Self-Consent for HIV Prevention 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
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
Adolescence ≠ Research Vulnerability

Failure to distinguish between vulnerabilities in adolescents’ lives & research vulnerabilities can lead to under-or over estimation of research risks.
Goodness-of-Fit Ethics (GFE)

- The burden of identifying research vulnerability does not simply lie in the fact that a Ss 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 research ethics relevant youth research assets and susceptibility to harm*
Importance of Participant “Expertise”

Science Establishment

- Ethical principles
- Regulations
- IRB & PI experience
- Traditional ethical protections

Participants

- Moral values
- Trust in the scientific enterprise
- Implementation in real world contexts
- How ethical decisions will affect their rights and welfare
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 LGBTY
- Perceived youth vulnerability ➔ guardian permission ➔ low recruitment
Justice: Fair Access

- Without youth involvement in research, PrEP will continue to be unavailable to LGBTY and prescribed off-label

Goodness of fit questions
- When is guardian waiver ethically justified?
- Is adolescent self-consent an adequate protection?
Guardian Permission: Are LGBTY “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)
HOW ARE WE STILL SO CONFUSED ABOUT MATURE MINOR LAWS?!
Waiver of Guardian Consent Under §46.408 Subpart D

Minimal Risk Research (§46.404)
“Research could not be practicably carried out”

Greater than Minimal Risk §46.405c, §46.405c, §46.406d, §46.407iii

“When guardian permission is not a reasonable requirement to protect the subjects (e.g. neglected or abused children)”
The Definitional Problem

SO YOU'RE TELLING ME

YOU'LL ONLY WAIVE GUARDIAN PERMISSION IF I WAS ABUSED?...
**Participants:** 74 sexually active 14 – 17 yr old LGBTY

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

Who would refuse?
61% of youth not “out” to parents;
21% of youth “out” to parents
Reasons for and against GP

**Reasons for GP**

- My parents are supportive of my sexual orientation
- Help with taking care of my health
- Help with informed and voluntary consent
- I can explain and get support

**Reasons against GP**

- 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
Is Guardian Permission “Practicable” or a “Reasonable Protection”?

- LGBTY at high HIV risk who lack parental support would not participate in a PrEP study if guardian permission was required.
- Many fear punishment or family rejection if their LGBT status was revealed through GP requirements.
- For these youth GP is neither “practicable” nor a “reasonable protection”.
IRBs should first consider whether adolescents recruited for HIV prevention research are “children” under Subpart D

If “children” is there evidence indicating the GP is not practicable or a reasonable protection

When GP is waived youth should be given the option of including parents in participation decision

A participant advocate can help provide appropriate substitute protections “an unbiased opinion”

Investigators should develop procedures for youth who test HIV+ that are: Sensitive to risk of “outing” and provide support for sharing diagnosis with parents or referring youth to age and LGBT appropriate HIV services.
CAN LGBTQY MAKE A “REASONED” PARTICIPATION DECISION
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”
Research 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”

• “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”
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”
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”
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”
• LGBTY can make a reasoned consent decision when investigators take an age appropriate educative approach

• Investigators should ensure that consent is fitted to informational, health and social needs of participants

• IC can be enhanced through fact sheets, respectful and caring delivery, welcoming questions, giving time to decide, and involving a youth advocate “I would like to see past results and proof”

• Given insurance and financial limitations, studies should carefully consider approaches to post-experimental access to PrEP “Make it clear at the beginning that it does not continue”