

# Ethical Risks and Remedies for Recruiting and Obtaining Consent in Adolescent Risk Research Involving Sexual and Gender Minority Youth (SGMY)

## PRIM&R Didactic Session E6

Celia B. Fisher, Ph.D.

Director, Center for Ethics Education

Marie Ward Doty University Chair in Ethics

Professor of Psychology

Director, NIDA funded HIV/Drug Abuse Prevention Research Ethics Institute

[Fisher@fordham.edu](mailto:Fisher@fordham.edu)

November 16, 2016



# Disclosure: Celia B. Fisher

---

*I have no relevant personal/professional/financial relationship(s) with respect to this educational activity*

# Celia B. Fisher, Ph.D.

Marie Ward Doty University Chair in Ethics, Fordham University



Director of the *Center for Ethics Education* and *NIDA funded HIV/Drug Abuse Research Ethics Training Institute*, Dr. Fisher's federally funded research and over 200 publications have championed the rights and welfare of vulnerable research participants including sexual, gender and ethnic minority children and adults, pediatric cancer patients and adults with intellectual disabilities.

# Learning Objectives

---

- **How to distinguish social vulnerability from research vulnerability in ways that minimize over or under-estimation of harm in adolescent risk research involving SGMY**
- **Apply empirical data on SGMY's attitudes toward the risks of being “outed” and their experiences with sexual health care to inform IRB decisions regarding waiver of guardian permission.**
- **Evaluate the ethically responsible design and implementation of recruitment, data collection and strategies for online adolescent health risk research and cognitive-behavioral RCTs.**

# Topics to be covered

---

- What we know about SGMY identity and vulnerabilities
- Case 1: In-person questionnaires on factors influencing LGBT mental health
- Case 2: Online survey of sexual health care disparities and attitudes toward participation in HIV prevention research
- Case 3: RCT with wait list control involving non-clinical SGMY to reduce depressive, anxiety, and co-occurring behavioral risks

# Sexual and Gender Minority Youth (SGMY) Terminology

---

- Sexual orientation is not the same as gender identity
- Sexual orientation (designations such as lesbian, gay, bisexual) refer to sexual attractions/partners
- Gender (designations such as transgender, gender non-conforming and cisgender) refer to gender identities
- Across gender identity youth are diverse with respect to sexual orientation.

# Who are Transgender Youth?

---

## Transgender male – female (MTF)

- Assigned male at birth and identify as female

## Transgender Female – male (FTM)

- Assigned male at birth and identify as female

## Transitioning medical care for MTF and FTM

- Some have taken pubertal hormone blockers (PHB) to delay puberty to allow time to make psychological, social and medical transition decisions
- 
- Use of hormone replacement therapy (HRT) to transition to secondary sexual characteristics consistent with their gender identity increases with age
- Majority will not have had gender re-assignment surgery (GRS)

# Who are Gender Non-Conforming (GNC) and Cisgender Youth (CI)?

---

## Gender Non-Conforming Males and Females

- Assigned male or female at birth and identify as bi-gender, gender fluid etc.
- Majority do not take hormone treatments and do not express interest in re-assignment surgery

## Cisgender males and females

- Gender identity consistent with sex assigned at birth



# Case 1: Community-Based Mental Health Survey Study

---

**“Minority stress and mechanisms of risk of depression and suicidality among SGMY”**

# SGMY Mental Health Disparities: What we Know

---

- Family rejection (punishment, homelessness, lack of acceptance)
- Societal stigma
- Peer bullying and physical victimization



- LGBTQ youth have higher levels of depression and suicidal ideation
- Internalized homophobia

# Case 1: “Minority stress and factors mediating depression and suicidality among SGMY”

- **Purpose:** Test hypothesis that relationship between “coming out”, LGBT victimization and depression & suicidal ideation is mediated by perceived burdensomeness and thwarted belongingness
- **Participants:** LGBT youth 15 – 21 years: Majority non-Hispanic White and African American who identify as a sexual or gender minority.
- **Recruitment:** Through community centers or college LGBT organizations
- **Cash Incentive:** \$20
- **Procedures:** Individual or group paper and pencil assessments conducted in private rooms at centers or on campus

# Case 1: Procedures and Measures

- **Background:** Sex at birth, sexual orientation label, gender identity
- **LGBT Coming Out Stress:** e.g. *when you told your parents for the first time you were LGBT 0 = no stress and 4 = extremely stressful*
- **LGBT Victimization Scale:** “Frequency of verbal, physical, and sexual harassment because you were LGBT”
- **Perceived burdensomeness:** e.g. “I think people in my life wish they could be rid of me”
- **Thwarted belongingness:** “These days, I feel disconnected from other people”

# Case 1: Reducing Research Vulnerability

---

As an IRB member what human subject protection questions would you raise when reviewing this case?

- What are the potential research benefits to participants and how can they be maximized?
- What are the potential research risks to participants and how can they be minimized?

# Case 1: Reducing Research Vulnerability

---

- Are survey questions minimal risk according to §46.102i?

*“The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of **routine physical or psychological examinations or tests.**”*

# Case 1: Reducing Research Vulnerability

---

- Does recruitment and testing environment enhance or diminish protections?
- How can one insure incentives are fair and non-coercive?
- What type of referral and disclosure policies are appropriate?

# Case 1: Reducing Research Vulnerability

---

- Is waiver of guardian permission for 15 – 17 year olds in this study permitted under §46.116 (referenced in §46.408)
  1. No more than minimal risk;
  2. Waiver does not adversely affect rights and welfare;
  3. Research could not be practicably carried out;
  4. Whenever appropriate additional pertinent information
- If so, what alternative procedures protect youth rights and welfare?



# Case 2: Online Sexual Health Survey

---

- Case 2: “Online study of sexual health discrimination and attitudes toward participation in HIV biomedical prevention studies among high risk SGMY”

# Sexual Risk: What we know

---

## Cisgender males

- Cisgender males who have sex with biological males (MSM) are at highest HIV/STI risk
- Age of first sexual encounter with a same sex partner is shortly after the onset of puberty (13 – 14 years)

## Transgender male – female (MTF)

- Most youth ages 14 – 21 will not have had gender re-assignment surgery so retain male genital anatomy
- Many have sex with biological males thus are at same high levels of HIV/STI risk as cisgender MSM

# HIV Preventive Interventions: What we know

---

- Consistent and appropriate condom use is an effective protection against HIV: *However it is inconsistently used among MSM*
- Pre-exposure prophylaxis (PrEP) medication is a low risk highly effective preventive treatment against HIV transmission
- In pill form, PrEP must be taken everyday: *However daily adherence is a problem among MSM*
- PrEP injections every 1 - 3 months has been found to be more effective than pills among some 18 – 21 year old MSM

# SGMY Health Services Inequities: What we know

---

Majority do not discuss sexual orientation or gender identity with a health care provider (HCP)

- Fearful MCP will not be accepting
- Fearful MCP will tell parents
- Majority HCPs assume youth is “straight”

Gender minority adults report avoiding or delaying health care out of experience with or fear of HCP stigmatization and discrimination

# SGMY Health Services Inequities: What we know

---

- Most HCPs do not bring up the topic of sexual orientation or gender identity.
- When sexual orientation or gender identity is discussed youth do not find the HCP information helpful for relevant HIV/STI protection
- When gender identity is discussed youth the HCP rarely mentions HRT benefits or risks

# Case 2: Research Design

---

- **Purpose:** To examine the relationship between MSMY sexual healthcare disparities, sexual health risk behaviors, and attitudes toward participation in an HIV prevention study comparing PrEP pills to injections.
- **Participants.** Sexually active YMSM ages 14 – 17 years
- **Compensation:** \$20 Amazon online gift card

# Case 2: Questionnaire Items

---

- **Sexual Behavior and HIV Risk:** Sexual partners use of condoms, sexual negotiation skills; concerns regarding HIV risk
- **Family and Peer Acceptance:** Questions on “outness”; LGBT peer harassment scale; Parental acceptance of LGBT identity, sexual activity, and sexual activity with males
- **Health Care Discrimination and Stress:** Positive and negative experiences with health care providers
- **Participation in HIV Prevention RCT:** Perceived participation risks and benefits following explanation of an RCT assessing PrEP pills versus injections.

# Case 2: Reducing Research Vulnerability

---

- Are survey questions minimal risk?
- How can risk be minimized and benefits maximized?
- All information throughout screener, consent and questionnaire written in **LGBT affirming language** (i.e. “While all sexually active teens can be at risk for HIV, some of the unique social challenges faced by LGBT youth may make safe sexual choices more difficult”)
- **Resources:** All respondents provided with list of online resources for LGBT youth



# Case 2: Online Recruitment

---

- Paid advertisements and promoted posts on *Facebook* targeted at youth whose profiles indicated romantic interest in male same sex partners, LGBT issues, organizations, or popular gay or MTF transgender figures.
- *Facebook* does not permit ads to have the term “sex” so ad said “Participate in a study on LGBT health”



# LGBT Health and Development Program

Like Page

Share your opinions to help improve the health of your community!  
Participate & earn \$!



LGBT teens research study

[XXX@University.edu](mailto:XXX@University.edu)

# Case 2: Online Screener

---

- Clicking on the picture will lead to a page providing a brief description of the study as learning about LGBT youth's sexual health experiences and attitudes.
- Interested youth directed to a link and told that they would fill out a brief set of questions to see if they qualified for the study. All responses to the screener anonymous and do not require names or identifying information.
- Screening questions include: Age, geographic region, race/ethnicity, sex assigned at birth, gender identification, and number of lifetime sexual partners who were biological males, number who were biological females.
- Youth who did not qualify thanked for their participation and given links to LGBT online resources and opportunity to include an email address if they wanted to be contacted for other studies.

# Case 2: Reducing Research Vulnerability

---

- Does the online advertising and screener adequately protect the rights and welfare of GSMY youth?

# Validity Challenges and Remedies for Online Research

---

- Age eligibility (phone interview; online multiple questions in different formats-age, DOB)
- Internet Protocol (IP) and response bots (need to monitor time frame of multiply generated surveys, unrealistic time lapse for responses)
- Easily generated multiple email addresses (need to look at IP addresses, similarities among email names, repetitive response bias)
- Require email address *and* text message with unique randomly generated ID and monitor text phone numbers

# Case 2: Enhancing Validity and Protecting Privacy

---

- Qualifying Youth given unique identification number and instructed to text the ID # and their email address to a secure text message account created for the study
- ID number checked against the completed screener
- Research team monitors ID numbers, text message numbers and emails to ensure against duplication
- Participants emailed link to Informed consent and survey
- Participants who have questions before and after the survey can email or text the research team.

# Case 1: Reducing Research Vulnerability

---

Has the investigator successfully balanced privacy protections and scientific validity?

# Case 2: Informed Consent Page

- **Purpose of study:** To better understand the sexual health care experiences of YMSM and their attitudes toward the risks and benefits of participating in an HIV prevention research study.
- **Nature of questions:** sexual behaviors, peer and family acceptance; experience with healthcare providers, opinions about HIV research
- **Voluntariness:** All items have a “do not wish to answer” option; an terminate session any time.
- **Compensation:** Online gift card; All questions must be answered; Upon completion immediately linked to email to project director in which they provide email address to send gift card #
- **Confidentiality:** No names are collected; responses are not linked to internet protocol, email address for compensation or other online identifiers; data not collected from terminated sessions. *Reminders on how to protect privacy on computers and mobile phones*
- **Consent Quiz.** Brief consent understanding interactive quiz



# Case 2: Reducing Research Vulnerability

---

As an IRB member what human subject protection questions regarding informed consent would you raise when reviewing this case?

Is waiver of guardian permission appropriate in this case?

If so, have appropriate additional protections been provided?

# Case 3: Social-Behavioral RCT Involving SGMY

---

- “Affirmative Cognitive-Behavioral Therapy for SGMY: A Randomized Trial of the Minority Stress Approach”

# Case 3: Research Design

**Purpose:** To test efficacy of a cognitive-behavioral treatment based on the minority stress model to reduce depression, anxiety and co-occurring health risks (i.e. alcohol use, condomless sex)

**Recruitment:** Social media and sexual networking websites and mobile applications, college campuses and counseling centers which provided a phone number for a brief screening interview.

## **Participants:**

- Sexually active SGMY 18 – 21 years:
- HIV negative; engaging in HIV risk behavior (at least one instance of condomless sex with a casual partner or a partner known to be HIV positive or status unknown);
- Experiencing symptoms of depression and/or anxiety in past 90 days (4 – item BSI);
- Not currently receiving mental health services.

# Case 3: Reducing Research Vulnerability

---

As an IRB member what human subjects protection questions regarding recruitment and screening would you raise when reviewing this case?

What are the risks and benefits involved in the sites selected for recruitment for YMSM?

Are inclusion criteria appropriate? Should there be mental health relevant exclusion criteria?

What recommendations would you make to enhance protections for excluded individuals?

# Case 3: Random Assignment to Conditions

---

- **Onsite informed consent:** Following an in-person assessment to confirm eligibility
- **Clinically valid measures:** Substance use disorders, depression, anxiety severity, sexual compulsiveness, safer sex self-efficacy at baseline, 3 months, 6 months
- **Stratified random assignment:** to treatment vs. 3-month waitlist based on depression, anxiety, both.
- **First treatment** occurred immediately the screening visit and weekly for 3 months.

# Case 3: Treatment Protocol

---

- **Individual treatment:** Focused on enhancing emotion regulation, reducing maladaptive cognitive and behavioral patterns, improving motivation and self-efficacy for behavior change.
- **Therapists:** Treatment conducted by advanced clinical psychology doctoral students supervised weekly
- **Treatment fidelity:** All treatments video recorded

# Case 3: Reducing Research Vulnerability

---

As an IRB member what human subjects protection questions regarding the treatment protocol?

What procedures would you recommend to protect Ss in the treatment group whose mental health is deteriorating during the 3 months?

What protections would you recommend to protect Ss in the waitlist group whose assessments indicated significant mental health deteriorating at 3 months?

# Questions?

**PRIMER's**  
**2016 Advancing Ethical  
Research Conference**  
November 13-16 • Anaheim, CA





**Visit our Ethics Center and our HIV/Drug Abuse Research Ethics Training Institute**

**[www.FordhamEthics.org](http://www.FordhamEthics.org) and  
[www.Fordham.edu/EthicsInstitute](http://www.Fordham.edu/EthicsInstitute)**

**Thank you!!**

**PRIMER's**  
**2016 Advancing Ethical  
Research Conference**  
November 13-16 • Anaheim, CA



# Acknowledgements and References

- **Funding:** National Institute of Minority Health Disparities of the National Institutes of Health under award number R01MD009561 (PIs C. B. Fisher & B. Mustanski).

## References

- Arbeit, M. R., Fisher, C. B. Macapagal, K. & Mustanski, M. (2016) Bisexual invisibility and the sexual health needs of adolescent girls. *LGBT Health*, 3(5): 342-349. doi:10.1089/lgbt.2016.0035.
- Baams, Laura; Grossman, Arnold H.; Russell, Stephen T. (2015) Minority stress and mechanisms of risk of depression and suicidal ideation among lesbian, gay and bisexual youth. *Developmental Psychology*. Vol. 51 Issue 5, p699-696. 9p. DOI: 10.1037/a0038994.
- Fisher, C. B. & Mustanski, B. (2014). Reducing health disparities and enhancing the responsible conduct of research involving LGBT youth. *Hastings Center Report*, 5, 28-31. PMID 25231783 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4617525>
- Fisher, C. B., Arbeit, M. Dumont, M., Macapagal, & Mustanski, B. (2016). Self-consent for HIV prevention research involving sexual and gender minority youth: Reducing barriers through evidence-based ethics. *Journal of Research on Human Research Ethics*. 11, 3-14. first published online 3.7.16 DOI: 10.1177/1556264616633963
- Harcourt J. (Ed). (2006). Current issues in lesbian, gay, bisexual and transgender health. *Journal of Homosexuality*, 51, Number 1. Special Issues
- Macapagal, K., Coventry, R., Arbeit, M., **Fisher**, C. B. & Mustanski, B. (2016). “I won’t out myself just to do a survey”: Sexual and gender minority adolescent’s perspectives on the risks and benefits of sex research. *Archives of Sexual Behavior*. Online July 28, 2016 DOI 10.1007/s10508-016-0784-5