Ethics & Social Justice in Sexual Health Research Involving Sexual and Gender Minority Youth

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The Adolescent Research Ethics Dilemma

- Respect youth's developing autonomy and protect them from research harms arising from age vulnerabilities
- Avoid over-protective policies that deprive them of participation in research essential to improving age appropriate health services
- Critically evaluate whether implicit systemic biases are placing an undue research burden on socially marginalized youth

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Vulnerability: The Definitional Problem

- CFR 46.111a(3) and 46.111b: Vulnerable populations (i.e. children) require additional safeguards to ensure "selection of subjects is equitable" and not subject to "coercion"
  - What safeguards are required above those stipulated in Subpart D?
  - To what extent do these "vulnerabilities" persist into adolescence

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Adolescence ≠ Research Vulnerability

Failure to distinguish between vulnerabilities in adolescents' lives & research vulnerabilities can lead to under-or over estimation of research risks

(Fisher, Brunquell et al., 2013)

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Goodness-of-Fit Ethics (GFE)

(Fisher & Goodman, 2009; Masty & Fisher, 2008)

- The burden of identifying research vulnerability does not simply lie in the fact that a participant is an adolescent
- Failure to recognize youth strengths can be as harmful as failure to recognize youth frailties
- Research vulnerability occurs when human subjects protections are not fitted to youth developmental strengths as well as needs
- *Empirical data is critical to identifying youth assets and susceptibility to harm*

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Waiver of Guardian Permission for HIV Prevention Research Involving SGMY

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The Ethical Challenge

- CDC recommends pre-exposure prophylaxis (PrEP) for high-risk populations to prevent HIV infection
- YMSM, bisexual women and transgender youth 13 - 24 comprise majority of new HIV diagnoses
- There are currently no evidenced-based HIV prevention programs for SGMY under 18 years

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Guardian Consent Challenge

- Perceived youth consent vulnerability

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- Guardian permission

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- Low recruitment

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- Smaller unrepresentative samples skewing findings

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- Lack of evidence-based HIV prevention programs for vulnerable youth

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Justice: Fair Access

- **Without youth involvement in research, evidence-based, developmentally appropriate PrEP interventions will continue to be unavailable to SGMY**

Goodness of fit questions

- When is guardian waiver ethically justified?
- Is adolescent self-consent an adequate protection?

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Guardian Permission: Are SGMY "Children" under Federal Regulations?

- OHRP classifies minors as "adults" if they have attained their state defined legal age for consent to treatment or procedures involved in a research study §45CFR 46.402a
- Most state mature minor laws permit youth independent access to HIV testing and treatment (Culp & Cauci, 2013)
- Some, like NYS, permit youth independent access to PrEP if a physician determines their consent competence.

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Waiver of Guardian Consent Permitted Under §46.408 Subpart D

- "When guardian permission is not a reasonable requirement to protect the subjects (e.g. neglected or abused children)"
- An appropriate substitute mechanism to protect the participant is provided
- Not inconsistent with law

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The Definitional Problem

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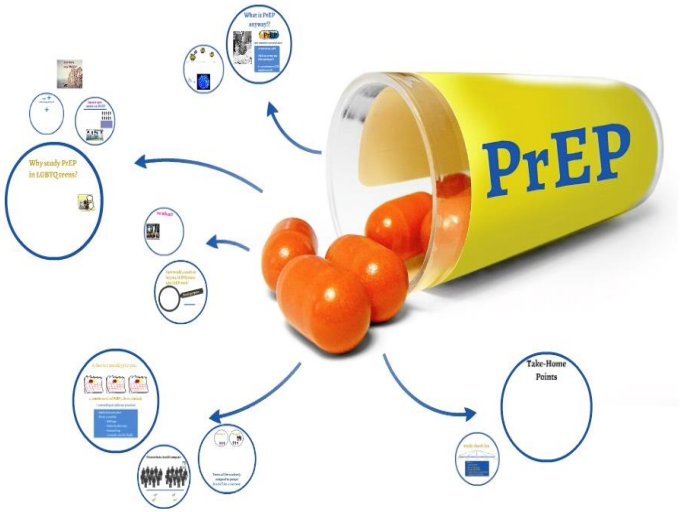
Guardian Waiver & Youth Self-Consent

Participants: 74 sexually active 14 – 17 yr old SGMY

Method: viewed animated descriptions of a PrEP HIV prevention study and responded to web-based survey questions and asynchronous focus group discussions



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Reference: Fisher, C. B. , Arbeit, M., Dumont, M., Macapagal, K., & Mustanski, B. (2016). Self-consent for HIV prevention research involving sexual and gender minority youth: Reducing barriers through evidence-based ethics. *Journal of Empirical Research on Human Research Ethics, 11,* first published online 3.7.16 DOI: 10.1177/1556264616633963

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PrEP Adherence Study Description

HIV Basics

- What is HIV
- How is it transmitted
- What is it like to get an HIV test

PrEP Basics

- How PrEP works to prevent HIV
- Does not protect against STIs
- Side effects: nausea, diarrhea, rare bone weakness
- Pill must be taken daily

Purpose of Study

- To test whether text messaging improves PrEP adherence for LGBTY

Random assignment: "like a coin toss"

- One group would get daily text message reminder to take pill

Inclusion Requirements

- Must be HIV negative
- At-risk sexual behavior
- Return to study appointment every 3 months for HIV testing and counseling

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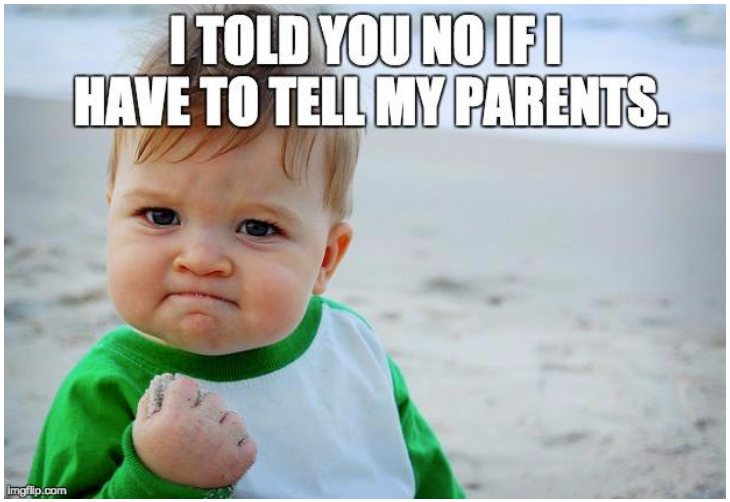
Would you Participate in a PrEP Study if Guardian Permission is Required?

61% of youth not "out" and 21% who were out to parents would refuse to participate if GP required



GP would "out me to parents"

"I'm out, but parents unsupportive"

"They would punish me or kick me out of house"

Parents would ask questions about sex

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Is Guardian Permission a "Reasonable Protection"?

- Research has found f**amily rejection and victimization** are significant risk factors for depression, suicidal ideation, and sexual risk behavior among SGMY (e.g. Baam et al, 2015)
- Over half the youth in our study feared punishment or family rejection if their SGMY status was revealed through GP requirements
- **For these youth GP is not a "reasonable protection"**

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CAN SGMY MAKE A "REASONED" PARTICIPATION DECISION

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Random Assignment

- *"I feel like being randomly put into groups is the fairest way to decide who gets the reminders and who doesn't"*
- *"Allowing us to choose our own group could in some way make the information irrelevant"*
- *"Feel a bit like a dog following orders"*
- *"They should do what's best for me"*

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Research Benefits

Direct Benefits

- *"Good to know my HIV status"* (60% of youth more likely to get tested in research then with their regular physician)
- "*Having protection against HIV on a daily basis*"
- "*Help me focus more on the possibility of getting HIV and in turn make me practice better sex*"

Indirect Benefits

- *"Because it would not only benefit myself, but possibly thousands of LGBTQ teens across the country in getting the help they need to prevent HIV"*

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Side Effects

- “It’s important to take into account risks when starting any medication”
- Whether I could “tolerate side effects”
- “My only concern would be the pill affecting my bones, but in the video they said there would be check-ups every couple of months so I would always make sure to ask how my bones were doing”
- Risks are “nothing compared to living with HIV”

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Privacy Risks

I'd "fear being outed [if] someone saw the text or pills"

"No one goes through my phone aside from my friends, and those that do know that I am not straight"

"I usually delete my texts"

"If I was that worried about privacy, I wouldn't be a part of that kind of study

Appreciation of Personal HIV Risk

- *"I would think about where it would fit in my lifestyle and if I needed it"*
- *"How sexually active I've been recently and the likelihood of me becoming active"*
- *"I'd weigh risks and benefits "both personal and for others"*

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Adherence Challenges

- *"I take birth control and Zoloft in the mornings so adding PrEP [is] easy to remember*

- *"I feel the commitment of having to take a pill everyday would be hard for me because I am kinda forgetful"*

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Implications for Guardian Permission Waivers for HIV Prevention Research Involving SGMY

- IRBs should first consider whether adolescents recruited for HIV prevention research are “children” under Subpart D
- If “children” there is sufficient empirical data suggesting that for a significant percentage of SGMY guardian permission is not a “reasonable protection”
- In addition, the data reported and prior research on youth consent abilities indicate SGMY can make a reasoned consent decision when investigators take an age appropriate educative approach

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GFE: Enhancing Youth Self-Consent

When Guardian Permission is Waived

- Investigators should ensure that consent is fitted to developmental, informational, health and social needs of participants
- IC can be enhanced through fact sheets, respectful and caring delivery, welcoming questions, giving time to decide: "I would like to see past results and proof"
- Consent "quizzes" should be viewed as educational opportunities not simply a means of exclusion
- Opportunities for youth to share decision-making with parent or other social supports should be clear
- A participant advocate can be available to provide appropriate substitute protections *"an unbiased opinion"*

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Justice: Fair Access

- For many SGMY guardian permission is not a protection against research risks *and* a significant barrier to participation in HIV prevention research
- Adolescence ≠ Research Vulnerability *if informed consent is tailored to their abilities and support needs*
- As IRBs seek to protect the rights and welfare of SGMY – we need to re-conceptualize access to HIV prevention trials as a critical health care right that requires protections against research exclusion.
- Without research participation, evidence-based, developmentally appropriate HIV interventions will continue to be unavailable to SGMY thus sustaining sexual health disparities in this population

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Thank You

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