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

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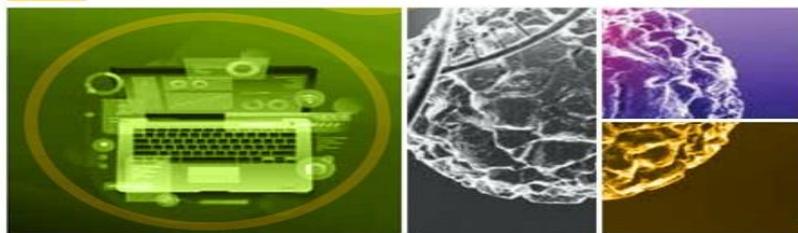
Policy brief No. 1

Policy brief on the adoption of a national research and information management system (NRIMS) as a tool for electronic review and registration of research in Uganda

Executive Summary

The Uganda National Council of Science and Technology, Busitema University and Mbale Regional Referral Hospital are implementing an EDCTP supported project on Scaling up of capacity of Research Ethics Committees in Uganda (SCRECU) aimed at building the capacity for Research ethics in Uganda. This project builds on an earlier one on Clinical Research Regulation and Ethics Capacity Development in Uganda (CREDU) that developed a clinical trials information management system (CRIMS) (CRIMS) only up to proof-of-concept level. Furthermore, it neither trained nor equipped the RECs to operationalize the system.

To address this gap, SCRECU set out to build a sustainable capacity for research ethics committees (REC) in Uganda through a national rollout of the CRIMS.

Under the SCRECU project curriculum for REC administrators and Information Technology Personnel on the use of the NRIMS was developed and delivered. The curriculum inter alia covered online submissions and management, post approval processes, amendments, revisions, SAEs, notifications, and enrolment of RECS into NRIMS. Testing of the system at every site was done and each trainee was followed up. The RECs were provided with ICT equipment to operationalize the NRIMS at their sites. The feasibility and effectiveness of the NRIMS is being monitored while its cost effectiveness is being evaluated through a nested study.

During the project implementation, a total of 26 REC Chairpersons, administrators and IT personnel and 26 REC were trained on NRIMS. and equipped with the requisite IT facilities. The NRIMS has so far registered over 8.500 researchers and leveraged to review 1.086

1.0   Introduction

The unique health, environmental, social and economic problems in the Sub-Saharan Africa (SSA) have attracted both local and international research interests. The Sustainable Development Goals (SDGs), from which most health researches derive their justification, define the global and society sector development agenda for 2015-2030;.

Research requires robust ethical processes in order to protect research participants through upholding the ethical principles of respect for autonomy, nonmaleficence, beneficence and justice. Researchers also desire a reliable high quality review of research with an efficient and timely delivery of review outcomes.

In Uganda complex clinical research is a growing phenomenon, but the capacity of the research ethics committees (RECs) to effectively use the clinical trials information management systems (CRIMS) to manage such complex research has lagged behind.

Over the last decade, noticeable progressive impacts of the steady investments in research safety culture through the initiatives by Uganda National Council for Science and Technology (UNCST) and its accredited and registered institutional RECs countrywide, and other national regulatory authority such as the National Drug Authority and Office of the President. Have been registered.. These actors need to be abreast with the bulk of research reviews, quality of review, as well as monitoring of research according to the stipulated research and ethics guidelines locally and internationally. However, there is a growing problem of coordination of submission of research protocols to these multiple ethical regulatory authorities including RECs. The process is usually slow; time consuming and therefore costly, much to the disenchantment of researchers who often have tight deadlines to meet. Furthermore, most researchers lack information on who should review protocols in Uganda.

In 2017 the European & Developing Countries Clinical Trials Partnership [EDCTP; CSA2015ERC-863] supported UNCST to develop a clinical trials information management systems (CRIMS) prototype through the Consortium for Clinical Research Regulation and Ethics Capacity Development in Uganda (CREDU) project.

In November 2019, the Clinical Research Information Management System was upgraded to National Research Information Management System (NRIMS) to encompass all research, Social Sciences, Agricultural Sciences, Physical Sciences, Engineering and Technology, and the Medical and Health Sciences.

In 2019, the EDCTP yet again provided a successor grant through Scaling up of capacity of Research Ethics Committees in Uganda (SCRECU) to build the capacity for RECs to effectively implement CRIMS so as to harmonize standards and improve on the quality of the in-country research approval process across all regulatory agencies via an online platform for review, registration and approval of clinical trials.

CONTEXT AND IMPORTANCE OF THE PROBLEM

Key issues

The following problems were identified through the projects

i. Lack of a robust ethical process that protects research participants by upholding the ethical principles of respect for autonomy, non-maleficence, beneficence and justice.

ii. Lack of reliable high quality review of research with an efficient and timely delivery of review outcomes.

iii. Failure of research regulation actors to stay abreast with the bulk of research reviews, quality of review, as well as monitoring of research according to the stipulated research and ethics guidelines locally and internationally

METHODOLOGY

The Consortium for Clinical Research Regulation and Ethics Capacity Development in Uganda (CREDU) project [EDCTP; CSA2015ERC-863] conducted a needs assessment among the regulatory authorities in Uganda by in 2017.

2.0   Findings

A review of the research information management system revealed that the process of submitting research protocols multiple ethical regulatory authorities including RECs is usually slow; time consuming and costly. There was therefore a growing problem of coordination of submission of research protocols to these multiple ethical regulatory authorities including RECs. Moreover, most researchers lack information on who should review protocols in Uganda.

Project interventions

In order to address the above challenges, the Scaling up of capacity of Research Ethics Committees in Uganda (SCRECU - CSA2018ERC-2315) carried out the following interventions:

i. Developed a curriculum, which covers online submissions and management, post approval processes, amendments, revisions, SAEs, notifications, and enrolment of RECS into NRIMS.

ii. Developed capacity among the RECs to adopt and implement the NRIMS as a tool for electronic review and registration of research in Uganda,

iii. Provided the RECs with the requisite infrastructure to facilitate the rollout of NRIMS

iv. Tested the feasibility and effectiveness of the CRIMS for review, registration and monitoring of research in Uganda and,

Outcome of the interventions

i.   Capacity Building

Under capacity building, the project developed a training curriculum, which was used to train all the RECs members, Administrators and Information Technology (IT) Personnel on the

National Research Information Management System NRIMS.

ii.   Testing the Feasibility and Effectiveness of the NRIMS

The project carried out a nested study where data on the entire cost of initiation, implementation and monitoring of the NRIMS were collected and analyzed.

The outcome from the analysis has informed guidelines for operationalization of NRIMS in Uganda and similar settings.

iii.   Infrastructure

The RECs have been equipped with the requisite ICT equipment to operationalize the NRIMS at their sites.

2.4   POLICY RECOMMENDATIONS

i.   The capacity of National Regulatory Agencies and RECs personnel should be developed so that they can perform data analytics on the real-time data generated through the NRIMS so that the output can be used for decision making and generating evidence based policies

ii.   The National Research Information Management System should be upgraded from time-time to address emerging issues in research

iii.   UNCST should integrate sustainability of NRIMS into its workplan and budget

3.0   Conclusions

SCRECU has rolled out sustainable NRIMS for high quality research regulatory oversight nationally. The NRIMS, which supports online research submissions, reviews, approvals, and post-approval processes is providing a one-stop center for research management in Uganda. It 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.

The Scaling up of capacity of Research Ethics Committees in Uganda (SCRECU - CSA2018ERC-2315) project has created a unified, networked and professional approach to capacity building.

The RECs in Uganda have embraced and are effectively using the CRIMS to automatically register all research into the registration database.

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UNCST: info@uncst.go.ug Tel: 0414-705-500

SCRECU project partners