SESSION FACILITATED BY: SUSAN VELDSMAN, ELENI FLACK-DAVISON, AND TANYA COETZEE

Opening and Welcome by Prof Ames Dhai (Wits) and Prof Himla Soodyall (ASSAf)

Ames Dhai
Professor Ames Dhai is the Founder and Past Director of the Steve Biko Centre for Bioethics at the Wits Faculty of Health Sciences (2007-2019), Professor of Bioethics and Health Law at the Wits School of Clinical Medicine and a member of the Academy of Science of South Africa (ASSAf). She is the immediate past Chairperson of the UNESCO International Bioethics Committee.

Himla Soodyall
Professor Himla Soodyall is the Executive Officer of the Academy of Science of South Africa (ASSAf). An ASSAf member since 2003, she was elected to the ASSAf Council in 2011 and appointed general secretary in 2014. Prior to joining ASSAf on 1 November 2018, she was employed as a Principal Medical Scientist in the Division of Human Genetics at the National Health Laboratory Service (NHLS) and the University of the Witwatersrand (Wits).

CIOMS 2016: Research Ethics Committee Functioning & Research Participant Safeguards

Johannes (Hans) van Delden
Prof Johannes (Hans) van Delden is a full professor of medical ethics at the University Medical Centre of Utrecht University, the Netherlands. He leads the project on patient and public participation for the hospital and for the medical school in the UMC Utrecht. He has worked for many years as a practicing nursing home physician. He has published nearly 350 international and over 125 national articles on the practice and ethics of end-of-life decisions, research ethics, and ethical issues in the care for the elderly. At his department, he has built a research team which has created a strong track record in the ethics of end-of-life decisions, research ethics, and ethics of biomedical innovation. He served as the chair of the International Bioethics Committee of UNESCO. He has served as the president of the Council of International Organisations of Medical Sciences (CIOMS), and as the chair of the workgroup for the revision of the CIOMS ethical guidelines for biomedical research.

Unified Interpretation of POPIA in the Context of Protection of Personal Information: ASSAf Draft Code of Conduct for Research

Michèle Ramsay
Prof Michèle Ramsay is the director of the Sydney Brenner Institute for Molecular Bioscience (SBIMB), Professor in Human Genetics and South African Research Chair in Genomics and Bioinformatics of African Populations at the University of the Witwatersrand (Wits). While being deeply committed to promoting research excellence in Africa and contributing to research that accurately represents African populations in global science, she actively promotes capacity strengthening in the fields of genomics and precision medicine. Michèle is co-chair of the International Hundred-thousand+ Cohorts Consortium (IHCC) and steering group member for developing the African Population Cohorts Consortium (APCC). As a member of the WHO Technical Advisory Group for Genomics (TAG-G) she contributes LMIC perspectives to global genomics, promoting ethical, equitable and fair principles and practices. She serves as chair of the Academy of Science of South Africa’s POPIA Committee to draft a national Code of Conduct or Guiding Framework for Research to inform a uniform interpretation of the Act.
Matty van Niekerk
Matty is the Head of the Department of Occupational Therapy at the University of the Witwatersrand, Johannesburg, where she lectures at both undergraduate and postgraduate level and supervises undergraduate and Master’s level research. Matty has been actively engaged in the regulation and governance of the profession of occupational therapy since 2006, serving both the Occupational Therapy Association of South Africa and the Health Professions Council of South Africa. She has also been a lecturer member of the Senate of the University of the Witwatersrand for 7 years, until December 2019. Matty is an enthusiastic occupational therapy educationalist and her work experience is in the field of vocational rehabilitation and medico-legal assessment, adolescent psychiatry as well as academia. Matty’s research interests lie in the impact of legislation of general application on health professions (education), and the broader notion of occupational justice particularly for hidden and hard-to-reach populations. She views skilful health professions education important to enhance occupational justice. She has published in the fields of ethics/professionalism, vocational rehabilitation and freedom of information legislation both as single author, and co-authored with her MSc and undergraduate students.

Susan Veldsman
Susan Veldsman is Director of the Scholarly Publication Unit at the Academy of Sciences in South Africa, responsible for driving the Open Science agenda, to raise the visibility, discoverability and accessibility of South African scholarly journals, improve the quality of SA research output, and support the development of policy frameworks in order to facilitate optimal use and access to publicly funded research. She received the Electronic Publishing Trust (EPT) award for her outstanding contribution to the promotion of Open Access in Developing Countries. Recently, she was the Co-chair of the IAP Report on “Combatting Predatory Journals and Conferences”, which was launched on the 16th March 2022. She also received special recognition for her role in establishing the SciELO SA platform in South Africa at the most recent SciELO 25 years celebrations.

Research Ethics Committee Functioning and Research Participant Safeguards: A Review of the Ethics in Health Research Guidelines (Department of Health 2015)

Shenuka Singh
Shenuka Singh is a Full Professor in the Discipline of Dentistry at the University of KwaZulu-Natal (UKZN). She is Deputy Chairperson of the National Health Research Ethics Council (NHREC) in South Africa (2023-2026), which is a ministerial appointment. She is a member of the Ethics in Dental Research Committee at the International Association of Dental Research (IADR). She is President-Elect of the IADR- South African Division (2024-2026). She was invited to be part of a World Health Organization joint working group (Regulation and Safety Unit and Health Ethics & Governance Unit) to develop a tool for benchmarking research ethics oversight in 2021. Prof Singh is the appointed Chair of the Biomedical Research Ethics Committee at UKZN from January 2024. She is also a member of the Human Sciences Research Council’s Research Ethics Committee (2019-to date). She was the appointed Research Ethics Chair for the Council for Science and Industry Research in South Africa (CSIR REC R&D: 2015-2018) and the Humanities and Social Sciences Research Ethics Committee at UKZN (2014-2018). As part of her ongoing engagement with research ethics, she conducted several training workshops at various institutions in South Africa such
as UKZN, DUT, MANCOSA, TUT, South African Medical Research Council (SAMRC), and the University of Zululand. She is an NRF-rated researcher and is actively involved in research and postgraduate supervision.

**Roundtable: RECs, Prof van Delden & NHREC & ASSAf**

**COMFORT BREAK**

**SESSION FACILITATED BY MS CAZ MCNAMARA**

**Harmonising Humanity: The Role of Research Management in Ensuring Participant Safety**

Dr Retha G. Visagie is prominent in Africa’s research ethics governance community. In 2014, she established the Research Integrity Office at the University of South Africa, catalysing research ethics reform on both national and international levels. Over the past five years, she has been dedicated to indigenising research ethics governance. She has championed policy changes, conducted research, initiated capacity-building programmes for academics and research ethics committees, and facilitated social dialogues to challenge research practices that may disadvantage Indigenous Knowledge Systems. She provides advisory services to several African higher education institutions, focusing on responsible research and ethical conduct. Dedicated to advancing Research Management in the SADC region, she serves on the Southern African Research and Innovation Management Association (SARIMA) Committee and co-founded the SARIMA Northern Regions Community of Practice for Research Ethics and Integrity. As a Non-Executive Director and Chair of the Executive Board at EthiXPERT, she strengthens ethical research capabilities in Africa.

**SA GCP 2020: SAHPRA Functioning & Research Participant Safeguards**

Lesley Burgess

Professor Lesley Burgess has been involved in clinical trials since 1992. To date, she has more than 100 publications to her credit, in addition to being the author of 4 chapters in internationally recognized textbooks for clinical research. She spent a number of years sitting on the Stellenbosch University Health Research Ethics Committee and is currently a reviewer of the Clinical Trials Committee of SAHPRA. At present, she is the director of TREAD Research and Paarl Research Centre, and also consults for various syndicates of Wits Health Consortium. TREAD Research is the only research unit in Africa to be awarded full accreditation with AAHRPP.

**The Element of Trust in Research**

Seeiso Koali

Dr Seeiso Koali is a Research Integrity Officer at the South African Medical Research Council (SAMRC). He provides guidance on research integrity matters, develops policies and guidelines. He also handles reported cases on breach of research norms/standards and possible research misconduct. He conducts training on research integrity as well as organizing training on Good Clinical Practice for the SAMRC staff and ensuring compliance to regulatory requirements that govern responsible conduct of research. Before joining the SAMRC, Koali was a senior lecturer at the National University of Lesotho, Department of Philosophy. Among other courses, he taught Medical Ethics, Bioethics, Introduction to Applied Ethics and Introduction to Moral Philosophy. Koali has also served
as a member of Institutional Review Board at Baylor College of Medicine Children’s Foundation-Lesotho in (2013-2016).

**Safeguarding Indigenous Knowledge in Research**

**Fikile Mnisi**

Fikile Muriel Mnisi has a Doctorate in Philosophy (i.e., Bioethics and Health Law) from the University of Witwatersrand, with a background in Biotechnology (i.e., Regenerative or Tissue Engineering). She has worked in both academic and private sector. She has founded a company called Khaca (Pty) Ltd which focuses on biotechnology policies, research, and ethics training and consultation. She has recently founded a NPC called Inkanyeti Foundation that focuses on addressing stigmas around mental illness. She is currently serving as an Animal Ethics Committee Member at the Tshwane University of Technology, and the Chairperson of Edenvale Regional Hospital. She is a biotechnologist, bioethicist, ethics educator, ethics consultant, researcher, early entrepreneur, and early community developer. Her main focus is in the fields of Biotechnology, Bioethics, and Legal and Social issues. She is interested in working in multi or trans-disciplinary environments to analyse, create and implement innovative solutions. Her passion is social justice (i.e. Harmony) whether it is allocative and/ or distributive justice on matters in biotechnology, medicine, or health, Ethics, Legal and Social Issues (ELSI,) and bio-politics to influence policy and decision-making.

**Clinical Trial Participant Consent: Industry Perspective with Focus on Vulnerable Population, Capacity Building and Inclusivity**

**Nathaniel Ramuthaga**

Mr Nathaniel Ramuthaga is a registered Medical Scientist with HPCSA a registered Natural Scientist with SACNASP and a certified Co-active Coach. He is currently working at Roche Pharmaceuticals as Clinical Operations Portfolio Leader (COPL) PDG, SA & SSA and Geo Lead Roche–SA& Africa. He has previously held the position of Country Head of Clinical Operations South Africa, Sub-Sahara- Roche PDG. He serves as a member of the IPASA Clinical Trials Group; a member of the South African Clinical Trials Association (SACRA); and a member of the Institute of Southern Africa Directors (IODSA). He has published several articles of research in peer-reviewed journals.

**Sorika van Niekerk**

SACRA EXCO Chairperson & Chief Operating Officer, Cytespace Africa Laboratories

Sorika joined the Clinical Research Industry in 1999 and her expertise covers all therapeutic areas with a specific focus on anti-infective diseases. Whilst being Executive Director of Clinical Operations, she was the main driver behind developing and implementing a strategy to expand Clinical Operations to the rest of Africa. The outcome of this strategy was the opening of offices in both East and West Africa. She has a passion for the development of people and as such she took responsibility for the development of an apprenticeship within the South African context to increase the availability of well-trained individuals within the clinical trial industry in Sub-Saharan Africa. Sorika continues to focus on the development and expansion of clinical trial & and laboratory infrastructures in Sub-Saharan Africa.
The Role of Research Integrity in Safeguarding Research Participant (Virtual: pre-recorded video)
Francis Kombe
Mr Francis Kombe is the Chief Executive Officer of EthiXPERT, South Africa; a Public Health and Community Engagement 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 MSoSc (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) and is currently awaiting to graduate from a Wellcome Trust funded PhD in Bioethics at UKZN. Before joining EthiXPERT, Kombe worked as a training coordinator at the KWTRP where he was involved in the strategic development and planning of health research fieldworkers. He has published widely in the field of community engagement, frontline staff, research integrity, fair study benefits and informed consent, among others. He is a co-founder and interim committee member of the African Research Integrity Network (ARIN).

There's More to Being Ethical than Compliance
Kevin Behrens
Kevin Behrens is Professor of Bioethics and the Director of the Steve Biko Centre for Bioethics at the University of the Witwatersrand, Johannesburg, South Africa. His research interests lie in applied ethics - in particular, bioethics and environmental ethics. A major emphasis in his work is on applying African moral philosophical notions to ethical questions. He has published widely in international and national journals. He holds a B2 rating from the National Research Foundation. He previously served on the Research Ethics Committee of the CSIR and is a member of the Clinical Ethics Committee of the Wits Donald Gordon Medical Centre. He is a member of the Board of the International Association of Bioethics, and lead of its sustainability working group.

Navigating the Technological Frontier in Health Research: Enhancing Engagement and Ensuring Ethics
Diana De Sousa
Dr Diana De Sousa, an esteemed Educational and Research Psychologist, serves as a Lecturer and Research Supervisor at The South African College of Applied Psychology (SACAP). Her focus is empowering children, adolescents, and young adults, nurturing their learning capabilities and life skills. As Head of Academic Standards and Quality Assurance and Chair of SACAP’s Research and Ethics Committee, she leads efforts to enhance educational standards and ethical research practices, solidifying SACAP’s reputation for excellence. Dr De Sousa holds a Ph.D in Psychology specializing in Developmental Cognitive Neuropsychology. With a dual master’s degree in Research Psychology and Educational Psychology, she has a notable publication record and contributed significantly to psychology and education nationally and internationally. She has held leadership roles in various professional organizations, advocating for mental health awareness and ethical practice within psychology.

Panel Discussion –Wits, ASSAf, NHREC, SARIMA, SAMRC, SAHPRA, SACRA, ARIN, REASA, Wits Steve Biko Centre for Bioethics, SACAP
Facilitated by Ames Dhai and Paul Ruff

Ames Dhai – already introduced
Paul Ruff
Paul Ruff is the Emeritus Professor in the School of Clinical Medicine, and was Head of Division of Medical Oncology at WITS Faculty of Health Sciences & CMJAH (2002-21). He is now Chair of WITS HREC (Medical) since August 2023. He is PI of SAMRC/WITS Common Epithelial Cancer Research Centre & co-PI of NIH Grant 1R01CA192627 with Columbia University, NY, USA, since 2015. He was ranked as a B2-rated scientist by the NRF(SA) in 2017 & has an H-index of 41. Prof Ruff is Chair of SAHPRA Clinical Trials Committee since 2015 and Member of NEMLC since 2017. Prof Ruff was appointed to ASCO International Affairs Committee (2013-16), ASCO International Clinical Trials Workshop Working Group (2015-18), ASCO International Quality Task Force (2020-23) and appointed Inaugural Chair of the ASCO Sub-Saharan Africa Regional Council in 2022.

LUNCH

Last Session Facilitated by …

Formal Welcome – Prof Lynn Morris, University of the Witwatersrand (Virtual: pre-recorded video)
Prof Lynn Morris is the Deputy Vice-Chancellor of Research and Innovation at the University of the Witwatersrand in Johannesburg, South Africa. She has a PhD from the University of Oxford and is Research Professor and founding Director of the Antibody Immunity Research Unit based at the National Institute for Communicable Diseases. Over the last 30 years she has been involved in HIV vaccine research making significant contributions to understanding the antibody response to HIV. Lynn is an NRF A-rated scientist, has published over 270 papers holding an H-Index of 64 and has featured in the Web of Science list of the world’s most highly cited researchers. She is a member of Academy of Science of South Africa (ASSAf) and a Fellow of the African Academy of Sciences (AAS), the Royal Society of South Africa (FRSSA) and The World Academy of Sciences (TWAS). Lynn has supervised and mentored over 50 post-graduate students and post-docs many of who have gone on to develop their own successful scientific careers.

Public Lecture: Research Participant Protections –The Latest CIOMS Guidelines
Prof Hans van Delden – already introduced

Open Q&A
Facilitated by Prof Himla Soodyall (ASSAf) and Prof Annie Temane (University of Johannesburg (UJ))

Himla Soodyall – already introduced

Annie Temane
Annie Temane is a Professor and Acting Executive Dean in the Faculty of Health Sciences. She holds a Masters and Doctorate degrees in Psychiatric Nursing Science from the University of Johannesburg. She served as Head of the Department for Nursing from September 2017 to June 2020 before taking on the position of Vice Dean of Research and Internalisation in the Faculty of Health Sciences. She has supervised and co-supervised numerous masters and doctoral candidates to completion and has published in national and international accredited journals. Her research interests lie in the fields of mental health and ethics. She serves on several committees internally and externally of the university. She also serves as a committee member on the UNESCO National Bioethics
Committee and SAMRC Bioethical Advisory Committee. She was recently appointed to serve on the Mental Health Ministerial Board Advisory Committee by the Health Minister, Dr Joe Phaahla. Prof Temane is actively involved in research ethical governance evident from her involvement and consultant service for qualitative research at the Steve Biko Bioethics Centre at the University of Witwatersrand and served on the editorial board of the in-house journal of the Department of Nursing, Health Gesondheid SA, as a sectional editor. She has been a panel member to review research grants for the National Research Fund and is a representative for the Faculty of Health Sciences at the Universitas Network (U21) Health Sciences Group in the mental health and medicine group. Her community engagement at Woodside Sanctuary for intellectually disabled people where she serves as a member of the board reflects her passion for mental health.

Reflection and Closure

Paul Ruff – already introduced

Biographies of Facilitators

Tanya Coetzee
Tanya Coetzee is currently working in the Office of Research Integrity at UNISA. Her work involves the promotion of research ethics and integrity processes at UNISA, and she is also a member of the Unisa Research Ethics Review Committee. As part of her passion, Tanya strives to bring research ethics and integrity to the forefront of all research processes. She recognizes the value of research ethics training from early undergraduate programs to build intrinsic moral codes and the ethics of care in all professions. Being passionate about research ethics and the important role of RECs, she is a past member of the Research Ethics Committee Association of Southern Africa Executive Committee. She also serves on the South African Medical Association Research Ethics Committee (SAMAREC). Further to this, she is part of the executive committee of the Community of Practice for Research Ethics and Integrity professionals under the auspices of SARIMA. She has trained more than 1700 researchers and postgraduate students in research ethics and integrity in the last four years.

Eleni Flack-Davison
Eleni Flack-Davison is an admitted attorney of South Africa, Legal Adviser, Research Compliance Manager, Head of the Office of Research Integrity, and the Research Data Protection Officer at the University of the Witwatersrand, Johannesburg. Eleni was a special adviser to the LOC for the 7th World Conference on Research Integrity in Cape Town. She is part of the REASA Executive Committee and heads up the Marketing and Communications sub-Committee. She has been part of the ASSAf drafting Committee in relation to the POPIA Code of Conduct for Research in South Africa. Eleni co-founded and co-Chairs the Northern Regions Research Ethics and Integrity Community of Practice (CoP) under SARIMA and co-Chairs the Steering Committee for the CoPs for Research Ethics and Integrity. The CoP has drafted ethics guidelines and toolkit for the SADC Region in terms of the Nagoya Protocol. Eleni is part of the SARIMA Research Management Portfolio Committee.
**Susan Veldsman**
Susan Veldsman is Director of the Scholarly Publication Unit at the Academy of Sciences in South Africa, responsible for driving the Open Science agenda, to raise the visibility, discoverability and accessibility of South African scholarly journals, improve the quality of SA research output, and support the development of policy frameworks in order to facilitate optimal use and access to publicly funded research. She received the Electronic Publishing Trust (EPT) award for her outstanding contribution to the promotion of Open Access in Developing Countries. Recently, she was the Co-chair of the IAP Report on “Combatting Predatory Journals and Conferences”, which was launched on the 16th March 2022. She also received special recognition for her role in establishing the SciELO SA platform in South Africa at the most recent SciELO 25 years celebrations.

**Ms Caz McNamara**
Caz has a Masters degree in Biochemistry (Rhodes University, 2006) and a Postgraduate Diploma in Research Management and Administration (Stellenbosch University, 2023) and has worked in the Academic Research Management sector for 15 years, and currently works at the Infectious Diseases and Oncology Research Institute at the University of the Witwatersrand, Johannesburg, South Africa. She holds Senior Research Management Professional (SRMP) accreditation through the International Professional Recognition Council (IPRC; [https://iprcouncil.com/](https://iprcouncil.com/)) and is the current Vice-President for Research Management at the Southern African Research and Innovation Management Association (SARIMA). She is a current member of EARMA and a former member of ARMS. She works closely with WARIMA as the Project Lead on the capacity development theme of the Science Granting Councils Initiative (SCGI) in Africa. Caz has also served on numerous conference Local Organising Committees: SAARMSTE, SARIMA, INORMS and WCRI, and has taught on entry/access programmes for ACE(ICT Education) and Research Methods for e-Science Masters.