Strengthening ethics review systems

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Ethics and Health

World Health Organization

Overview

- Normative framework
  - Consultative Expert Working Group on Research and Development – Financing and coordination
  - UNAIDS/ WHO guidance document
    - Vulnerable populations
    - Availability of outcomes
- Strengthening ethics review systems
  - Operational standards /RECs – Oversight of RECs
  - Improving transparency in research (ICTRP)

  e.g. Pan African Clinical Trials Alliance
- Building global consensus

  e.g. working group of NECs on Biobanking

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Consultative Expert Working Group on Research and Development – Financing and coordination on Research and Development – Financing and coordination

- To facilitate equitable access to the benefits of research, suggestions are made to delink the costs of R&D and the prices of health products

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UNAIDS/WHO guidance document on Ethical Considerations in Biomedical HIV Prevention Trials

- Vulnerable populations (Guidance 8)
  - Multiple vulnerabilities: cultural, social, economical, political
  - Multiple groups: women, children, adolescents, MSM, PWID (IDU), sex workers, indigenous, poor, etc.

➡ Asses determinant of vulnerability at an early stage

➡ Design of the protocol should consider incidental risks of social harm and establish measures to prevent them.

"If the risk of exploitation is severe, the research should not be conducted."

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UNAIDS/WHO guidance document on Ethical Considerations in Biomedical HIV Prevention Trials

- Availability of outcomes

"Researchers should inform trial participants and their communities of the trial results. During the initial stages of development of a biomedical HIV prevention trial, ***trial sponsors and countries should agree on responsibilities and plans to make available as soon as possible*** *any biomedical HIV preventive intervention demonstrated to be safe and effective, along with other knowledge and benefits helping to strengthen HIV prevention, to all participants in the trials in which it was tested, as well as to other populations at higher risk of HIV exposure in the country."*

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Strengthening ethics review systems

Standards and Operational Guidance for Ethics review of Health related Research with Human Participants

http://www.who.int/ethics/publications/research_standards_9789241502948/en/index.html

Indicators for the oversight of RECs at country level

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Strengthening ethics review systems

- Joint reviews of multicenter trials

  e.g. DNDi proposal on African Trypanosomiasis Treatment

  African Vaccine Regulatory Forum (AVAREF)

- Recommendations for the implementation of existing guidance in specific cases

  e.g. placebo controlled vaccine trials

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International Clinical Trial Registry Platform (ICTRP)

- WHA 2006

  "A voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others"

- Network of 15 WHO data providers

- More than 220 000 registered

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Data providers

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ICTRP (cont.)

A shared responsibility aiming to

- improve transparency
- ensure greater accountability
- prevent unnecessary duplication
- identify gaps in research
- prevent publication bias and selective reporting
- improve trial design
- improve public trust

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Future perspectives/ trial registration

- Include information on ethical approval:
  - RECs
  - Justification for the ethics approval

- Include information about results of the research

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WHO technical support to countries

Pan African Clinical trial Alliance

- RECs and NRAs from 20 Sub Saharan African countries (AVAREF)
- Focus on coordination and harmonization of ethics review and approval including clinical trail registration
- Common procedural framework

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Consensus building

- Global Summit of NECs, Working group of on Biobanking
  - Identification of questions to be addressed
    - Consent
    - Public engagement
    - Role of RECs
    - Harmonization of legal frameworks
    - Governance
    - Benefit sharing
    - etc.
  - Coordination with on going initiatives in other international organizations

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Conclusion

Strengthening national ethics review systems

- Ethical norms based on universal principles (e.g. DoH – CIOMS – UNAIDS/WHO)
- Strong institutions (RECs)
- Harmonized procedures (including registration of CT publication of results, etc.) to ensure good governance: transparency, accountability, equitable access to information, participation of all stakeholders

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http://www.who.int/ethics/en