UNCST

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

THE REPUBLIC OF UGANDA

2021 HYBRID VIRTUAL EVENT

11th ANREC

ANNUAL NATIONAL RESEARCH ETHICS CONFERENCE

THEME

Fostering Research Integrity & Responsible Conduct of Research in Uganda and the Region

13th-16th SEPTEMBER 2021 KAMPALA UGANDA

UNCST @UNCST_Uganda www.uncst.go.ug

Special Thanks to the Partners

UGANDA NATIONAL COUNCIL FOR SCIENCE & TECHNOLOGY

THE REPUBLIC OF UGANDA

Safe Drugs Save Lives

UNHRO
Uganda National Health Research Organisation

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Welcome Message Executive Secretary, UNCST

I wish to welcome all of you to the virtual 11th Annual National Research Ethics Conference (ANREC), the first of its kind in the "new normal" occasioned by the COVID-19 pandemic.

The impact of the COVID-19 pandemic on health, economies and livelihoods at national and global levels is unprecedented. It has no doubt transformed the way research and business is conducted. At national level, it has created a lot of demand for scientific and research outputs, human resources, and infrastructure. This and other pre-existing challenges constitute the context for research involving humans and animals today, as we seek to provide lasting solutions to societal problems.

The implications of these emerging challenges at national and global level are that research:

1. Must be responsive to pertinent issues.
2. Should be conducted promptly in order to generate timely solutions.
3. Will more than ever before require participation of humans and animals as subjects.
4. Incorporates standard operating procedures (SOPs) for prevention of spread of COVID-19 in protocols.
5. Outputs (especially vaccines, treatments, etc.) are highly demanded and yet there are regulatory and intellectual property considerations involved.

The ANREC has over the last decade evolved into a robust platform for training, networking and addressing pertinent issues regarding the ethical conduct of research in Uganda and at global level. This Conference has been pivotal in training, establishing regulatory infrastructure and guiding Research Policy and Practice in Uganda. In so doing, ANREC ultimately contributes to: research outputs that benefit society, the quality of Uganda's human resources, creation of employment, infrastructural capacity building and foreign exchange for the country.

The theme for the 11th ANREC is **Fostering Research Integrity and responsible conduct of research in Uganda and the Region**. It is a virtual conference.

Considerable progress has been made in terms of policy reforms and establishment of regulatory mechanisms both at institutional and national level, in ensuring safety of research participants (both human and animals). The conference will address issues of quality of protocols submitted to regulatory bodies, efficiency in research protocol review; and building capacity regulatory support mechanisms such as guidelines, RECs, etc. Participants will further discuss ethical dilemmas arising in the conduct of research in Uganda, selective data reporting, reproducibility of scientific findings, among others. The conference will also seek to contribute to fostering confidence and trust in research findings. We will at this ANREC also officially launch the National Research Bio banking Guidelines and National Guidelines for Use of Animals in Research and Teaching.

The 11th ANREC will feature highly respected international and local speakers who will share, experience and incites on a wide array of issues related to the theme. We envisage a very productive and inspirational engagement. We invite you to fully participate for the 3 (three) days.

As I conclude, I wish to once again welcome all of you participants from around the world, and in a special way Dr. Gowri Gopalakrishna our Keynote Speaker. We have guests from the East African Community, Africa Region, Europe, and Uganda.

I wish to thank the Minister for Science, Technology and Innovation (MOSTI) – Hon. Monica Musenero and the Minister for Agriculture, Animal Industry and Fisheries Hon. Frank K. Tumwebaze for kindly accepting to preside over the Conference and launch of the National Research Bio banking Guidelines and National Guidelines for Use of Animals in Research and Teaching respectively.
We acknowledge support from key partners National Drug Authority (NDA), Uganda National Health Research Organization (UNHRO), and the Office of the President and all the institutions and individuals who are made time to participate in this Conference as facilitators, presenters and resource persons.
I would like to the thank the 11th ANREC Planning Committee under the leadership of Dr. Gertrude Kiwanuka from Mbarara University of Science and Technology (MUST) for their dedication and innovativeness in making this virtual event a reality.

Thank you and I wish you fruitful discussions.

Dr. Martin Patrick Ongol (PhD)
Ag. Executive Secretary, UNCST

Welcome Message Chairperson Advisory and Planning Committee

Dear colleagues,
On behalf of the Advisory and Planning Committee (APC) of the 11th ANREC, it is my pleasure and great honor to extend to you all a warm welcome to the virtual 11th Annual Research Ethics Conference (ANREC). The theme of the conference "Fostering research integrity and responsible conduct of research in Uganda and the region" will underpin the need to uphold the highest ethical standards in research, and explore our experiences and lessons learned from a wide range of professional backgrounds.

The 11th ANREC will feature highly respected international and local speakers who will share, discuss, and analyze current and new practices that promote research integrity. It will provide a wonderful forum for you to refresh your knowledge base, and together we shall explore challenges and controversies of conducting research during public health emergencies. The COVID-19 pandemic has changed how research is being conducted in Uganda just like in other parts of the world, and has transformed research publishing. As such, a discourse on justice and the law when there is breach of the key areas of responsible conduct of research becomes imperative.

A special feature of this Conference is the launch of guidelines: National Research Bio banking Guidelines and the long awaited National Guidelines for Use of Animals in Research and Teaching. This unique and unmissable 2021 ANREC should end with some strong take-home messages.
We are looking forward to seeing you at this virtual conference. We hope you will join us and make this a memorable ANREC.

Dr. Gertrude N. Kiwanuka (PhD)
Chairperson, 11th ANREC Advisory & Planning Committee

Conference Advisory and Planning Committee (APC)

Dr. Gertrude N. Kiwanuka
Mbarara University of Science & Technology **(Chairperson-APC)**

Dr. David K. Kaawa-Mafigiri
Makerere University, College of Humanities & Social Sciences
(Vice Chairperson-APC)

Dr. John Barugahare
Makerere University College of Humanities & Social Sciences

Ms. Susan Nakubulwa
Mildmay Uganda - Research Ethics Committee

Dr. Gerald Obai
Gulu University - Research Ethics Committee

Dr. Sylvia Angubua Baluka
Makerere University, College of Veterinary Medicine, Animal Resources and Bio-security

Mr. Claude Kirimuhuzya
Kampala International University Western Campus - Research Ethics Committee

Dr. Helen Byomire Ndagije
National Drug Authority

Dr. Lawrence Mugisha
Makerere University, College of Veterinary Medicine, Animal Resources and Bio-security

Ms. Hellen Opolot
Uganda National Council for Science and Technology

Dr. Sam Okware
Uganda National Health Research Organization

Ms. Deborah Kasule
Uganda National Council for Science and Technology

Mr. Collins Mwesigwa
Uganda National Council for Science and Technology

Ms. Winfred B. Nazziwa
Uganda National Council for Science and Technology

Dr. Frederick Nelson Nakwagala
Mulago National Referral Hospital

1.0 INTRODUCTION

The Uganda National Council for Science and Technology (UNCST) adopted the concept of the Annual National Research Ethics Conference (ANREC) in 2009 to provide a forum for sharing experiences, discussing contemporary issues relevant for human research, building capacities, sensitizing the public and identifying options for addressing ethical dilemmas experienced in the conduct of research in Uganda. The ANREC has been organized by UNCST since 2009, as a platform for interaction among various actors involved with human and animal subjects' research. It brings together researchers, regulators, policy makers, members of research ethics committees, civil society groups and research communities. The previous ANREC demonstrated the gradual development of research ethics in Uganda and the region, conference participants shared ideas and experiences on the evolution of research ethics focus was on the past, present and future of research ethics in Uganda and the region. The 10th ANREC explored ways to advance research ethics in Uganda and in East Africa, and align with global developments in the field.

Brief of the 11th ANREC

The 11th Annual National Research Ethics Conference 2021 is under the theme; **Fostering Research Integrity and Promoting Responsible Conduct of Research in Uganda and the Region**. Conference participants will share ideas and experiences on how researchers can integrate ethical considerations in the design and implementation of their research projects and how research institutions and universities can build credible, reliable and predictable systems for scientific and ethical research. Therefore, the 11th ANREC is an opportunity to explore ways to foster research integrity and promote responsible conduct of research in Uganda and the Region. In addition, the 11th ANREC comes at a time when the US Federal Policy for the protection of Human Subjects or Common Rule has been amended for the first time since its publication in 1991. Uganda is also in the process of issuing revised guidelines for research involving humans as research participants, guidelines for community engagement in research, Bio banking guidelines as well as guidelines for use of animals in research and teaching. The 11th ANREC, therefore, will be an opportunity to examine these developments and their implications on research ethics in Uganda and the region.

Not forgetting the COVID-19 pandemic which has shaken the whole world, including the research enterprise. The pandemic has had profound impact on research, from research programs having to halt their operations to the rapid initiation of COVID-19 vaccine and treatment trials, to restarting research programs and protocols under physical/social distancing guidelines. The pandemic has presented dire ethical challenges in the face of significant risks and resource shortages that have forced policy makers, research regulators, medical care providers, and the affected public to make difficult decisions. The 11th virtual ANREC will also address a variety of topics related to the pandemic's effect on research both what have we have learned and what we should consider moving forward.

The 2021 ANREC will be streamed virtually from 14th – 16th September 2021 at 9:00am – 1:00pm each day. The Conference is organized in plenary sessions and will have keynote addresses, case study discussions and panel discussions. The Guests of honour will launch the National Research Bio banking Guidelines and National Guidelines for Use of Animals in Research and Teaching during the opening and closing session of the conference.
We hope that you will find the conference valuable!

2021 HYBRID VIRTUAL EVENT

11th ANREC

ANNUAL NATIONAL RESEARCH ETHICS CONFERENCE

Safe Drugs Save Lives

THEME: **"FOSTERING RESEARCH INTEGRITY & RESPONSIBLE CONDUCT OF RESEARCH IN UGANDA AND THE REGION"**

13th - 16th SEPTEMBER 2021
CONFERENCE PROGRAM
@Next Media Conference Center

Day 1: Monday 13th September 2021 Chair: Dr. Frederick Nelson Nakwagala

Time	ACTIVITY
9:00am - 1:00pm	Forum for REC Chairpersons in Uganda **(for Research Ethics Committees Chairpersons ONLY)**

Day 2: Tuesday 14th September 2021

8:30 - 9:00am	Registration of in person participants & logins for online participants **- UNCST Secretariat**
9:00 - 10:50am	**SESSION 1 (PLENARY):** Moderator/ Chair : **Dr. Gertrude Kiwanuka**
9:00 - 9:20am	**WELCOME REMARKS:** a. Chair Organizing Committee b. Secretary to the Authority, NDA c. Director General, UNHRO d. Executive Secretary, UNCST
9:20 - 9:50am	**KEY NOTE ADDRESS 1:** Research Integrity and Responsible Conduct of Research: A Dutch case study *Dr. Gowri Gopalakrishna, Amsterdam University Medical Centre, The Netherlands*
9:50-10:30am	**OFFICIAL OPENING:** a. Chairperson, UNCST b. Hon. Minister of Science, Technology and Innovation & Launch of National Research Bio banking Guidelines
10:30 - 10:35am	**GROUP PHOTOGRAPH**
10:35-10:50am	**HEALTH BREAK**
10:50am-1:00pm	**SESSION 2 (PLENARY):** Chair: **Dr. Frederick Nelson Nakwagala & Dr. Stella Neema**
10:50-11:20am	a. Promoting Responsible Conduct of Research in Uganda and the Region: Best practices and the Impact of Research *Prof. Nelson K. Sewankambo, College of Health Sciences, Makerere University*
11:20 - 11:50am	b. Research Integrity: Experiences and lessons in the last 10 years in the region *Dr. Lyn Horn, Director, Office of Research Integrity, University of Cape Town, South Africa*
11:50am - 12:20pm	c. Research Integrity during pandemics/public health emergencies: reflections on COVID-19 research. *Dr. Tom Lutalo, Chairperson, Uganda Virus Research Institute Research Ethics Committee*
12:20 - 1:00pm	**PANEL DISCUSSION (Q&A SESSION)**
1:00 - 2:00pm	**LUNCH & DEPARTURE**

Day 3: Wednesday 15th September 2021

8:30 - 9:00am	Registration of in person participants & logins for online participants **- UNCST Secretariat**
9:00 - 11:00am	**SESSION 1 (PLENARY):** Chair: **Dr. David K. Kaawa-Mafigiri & Mr. Claude Kirimuhuzya**
9:00 - 9:30am	**KEY NOTE ADDRESS 2:** Policy, Ethical and Legal Frameworks for Research Integrity in the East African Region *Dr. Francis Kombe- Chief Executive Officer EthiXPERT, South Africa*

	INTEGRITY IN RESEARCH PUBLICATION, DATA USE & INFORMED CONSENT
9:30 - 10:00am	a. Latest Revisions of the Common Rule and Implications for Research in Uganda and the Region. *Dr. Jaime Hernandez, Public Health Program Analysist, Office of Human Research Protection, US Department of Health and Human Services*
10:00 - 10:30am	b. Informed Consent for Research during epidemics and research integrity: challenges, controversies and lessons for the future. *Dr. Francis Bajunirwe, Mbarara University of Science and Technology*
10:30 - 10:45am	**PANEL DISCUSSION (Q&A SESSION)**
10:45 - 11:00am	**HEALTH BREAK**
11:00am - 1:50pm	**SESSION 2 (PLENARY):** Chair: Dr. Erisa Mwaka & Ms. Susan Nakubulwa
11:00 - 11:30am	a. Misconduct in Research publishing: Who is responsible for what at all levels of publication? The role of Journal Editors in assuring the Integrity of Research data. *Prof. James K. Tumwine, Prof. Emeritus College of Health Sciences, Makerere University*
11:30am – 12:00pm	b. Beyond ethics: Data protection and privacy as a legal obligation for researchers in Uganda *Dr. Adrian Jjuuko, Chairperson, The AIDS Support Organisation (TASO) Research Ethics Committee*
12:00 – 12:30pm	c. Compassionate Use and or Emergency use of unproven and unregistered products during the COVID-19 pandemic: Looking backward, Moving forward. *Dr. Helen Byomire Ndagije, Director Product Safety, National Drug Authority*
12:30-1:00pm	**PANEL DISCUSSION (Q&A SESSION)**
1:00-2:00pm	**LUNCH & DEPARTURE**

Day 4: Thursday 16th September 2021

8:30 - 9:00am	Registration of in person participants & logins for virtual participants - UNCST Secretariat
9:00 - 10:45am	**SESSION 1 (PLENARY):** Chair: Dr. Gerald Obai & Prof. Pauline Byakika
9:00 - 10:30am	**PANEL DISCUSSION** Regional Perspective: Fostering Research Integrity & Responsible Conduct of Research *(delegates from the Region)* 1. Dr. Eugene Mutimura, *Executive Secretary, National Council for Science & Technology (NCST), Rwanda* 2. Dr. Martin Ongol, *Acting Executive Secretary, Uganda National Council for Science & Technology (UNCST), Uganda* 3. Mr. Boniface Wekesa Wanyama, *Director for Research, Accreditation & Quality Assurance, National Commission for Science, Technology & Innovation, (NACOSTI), Kenya* 4. Prof. Tatien Masharabu, *Executive Permanent Secretary, National Commission for Science, Technology & Innovation (STI), Burundi* 5. Dr. Amos Nungu, *Director General, Tanzania Commission for Science & Technology (COSTECH), Tanzania* 6. Dr. Solomon Benor, *Director General for Science & Research Affairs, Ministry of Science & Higher Education, Ethiopia* 7. Prof. Elijah Malinga Wanda, *Director General, National Commission for Science and Technology (NCST), Malawi*
10:30-10:45am	**HEALTH BREAK**

10:45am - 1:00pm	**SESSION 2 (PLENARY):** Chair: Dr. Lawrence Mugisha & Dr. John Barugahare **ETHICAL ISSUES IN ANIMAL & NATURAL PRODUCTS RESEARCH**
10:45 - 11:15am	A global perspective on research integrity in natural products research and development: Lessons for Uganda *Dr. Barbara Zawedde, Mukono Zonal Agricultural Research & Development Institute, NARO*
11:15 - 11:45am	Ethical Issues for Life Sciences, and Research Involving Animals as Research Subjects *Dr. David Lewis Senior Lecturer Pharmacology & Bioethics, University of Leeds, UK*
11:45am -12:00pm	**PANEL DISCUSSION (Q&A SESSION)**
12:00 – 1:00pm	**SESSION 3 (PLENARY):** Chair: Dr. Gertrude Kiwanuka & Dr. Sylvia Angubua Baluka **LAUNCH OF GUIDELINES & CLOSING**
12:00 – 12:10pm	Summary of Proceedings, *Chairperson Advisory & Planning Committee 11th ANREC, Dr. Gertrude Kiwanuka*
12:10pm – 12:30pm	a. Background & process of development of National Guidelines for Use of Animals in Research and Teaching, *Dr. Lawrence Mugisha, Chairperson Task Force* b. Launch of the National Guidelines for Use of Animals in Research and Teaching, *Honorable Minister, Ministry of Agriculture, Animal Industries & Fisheries (MAAIF)*
12:30 – 1:00pm	**CLOSING REMARKS** *Honorable Minister, Ministry of Agriculture, Animal Industries & Fisheries (MAAIF)*
1:00-2:00pm	**LUNCH & DEPARTURE**

NOTE: MONDAY 13th September 2021

8:30 - 9:00am	**33rd FRECU Meeting** *(Pre Conference activity) attended by REC Chairpersons only.*

REC Accreditation

RECs are established in or by an organization to conduct initial and continuing review of research projects with the primary goal of protecting the rights and welfare of research participants. An Organization that wishes to establish a REC applies for REC Accreditation at the UNCST.

Stages of Accreditation

1. The REC undertakes self-assessment to identify the REC'S strengths, achievements and areas that need improvement. During self-assessment, the REC may engage an expert to facilitate the exercise. The REC submits a report of the self – assessment to UNCST along with an application for accreditation.

   The following should be considered in conducting self-assessment;
   - REC written policies & Standard Operating Proceedures (SOPs)
   - Extent to which Policies and SOPs are followed
   - Updated REC Membership Roaster
     (REC members should normally be given appointment letters);
   - CVs of all REC Members
   - Training for REC Members in Basic Research Ethics
   - Protocol Application Forms that Researchers use
   - Fees Policy and Structure
   - Reviewer Checklists
   - Consent Templates
   - Template Letters
   - REC Secretariat and Staffing
   - Frequency of REC Meetings and Protocols Reviews
   - Monitoring of Studies

2. The REC Accreditation Committee of Research Ethics Committee (ACRECU) reviews the REC's application and inspects the REC's host institution.

Accreditation is granted to a REC for a period of three (3) years. After the 3 years, a REC can apply for renewal of accreditation, through the same stages as indicated above.

REC accreditation forms and guidelines are available at the www.uncst.go.ug

Bio Sketches & Abstracts for the Paper Presenters & Panel Members

Tuesday 14th September 2021

KEY NOTE ADDRESS 1: Research Integrity and Responsible Conduct of Research: A Dutch case study

Dr. Gowri Gopalakrishna, Amsterdam University Medical Centres, The Netherlands
Email: g.gopalakrishna@amsterdamumc.nl

Dr. Gowri Gopalakrishna is an epidemiologist with many years of public and private public health policy experience. Some of her more notable contributions include her role in the control and containment of the SARS outbreak in Singapore in 2003. In her current role as lead researcher on the Dutch National Survey on Research Integrity (NSRI2020), she works closely with lead PI, Prof. Lex Bouter, to design, implement and analyze results of one of the world's largest surveys on research integrity. She was featured in the Dutch media this year on her SARS experience and later on the impact of speed science, open science and research integrity during the COVID pandemic. She is currently also Chair of the Equity Coordinating Committee of the International Federation of Biosafety Associations, focused on improving equity, diversity and inclusion of marginalized groups in biosafety and biosecurity as a profession.

ABSTRACT

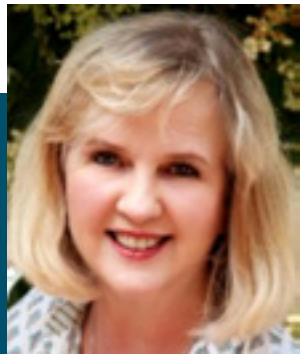
Public trust in research is essential in order to meet important challenges of society. Trust in research is earned through transparent, responsible research practices. Traditionally, research integrity studies have focused on research misbehaviors and their explanations. Over time attention has shifted from detecting and sanctioning research misconduct towards preventing questionable research practices. So far little attention has been given to responsible research practices and how these can be fostered optimally. Especially in regards to open methods, open codes and open data. My talk will touch on results from a large survey among academics in The Netherlands as a case study showing the prevalence of different research practices across academics in The Netherlands. I will discuss the factors associated with these behaviours as well as their implications and areas of focus for research institutions as a whole when it comes to fostering research integrity. These findings can help in understanding ways by which responsible research practices can be made more universal across disciplines and academic ranks so as to increase transparency and trustworthiness of research. I will end my talk by sharing some reflections on the COVID-19 pandemic and its impact on research integrity.

PAPER 1: Promoting Responsible Conduct of Research in Uganda and the Region: Best practices and the Impact of Research

Prof. Nelson K. Sewankambo, Makerere University, College of Health Sciences
Email: sewankam@infocom.co.ug

An Emeritus Professor of Medicine, former Principal of Makerere University College of Health Sciences, and previously a Dean of Makerere University Medical School. He is an active researcher for nearly forty years. The combination of researcher and leadership roles demanded great attention to championing and strengthening research capacity development of upcoming researchers and research users. He encouraged and motivated approaches through experiential learning, formal training and education at Masters, PhD and pos-doc levels to achieve the highest standard of research ethics along with responsible conduct of research and knowledge translation of health research evidence to inform policy and decision making. He received recognition as a fellow of Uganda National Academy of Sciences, African Academy of Sciences, The World Academy of Sciences, the London School of Hygiene and Tropical Medicine, Karolinska Silver Medal, and Honorary Doctorates at McMaster University and Johns Hopkins University School of Public Health among others.

PAPER 2: Research Integrity: Experiences and lessons in the last 10 years in the region



Dr. Lyn Horn, MBBch, DTM&H, DCH, DipIRE, MPhil, PhD: Director, Office of Research Integrity, University of Cape Town, South Africa
Email: lyn.horn@uct.ac.za

Lyn Horn is currently the Director of the Office of Research Integrity at University of Cape Town (UCT) and an Extraordinary [Honorary] Associate Professor in the Centre for Applied Ethics at Stellenbosch University. Prior to moving to UCT almost 3 years ago she held the position of Research Integrity Officer at Stellenbosch University for five years. She is a medical doctor with a PhD in Bioethics. She worked as a clinician in the public health sector for the first twenty years of her career before transitioning to an academic work environment in 2004. Working

as a medical officer in a variety of clinical settings including mission hospitals, mine hospitals and as a TB medical officer for the City of Cape Town, triggered her interest in applied ethics and further study in this field. Her academic interests have shifted over the years but include public health ethics and social justice, research ethics and more recently research integrity. She served a three-year term on the National Health Research Ethics Council and has been actively involved in either chairing or running research ethics committees for the last 15 years (in both the biomedical and humanities domains); she has been teaching research ethics at her home institutions since 2004 has taught on the University of Kwazulu Natal UKZN SARETI programme for many years. In her current position at UCT she is actively involved in promoting and facilitating the responsible conduct of research across the entire university. She also provides support and advice to research misconduct investigations.

Lyn serves as the bioethics consultant for four international EDCTP funded clinical trials relating to Tuberculosis and HIV that are currently active in several African countries, hence she remains closely involved with research teams implementing clinical trials in Africa. Her particular role is to ensure that the interests of research participants are safe-guarded. In 2019 she led a successful [South] African bid to host the 7th World Conference on Research Integrity on African soil for the first time. This prestigious international conference will be held in Cape Town in May 2022. In her spare time, she paints as often as she can and enjoys walking in the many nature reserves in and around Cape Town.

ABSTRACT

Research Integrity encompasses all aspects of the research life cycle from the point a researcher first starts thinking about her project, writing a proposal, finding funding, considering the ethical implications of the project, data collection and so on. While ensuring that a project has been adequately reviewed and approved by a research ethics committee is essential, it also important for researchers and ethics committee members to be aware that once this box is ticked there is still so much more that the ethical, responsible researcher must do.

Integrity lapses at any stage can have severe consequences for the project and the scientific enterprise as a whole and have severe repercussions on researchers, research teams and the institution. Undesirable research practices may not be blatantly intentional, but can creep in, often driven by the many pressures that being a researcher involves. In this paper I will talk about the concepts of research integrity, research misconduct and questionable research practices (QRPs) and why they matter so much. Some examples of recent actual cases will be used to highlight why the stakes around the responsible conduct of research (RCR) are so high and why anyone can be adversely affected by integrity lapses, including those of colleagues or co-authors. I will then focus on what we can do to promote a culture of research integrity at our institutions and regionally, and highlight what has been achieved so far. This will include a discussion on Responsible Conduct of Research (RCR) training and the development and implementation of institutional Research Integrity Promotion Plans. I will conclude by highlighting the opportunities for participation in the forthcoming 7thWorld Conference of Research Integrity, including both travel and attendance grants aimed primarily at participants from Africa.

PAPER 3: Integrity during pandemics/ public health emergencies: reflections on COVID-19 research.

Dr. Tom Lutalo, Chairperson Uganda Virus Research Institute Research Ethics Committee
Email: tomlutalo@gmail.com

Dr. Tom Lutalo is the Assistant Director, Research, Uganda Virus Research Institute (UVRI); Senior Investigator with Rakai Health Sciences Program (RHSP) and Chairperson, UVRI Research Ethics Committee. He has long-term interests in the field of epidemiology (infectious diseases, field epidemiology and reproductive health). His major has been the prevention of HIV, STIs and unwanted pregnancies; especially in the demographic consequences of HIV including effects of HIV on fertility, family planning use and mortality at the individual and population levels. He headed a community randomized trial of intensified family planning promotion in Rakai, SW Uganda; participates in all aspects of the NIH and Gates funded Rakai HIV prevention trials.

He currently is the Head of Epidemiology and Data Management as Assistant Director Research at the Uganda Virus Research Institute (UVRI) where he coordinates data Management and analysis of studies that have included Evaluation of the pMTCT program in Uganda, Evaluating new diagnostic kits, HIV drug resistance studies, mortality studies at the National level and Early Warning Indicator studies.
He has over 80 publications specifically focusing on HIV dynamics, Evaluation of Diagnostic kits (including COVID-19 kits), adolescent health and contraceptive behavior. He continues to provide leadership and oversight to collaborative and network studies such as the Analyzing Longitudinal Population-based HIV/AIDS datasets (ALPHA) based at London School of Hygiene and Tropical Medicine. He has also supervised and supported several students from Ugandan Institutions of higher learning and universities in USA, pursuing Masters and PhD studies.
He has been a chair of the UVRI REC since 2009 where they review between 8 to 15 new proposals per month.

ABSTRACT

The famous investor, Warren Buffet's quote often used when talking about integrity and business goes like "In looking for people to hire, look for three qualities: integrity, intelligence and energy. And if they don't have the first, the other two will kill you". Unethical processes and fraud risk factors increase during health emergencies because entities and individuals use weakened internal controls and people find it easier to rationalize their actions. These risk factors require three elements – opportunity, pressure, and rationalization – to be present (known as the Fraud Triangle). COVID-19 offers all three and more. Research integrity remains crucial in the COVID-19 crisis, given the need for robust, evidence-based conclusions. The COVID-19 pandemic has potentially compromised the ability of researchers to undertake effective compliance

monitoring, supervision and oversight, creating an opening for unethical behavior.

The pandemic has so far had a tremendous effect on all examined accounts of scholarly publications: A sharp increase in publication volume has been witnessed and it can be almost entirely attributed to the pandemic; a significantly faster mean time to acceptance for COVID-19 papers is apparent, and it has (partially) come at the expense of non-COVID-19 papers; and a significant reduction in international collaboration for COVID-19 papers has also been identified.

The scientific and scholarly community has established rules that govern robust, peer-reviewed and trustworthy research. Failing to follow these rules will have a detrimental effect on research: bad practices will distort our knowledge of COVID-19 and will obstruct or delay our efforts to stop the pandemic and save lives" (http://www.enrio.eu/about-enrio)

Ethical research governance has been overtaken by political decisions and some researchers have taken this opportunity to side with non-scientifically reviewed decisions driven by individualism instead of a scientific good. During public health emergencies there is a need to promote ethical decision processes and regulatory authorities need to have at hand two platforms: firstly, a platform that clearly sets out the competencies around which to pivot the integrity being sought, and secondly how to assess the proficiency with which the researcher is able to apply that integrity.

The rapid spread of COVID-19 and its transition into a global pandemic, propelled researchers to begin the search for diagnostic tests, treatments and vaccines in earnest. For example, over 95% of the COVID-19 diagnostic kits evaluated at UVRI have not been recommended for use to MoH even when the manufactures document excellent performance (sensitivity and specificity of 100%). According to Prof. Katrina Bramstedt (Journal of Medical Ethics), the COVID-19 pandemic has created a flood of potentially substandard research amid the rush to publish, with a string of papers retracted or under a cloud and a surge in submissions to pre-print servers where fewer quality checks are made. This has implications for patients, clinicians, and potentially government policy.
As of August 2021, a total of 6454 studies for COVID-19 were registered on the international clinical trial registry ClinicalStudies.gov.

A study by El-Menyar A, Mekkodathil A, Asim M, et al found that the median days for dissemination of findings in some journals were 114 days (IQR 61–189). A comparative analysis revealed that RCTs were disseminated earlier (median 79 days; IQR 52–131) when compared to observational studies (median = 144 days; IQR 69–206) (p = 0.003) (Science Progress. April 2021). Several papers have been retracted from high impact journals; in which the average period till publication was only 33 days. In some cases, retraction of papers occurred within 10–48 days. Expedited reviews, research approval and early publications of COVID-19 related studies could have an impact on the quality of publications. However, the huge number of publications in short time creates confusion for readers during the early phases of the pandemic. Retraction of papers is alarming but ensures research integrity and correctness of scientific information. These abbreviated processes could affect patient care and public awareness.
It is imperative to follow rapid but rigorous ethical standards for research approval, research conduct and peer-review processes for diagnostics, therapeutic and vaccine research and development and publications during health pandemics.

UNCST LIBRARY & RESOURCE CENTRE

The UNCST has continued to manage a well-equipped Library / Resource Centre whose main function is to maintain a collection of Scientific and Technical information on Science and Technology both at National and international level.

The Library has a variety of resources in different thematic areas of research. The collection has grown over the years and this is attributed to our local and international stakeholders including researchers who have continuously provided various publications.

The Resource Centre holds over **Fifty Thousand collections** in form of books, journals, research reports, textbooks, maps, pictures, drawings and Newspapers.

Our collection has the following subject areas: **Health, Pharmacy, Science and Technology, Physics/Chemistry, Natural Resources and Development, Environment, Pasture and Forest lands, Energy, Water and Wetlands, Wildlife and Biodiversity, Education, Business Management, Law, Economics and Development, Biotechnology, Foods and Nutrition, Gender, Population studies.** We also have **the Encyclopedia of Science and Technology, Macropaedias and research reports/dissertations** on research studies undertaken in Uganda since 1990 covering the following thematic areas: **Sciences, Natural Sciences, Medicine and Veterinary Sciences, Physical Sciences Agricultural Sciences And Industrial Sciences.**

The Resource Center is a focal point for WHO publications in Uganda.

for more information, please contact,
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Wednesday 15th September 2021

KEYNOTE ADDRESS 2:
Policy, Ethical and Legal Frameworks for Research Integrity in the East African Region

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Mr. Francis Kombe is a Public Health practitioner and bioethicist, with a passion in Research Integrity. He has a wealth of experience working in international health research institutions, where he has held various leadership positions. Kombe holds an MSocSc (research ethics) from the University of KwaZulu-Natal (UKZN), South Africa; Master of Public Health (MPH) and Postgraduate Diploma in Public Health (PGDPH) from London School of Hygiene and Tropical Medicine-UK (LSHTM). He is currently pursuing a PhD in Bioethics at UKZN, focusing on the Implications of fieldworkers' institutional support systems for research integrity practices in Africa. Before joining EthiXPERT, Kombe worked for COHRED'S as the Africa Region's lead consultant for RHInnO Ethics, a project that aims to build the capacity of research ethics committees in Africa, and was a training coordinator at the KWTRP where he was involved in strategic development and planning for fieldworkers' training. He is a founding and steering committee member of the African Research Integrity Network (ARIN), a member of the Pwani University REC and an expert committee member of the Data Governance Committee at the African Academy of Sciences. He has published widely in the field of community engagement, frontline staff, research integrity, fair study benefits and informed consent, among others.

ABSTRACT

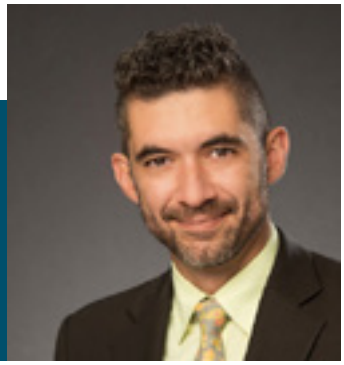
Research Integrity is the cornerstone of scientific research. Scholars, scientists and the public at large trust in the outcomes and products of research because they believe they convey truth, are verifiable and replicable, and reflect honest, hard work, and the data were collected using accurate and appropriate methods. Where these principles are questionable, the trust in the individual researcher and the entire research enterprise is severely undermined.

Although Africa has made tremendous advancements in research ethics, including raising awareness, acceptability, building capacity, developing regulatory policy and legal frameworks, the importance of research integrity in and for Africa remains is not well understood. As the rest

of the world moves ahead with developing legal and regulatory frameworks for Research Integrity, there is a need for African scholars, academics and researchers to engage in inter-disciplinary, inter-cultural and inter-generational dialogue, debate, sensitisation and consultations around issues of research integrity. Importantly, we need more reflection on how principles of research integrity can be practically interpreted, institutionalised, promoted and implemented in the diverse settings of Africa

This session will engage the audience on how complex issues about knowledge, cultural diversity, socio-economic inequalities and power relation affect research integrity and how these should inform the debate around policy, ethical and legal frameworks for Research Integrity in and for East Africa.

PAPER 1: Latest Revisions of the Common Rule and Implications for Research in Uganda and the Region.



Dr. Jaime Hernandez, J.D., M.Be: Public Health Program Analysist, Office of Human Research Protection, US Department of Health and Human Services
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Dr. Jaime Hernandez is an attorney and bioethicist currently serving as a Public Health Analyst with the Division of Policy and Assurance at the United States, Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP). Before joining OHRP, Mr. Hernandez was a Senior Research Investigator at the University of Pennsylvania, Department of Medical Ethics and Health Policy. Prior to that, he was a Litigation Associate at Hughes Hubbard & Reed, L.L.P. He also served as an IRB Administrator at the University of Pennsylvania, Office of Regulatory Affairs. Mr. Hernandez obtained his Juris Doctorate (J.D.) at the University of California at Berkeley and his Masters in Bioethics (M.Be.) at the University of Pennsylvania.

ABSTRACT

This presentation will provide a brief summary of the resent revisions to the United States, Department of Health and Human Services (HHS) regulations for the protection of research participants. In doing so, this presentation will clarify which research must comply with these regulations, and which of the resent changes are most likely to affect research in Uganda and other countries in the region.

PAPER 2: Informed Consent for Research during epidemics and research integrity: challenges, controversies and lessons for the future.

Dr. Francis Bajunirwe, Senior Lecturer Department of Community Health, Mbarara University of Science and Technology
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Francis Bajunirwe is a Senior Lecturer in the Department of Community Health at Mbarara University of Science and Technology. He completed his medical degree at Makerere University and doctoral training in Epidemiology at Case Western Reserve University supported by the Fogarty AIDS International Training and Research Program. His research is in the field of implementation science, infectious diseases and research ethics. He has conducted community based epidemiologic studies to evaluate uptake and impact of interventions for HIV and tuberculosis treatment in rural Uganda, family planning and programs for prevention of mother to child transmission of HIV. He has led a program for implementation of a mobile pharmacy system to improve adherence to antiretroviral therapy in two districts in rural western Uganda.

He is passionate about training and capacity building for Epidemiology and Research Ethics. Currently, he is a PI on a US-Fogarty center supported grant at Mbarara University of Science and Technology to mentor junior faculty. On this grant, he leads the implementation and also serve as mentor, supports research activities and conducts training on scientific manuscript writing and Responsible conduct of research. He is also co-Investigator on the NIH funded new Masters of Public Health program in Research Ethics track at Mbarara University of Science and Technology.

He teaches graduate level courses on Infectious disease control, Epidemiology, Biostatistics, Clinical Trials and Research Ethics and supervises graduate level students, both Masters and PhD. Currently, he serves as the Chair of Research Ethics at Mbarara University of Science and Technology and has served UNCST as Chair of the 2018 Annual National Research Ethics Conference (ANREC) and also chaired and served as member of several UNCST joint reviews.

ABSTRACT

Informed consent is a foundational component of ethical research and ensures that study participants are enrolled in studies voluntarily. The process for obtaining informed consent varies considerably depending on the nature of study participants and study design. Settings such as epidemics present opportunities to examine new research questions, test new products such as drugs and vaccines. However, these epidemics may be a coercive force and hence present significant challenges in obtaining informed consent and maintaining research integrity.

This paper examines the unique challenges posed to the informed consent process when research is conducted during an epidemic such as how informed consent informed consent should be achieved when study participants are in isolation, face stigma or have fear and anxiety due to infection

with an untreatable and highly fatal condition or the study involves a placebo. The challenge to obtain informed consent may be further confounded by heightened individual and community tensions due to suspicion and lack of trust. Community resistance to participate in research has been cited during Ebola epidemics and more recently in the COVID-19 epidemic. What should investigators do when for instance communities at risk for Ebola reject invitations to participate in experimental ring vaccination exercises?

The paper proposes some innovative ways to overcome some of these challenges to ensure that research integrity is maintained. Neglected approaches such as thoughtful ways of community engagement and mobilization may foster community buy-in and enhance a smooth informed consent process. Innovative approaches such as use of surrogates, over the telephone, or use of audio or visual recordings or other digital platforms such as video chat consents or screen shots of consent forms may provide alternate approaches to standard approaches, and need to be considered but may not be without controversy.

PAPER 3: Misconduct in Research publishing: Who is responsible for what at all levels of publication? The role of Journal Editors in assuring the Integrity of Research data

Prof. James K Tumwine, **Prof Emeritus** College of Health Sciences, Makerere University
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Prof. James Tumwine is founder editor in chief African Health Sciences (AHS). He founded AHS in 2001 and since then it has been indexed on renowned platforms such as PUBMED/MEDLINE; WEB OF SCIENCE (Science Citation index); AFRICAN JOURNALS ONLINE (AJOL), AFRICAN MEDICUS INDEXUS etc. He is editor on many international journals including PLOS MEDICINE.

He was recently appointed Emeritus professor at Makerere University College of Health Sciences (CHS); and is supporting learning, research and publication at Kabale University School of Medicine (KABSOM). He coordinated research and publications at Makerere University CHS and chaired the School of Medicine Research Ethics Committee (SOMREC). Currently he serves as the Vice Chairperson on the Infectious Diseases Institute Research Ethics Committee (IDI REC)

ABSTRACT

With the advent of social and other media there has been a proliferation of fake news and dys-information. In fact, the WHO has coined the term "infodemic." Academic journals have a critical role to play, acting as gatekeepers, participating in guarding the integrity of research data.

The presentation will highlight the importance of "good publication practice" by academic journals. Implicitly, it will also touch on the publication process including appropriate (conceptualization) study design, ethical approval, data analysis, authorship, peer review, and misconduct.

PAPER 4: Beyond ethics: Data protection and privacy as a legal obligation for researchers in Uganda

Dr. Adrian Jjuuko, LLD: Chairperson, The AIDS Support Organisation (TASO) Research Ethics Committee
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Dr. Adrian Jjuuko is a Ugandan human rights lawyer, researcher and activist, with over 13 years experience. He is the Executive Director of Human Rights Awareness and Promotion Forum (HRAPF), a legal advocacy and research-oriented organisation. He is the chairperson of the Research Ethics Committee of The AIDS Support Organisation (TASO). He was a 2018 Mandela-Washington Fellow under the Young African Leadership Initiative (YALI) based at the Presidential Precinct in Virginia, USA. He holds a Doctor of Laws Degree from the University of Pretoria.

ABSTRACT

For a long time, the data protection regime in Uganda has been based on easy to disregard ethical principles that were not legally binding. These principles have been laid down in documents such as the Nuremberg Code, 1947, the Guidelines in Helsinki Declaration (1964) and the Belmont Report (1979), and for Uganda's context in the Uganda National Council for Science and Technology (UNCST)'s National Guidelines for Research involving Humans as Research Participants, 2014. However persuasive, esteemed and well intentioned these documents were, they had no legal force in Uganda. Protection was only largely left to the broad and undefined protection of the right to privacy under article 27 of Uganda's Constitution. Indeed, the lack of jurisprudence in Uganda's courts on this subject shows that researchers were largely untouchable and they could get away with violations of data privacy. This has now changed with the coming into force of the Data Protection and Privacy Act, Act No. 9 of 2019 on 3rd May 2019. The Act gives legal force to the principles that have for long guided research in Uganda and beyond. These are: accountability; fair and lawful collection of data; the minimalist principle; the right to be forgotten; quality; transparency and participation; and data security, among others. Informed consent and protection of confidentiality are at the center of the whole scheme of the law. The Act imposes penalties in case of violations of its provisions of up to ten years imprisonment or a fine of up to four million and eight hundred thousand shillings or both or for companies a fine of up to 2% of its annual gross turnover. The Act also gives power to research subjects to sue researchers and other data collectors for compensation in courts of law for violation of their data privacy. This will have serious ramifications for the research industry if the standards are violated. Already research subjects have shown that they can take on the hitherto all-powerful researchers before courts of law. This was recently seen in the case of Mukoda alias Naigaga v International Aids Vaccine Initiative & 11 Ors, (2020) which focused on informed consent. The Act backed up by existing laws such as the Uganda National Council for Science and Technology Act, 1990 send a serious message to persons collecting personal data including researchers to respect and preserve the privacy of research subjects. The Act

is no toothless barking dog as it has established a personal data protection office within the National Information Technology Authority (NITA) to oversee the enforcement of its provisions. This paper analyses the Data Protection and Privacy Act, 2019 with its attendant Regulations and other existing laws, and their potential and actual implications for research integrity in Uganda. It concludes with recommendations to UNCST and other regulators on how to take advantage of the new legal regime in order to ensure that the rights of research subjects are well protected.

PAPER 5: Compassionate Use and or Emergency use of unproven and unregistered products during the COVID-19 pandemic: Looking backward, Moving forward

Dr. Helen Byomire Ndagije, Director Product Safety, National Drug Authority
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Dr. Helen Byomire Ndagije has an accomplished regulatory career as the Director Product Safety and is currently the President of the African Chapter of International Society of Pharmacovigilance. Helen has been part of the organizing committee of ANREC for eleven years running. The World Health Organization (WHO) has frequently used her expertise to advise on regulatory challenges in medicines for treatment and prevention of Ebola, TB, HIV, neglected tropical disease and more recently COVID-19 vaccines at national regional and international level. Over time, she has moved from clinical trial manager of two trials to principal investigator on a couple of grants to streamline clinical research regulation and ethics development capacity in Eastern Africa. Helen has assessed the clinical trial system of Zanzibar Food and Drug Agency using the WHO Rapid Benchmarking tool. She lectures about regulation of clinical trials in the department of Pharmacy at Makerere University. She has served as a board member of the Pan African Clinical Trials' Registry Advisory Group. She was recognized in 2018 by the WHO AFRO Regional Director for spearheading African Vaccine Regulatory Forum, an initiative promoting the collaboration between national ethics committees and national medicines regulatory agencies as a vice chairperson who was also the lead regulators' representative.

ABSTRACT

The context of a public health emergency requires triggering mechanisms for emergency use authorization or conditional marketing authorization by the national medicines regulatory agency. Emergency use authorization refers to a process where products may be authorized for use, based on less comprehensive safety, efficacy and quality data than what would be normally required and where the benefit of immediate availability of the

medicine outweighs the risk inherent in the fact that additional data are still required. However, Uganda's legal and regulatory framework has been adapted based on section 8(4) of the National Drug Policy and Authority Act (Cap 206) to allow importation of medicines and vaccines not appearing in the national formulary to meet emergency or extraordinary circumstances during the COVID-19 pandemic. In response to the pandemic, there has been great interest in developing novel therapies, including the use of repurposed drugs, to treat SARS-CoV-2. Strategies have to be put in place to ensure fast access to existing and novel treatments that show evidence of effectiveness. In such a situation, there is a need for a multidisciplinary and multi-sectoral actions encompassing all health workers like public health officials, policymakers, funders and development partners, researchers, ethics committees, healthcare workers, and public health practitioners as well as key sectors like finance and Governance to put in place different measures to mitigate the spread and risk of the outbreak. In this presentation an assessment of the dynamics of this regulatory pathway is done and solutions on the way forward have been proposed.

Thursday 16th September 2021

PANEL DISCUSSION

Topic: Regional Perspective: Fostering Research Integrity & Responsible Conduct of Research

Panel Members

01

Dr. Martin Patrick Ongol, Acting Executive Secretary, Uganda National Council For Science & Technology (UNCST), Uganda

Dr Martin Patrick Ongol holds a PhD in Applied Bioscience from Hokkaido University, Japan and has over 25 years of professional experience. His areas of expertise include: strategic planning, organizational development, policy analysis, food security, nutrition, food systems, research management, applied microbiology, molecular biology, agricultural development, agricultural market systems development, impact evaluation, and program management.

Currently is the Acting Executive Secretary, Uganda National Council for Science and Technology (UNCST). Previously he was an Advisor with the UK Department for International Development (DFID) leading a £43 million Program, aiming at transforming agriculture in Rwanda through commercialization, research and Innovation. Before joining DFID, Dr Ongol served as the Director of Research, Innovation and Postgraduate Studies, University of Rwanda - College of Agriculture, Animal Sciences (UR-CAVM). As Director of Research, he led in strategic re-orientation and strengthening of UR-CAVM's research and Innovation agenda which resulted into enhanced research impact, greater funding, extensive collaborations and strengthened capacity building initiatives.

From 2015 to 2018, he was the Vice President, East African Research and Innovation Managers Association (EARIMA). At a continental level he was a resource person for Rwanda in drafting of Science Agenda for Agriculture in Africa (S3A). His contributions lead to Rwanda becoming one of the first countries in Africa selected for implementation of the S3A by Forum for Agriculture Research in Africa (FARA). He has won several internationally competitive research grants from The World Academy of Sciences (TWAS), International Foundation of Science (IFS), International Food Policy Research Institute, Swedish International Development Agency (SIDA), EU-ACP secretariat, International Centre for Tropical Agriculture (CIAT), and HarvestPlus. Dr Ongol has authored over 47 scientific papers published in internationally accredited scientific platforms. Two of his research outputs were patented in Japan.

02

Prof. Tatien Masharabu Executive Permanent Secretary, National Commission of Science, Technology and Innovation (STI), Burundi

Prof. Tatien Masharabu is the Executive Permanent Secretary for the National Commission of Science, Technology and Innovation (STI), Burundi. He is a Member of the Governing Board of the East African Science and Technology Commission (EASTECO), and Chairperson for the Eastern Africa Land Administration Network (EALAN). He is also the Team Leader for the Bioinnovate Africa Programme's Project on Plants extracts to prevent malaria in Eastern Africa. Professor at the University of Burundi, Faculty of Sciences, Biology Department. Tatien Masharabu (Ph.D.) is the former Director for Research and Innovation at the University of Burundi, former Director General for Science, Technology & Research, within the Ministry of Higher Education and Scientific Research, Burundi, and former Member of the Inter-University Council for East Africa (IUCEA) Audit Committee. Prior to that, he was the Research Coordinator of the University of Burundi between January and April 2012. Between 2011 and 2012, Masharabu was a member of the Independent Panel of Experts on the "Governance of STI in the East African Community".

Prof. Masharabu holds a doctorate degree in Science from the Interfaculty School of Bioengineering, Université Libre de Bruxelles, Belgium (2011), a Master's degree in Life Sciences (Université Libre de Bruxelles, Belgium, 2007), a Master's degree in Applied Biology (University of Burundi, Burundi, 2004), a Bachelor's degree in Biological Sciences (University of Burundi, Burundi, 2002). He has, so far, authored and co-authored several scientific papers in peer-reviewed as well in Conference proceedings in the fields of Botany, Landscape Ecology, Climate change and Biodiversity conservation, Land and Natural Resources Administration, and STI outlook.

03

Mr. Boniface Wekesa Wanyama, Director for Research, Accreditation and Quality Assurance, National Commission for Science, Technology and Innovation, (NACOSTI), Kenya

Mr. Boniface Wekesa Wanyama is the Ag. Director for Research, Accreditation and Quality Assurance at the National Commission for Science, Technology and Innovation (NACOSTI), Kenya. He heads matters related to the quality assurance of research which includes: Heading the Secretariat of the National Bioethics; Accreditation of Institutional Ethics Review Committee; Registration and Accreditation of Research Intuitions and Monitoring and Evaluation of Research Projects. He has work experience in Bioethics and Research Ethics spans for over eighteen (18) years. He has hosted and participated in regional and international Conferences on Bioethics and research ethics.

On an international front, he served (2011-2015) as the Deputy National Coordinator for the African Regional Cooperative Agreement for Research, Development and Training related to Nuclear Science and Technology, the UN body responsible for peaceful application of atomic energy. He is also a member of the Governing Council of the African Centre for Technology Studies, a Regional Science and Technology Think Tank. Mr. Wekesa has held high international positions including being a Vice-Chairman of the Social and Human Sciences Commission at the UNESCO General Conference (2009); part of the Kenyan delegation to the Executive Board of UNESCO (2009-2010); and Kenya's representative to the Intergovernmental Bioethics Committee of UNESCO (2009-2013). He is also a national trainer in research ethics.

04

Dr. Amos Nungu, Director General, Tanzania Commission for Science and Technology (COSTECH), Tanzania

Dr. Amos Muhunda Nungu is the Director General of the Tanzania Commission for Science and Technology (COSTECH). Dr. Nungu has held various managerial and professional responsibilities including: The Assistant Director – Directorate of Science, Technology and Innovation at Ministry of Education, Science and Technology; and Head of India – Tanzania Centre of Excellence in ICT at Dar es Salaam Institute of Technology. He has initiated, managed and participated in many projects, including those under the European Union (FP7 & H2020), the Swedish International Development Cooperation Agency (SIDA) and the Norwegian Agency for Development Cooperation (NORAD).

He has also saved as a Board member at the Muhimbili University of Health and Allied Sciences (MUHAS), and Mbeya University of Science and Technology (MUST). Dr. Nungu holds a PhD and MSc. degrees in Information Technology (Communication Systems) from the Royal Institutes of Technology (KTH) – Sweden; and a BSc. in Computer Science from University of Dar es Salaam.

05

Dr. Solomon Benor, Director General for Science & Research Affairs, Ministry of Science and Higher Education, Ethiopia

Dr. Solomon Benor is the Director General for Science and Research Affairs at MoSHE, he has substantial science leadership experiences with the following activities; conducting policy-oriented research on national prioritized STI sectors; setting policies and strategies that enhance science, science culture, research, and research ethics at higher education institutions; providing professional support in resource mobilization and partnerships development in STI; leading the evaluation and accreditation system of national scientific journals; overseeing and developing policy on national Science, Technology, Engineering and Mathematics

(STEM) education; networking universities with private and public, industry and research community in Ethiopia; and providing various capacity building programs in research, science, technology and innovation.

Dr Solomon has over 24 years of research experiences in biodiversity conservation, plant biotechnology, plant breeding, and environmental sciences. He has extensive national and international research work experiences, namely he worked as a Post-Doctoral Scientist at BecA-ILRI HUb in Nairobi, Kenya; Research Fellow at Leibniz Institute of Plant Genetics and Crop Research in Gatersleben, Germany; TWAS Research Fellow at Nanjing Agricultural University in Nanjing, China; Researcher at Norwegian Institute of Gene Ecology in Tromsoe, Norway; Lecturer at Hawassa University, Ethiopia; and Plant Breeder at Sirinka Agricultural Research Center, Ethiopia.

Dr Solomon has produced several scientific papers published in peer-reviewed journals and proceedings. Educational backgrounds of Dr Solomon include PhD in Plant Molecular Genetics at Kassel University, Germany; M.Phil in Plant Molecular Biology at Tromsoe University, Norway; BSc in Plant Sciences at Haramaya University, Ethiopia; and Diploma in Animal Sciences at Addis Ababa University, Ethiopia.

Dr Solomon served as editorial member and associated editor for the Ethiopian Journal of Crop Science, and Abyssinian Journal of Science and Technology. Currently, Dr Solomon is Board member of Haramaya University; member of the Ethiopian Biotechnology Society, Ethiopian Crop Science Society, and Biological Society of Ethiopia.

06

Dr. Eugene Mutimura, Executive Secretary
National Council for Science and Technology
(NCST), Rwanda

Dr. Eugene Mutimura is a Rwandan scientist and researcher. He is currently the Executive Secretary of the Rwanda's National Council for Science and Technology (NCST). Prior to this appointment, Dr Mutimura served as the minister of education of the Republic of Rwanda. Prior to his appointment as minister of education, Mutimura coordinated the Eastern and Southern African Centers of Excellence project funded by the World Bank in eight countries, to support research and education in sixteen universities. He was a recipient of the Fulbright Scholarship He obtained his doctoral degree from the University of Witwatersrand, Johannesburg 2007 and previously worked at the Regional Alliance for Sustainable Development.

07

Prof. Elijah Malinga Wanda, Director General,
National Commission for Science and
Technology (NCST), Malawi

PAPER 1: A global perspective on research integrity in natural products research and development: Lessons for Uganda

Dr. Barbara Mugwanya Zawedde, PhD, Director of Research, National Agricultural Research Organization (NARO), Mukono Zonal Agricultural Research and Development Institute
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Dr. Barbara Mugwanya Zawedde, is the Director of Research, National Research Organization (NARO), Mukono Zonal Agricultural Research and Development Institute. She is the former Vice Chairperson Uganda Biotechnology and Biosafety Consortium, Coordinator Uganda Biosciences Information Center, Senior Knowledge Management Officer of NARO. For 17 years, she participated in the formulation of the National Biosafety Framework for Uganda, and some other African Countries. Part-time Lecturer for Biosafety, Bioethics and Biopolicy Course for Postgraduate Program at College of Agricultural and Environmental Sciences, Makerere University. Currently she is the Chairperson for the NARO Institutional Biosafety Committee, Member of the NARO Institutional Animal Care and Use Committee, Delegate to the International Convention on Biological Diversity.

Dr. Barbara Mugwanya Zawedde, has a PhD (Major: Plant Breeding, Genetics and Biotechnology; Minor: Environmental Science and Policy), Certificates in Science Communication, Intellectual Property Management and Technology Transfer, and Certificate in Project Management, MSc (Crop Protection), BSc (Agriculture), Certificate in e-Technology Computing

ABSTRACT

Research integrity is pertinent to make sure that research is conducted according to the highest standards of practice including minimizing adverse effects to the subjects and receivers of the outcomes. Globally, the areas of research integrity and research ethics are receiving increased attention from scientific governance. This is attributed to increasing cases of research misconduct and other forms of ethically questionable behaviors being reported. The most common questionable research related practices include fabrication and falsification of methods and results, selectively citing literature, lack of informed consent from participants and subjects, subjects' safety issues and plagiarism. The causes responsible for the declining research integrity in research can be categorized as individual factors, and institutional environments shaped by policies plus requirements of journals and funding agents. Integrity issues related to product development especially natural products include ownership, intellectual property management, access and benefit sharing, and involvement of private sector. The task to enhance research integrity has required adoption of innovative, collaborative and coordinated approaches. Some of the approaches used are to address individual "bad apples" and to improve the institutional environments by different research governance bodies are shared this paper.

PAPER 2: Ethical Issues for Life Sciences, and Research Involving Animals as Research Subjects

Dr. David Lewis Senior Lecturer Pharmacology & Bioethics, University of Leeds, UK
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Dr Dave Lewis is a Senior Lecturer (Associate Prof) in Pharmacology and Bioethics at the University of Leeds, UK. With over 35 years' experience of the use of animals in research, he is an international recognised expert in education and professional education in research animal sciences, welfare and ethics. He has Chaired the International Union of Basic and Clinical Pharmacology's Integrative & Organ Systems Pharmacology Initiative for 11 years, working with Professional and Regulatory Bodies, and NGO's in India, China and across Africa to co-create and co-deliver professional education in research animal sciences and ethics. He has received multiple awards including a UK Advance HE National Teaching Fellowship, and Fellowship of the British Pharmacological Society & its Zaimis Prize for his exceptional contribution to pharmacology education globally.

ABSTRACT

Animals have been used in scientific and medical research for over 2,000 years. Their use provokes strong emotions, from those fundamentally opposed to others fully supportive. This presentation will consider the ethical issues surrounding the involvement of animals in research, the viewpoints of different stakeholders globally, and the influence of culture and Society on these different perspectives.

In the author's view, the use of animals in research is a privilege not a right. If there is no alternative to their use to achieve the same scientific outcomes, researchers should be minimising the harms to their research animals through application of the principles of humane experimental technique (The 3Rs: Replacement, Refinement & Reduction of the use of animals in research). He will outline these principles, discuss the extent to which they are applied across the world, and provide examples of how, by not considering animal welfare, data from research animal studies becomes meaningless. It is neither reproducible, reliable nor translatable to humans. He will share the concept of an Institutional or Organisational "Culture of Care", and the need for all those involved in the care and use of research animals to buy into and fully engage with this.

PAPER 3: Background & process of development of National Guidelines for Use of Animals in Research and Teaching

Dr. Lawrence Mugisha Associate Professor, Makerere University Team Leader, Eco-Health Research Group
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Dr. Lawrence Mugisha is Associate Professor, College of Veterinary Medicine, Animal Resources & Biosecurity (COVAB), Makerere University; Adjunct Professor, College of Veterinary Medicine (CVM), University of Minnesota and Mississippi State University, USA and a Team Leader for EcoHealth Research Group under Conservation & Ecosystem Health Alliance (CEHA).

Mugisha holds a Bachelor of Veterinary Medicine (2000), Master of Science in Wildlife Health and Management (2004), PhD (2011) focusing molecular diagnostics of infectious diseases in great apes. Mugisha has over 16 years of experience in zoonotic disease research at human, livestock and wildlife interface, Uganda. His current research areas include: Zoonotic neglected pathogens (Leptospirosis and Brucellosis); Tick-borne Pathogens (Tick Microbiome), COVID-19, and Antimicrobial Resistance (AMR) at human-livestock and wildlife interface.

Mugisha has served on several national and internationals committees in the field of science, research and governance. Currently, he is a member of Scientific Committee on Presidential Scientific Initiatives on Epidemics (PRESIDE), Committee Member on National Biosafety Committee (NBC), UNCST, Chairperson, Institutional Animal Care and Use Committee (IACUC) to be Accredited, SVAR, Makerere University. More recently, he was a Chairperson National Taskforce for Developing National Guidelines for use of animals in research and teaching.

ABSTRACT

Use of animals in research and teaching has contributed to major breakthroughs in drug discovery and development, understanding of biological and physiological process and validating safety and efficacy of several therapeutic drugs in humans and animals. However, continued use of animals in research requires valid scientific justification and ethical considerations under well established policies and ethical guidelines. Most countries in Low- and Middle-Income Countries (LMICs) in Africa including Uganda lack comprehensive legal and policy frameworks for use of animals in research. Hence, Uganda National Council for Science and Technology (UNCST) in recognition of the existing gap, initiated the process of establishing the National Guidelines for Use of Animals in Research in November 2018. UNCST appointed a National Taskforce (NTF) of 18 members composed of multidisciplinary professionals from veterinary, medicine, social sciences that led the drafting of the guidelines.

The NTF developed the guidelines by reviewing several international and national documents and publications in animal welfare, guidelines, policies and laws. The NFT conducted several write shop meetings and workshops that led the development of the draft guideline that was subjected to reviews by stakeholders and designated reviewers. The final version of the guidelines was presented to UNCST Management Board that approved the guidelines in January, 2021. The approved National Guidelines for Use of Animals in Research and Teaching will help scientists, research and academic institutions to establish ethical committees, standard operating procedures that will facilitate ethical use of animals in research while observing and maintaining their welfare.

RESEARCH REGISTRATION & CLEARANCE PROCESS

The goal of the uncst strategic plan [2020/21-2024/25] is utilizing research to drive innovations for improved household incomes and sustainable livelihoods for all ugandans. in achievement of this goal, a sound ethical environment for research and technology investment is paramount in uganda. research ethics approval is designed to ensure that a particular research project meet relevant ethical and scientific standards. sections 4 and 5 of the uncst act (cap 209) mandates uganda national council for science and technology (uncst) to acts as a clearing house for all information on research and experimental development in uganda. within this framework, the uncst registers and issues research permits to all persons intending to carry out research in uganda.

Oversight of research is done first at the institutional level by Research Ethics Committees (RECs), Institutional Animal Care and Use Committees (IACUCs), Uganda Wildlife Authority (UWA), National Forest Authority (NFA) and any other authorized lead agencies then second at the national level by the Uganda National Council for Science and Technology (UNCST) in collaboration with Uganda National Health Research Organization (UNHRO). UNCST liaises with the research secretariat, office of the President to obtain security verification and clearance for the researcher. An additional requirement with regard to clinical trials is for the researcher to obtain a certificate from the National Drug Authority (NDA) in respect of a trial drug.

The UNCST developed and has implemented the National Research Information Management System (NRIMS), which is an E-regulatory system that supports national regulatory agencies in data capture, data management, data validation, quality control as well as ensure regulatory compliance of all research in Uganda. The system also ensures that regulatory agencies are efficient in coordinating high quality review of research protocols, and that they adhere to stipulated turnaround time for protocol approvals.

The national research clearance process is stipulated below;

STEP 1

Submission is made /Uganda Wildlife Authority (UWA)/National Forestry Authority (NFA)/Department of museums and monuments /National Biosafety Committee (NBC) for scientific assessment and then to a local Research Ethics Committee (REC) and or Institutional Animal Care and Use Committee (IACUC) for scientific and ethical approval.

For submission to the REC, please contact the accredited committee at your institution of affiliation or obtain contacts via the UNCST website at the following link: https://www.uncst.go.ug/research-ethics-committee-accreditation/. The proposal and all data collection tools including consent forms (where applicable) should be submitted for review.

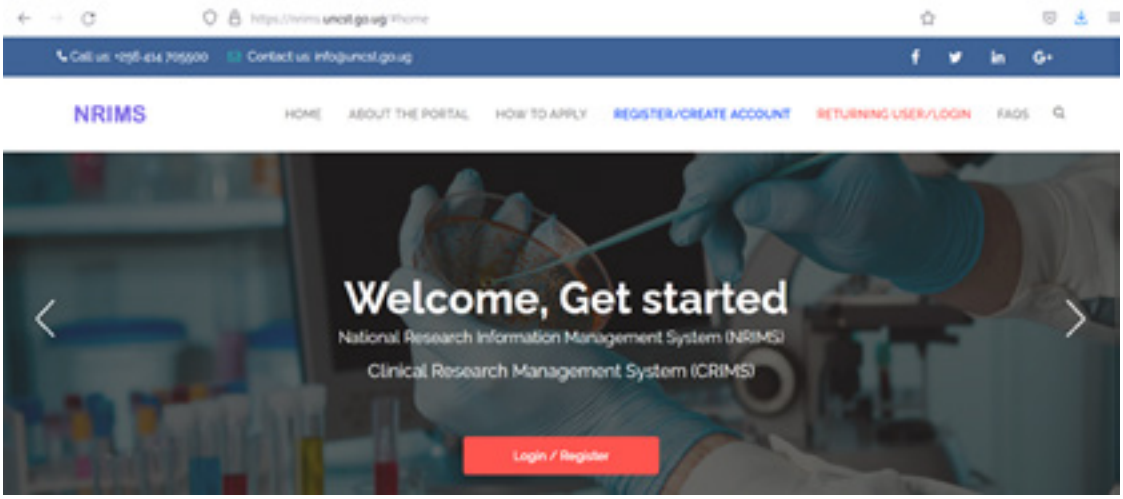
After identification of the appropriate REC or IACUC, the researcher may go ahead and create an account and fill out the appropriate requirements for review in the National Research Information Management System (NRIMS): *https://nrims.uncst.go.ug/ .*

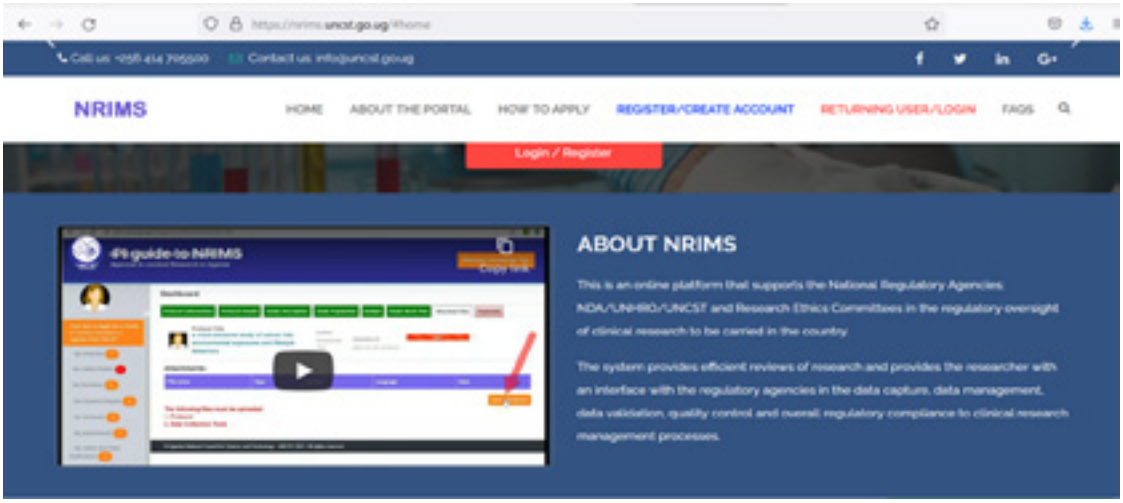
STEP 2

Once approval is obtained, just with a click of a button the submission is made to the UNCST. The PI should have soft copies of the documents below ready before making a submission;

a) Letter of introduction/recommendation from the organization of affiliation in Uganda (***for foreign investigators only***). The letter should mention the names of the foreign investigators and it should be addressed to the Executive Secretary, UNCST.
b) An administrative clearance letter from the head of the organization where the research is going to be conducted. This should be addressed to the PI or Executive Secretary, UNCST.
c) Admission letter for academic research (this applies to only East African students)
d) CVs for each investigator on the study team. The CVs should be dated and signed or initialed on each page
e) Proof of payment of research administration and clearance fees for the study. The fees are as follows;

Amount	300 US Dollars or 50 US dollars for East African Students *(except those pursing post doc studies and fellowships)*
Bank	Any Standard Chartered Bank
Account Name	Uganda National Council for Science & Technology (UNCST)
Account No.:	8705611811400 *(US Dollar account)* 0105610632101 *(Uganda shillings account)* *use the prevailing bank rate*
Swift Code:	SCBLUGKA





STEP 3

UNCST makes submission of RS6 forms on behalf of the researcher to research secretariat, office of the President to obtain security verification and clearance to study districts.

Note: An institution that wishes to transfer human/plant/animal materials for research and or further investigations, must obtain an export and import permit from the UNCST.

3.0 RESEARCH ETHICS COURSES OFFERED BY UNCST

The Uganda National Council for Science and Technology (UNCST) by virtue of its mandate provides a national framework for regulating the conduct of research involving humans as research participants in the country. And anyone who wishes to conduct research involving humans as research participants should be knowledgeable in research ethics. The UNCST therefore offers research ethics trainings to equip research teams with knowledge and skills to conduct of research in a responsible manner. Some of the short courses offered include but not limited to; Human participant Protection Course (HPPC), Responsible Conduct of Research (RCR) and Good Research Regulatory Practice Course (GRRP).

The courses are most suitable for Investigators, Research Ethics Committee members, research regulators; policy makers, students, regulatory affairs coordinators, project managers, research administrators, study unit heads, study coordinators, study counselors, scientists, research data managers, research assistants, REC administrators, study pharmacists etc. The courses are intended to equip trainees with basic knowledge in research ethics and enhance their capabilities to address associated ethical challenges that may arise in various research activities.

1. Human Participant Protection Course (HPPC)

The HPPC is intended to improve the quality of research protocols submitted for REC review, improve the quality of ethical review by the RECs, improve researcher's and regulators adherence to good ethical practices. The expected learning outcome is increased protections for human research participants and their communities.

Course Content

The course covers the following topics;

1. Evolution of research ethics
2. Research designs
3. Principles of research ethics
4. Regulatory system of research in Uganda
5. Responsibilities of investigators, sponsors and host institutions
6. Care for participants in research
7. Informed consent process
8. Monitoring and reporting protocol events
9. Conflicts of interest
10. Research ccompliance audits and monitoring
11. Good ethical Review
12. Bio-banks, data ownership and use
13. Risk Benefit Assessment in Research

2. Good Research Regulatory Practice Course (GRRPC)

The GRRP course provides a framework for imparting best research regulatory practices to the trainees by creating awareness and application of established professional, ethical and legal provisions in enforcing research integrity. GRRP equips trainees with knowledge to become efficient, reasonable and responsible research regulators by enhancing their capacity to identify, manage and prevent research integrity glitches as well as provide support to research teams to nurture research integrity.

Course Content

The course covers the following areas and topics:

1. Evolution research ethics guidelines and regulation: lessons learnt from past cases
2. Purpose elements of a research protocol and study designs
3. Effective review and monitoring of informed consent in research
4. Effective review and monitoring of informed consent in research
5. Legal and human rights issues in research
6. Data Sharing
7. Key considerations in collaborative research (Investigator, authorship, capacity building, technology transfer, MTAs, intellectual property)
8. Common Ethical Issues in Specific Social Science Research Method
9. Conflict of interest in research and research regulation
10. Introductory Aspects in Clinical Research Jurisprudence
11. Quality review of a research protocol
12. Getting the best out of an IRB meeting
13. Considerations of research integrity by regulatory bodies
14. Prevention and management of legal liability in research
15. Communication in research regulation
16. The role of the regulators in ensuring rights, welfare and care of participants
17. Research compliance monitoring
18. Framework/Criteria for Identifying and Weighing Ethical Issues in Social Research
19. Issues surrounding study close out in Social Sciences research

3. Good Clinical Practice course (GCP)

Good Clinical Practice is an international standard for clinical trials that ensures that the rights, safety, and well-being of clinical trial participants are protected and that the clinical trial data are credible. The principles of GCP help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. This course aims to provide the researcher and research teams with the basic principles of GCP and how these principles can be applied practically in the research setting.

The GCP training aims to ensure that; the rights, safety, and well-being of human subjects are protected, clinical trials are conducted in accordance with approved plans with rigor and integrity and data derived from clinical trials are reliable.

Course Content

1. Research Team
2. GCP Principals and ICH Guidelines/Research Historical Perspective
3. Regulatory system of research in Uganda & Requirements
4. Sponsor's Responsibilities
5. IRB/REC Responsibilities
6. Investigator's Responsibilities
7. Investigational product
8. Source /Essential documentation
9. Informed Consent process
10. Research Quality Management
11. SAE identification, Management and reporting
12. Study Protocol, Amendments /Deviations & Violations
13. Care for research participants in research
14. Risk Benefit assessment in research

The courses area delivered face to face between the tutors and the trainees. It involves brief presentations, cases studies and small group exercises and is conducted for a period of four (4) days. A reasonable course fee is charged. Tailor– made courses and or training are offered as well.

Special arrangements can be made to deliver the courses upon request by a particular group or institutions. An interested institution can write to the Executive Secretary UNCST requesting for the training.

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

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