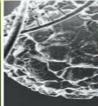






Scaling up of Capacity of Research Ethics Committees in Uganda







## project partners







Scaling up of capacity of Research Ethics Committees in Uganda (SCRECU). The SRCEU project launched.

Newsletter No. 1

Scaling up of capacity of Research Ethics Committees in Uganda (SCRECU) project is set to revolutionize and enhance the efficiency of multi-REC ethical review and registration research proposal; and monitoring of research ethics committees in Uganda

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 a Clinical Trials Information manage Management System (CRIMS) aimed at improving clinical trial management and harmonizing standards of the in-country approval across all regulatory agencies as well setting up a sustainable in Ugaonline platform for reviewing and approving clinical trials. 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 the National Research Information Management System in order to encompass all research in: Social Sciences, Agricultural Sciences, **Physical** Sciences, Engineering and Technology and the Medical and Health Sciences. Although the CREDCU project developed the CRIMS/NRIMS, the outstanding challenge is that the Research Ethic Committees (RECs) were not able to tap into and use the system for the purposes and good intentions it was built to accomplish. Due to lack of lack of capacity to operationalize an effective CRIMS at the REC level countrywide. Moreover, the RECs, which are accredited by the UNCST with the role of reviewing and monitoring research with the mandate from the UNCST, are to keep abreast with both the bulk of research reviews as well as monitoring of research according to the nationally and internationally stipulated research and ethics guidelines. Furthermore, there was a growing problem of submission of research to multiple

ethical regulatory authorities including UNCST, National Drug Authority (NDA), and the Office of the President especially for international research before researchers can commence their activities in Uganda.

The CREDU project only developed CRIMS to proof of concept level; it neither trained nor equipped the RECs to operationalize the system nationally

Through the needs assessment conducted among the regulatory authorities in Uganda by 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) (CSA2015ERC-863), the following conclusions were made:

- i. There are functional ethics and drug regulatory bodies in Uganda, but for various reasons which include inter alia their geographical location in the country, lack of overall networking fora and lack of a robust eplatform, make the work of these regulatory bodies fragmented and often times duplicated; thereby reducing efficiency and clarity of roles.
- ii. In this digital era, it is important to have innovations that utilize e-platforms that are capable of performing enhanced study participant safety, and networking and promoting seamless communications between the various regulatory authorities. Such platforms also improve working environment and when used well they improve efficiency.
- iii. There were some electronic platforms that had been piloted by the NDA, especially

RHINNO.This was usable to a degree, but had limitations on the cost, the number of accounts that could be operated, the need for heavy investment on effective Internet connectivity, and inability to customize locally desirable functions of the regulatory authorities.

In order to address the above challenges, UNCST sought and was awarded a re-entry grant from the European & Developing Countries Clinical Trials Partnership (EDCTP) on capacity strengthening of RECs in 2019 under a successor project entitle Scaling Up of Capacity of Research Ethics Committees in Uganda (SCRECU).

The project implemented by UNCST and partners; Buistema University and Mbale Regional Referral Hospital is building on the achievements of CREDU with a view to making UNCST a centre of excellence for research ethics in the Eastern Africa region. It has trained 25 RECs on the use of NRIMS, online review and equipped them RECs with the requisite equipment and Internet connectivity. Through the training programme, SCRECU has empowered the REC institutions and other stakeholders with well-qualified REC administrators through capacity building and skills.



Training REC administrators and IT personnel at the Busitema main Campus



Dr. Maxwell Otim-Onapa, PI SCRECU giving out the tablet computers to the FRECU chairperson Mulago Research Ethics Committee at Africana Hotel, Kampala



Dr. John Lule form the UNHLS REC happy to receive the tablets for his REC members

The project in year II will carry out scientific evaluations of the system to better inform the

guidelines on the use of NRIMS in the country and adoption of the system by other countries objective of the project of building sustainable capacity for the NRIMS 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...

Although the project has been affected by the Covid-19 pandemic, it has so far attained major milestones, which include:

- Training of 25 institutional research ethics committees' chairpersons, administrators and IT officers on the CRIMS/NRIMS
- Equipping 25 RECs with laptops, LCD projectors, printers, tablet computers

## **Project secretariat**

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## **SCRECU** project partners







