



# Zimbabwe Perspective: Pregnant Women as Clinical Trial Participants

**Sithembile Ruzario**

**Senior Research Compliance Officer**

**Medical Research Council of Zimbabwe**

# Introduction

- ▶ Pregnant women deserve more from clinical research than what they are getting.
- ▶ Justice requires a research agenda that adequately addresses the health needs of pregnant women.

# Global Forum in Bioethics of 2016

- ▶ NEC reps attended the 2016 GFBR : Theme was “Ethics of Research in pregnancy”
  - Inclusion of pregnant women in research
  - Cultural norms for consent
  - Community engagement
  - RECs to consider both risks of participation and non-participation
- ▶ Awarded a fellowship to improve ethical practice for research in pregnancy

# **Ethics Guideline for Inclusion of Pregnant Women in Research : Zimbabwe**

- ▶ **Participation in Research by Pregnant Women**
- ▶ **Overcoming Barriers to Include Pregnant in Research**
- ▶ **Ethics Committees**
- ▶ **Potential Individual Benefits and Risks**
- ▶ **Informed Consent**

# MRCZ Annual Health Research Forum

- ▶ Topic on inclusion of pregnant women in CTs
- ▶ Need to find ways of ensuring that we generate data on safety of drugs during pregnancy
- ▶ Change of culture among RECs, researchers OBGYNs, antenatal HCW, funders, drug manufacturers etc.
- ▶ From justifying inclusion to justifying exclusion as a country

## Change in Attitude

- Approved study : Qualitative assessment of acceptability of vaginal ring and oral PrEP during pregnancy and breastfeeding
- REC now requesting strong justification on exclusion of pregnant women, including withdrawal of study product

## Conclusion

- ▶ Pregnant women deserve access to *effective* treatment
- ▶ Pregnant women deserve access to *safe* **treatment**
- ▶ Pregnant women deserve *equitable* *access* to trials carrying the prospect of direct benefit

THANK YOU

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