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.
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