SCRECU

SCALING up of Capacity of Research Ethics Committees in Uganda

EDCTP
European & Developing Countries
Clinical Trials Partnership

European Union

project partners

UNCST — UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

MBALE REGIONAL REFERRAL HOSPITAL
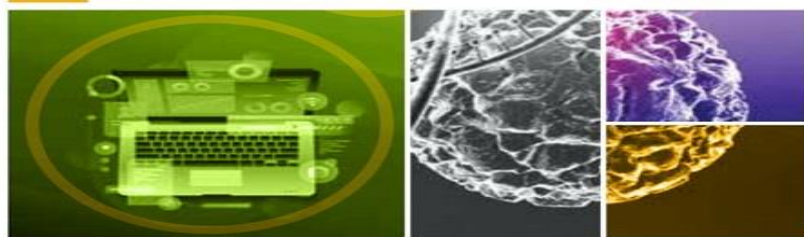
BUSITEMA UNIVERSITY — Pursuing Excellence

Scaling Up of Capacity of Research Ethics Committees in Uganda (SCRECU) rolls out the National Clinical Trials Information Management System (NRIMS). **Newsletter No. 3**

The Uganda National Council for Science and Technology and partners implemented the Consortium for Clinical Research Regulation and Ethics Capacity Development in Uganda (CREDU) project funded in 2017 by the European & Developing Countries Clinical Trials Partnership (EDCTP). The project that was concluded in June 2019 developed the Clinical Trials Information Management System (CRIMS) meant to improve clinical trial management in the country. CRIMS aimed at harmonizing standards of the in-country approval across all regulatory agencies as well set up an online and sustainable platform for review and approval of a clinical trial. The initiative to build the CRIMS with the ability to address the needs of the regulatory agencies was to enable integration and harnessing of the research potential whilst protecting the safety, rights, and welfare of the individual study participants, community, researcher, sponsor, and the country at large. In November 2019, the Clinical Research Information Management System developed under

the CREDU was upgraded to National Research Information Management System to encompass all research, Social Sciences, Agricultural Sciences, Physical Sciences, Engineering and Technology, and the Medical and Health Sciences. The outstanding challenge, however, was that the Research Ethics Committees (RECs) in the country were not able to tap into and use the system for the purposes and good intentions it was built to accomplish even after it was fully developed.

The Uganda National Council for Science and Technology (UNCST) in collaboration with Mbale Regional Referral Hospital and Busitema University is therefore implementing a two-year project funded by the European Developing Countries Clinical Trials Partnerships (EDCTP) to scale up the Capacity of Research Ethics Committees in Uganda (SCRECU).

The main objective of the project is to build sustainable capacity for the CRIMS framework for all the RECs in Uganda with capabilities of facilitating multi-REC ethical review of research, national registration of research,

and subsequent monitoring of approved studies by research ethics committees in Uganda.

Figure 1: SCRECU Team Conducting Training of REC Admins and IT Personnel

1. **Follow-up Visits**

Pursuant to the objective above, SCRECU trained REC Administrators and IT personnel equipped them with tablets. The project team undertook follow-up visits to each of the trained RECs to ascertain the impact of this intervention and the adoption of NRIMS was made. The following RECs were visited:

1. National HIV/AIDS Research Committee (NARC - REC)
2. Uganda Virus Research Institute (UVRI - REC)
3. Joint Clinical Research Centre (JCRC - REC)
4. Mbarara University of Science and Technology (MUST - REC)
5. Makerere School of Medicine Research Ethics Committee (SOM-REC)
6. Makerere School of Biomedical Sciences Research Ethics Committee (SBS - REC)
7. The AIDS Support Organization (TASO - REC)
8. Makerere School of Health Sciences REC
9. Mengo Hospital Research Ethics Committee (MH -REC)
10. Mbale Regional Referral Hospital Research Ethics Committee (MRRH - REC)
11. Mildmay Uganda Research & Ethics Committee (MUREC)
12. Mulago Hospital Research & Ethics Committee (MHREC)
13. Clarke International University Research Ethics Committee (CIU - REC)
14. Hospice Africa Uganda Research Ethics Committee (HAUREC)
15. Gulu University Research Ethics Committee (GUREC)
16. Vector Control Division Research Ethics Committee (VCD - REC)
17. Uganda Cancer Institute Research Ethics Committee (UCI -REC)
18. St Francis Hospital Nsambya REC
19. Kampala International University Research Ethics Committee (KIU - REC)
20. Makerere University School of Social Sciences Research Ethics Committee (MAKSS REC)
21. Makerere University School of Public Health Research Ethics Committee (HD REC)
22. CURE Uganda Research Ethics Committee (CUREC)
23. Uganda National Health Laboratory Services Research Ethics Committee
24. Uganda Christian University Research Ethics Committee (UCI - REC)
25. Lacor Hospital Research Ethics Committee (LHREC)

Figure 2: SCRECU Team Led by Dr. Ronald Mulebeke at CURE REC

2. Key Findings

2.1 Key Outputs

The project team found out the following:

a. All REC Administrators and IT support have been trained in the use of NRIMS for management of Submissions, review and feedback processes, approvals, and post-approval processes.
b. Regular follow-ups for support and feedback gathering are made through virtual meetings and the embedded chat platform.
c. Feedback is used as the basis for system updates, patches, and continuous improvement of the platform.
d. All 27 Accredited Research Ethics Committees (RECS) are using NRIMS.
e. NRIMS has registered over 10,000 researchers (UNCST and 26 RECs).
f. Over 6,000 Applications have been received.
g. Over 2,500 Approvals have been granted online.

2.2 Impact

a. Increased efficiency in the institutional workflows such as facilitation of working remotely for staff and stakeholders within the regulatory system.
b. Increased growth of the UNCST internet presence.
c. Increased demand for UNCST services has positioned UNCST on a path to a center of excellence for service provision in research and grant management in the region.
d. Improved efficiency and reduction of response times to clients and stakeholders.
e. Reduction of paperwork by over 95 percent
a. PIs used to submit as many copies as the number of members of a REC
b. Reduced cost in printing and courier
f. Reduced turnaround time in approvals by at least 50 percent.

g. Quorum has improved. 90 percent of the RECs are recording 100 percent quorum for meetings in the last 1 year.

h. PIs respond to comments in a period of 1-4 days. The previous average was 4 weeks.

3. Outcomes

a. Facilitate continuity of research regulation workflows amidst the pandemic thereby guaranteeing the safety of the regulatory officers while allowing research activities to continue.
b. Demonstrate resilience in executing amidst the challenges of the pandemic.
c. Real-time and location-independent access to work resources leading to Improved effectiveness and efficiency

d. Real-time access to data for quick analyses and inferences for reporting and decision-making.
e. Reduced risk, early detection, and correction of errors within work processes leading to better quality outputs.
f. Data Analytics for the Regulator and Individual Institutions using NRIMS.

4. Conclusion

NRIMS is a one-stop center for research management in Uganda (Fig. 3). It supports online research submissions, reviews, approvals, and post-approval processes. NRIMs is currently hosting over Twelve thousand local and international researchers. UNCST is on the path to a CoE Status on Research Regulations and Management in Uganda and the Region and in pursuit of a regional Research Regulation and Management System.
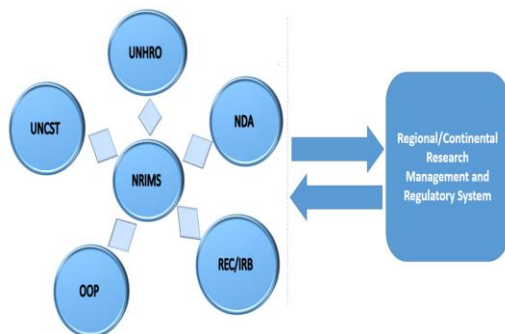
Regional regulatory agencies such as Mathari in Kenya have adopted NRIMS. UNCST is customizing NRIMS for the College of Medicine REC-University of Malawi which was delivered by the end of October 2021. Other regional regulatory agencies are benchmarking with the UNCST and are in the process of adopting NRIMS as a platform for research management in their respective jurisdictions.

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SCRECU project partners

Figure 3: NRIMS Workflows