs during a research study	614	4.81	1.64
Having your finger pricked to test your blood for HIV during a research study	616	4.60	1.68
Being interviewed with a group of other teenagers about sexual issues for a research study	613	4.53	1.70
Getting your urine tested for drugs during a research study	613	4.48	1.80
Getting an injection (a shot) of medication every three months that can help you prevent HIV for a research study	616	4.38	1.87
Talking to a researcher about your sexual behaviors	615	4.05	1.73
Having to ask your parents for permission to participate in a research study about your alcohol and drug use	612	3.65	1.91
Being in a study where you don't know, and don't get to decide, whether you get an HIV prevention pill or a placebo	609	3.32	1.78
Having a matchstick-sized implant containing medication inserted in your upper arm that can help you prevent HIV for a year in a research study	615	3.32	1.76
Having to ask your parents for permission to participate in a research study for LGBT teens	614	3.12	2.01
Having to ask your parents for permission to participate in a research study about your sexual behavior	615	2.56	1.57
Having the inside of your butt swabbed to test for STIs during a research study	615	2.07	1.40

Note. Items were rated on a 7-point scale ranging from extremely uncomfortable (1) to extremely comfortable (7).

**2** Adolescents are willing to participate in different types of sexual health research studies and share their de-identified data/samples with other researchers

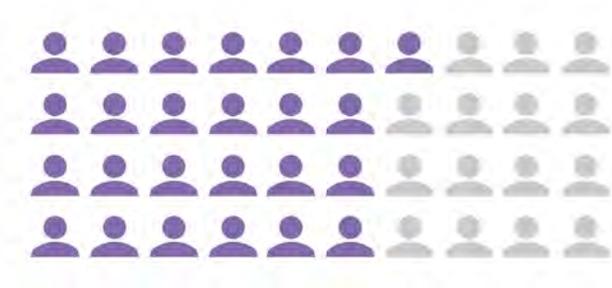
**50% of Transgender Adolescents and Young Adults Surveyed Were Willing to Participate in a PrEP Adherence Study**



(Fisher et al., 2017)

Our studies consistently showed that many SGM adolescents were willing to participate in sexual health research. Fisher et al. (2017) examined transgender adolescents' and young adults' (N = 150, ages 14-21) attitudes toward the benefits and risks of participation in a hypothetical pre-exposure prophylaxis (PrEP) adherence study within the context of their sexual and healthcare experiences and family acceptance. Online survey results showed 50% would definitely or probably participate in a hypothetical 12-month study exploring whether daily text messages (versus no text messages) increased PrEP adherence.

Participation facilitators included prior sexual and healthcare experiences (e.g., increased number of sexual partners, STI testing history, and comfort discussing sexual orientation and HIV protection with healthcare providers) and study access to PrEP and healthcare services (e.g., daily HIV protection, not having to rely on a partner for protection, regular health checkups). Barriers to participation included lack of concern about HIV, potential medication side effects, logistics of getting to quarterly meetings, remembering to take PrEP daily, and reluctance to discuss gender identity with study staff. Parent/guardian permission requirements were a participation barrier for those under age 18.



**63%**  
**of adolescent MSM**  
would participate in a year-long randomized clinical trial (RCT) involving PrEP for HIV prevention

(Fisher et al., 2018)

Data collected in another online survey showed that 62.6% of 198 adolescent MSM (ages 14-17) would definitely or probably participate in a hypothetical year-long randomized clinical trial (RCT) comparing the effectiveness and safety of oral and injectable PrEP for HIV prevention (Fisher et al., 2018). Fisher et al. (2018) also reported that adolescents can consider both benefits and risks of PrEP in making informed research decisions to enroll in biomedical PrEP trials. Reasons to participate included HIV protection, access to sexual health services, and altruism (representing 14.4%, 33.5%, and 18% of responses, respectively). Reasons against participation included the belief they were not at risk for HIV, medication side effects and injection discomfort, confidentiality concerns, and logistical concerns (8%, 4%, 16.8%, and 10% of responses, respectively).

**71% of Adolescent MSM  
Surveyed Were Willing  
to Participate in a HIV  
Testing Study**



(Gray et al., 2020)

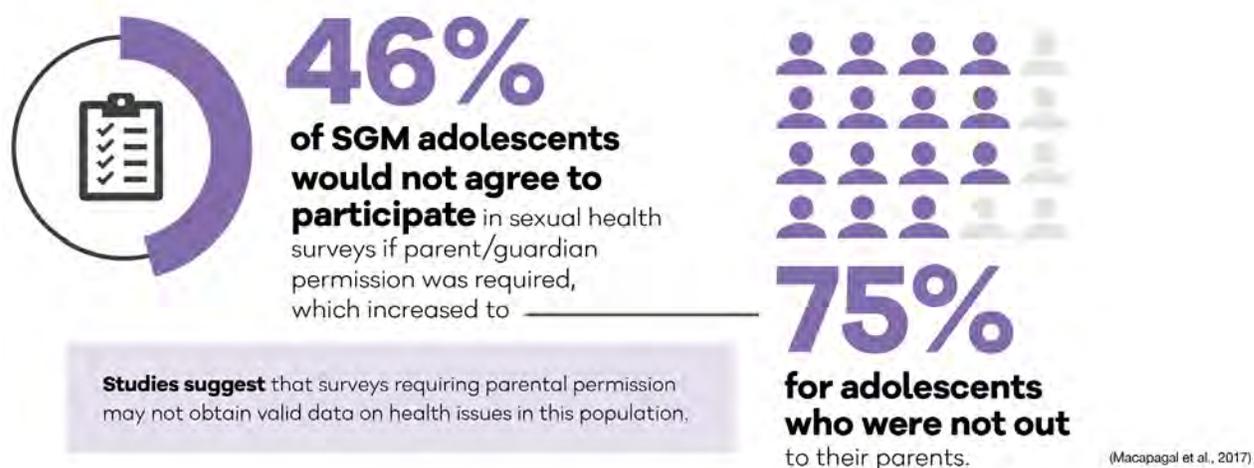
Gray et al. (2020) reported that 70.8% of adolescent MSM (N = 198, ages 14-17) surveyed strongly or somewhat agreed they were willing to participate in a hypothetical study that required them to get an HIV test. Perceived HIV risk, free access to HIV testing, access to counseling and referral if testing positive, confidentiality protections, and lack of access to a trusted physician were positively associated willingness to participate in a HIV surveillance study requiring HIV testing. Significant participation barriers included telling others if one tested positive for HIV and parent/guardian permission requirements.

A majority of SGM adolescents (N = 197, ages 14-17) surveyed were willing to share de-identified survey responses (92.9%) and blood samples (68.0%) with other researchers and shared concerns related to confidentiality and privacy loss (e.g., fear that their parents could gain access to information on sensitive topics such as HIV test results, sexual behavior, or their SGM identity) after de-identification was explained (Matson et al., 2019). Researchers need to make sure participants understand explanations of data security protections in order to make well-informed decisions about participation in research.

Collectively our findings showed SGM adolescents were willing to participate in a variety of sexual health studies and share their de-identified survey responses and blood samples with other researchers as well as consider risks and benefits of participating in research studies. Requiring parental/guardian permission was a barrier to participation in sexual health research for SGM adolescents.

### 3 Requiring parental permission is a barrier for SGM adolescents to participate in sexual health research, especially among SGM adolescents who are not out to parents

Critical ethical questions arise concerning whether adolescents should obtain parent/guardian permission for participation in sexual health research. Requiring parent/guardian permission may put some SGM adolescents at risk of harm and/or limit SGM adolescent participation in sexual health research, jeopardizing the validity of study findings (Mustanski, 2011). Findings across studies consistently showed that parent/guardian permission requirements create a barrier to participation in sexual health surveys, HIV testing studies, and PrEP adherence trials for SGM adolescents, especially for those who are not out to parents. We conducted asynchronous online focus groups with SGM adolescents (ages 14-17) to examine parent/guardian permission requirements and willingness to participate in hypothetical sexual health surveys (Macapagal et al., 2017), HIV surveillance studies (Mustanski et al., 2017), and PrEP adherence trials (Fisher et al., 2016).

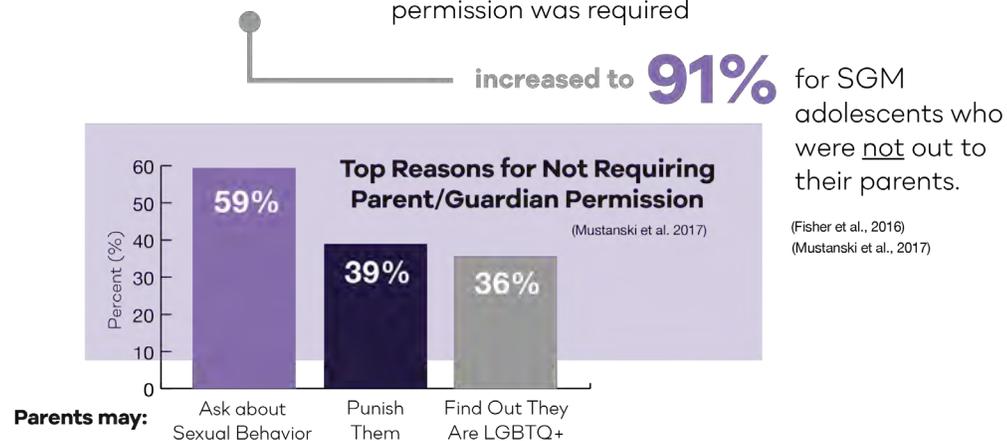


Macapagal et al. (2017) reported 45.9% of adolescents would not agree to participate in sexual health surveys if parent/guardian permission was required. In online focus groups, participants also frequently stated they would not fill out the survey for the

present study if parent/guardian permission was required and participants who were not out more frequently discussed a lack of willingness to obtain parent/guardian permission than those who were out (75% not out vs 25% out) (Macapagal et al., 2017).

## For SGM adolescents:

- ▶ **44%** would not participate in a HIV testing study if parent/guardian permission was required
- ▶ **78%** were unsure about or unwilling to participate in a PrEP adherence trial if parent/guardian permission was required



Similarly, 44.1% of SGM adolescents would not participate in a HIV testing study if parent/guardian permission was required, furthermore, 66% believed parent/guardian permission should not be required for a HIV testing study (Mustanski et al., 2017). The most frequently endorsed reasons for not requiring parent/guardian permission were that parents might ask questions about their sexual behavior (59.3%), punish them (39%), and find out they are LGBTQ (35.6%) (Mustanski et al., 2017). Consistent with these findings, more than 75% of AMSM (ages 14-17) surveyed would not agree to be in a surveillance study involving HIV testing if parent/guardian permission was required (Gray et al., 2020). Notably, adolescent MSM who were not out to parents were less likely to participate if guardian permission was required (Gray et al., 2020).

Of 59 SGM adolescents (ages 14-17), a majority (78%) were unsure about or unwilling to participate in a PrEP adherence trial if parent/guardian permission was required, especially those who were not out to parents (91%) (Fisher et al., 2016). In line with these results, Fisher et al. (2017) reported that 48.5% of transgender adolescents (ages 14-17) surveyed would probably or definitely not participate in a PrEP trial if parent/guardian permission was required. The primary parent's acceptance of the adolescent's gender identity and sexual orientation significantly predicted whether they would agree

to participate in a PrEP trial with parent/guardian permission requirements. Findings from online focus groups showed SGM adolescents were uncomfortable talking to parents or guardians about sexual orientation or gender identity, sexual health, and HIV, which may create barriers to asking for parent/guardian permission in sexual health research among SGM adolescents (Macapagal et al., 2017; Mustanski et al., 2017).

**“I believe it could harm some [teens] because of the risk of being let out of the closet. I know some people whose family would not approve of any other sexuality [other than heterosexuality]. Such as my own, my mother would turn on me for not being her perfect image.”**

**-#581, 15-year-old bisexual female, out  
(Macapagal et al., 2017)**

Adolescents’ ability to make independent decisions about their lives was also a reason against obtaining parent/guardian permission (Macapagal et al., 2017; Mustanski et al., 2017); “youth expressed that their parents or guardians should not be aware of their ‘business’ especially as it pertained to sex and sexuality” (Macapagal et al., 2017).

**“I don’t think that [HIV testing] is a topic where a teen should need special permission to participate... To me, it falls under the category of personal wellness, and that’s just not something I should need my parents’ consent for.”**

**-17-year-old out, bisexual male  
(Mustanski et al., 2017)**

Though SGM adolescents more frequently described their concerns about obtaining parent/guardian permission, a minority were willing to ask for parental permission to participate in sexual health studies if their guardian was accepting of their sexual orientation or gender identity (Macapagal et al., 2017; Mustanski et al., 2017).

**“HIV prevention is very important to me and [my parents] know how important it is to me. They are cool with me being gay and celebrate me whenever I try to better the community.”**

**-17-year-old lesbian female, out  
(Macapagal et al., 2017)**

Other SGM adolescents did not explicitly mention whether their parents were supportive, but said their parent(s)/guardian(s) would agree or would not care if they participated (Macapagal et al., 2017).

Requiring parental permission creates undue barriers to participation in sexual health research, especially for SGM adolescents who are not out about their sexual orientation or gender identity. At the same time, a minority of SGM adolescents were open to involving their parents in the research process. It is critical to recognize that only including the minority of youth willing to get parental permission will overrepresent youth who have accepting parents and therefore produce invalid results that would lead to incorrect conclusions and poor public health planning. Altogether our research provides evidence that SGM adolescents support parent/guardian permission waivers for research on sexual behavior, SGM identity, and other sensitive health behaviors.

4

Parents recognize the value of sexual health research participation and parent/guardian permission waivers. Parents also recommended protections for adolescent participants if a waiver of parent/guardian permission is granted.

Mustanski et al. (2018) studied parents' perspectives toward risks and benefits of parent/guardian permission waivers for a hypothetical PrEP adherence trial in phone interviews with parents (n = 30) of adolescent boys (50% known/presumed heterosexual; 50% sexual minority). Eighty-seven percent of parents perceived potential benefits (e.g., HIV prevention, increased awareness of risk behavior, and sexual health education) of their sons participating in a PrEP adherence study. Parents identified increased comfort with participation as a benefit of parent/guardian permission waivers. Parents often noted that the benefits of a parent/guardian permission waiver could be more significant for particular groups of adolescents, such as sexual minority youth or youth of color, whose parents might not support their sexual orientation or sexual behavior (Mustanski et al., 2018). In other interviews with parents (N = 31) of SGM individuals, most believed parent/guardian permission was not necessary for a behavioral HIV surveillance study (74.2%) and expressed concerns about scientific validity (e.g., requiring parent/guardian permission could result in an unrepresentative sample and impact the validity of study findings) and negative consequences for SGM adolescents if parent/guardian permission was required (e.g., verbal harassment, shaming, and expulsion from the home) (Newcomb et al., 2016).

Also, parents' attitudes toward parent/guardian permission waivers were aligned with federal regulations regarding adolescent self-consent to research, which recognize adolescents' autonomy over their sexual healthcare under most state laws (Mustanski et al., 2018; Newcomb et al., 2016).

**“So at 17, he’s certainly afforded his own level of privacy and liberty, and so he would be able to maintain that. Also if he had questions and wanted to talk about it, he could come to me with it in his own way versus walking past me every day going ‘oh my god she knows.”**  
**-Mother of a 17 year-old gay son (Mustanski et al., 2018)**

Of the 26 parents who responded to the interview question about concerns related to parent/guardian permission waivers for a PrEP adherence trial, 54% referenced the value of parental monitoring of medication side effects, 23% discussed being too immature to decide whether to participate in a PrEP trial or adhere to PrEP independently, and 12% had no concerns (Mustanski et al., 2018). In Newcomb et al. (2016), 51.6% of parents mentioned developmental issues as a consideration in requiring parent/guardian permission, primarily due to concerns about adolescents’ ability to understand research participation risks. Some parents (32.3%) said parent/guardian permission requirements should depend on age because 13-17 years of age represents a period of substantial developmental change (Newcomb et al., 2016).

Parents discussed actions researchers could take to help protect adolescents taking part in research without parent/guardian permission requirements. Recommendations included ensuring access to medical and mental health professionals during study participation to provide health assessments, offer support, and answer any potential questions (Mustanski et al., 2018).

**“If you’re asking about side effects and things like that it should probably be some sort of a medical personnel... somebody with some clinical background who could say ‘oh that actually is a side effect of this medication’ or ‘that’s not a side effect of this medication’ or ‘okay that’s a side effect but we don’t need to worry about it’ or ‘it might be a side effect that we do need to worry about.”**  
**-Mother of a 14-year old bisexual son (Mustanski et al., 2018)**

**“I would hope that [medical professionals] would...make sure that he’s definitely following the instructions and taking the medication the way he’s supposed to be.”**  
**-Father of a heterosexual 14-year-old (Mustanski et al., 2018)**

**“[I would want] a lot of counseling, to be sure that they do objectively understand all the things in consideration... To help decide whether, whether the study is really informing him objectively, recruiting him objectively.” -Mother of a 17-year-old heterosexual son (Mustanski et al., 2018)**

Parents also mentioned protections that represented standard procedures in any IRB-approved study, such as providing developmentally appropriate information and making sure adolescents understand study procedures during the consent process, as well as protecting confidentiality (Mustanski et al., 2018).

## Can SGM adolescents provide informed, rational, and voluntary consent if parent/guardian permission is waived?

Obtaining informed consent is a regulatory obligation and fundamental to ethical research (Department of Health and Human Services, 1979). Providing adequate and understandable information remains the principal prerequisite of the informed consent process. In the context of sexual health research with adolescents, all study-related procedures should be presented and tailored to the participants’ age, both verbally and in writing, to enable full comprehension of study design and the voluntary nature of participation as well as appreciation of the potential significance of risks and benefits. Our studies demonstrated that when providing study information in this way, SGM adolescents consider both benefits and risks of procedures/medications in sexual health research and understand how they might impact their health. For example, Fisher et al. (2016) found that SGM adolescents understood the health-related benefits, side effects, and limitations of PrEP for preventing HIV and STIs in a hypothetical PrEP adherence trial, suggesting that SGM adolescents are prepared to provide informed and voluntary self-consent to age- and population-appropriate procedures for HIV prevention.

### **Majority of Adolescent MSM Understood and Appreciated Consent Information**

at the same level as  
18-19 year-olds



(Fisher et al., 2021)

In an online survey, Fisher et al. (2021) used a modified MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) to assess the consent capacity of adolescent MSM (N = 214, 14–17 years) for trials evaluating oral and injectable PrEP, comparing their performance to adult MSM (18–19 years) for whom parent/guardian permission is not required. Fisher et al. (2021) reported that 100% of 16-17-year-old adolescent MSM understood and appreciated consent information described in this hypothetical PrEP trial at the same level as 18-19 year-olds; and that the majority (83%) of 14–15 year-olds demonstrated similar competencies. These results provide empirical support for the ability of adolescent MSM represented in this sample to independently consent to a comparative oral and injectable PrEP randomized clinical trial based on their ability to understand, appreciate, and reason about their participation choice at adult levels. Data also identified vulnerabilities during informed consent, including misconceptions about inclusion criteria (e.g., not understanding that engaging in unprotected anal sex was the correct inclusion criteria), random assignment (e.g., difficulty understanding the pre-randomization 5-week lead-in period of cabotegravir pills required to ensure the safety of the injectable form of PrEP during the experimental phase of the study), and the study’s purpose (e.g., focusing on just safety (side effects) or efficacy (adherence), or only one medication). However, these consent vulnerabilities existed across age groups, which argues against using these vulnerabilities as a reason to deny minor adolescents with consent capacity the ability to engage in research without guardian permission. At the same time, these findings suggest that MacCAT-CR format should be utilized for both mature minors and young adults during future PrEP RCT pilot studies to identify the nature of prospective participant consent vulnerabilities and to inform strategies for remediating misconceptions and strengthening comprehension during informed consent procedures (Fisher et al., 2021).

Unlike prior studies focused on parents’ and adolescents’ perspectives toward consent and participation in sexual health research, Fisher et al. (2021) empirically assessed decisional capacity, which further bolsters evidence that SGM adolescents both feel they should be given the autonomy and actually have the capacity to consent to participate in sexual health studies independently. This research provides evidence that can inform IRBs’ decisions about waivers of parent/guardian permission and ways to developmentally tailor consent approaches that enhance youth’s understanding of experimental procedures.

## Guide for Researchers

### 1. Build your knowledge base before you submit your proposal/application



**Review case examples and/or protocol papers** from relevant research on the population you want to work with. Mustanski (2011) presented a case example and recommendations for investigators on how to navigate the IRB review process based on prior experience conducting studies with SGM youth.

-  **Educate yourself on relevant ethical, legal, and regulatory principles.** Review your profession’s ethics code for research and the U.S. Department of Health and Human Services Office for Human Research Protection’s regulations relevant to the type of research you would like to conduct, the population you would like to work with, and consent waivers. Mustanski (2011) demonstrated in a “Case Example” how to apply relevant ethical, legal, and regulatory principles to a SGM adolescent and young adult sexual health study protocol.
  
-  **Familiarize yourself with federal/local regulations and consider how they apply to your work.** For example, learn about federal and local laws on age to self-consent to HIV testing services if conducting a HIV testing study. See sources and ways to identify sources of information about federal and local laws under bullet five in “Recommendations for Investigators” in Mustanski (2011).
  
-  **Gather information from the community and colleagues to inform the research process.** Develop a community advisory board with the population you would like to work with and/or those who work closely with your target population, and consult with colleagues with expertise in research with your target population.
  
-  **Review your local institution’s IRB guidelines, templates, checklists, and policies.** If they do not have guidelines that address self-consent or waivers of parental permission consider looking for guidelines from other universities in your jurisdiction.
  
-  **Collaborate and consult with your IRB about your proposal/application** early on so that you can identify any potential concerns to address in your protocol.
  
-  **Review empirical evidence to inform whether your research meets minimal risk criteria and can practically be carried out without a waiver.** Search for data on minimal risk/comfort with participating and perspectives toward parental permission requirements for research similar to your study (Appendix A lists our studies on SGM adolescents/parents). If no empirical evidence exists, consider conducting formative research to collect data to include in your protocol by adapting questions from Macapagal et al. (2019) to assess comfort with procedures or topics relevant to your area of research. Also, adapt the methods/questions we used to collect data on perspectives toward parental permission requirements and waivers for the type of study you would like to conduct if no data exist (see Appendix A).

## 2. Use your knowledge base to prepare your application/proposal's materials

### A. Protocol

-  **Cite sources that support your target population's inclusion in research.** Some sources that support the inclusion of adolescents in health research are the “APA Resolution on Support for the Expansion of Mature Minors’ Ability to Participate in Research” (American Psychological Association, 2018) and “Guidelines for Adolescent Health Research: A position paper of the Society for Adolescent Medicine” (Santelli et al., 2003).
-  **Provide empirical data about the risks and benefits of the research** since the IRB may be unfamiliar with your area of research. If applicable, cite our studies that collected data from SGM adolescents on perceived risks and benefits of participation (see Appendix A).
-  **Justify requests for waivers of parental permission.** See Appendix B for relevant information to include in protocols and how to justify waivers of parental permission for studies of SGM adolescents in IRB submissions. Mustanski (2011) also includes examples from a protocol requesting a waiver of parental permission for a study of SGM adolescents in “Appendix 1: Relevant Sections from an IRB Application Related to Waivers of Parental Consent.”
-  **Cite evidence of the population’s capacity to consent, especially if raised as a concern by the IRB.** See our “capacity to consent” studies with SGM adolescents in Appendix A. Fisher et al. (2021) provides a tool/framework for how to assess capacity to consent if no data exist for your type of research/study or there is ethical or scientific value in assessing it within your study.

### B. Consent forms and capacity to consent assessments

-  **Tailor consent information to your population.** For example, ensure language is at an appropriate reading level and tailor consent information to address consent vulnerabilities for your type of research (see “Consent Vulnerabilities” in Fisher et al. (2021)).
-  **Include additional protections for adolescents when parental permission is waived,** such as consent capacity assessments vetted by adolescents and tested in our studies (see Appendix C for sample consent forms and consent

capacity assessment questions). See Mustanski et al. (2017) “Facilitating informed consent” for ways to ensure adolescents can make informed consent decisions when parental permission is waived.

- ✔ **Present consent information in videos and other multimedia content** in addition to written information per SGM adolescents’ recommendations (see Appendix D for sample videos included in some of our studies).

### C. Data collection materials

- ✔ **Incorporate ethics-related questions** in your research (e.g., rationale for non-participation during the screening process, comfort/discomfort with study procedures, and adequate protections for youth and other vulnerable populations), especially when a topic or method is novel or when it is unclear from the empirical literature how a particular population might experience the research study (see Appendix E for sample ethics questions).

### D. Other helpful materials

- ✔ **Prepare materials for adolescents to share or use to discuss the study with parents.** SGM adolescents were capable of making informed decisions about participation in studies on their own, but that does not mean we universally recommend against parental involvement, especially for SGM adolescents who would like to involve their parents (see Appendix F for sample FAQ sheet for parents).

## 3. Meet with the IRB and ask questions during the review process

- ✔ **Attend the initial meeting where your work will be reviewed if possible to answer questions.** For example, the NIH Intramural Research Branch has invited researchers to participate in their protocol’s initial review, to answer board member questions, and collaborate on setting appropriate risk reduction procedures and protections.
- ✔ **Request a meeting with IRB staff and/or board chair for clarification when questions are raised during the IRB review that are not clearly articulated or not sufficiently addressed.** In our experience, solely relying on formal written communication to optimize the most ethical and scientifically valid approach is much less efficient and effective.

## 4. Educate your IRB and share findings from your ethics research (ongoing)

-  **Serve on your IRB.** Being a member of your IRB means that you bring your expertise to the meeting and gives you a unique opportunity to educate the other board members about your area of research and/or the population you work with and facilitate identification of appropriate protections and risk reduction procedures.
-  **Suggest articles or offer to provide education that may inform the IRB about risks and benefits of the kinds of research you conduct.** Most IRBs undergo continuing education.
-  **Collect and publish data on ethics issues in research.** See Appendix E for sample ethics questions.
-  **Share recommendations from empirical ethics data with your IRB, and integrate participant suggestions into your work.**

## Conclusion

This report synthesized ethics data that we collected and published on SGM adolescents' involvement in sexual health research. Our research found that parent/guardian permission requirements create barriers to participation in sexual health research for SGM adolescents, especially those who are not out about their SGM identity to parents/guardians. Our studies also showed that SGM adolescents under 18 can make reasonable, informed, and voluntary decisions about participation in sexual health research. The American Psychological Association released a resolution that cited our work to support waivers of parent/guardian permission, "Therefore Be It Further Resolved, in accordance with current regulations, APA asks IRBs to waive the parental permission requirement when it potentially could harm the mature minor and when alternative and appropriate research protections are in place" (American Psychological Association, 2018). This shows how collecting and publishing ethics data can inform guidelines and recommendations. We can do more (and more innovative) sexual health research with SGM adolescents than we would have been able to without the evidence base from our ethics research. Our guide for researchers covers how to a build, use, and share your knowledge base on conducting research with the population you want to work with. In closing, our call to action for researchers is to collect, publish, and synthesize empirical evidence on ethical issues in research on novel topics and with other underrepresented populations to enable more data-driven IRB reviews in the future.

## Appendices

Appendix A. List of our studies with empirical evidence on ethics issues to cite in protocols for sexual health research with SGM adolescents.

Study	Population	Study or procedures type	Ethics Topics Assessed				
			Willingness	Risks/benefits	Minimal risk/comfort	Parental permission	Capacity to consent
Fisher et al. (2016)	SGM adolescents	PrEP adherence trial <sup>a</sup>	X	X		X	X
Fisher et al. (2017)	Gender minority adolescents	PrEP adherence trial <sup>a</sup>	X	X		X	
Fisher et al. (2018)	Adolescent MSM	Biomedical PrEP trial <sup>a</sup>	X	X			
Fisher et al. (2021)	Adolescent and young adult MSM	Biomedical PrEP trial <sup>a</sup>					X
Gray et al. (2020)	Adolescent MSM	HIV testing surveillance study <sup>a</sup>	X	X		X	
Macapagal et al. (2019)	SGM adolescents	Various sexual health research procedures <sup>a</sup>			X	X	
Macapagal et al. (2017)	SGM adolescents	Sexual health surveys <sup>a</sup>		X	X	X	
Matson et al. (2019)	SGM adolescents	Sharing de-identified data and blood samples <sup>a</sup>	X				
Mustanski (2011)	SGM adolescents	Sexual health research interviews/surveys <sup>b</sup>			X	X	
Mustanski et al. (2017)	SGM adolescents	HIV testing surveillance study <sup>a</sup>		X		X	
Mustanski et al. (2018)	Parents of sexual minority and straight adolescent boys	PrEP adherence trial <sup>a</sup>		X		X	
Newcomb et al. (2016)	Parents of SGM individuals	HIV testing surveillance study <sup>a</sup>				X	

Note. <sup>a</sup>Assessed ethics topics in the context of a hypothetical study or study procedures; <sup>b</sup>assessed ethics topics in the context of a real/non-hypothetical study.

## Appendix B. Relevant information to include in protocols and how to justify waivers of parental permission for studies of SGM adolescents

**Cite local laws and regulations, when necessary (e.g., laws on age to self-consent for health services similar to procedures included in your study).**

The Department of Health and Human Services (2022) website states the following:

*“Children’ are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a)). In the United States the legal age of adulthood is a matter of state and local law. This means that who is legally considered a child may vary from state to state; in a large majority of states eighteen years of age is the legal age of adulthood, but this is not true in every state, locality, or territory. Also, there may be exceptions to who is considered a child and additional laws in places that define emancipated minors. The definition of ‘children’ also takes into account the particular treatments or procedures involved in the proposed research; for example, in some places individuals who are sixteen years of age may legally consent to certain medical treatments, and so if the involvement of human subjects in a proposed research activity consists of these treatments, then they may be considered as adults for that purpose. If a proposed activity includes something for which the subject has not yet reached the legal age of consent, however, that person must be considered a child.”* ([https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html#:~:text=The%20human%20subject%20research%20regulations%20define%20%E2%80%9Cchildren%E2%80%9D%20as%20follows%3A,CFR%2046.402\(a\)\)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html#:~:text=The%20human%20subject%20research%20regulations%20define%20%E2%80%9Cchildren%E2%80%9D%20as%20follows%3A,CFR%2046.402(a))))

Human subjects regulations define “Children” as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a))”. Because adolescents can independently consent to many sexual health services (e.g., HIV or STI testing and treatment) in most states (Guttmacher Institute, 2022) (<https://www.guttmacher.org/state-policy/explore/minors-access-sti-services>), it has been argued adolescents in states that can self-consent to these services can also self-consent to research on these services (Fisher & Mustanski, 2014; Nelson et al., 2010). For example, Northwestern University’s IRB released guidelines that outline circumstances in which minors may consent to research participation (Northwestern University, 2022):

“In Illinois, the legal age for consent to medical treatment is usually 18 years old. Some exceptions apply under Illinois law that permit a minor to consent to medical treatment for him or herself, and these exceptions depend on the minor’s legal status (e.g., emancipated minor, pregnant or married minors, minors who are parents) or the medical condition or treatment received by the minor (e.g., sexually transmitted diseases and HIV, drug and alcohol abuse, mental health services). A detailed discussion of the circumstances in which minors can consent to medical treatment under Illinois law is beyond the scope of this guidance document – if you need further assistance on this topic, contact the NU Office of General Counsel. A minor who understands the risks, benefits, and alternatives to certain health services may give informed consent (i.e., parental permission is not required) for research participation when the research involves solely treatments or procedures for which minors can give consent under the law of the jurisdiction where the research will take place – if some of the treatments or procedures encompassed by the research would require parental permission under applicable law, then parental permission is required for all of the research procedures and treatments to be used in the study. The decision to allow minors to consent on their own behalf to research participation must be made by the IRB on a case-by-case basis after careful consideration of the nature of the research, anticipated benefits, and potential risks, and may also require consultation with NU’s Office of General Counsel. For research involving children that will take place outside Illinois, the investigator is responsible for understanding local requirements regarding who qualifies as a “child” and whether local requirements provide any other unique protections to children. Researchers working in other states or countries should consult with local collaborators, ethics committees, or other relevant sources about the applicable laws and regulations of that jurisdiction.” (Northwestern University, 2022)

## Explain why the study meets requirements to waive parental permission

U.S. Federal Regulations also offer two special exemption clauses to waive parental consent requirements when participants meet the definition of being children: i) if research risk is minimal, and the research could not be practically carried out without the waiver (45 CFR 46.116d) or ii) when parental permission is not a reasonable requirement (e.g., neglected or abused children) (CFR 46.408c). A recent resolution by the American Psychological Association advocated for the routine inclusion of SGM adolescents as a group where parent/guardian permission is not a reasonable requirement (American Psychological Association, 2018).

To waive or to alter informed consent elements, the IRB must determine that the research involves no more than minimal risk to subjects, the research could not practicably be carried out without the waiver or alteration, the waiver or alteration will

not adversely affect the rights and welfare of the subjects, and where appropriate, the subjects will be provided with additional information about their participation. The IRB must ensure that these four criteria are met before approving a waiver or alteration of consent. Researchers requesting a waiver or alteration will need to justify how their study meets each of the requirements. Mustanski (2011) includes sample excerpts from a protocol that address each of the four points. We include additional examples of what types of information to include for each of the sections below.

**1. Explain why the proposed research presents no more than minimal risk to the subjects who participate**

-  Review and cite evidence demonstrating that the population you want to work with is comfortable with the study procedures (see “minimal risk/comfort” studies in Appendix A). If no empirical evidence exists, collect data to include in your protocol by adapting questions from Macapagal et al. (2019) to assess comfort with other research procedures or topics relative to every day events.
-  Mention that participants can stop participating at any time and whether there will be any adverse consequences to stopping participation (if applicable).
-  Describe all the measures taken to minimize loss of confidentiality.
-  Describe an appropriate mechanism for protecting participants when parental permission is waived. Ensure the presence of and describe how unbiased advisors, such as youth advocates, can assist adolescents in making informed decisions about participation when they desire such a consultation when requesting waivers of parent/guardian permission. Also, provide and explain that participants will have access to medical or mental health professionals and hotlines and other resources during participation (if applicable).

**2. Describe whether or not the waiver of consent adversely affects the rights and welfare of subjects.**

-  Explain how the protections put in place will ensure that participants’s rights will not be violated. For example, inform that the evaluation of the decisional capacity of youth and the presence of independent youth advocates helps assure that participants’ rights are not violated.

- ✓ Discuss how the waiver may help protect the rights and welfare of participants. For studies of SGM adolescents, express concerns about confidentiality issues, including that reluctance to discuss SGM identity with their guardians and poor parental acceptance of SGM identity can put some adolescents at risk for parental harassment, abuse, or expulsion from the parental home if parental permission is required (see “parental permission” studies in Appendix A).

**3. How and why alter the consent process? Would it be possible to conduct the research without a waiver of parental permission?**

- ✓ Explain why it would not be possible to conduct the research without a waiver of parental permission. Cite available evidence or adapt the methods/questions used to collect data on perspectives toward parental permission requirements and waivers for the type of study you would like to conduct if no data exist (see “parental permission” studies in Appendix A). For studies of SGM adolescents, requiring parental consent can negatively impact the validity of the findings, reduce confidentiality and comfort of youth, and place some youth at risk, so altering the consent process by waiving parental permission can be a reasonable requirement for research with SGM adolescents.

**4. Please explain your plans, when appropriate, for providing any pertinent information to the subjects at a later date (e.g., after their participation in the study):**

- ✓ If appropriate, explain if information will be deliberately withheld from participants to accomplish study aims (e.g., psychological experiment with deception).

## Appendix C. Sample capacity to consent assessments used in studies with SGM adolescents

We also recommend including additional protections in studies for adolescents when parental permission is waived, such as consent capacity assessments vetted by adolescents and tested in our studies. Here are a few sample consent forms and capacity to consent assessments used in previous studies:

### Online focus group study with SGM adolescents (ages 14-18)

- **Materials:**  
Online consent form and capacity to consent assessment:  
<https://doi.org/10.21985/n2-qjz9-ae96>
- **Procedure:** The consent form and capacity to consent assessment was entirely online. Participants had the opportunity to re-review parts of the consent form containing content relevant to the capacity to consent question(s) they missed (if any), then answered the capacity to consent question(s) they missed a second time. If they did not answer capacity to consent questions correctly on the second attempt, they were not eligible to enroll in the study. *Note: If participants passed the online capacity to consent assessment, study staff scheduled a follow up phone call to conduct an ID check and share additional information about the study with participants, but the consent process was entirely online.*

### Online sexual health intervention for adolescent MSM (ages 13-18)

- **Materials:**  
Online consent form and capacity to consent assessment:  
<https://doi.org/10.21985/n2-g6x9-dj56>  
Verbal consent and capacity to consent assessment process:  
<https://doi.org/10.21985/n2-w2pr-y858>
- **Procedure:** The online consent form and capacity to consent assessment was administered online. If participants missed any capacity to consent questions after reviewing the online consent form, then study staff reviewed the consent form and administered capacity to consent questions on the phone with participants. If participants did not answer capacity to consent questions during the phone call, they were not eligible to enroll in the study.

## Appendix D. Sample multimedia content for the consent process

SGM adolescents recommended including study information in videos and multi-media content along with written information during the consent process. Here are few examples of videos we created to explain study information:

- Video for an online sexual health intervention for adolescent MSM (ages 13-18):  
<https://doi.org/10.21985/n2-q30d-x724>
- Video for a hypothetical biomedical trial comparing the effectiveness and safety of oral and injectable PrEP included in online survey assessing SGM adolescents (ages 14-17) and young adults (ages 18-19) capacity to consent (Fisher et al., 2021):  
<https://doi.org/10.21985/N2BF6C>

## Appendix E. Sample ethics-related questions to adapt and include in research studies

### **Assess rationale for non-participation during screening, consent, and requests to withdraw from the study:**

*Thank you for letting us know. We'd appreciate it if you tell us why you aren't interested in taking part in this study, which can help us improve our studies in the future. \_\_\_\_\_*

### **Assess comfort/discomfort with research procedures or topics (especially in novel research methods or topics) (Macapagal et al., 2019; Macapagal et al., 2017):**

*How comfortable did you feel answering the survey questions about drug and alcohol use?*

- *Very uncomfortable*
- *Somewhat uncomfortable*
- *Neither uncomfortable, nor comfortable*
- *Somewhat comfortable*
- *Very comfortable*

### **Assess opinions on adequate protections for adolescents and other vulnerable populations:**

**(for adolescents)** *If your parents weren't involved, what could the researchers do to help you decide if you want to be in the study?*

**(for parents)** *What do researchers need to do in order to ensure the safety and well-being of [name of teen] in a study that involves HIV testing without your permission?*

## Appendix F. Sample resource created for SGM adolescents who opt to involve parents/guardians

For adolescents who opt to involve their parents, it may be helpful to prepare materials for adolescents to share or use to discuss the study. Here is an example of information made available on a website for adolescents in an online study:

### Information for Parents

Below we answer questions commonly asked by parents about the [study name].

#### **How much will this cost me?**

This program is provided to your child at no cost.

#### **Why is this only for guys? Why can't my daughter participate?**

We've tailored this study to only focus on health issues facing teen guys. As I'm sure you're aware, young men and young women have many different concerns and behaviors relevant to their health, so it makes sense to tailor programs to their own unique needs.

#### **How can my child be in a study without my permission?**

The [study name] has been classified as a minimal risk study, meaning ethics experts have decided being in this study presents no more risks than experienced in everyday life or a typical doctor's visit. Some teens may feel uncomfortable talking to their parents about enrolling in health-related research. In addition, our previous research has shown that teens have the capacity to understand the benefits and risks of participating in a study and make an informed decision about their participation. Allowing teens to make their own decision about participation ensures that all eligible teens are able to participate in our study, including those who may feel uncomfortable talking to a parent or may not be in contact with a parent.

#### **How is my child's information used?**

The information your child provides will help us understand how online programs can improve teens' health.

#### **Will my child's data be kept confidential?**

Participant data is kept completely confidential. Participant names will never be used in any reports of this research, and only select members of the study staff will have access to participant data. Any identifying information will be changed to protect teens' confidentiality. The federal government has given us a certificate to help us protect against disclosing your child's information.

**What if my child contacts you about a serious health issue (depression, anxiety, etc.)?**

We take the needs of our participants very seriously. This program isn't intended to assist in an emergency, and in a crisis participants should always call 9-1-1 or a crisis hotline. We provide a 24-hour hotline number that is always accessible within the program. At the same time, we fully understand that working with teens means that stress, trauma, mental illness, violence, and other issues can be present in the lives of our participants, and our team is prepared to provide appropriate resources and referrals to participants as required. Our team includes a licensed Clinical Psychologist who is on call and can provide options and referrals.

**If your study is only available over the internet, won't this exclude teens who don't have internet access?**

Despite what we might assume, Internet access is high across income and race after accounting for computers, tablets, and smartphones, with 92% of teens going online daily. Internet-based health programs that work across smartphones, tablets, and computers have the greatest potential for reach with diverse teens. We hope that this program will increase the options that youth have when they are looking for accurate health information.

**Do you really think an online program will significantly improve my child's health?**

There has been a lot of compelling research showing how effective online interventions can be at improving health behaviors. In our previous studies, many programs have resulted in improvements that are comparable to interventions delivered by people.

**Will [study name] interfere with my child's schoolwork?**

[study name] is broken down into short sections that do not have to be completed at once, so participants can do them when they have time.

**Is [study name] trying to replace the health education my child is already receiving?**

[study name] is not meant to replace participants' health education, but rather supplement it. We understand that there is often not enough time for schools to cover all health-related topics, and we hope that [study name] can fill some of those gaps.

**I have a question that's not on your website. Who do I contact with additional questions?**

Contact the [study name] team at [institute name]. You can email us at [study email] or call us at [study phone number].

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