

Ethics Guidance to Advance HIV Research for Pregnant Adolescents

Suzanne Day, PhD
Anne Drapkin Lyerly, MD

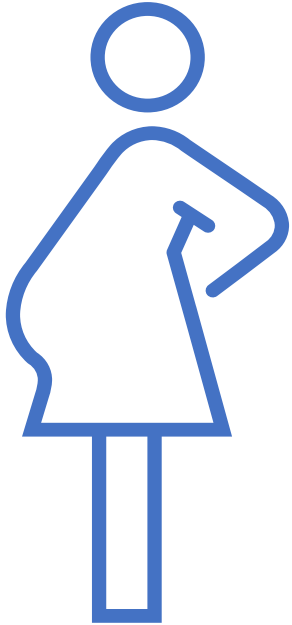
The Future of HIV Prevention Clinical Trials Summit
June 12, 2025



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL



The Issue: Exclusion of Pregnant Adolescents



- Adolescents face **disproportionate burden** of reproductive health issues¹ and **greater risk** of HIV acquisition, vertical transmission, and maternal & fetal morbidity & mortality²
- Despite increasing attention to HIV among adolescents and pregnant adults, **pregnant adolescents are often excluded** from biomedical HIV research
- As a result, there is a **lack of evidence** to inform prevention and treatment strategies

¹ WHO. *Adolescent and Young Adult Health, 2023*; ² Toska et al., *Glob Public Health*. 2020;15(11):1655-1673.

The Harms of Exclusion



Photo: Muhammad Daudy, unsplash.com

- Due to physiological and social differences,³ evidence gaps may lead to **inappropriate dosing, delivery, selection of drugs** for pregnant adolescents.
- Due to drug approval processes, pregnant adolescents may **lack access to drugs** approved for adult use.
- Pregnant adolescents may **lack access to trials** with the prospect of benefit (or be harmed when pregnancy requires them to discontinue a trial)

³ Stranix-Chibanda et al., *Clin Infect Dis*. 2021;73(7):e1893-e1900.

The Challenge: Barriers to Inclusion



- Regulatory/legal constraints
- Protectionism/risk assessment
- Myths & misperceptions about adolescents/pregnancy
- Ethical challenges

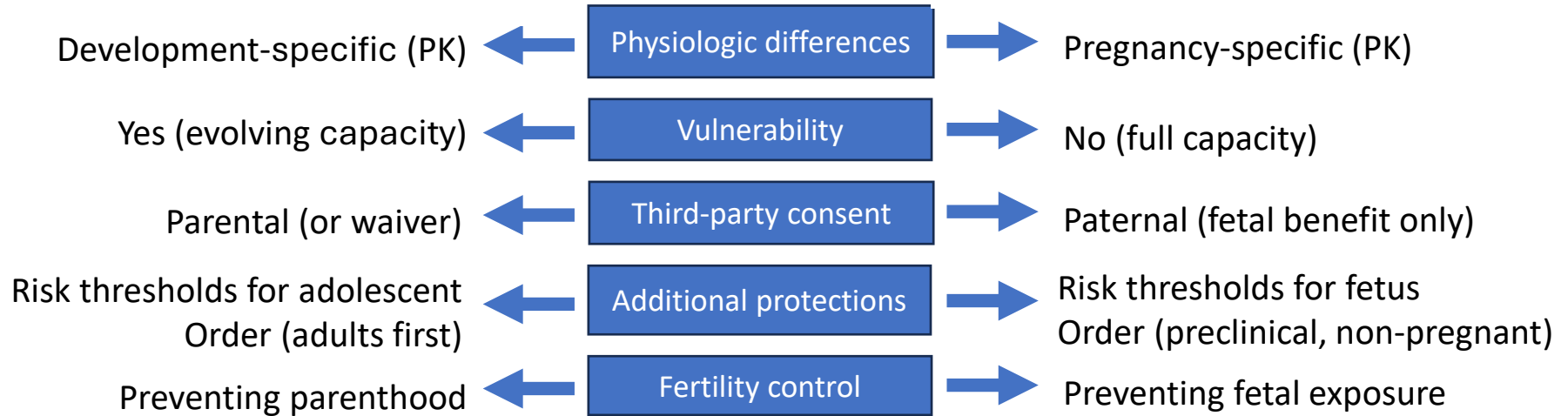
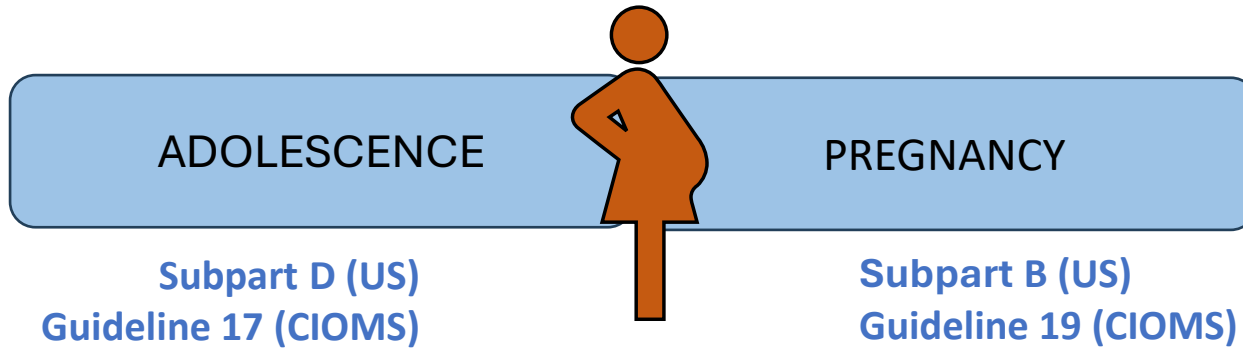
Guidance is needed to navigate these barriers for ethical inclusion of pregnant adolescents.

Ethical Tension



Ethical imperative
to conduct research with
pregnant adolescents

Ethical complexities
of conducting research with
pregnant adolescents



Solution: The PREPARE Project



**Engagement/
Empirical Research**



**Conceptual-Analytic
Research**



**Ethics Guidance
Development**

PHASES Ethics Guidance, 2020

PHASES
PREGNANCY + HIV/AIDS
SEEKING EQUITABLE STUDY

Ending the evidence gap
for pregnant women
around HIV & co-infections:

A CALL TO ACTION

The PHASES Working Group
Pregnancy and HIV/AIDS: Seeking Equitable Study

issued July 2020

- 12 recommendations, four themes, to advance the inclusion of pregnant adults in HIV/co-infections research
- PDF available online (scan for website)



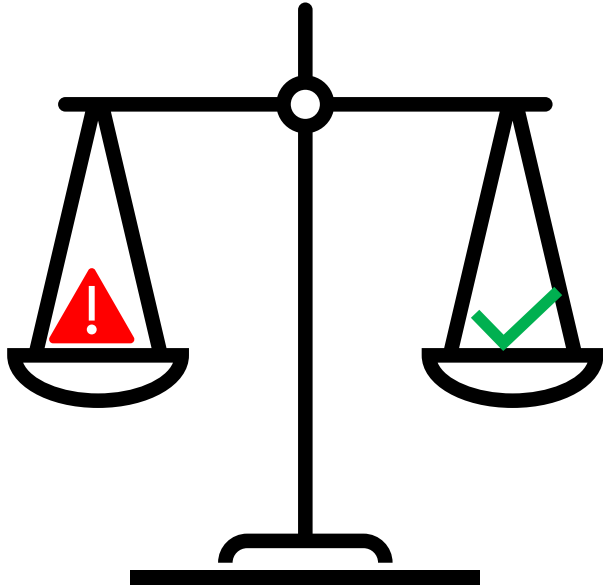
PHASES
PREGNANCY + HIV/AIDS
SEEKING EQUITABLE STUDY

PREPARE Empirical Research



- Three sites: USA, Malawi, Botswana
- 120 interviews with ever-pregnant adolescents living with & at-risk of HIV
- 33 interviews with key communities of interest (investigators, bioethicists, policy-makers, and others)
- 2 Youth Advisory Boards (Botswana & Malawi)

Empirical findings informing ethics guidance



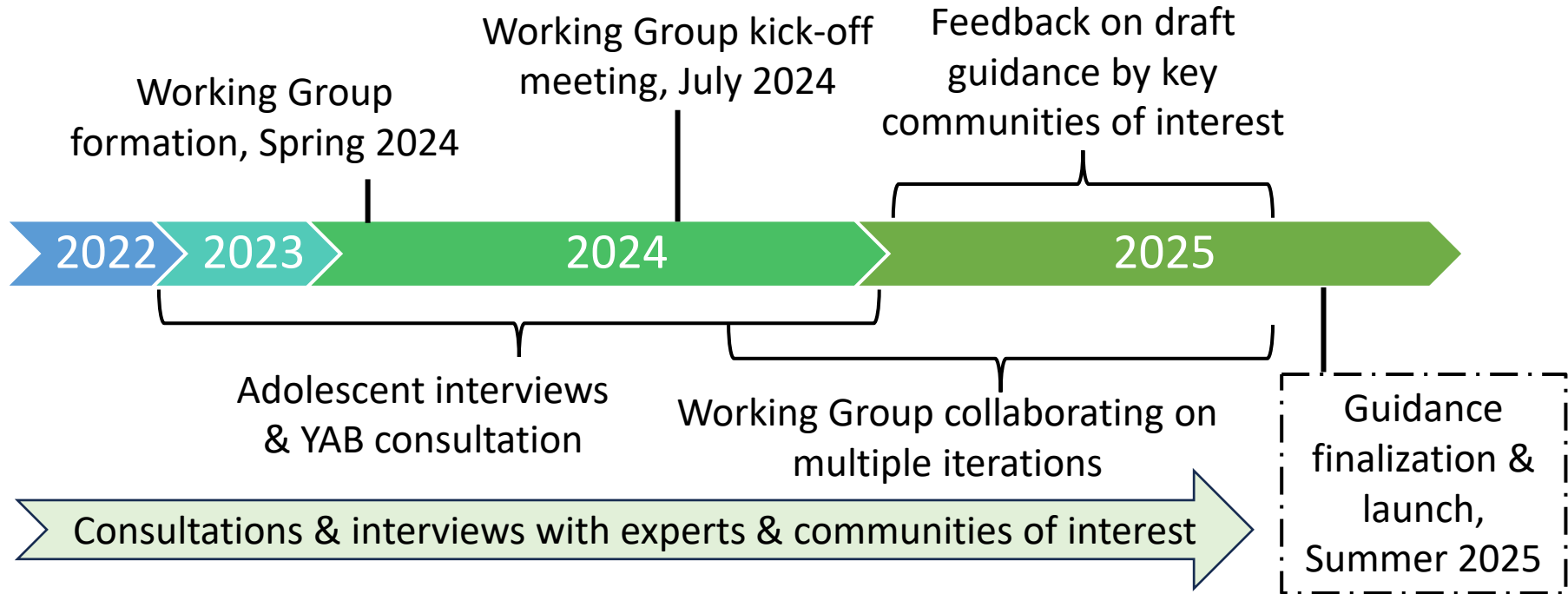
- How adolescents assess risks & benefits of participation during pregnancy.
- How existing rules (e.g., consent, contraceptives) impact participation decisions.
- Recommendations of key experts for aligning ethical guidance with adolescent capacities and the need for evidence.

The PREPARE Working Group

- 44 members
- Includes researchers, ethicists, policy & legal experts, community-based organizations, ethics review board members
- Based in/working in US & African countries

Goal: To develop concrete and actionable guidance for advancing timely, ethically responsible HIV/co-infections research with pregnant adolescents.

Ethics Guidance Development Process



PREPARE Ethics Guidance, 2025

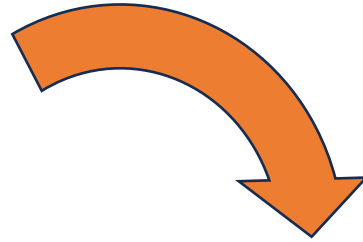
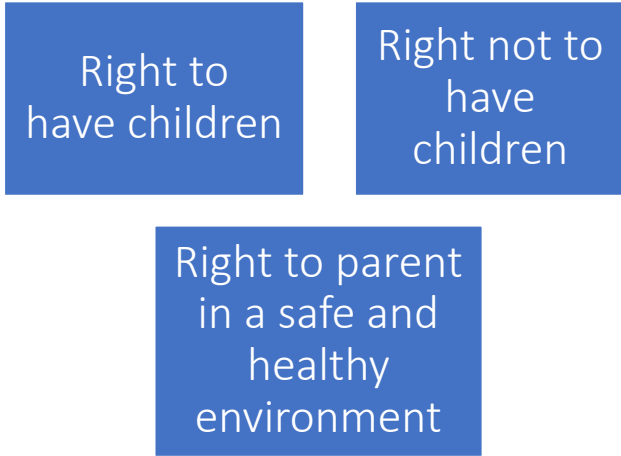
(Cover TBD)



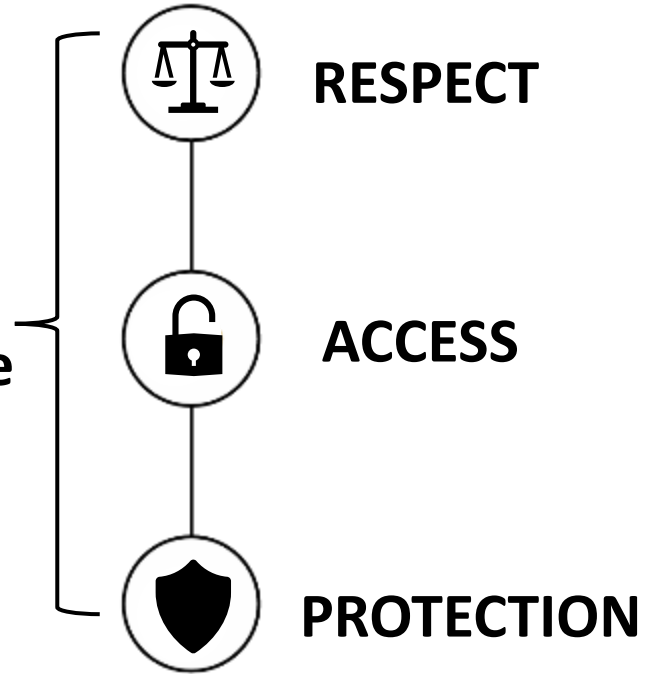
- Building on the foundation of PHASES
- 9 recommendations across three themes, with practical implementation strategies
- Iteratively developed by PREPARE Working Group, informed by empirical & conceptual research

A framework informed by reproductive justice

Reproductive Justice⁴



PREPARE Ethics Guidance Framework



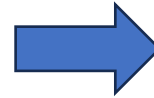
⁴ Ross & Solinger. *Reproductive Justice: An Introduction*. U. California Press, 2017.

Underlying conceptual shifts



RESPECT:

Vulnerable population

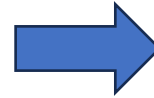


Complex population



ACCESS:

Presumptive exclusion

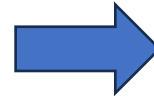


Fair inclusion



PROTECTION:

**Protection from
research**



**Protection through
research**

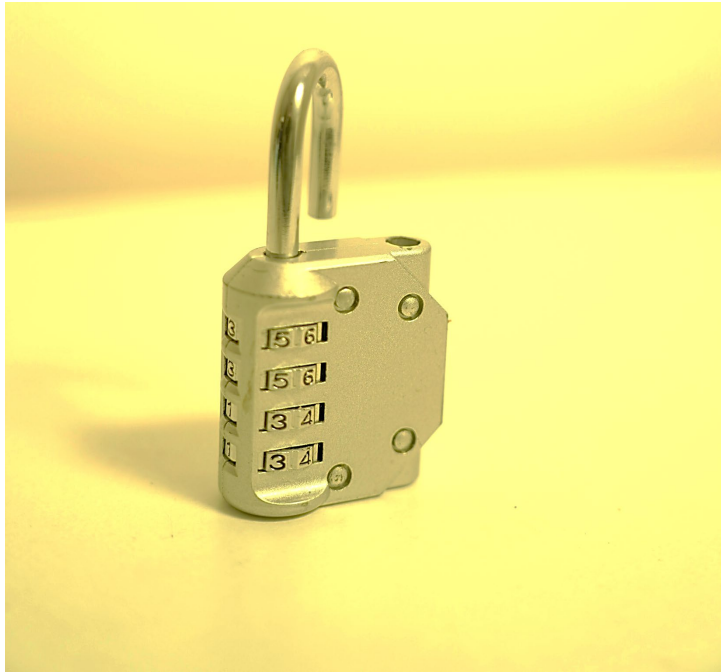
Recognize and Support Pregnant Adolescents' Right to Respect



Photo: Eyitayo Adekoya, [unsplash.com](https://unsplash.com/photos/Eyitayo-Adekoya)

1. Center adolescents in research participation decisions
2. Accommodate full range of reproductive preferences
3. Engage adolescents as partners across all study stages

Promote Access for Pregnant Adolescents



4. Presume inclusion of adolescents in adult pregnancy trials
5. Expand considerations beyond age cut-offs
6. Ensure post-study access to interventions by adolescents

Re-envision Protection for Pregnant Adolescents



Photo: Christian Walker, unsplash.com

7. Weigh the harms of exclusion
8. Gather relevant adolescent-specific safety data
9. Creatively address in-study safety concerns



Next Steps for PREPARE

- Continued engagement with PREPARE Working Group
- Finalize & launch Ethics Guidance (IAS 2025 in Kigali, Rwanda)
- Dissemination of Guidance & empirical findings

PREPARE UNC Team at AIDS 2024, Munich



THANK YOU!

**To all participants & collaborators,
Youth Advisory Boards,
The PREPARE Working Group,
& our study team**

Funder: NIH (NIAID 5R01AI108368-08)

Contact Info:

suzanne.day@med.unc.edu



UNC
CENTER FOR
BIOETHICS



PREPARE Website:

