SUMMARY OF PROCEEDINGS

10TH ANREC

"Evolution of research ethics in Uganda and the region: Past, Present and Future"

Key Note

- Vulnerability may be consent-based, risk-based, or justice-based
- For CHIMS studies, it is important to assess vulnerability and risk, to participants and to third parties.
- While assessing risk, determine who is at risk and the nature of risk
- Consider risk to third parties in addition to individual participants

KEY NOTE

- Vulnerability extends beyond participant therefore a need for a holistic consideration of circumstances balancing ethical principles being key.
- Countries to develop mechanisms to compensate research related injury.
- Issues related to data sharing include;
  - -confidentiality in data sharing
  - -IP arising from open data
  - -incentivizing data sharing etc.

Status of research and regulation in Uganda

- Nominal growth in scholarly output over the years with low socio-economic impact of research.
- Significant changes in research ethics landscape in Uganda since 1970 when National research Council was formed.
- The number of RECs is growing and regulatory frameworks to ensure quality reviews by RECs.

Emerging Issues: E-data, animal and genetic research

- Tracing participants is possible through matching and geo-coding
  - hindrance to confidentiality
  - Data handlers need to be trained on research ethics.
- Uganda is ready for e- capture but not fully ready for e-consent given the low literacy rates
- Protecting privacy of research participants genetic information is very vital in genomic research
- Need to develop guidelines on animal research.
  - Holding up the accreditation REC for the livestock sector

Trends in research regulation

- Joint reviews enable National Regulatory Authorities and Ethics Committees to validate their findings with peers and experts.
- CIOMS provides guidance on how universal ethical principles should be applied.
  - CIOMS should be set in a local context
  - No ethical imperialism, local laws and community engagement, evolutionary
- Research misconduct is on the rise
  - Not reporting misconduct is misconduct itself.
  - Institutions should foster research integrity by developing RM policies.

Harmonisation of research regulatory systems in East Africa

- Need for a regional research regulatory systems to foster growth in Science
- Harmonization will make the region attractive and competitive for research
- “Regulatory learning”, as a dynamic evolutionary process
- Decentralization of the research regulatory system.

National level:

harmonization

arbitration

accreditation

REC
approval

REC
Approval

Controlled Human Infection Models

- New paradigm for understanding the infectious process
- Challenges the 'do no harm'
  - Instead "harm to prevent further harm"
- Is Uganda ready?
- The rule of the double effect
- CHIMS study must meet several conditions including:
  - Social and scientific value
  - Ethical considerations
  - Adhere to human protection of international standards.
  - Compensation plan and treatment

Ethical Issues with GMOs

- GMOs need to be understood with in the socio cultural context
- Uncertainty surrounds the use of GMOs
  - Long term consequences of GMOs?
  - transmission of unintended effects on non target organisms and biodiversity ?
  - transgenic proteins and DNA taken up from the GIT?
  - Toxicants, altered genes in unpredictable ways?
  - Use of antibiotics and emergence of drug resistance

Compliance issues in clinical trials

- Clinical trial insurance is emphasized in all international documents that regulate research.
- Majority of applicants do not submit an insurance policy
- Insurance is confused with professional indemnity for the investigator team
  - Presentation of certificates only
- Abuse of regulatory vacuum by study sponsors
- Survey for inspection of GCP compliance
  - Evidence of breaches in several areas- premises, IMP investigational medicinal product handling,QA/QC

Panel Discussion

- **Kenya** fairly advanced in the region provides mandatory health insurance for study participants
- **Rwanda** has a national bioethics committee but with several layers of approval
- **South Sudan** : regulatory framework in infancy
- **Burundi:** challenges with translation and local context for consent
- **Ethiopia:** significant delays due to over centralisation of research regulation
- **Malawi**: Oldest research ethics committee established in 1974 and IRBs are semi autonomous

Recommendations

- Need to build capacity in improving quality of research protocol review.
- Strengthen RECs within institutions and accreditation of RECs to move towards an efficient decentralized regulatory system
- Uganda should work on developing a policy on financing R&D and bridging the gap between research and industry.
- Encourage more training and research in Bio-ethics
- Organize joint-review platforms to promote capacity of regulators and improve quality of reviews for clinical trials.
- Research regulatory system needs to move from being based on guidelines and be backed by laws

Recommendations

- Efforts in place to harmonize regional bioethics governance.
- Poor health infrastructure presents challenges to the "standard of care"
- Academic institutions closely engaged in research supervision
  - Research supervisors should be well trained in research and actively supervise
  - Policy on Scientific misconduct
  - Students increasingly have challenges picking new areas of research study topics. There is a risk of not getting new knowledge
- Insurance for research participants should be provided
- Development of guidelines for animal care and use

THANK YOU