

WEBINAR

# Ethically Managing Data Transfers for Research in South Africa

DATE: 23 JUNE 2022 | TIME: 14.30 – 16.30 SAST | PLATFORM: ZOOM

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science & innovation

Department:  
Science and Innovation  
REPUBLIC OF SOUTH AFRICA



The SA Medical Research Council, in collaboration with the Department of Science & Innovation invite you to a webinar on **ETHICALLY MANAGING DATA TRANSFERS FOR RESEARCH IN SA**. The open science movement is gaining momentum in the country. It encourages data sharing & collaboration across borders. The Draft National Open Science Policy & the Draft National Data & Cloud Policy promote open data sharing in line with international best practice. Health research is currently regulated by the National Health Act, 61 of 2003, its Chapter 8 Regulations, the SA Materials Transfer Agreement template & the 2015 Department of Health Ethics in Health Research guidelines. The Protection of Personal Information Act, 4 of 2013 (POPIA) has prompted discussion & debate around the use of research participants' personal information & transfers of their data outside of SA. Most of these discussions have focussed on consent & the protection of privacy within this context, with limited consideration of the wider issues related to the use of personal information for research in SA in the context of the ethical values & universal principles that underpin the research landscape, namely, equity, reciprocity, justice & solidarity. POPIA offers a regulatory framework on how to process data in a manner that protects the research participant & provides mechanisms by which data can be transferred outside of SA. However, it does not consider the other rights & interests that are at stake in the sharing of data for research purposes. In the rush to ensure compliance with POPIA for access, use & sharing of personal information, there is the risk that other rights & ethical interests are overlooked. A Data Transfer Agreement (DTA), with an integrated bioethics approach to the use of personal data can guard against this by situating the protection of personal data amongst the relevant ethical principles, rights & interests at stake. Currently there is no uniform guidance on what provisions should be incorporated into a DTA that includes both legal & ethical safeguards for research participants when their data is shared within & outside the country.

## WEBINAR OBJECTIVES

- 1 To examine the need for & potential challenges associated with data sharing for research purposes.
- 2 To reflect on community concerns, perceptions & expectations when their data is used & shared for research purposes.
- 3 To consider the use of Data Transfer Agreements as a tool for the ethical management of data.
- 4 To explore international perspectives on the ethical management of data sharing.

## PROGRAM

### Session One: Understanding the Context

Chairs: Profs Ames Dhai & Melodie Labuschaigne		
Profs Ames Dhai & Melodie Labuschaigne	Welcome & house rules	2.30 – 2.35
Prof Glenda Gray & Ms Glaudina Loots	Official opening & welcome	2.35 – 2.45
Dr Rizwana Mia	Perspectives from a scientist: Challenges & recommendations in working with genomics data	2.45 – 2.55
Ms Nomampondo Barnabas	Community viewpoints & expectations	2.55 – 3.05
Dr Bonginkosi Shozi	The multidimensional legal nature of human genomic data	3.05 – 3.15
Panel discussion		3.15 – 3.30

### Session Two: Managing Data Transfers

Chairs: Prof Safia Mahomed & Dr Ciara Staunton		
Ms Eleni Flack-Davison	An overview of POPIA & an update on the <i>Assaf Draft</i> Code of Conduct for Research in SA	3.30 – 3.40
Dr Deborah Mascalzoni	Managing data transfers for research – Perspectives from Italy	3.40 – 3.50
Prof Ma'n Zawati	Managing data transfers for research – Perspectives from Canada	3.50 – 4.00
Panel discussion		4.00 – 4.25
Dr Mongezi Mdhluli	Closure & next steps	4.25 – 4.30



## PROFESSOR GLENDA GRAY

President & CEO: SAMRC

An NRF A1 rated scientist, CEO & President of the South African Medical Research Council (SAMRC), Professor Glenda Gray is a qualified pediatrician & co-founder of the internationally recognised Perinatal HIV Research Unit in Soweto, South Africa. Prior to her appointment at the SAMRC, she was the Executive Director of the Perinatal HIV Research Unit, an affiliate of Wits University. Glenda's global profile includes a role as Co-PI of the HIV Vaccine Trials Network (HVTN), a transnational collaboration for the development of HIV/AIDS prevention vaccines. She is also Director of International Programmes for HVTN & Chairperson of the Board of the Global Alliance for Chronic Diseases, & a member of the Institute of Medicine of the National Academies, USA. She received South Africa's highest honour - the Order of Mapungubwe - for her pioneering research in PMTCT. Other prestigious accolades include the Nelson M&ela Health & Human Rights Award for significant contributions in the field of mother-to-child transmission of HIV. Selected as one of Time's 100 Most Influential People in the World, Glenda is a recognised leader in her field. Her qualifications include an MBBCh, FCPaed (SA), DSc (honoris causa SFU), DSc (honoris causa SUN), LL.D (Rhodes).



## MS GLAUDINA LOOTS

Director: Health Innovation, Department of Science & Innovation, South Africa

Glaudina Loots is the Director for Health Innovation at the Department of Science & Innovation in South Africa & as such is responsible for the implementation of the health components of the Bioeconomy strategy for South Africa. She concentrates on enabling research & innovation that leads to discovery & evaluation of new drug & treatment regimes, the development of new vaccines & new robust diagnostics, as well as the development of medical devices & digital health applications. Glaudina was instrumental in the creation of the Strategic Health Innovation Partnership Initiative (SHIP) at the South African Medical Research Council. Amongst others, Glaudina is a member of the Ministerial Advisory Committees on COVID-19 Vaccines, the South African National Health Research Committee, the South African National AIDS Council, & the Advisory Board of the "Towards an HIV Cure Initiative" of the International AIDS Society, as well as the steering committee of various research centres of excellence, such as SACEMA; the CAPRISA CoE for HIV Prevention & the API Technology Innovation Cluster. Glaudina is also an advisory board member of the Partnership for African Vaccine Manufacturing (PAVM) & is a Board member of European Developing Country Clinical Trials Partnership (EDCTP). She also serve as an alternative Director on the Board of The Biovac Institute, a Public-Private-Partnership aimed at the local manufacturing of vaccines & biologics.



## **MS RIZWANA MIA**

### Senior Program Manager: SAMRC

Rizwana Mia is responsible for developing the South African Precision Medicine program & incorporating the South African Precision Medicine Think Tank. She has spearheaded strategic partnerships in creating programmatic research as well as core infrastructure to enable & position South Africa in the area of precision medicine. She currently conducts genomics research & leads the SHIP Precision Medicine program at the GIPD unit. From 2017-2020: She spearheaded a partnership with the BGI-Shenzhen, conceptualized the business plan, secured funding, designed & established the SAMRC Genomics Centre which launched on the 29 July 2019. The Centre boasts a large-scale high through-put workflow to localize large scale human genome sequencing studies on the African Continent. She is currently a co-investigator on a genomic sequencing study looking at HIV host immune control in a cohort of paediatric HIV non-progressors, in collaboration with UKZN & University of Oxford. She is also a co-investigator on a pilot low range sequencing study involving population genomics. She is the SAMRC Lead investigator on the European-Africa Personalized Medicine Consortium (EU-Africa PerMed), to drive the ecosystem development of the Personalized Medicine Agenda for Africa. Rizwana currently serves as a member of the KwaZulu-Natal Research & Innovation Sequencing Platform (KRISP) Advisory Board; The Life Science Economy Alliance Board of the China Belt & Road Program; the SAMRC Genomics Working Group of the Bioethics Advisory Panel; & the SAMRC Genomics Centre Steering Committee. She also serves on local & international review committees such as the European Research Area Network (ERAPerMed) & has helped SAMRC integrate into the International Consortium for Personalized Medicine (ICPerMed).



## **MS NOMAMPONDO BARNABAS**

### Head of Recruitment & Retention: Clinical HIV Research Unit

Nomampondo is currently working for Clinical HIV Research Unit based at Helen Joseph as Head of Recruitment & Retention Department. She started her HIV / AIDS journey as a volunteer for NAPWA KZN (National Association of People With HIV&AIDS) in 1997. She worked for KZN Dept. Of Health & Aids Foundation as a field worker for "Faces of Aids" project. Then, was appointed as a provincial co-ordinator for NAPWA KZN. She has served as a national chairperson for International Community of Women living with HIV&AIDS (ICW) in South Africa. Nomampondo is currently a member of the strategic advisory committee for Higher Health, Wits HREC & Biobank Ethics Committee. While in KZN she served on the research ethics committee at N.R. Mandela school of medicine – University of Natal as a community representative. She served as a board member for Gender Aids Forum & Tugela Aids Programme, DSMB member for Keshobora study - WHO Trial, trustee for Southern Africa Anglican AIDS Healthcare Trust. Noma served as community track co-chair & chair for different S.A AIDS conferences. She has acquired a wealth of experience locally, regionally & globally. Noma is locally & internationally recognized for providing the voice of the voiceless.



### **DR BONGINKOSI SHOZI**

Research Scholar: Institute for Practical Ethics, University of California, San Diego

Dr Bonginkosi Shozi is currently a postdoctoral research scholar at the Institute for Practical Ethics, at the University of California, San Diego. He is also an Honorary Research Fellow at University of KwaZulu-Natal's School of Law, affiliated with the Health Law & Ethics Research Interest Group. Dr Shozi conducts research on the legal, ethical & human rights implications of novel health-related technologies from an African perspective. This includes genetic technologies — such as CRISPR — as well as assisted reproductive technologies, & pharmaceutical products.



### **MS ELENI FLACK-DAVISON**

Legal Adviser, Research Compliance Manager, Head: Office of Research Integrity & Research Data Protection Officer: University of the Witwatersrand, Johannesburg

Eleni Flack-Davison holds a BA, LLB & LLM & is an admitted attorney of the High Court of the Republic of South Africa. She provides legal services & legal advice to the Senior Management of the University as well as to academics / researchers, that enables research & innovation through research contracts as well as the management & operation of the Research Office: Legal Services. As the Research Compliance Manager, her duties include but are not limited to supervision, management, & oversight of the University Research Ethics Committees & management of the Ethics administrative personnel. Eleni is a special adviser to the LOC for the 7th World Conference on Research Integrity (WRCI) which will be held in Cape Town in 2022. She is part of the Research Ethics Associations of Southern Africa (REASA) Executive Committee & on the Marketing & Communications sub-Committee. She has been part of the Academy of Science of South Africa (ASSAf) drafting Committee in relation to the POPIA Code of Conduct for Research in South Africa. In 2021, she has co-Chaired the launch of the Northern Regions Research Ethics & Integrity Community of Practice (CoP) under the auspices of the Southern African Research & Innovation Management Association (SARIMA). The CoP took on the mammoth task of drafting ethics guidelines & toolkit for the SADC Region in terms of the Nagoya Protocol.



### **DR DEBORAH MASCALZONI**

Senior Researcher: Center for Research Ethics & Bioethics, Uppsala University (Sweden) & Institute for Biomedicine of Eurac Research (Italy)

Dr Deborah Mascalzoni senior researcher at the Center for Research Ethics & Bioethics (CRB), Uppsala University & is research group leader of the ELSI group at the Institute for Biomedicine (IfB) of Eurac Research in Bolzano, Italy. Her main research interests are genetics & new technologies including informed consent, rare diseases & vulnerable communities, participant & patient communication, privacy & data sharing. She has been working in projects focusing on research participant engagement, participant right & dynamic consent. Deborah Mascalzoni holds a PhD in Bioethics from the Faculty of Law at University of Bologna & has a comprehensive ELSI background. She is author of more than 60 peer reviewed articles, several book chapters, & published a book. She obtained over 2.000.000 Euro in grant applications from both European & Italian funding bodies. Some of her funded projects are Cyberhealth (on cybersecurity in health research, aiming to develop recommendations for resilient governance mechanisms for health cyberspace that can meet social expectations regarding the security & privacy of health data, while enabling broad use of health data to benefit society; & RD Connect – Rare diseases Connect (on building infrastructures for data sharing, aiming to create a unique infrastructure for rare disease research free to use by scientists & clinicians in Europe & around the world. Deborah designed & developed, together with IT experts, the Dynamic Consent Platform for the Cooperative Health Research in South Tyrol (CHRIS) study at Eurac Research, applied to more than 13000 individuals since 2011. She has extensive experience in drafting policy documents & she is member of the code of conduct drafting group for BBMRI ERIC. She serves as advisor in different projects & is a member of different international & national advisory boards.



### **PROFESSOR MA'N H. ZAWATI**

Executive Director Centre of Genomics & Policy: McGill University (Canada)

Ma'n H. Zawati (LL.B., LL.M., Ph.D. (DCL)) is an Assistant Professor at McGill University's Faculty of Medicine & the Executive Director of the Centre of Genomics & Policy in the Department of Human Genetics. He is also an Associate Member of the Faculty of Law at McGill University. His research concentrates on the legal, ethical & policy dimensions of health research & clinical care, with a special focus on biobanking, data sharing, professional liability, & the use of novel technologies (e.g. mhealth apps, WGS, WES) in both the clinical & research settings. His work is interdisciplinary, drawing together perspectives from law, ethics, bioinformatics, genomics, & policy. In 2015, he was awarded the Queen Elizabeth II Diamond Jubilee Scholarship (stay at Oxford University) & was named a Royal Society of Canada Delegate for the IAP Young Scientists of the Year international symposium. In 2021, Prof. Zawati received his J1 FRQS Career Award.



## PROFESSOR SAFIA MAHOMED

School of Law, University of South Africa

Safia Mahomed is an Associate Professor at UNISA's School of Law & an honorary Associate Professor at the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand. Her research interests cluster around questions regarding health law & bioethics. Safia is an admitted attorney with a PhD from the University of the Witwatersrand (2018). One outcome of Safia's PhD thesis, A Material Transfer Agreement (MTA) Template was used by the National Department of Health to inform the gazetted MTA for national use. Safia is a current member & former Chair of UNISA's Biotechnology & Medical Law Flagship. She is also a member of various national & international committees. In 2018, Safia was awarded UNISA's Principal's prize for excellence in research. Currently she is a fellow of the National Department of Higher Education's Future Professor's Programme (Cohort 1) & holder of UNISA's Vision Keepers Grant. Safia is an editor of the South African Journal on Human Rights & has published & presented her research both nationally & internationally.



## DR CIARA STAUNTON

Senior Researcher: Institute for Biomedicine, Eurac Research (Italy)

Dr Ciara Staunton is a Senior Researcher at the Institute for Biomedicine, Eurac Research (Italy). In addition she is an Honorary Research Associate at the Faculty of Health Sciences, University of Cape Town, a Consultant to the South African National Institute for Communicable Diseases, & a Visiting Researcher at the Faculty of Law & Business, Middlesex University (London). Her research focuses on the governance of new & emerging technologies, in particular stem cell research, genomic research & biobanking. Ciara's current research focuses on the sharing of health data for research. She has been in receipt of grants from the Wellcome Trust, the National Institutes of Health (NIH) & the Irish Research Council. She has been involved in the development of policy in Ireland, Bahrain & Africa & led the development of the *Framework for the Governance of Personal Data for the Access to COVID-19 Tools Accelerator*. From 2010-2013 she was a post-doctorate researcher at the Centre for Medical Ethics & Law, Stellenbosch University. During this time she co-ordinated the Advancing Research Ethics in Southern Africa (ARESA) Program & was a member of the H3Africa Ethics & Regulatory Issues Working Group. She obtained her PhD from NUI, Galway for her thesis *The Regulation of Stem Cell Research in Ireland*. Prior to starting her academic career, she was a Legal Researcher at the Law Reform Commission of Ireland.



## PROFESSOR MELODIE LABUSCHAIGNE

School of Law, University of South Africa

Professor Melodie Labuschaigne is Professor in Medical law & Ethics in the Department of Jurisprudence in the School of Law, University of South Africa. She is a former Director of the School of Law & Deputy Executive Dean of the College of Law at UNISA. She obtained the degrees BA, BA (Hons), MA & DLitt from the University of Pretoria, & the degrees LLB & LLD (in medical law) from the University of South Africa. She has published numerous articles on medico-legal issues; the legal regulation of stem cell research & human tissue, genomic & genetic research, gene editing, assisted reproduction & the National Health Insurance Bill, locally & internationally & has presented many local & international conference papers. She is a recipient of the Chancellor's Award for Excellence in Research from the University of SA, the Women in Research Leadership Award, & the Hugo de Groot Prize. She has been involved with the revision & drafting of health legislation for many years & is regularly approached to provide legal opinions on legal issues relating to medical law. During 2016-2018 she served on the Academy of Sciences of South Africa consensus panel on *Human genetics & genomics in South Africa*. She serves on several boards & currently serve on the National Health Research Ethics Council & the Bioethics Advisory Panel of the SAMRC. She is also the chair of the Genomics working group of the BAP of the SAMRC.



## PROFESSOR A. DHAI

Chairperson Bioethics Advisory Panel: SAMRC

Professor Ames Dhai (MASSAf, PhD, MBChB, FCOG, LLM, PGDip-IntResEthics), is Founder & Past Director of the Steve Biko Centre for Bioethics at the Wits Faculty of Health Sciences (2007 – 2019), Professor of Bioethics & Health Law at the Wits School of Clinical Medicine, Specialist Ethicist at the Office of the President & CEO of the South African Medical Research Council (SAMRC), member of the Academy of Science South Africa (ASSAf), & Chairperson of the UNESCO International Bioethics Committee. Some of her current activities include: Honorary Professor in the College of Human & Health Sciences, Swansea University, UK; Chairperson of the SAMRC Bioethics Advisory Panel; Chair of the Human Sciences Research Council Research Ethics Committee, Chair of the ASSAf Biosafety & Biosecurity Committee; member on several consensus panels of the ASSAf, including the ASSAf Panel on Gene Therapies & Gene Editing ELSI; Vice-Chair on the Ministerial Advisory Committee for COVID-19 Vaccines where she heads the Technical Working Group on Mandatory Vaccinations; member of the Ministerial Advisory Committee on Unrelated Organ Transplants & a member of the Advisory Committee to the SA Law Commission Project on Medical Litigation. She is Editor-in-chief of the South African Journal of Bioethics & Law & Associate Editor of the South African Medical Journal. Professor Dhai is a leading authority in Bioethics both internationally & locally, & can be credited with entrenching bioethics & human rights as an integral aspect of health sciences in SA. She has published extensively in this field.



## DR. MONGEZI MDHLULI

### Chief Research Operations Officer: SAMRC

Dr. Mongezi Mdhului is the Chief Research Operation Officer (CROO), reporting directly to the South African Medical Research Council's (SAMRC) President and the CEO.

Dr Mdhului is a member of the Executive Management Committee (EMC), attends and participates at the SAMRC Board meetings, and contributes to the achievement of the SAMRC strategic goals, values and key performance indicators.

Dr. Mdhului's function is to provide visionary leadership, strategic management, and excellence in the development, implementation, management and oversight of the SAMRC strategic goals and objectives. He drives relationships with diverse group of stakeholders including internal, national and international partners.

He works with the President and CEO of the SAMRC to develop and implement strategies and plans, promotes good corporate governance through adherence to all relevant statutory legislation and regulations and appraises the President and CEO about potential strategic risks to the research operations.

He partners with the Executive Director: Research Strategy to ensure the implementation of Research Strategy, provides input into setting of the overall organizational budget, lead an optimal team structure to achieve organizational mission, support its growth and development, and guide the team towards achievement of set goals within agreed budgets. Dr Mdhului holds PhD and MBA degrees.