“Explore the Frontiers of Safeguarding Research Participants with the Application of Research Ethics Principles from the Latest CIOMS Guidelines”

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Proceedings of Public Lecture

Explore the frontiers of safeguarding research participants with the application of research ethics principles from the latest CIOMS Guidelines.

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The Academy of Science of South Africa (ASSAf) was inaugurated in May 1996. It was formed in response to the need for an Academy of Science consonant with the dawn of democracy in South Africa: activist in its mission of using science and scholarship for the benefit of society, with a mandate encompassing all scholarly disciplines that use an open-minded and evidence-based approach to build knowledge. ASSAf thus, adopted in its name the term ‘science’ in the singular as reflecting a common way of enquiring rather than an aggregation of different disciplines. Its members are elected based on a combination of two principal criteria, academic excellence and significant contributions to society.

The Parliament of South Africa passed the Academy of Science of South Africa Act (No 67 of 2001), which came into force on 15 May 2002. This made ASSAf the only academy of science in South Africa officially recognised by government and representing the country in the international community of science academies and elsewhere.

This report reflects the proceedings of Public Lecture: Explore the Frontiers of Safeguarding Research Participants with the Application of Research Ethics Principles held in a hybrid format (Zoom/Protea by Marriott Hotel, Wanderers, Johannesburg).

Views expressed are those of the individuals and not necessarily those of the Academy nor a consensus view of the Academy based on an in-depth evidence-based study.
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SESSION 1

Programme Directors: Mrs Eleni Flack-Davison, University of the Witwatersrand; Mrs Tanya Coetzee, University of South Africa; Mrs Susan Veldsman, Academy of Science of South Africa

The sponsors that supported the public lecture and contributed to the event were acknowledged, namely the University of the Witwatersrand, the National Health Research Ethics Council, Southern African Research and Innovation Management Association, UNISA, the Council of International Organizations of Medical Sciences, ASSAf, the South African Health Products Regulatory Authority, the Steve Biko Centre for Bioethics, the South African Clinical Research Association, the South African Medical Research Council, the Research Ethics Committee Association of Southern Africa, the University of Johannesburg, the African Research Integrity Network and the South African College of Applied Psychology.

OPENING AND WELCOME

Prof Ames Dhai, University of the Witwatersrand; Prof Himla Soodyall, Academy of Science of South Africa

Prof Soodyall welcomed participants to the public lecture, hosted in partnership with the University of the Witwatersrand (Wits). ASSAf, a membership-based organisation with over 680 members nominated through a rigorous vetting process, ASSAf brings together academics and organisations for exchanges on topical issues related to science and research and produces proceedings of workshops and events, which are freely available on the ASSAf website. Regular publications include the peer-reviewed South African Journal of Science and Quest magazine, a popular science periodical aimed at learners and the general public.

An email to the Wits research office led to the decision to organise this public lecture, which signifies the commitment of the Wits Ethics Committee and the national and regional research ethics communities to safeguard research participants in medical research. Preceding the event, a consultative meeting was held to deliberate how Africa could contribute towards the next revision of the Declaration of Helsinki1 (DoH), which was last revised in 2013. The theme of the forum, namely vulnerability and community engagement, mirrors the focus of the public lecture, particularly on contextual vulnerability in Africa. The balance between protecting the vulnerable from possible exploitation in research trials, and including the vulnerable and the non-vulnerable to ensure fair distribution of research is important. A paternalistic, patronising approach to research ethics could cause more harm than good by excluding vulnerable groups from the benefits of studies, thus making them more vulnerable. Therefore, the importance of safeguards and correct balances would be deliberated at the public lecture.

CIOMS 2016: RESEARCH ETHICS COMMITTEE FUNCTIONING AND RESEARCH PARTICIPANT SAFEGUARDS

Prof Hans van Delden, CIOMS and University Medical Centre Utrecht University, The Netherlands

The Council for International Organizations of Medical Sciences (CIOMS)2 was founded in 1949 by the World Health Organization (WHO) and UNESCO, with the mission to advance public health.

2 https://cioms.ch
through guidance on health research, ethics, and the development and safety of medical products. CIOMS consists of 31 international member organisations representing professionals in biomedical disciplines, and ten national member organisations, including national academies of science and medical research councils. The executive committee consists of representatives from ten member organisation. Key focus areas of CIOMS are pharmaceutical vigilance and bioethics, and guidelines on these are freely downloadable from the CIOMS website.

The International Guidelines on Good Governance Practice for Research Institutions3 were first promulgated in 1982, arising from the need for more specifications and explanations than those contained in the Declaration of Helsinki (DoH). The DoH, with its 37 clauses, serves as a high-level document that is easily accessible and understandable. The CIOMS guidelines elaborate on how the clauses in the DoH and fundamental ethical principles can be applied effectively in worldwide medical research across different cultures, religions, traditions, and socioeconomic circumstances, particularly in low- and middle-income countries (LMICs). These guidelines include commentaries with definitions, explanations, and additional details on the topics covered. The guidelines have been widely used, especially in LMICs, and have been translated into several languages. There is close alignment between the DoH and the CIOMS guidelines.

The guidelines promulgated in 1982 have been revised by working groups in collaboration with the WHO and advisors from the World Medical Association (WMA), UNESCO, and the Council on Health Research for Development (COHRED). CIOMS member organisations were consulted during the revision process, and they submitted feedback on draft documents. The updated guidelines were published in November 2016.

The guidelines are intended as a response to current developments in health research, such as new trial designs and evolving research methodologies. Current challenges in health research include the protection of participants while simultaneously ensuring access to the benefits of research (particularly in low-resource settings), translating research for the benefit of society, promoting responsible science, and reducing research waste4. The lack of patient and public involvement and engagement is a concern, and governmental research infrastructures such as biobanks and big data repositories have also become a pressing issue.

In response to these challenges, the revised 2016 guidelines bring about a fundamental change by prominently positioning the social value of research, explicitly stated in Guideline 1. The guidelines are interconnected, with overlap between them. Key changes introduced in the revision include more detailed specifications for research conducted in low-resource settings (Guidelines 2 and 6). Notably, provisions for ancillary care are emphasised, mandating researchers to direct participants with health needs to appropriate care facilities, irrespective of whether their specific medical condition was the focus of the study. Guideline 3 addresses the equitable distribution of burdens and benefits. More emphasis is placed on patient and public involvement and engagement (PPIE), emphasising the need for a meaningful, participatory process. Guidelines 11 and 12 address broad informed consent in biobanking and databanking for the purpose of good governance. A contextualised concept of vulnerability is explained in Guideline 15.

Guideline 23 defines Research Ethics Committees (RECs) as the central actor in the process and practice of research ethics and defines the tasks as follows:

- RECs must review research proposals according to principles in the guidelines.
- RECs must combine scientific and ethical review to ensure the social value of the research.
- RECs must be formally established and mandated, with adequate support and resources.

3 https://cioms.ch/publications/product/international-guidelines-on-good-governance-practice-for-research-institutions/
4 ‘Research waste’ refers to poor-quality research output that is often perceived as of minimal use to health policy-makers and clinicians. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10699190/
• RECs must consist of multidisciplinary membership, who are duly qualified and independent and who must undergo research ethics training.

• Legitimate appeals against decisions should be possible.

In multinational studies, reviews must be done by RECs in both the host and sponsoring countries. To harmonise reviews and maintain quality in this process, quality indicators should be developed. This will enable trust between RECs.

To date, CIOMS has published reports that are freely available on the CIOMS website, covering various topics such as clinical research in resource-limited settings; patient involvement in the development, regulation and safe use of medicines; and good governance practice for research institutions. Reports that are in preparation focus on real-world data and real-world evidence in regulatory decision-making, and risk–benefit balance for medicinal products. The reports follow the idea of open science, and are not only open-access publications but also open to society.

The 2022 report “Patient involvement in the development, regulation and safe use of medicines”5 promotes the notion that patients should be involved throughout the process of developing treatments, and requires a cultural shift to view patients as partners. The principles for involving patients are based on the premise that patients know best how their condition affects them. Engagement must involve a full range of patient views, including marginalised communities, as well as family carers and other caregivers. Patients should be properly reimbursed for their time and expenses, and their independence must be maintained.

CIOMS remains active in the field of research ethics, responding to challenges and addressing them in updated guidelines. In this regard, the RECs play a central role, but other parties also carry the responsibility of upholding research ethics principles.

UNIFIED INTERPRETATION OF POPIA IN THE CONTEXT OF PROTECTION OF PERSONAL INFORMATION: ASSAf DRAFT CODE OF CONDUCT FOR RESEARCH

Prof Michèle Ramsay, Chair: ASSAf POPIA Committee, University of the Witwatersrand; Mrs Matty van Niekerk, University of the Witwatersrand; and Mrs Susan Veldsman, ASSAf

The Protection of Personal Information Act (No. 4 of 2013) (POPIA) became effective on 1 July 2020, with a one-year grace period provided to entities for compliance. Chapter 7 of POPIA describes the process for organisations and business entities to develop codes of conduct, offering guidance on interpreting POPIA within their respective sectors and concerning the types of information handled. In the research sector, the development of an industry best practice guide is essential to ensure consistent interpretation and application of POPIA.

ASSAf has taken the initiative to draft a code addressing significant aspects affecting the research and science sector in South Africa, which may not be explicitly clear in the Act. One such aspect is the practical application of high-level principles to research, particularly concerning the use and processing of data containing personal information. While POPIA provides exceptions for processing personal information for research purposes, their application remains open to interpretation. To ensure consistency in interpreting and implementing the Act, a uniform approach to regulating personal information for research is necessary across government departments, academic institutions, research councils, and the private sector. This is essential for establishing South Africa as a safe haven for research data. Furthermore, preparations for a possible application to the European Commission for an adequacy decision under the General Data Protection Regulation (GDPR)6 are underway, reflecting South Africa’s

5 https://cioms.ch/publications/product/patient-involvement/
6 The European Commission has the power to determine, on the basis of article 45 of Regulation (EU) 2016/679 whether a country outside the European Union offers an adequate level of data protection. https://commission.europa.eu/law/law-
commitment to aligning its data protection standards with international norms and facilitating data exchange with the European Union.

In addition to the aforementioned considerations, the development of a code or best practice framework is crucial to ensure accountability for non-compliance among research institutions and researchers. This code will apply to both industry and academia, encompassing all disciplines that involve the collection, processing, and storage of personal information as part of research activities. In this context, research is defined as the process of generating, preserving, augmenting, and improving knowledge through investigations and methods relevant to various scientific fields or disciplines. It is imperative that research endeavours recognise the intrinsic value of knowledge for the betterment of society, promoting principles of open science and transparency. Furthermore, given the ethical implications inherent in research involving personal information, most research endeavours are intended for publication and therefore must undergo independent ethics review. This ensures that research activities adhere to ethical standards and uphold the rights and well-being of research participants. The framework governing research in South Africa is outlined in Chapter 2 of the Bill of Rights, which states that “everyone has the right not to be subjected to medical or scientific experiments without their informed consent”. In addition to constitutional provisions, the National Health Act⁸ and the Department of Health’s Guidelines on Ethics in Research play a pivotal role in regulating research activities. These regulations apply broadly to research endeavours that involve human participants and are not limited solely to health-related studies. They mandate that individuals participating in research projects provide informed consent, thereby ensuring that participants are fully aware of the nature and risks of their involvement. Furthermore, the establishment of health ethics committees is required under these regulations. These committees play a crucial role in reviewing research protocols to ensure compliance with ethical standards and safeguarding the rights and welfare of research participants. To enhance oversight and coordination, health ethics committees must be registered with the National Health Research Ethics Council (NHREC), ensuring consistency and accountability in the ethical review process across different research institutions and settings.

The code must align with international standards on open science, and data protection laws and regulations, such as the GDPR, and those in the African Union and European Union.

In line with ASSAf’s objectives of promoting common ground in scientific thinking across all disciplines and supporting the development of intellectual capacity, as well as offering effective advice to facilitate appropriate action in relation to the needs, opportunities, and challenges of all South Africans, ASSAf views the balancing of the right to privacy of research participants against the collective public interest in scientific research as an integral part of its role. Therefore, ASSAf has taken the lead in drafting a framework for a POPIA code of conduct for research.

The development of the code involved establishing steering and drafting committees, which convened regular meetings and organised public consultation forums. Following the announcement of the publication of a draft code and the invitation for comments, responses were carefully reviewed and incorporated into the code. Subsequently, the finalised code was submitted to the Information Regulator for input and feedback in July 2023. It’s noteworthy that the stakeholders engaged in this process represented 92% of South Africa’s research institutions.

Compliance with POPIA raises important questions regarding the protection of personal information of research participants. Firstly, it is necessary to define the nature of special personal information as well as the nature of vulnerability in the context of health-related research. Secondly, the conceptual safeguards necessary to protect research participants and their data.

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must be established, with specific reference to consent that is necessary to comply with the protection of personal information for research purposes. This includes special personal information such as health-related data, genetic data, and data on children. Additionally, clarity is needed on the concepts of ‘de-identification’, ‘anonymisation’, and ‘pseudonymisation’. Guidance is required on managed access to datasets containing special personal information.

According to CIOMS, vulnerability requires judgement about both the probability and degree of physical, psychological, or social harm, as well as greater susceptibility to deception or having confidentiality breached. This relates not only to the initial consent to participate in research but also to ongoing participation in research studies. CIOMS defines vulnerable persons as those who are relatively (or absolutely) incapable of protecting their own interests due to impairments in decisional capacity, education, resources, strength, or other attributes needed for self-protection. Additionally, circumstances, whether temporary or permanent, in which they live can make it less likely that others will be vigilant about or sensitive to their interests. This includes people who are marginalised, stigmatised, or face social exclusion and prejudice, increasing the likelihood that others might place their interests at risk, whether intentionally or unintentionally.

In POPIA, ‘special personal information’ encompasses a range of sensitive data, including religious or philosophical beliefs, race or ethnic origin, political persuasion, health status, sexual orientation and practices, biometric information (including genetic data), and criminal behaviour.

In the view of the committee, POPIA and CIOMS are aligned on the issues of vulnerability and special personal information, as both recognise that certain types of information can lead to vulnerability, stigma, marginalisation, social exclusion, or prejudice. Both POPIA and CIOMS acknowledge the importance of safeguarding individuals, including children, who may be unable to protect their own interests. However, while special personal information is not prohibited from processing outright under POPIA, certain conditions must be met for its use, particularly in research. CIOMS highlights the risks associated with excluding vulnerable populations from research, as doing so may fail to address their specific interests and needs. While some data, such as banking details, may be less sensitive and subject to processing with appropriate safeguards, other types of data, particularly those related to health or genetic information, require careful justification for processing.

It is important to put safeguards in place to protect research participants, including:

- Deidentifying, anonymising or pseudonymising of the personal information
- Adhering to a POPIA code of conduct, best practice framework, or other industry standard as best practice
- Obtaining appropriate participant consent
- Successfully obtaining ethical approval from a REC
- Encryption of data or providing a restricted environment for high-risk research.

The terms ‘deidentification’, ‘anonymisation’, and ‘pseudonymisation’ warrant attention due to their varied interpretations by different regulatory bodies. According to POPIA, ‘deidentification’ involves the complete removal of all identifying information. As a result, once deidentification is performed, POPIA no longer applies, as there is no identifiable information remaining. However, the GDPR refers to the process of removing identifiable data as ‘anonymisation’. On the other hand, ‘pseudonymisation’ is a distinct concept that involves masking identifying information, allowing for a reversible process. It’s important to note that even with pseudonymisation, if the masking code used can potentially lead to the identification of an individual participant, both POPIA and the GDPR must be applied to ensure compliance with data protection regulations.

RECs play a crucial role in appreciating the significance of research being both responsible and meaningful, while also adhering to ethical principles and legal requirements. This necessitates a thorough understanding of POPIA and its implications for research practices, ensuring that data
It is considered best practice to obtain prior informed consent from participants to use and share their data, and in some situations, a third party, such as a REC, can take responsibility for decision-making regarding further processing and the good governance of the information. However, according to POPIA, consent is not required to collect special personal information for research purposes if all of the following conditions are met: the data will only be used for research purposes; the data will not be published in an identifiable form; the research is in the public interest, or obtaining consent would involve a disproportionate effort, and there are sufficient safeguards in place to ensure that the research does not unduly compromise the participants’ privacy.

Special personal information should not be deposited in open-access databases unless appropriately consented and safeguarded. The difference between open access and managed access is important, especially for data in the health sector. According to the Berlin Declaration⁹, open access refers to free access to information and unrestricted use of electronic resources for everyone. This means that anyone can download the data directly from a source, without restriction. However, in health research, managed access to personal information is usually advisable. In this case, access would be granted by a data access committee and/or through a predetermined process, and the parties usually enter into a legally binding data access agreement, whereby participants agree to the good governance of the data by a trusted third party who makes decisions on their behalf.

For research data provided to a research data repository, POPIA consent will typically not be required, provided that the conditions for the release of the data are appropriate given the nature and context of the research data/study. Recipients of research data must ensure that safeguards are in place to restrict further use and sharing of data, and they must ensure compliance with POPIA-equivalent rules or standards.

For researchers and RECs, an industry standard on best practices is essential for implementing sufficient safeguards to ensure that research does not unduly compromise the privacy of research participants. ASSAf is working with the research community across government departments, academic institutions, research councils, and the private sector to develop a best practice framework to ensure consistency in interpreting and implementing the Act and a uniform approach to regulating personal information for research. POPIA is not intended to be a barrier to research but should be viewed as an opportunity to encourage good practice in the protection of personal information collected during research.

RESEARCH ETHICS COMMITTEE FUNCTIONING AND RESEARCH PARTICIPANT SAFEGUARDS: A REVIEW OF THE ETHICS IN HEALTH RESEARCH GUIDELINES (NATIONAL DEPARTMENT OF HEALTH, 2015)

Prof Shenuka Singh, NHREC: Deputy Chairperson; University of KwaZulu-Natal

According to Section 71.1 of the National Health Act (No. 61 of 2003) (NHA), all institutions must establish or have access to a REC to review and approve research proposals. This requirement applies to both Human Research Ethics Committees (HRECs) and Animal Research Ethics Committees (ARECs), both of which need to be registered with the NHREC.

Section 72 of the NHA stipulates the terms of reference for the NHREC, namely:

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⁹ https://openaccess.mpg.de/Berlin-Declaration
• Determine guidelines for the functioning of HRECs and ARECs
• Register and audit RECs
• Set norms and standards for the conduct of research, especially with human participants and research involving animals
• Adjudicate complaints about the functioning of RECs
• Refer misconduct or violations to the relevant statutory bodies in the ethical code of conduct and institute disciplinary action
• Set up working groups within the NHREC to carry out its mandate.

This presentation focused on the DoH 2015 guidelines, given that the updated guidelines are still in progress. Currently, 46 HRECs and 21 ARECs are registered with the NHREC. Registration is voluntary and requires the REC to meet the necessary criteria. Onsite audits are conducted for compliance. Registration is valid for five years, and annual reports on the REC’s activities must be submitted to the NHREC. A register of all registered RECs is available on the NHREC website. Registration is revoked for non-compliance, and RECs must implement rectification measures to re-register.

The main purpose of a REC is to ensure that the rights, dignity, and interests of research participants are upheld, and that research is scientifically sound. The responsibility of each REC member is to ensure that any proposed research provides adequate protection for study participants and complies with the standards for ethical research, while also maintaining scientific integrity. If animals are involved in research, the REC must ensure their welfare and interests according to criteria set in the South African National Standards for the care and use of animals for scientific purposes.

RECs are required to have terms of reference and standard operating procedures in place. The terms of reference outline the mandate, statutory requirements, positioning within the institution and the responsibilities, accountabilities, and reporting structures. The standard operating procedures provide details on the operational aspects, daily functioning, governance processes, and how tasks are carried out. REC membership must be multidisciplinary, multisectoral, pluralistic, and inclusive.

The 2015 guidelines stipulate that a REC must have at least nine members, with a quorum constituting an overall majority; if there are more than 15 members, the quorum is 33%. Members must come from a range of specified fields. For ARECs, these include veterinarians, scientists with substantial and recent experience in the use of experimental animals, representatives from animal welfare organisations, as well as representatives not involved in animal experimentation. For HRECs, members need to have a background of professional care, counselling or health-related treatment of people, professional training and experience in qualitative research methodologies (at least one member), professional training and experience in quantitative research methodologies, expertise in biostatistics, and research ethics. Both ARECs and HRECs must include a layperson in the committee, preferably from the community in which the research is conducted, to ensure the community’s voice and interests are upheld. The RECs must also be diverse in terms of seniority, rank, ethnicity, culture, and gender. All REC members need to have appropriate qualifications and experience, in addition to having completed a recent research ethics training course (within 3 years). A code of conduct is necessary to guide members’ conduct, integrity, diligence in attending meetings, confidentiality, and declarations of conflict of interest. Institutions must indemnify RECs from decisions and take legal responsibility for pronouncements.

REC members have to receive induction and orientation when joining a committee, and regular ethics training and refresher courses must be conducted. Several free online courses on research

10 https://www.health.gov.za/nhrec-home/
ethics are available; however these are mostly generic, and context-specific workshops for specific instructions are essential.

The standard operating procedures must cover aspects regarding the functioning of the REC, including frequency of meetings, preparation of agendas and minutes, attendance registers for meetings, the nature of committee meetings, quorum requirements, guidance on decision-making, conflict of interest, confidentiality, the review process, and continuing monitoring and re-certification procedures. There must be a formal application process in place, and RECs must inform researchers of the requirements, including templates for information sheets, consent forms, as well as the submission of data collection tools, such as, questionnaires, interview schedules, data extraction sheets, advertisements, videos, dramatisations, and letters for recruiting potential study participants.

When preparing submissions, researchers must consider the literacy levels of participants and the level and readability of the participant documentation. For community-based research, there must be evidence of consultation and plans for community engagement. AREC submissions must detail how the welfare of the animals will be ensured, including monitoring schedules and lists of persons responsible for different aspects of the research.

Feedback to applicants is formalised in the form of review reports, which must include information on how the decision was reached. The REC chairs are responsible for consolidating/overseeing the review reports and ensuring that feedback is constructive, collegial, and highlights the issues that need to be addressed. The REC must build researcher confidence in the research ethics process.

Reciprocal reviews recognise prior review and approval of a research proposal by another registered REC to avoid duplication of effort and unnecessary delays in the processes.

Monitoring of research projects is crucial because RECs need to oversee the approved studies being conducted in the field. This is achieved through random visits to research sites and scrutinising monitoring sheets, signed consent forms, and records of interviews.

Principal investigators must submit regular (at least annual) reports to the REC on progress to date, enrolment status of participants, and evidence of the study’s completion. RECs must also submit annual reports to the NHREC. Where researchers encounter problems with the REC, or if research participants have issues with researchers, a complaints process should be in place. If there is an issue with the REC, procedures and mechanisms are needed for escalation to structures other than the REC, such as the senior institutional management as well as the NHREC. The NHREC must guide both RECs and researchers through the various processes, ensuring ongoing discussion, facilitation, and dialogue between the parties.

**ROUNDTABLE: ALIGNMENT OF RESEARCH ETHICS PRINCIPLES BETWEEN INITIATIVES IN TERMS OF CIOMS, WITH RECS, PROFESSOR VAN DELDEN, NHREC AND ASSAf**

**Facilitated by:** Mrs Susan Veldsman, Mrs Eleni Flack-Davison and Mrs Tanya Coetzee

**Comment:** Foremost in the discussion of research ethics is the importance of good science. Without good science, any research becomes irrelevant.

**Comment:** Some South African RECs are weak and not functioning optimally. It is essential to address these challenges through capacity building and mentorship because the lack of capacity in some RECs places an undue burden on other committees.

**Response from Prof Singh:** Capacity building is an institutional responsibility. RECs are positioned within institutions, whose role it is to review research ethics protocols prospectively to ensure that participants’ interests, rights and dignity are upheld. It is imperative that processes are put in place to ensure that REC members understand the principles of both research and review.

**Comment:** Currently there is no formal process for reciprocity. It is important that RECs work
together, and those with more experience and expertise must upskill the less effective committees. This can also improve reciprocity.

Response from Prof Singh: The concern with respect to guidelines around reciprocity is valid because it is not explicitly elaborated on in the DoH 2015 guidelines. The updated DoH guidelines provide a much more clear process on the roles and responsibilities of the RECs involved in the reciprocal review process. With reciprocity comes trust. Unfortunately, some RECs might still be distrustful of the review processes of other RECs. Therefore, trust-building must occur between RECs to truly optimise reciprocity in the ethics review process.

Response from Prof van Delden: A good approach to address the trust between RECs is implementing quality indicators. Once there is trust in other committees, there is no need for dual reviews within a country. This means that if a REC has reviewed a research protocol according to the quality indicators, there is no need for this to be repeated by another REC, which would save time and resources and enable RECs to conduct more active reviews. In the Netherlands, only the Central Committee defines quality indicators.

Comment: The tendency of high-powered researchers to put pressure on RECs and exert influence on regulatory authorities to play the system is of great concern. This is unfair to the RECs and to other researchers.

Response from Prof Dhai: This is an issue of both research and professional integrity. Each person must reflect on his/her own integrity. RECs can raise the issues, but researchers themselves have to make the paradigm shift in their mindset.

Question: RECs must do both active and passive monitoring. The need for active monitoring (after approval of the projects) is evident, but it is complex, time consuming, and resource heavy. Has active monitoring been instituted in the Netherlands, for example, and what was the experience in this regard? Has CIOMS considered giving more guidance on both active and passive monitoring?

Response from Prof van Delden: Active oversight and exchanging experiences could be a way of educating one another to improve the quality of RECs. For example, in the Netherlands, there was no law regulating the use of biological specimens after a project has ended, and institutions formed their own committees to draw up protocols regarding bio-banking. These protocols were circulated between institutions for review and to ensure consistency in the protocols. The CIOMS guidelines stipulate active monitoring of research studies, but RECs are often overburdened and do not have the capacity or time to attend to this. CIOMS could indeed do more to provide guidance on active and passive monitoring.

Comment from Prof Singh: The updated draft guidelines are currently out for public comment and stakeholder input, presenting the opportunity to scrutinise the sections that were unclear in the 2015 guidelines and make constructive contributions.

Question: Concerning leading researchers who are not compliant, a recent application for a multi-institutional project required that each institution assess and approve the project separately. The researcher received provisional clearance from his affiliated institution on condition that corrections and amendments were made to the protocols before sending the proposal to the other institutions. However, the application was sent out without amendments and most institutions gave clearance. One institution rejected the application and required corrections to some seriously flawed aspects. The applicant refused to make the corrections, and the situation resulted in negative press for the institution. When the REC chair of the home institution was requested to intervene, the response was that since the applicant was of good standing, he was granted provisional approval and the REC assumed that the corrections would be made. In such cases, where does responsibility for final ethical clearance reside?

Response from Prof Singh: This is an example of the importance of standard operating procedures (SOPs), especially for studies at multiple sites that require multiple or reciprocal reviews, where detailed guidelines are essential. The DoH guidelines on Ethics in Health Research
(2015) stipulate that SOPs must be in place, but no details are provided regarding the required content that must be drafted at the institutional level. It must be made clear that RECs are not responsible for all research in an institution but have the sole function of reviewing protocols for the purpose of protecting study participants. The research office has oversight over the integrity of research processes. With regards to the query, more detail is required, seeing that this is very context-specific.

**Question:** How can one check whether a multinational research proposal has been approved in a regional country, especially where the study involves several higher education institutions?

**Response from Mrs Veldsman:** The framework includes a chapter on what other countries need to comply with to ensure that the code is adhered to.

**Response from Prof Singh:** RECs should request parallel research ethics clearance letters from the local RECs in the country where the study will be conducted (and also comply with the ethical-legal requirements); or provide evidence that such RECs are non-existent in these settings. In cases where RECs are non-existent, the applicant can request a waiver from their own institution to grant approval for research at another institution, however, noting that the approving REC does not have jurisdiction in another country.

**Question:** In the presentation on special information, it was stated that this does not exclude vulnerable populations and that these require processing rather than special procedures. Are special procedures or measures no longer required, or does the code of conduct include provisions for researchers to specify that there are procedures and processes in place that necessitate safeguards for vulnerable groups?

**Response from Mrs van Niekerk:** POPIA determines categories in which the Act is applied with certain provisions. The best approach is to avoid processing special information if possible. However, when data is processed, the POPIA rules apply and extra measures are not necessary.

**Response from Prof Ramsay:** The reason for this approach is to safeguard participants and their privacy. When working with special personal information, it is essential to document the safeguards and how the risks are managed and balanced.

**Question:** Do the new guidelines require the establishment of data management committees for regulatory oversight? Should these committees be within the REC, or can they be stand-alone committees?

**Response from Prof Singh:** Again, noting that the presentation has not covered the updated DoH guidelines, a general comment is that there must be provisions to ensure that proper data management processes are in place with respect to data storage, access, and security. This is part of what RECs review. However, it is not the REC’s responsibility to ensure that this is implemented. This role lies with the institution. In terms of getting access to the data, it should be the role of a subcommittee to determine the competence of applicants requesting access, data sharing, and the secondary use of data. This is specifically important for the secondary use of datasets.

**SESSION 2: PARTICIPANTS IN HEALTH RESEARCH – KEY STAKEHOLDER PERSPECTIVES**

**Facilitated by Ms Caz McNamara (Wits and SARIMA)**

**HARMONISING HUMANITY: THE ROLE OF RESEARCH MANAGEMENT IN ENSURING PARTICIPANT SAFETY**

**Dr Retha Visagie, UNISA Manager: Research Integrity, Co-Chair of SARIMA Community of Practice for Research Ethics and Integrity**

Harmonising humanity in research ethics entails collective efforts globally to align research practices and ethical standards with human values such as dignity, integrity, respect, and safety. It is imperative to promote ethical research conduct that prioritises the well-being and rights of
participants in research studies while fostering regulatory collaborations and unity among researchers, research managers, ethicists, regulatory agencies, and patients or participants worldwide. Local and international organisations and regulatory bodies such as CIOMS and the South African NHREC, together with other role-players such as research management professionals, comprise a global research community guided by shared ethical values and principles.

In his book *Finding Common Ground: Consensus in Research Ethics across the Social Sciences*¹¹, Ron Iphofen ponders how to build upon existing research ethics developments without duplicating current structures. From a harmonisation perspective, he proposes assessing previous work and exploring new approaches without losing sight of the valuable knowledge and experience that have been attained. The development of new codes and guidelines without adequate sharing and cross-fertilisation of new ideas should be avoided.

'Universality', which refers to the adoption of universally accepted ethical principles without consideration of context or culture, is widely contested in scholarly debates on research ethics particularly from a colonial perspective. This presentation argues that harmonising efforts should focus on finding common ground without marginalising local values and contexts.

Research managers are key in ensuring participants’ safety and promoting the uptake of contextually relevant guidelines. According to SARIMA’s competency framework, the role of research ethics managers is to promote, foster and support research ethics and integrity compliance and responsible research conduct on a strategic level. They must interpret international codes and practices, set the tone for organisational ethics, foster and implement codes of conduct and institutionalise practices in research ethics. Furthermore, they must remain abreast of current developments and engage in ongoing dialogue, knowledge-sharing and capacity-building initiatives to promote the safety of participants. Establishing or participating in CoPs and education programmes, conducting research, and acting as catalysts for change will increase the impact of the work of research ethics managers.

As a response to the history of exploitative research practices in Africa, integrated community consultation, enhanced cultural awareness and bringing compassion into research practices have gained prominence. The SAN Code of Research Ethics¹², launched in 2017, emphasises the principle of care, while the TRUST¹³ Global Code of Conduct for Equitable Research Partnerships¹⁴ similarly positions care as a foundational principle. These guidelines underpin ethical research that is informed by local requirements and is built on mutual trust. The 2021 CIOMS consensus report on clinical research in resource-limited settings¹⁵ affirms the need to address exploitative research. Despite significant progress in past decades, and even with the best intentions, some projects have had adverse effects on the study participants or communities involved.

The global perspectives in this regard are diverse and sometimes contradictory, and exploitative research in resource-limited settings by high-income countries (referred to as ‘ethics dumping’) continues to occur. The 2021 consensus report expands upon the 2016 CIOMS guidelines, outlining characteristics and circumstances contributing to the vulnerability of participants.


13 TRUST was a pluralistic project that aimed to foster adherence to high ethical standards in research globally and to counteract the practice of ‘ethics dumping’ or the application of double standards in research, by co-developing with vulnerable populations tools and mechanisms for the improvement of research governance structures (https://trust-project.eu/).


Researchers engaged in clinical research in resource-limited settings need to assess vulnerability by comprehensively understanding the local context of the study.

In 2021, research managers from the CoP for Research Ethics and Integrity, supported by SARIMA and the Southern African Network for Biosciences (SANBio), formulated a comprehensive set of research ethics guidelines tailored for SADC. The guidelines serve the entire SADC research community and address self-regulation of professional, ethical and legal research integrity and ethics responsibilities, including adherence to the Nagoya Protocol. The SADC guidelines underpin ethical research informed by local requirements and include a section focusing explicitly on research that addresses the local realities of the sample communities. In line with harmonising principles, the section on vulnerability in the guidelines draws from the 2021 CIOMS consensus report and the 2015 South African National Department of Health’s ‘Ethics in Health Research: Principles, Processes and Structures’. However, the SADC document differs from these with respect to its stance on research integrity and ethics, including guidance on the application of the Nagoya Protocol. The CoP held several stakeholder meetings in the SADC region, which resulted in requests for guidance on the use of artificial intelligence (AI) in research ethics. These are currently being formulated.

In conclusion, research managers are in an ideal position to mitigate risks and ensure participant safety by contributing to the development of guidelines. The institution-wide implementation of guidelines and codes of conduct, policy integration, and advocating for change should purposefully include research managers in working groups to harmonise research ethics guidelines.

SA GCP 2020: SAHPRA FUNCTIONING AND RESEARCH PARTICIPANT SAFEGUARDS

Prof Lesley Burgess, SAHPRA and Stellenbosch University

The SAHPRA Good Clinical Practice (SA GCP) guidelines were implemented in October 2021. The guidelines represent a significant improvement on the 2015 National Department of Health (NDoH) guidelines and are closely aligned to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) GCP guidelines and the Clinical Trial Committee (CTC) policies.

The GCP guidelines address design, planning, management, conduct, and regulation of clinical trials involving human participants. They do not restate the ethical principles that underpin sound and ethical research, as these are adequately outlined in the 2015 NDoH guidelines. While the GCP details the conduct of clinical trials, research infrastructure and research ethics are covered in the NDoH guidelines. Researchers are therefore required to adhere to both the GCP and NDoH guidelines. In cases of conflict of interpretation, the GCP takes precedence.

Section 2 of the GCP highlights several key concepts in clinical trials but relies on the DoH guidelines for more information on various aspects, including ethical principles, justification for trials, risks, burdens and benefits, rights and safety of participants, informed consent, ethics reviews, trial incentives and participants’ reimbursement, scientific requirements for research

16 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. https://www.cbd.int/abs/about/default.shtml
protocols and data management, and dissemination of research results.

Some concepts have been updated, and the following changes are noteworthy:

- An important revision was on trial incentives and participants’ reimbursement (section 2.7). Reimbursement of participants’ expenses should not be an incentive. The costs of transport and refreshments must be covered by the trial. Where participants incur expenses, a fair rate should be calculated using the time, inconvenience and expenses (TIE) method.
- The GCP touches broadly on vulnerability, but refers to the 2015 NDoH guidelines for details.
- RECs and REC training are accorded high priority in the GCP, including the need for follow-up training on the GCP every three years.
- The GCP differentiates between principal investigators (PIs) and sub-investigators. PIs carry the burden of work and responsibility, but in the case of co-PIs, the sharing of roles must be defined. For multi-centre studies in South Africa, a national principal investigator (NPI) takes overall responsibility for conducting a trial.
- Informed consent is addressed, especially in the context of substantial vulnerability. Electronic consent is increasingly used abroad, and will become more relevant in South Africa as well.
- With regard to records and reports, the amended guidelines prescribe that documents must be retained for at least ten years after the termination of the research project, or at least two years after the formal discontinuation of the clinical trial.
- Progress reports must be submitted to SAHPRA every six months, or more frequently as requested.
- The concept of ‘sponsors and contract research organisations’ (CROs) has undergone significant revision. This is relevant in cases where international entities contract research in South Africa.
- The handling and disposal of investigational products and trial-related waste has received more attention. Research protocols must include a section on waste management, especially consumables (syringes and needles) and potentially dangerous chemicals.

However, some important matters are not addressed by the SA GCP and need to be heeded by research applicants and RECs when submitting research protocols. These include:

- Conflict of interest
- Insurance against trial-related injuries
- Professional indemnity
- Sponsor indemnification
- Continuing care after research (post-clinical trial access)
- Assessing safety and minimising risk
- Human reproduction considerations
- New technologies
- Electronic signatures
- Therapeutic misconception and dual roles
- Conducting clinical trials during a pandemic.
ELEMENT OF TRUST IN RESEARCH

Dr Seeiso Koali, Research Integrity Officer: South African Medical Research Council

A person with integrity consistently demonstrates virtuous character, regardless of circumstances or consequences, forming the foundation of trust. Trust is a continuous belief in the fulfilment of an entrusted act. When participants are recruited for research, they have limited information about the study, making trust essential for them to feel safe. Trust is earned relationally and is the key element in accepting other people’s research findings. Consistently upholding moral qualities strengthens the element of trust, which is especially crucial in research. While innate moral qualities or virtuous characters may not always be present in individuals, they can be developed through training and awareness. The key qualities of trustworthiness in research include consistency, integrity, honesty, and transparency. Trustworthiness cultivates mutual relationships between researchers, research participants, and communities, reframing participants not merely as subjects but as individuals deserving respect and protection of their innate human rights. Voluntary informed consent should not be a mere checkbox requirement; rather, it should offer honest information enabling participants to make fully informed decisions. The privacy of participants is safeguarded by protecting the information of research participants. This requires data integrity and controls to prevent unauthorised access to information.

Ubuntu\textsuperscript{20} is fundamental in safeguarding the welfare of research participants, fostering harmonious and loyal interrelationships between participants and researchers. It cultivates moral, humane, caring, respectful, and polite attitudes towards participants, recognising their intrinsic value beyond being mere means to an end. However, trust entails vulnerability. Participants entrust researchers without certainty of their intentions, making them vulnerable to exploitation. Trust is broken when researchers fail to meet expectations.

According to Stephen Covey\textsuperscript{21}, credibility is rooted in integrity, supported by intent and realised through capabilities and competence, resulting in trust. Researchers and research institutions have to restore trust in health research by focusing not only on regulatory and compliance systems, but also on promoting trustworthiness. Awareness and educational programmes can assist in fostering and encouraging research that is conducted through the lens of research integrity.

SAFEGUARDING INDIGENOUS KNOWLEDGE IN RESEARCH

Dr Fikile M. Mnisi, Research Ethics Committee Association of Southern Africa (REASA) and Khaca (Pty) Ltd

For centuries, indigenous people around the world have developed their own knowledge systems, collectively called ‘indigenous knowledge’ (IK) or ‘traditional knowledge’ (TK). This knowledge was generated from everyday practice and experiences and passed on through generations, mainly in oral form. Indigenous knowledge is situational knowledge\textsuperscript{22} that originated over time through the process of learning and sharing by members of a particular community, and it is refined and enriched with expertise gained over several generations. It is an integral part of the cultural identity of a community and often plays a vital role in people’s livelihoods, especially in developing countries.

\textsuperscript{20} Ubuntu (often translated as "I am because we are") describes a set of closely related African-origin value systems that emphasise the interconnectedness of individuals with their surrounding societal and physical worlds.

\textsuperscript{21} Stephen M.R. Covey and Rebecca R. Merrill. \textit{The SPEED of Trust: The One Thing That Changes Everything}. 2008. Simon and Schuster. ISBN 1416549005, 9781416549000

\textsuperscript{22} ‘Situational knowledge’ is the knowledge gained from awareness of the surroundings, and from dealing with and understanding certain situations.
UNESCO defines local and indigenous knowledge as the understanding, skills and philosophies developed by societies through long histories of interaction with their natural surroundings. In most cases, this constitutes shared belief systems and rules about physical resources, social norms, health, ecosystems, cultures and livelihoods of the communities in both rural and urban settings. Local decision-making in agriculture, health care, food preparation, education, natural resource management, and a host of other activities are based on IK.

The World Intellectual Property Organisation (WIPO) describes IK under the following broad categories:

- Traditional knowledge (in the strict sense), which includes technical know-how, practices, skills, and innovations related to biodiversity, agriculture, or health
- Traditional cultural expressions and folklore, which are cultural manifestations such as music, art, designs, symbols, and performances
- Genetic resources such as genetic material of actual or potential value found in plants, animals, and micro-organisms.

The United Nations Declaration on the Rights of Indigenous People²³ states in article 31 that:

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge, and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literature, designs, sports and traditional games, and visual and performing arts. They also have the right to maintain, control, protect, and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

In conjunction with indigenous peoples, States shall take effective measures to recognise and protect the exercise of these rights.

In South Africa, safeguarding IK is of particular importance, because of the rich diversity of knowledge systems. Historically, IK was undermined and misappropriated, and indigenous communities were unable to receive benefits from the products generated from their knowledge.

Furthermore, the concepts of social Darwinism and eugenics have in some cases been entrenched in research on race and knowledge cultures.

As a result, researchers must be trained to safeguard IK, not only in rural but also in urban settings, and be sensitive in using it with integrity. Inclusivity in research on IK includes understanding methods that were used in the communities to gather information and applying them as part of research methodologies. A digital system on indigenous knowledge should be created to prevent plagiarism and the appropriation of knowledge that belongs to a particular community.

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The debate on the sharing of clinical research information is fundamental to informed consent, especially in vulnerable populations. The evolution of policies and guidelines on the sharing of clinical research information is presented in Figure 1, denoting milestones such as the inceptions of guidelines, policies and laws in the global space. Specific mention is made of South African developments in response to global policies. In addition to government policies, the pharmaceutical industry has its own policies to address participant-centric processes in compliance with legislated global and local standards.

In South Africa, the health research sector is facing more questions than answers related to ethics, many of which are continuously deliberated by the research community at relevant forums. Many issues that are regarded as important for the pharmaceutical industry and its collaborators have already been raised in earlier presentations and are mentioned here.

Figure 1: The evolution of the sharing of clinical research information
The voice of the participant in consultations during patient advocacy groups is central to informed consent. For participants to be able to contribute meaningfully in safety reporting, there needs to be an emphasis on lay terminology rather than medical terms. Understandable language and attentiveness to differences in dialect and meaning create a respectful space for participants to contribute.

The consenting process must adhere to transparency and must uphold participant autonomy and respect. The choice and appropriateness of language using interpreters is important to avoid potential problems such as coercion. Post-trial patient management must be carried out in a similar manner to the standard of the research.

Home and mobile visits can reduce the burden to participants. The way in which research results are shared with participants is often problematic when participants are unable to interpret formal reports. Summaries must be drafted that are easily understood by laypersons.

During studies where participants visit institutions, compensation for transport and meal expenses is important. Overnight accommodation for participants and caregivers, as well as childcare costs, can be a challenge for participants, especially when travelling from remote areas.

It is important to ensure that research is inclusive of vulnerable persons. Pregnant women have higher risk factors, but should not be excluded from research that they can benefit from. Similarly, disabled persons must be included and accommodated through braille translations for blind participants, voice-recorded materials for hearing-impaired participants, and home visits for physically disabled persons. Other vulnerable communities include incapacitated participants, marginalised communities, prisoners, asylum seekers and undocumented immigrants. Research on undocumented children is particularly problematic. However, excluding these vulnerable groups from research will potentially discriminate against them. Other challenges include sharing of resources, diversity of participants, and accessibility of participants. Language barriers, for instance, require clarification to avoid misconceptions. Participants’ knowledge of the research can be improved by demystifying the research and involving communities and religious and cultural groups.

The regulatory and ethics requirements also have an impact on the location of research, the selection of research participants, and the skill sets available.

**THE ROLE OF RESEARCH INTEGRITY IN SAFEGUARDING RESEARCH PARTICIPANTS**

*Mr Francis Kombe, Interim Chair, African Research Integrity Network*

The African Research Integrity Network (ARIN) is an informal network that brings together like-minded people to promote a culture of integrity among African researchers, institutions and decision-makers, guided by African perspectives, values, and inclusive thinking. The key objectives are to sustain dialogue, engagement and networking among African role-players and stakeholders; to develop awareness and understanding of research integrity among African scholars; to share information and resources on research integrity with the aim of building capacity and leadership in research integrity for Africa; and to contribute to the development of research integrity policies and guidelines for Africa.

The CIOMS guidelines are fundamental to ARIN, providing international ethical guidelines for biomedical research involving human subjects. CIOMS is relevant in the context of Africa, through the application of universal ethical principles in conducting research in low-resource settings to protect the welfare and safety of research participants. CIOMS requires commitments related to research ethics committees, researchers, research institutions, journals, funders and sponsors in different contexts and populations. Research integrity focuses on the conduct of individual researchers, misconduct and questionable research practices.

When the CIOMS guidelines and research integrity are juxtaposed, similarities and areas of overlap become evident. Both are underpinned by transparency, trustworthiness and public
accountability of the research enterprise. However, there are differences in the application of research ethics codes. Central to the CIOMS guidelines is the promotion of universal ethical principles. The obligations are placed primarily on RECs, but also on researchers, research institutions, journals, and funders. Research integrity speaks to the ethical behaviour of researchers and the responsible conduct of research.

Guideline 1 in CIOMS (scientific and social value and respect for rights) emphasises the quality and relevance of information and their contribution towards policy. However, there are important gaps related to professional conduct. This has implications for the quality of information to be produced and the integrity of research findings. Given the focus on the social value of research to participants and communities and the value of applying data to address community needs, the imperative for the professional conduct of researchers is shifted to the background. In Africa and developing countries in other regions, the individuals engaged in collecting field data are not always the researchers themselves. Field workers are often employed to collect the data, and have an impact on the ethical conduct of the research on the ground. The behaviour, welfare, safety and risks to field workers is not addressed in the CIOMS guidelines. The implications of gathering data using new technologies such as AI and chatbots are also lacking.

Guideline 2 relates to research conducted in low-resource settings and covers fairness to participants and the communities in which research is conducted. However, fairness between researchers is overlooked. Fairness between researchers involves power imbalances and exerting influence over other researchers, as well as fair-mindedness in diversity and inclusivity, especially in collaborative research. The Cape Town Statement on Research Integrity24 has addressed this issue, especially regarding the role that research institutions and funders can play in addressing barriers to fairness, diversity, and inclusivity.

The requirements for RECs and their role in reviewing protocols are discussed in Guideline 23, which details issues related to protocol amendments, deviations, violations, and sanctions. The guideline acknowledges that RECs lack the authority to sanction researchers involved in serious deviations, but it does not guide actions that the REC can take. The CIOMS guidelines and research integrity are interconnected in the necessity to establish an office of research integrity and the opportunity it creates to address research misconduct and deviations.

Both research ethics and research integrity are fundamental to health research, and the guidelines should highlight the importance of research integrity in promoting participants’ safety, welfare, and protection. There is a need for the scope of the CIOMS guidelines to be extended to cover issues related to individual research conduct and their implication for scientific integrity. The scope should also address power influence and imbalances, and emphasise the need for funders and research institutions to create an environment that promotes fairness, diversity, and inclusivity.

THERE’S MORE TO BEING ETHICAL THAN COMPLIANCE

Prof Kevin Behrens, Director, Steve Biko Centre for Bioethics, University of the Witwatersrand

The news reports from the beginning of 2024 regarding decades of humiliation and abuse of students at the Wilgenhof men’s student residence at Stellenbosch University, in the name of initiation, have brought back memories of ‘ontgroening’ (initiation) for those who experienced it at white high schools in the final decades of apartheid in South Africa. Many schoolboys (and girls) endured humiliation and abuse in their first weeks of high school, to a slightly lesser degree than what was reported at Wilgenhof. Similar practices continue to happen in the USA’s sorority and fraternity systems, at Belgian universities and in some of the most prestigious schools in the

24 https://www.wcrif.org/guidance/cape-town-statement
British Isles.

It is astounding that such unethical practices continue into the 21st century, even though rules, laws, standing orders and other regulatory requirements prohibit unethical behaviour. While the reasons for this are complex, it is evident that devising more rules and regulations is not enough to change behaviour.

A pressing question is how to teach bioethics in such a way as to alter the behaviour of students who will become future health professionals and scientists. Although the scholarly literature does not answer the question satisfactorily, three insights are shared based on observations and experience.

1. Research shows that those who obey the law do so, not out of fear of punishment, but because they believe it is legitimate.

Tom Tyler’s research indicates that American citizens mainly obey the law because they believe it is a legitimate authority. The crux lies in making appropriate laws that are worthy of respect, make sense, and help people understand the underlying reasons for the rules.

Many South African schools have for decades enforced a multitude of senseless, unnecessary rules about the length of boys’ hair, the requirement to walk in single file and in silence between classes, and prescriptions on school uniforms as a mechanism for total control over the student body. When corporal punishment was still lawful, most boys were subjected to lashes because they had no respect for the petty rules and tried to shun them whenever they could. The punishment was borne with pride as a sign of rebelling against a system of rules that made no sense.

The research ethics community must not fall into the trap of making rules, regulations and guidelines to micromanage processes of ensuring ethical research. There are many restrictions, in the CIOMS guidelines, but they must make sense and serve a legitimate purpose so that they are worthy of respect. Translational work is needed to explain the underlying normative reasons for the rules. Even though the CIOMS guidelines succeed in spelling out what underlies the thinking behind the rules in the commentaries and explanations, the research community is falling short in implementing the rules.

One of the possible reasons for resistance to RECs and for individuals who try to bend or bypass the rules is insufficient explanation of the rationale and purpose of the rules and guidelines. Since compliance to the rules is expected, RECs must ensure that people understand the underlying motivations.


The preamble to the CIOMS guidelines states that, “Although the Guidelines focus primarily on rules and principles to protect humans in research, both virtues and protections are essential to reliably safeguard the rights and welfare of humans”. The research ethics communities must support the development of the moral character of researchers to satisfy compliance, even when they could get away with not doing so. Ethics teaching should be focused on virtue, character, and moral development. The need for moral motivation is as important as the need for compliance.

In the student initiation example, the mixed messages that students received from prominent ‘old boys’ through the media imply that rules do not have to be taken seriously. The moral crisis in many countries is partially due to leaders that lack integrity and consistency in their moral judgement. A more concerted focus on virtue, character and moral motivation is required, not


26 This refers to mostly white schools from pre-1994.

just in the field of research ethics but more broadly in society.

3. The rules we do not make matter as much as the ones that we do.

CIOMS and the research ethics community are increasingly confronted by global problems. The WHO has warned that the role of climate change and environmental sustainability should not be ignored in health policies. To this end, a global bioethics forum is planned for 2024, focusing on ethical issues arising from research on health and climate change.

Climate change poses a serious global threat. The African philosopher Felix Murove28 stated that “human well-being is indispensable from our dependence and interdependence with all that exists, and particularly with the immediate environment on which all humanity depends.” Human health depends on the health of the Earth. By failing to make rules to protect the Earth, humans themselves are not protected. The rules that are not made matter as much as the ones that are.

**NAVAIGATING THE TECHNOLOGICAL FRONTIER IN HEALTH RESEARCH: ENHANCING ENGAGEMENT AND ENSURING ETHICS**

Dr Diana De Sousa, South African College of Applied Psychology (SACAP), SACAP Research Ethics Chair

Artificial intelligence (AI) and its implications for ethical frameworks and guidelines is an emerging field. The transformative impact of data-centric AI across various industries including health care and associated health research cannot be ignored. AI has revolutionised processes of enabling personalised services and fostering innovation in the healthcare research industry. A balanced approach integrating technological solutions, regulatory frameworks, and ethical guidelines is recommended to effectively address ethical concerns and maintain trust in AI systems used in health research.

The increasing use of AI in health research has given rise to a paradigm shift from a focus on algorithms to optimising data quality, and the recognition that robust and ethical source data significantly enhances the effectiveness and fairness of AI applications. Existing studies on AI highlight the interplay between technological advancement and ethical responsibility. Technological advancements must be balanced with ethical responsibility to ensure alignment with societal values and beneficial outcomes for all stakeholders involved.

The benefits in the applications of data-centric AI in many sectors (such as healthcare, finance, automotive, agriculture, marketing, and manufacturing) have been detailed by Patel29. For instance, in healthcare, AI can improve patient outcomes through personalised treatment plans; in finance, it can enhance operational efficiencies through fraud detection algorithms; in automotive, it can reduce traffic congestion through predictive traffic management systems. However, AI also presents ethical challenges. Integrating privacy consideration into AI technology design requires more robust data protection policies to prevent the misuse of personal data. Contextual integrity, consent, and transparency need to be addressed to ensure that dynamic consent models reflect ongoing consent in data usage.

Another concern is bias mitigation in AI systems. This entails exploring how biases in the data may lead to discriminatory AI outcomes that perpetuate social inequalities. Rigorous testing and auditing of AI systems are critical to identify and mitigate biases to ensure fairness and equitable outcomes. An example is the collection of information from smart personal devices, such as voice assistants and connected applications that gather personal data without explicit consent

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from the user, raising issues of data security and the potential misuse of this data for targeted advertising. Accountability challenges can occur, for example, where self-driving cars cause accidents, raising questions about liability, necessitating clear guidelines for accountability, particularly in AI applications impacting public safety.

To fully leverage the capabilities of AI, the risks and benefits must be balanced, while mitigating unintended consequences that could harm public trust and societal welfare. The benefits of data-centric AI, such as improved decision-making and efficiency, must be carefully weighed against the risks, including privacy breaches and biased outcomes. This requires developing robust ethical frameworks, effective regulatory policies, and engagement with stakeholders. While advancements in data-centric AI drive progress, they must be aligned with ethical norms and societal values to ensure a future where technology and humanity can coexist.

Notwithstanding the potential risks, AI can be used effectively in health research. Generative AI applications such as ChatGPT can be applied to understand social psychology processes and concepts of social group influences, decision-making, adherence to norms, and phenomena such as conformity and persuasion. The advantages of AI for health research include the capability for the analysis of extensive textual data and multidimensional computations due to its ability to draw from different data points simultaneously. Automatic coding and categorisation processes can reduce coder bias to increase the reliability of research results and strengthen research outcomes. AI can also lead to innovation in research methods and identify new research areas and questions to explore.

However, AI also introduces potential ethical challenges and constraints for health researchers, stemming from inherent biases within AI training data. It is important to implement continuous monitoring and bias rectification during chatbot operation to mitigate these biases effectively. Researchers should prioritize transparency by providing clear explanations of how the AI system operates and arrives at its predictions, detailing its functionality, limitations, and potential biases. The intricate internal workings of AI and the looming threat of AI-generated misinformation pose significant challenges for researchers. To navigate these complexities, researchers must remain proactive in staying abreast of the latest ethical guidelines, best practices, and technological advancements. This can be achieved through active participation in professional networks, attendance at conferences, and collaborations with domain experts. By adopting a proactive approach to ethical considerations and technological understanding, researchers can effectively harness the potential of AI while mitigating associated risks.

The development of ethical frameworks and guidelines for the responsible and ethical use of AI in health research are both a necessity and a moral imperative to ensure that the advancement of AI aligns with societal values and contributes to societal betterment. This imperative holds particularly true in the realm of social psychology research, where the ethical and responsible use of chatbots, such as ChatGPT, is paramount. As we embrace ChatGPT’s potential in health research, we must navigate the promise and peril it presents with a steadfast commitment to ethical integrity, balancing reverence for the insights it offers with responsibility for upholding ethical considerations in the study of humanity.

**PANEL DISCUSSION – WITS, ASSAf, NHREC, SARIMA, SAMRC, SAHPRA, SACRA, ARIN, REASA, WITS STEVE BIKO CENTRE FOR BIOETHICS, SACAP**

**Programme Directors: Prof Ames Dhai and Prof Paul Ruff**

Prof Ruff stated that researchers must bear in mind that the most important person in medical research is the patient or the participant. Other parties involved include the researchers, ethics committees, institutions, sponsors, and regulators. It is encouraging that there is increasing transparency in the interaction between these groups. There is a need for more cooperation between the sponsors, funders and regulators, and for RECs to inform researchers on ethical requirements to create better understanding and compliance.
Dr De Sousa commented how the presentations highlighted the research ethics community’s capacity for innovation in address evolving research ethics challenges, indicating a pathway toward more effective and ethically sound research practices.

Prof Ruff stated that behaviour and trust are declining in society at large, creating antagonism that might impact the research community. Prof Behrens responded that there is increasing pressure for the use of AI with less regulation imposed, which could be dangerous. The scientific community should be considering the ethical aspects concurrently with the scientific developments. This had been done successfully in the development of the CRISPR gene-editing technology, where the scientists themselves saw the need to include ethicists. The presentations and the good attendance at this event are testimony to the progress being made in terms of research ethics, but there is a need for more action.

Prof Ruff posed the view that traditional medicine and values are very important, but the right balance is required between good science and understanding people’s needs. Dr Mnisi responded that traditional knowledge is diverse and complex, however, global ethics is the commonality between traditional knowledge and science and offers an opportunity to connect these fields by looking at the underlying common values.

Prof Dhai referred to the stereotyping of the pharmaceutical industry and remarked that the insight given in the presentation by Mr Ramuthaga was inspirational because it showed a different side. The evolution in thought processes to bring an industry perspective to research ethics is interesting to contemplate. Mr Ramuthaga responded that researchers often fail to appreciate that, regardless of whether research is done for industry or academic advancement, the research will be doomed if the participants are exploited. The pharmaceutical industry recognises that the patient or participant is the most important person. Research in the industry must create partnerships with universities to build capacity for the benefit of the health sector in the long term.

Prof Dhai commented that during the deliberations for the revision of the Declaration of Helsinki, there was considerable focus on informed consent, although this is only one component of the research ethics ecosystem. The time spent on issues such as post-trial access, the standard of care in placebo-controlled trials, and adequate and meaningful communication in REC reviews must be balanced against the emphasis on informed consent.

Prof Dhai asked Dr Koali to share his experience with the submission of applications and reports as head of the SAMRC research integrity office. Dr Koali noted that when training on research ethics was first offered at the SAMRC, researchers tended to consider the stance on the value of research integrity to be a rhetorical statement. Research integrity was seen as a code or principle merely to be followed. However, when the issues were unpacked, participants recognised that researchers reveal their integrity in the way that they conduct their research. This includes being honest, trustworthy and loyal, and respecting the dignity of research participants as well as fellow workers and collaborators. The focus of the research ethics training at the SAMRC is on research ethics guidelines, and in a separate session, more emphasis is placed on individual integrity. This has resulted in fewer complaints and challenges regarding research ethics applications.

Prof Dhai commented that Dr Visagie’s presentation persuasively made the point that the safeguarding of participants is a collective effort. The general view is that RECs must ensure that participants are protected in research, but this is a collective effort and shared responsibility of everyone involved in the research, including the regulators and the ethics committee members. Research managers are in an ideal position to mitigate against the risks. There are also guidelines (such as CIOMS) that are directed at institutions and managerial positions to ensure good governance and compliance. Dr Visagie was asked whether in her opinion this was unfolding and whether in her experience managers are implementing checks and balances to mitigate against the risks. Dr Visagie commented that positive change was evident in the establishment of communities of practice that provide institutions with opportunities to learn from one another. Members of RECs are often isolated, and the CoP is a means to reach out to other colleagues. RECs should play a bigger role in advocating for change. They need to be strategically
positioned in universities to be able to influence the Councils. RECs must ensure that there are clear and policies to protect research participants, and research managers must become part of Council committees to influence Council.

Prof Dhai asked Mr Kombe how he viewed CIOMS compared to the Declaration of Helsinki. Mr Kombe replied that they play different but complementary roles. CIOMS is more dynamic because several revisions have been made to keep up with changes in health research ethics. Some revisions are specific in addressing emerging areas in the field of health research, which is a dynamic field. It is also important to regularly review and update standard operating procedures. The Declaration of Helsinki has not enjoyed the same rigour in revision.

**FORMAL WELCOME – UNIVERSITY OF THE WITWATERSRAND**

*Virtual address by Prof Lynn Morris, Wits*

The interest, enthusiasm and energy evident in the discussions on research ethics are encouraging. The public lecture represents a unique gathering of statutory bodies, academia, and industry to collaboratively deliberate on a comprehensive framework to safeguard research participants and uphold ethical principles in research. It is a privilege to welcome Prof Hans van Delden from CIOMS and the University Medical Centre of Utrecht to this event as a guest speaker. A vital aspect of ethical research is the protection of personal information. In an era where data are increasingly used in medical advancements, it is imperative to uphold the highest standards in safeguarding the privacy and confidentiality of individuals. The advancements in AI, data-driven research and the increasing use of technologies and machine learning require stringent protection of participant privacy and data security.

The latest CIOMS guidelines provide updated recommendations to navigate issues such as anonymisation, encryption and storage practices to minimise the risk of data breaches and unauthorised access. Research methods increasingly incorporate digitisation, for instance in online surveys, virtual trials and data collection through wearable devices. This necessitates informed consent that is truly informed, and adapting consent processes to ensure that participants fully understand the implications of sharing data electronically.

The CIOMS guidelines emphasise the importance of transparency and accessible information, as well as the ongoing reassessment of consent throughout the research process.

Institutions have an important role in fostering ethical research practices, promoting collaboration and providing guidance. The synergy between organisations is integral to creating an ethical and supportive environment for research, strengthening ethical frameworks, and ensuring that the pursuit of knowledge is conducted responsibly with due consideration for all stakeholders. The commitment to ethical research should extend beyond national borders. Continental engagement and international recognition reinforce the importance of a unified approach to ethical standards.

Upholding research integrity and transparency is essential to maintaining public trust and ensuring the credibility of research findings. The guidelines underscore the importance of research transparency, including pre-registration of study protocols, sharing of data and materials, and adherence to best practices in reporting research results. Researchers should embrace open science principles, foster collaboration and data sharing, and adhere to ethical standards throughout the research life cycle.
In conclusion, the research ethics community and stakeholders are encouraged to embark on a journey of shared knowledge collaboration and ethical inquiry, with a commitment to the principles outlined by CIOMS. By applying these principles, researchers will be able to navigate the complex ethical landscape of research, safeguard the rights and welfare of participants, and contribute to the advancement of knowledge responsibly and ethically.

All institutions that have contributed to this event are acknowledged. Without their generous support, the event could not have taken place.

PUBLIC LECTURE: RESEARCH PARTICIPANT PROTECTIONS – THE LATEST CIOMS GUIDELINES

Prof Hans van Delden, CIOMS and University Medical Centre of Utrecht, the Netherlands

Research ethics was born from a history of scandal (for example, the human experimental trials during World War II and the Tuskegee study) and controversial studies (such as placebo-controlled trials in LMICs). It is therefore understandable that the reigning belief in research ethics is the need for protection.

The CIOMS guidelines follow the notion that scientific enquiry in health is primarily concerned with how to conduct research, and the conditions under which humans can be involved in research. Virtues are not a central part of the guidelines. However, it is important to pay attention to virtues for a number of reasons. Research ethics and research integrity are connected, but have developed into separate fields since the guidelines were drafted. Open science draws attention to the importance of virtues. Open access provides free access to published articles, but open science also enables community consultation. Science should be open in all stages of research, not only during the proposal phase. There needs to be openness in how the research is conducted, which includes openness towards fellow researchers and collaborators.

The ‘public or perish’ mindset still prevails in academic culture despite attempts to abolish it. An open research culture fosters creativity in a safe research environment. This is endorsed in the 2023 CIOMS report on Good Governance Practice for Research Institutions (GGPRI)30.

The principal international guidelines for clinical research are contained in the Declaration of Helsinki (DoH), the CIOMS guidelines and the UNESCO Universal Declaration on Bioethics and Human Rights31. Whereas CIOMS is aimed at organisations and institutions, the DoH addresses the medical community, and the UNESCO declaration guides member states.

The classic view with respect to the protection of the vulnerable is to safeguard participants at all costs from detrimental effects. In recent years, a new approach has taken root, namely that research is a social good and not something to be protected from. Alex London32 states that “research with human participants is connected to social purposes of sufficient moral weight that they ground a moral imperative with two aims, namely, to promote research with social value and that the research is organized on terms that respect the status of its many stakeholders, especially study participants, as free and equal.”

Nevertheless, research as a social good still requires protection for the vulnerable. The classic approach to vulnerability identified entire groups as vulnerable (such as minority groups or marginalised groups), often excluding them from research. This approach is no longer followed because it is considered more important to take a contextual view to determine when someone is vulnerable. This is the case, for instance, when persons have relative or absolute impairments in decisional capacity, education, resources, strength or other attributes, so that they cannot

30 https://cioms.ch/working_groups/principles-of-good-governance-for-research-institutions/
protect their own interests. Persons can also be vulnerable because their circumstances make it less likely that others will be vigilant about, or sensitive to, their interests. This includes circumstances that are manufactured such that they actively harm people’s ability to protect themselves. A layered conception of vulnerability is presented in the CIOMS guidelines, which take the different levels into account.

The DoH states in Guideline 19 that, “Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.” To provide mechanisms and instruments for protection in research, a vulnerability toolkit was formulated. Although not prominently featuring in CIOMS, it forms an important backbone of the guidelines. The toolkit recommends different elements of protection and the situations under which these are applied, namely:

- **Subsidiarity principle:** The research could not have been done with other non-vulnerable groups, for example research on elderly persons, or persons with specific disorders. In this case, medical research is only justified if the research cannot be carried out in a non-vulnerable group. The group should stand to benefit from the knowledge, practices or interventions that result from the research (DoH Guideline 20).

- **Group specificity:** The research is aimed at certain groups which are very different from other groups (for example, children or infants), but the condition is that the group will benefit from the research. Medical research is only justified if the research is responsive to the health needs or priorities of this group. In addition, the group should stand to benefit from the knowledge, practices, or interventions that result from the research (DoH Guideline 20).

- **Special conditions on post-trial access:** Post-trial access denotes access to the invention that was proven effective in the project. Research can only involve vulnerable individuals if they stand to benefit from the knowledge and have access to support after the research has been concluded.

- **Special conditions or limits on risk:** Research can only involve patients if there is minimal risk or a minor increase over minimal risk, and if there is sufficient social value to justify the involvement (DoH Guideline 28). Subjects incapable of giving informed consent must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risks and burdens.

- **Informed consent by proxies:** Where someone is not able to protect him/herself, a proxy gives assent on behalf of the person. Assent entails accepting and showing willingness to participate in the research project without giving full informed consent.

- **Independent advocates:** Where only certain vulnerable groups in a community can be involved, independent advocates engage in the protocol to protect the group.

- **Community involvement:** Communities exist for mutual protection and support, as demonstrated in the Ubuntu principle. Patient and public involvement and engagement (PPIE) involve the community. Vulnerable participants are protected through community involvement that gives contextual information on what might make persons vulnerable, what socially appropriate measures can be taken to prevent this, how communities could help researchers reach that goal, and how vulnerable persons can be included in the research. CIOMS argues that exclusion must be justified because the research may lead to increased vulnerability since those groups will not have access to the benefits of research.

Nonetheless, there are issues raised by the toolkit that are not addressed and need deliberation. These centre around the question of whether all vulnerable persons should be equally protected, even if the level of vulnerability differs. A likely approach would be to differentiate according to levels of protection due to the layers of vulnerability.
Furthermore, if vulnerability is not a group characteristic, it is not clear whether the protection should be uniform for the group. RECs must choose between the proportionate protection mechanism for each instance or guidelines with one-size-fits-all approaches.

The balancing of protection and access presents a dilemma. Should it make a difference whether the participants can benefit from the research or not? An unjust distribution of burdens and benefits arises when research done in low-income countries leads to outputs that will be used in the First World. Another consideration is that vulnerable people might want to show solidarity and participate in research even if they do not derive the benefit themselves. Applying the mechanisms in the toolkit without judgement might create unintended disadvantages and overprotection. The task of RECs is not to merely apply the rules but involves arguing a case, reasoning, interpreting, and weighing up different scenarios and facts. This is one of the reasons why different RECs might arrive at different outcomes.

The subsidiary principle in the toolkit presents a problem in interpretation because generalisability is a normative claim. Furthermore, group specificity creates local social value, and the interests of the vulnerable may still be subsumed to those of others (albeit from the same group). This raises the question of whether vulnerable groups should be prevented from helping other (vulnerable) groups. The special conditions on risk in the toolkit may slow down the development of interventions.

The CIOMS 2016 guidelines address vulnerably through the following mechanisms:

- For adults who are incapable of giving informed consent (Guideline 16), the mechanism of proxy consent, limits on risk (dependent on social value) and group specificity are applied. The subsidiarity principle must be limited to non-therapeutic research.

- For children and adolescents (Guideline 17), proxy consent applies, subsidiarity only for non-therapeutic research, limits on risk (dependent on social value), and group specificity. However, this can be contested, and RECs should exercise discretion in weighing up the benefits and costs (for example, duration of studies).

- For pregnant women (Guideline 19), the limits on risk and group specificity are applied.

The task of protecting the vulnerable is generally viewed as the role of RECs. Yet, this limits ethical responsibilities, which should be shared by RECs in cooperation with other regulatory bodies, researchers, research institutions and the communities in which the research takes place. Protective measures are needed, not only in the proposal and planning stages but also while conducting research.

Community engagement in research is understood as a way to protect the vulnerable but has other important benefits. Engagement shows respect for communities and their traditions, underscoring the valuable contribution that communities can make to the successful conduct of research and preventing research waste. The relevance and acceptance of the proposed research to the affected community is safeguarded. Most importantly, it offers an opportunity to co-create. In this light, it is more appropriate to talk of engagements of communities, because all communities in the process (scientists, health practitioner communities, and communities in society) should interact on an equal basis.

OPEN QUESTIONS AND ANSWERS

Facilitated by Prof Himla Soodyall (ASSAf) and Prof Annie Temane (University of Johannesburg)

Prof Soodyall noted that prior to the meeting, questions for discussion were sent to the presenters and facilitators. The questions covered four thematic areas: human participants, RECs, research trials, and training of participants and RECs. Most questions had been covered in the presentations, but some questions needed to be discussed.
Prof van Delden responded to the question of whether RECs could be wrong and could arrive at wrong conclusions. He said it was important to realise that because interpretation and specification are involved, RECs can have different views from researchers or from other RECs, which leaves space for discussion on how to interpret the guidelines.

Comment: *Ubuntu* implies a multiple-way relationship and is a way of recognising the humanity in research by placing researchers themselves in the participants' shoes. Another aspect is that of researchers protecting themselves and protecting the trust in research. In South Africa, the Batho Pele (People First) principle recognises that people come first, which has broader implications with respect to the purpose of research, the research methodology, the value of people in the research, and the value of advancing research. Putting people first is an ethical priority.

Response from Prof van Delden: The reason for prioritising social value in the CIOMS guidelines was to indicate that any action has the potential to improve (or harm) the health and well-being of people. The concept of engagement of communities implies an interest in the other, and having discussions to find the best approach for research questions.

Comment: It does a disservice to participants to describe them as having limited resources, rather than recognising that there are competing demands for their resources.

Comment: It is important for RECs to have an understanding of the research field in which proposals are submitted. For instance, occupational therapy as a research field is not well known, and because it has a broad scope, the depth of the field and research approaches are not well understood. In such circumstances, it might be difficult for the REC to understand the nuances of research applications. A potential way of addressing this is to become a member of the REC and capacitate the committee in a direct way. Furthermore, the researcher submitting the ethics application also has a responsibility to make sure that the REC understands the research protocol through clear communication.

Comment: The distinctions between who is vulnerable, when a person is vulnerable, and what makes a community vulnerable are important. In this view, however, the aspect of social structure and history is absent since history shapes social structure. Researchers must ask what is known, but also what is not known about social structure and its history, because other factors can make people vulnerable.

Comment: *Ubuntu* can also be interpreted as the context in which people come first, and can be applicable to only one community. Moreover, there must be a shift away from anthropocentrism. In some cases, communities live in interaction with their environment (such as fishing communities), and it is necessary to place the environment as the main means of subsistence first.

Prof van Delden acknowledged that the guidelines are anthropocentric and that future revisions would need to pay more attention to environmental issues. The field of biomedicine, for example, must give attention to environmental issues, because of the hazardous pollution that the research can create.

Comment: A problem could arise if persons in regulatory positions or staff in the institutional research office submit an application to the REC, but are not convinced that the application should be approved. If such an application is indeed approved, what recourse does the research office have?

Prof van Delden responded that it is very rare for a REC to be too lenient in its decisions. Most authorities and regulators have their own protocols to deal with such cases. If a person is part of the process of approval and does not agree with the general view, it is best that they be excused from the process. However, there are some cases of questionable REC decisions that would not be upheld under scrutiny by another authority. Prof Temane added that in such cases, trust, honesty, and transparency are essential.

Prof Dhai cautioned that ethically flawed protocols should not be submitted in the first place.
Regulators and staff must recognise and correct any shortcomings, or instruct the applicants to make corrections. Flawed protocols that have been approved should be flagged for the REC to investigate. Prof van Delden added that such protocols are often filtered out in the ethical committees.

**Question:** Where can the new guidelines be accessed? Prof van Delden referred to the CIOMS website where the guidelines and related documents are freely available.

**Question:** Are there any limits when involving vulnerable participants, for example, children, and can they enroll in more than one study simultaneously, or in a subsequent study?

Prof van Delden replied that RECs are usually not in a position to know this when they assess the protocols. The CIOMS guidelines state that the burden of research should be equitably distributed, but it is not easy to enforce. Pharmaceutical trials typically limit participation to one study, to make sure that there are no interfering factors that will impact the trial.

**Question:** What are the possible consequences of developing health issues from participating in continuous studies? It is known that some people participate in studies as a means of income, especially in lower-income areas.

Prof van Delden replied that it will not be known to any party other than the participants themselves whether they are involved in more than one study, but they need to declare this in the informed consent forms.

**Question:** Research fatigue can be an issue, especially in poorer communities, where payment is regarded as an incentive for people to participate in as many studies as they can. Does the CIOMS guideline address this?

Prof van Delden responded that ‘research fatigue’ is not mentioned in the guidelines per se, but the concept is understood. Multiple interventions should be avoided, because participants would not be in a position to deliver what is expected from them in multiple projects, for instance keeping diaries. It is not in the interests of research, or in the interests of the participant, to be involved in more than one study simultaneously. However, this is difficult for RECs to monitor and prevent and is the responsibility of the researcher. Prof Ruff added that it is not unreasonable for someone to be involved in several sequential trials in a field such as cancer research, where participants are involved in the first phase and then in subsequent phases.

**Comment:** There have been issues around privacy and the legal aspects of including names of organisations in applications, which could cause risk to an organisation.

Prof van Delden responded that data anonymisation demands that people and institutions are protected and that personal information cannot be linked to a person. It is important to remove names from research protocols, including the names of individuals involved as well as the names of institutions. Sometimes it can also happen that, even if no names are mentioned, the institution is described in such a way that it is possible to identify it. Researchers must be trained on issues such as the principles of research ethics and the application process.

Prof Soodyall thanked the speakers and the audience for their participation, and for sharing inputs and insights from a personal perspective. It is important to note that persons serve on RECs on a voluntarily basis, and researcher must appreciate the time and dedication that involved to facilitate research that ensures the safeguarding of participants.

**REFLECTION AND CLOSURE**

Prof Paul Ruff, University of the Witwatersrand

The deliberations of the day confirmed that vulnerability and guidelines to safeguard research participation are nuanced. There are different reasons for vulnerability, and the context of each case needs to be considered. However, it is imperative that research does not exclude vulnerable groups, because they ultimately need to benefit from the research. To enable the
appropriate research to take place, it is essential to mitigate situations where necessary.

Communication between ethics committees, regulators, researchers and sponsors is crucial because it will lead to better research. RECs must communicate openly and need to be approachable.

Capacity building of researchers on research ethics is a priority. However, in South Africa, research ethic training is generally limited to the larger universities. It is the responsibility of the whole research community to increase the capacity of researchers, especially in less-resourced universities and institutes. It is equally important to build the capacity of RECs through communication and partnerships between RECs of different universities.

There is ongoing discussion on post-trial access, which is a complex issue. The comparative and concomitant medication that was provided during the trial phases is not always available at hospitals, and it is the sponsor’s responsibility to provide this. After trials are completed, many sponsors make the medicines available to participants until the product is registered on the market. Thereafter, most participants will not have access to the treatments, due to high costs, or because they will not be marketed in the country. SAHPRA’s policy dictates that medicine should be made available to participants for four years after the study is completed. To prevent adverse health effects, participants need to continue treatments in the long term, but it is debatable whether pharmaceutical companies have an obligation to ensure that participants continue to receive medication. The heart of the matter is that medicines are too costly and unaffordable to many people. The current policy must be updated to address this problem, which remains a difficult ethical dilemma.

Participants must be adequately reimbursed for their involvement, and the TIE principle (Time, inconvenience, and effort) is effectively applied. Exceptions should be handled on a case-by-case basis.

In conclusion, the discussions have been productive and provided answers to pressing issues, but also raised additional questions. It is proposed that gatherings of this kind should be held at least every two years and that there is ongoing communication in the Community of Practice for research ethics in health research.
**APPENDIX 1: LIST OF ACRONYMS**

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<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>AI</td>
<td>Artificial intelligence</td>
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<td>AREC</td>
<td>Animal Research Ethics Committees</td>
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<td>ARIN</td>
<td>African Research Integrity Network</td>
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<td>ASSAf</td>
<td>Academy of Science of South Africa</td>
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<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
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<tr>
<td>CIOMS</td>
<td>Council of International Organizations of Medical Sciences</td>
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<tr>
<td>CoP</td>
<td>Community of Practice</td>
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<tr>
<td>CSIR</td>
<td>Council for Scientific and Industrial Research</td>
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<td>CT</td>
<td>Clinical Trial</td>
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<td>DOH</td>
<td>Declaration of Helsinki</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>EU</td>
<td>European Union</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FDAAA</td>
<td>Food and Drug Administration Amendments Act</td>
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<td>FPI</td>
<td>First Patient In</td>
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<td>GCP</td>
<td>Good Clinical Practice</td>
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<td>Human Sciences Research Council Research</td>
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<td>ICJME</td>
<td>International Committee of Medical Journal Editors</td>
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<td>ICTRP</td>
<td>International Clinical Trials Registry Platform</td>
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<td>IK</td>
<td>Indigenous knowledge</td>
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<td>LMICS</td>
<td>Low- and Middle-Income Countries</td>
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<td>NDoH</td>
<td>National Department of Health</td>
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<td>National Health Research Ethics Council</td>
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<td>National Research Foundation</td>
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<td>PAS</td>
<td>Physician-assisted Suicide</td>
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<td>PI</td>
<td>Principal Investigator</td>
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<tr>
<td>POPIA</td>
<td>Protection of Personal Information Act</td>
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<td>REASA</td>
<td>Research Ethics Committee Association of Southern Africa</td>
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<td>REC</td>
<td>Research Ethics Committees</td>
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<td>SADC</td>
<td>Southern African Development Community</td>
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<td>SAHPRA</td>
<td>South African Health Products Regulatory Authority</td>
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<td>SAMRC</td>
<td>South African Medical Research Council</td>
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<td>Acronym</td>
<td>Description</td>
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<tr>
<td>SANCTR</td>
<td>South African National Clinical Trials Register</td>
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<td>SARIMA</td>
<td>Southern African Research and Innovation Management Association</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<tr>
<td>UKZN</td>
<td>University of KwaZulu-Natal</td>
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<tr>
<td>UNESCO</td>
<td>United Nations Educational, Scientific and Cultural Organization</td>
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<td>UNISA</td>
<td>University of South Africa</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>Wits</td>
<td>University of the Witwatersrand</td>
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APPENDIX 2: BIOGRAPHIES

Prof Kevin Behrens is professor of bioethics and director of the Steve Biko Centre for Bioethics at the University of the Witwatersrand. His research interests lie in applied ethics, particularly 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 leads the sustainability working group.

Prof Lesley Burgess has been involved in clinical trials since 1992. She has over 100 publications to her credit, in addition to being the author of four chapters in internationally recognised textbooks for clinical research. She served on the Stellenbosch University Health Research Ethics Committee and is currently a reviewer for the Clinical Trials Committee of the South African Health Products Regulatory Authority (SAHPRA). She is the director of TREAD Research and the Paarl Research Centre, and consults for various syndicates of Wits Health Consortium. TREAD Research is the only research unit in Africa to be awarded full accreditation with the Association for Accreditation of Human Research Protection Programs (AAHRPP).

Mrs Tanya Coetzee is currently working in the research integrity office at the University of South Africa (UNISA). Her work involves the promotion of research ethics and integrity at UNISA, and she is a member of the Unisa Research Ethics Review Committee. As part of her passion, Mrs Coetzee strives to bring research ethics and integrity to the forefront of all research processes. She recognises the value of research ethics training starting from early undergraduate programmes to build intrinsic moral codes and the ethics of care in all professions. 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 (SAMREC). Further to this, she is part of the executive committee of the Community of Practice for Research Ethics and Integrity under the auspices of SARIMA. She has trained many researchers and postgraduate students in research ethics.

Dr Diana De Sousa, an esteemed educational and research psychologist, is a lecturer and research supervisor at the South African College of Applied Psychology (SACAP). Her focus is on empowering children, adolescents and young adults, and 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 PhD in Psychology, specialising in developmental cognitive neuropsychology. With a dual Master’s in Research Psychology and Educational Psychology, she has a notable publication record and has contributed significantly to psychology and education nationally and internationally. She has held leadership roles in various professional organisations advocating for mental health awareness and ethical practice within psychology.

Prof Ames Dhai is the founder and past director of the Steve Biko Centre for Bioethics at the Wits Faculty of Health Sciences, Professor of Bioethics and Health Law at the Wits School of Clinical Medicine and a member of ASSAf. She is the immediate past chairperson of the United Nations Educational, Scientific and Cultural Organization (UNESCO) International Bioethics Committee. Some of her current roles include chairperson of the South African Medical Research Council (SAMRC) Bioethics Advisory Panel, chair of the Human Sciences Research Council Research (HSRC) Ethics Committee, chair of the South African National Blood Service (SANBS) Research Ethics Committee, chair of the ASSAf Biosafety and Biosecurity Committee and board member of the South African Medical Association (SAMA). She was the vice-chair on the Ministerial Advisory Committee for COVID-19 Vaccines where she headed the technical working group on mandatory vaccinations. She served two terms as deputy chair of the National Health Research
Ethics Council (NHREC) and was a member of the board of the Health Professions Council of South Africa (HPCSA). Prof Dhai is a leading authority on bioethics, both internationally and locally, and can be credited with entrenching bioethics and human rights as an integral aspect of health sciences in South Africa.

Mrs Eleni Flack-Davison, an admitted attorney of South Africa, is the legal adviser, research compliance manager, head of the office of research integrity, and research data protection officer at the University of the Witwatersrand, Johannesburg (Wits). She was a special adviser to the local organising committee for the 7th World Conference on Research Integrity in Cape Town. She is part of the executive committee of the Research Ethics Committee Association of Southern Africa (REASA) and heads the marketing and communications sub-committee. She has been part of the Academy of Science of South Africa (ASSAf) drafting committee for the Protection of Personal Information Act (POPIA) code of conduct for research in South Africa. Mrs Flack-Davison co-founded and co-chairs the Northern Regions Research Ethics and Integrity Community of Practice (CoP) under the Southern African Research and Innovation Management Association (SARIMA) and co-chairs the steering committee for the CoP for Research Ethics and Integrity. The CoP has drafted ethics guidelines and a toolkit for the Southern African Development Community (SADC) region in terms of the Nagoya Protocol. Mrs Flack-Davison is part of the SARIMA Research Management Portfolio Committee.

Dr Seeiso Koali is Research Integrity Officer at the South African Medical Research Council (SAMRC). He provides guidance on research integrity matters, develops policies and guidelines and deals with reported cases of breach of research standards and misconduct. He conducts training on research integrity and good clinical practice for the SAMRC. Dr Koali holds a PhD in Bioethics from Wits and an MSc in Medical Bioethics and Health Law from the Wits Steve Biko Centre for Bioethics. He also has an MPhil in Biomedical Ethics (Stellenbosch University), a postgraduate diploma in Public Health (University of the Western Cape), Honours in Philosophy (National University of Lesotho) and BA in Philosophy (Urbaniana Pontifical University, Rome, Italy). Before joining the SAMRC, Dr Koali was a senior lecturer in the Department of Philosophy at the National University of Lesotho. Among other courses, he taught medical ethics, bioethics, applied ethics and moral philosophy. Dr Koali has served on the institutional review board at Baylor College of Medicine Children’s Foundation in Lesotho.

Mr Francis Kombe is the CEO of EthiXPERT, South Africa. He is a public health and community engagement practitioner and bioethicist, with a special interest in research integrity. He has a wealth of experience working in international health research institutions, where he has held various leadership positions. Mr Kombe has a Master in Social Science degree from the University of KwaZulu-Natal, a Master of Public Health (MPH) and a postgraduate diploma in Public Health from the London School of Hygiene and Tropical Medicine. He is currently waiting to graduate with a Wellcome Trust-funded PhD in Bioethics at UKZN. Before joining EthiXPERT, Mr Kombe worked as a training coordinator at the KEMRI-Wellcome Trust Research Program, where he was involved in the strategic development and planning of health research fieldwork. He has published widely in the field of community engagement, frontline staff, research integrity, fair study benefits and informed consent. He is a co-founder and interim committee member of the African Research Integrity Network.

Ms Caz McNamara has a master’s degree in biochemistry from Rhodes University and completed a postgraduate diploma in research management and administration at Stellenbosch University in 2023. She has worked in academic research management for 15 years. She currently works at the Wits Infectious Diseases and Oncology Research Institute. She holds Senior Research Management Professional (SRMP) accreditation through the International Professional Recognition Council (IPRC) and is the current Vice-President for Research Management at SARIMA. She is a member of the East African Research and Innovation Management Association (EARMA) and a former member of the Australasian Research Management Society (ARMS). She works closely with the West African Research and Innovation Management Association (WARIMA) as the project lead on the capacity development theme of the Science Granting Councils Initiative (SCGI) in Africa. Ms McNamara has also served on numerous conference local
organising committees for the Southern African Association for Research in Mathematics, Science and Technology Education (SAARSTE), SARIMA, the International Network of Research Management Societies (INORMS) and the World Conference on Research Integrity (WCRI), and has taught on entry/access programmes and research methods.

Dr Fikile Muriel Mnisi has a background in biotechnology and a PhD from Wits. She is a biotechnologist, bioethicist, ethics educator and consultant, researcher, entrepreneur and community developer. Her main focus is in the fields of biotechnology, bioethics, and legal and social issues. She is interested in working in multi- and transdisciplinary environments to analyse, create and implement innovative solutions. Having worked in the academic and private sectors, she founded a company called Khaca (Pty) Ltd, which focuses on biotechnology policies, research, and ethics training and consultation. She recently initiated a non-profit company called Inkanyeti Foundation to address stigmas around mental illness. She currently serves on the Animal Ethics Committee of the Tshwane University of Technology and is the chairperson of Edenvale Regional Hospital. Her passion is harnessing social justice on matters in biotechnology, medicine, health, ethics, legal matters and biopolitics to influence policy and decision-making.

Prof Lynn Morris is the Deputy Vice-Chancellor for Research and Innovation at Wits. 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. She is an NRF A-rated scientist, has published over 270 papers, has 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 ASSAf and a fellow of the African Academy of Sciences, the Royal Society of South Africa and The World Academy of Sciences (TWAS). Prof Morris has supervised and mentored over 50 postgraduate students and postdoctoral fellows, many of whom have gone on to develop their own successful scientific careers.

Prof Michèle Ramsay is director of the Sydney Brenner Institute for Molecular Bioscience (SBIMB), professor in Human Genetics and holds the South African Research Chair in Genomics and Bioinformatics of African Populations at the University of the Witwatersrand. 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. Prof Ramsay is co-chair of the International Hundred Thousand Plus Cohort Consortium (IHCC) and steering group member for developing the African Population Cohort 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 ASSAf’s POPIA Committee, which has drafted a national code of conduct for research to inform a uniform interpretation of the Act.

Mr Nathaniel Ramuthaga is a registered medical scientist with the 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. He has previously held the position of country head of clinical operations for Roche PDG, in sub-Saharan Africa (SSA). He is a member of the Innovative Pharmaceutical Association South Africa (IPASA) clinical trials group, the South African Clinical Trials Association (SACRA) and the Institute of Directors South Africa (IoDSA). He has published several research articles in peer-reviewed journals.

Prof Paul Ruff is emeritus professor in the School of Clinical Medicine, and was head of the division of medical oncology at the Wits Faculty of Health Sciences and Charlotte Maxeke Johannesburg Academic Hospital. He chairs the Wits HREC (Medical) and is principal investigator (PI) in the SAMRC/Wits Common Epithelial Cancer Research Centre and co-PI of a National Institutes of Health project in collaboration with Columbia University, USA. He is ranked as a B2-rated scientist by the NRF and has an H-index of 41. Prof Ruff is chair of the SAHPRA Clinical Trials Committee and a member of the National Essential Medicines List Committee in South Africa. Prof Ruff serves on several committees of the American Society of Clinical Oncology (ASCO), namely the
International Affairs Committee, the Clinical Trials Workshop Working Group, and the International Quality Task Force. He was appointed inaugural chair of the ASCO sub-Saharan Africa Regional Council in 2022.

Prof Shenuka Singh is a full professor of dentistry at the University of KwaZulu-Natal (UKZN). She has a doctoral degree in clinical and research ethics from Stellenbosch University and another in the field of dental public health from the University of the Western Cape (UWC). She is the deputy chairperson of the National Health Research Ethics Council (NHREC) in South Africa and 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. In 2021, she was invited to be part of a WHO working group (Regulation and Safety Unit and Health Ethics & Governance Unit) to develop a tool for benchmarking research ethics oversight. Prof Singh is the appointed chair of the Biomedical Research Ethics Committee at UKZN; she is a member of the HSRC’s Research Ethics Committee and was appointed as Research Ethics Chair for the Council for Scientific and Industrial Research (CSIR) and the Humanities and Social Sciences Research Ethics Committee at UKZN. She is an NRF-rated researcher and is actively involved in research and postgraduate supervision and training. She has presented papers at local and international conferences (including keynote addresses). She received the 2018 UKZN College of Health Sciences Teaching Excellence Award and was also awarded the UKZN Certificate of Excellence in Teaching.

Prof Himla Soodyall is the executive officer of ASSAf. A member since 2003, she was elected to the ASSAf council in 2011 and appointed general secretary in 2014. Prior to joining ASSAf, she was employed as a principal medical scientist in the Division of Human Genetics at the National Health Laboratory Service (NHLS) and University of the Witwatersrand (Wits). Her research focuses on using molecular genetic tools to reconstruct the evolutionary history and affinities of sub-Saharan African populations. She is the recipient of numerous awards and accolades, including the Order of Mapungubwe (Bronze Medal) presented to her by President Mbeki in 2005. She was inducted into the National Academy of Sciences, USA, as an international member.

Prof Annie Temane is professor and acting executive dean in the Faculty of Health Sciences at the University of Johannesburg. She holds a master’s and doctoral degree in psychiatric nursing science from the University of Johannesburg. She served as head of the Department of Nursing before taking on the position of Vice-Dean of Research and Innovation in the Faculty of Health Sciences. She has supervised and co-supervised numerous master’s and doctoral candidates, and published in national and international accredited journals. Her research interests lie in the fields of mental health and ethics. She serves on the UNESCO National Bioethics Committee and the SAMRC Bioethical Advisory Committee. She was recently appointed to serve on the Mental Health Ministerial Board Advisory Committee. Prof Temane is actively involved in ethical research governance, evident from her involvement and consultant service for qualitative research at the Steve Biko Bioethics Centre at the University of the Witwatersrand. She has served on review panels for the National Research Foundation, 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.

Prof Johannes (Hans) van Delden is a full professor of medical ethics at the University Medical Centre (UMC) of Utrecht University in the Netherlands. He leads the project on patient and public participation for the hospital and the UMC medical school. He worked for many years as a practising 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. In his department, he has built a research team with a strong track record in the ethics of end-of-life decisions, research ethics, and ethics of biomedical innovation. He served as chair of the International Bioethics Committee (IBC) of UNESCO, president of the Council of International Organizations of Medical Sciences (CIOMS), and chair
of the working group for the revision of the CIOMS ethical guidelines for biomedical research.

Mrs Matty van Niekerk is head of the Department of Occupational Therapy at the University of the Witwatersrand, where she lectures at both undergraduate and postgraduate levels and supervises undergraduate and master's research. She holds a Master of Science in Medicine in Bioethics and Health Law from the Steve Biko Centre for Bioethics at Wits, a postgraduate diploma in Health Professions Education and Leadership from the Foundation for Professional Development in South Africa, as well as a postgraduate diploma in Vocational Rehabilitation from the University of Pretoria. She completed undergraduate studies in occupational therapy at the University of Pretoria and an undergraduate law degree at the University of the Free State. She is currently enrolled for a PhD in occupational therapy focusing on the Protection of Personal Information Act. Mrs van Niekerk 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 been a member of the Senate of the University of the Witwatersrand. Her research interests lie in the impact of legislation of general application on education in health professions, and the broader notion of occupational justice, particularly for hidden and hard-to-reach populations. She has published in the fields of ethics and professionalism, vocational rehabilitation, and freedom of information legislation.

Mrs Susan Veldsman is director of the Scholarly Publishing Unit at ASSAf. She is responsible for driving the open science agenda to raise the visibility, discoverability and accessibility of South African scholarly journals, improve the quality of research output, and support the development of policy frameworks 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. She was co-chair of the 2022 InterAcademy Partnership (IAP) report on ‘Combatting predatory journals and conferences’. She also received special recognition for her role in establishing the Scientific Electronic Library Online (SciELO) platform in South Africa.

Dr Retha Visagie is prominent in Africa’s research ethics governance community. She established the Research Integrity Office at UNISA, catalysing research ethics reform on both national and international levels. Dr Visagie has been dedicated to indigenising research ethics governance and 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 SARIMA committee and co-founded the SARIMA Northern Regions Community of Practice for Research Ethics and Integrity. As non-executive director and chair of the executive board at EthIXPERT (a non-profit pan-African organisation that aims to build responsible and ethical research capacity in and for Africa), she strengthens ethical research capabilities in Africa.