ARESA

ADVANCING RESEARCH ETHICS
TRAINING IN SOUTHERN AFRICA

NEWSLETTER

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Dear REC Members

We are delighted to circulate this issue of the ARESA Newsletter to you. The 10th Annual ARESA Research Ethics seminar was held at the Radisson Blu Hotel at the Waterfront on 27 October 2022.
In keeping with emerging challenges in Research Ethics, the ARESA seminar was themed: Data Ethics for Research Ethics Committees (RECs) and Researchers. This newsletter highlights various proceedings through summaries of the plenaries. National and international speakers were invited to discuss current and pertinent topics related to Data Science and Ethics. This event heralded a new era in research ethics for delegates from various countries in sub-Saharan Africa. We were delighted to welcome back so many graduates of the ARESA program (2011-2017).

We wish you happy reading!

HIGHLIGHTS FROM THE 10TH ANNUAL ARESA RESEARCH ETHICS SEMINAR

27 October 2022

For the first time in its history, the ARESA seminar was hybrid. This year, 87 delegates from various Southern African Research Ethics Committees (RECs) attended the in-person annual seminar There were 3 plenary sessions namely, **Challenges for Research Ethics Committees (RECs), Data Literacy and Stakeholder Engagement and Data Sharing in An Era of Digitalization: Low- And Middle-Income Countries.** At the end of each plenary session, the speakers engaged with attendees in a panel discussion.

The first plenary session titled 'Challenges for Research Ethics Committees (RECs)' was chaired by **Prof Stuart Rennie** who is an Associate Professor in Social Medicine at the University of North Carolina (UNC) at Chapel Hill (USA). The panel discussion was led by **Effy Vayena**, a Professor of Bioethics at the Swiss Federal Institute of Technology (ETHZ), **Nezerith Cengiz**, a Research Assistant and **Keymanthri Moodley** a Professor of Bioethics at Stellenbosch University.

Health data can fuel the transformation of the health sector towards 21st century treatments and care, to respond to public health challenges, to improve health systems and to allow for scientific discovery. Health data can help change how health systems work. As there can be a shift towards prediction and prevention that can help reduce costly treatment interventions. However, there needs to be appropriate health data governance to enable secure and privacy-protective data uses. Prof Vayena provided an overview of the Swiss Personalised Health Network. The Network's aim was to enable nationwide accessibility and exchange of health data of patients and healthy citizens.

Data Driven Health Research: The Swiss Framework for Responsible Data Processing
–Prof Effy Vayena

It required the establishment of coordinated data infrastructures to make health data available, interoperable, and shareable for research in Switzerland. There was a need for ethical guidance and a framework was developed for responsible data processing. Guidance was produced through a review of literature around data sharing and data access, which elicited 230 documents from 32 different organizations. They searched for principles and guidelines in available literature and documents.

Policy themes were identified, and the most common themes were data quality and curation, autonomy (consent) and privacy. Some Less common principles identified included solidarity and sustainability, which highlighted that autonomy and privacy principles were most important. Guidelines were derived from these principles. For respect for persons, guidelines that were developed included: consent, broad consent, communication of clinically actionable findings, mechanism for revocation of consent, and the return of results if requested. This research highlighted important differences between what stakeholder groups might consider appropriate in terms of data processing and sharing. For privacy and confidentiality, guidelines included: following existing guidelines for data security, and motivation for sharing data.

Exploring REC Perspectives on Data Governance in Sub-Saharan Africa

– Nezerith Cengiz

Data governance is the practice of safeguarding information and includes legal and ethical frameworks that govern data transfer and sharing. Data sharing in research is becoming more common and there is an increased need to safeguard data. It is unclear how RECs in Sub-Saharan Africa (SSA) navigate data governance and review data intense protocols. A descriptive cross-sectional study of REC members in SSA was conducted. The survey instrument was piloted on REC members from Stellenbosch University and included open and closed questions. Three hundred individuals were invited to take part and 140 responses, from participants based in 34 SSA countries, were received. The majority of respondents were male, with 46% of respondents holding a doctoral degree. Overall, there was an awareness of data protection and restrictions on trans-border flows of research. Forty percent of respondents indicated that national restrictions on trans-border flow of data were adequate. There was higher awareness of MTAs than DTAs, and 74% of respondents indicated that RECs were responsible for reviewing these agreements. Fourteen percent of respondents indicated receiving no training regarding the review of data sharing protocols and 64% of respondents indicated difficulty in reviewing data intense protocols.

Seventy-one percent of respondents felt that data sharing could be better regulated, and 64% of respondents did not have data access committees. Limitations included a predominance of responses from specific SSA countries, and the internet-based nature of the survey may have excluded those without internet access. In conclusion, these study findings indicate variability in data governance and regulation across different countries in SSA, as well as variability in REC members' perceptions of national laws and institutional policies. There was a unanimous need for training in data governance. In addition, RECs would benefit from reformation to improve data governance and review.

ASSAf Code of Conduct for Research: Fit for Purpose?

– Prof Keymanthri Moodley

There has been much discussion in South Africa over the past few years regarding data protection legislation. The POPI Act No 4 of 2013 attempts to balance the right to privacy, the right to access information and the right to freedom of expression, with public interest. When considering the POPI Act, it is important to distinguish between data and information.

While the POPI Act applies broadly to research, some types of research are exempt. De-identified information (that cannot be reasonably re-identified) and information from deceased persons is excluded according to the Act. The Code has interpreted de-identified data as anonymized data; however, it recognizes that it might not be possible for data to be fully de-identified given that multiple, voluminous data sets exist and could be linked. Genomics data is also difficult to anonymise. The Code recommends that the POPI Act should be followed even for de-identified data.

The concept of the responsible party is important to understand. A responsible party can be juristic (research institution) or a natural person (a researcher) and there may be multiple responsible parties. This has significant implications for litigation. The POPI Act refers to data subjects who may launch legal action if they feel their data has not been used appropriately and that this has resulted in harm. Importantly, the Code also refers to a risk assessment of research projects. Examples of issues that should be considered in a risk assessment include children or vulnerable groups, specific personal information, automated decision-making, data collection from other sources, disclosure to third parties, access to other countries, and any unique identifiers.

Another important concept in both the Code and the POPI Act is the concept of minimality, that is collecting the minimal amount of data needed to answer research questions.
In terms of the Code and the Act, the collection of data on race, gender, ethnicity and age must be justified as being specifically needed for research. However, this may lead to a clash between funder requirements and the POPI Act. Issues of consent are also critical, and the Code clearly differentiates between regular consent for research and POPIA consent. Many argue that the Code ought to provide a template for data transfer agreements as an annexure. Data is fed into algorithms for artificial intelligence, and it is therefore essential that data are collected in a robust and unbiased way. The Code is important for all researchers and REC members to read and understand.

(Rapporteur: Prof T Burgess)

The second plenary session titled 'Data Literacy and Stakeholder Engagement' was chaired by **Dr Alwyn Mwinga** who is a Physician trained at the University of Zambia with a special interest in bio-ethics. The panel discussion was led by **Suzanne Day**, an Assistant Professor at the University of North Carolina (UNC), **Dr Nair**, (Senior Lecturer) and **Dr Obasa** (Lecturer) at CMEL Stellenbosch University and **Dr Chingarande** a visiting Fellow in the National Institutes of Health (NIH)

The Ethics of Crowdsourcing?

– Assistant Prof. Suzanne Day

Prof Day highlighted the ethical red flags raised in data science from a data justice perspective such as biased algorithms, surveillance for control/exclusion and the unequal distribution of risks. She explained that crowdsourcing involves having a group attempt to solve a problem and then sharing /implementing the solutions that emerge – she gave examples of crowdsourcing initiatives such as the Sydney Opera House Design Contest, the LEGO Ideas Platform and the OBSSR Scientific Priorities at the NIH. Suzanne also observed that there are several barriers to public involvement using crowdsourcing which include lack of data literacy/transparency; growing gap between experts and public; inability to opt out; lack of consent to participate in crowdsourcing.

The main challenge of crowdsourcing is how to foster community engagement in data science since it is not widely understood, and there is lack of transparency. As such, she emphasized that there is a critical need for community engagement in crowdsourcing to narrow the information gap; incorporate community values and concerns; and address unanticipated risks. She recommended that community engagement in crowdsourcing should be tailored to the local context, be meaningful, acceptable, and feasible within the context where crowdsourcing is being implemented. In her opinion, community engagement could result in stakeholder driven and acceptable perspectives. However, she observed that there are some cautions and limitations to community engagement in crowdsourcing such as "who (and how) we engage will impact the kinds of ideas we receive; how even is the playing field for participation in crowdsourcing on data science research and to what extent will participants benefit from sharing ideas." Prof Day also noted that crowdsourcing has several benefits which include having an inclusive approach: ensuring a bottom-up approach to problem-solving (vs a top-down approach) and ensuring engagement of the community in problem-solving. In conclusion, Prof Day discussed the different ways of mitigating ethical risks in crowdsourcing such as: involving community in organizing crowdsourcing; including multiple ways to submit ideas: ensuring community representation in evaluation; sharing ideas widely for community benefit and involving finalists in the implementation stage (co-creation).

Perspectives of South African Research Participants on Data Sharing and Community Engagement for Big Data Health Research

– Dr Nair and Dr Obasa

In Dr Nair's presentation, she highlighted the big data sources for health research such as digital devices and health records. She also observed that the main challenge of big data is the lack of awareness of uses of data. She highlighted other ethical challenges of big data such as data ownership; bias and discrimination; privacy, confidentiality and safety and community engagement. In her presentation, Dr Nair defined crowdsourcing as an open call through a challenge contest/hackathon which intends to obtain collective wisdom/a wide range of skills.

She then explained the aims of the REDSSA Crowdsourcing Project which were to solicit feedback from stakeholders on the mechanisms of community engagement; to get feedback to inform the development of community education tools for Big Data health research and to assess the level of comfort of research participation. The REDSSA Project included study participants >18 years who were enrolled in a research study at FAMCRU.

The second presenter on this topic was Dr Emmanuel Obasa. He explained the results of the study. He described participant characteristics specifying that 23 participants were enrolled into the study between 19 September and 20 October 2022. Most participants were in the age range of 18 – 35, 91% of participants were males; 52% of participants had attended high school; 43% of participants accepted the future use of de-identified routine health data; participants also suggested different strategies for engaging communities such as the use of digital technology and social media platforms to bring awareness and engagement; the use of print media and face to face community meetings. The findings revealed that community engagement and education were needed in this area; that the participants demonstrated understanding of their communities and their needs; that the participants appreciated that a "one size fits all" approach would not work; and that a gap in knowledge among experienced research participants exists.

Public Engagement in Data Intense Research

– Dr Rugare George Chingarande

Dr Chingarande explained the Target Pregnancy Predictor Algorithm used in the United States to accurately predict women's childbirth risk. George highlighted that Target did not have a license to conduct market research and it did not adhere to the ethical principles in conducting the research. Regarding community and participatory research, he emphasized the need for community engagement and its value in the research process in that it builds trust in the research process/researchers, and it ensures community participation.

He observed that where there is no community engagement, research messages can be misinterpreted, or intentions misconstrued. He described the four "Multiheaded Disengagement Monster"

- Researcher-Participant Disengagement,
- Participant-Research Project Disengagement,
- Participant-Participant Data Disengagement
- Intra-Organizational Disengagement.

George described the different characteristics of good public engagement such as purpose driven, transparency of process, dialogic communication, inclusivity, impact orientation-begin with the end in mind, continuous evaluation, cost-effectiveness and empowerment. In conclusion, he indicated that "data intense health research will unleash and accentuate disparities of inequities the scale of which the world has never experienced and cannot even begin to fathom."

(Rapporteurs: T. Mtande and F. Masiye)

The third plenary session titled "Data Sharing in an ERA of Digitalization: Low-and-Middle-Income Countries" was chaired by **Walter Jaoko** who is a Professor of Medical Microbiology and Tropical Medicine at the University of Nairobi. This panel discussion was led by **Stuart Rennie**, an Associate Professor in Social Medicine at UNC at Chapel Hill (USA), A/**Prof Wim Delva and Prof. Hassan Mohammed** from Stellenbosch

Consent or Pseudo-Consent in Terms and Conditions for Data Sharing

– A/Prof. Stuart Rennie

Location data derived from cell- and smartphone activities show patterns of human movement that can be vitally important for public health research. For example, how people moved during the COVID-19 pandemic, as revealed through their phones, can be correlated with stay-at-home mandates and other public health measures. This can help determine to what extent the public adhered to these measures, which can be useful for future public health emergencies. But phone-derived location data can have many other public health-related research uses and benefits, such as disease transmission tracking or air pollution exposure. One ethical issue about the public health research use of phone-derived location data concerns informed consent.

Although there are exceptions, typically when data is collected from an individual for research purposes, the individuals are asked for their consent or are at least explicitly notified about this use of their data. In the public health research use of location data, the location information collected passively, i.e. whenever users move and make use of their phones. Users do not have to 'do' anything to make this happen, including explicitly consenting for this to occur.

Most people do not even know if it is happening. It is enough that they agreed to the 'terms and conditions' (Ts and Cs) of the contract they agreed to when they subscribed to a mobile phone operator, which typically (and vaguely) states that data may be used for 'research' or by 'third parties.' Using phone-derived location data for public health research gathered on the basis of 'Ts and Cs' raises a number of ethical issues. It is not difficult to argue that the standards for agreeing to 'Ts and Cs' are much lower than those for consenting to health research generally. Ultimately, it might be better to call it pseudo-consent. Is this a problem, and if so, what should be done about it? Should 'Ts and Cs' be made more explicit when it comes to the research collection and use of location data, i.e. should they be made more like informed consent processes? Or is this approach futile, and we should focus our ethical energies instead on how this passively collected (and potentially revealing) location data is used and shared?

Identifiable Information and Precision Prevention in the Time of COVID-19: Challenges and Opportunities

– Assoc Prof Wim Delva

The World Health Organization's guidance on Ethics & Governance of Artificial Intelligence (AI) for Health presents six consensus principles to ensure AI works to the public benefit of all countries. These include that "AI should be intelligible or understandable to developers, users and regulators" and that "AI used in health care is designed to encourage the widest possible appropriate, equitable use and access, irrespective of age, gender, income, ability or other characteristics". These are clearly principles that are worthwhile pursuing. "However, I wish to critique the implicit narrative is that human intelligence and the "traditional" technology that is currently in use in medicine is interpretable, explainable and equitable, and that AI is at risk of not meeting these criteria."

Sharing of Public Health Data in South Africa

– Prof. Hassan Mohammed

Both the COVID-19 pandemic and the enactment of the Protection of Personal Information Act (POPIA) have raised questions about the use of routinely available personal health data.

Questions about public health versus individual rights are part of these debates. All health systems are required to collect individual data (patient folder – legal document) and report on performance (aggregated data) – auditable through the Auditor-General's office.

Prof Mohammed said health care practitioners should ensure that patients are aware that personal information about them will be shared within the health care team - and patients must be told the reasons for this. The health care practitioner must make sure that any recipient to whom personal information about patients is disclosed, understands that it is given to them in confidence, which they must respect. In situations, where health care practitioners have considered all the available means of obtaining consent, personal information may be disclosed in the public interest where the benefits to an individual or to society of the disclosure outweigh the public and the patient's interest in keeping the information confidential.

He acknowledged that more work needs to be done to increase patient awareness of use of data – through posters and information leaflets at health facilities. There should be provision for an opt out option – which might be challenging and not practicable.

Also, there is a need to strengthen governance, and clarify when individual permission/ consent is needed for use of data. Large amounts of personal health data are captured via electronic databases. These data can be an amazing resource to enhance patient management, track health system performance more accurately and for research/knowledge generation. It is important to obtain consent for the use of data or at the very least, patients should be made aware of how data might be used. Nevertheless, data protection/ patient confidentiality remains paramount except where public interest considerations apply.

(Rapporteurs: A/Profs V. Chalwe and J. Ochieng)

Take-home points from panel discussions

Data collected, stored and inputted into algorithms for artificial intelligence must be robust and unbiased.

The Code of Conduct and the POPI Act is important for all researchers and REC members to read and understand. However, it is also unclear if the Code will provide a template for DTAs.

We have entered an era with an enormous amount of data which has become a resource; however, data protection and patient confidentiality remain paramount except where public interest considerations apply.

This seminar has drawn attention to issues of data governance and security, and quality.

All data obtained is critical to the system's function, including patient management, referrals, appointments, disease notifications, researchers' access, etc.

There are provisions to protect such data that include elements embedded in the consent process, password protection of systems, level of access, supervisor authorization and policies governing this system.

The use of CDR data to study human mobility and COVID-19 transmission patterns has limitations and ethical issues related to consent.

There is a need for extensive community engagement in mobility and transmission pattern research and potential human rights-compromising use of such data by governments.

For community engagement to be effective, there is a need for dialogue and building trust with the individuals concerned.

Crowdsourcing provides a bottom-up approach to improve awareness amongst community members about data science research.

There is more that needs to be done to improve community engagement amongst people with low literacy levels. Creative interventions such as using videos to explain research concepts are needed.

ARESA ALUMNI NEWS

Prof Singh gave her inaugural talk as a full professor at the University of KwaZulu Natal (UKZN)

Dr Farayi Moyana is a dental surgeon and a lecturer at the Harare Institute of Technology (HIT) in the School of Allied Health Sciences. Dr Moyana is a new member of the REDSSA African Consortium of Bioethicists.

Dr Liya Wassie is a Senior Scientist and a site Principal Investigator at the Armauer Hansen Research Institute. Dr Wassie is a new member of the REDSSA African Consortium of Bioethicists.

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UPCOMING CONFERENCE

17th Annual International Conference on
Clinical Ethics and Consultation (ICCEC)
UNIVERSITA CATTOLICA DEL SACRO CUORE
ROME, ITALY – JUNE 7 -10, 2023

UNIVERSITÀ CATTOLICA del Sacro Cuore

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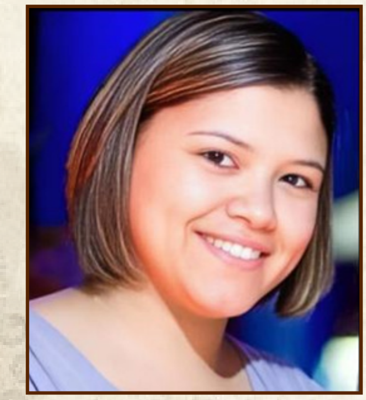

Kelsey "February" Engelbrecht

In Memorium

The Centre for Medical Ethics and Law and the ARESA graduates wish to express their sincere condolences to the friends and family of Ms Kelsey 'February' Engelbrecht. Kelsey worked as an administrator at the Centre from around 2010 to 2018. Her efficiency was commended by students and staff alike and her work ethic was exemplary. Despite her health challenges, she obtained a finance degree studying part-time. Kelsey then joined a bank to pursue her love of working with numbers. Since 2018 she has been in regular contact with Prof Moodley.

Two years ago, we were delighted to hear that she had a baby girl, Tamia Sonja. Many ARESA graduates recall her support during the PGDip program and have sent wonderful messages of condolence. Our thoughts and prayers are with her husband, Dane Engelbrecht, her lovely daughter Tamia, her aunt Elvira Rohland, senior administrator at the REC at our Faculty, her cousin Janaline February in the Grants Office and the rest of her family. We will always remember Kelsey with much love and respect.

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