Pandemic Ethics and Post-Trial Access: A review of National Ethics Committee Guidelines in Tanzania.

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Pandemic Ethics Project in Tanzania

- Ethical approval obtained in March 2024
- Data collection - **ongoing with WP1, WP2 & WP3**

WP 1: Review of grey and scientific literature and social media on PTA

WP 2: Experiences, roles, responsibilities, perceptions, challenges, and expectations of Stakeholders on PTA

WP3: Investigate public perception of PTA on COVID-19 trials

Method:

WP1: Review of National Ethics Guidelines for Clinical Trials and Covid-19

WP2: IDIs with Stakeholders

FGDs with patients/participants of COVID-19

WP3: Survey Questionnaire for REC on PTA

Brief background of the COVID-19 era in Tanzania

Review of National Ethics Guidelines in Tanzania

WP1: Five (5) guidelines reviewed were namely:

1. Ethics for Health Research in Tanzania NIMR, 3rd ed, 2023
2. Reviewing Health Research protocols NIMR, 1st ed 2022
3. *Standard Operating Procedures for NatHREC - NIMR, 3rd ed 2023*
4. National Research Integrity Framework of Tanzania COSTECH, 1st ed, 2020
5. Application to conduct clinical trials in Tanzania. TMDA, 3rd ed 2017

Preliminary findings

- PTA did not feature explicitly in the guidelines
- Provisions for PTA are specified in different sections differently

Commonly termed as:

- Capacity Building,
- Royalties,
- Material Transfer Agreements
- Benefits sharing

WP2. Interviews with stakeholders

Stakeholders perception of the terms

- Post-trial arrangements and post-trial access are perceived differently by different stakeholders.
- Common terms include: - Capacity building
  - Access to investigational products after study completion
- Though inclusive in directives for benefit sharing and capacity building, the guidelines are not explicit about post-trial arrangement or post-trial access.

Importance of PTA

- Stakeholders believed that PTA is important; however, they declared that during the protocol review process and implementation of Clinical Trials, PTA was not emphasized

Recommendation

- Stakeholders call for govt intervention and regional collaboration to enforce PTA issues

Conclusion remarks

WP1:

- Specific guidelines for Post Trials Access both at NIMR and TMDA need to be developed to ensure PTA issues are discussed and followed up

WP2:

- Need for creating awareness among stakeholders on the inclusion of PTA
- Need for govt and regional initiatives towards enforcing PTA issues

Way forward

- Need for regional initiatives to address the PTA (AU)

Thank you for your attention

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