

Stakeholder interviews: Strengthening ethics and Regulatory Capacity in Sierra Leone

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Purpose of the needs assessment

- ▶ SLESRC and the Pharmacy Board of Sierra Leone (PBSL, the National Regulatory Authority) face major capacity challenges in carrying out their mandates to perform ethical and regulatory oversight of research in a timely fashion.
 - ▶ Relevant in light of recent disease outbreaks
- ▶ These include: a lack of infrastructure; limited financial and administrative support; a small pool of expert reviewers and regulators; and a lack of comprehensive governance structures.
- ▶ SECRLE Project aims to strengthen ethics and regulatory governance and practice in Sierra Leone in order to ensure research is conducted in a contextually appropriate and rigorous manner to protect the rights of participants and ensure that the positive impact of research in Sierra Leone is maximised.
 - ▶ To strengthen the governance structures of SLESRC
- ▶ As part of this project, a research capacity assessment of research ethics and regulatory committees was conducted



Rapid Assessment

- ▶ Conducted to identify challenges and opportunities for ethics and regulatory capacity.
- ▶ Interviews with key informants from
 - ▶ SLESRC [past (historical perspective) and current members]
 - ▶ MoHS
 - ▶ PBSL
- ▶ Snapshot of findings
- ▶ Full report to follow

Preliminary Findings



Findings: Structure and governance

- ▶ Communication
 - ▶ Intra level: Clear reporting lines
 - ▶ Inter level: no formal procedure but all lines of communication should go through the Chairman/Secretariat (through the Chairman)
 - ▶ Regulatory: PBSL-SLESRC – joint reviews
 - ▶ Changes in the face of a Public health emergency
 - ▶ Multi-country trials
- ▶ Accountability
 - ▶ SLESRC - Chairman
 - ▶ PBSL – Registrar and Chairman of the Committee
- ▶ Approval
 - ▶ Consensus
 - ▶ Expedited review – e.g. in line with public health emergencies (comes at a cost)
 - ▶ Scope – goes beyond the health sector (only one National Ethics/Regulatory committee)

Findings: Structure and governance

- ▶ Membership
 - ▶ Varied – multi sectoral and multi disciplinary
 - ▶ External provision of expertise feasible
 - ▶ Charter/Constitution
 - ▶ Not in place
 - ▶ Process to get approval underway
 - ▶ Interim: CMO appoints with consultation with the relevant directorate AT THE mohs(DTR/DPPI)
- ▶ Gender considerations
- ▶ Cultural and religious considerations
- ▶ PBSL – guidelines with clear TOR, selection criteria informed from well established authorities at International and regional level.
 - ▶ Experts reviewers broadly speak to 4 identified areas of the review process

Findings: Structure and governance

- Conflict of interest
 - No written policy in place
 - Member will recuse from the process
 - PBSL – guidelines in place
 - Expert reviewers do not work for the authority - independence

Operational support/Resources

- Resource allocation
 - Currently no funding from GOSL
 - Dependent on fees collected
 - Can impact number of times the committee can meet
- Support
 - 1 Secretary
 - Allocated office space for the secretary
 - Space not conducive for review meetings
 - Conference room at COMAHS

Operational support/Resources

- Resource allocation
 - Ongoing challenge
 - Relevant department gets funding from the MOF, but inadequate
 - Fees collected from reviews paid into the consolidated fund
- Compensation to reviewers
 - *“Abysmal”*



Training

- No formal training (new members)
 - Opportunistic approach leveraging on research experience of members (new)
- Knowledge/resource sharing amongst members
- **PBSL: Budget implications**
 - **Partner support**

Policies and procedures

- No standing SOP although some written guidelines available (submission requirement, review process)
 - Membership, committee governance, decision making, communication, follow up, monitoring, documentation and archiving, training, quality assurance, procedures for coordination with other ethics and regulatory bodies
- **Transparency, accountability and quality**
 - Decision making transparent – guideline available to guide the process (to be reviewed by the project)
 - Open discussion ensuring that all views are captured
 - Consensus
 - Review process transparent
 - Example: Expedited review
 - Evaluation
 - Self and external evaluation: no written procedures in place
 - Complaints: DTR – committee; Field – Chairman (information sheet)
- **Mandatory Post approval conditions**
 - Resource constraints – not feasible



Key Preliminary findings

- ▶ SECRLE project placed to be impactful
- ▶ No written policy/limited written guideline
 - ▶ Where available to be reviewed
- ▶ Resource challenges to be addressed in a sustainable manner
- ▶ Post approval monitoring process to be developed and implemented

Thank you

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