DESK REVIEW REPORT PRESENTATION

Strengthening Ethics and Regulatory Capacity in Sierra Leone- SERCLe Stakeholders' Workshop 25 & 26 March 2021 at Family Kingdom Resort

PRESENTER

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PARTICIPANTS

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UNITY SERVICE LEARNING

MINISTRY OF HEALTH AND SANITATION
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Introduction

The Sierra Leone Ethics and Scientific Review Committee and the Pharmacy Board Sierra Leone (the National Regulatory Authority) face major capacity challenges.

The SLESRC faces the following challenges:

- Inadequate infrastructure to conduct reviews
- Limited financial and administrative support
- A small pool of expert reviewers
- Inadequate or lack of specialised training in biomedical ethics
- Lack of comprehensive governance structure
- Inadequate guidelines, policies and Standard Operating Procedures

Strengths of the SLESRC

- Experienced members
- Office space
- Self-funded through administrative charges
- Bank account
- Coordination structures

Need to Develop/Review policy documents

Research applications have increased with challenges related to:

1. vulnerable patients
2. high biohazard risk
3. novel therapeutics and
4. diagnostics

Thus:

- increased committee work-load
- need revised documents

Current documents used by the SLESRC

The SLESRC is currently using two documents:

1. **Research application guidelines-** This is to guide research applicants on submission requirements

SLESRC Application Guidelines

1. **TOR for the SLESRC-**Committee composition, mandate, responsibilities, COI,**etc.**

Objective of the Desk Review

- To review SOPs, policies and guidelines that are currently used both within Sierra Leone, the sub-region, other African countries as well as other countries across the world that are relevant to this work

Methodology

An analysis of secondary data that is publicly available both within and outside Sierra Leone.

This analysis assessed contents of various available documents relating to SOPs, guidelines and general policies on governance, administration and financial management.

Documents were selected if the contents covered some or all but not limited to the following:

- Research Ethics Committees both national and institutional
- Governance issues including financial management
- Documentation requirements for research protocol submission, Clinical trials/good clinical practice
- Informed consent processes for all categories of research participants and assent procedures
- Researchers/Reviewers responsibilities before, during and upon completion of research
- Community involvement in research and cultural consideration

Results Guidelines

Links to Guidelines:

- SLESRC Application Guidelines
- PBSL Guideline for Good Clinical Practice
- WHO Standards and operational guidance for ethics review of health-related research with human participants
- Government of Singapore Human Biomedical Research Regulations

Result Guidelines

Links to Guidelines:

- Operational Guidelines for the Establishment and functioning of Data Safety Monitoring Boards:UNICEF/UNDP/WORLD BANK/WHO
- Ottawa Office of Research Ethics and Integrity, University of Ottawa
- International Ethical Guidelines for Health-Related Research Involving Humans (CIOMS in collaboration with the WHO)-GEVEVA 2016
- International Ethical Guidelines for Epidemiological Studies CIOMS in collaboration with the WHO-GEVEVA 2009
- ICH Good Clinical Practice

Results Policy Documents

Policy documents:

- Declaration of Helsinki
- Office of Community Development and Disaster unit: Financial and Administrative Policies and Procedures
- Eastern International College Administrative and Operational Policies vand Procedures Manual
- Policies and Procedures Handbook Walker & Co 2008
- UK Research Directorate, University College, London Hospitals-COVID-19 Recommendations

Result SOPs

SOPs:

- Ghana Health Service Ethics Review Committee
- Enhancing Research Ethics Committee in Egypt
- Tanzania National Institute for Medical Research
- Guidelines of ethics for health research in Tanzania
- Tanzania Institutional Review Board
- Cameroon List of collected SOPs from African Research Ethics Committees

Result SOPs

SOPs:

- Nigeria National Health Research Ethics Committee
- UK Health Health Departments Research Ethics Service
- South Africa Human Ethics Research Committee
- Manila, University of the Phillipines Research Ethics Committee Board
- The Irish Council for Bioethics
- Nigeria- National Code of Health Research Ethics
- WHO Regional Office for Africa-African Regulatory Agencies Ethics Committees to expedite COVID-19 Clinical trials review

Result SOPs

SOPs:

- Ireland: The Irish Council for Bioethics
- Western Pacific Regional Office-The Ethics Review Committee
- Kenya: Aga Khan University-Institutional Ethics Committee

Training website

Training Website:

Center for Bioethics and Research

Key Findings

- Selected SOP contents seem to follow the WHO's standards and guidance, the guidelines and codes of best practice as well as the statues and regulations
- The SLESRC is currently using two official documents which are the application guidelines (which includes two forms-check list for ethical clearance and essential elements for the information sheet and TOR for the committee
- The SLESRC does not have any SOPs and or policy documents for its operations

Key Findings

- Institutional (University) SOPs are available for other countries which would be useful for our institutions if needed
- Ethics committees in other countries are using different standard forms for their operations. Examples: exemption, feedback, progress report, review evaluations, COI etc
- Ethics training courses are available for example in Nigeria with Center for Bioethics and Research which includes online courses. This will be useful for committee members
- I also observed that, the SLESRC does not have any legal legislation/law to protect itself in case of any legal action (if required) if there are compliance issues. An Act/Law is yet to be passed through parliament for the SLESRC as in the of the PBSL
- SOPs for Nigeria, Ghana, South Africa, Tanzania, Zambia, Kenya contain very useful materials

Ethics Concern and Limitations

- The desk review was done using already published secondary data and therefore did not require any ethical clearance, as no one was interviewed either physically or virtually
- The desk review only covered those documents that could be accessed and downloaded and has been limited to only 31 selected documents most of which (SOPs) from Africa and other parts of the World. Details of these documents can be found in the links included in the Results Slides

Recommendation

- Modify current SLESRC application guidelines to include any other useful required information to complete protocol submission process
- Build on the current PPT used by the committee and TOR for its operations to develop SOPs which is best practice as in other countries
- Explore the possibility of undertaking training programs organised by the Center for Bioethics and Research which will form part of education for committee members which is best practice
- Ensure Research Ethics is a significant part of the Health Policy/ and or Act.
- Ensure revised operational documents incorporate guides relating to the current COVID-19 pandemic (especially precautionary measures) and any other emergency disease outbreak
- Explore other options of raising funds from other sources including Government and or extra charges for defaulters to compliment funds raised from the administrative charges.

Thank You.