

LEGAL BARRIERS TO ADOLESCENT PARTICIPATION IN RESEARCH ABOUT HIV

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Why We Did this Study

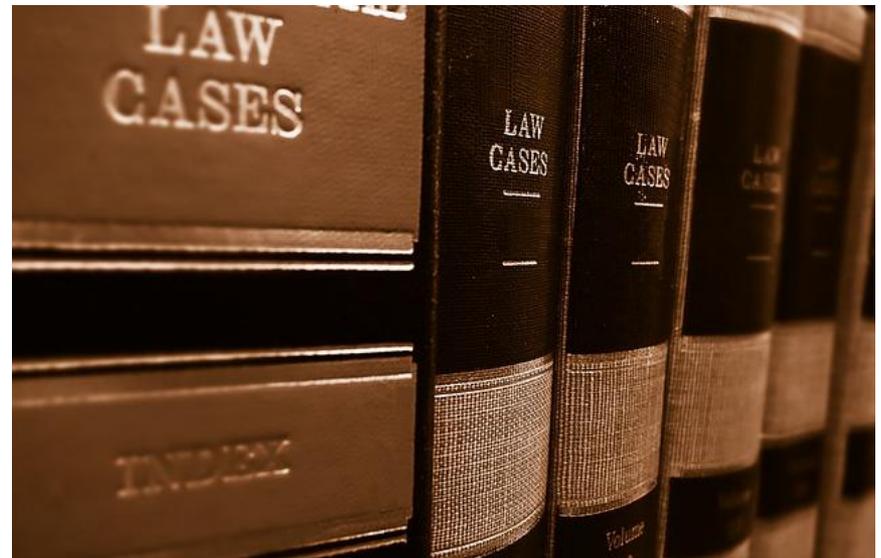
- Research ethics consult service
 - Issue: IRB did not approve NIH funded study to allow adolescent males ages 15-17 to participate in pre-exposure prophylaxis (PrEP) HIV study without parental permission.
 - Question: Is it ethical and legal for at-risk minors to self-consent to participation in HIV prevention clinical trials?

What We Did

Ethical Analysis



Legal Analysis



What We Found

- Ethics: At-risk minors who have the mental capacity to consent should be allowed to consent to participation in HIV prevention clinical trials without parental permission.
- Law: Federal research regulations defer to state law re minor consent.
 - All states and the District of Columbia have recognized the importance of permitting minors to consent to **treatment** for sexually transmitted infections (STI).
 - Thirty-four (at the time of the study) states have statutes authorizing minor consent to HIV testing and treatment (includes Texas), or testing alone.
 - Only 7 states have statutes specifically authorizing minors to consent to preventative services for STIs.

What Our Results Mean and Why this Matters

- Access to PreP and other STI prevention services is not explicitly prohibited by Texas state law if treatment is defined to include prevention.
- Confusion on statutory interpretation is hindering important research to identify interventions to decrease new HIV infection in at-risk youth.
- IRBs can adopt policies in line with broad but reasonable interpretation of state law that defines “treatment” as including prevention.

Acknowledgments

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