**Priority Goal 1: Advance responsible HIV prevention research in pregnant and lactating people (PLP) using a Reproductive Justice framework.**

Reproductive Justice is the human right to maintain personal bodily autonomy, have children, not have children, and parent children in safe and healthy communities. Developed by a Black women’s collective in 1994, Reproductive Justice can attend to the differences and leadership of African and other Black and Brown women, trans and gender diverse people, and young people within the human rights framework. The PLP ethics review working group emphasizes the importance of access to basic reproductive rights, comprehensive sexual and reproductive health care.

- **Center PLP in all efforts to set and advance a HIV prevention research agenda responsive to their needs.**

**Action Steps:**
- Organizations responsible for setting HIV prevention research priorities, including the World Health Organization (WHO), the United Nations Population Fund (UNFPA), product developers, and researchers, should prioritize engagement with PLP, including ethical consultation and centering in their research agendas.
- Researchers, civil society, and advocates should engage with other stakeholder groups addressing intersecting oppressions to advance the goals of this action plan and develop HIV prevention research responsive to the needs of these marginalized populations.

**Join together with key allies addressing intersecting oppressions and identify and develop shared goals to advance the HIV prevention research agenda responsive to the needs of these marginalized populations.**

**Action Steps:**
- Researchers, civil society, and advocates should engage with other stakeholder groups addressing intersecting oppressions to advance the goals of this action plan and develop HIV prevention research responsive to the needs of these marginalized populations.
- Researchers, civil society, and advocates should engage with other stakeholder groups addressing intersecting oppressions to advance the goals of this action plan and develop HIV prevention research responsive to the needs of these marginalized populations.

*"Without being able to bring in an intersectional approach, without being able to think of all these different distinctions and challenges combined with the changes in the way we engage with community, we wouldn’t be having this conversation quite frankly... there has to be an emphasis on centering blackness in this conversation." — Think tank participant*

**Identify potential challenges to and solutions for advancing equitable clinical research with PLP in restrictive reproductive health policy environments.**

**Action Steps:**
- Researchers, civil society, and advocacy groups should work together to address potential challenges to PLP clinical research, focusing on ensuring that research is conducted with the consent and active participation of PLP individuals.
- Researchers, civil society, and advocates should develop strategies to engage with key stakeholders, including PLP communities, to advance the goals of this action plan and develop HIV prevention research responsive to the needs of these marginalized populations.

**Ensure that contraception requirements for pre-licensure trials are sensitive to actual fetal risk, as set out in the WHO/IMPACT/JAS Call to Action**, and incorporate evidence-based contraceptive counseling when indicated.

**Action Steps:**
- Product developers should remove contraception requirements in pre-licensure trials once non-clinical reproductive health services that promote women’s health and autonomy are available to non-pregnant populations.
- Researchers, civil society, and advocates should work to ensure that clinical research with PLP is conducted with the active participation of PLP individuals, ensuring that research is conducted with the consent and active participation of PLP individuals.

**Priority Goal 2: Engage stakeholders in an early, sustained, and meaningful way in the design and conduct of biomedical HIV prevention trials to the distinctive complexities of research with PLP.**

Early, sustained, and meaningful stakeholder engagement and participatory practices are critical to supporting equitable clinical trial design and conduct. The unique sociocultural, legal, and ethical contexts of HIV prevention research necessitating approaches that are sensitive and attuned to these complexities include:

- **Develop and disseminate good Participatory Practice (GPP) best practices specific to biomedical HIV prevention research with PLP in all their diversities.**

**Action Steps:**
- **AVAC and PHASES** will conduct a workshop on participatory research methods specific to biomedical HIV prevention research with PLP, including the role of community members and advocates in design, implementation, and monitoring.

**I think one of the priority issues is improving literacy around pregnant and breastfeeding populations.**

**Action steps:**
- **AVAC and PHASES** will convene a PLP ethics review working group including influential stakeholders, including PLP community members and advocates, to develop a GPP framework for biomedical HIV prevention research with PLP.

**Priority Goal 3: Develop and harmonize regulatory frameworks and approaches that promote the responsible generation of data specific to PLP for new therapeutics.**

Regulatory frameworks across jurisdictions that are harmonized to protect PLP through research have the potential to be pivotal catalysts for advancing the evidence base. The global distribution of PLP and the varying clinical contexts in which they are likely to be found means that there is a critical need for harmonized guidelines and best practices that provide for the responsible generation of data specific to PLP as a component of a responsible global HIV prevention research portfolio.

**Incentivize and/or require the generation of data specific to PLP for approval of new therapeutics.**

**Action Steps:**
- Advocates should identify and coordinate with key stakeholders to encourage national governments, especially in areas with high HIV burden and/or out-sized global influence, to ensure that regulatory frameworks are inclusive of the needs of PLP.
- Researchers and civil society, with the support of funders and in partnership with other key stakeholders, should advocate for their meaningful engagement in the process.

**Accelerate the ethical inclusion of PLP in research and generate PLP-specific data as early as possible in product development, as set out in the PHASES Guidance** and the USP/GMP/IMPACT/JAS Call to Action framework, through harmonized regulatory approaches.

**Action steps:**
- The National Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), African Medicines Regulatory Harmonisation (ARMH), and other drug regulatory harmonization organizations should be engaged to align regulatory guidelines for the responsible inclusion of PLP in pre-licensure drug development trials.
- Researchers, civil society, and advocates should work together to advance the adoption of harmonized regulatory frameworks by regulatory agencies in Africa that promote the responsible generation of needed data for a historically excluded PLP population.

**Create and disseminate resources to support investigators to develop protocols that facilitate the responsible generation of data specific to PLP in biomedical HIV prevention research.**

**Action Steps:**
- The HIV/AIDS Vaccines Ethics Group (HAVEG, UKZN) will collate the current ethics guidelines for vaccine development and generate PLP-specific data as early as possible in product development.

**Develop and disseminate resources to support REC/IRB members to review protocols that facilitate the responsible generation of data specific to PLP in biomedical HIV prevention research.**

**Action Steps:**
- The HIV/AIDS Vaccines Ethics Group (HAVEG, UKZN) will develop and disseminate resources to support REC/IRB members to review protocols that facilitate the responsible generation of data specific to PLP in biomedical HIV prevention research.

**Develop and disseminate resources to support IRB members to review protocols that facilitate the responsible generation of data specific to PLP in biomedical HIV prevention research.**

**Action Steps:**
- The PLP ethics review working group will consider the implications of current leading ethics guidelines for HIV prevention research with PLP as a component of responsible global HIV prevention research portfolio.
- The HIV/AIDS Vaccines Ethics Group (HAVEG, AVAC/CASPR and PHASES) will convene a PLP ethics review working group including influential stakeholders, including PLP community members and advocates, to develop a GPP framework for biomedical HIV prevention research with PLP.

**Ethics review of protocols is intended to ensure that principles and practices for responsible human participation in biomedical HIV prevention research with PLP in all their diversities are adhered to.**

**Next Steps:**
- Further feedback from think tank participants will be solicited and integrated.
- The portfolio will be brought through think tank participants’ networks and to key allies addressing intersecting oppressions.
- **AVAC** and **PHASES** will engage think tank participants and other stakeholders to implement action steps.

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