Ethical Principles for Review of Research Protocols in the Nigerian National Code for Health Research Ethics

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Nigerian National Code for Health Research Ethics

- The collective concern of the government & the people of Nigeria to ensure the protection of human participants in scientific research to the highest possible ethical standard

Nigerian National Code for Health Research Ethics

- Applies to all health research involving human participants, conducted, supported or otherwise subject to regulation by any Institution in Nigeria

Ethical Principles

- Social and Scientific Value
- Scientific Validity
- Fair Selection of Participants
- Maximize Benefits and Minimize Risks
- Independent Review

Ethical Principles

- Informed Consent
- Respect for Potential and Enrolled Participants
- Trust Relationship
- Protection of All Interests
- Compliance with the Principles of Good Clinical & Laboratory Practice

Social & Scientific Value

- To participants, community or society
- Contribution to improvement in health
- International collaborative studies should be integrated with capacity building, technology transfer and health care delivery strategies
- Value to researchers, institutions, communities & the country

Scientific Validity

- Clear scientific objectives
- Valid design and methodology
- Adequate power to detect effects
- Clinical equipoise for clinical studies
- Adequate operational plans
- Credible data analysis plan

Fair Selection of Participants

- Justice in choice of research sites and communities and recruitment of participants
- Equitable distribution of burden and benefit of research by groups, communities, participants and researchers
- Safeguards to protect vulnerable groups while participating in research that advance their health and wellbeing

Maximize Benefits & Minimize Risks

- Favourable risk benefit ratio at individual or community level
- Comprehensive delineation of risks and benefits for participants during the research
- Therapeutic procedures must fulfill requirements of clinical equipoise
- Risk-knowledge calculus to ensure that risks are reasonable compared to the knowledge to be gained

Independent Review

- Ethical oversight provided by an independent umpire to minimize conflicts of interests & ensure balanced judgements of research participants, researchers, sponsors and institutions

Informed Consent

Components:

- adequate information
- appropriate consent process
- comprehensible consent forms
- freely-given authorisation
- adequate protection of people with diminished autonomy and vulnerable populations

Respect for Potential & Enrolled Participants

- Participants should be seen and treated as partners in the research enterprise
- Rights to privacy should not be needlessly compromised
- Voluntary participation and withdrawal of participants
- Provision of information about research progress
- Community consultation or assent where and when necessary

Trust Relationship

- Transparency in all matters relating to the research enterprise
- Clear description of goals, risks, benefits, alternatives to participation and voluntariness
- Appropriate engagement of individual participants and communities
- Respect for local socio-cultural values
- Provision of relevant and timely feedbacks to communities

Protection of All Interests

- Participants, researchers, sponsors and communities
- Capacity building and respect for socio-cultural differences
- Protection and compensation for intellectual property, indigenous knowledge and contributions
- Satisfactory parameters for benefit sharing agreements, materials transfer agreements, patent rights, intellectual property and royalties' distribution

Compliance with the Principles of Good Clinical & Laboratory Practice

- Highest ethical and scientific standards for safety & wellbeing of trial participants
- Harmonized Tripartite Guideline for Good Clinical Practice
- Clinical Investigation of Medical Devices for Human Subjects
- Other regulations and guidelines

Resources and Further Readings

- National Code of Health Research Ethics, Federal Ministry of Health, Abuja, Nigeria, 2007
- Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? JAMA. 2000; 283(20) :2701-11
- Harmonized Tripartite Guideline for Good Clinical Practice (ICH-GCP E6)
- Clinical Investigation of Medical Devices for Human Subjects, ISO 14155-1, 14155-2 (2003)
- REC Administrator 101
- CIOMS Guidelines