Governance of Health Research updated in South Africa

The much-awaited revision of the South African Ethics in Health Research Guidelines: Principles, Processes and Structures[1] was recently published. This is the 3rd edition, with the previous one issued in 2015. The Guidelines provide the minimum national benchmark of norms and standards for responsible and ethical conduct of research in South Africa. They apply to, *interalia,* research ethics committees (RECs) and researchers from all disciplines who involve human participants or animals in their research. The Guidelines have been issued by the South African National Health Research Ethics Council (NHREC) under the auspices of the National Department of Health. While the guidelines also provide for protection of animals in health research, this editorial focuses on safeguards for human participants.

The Guidelines are structured into six chapters and a set of appendices, and begins highlighting that South Africa is a democratic state in which human dignity, equality, and the advancements of human rights are respected, promoted and protected in terms of the Constitution. Section 12(2) of the Constitution provides for protection against research abuse, by affirming everyone's right to bodily and psychological integrity including the right "not to be subjected to medical or scientific experiments without their informed consent." This principle echoes Article 7 of the United Nations International Covenant on Civil and Political Rights. Statutory authority for governance of health research is provided for in the National Health Act 61 of 2003 (NHA). The NHREC, established in 2006, determines the necessary research ethics infrastructure as per section 72 of the NHA including developing norms and standards for research with human participants and animals, as well as clinical trials. The authoritative status of the Guidelines originate from the NHA, making them legally binding. The legal status of the Guidelines are further elucidated in the NHA's associated regulations. With the enactment of the Protection of Personal Information Act 4 of 2013 (POPIA), which regulates processing of personal information, a response to measures to protect privacy, an additional layer of regulation now applies to research. POPIA categorises research activities as "legitimate interests" and stipulates that the right to privacy confers protection against the unlawful collection, retention, dissemination and use of personal information. Consent for the processing of personal information is emphasised in POPIA.

Relevant ethical principles, the role of these principles and the key norms for ethical research with human participants are described in the Guidelines. Beneficence and non-maleficence, the first principle discussed, pertains to the ethical obligation to maximize benefit and to minimise harm. It further states that research should strive to improve or understand what it means to be human, even as a medium- to long-term goal. The Guidelines state that if the research is not directed to this end, it is doubtful that it will be ethical. The intention of this caution is to prevent futile research. The second principle described is distributive justice, which it aligns with equity and signifies that a fair balance of risks and benefits amongst all role players in research, is needed. This includes not only participants but participating communities and the broader South African society. There should be reasonable likelihood that the population from which participants are drawn will benefit from the research results. The third broad principle is respect for persons (dignity and autonomy). The self-determination of persons capable of deliberation must be respected. Persons who have diminished capacity or lack capacity must be protected against harm emanating from choices they make. Primary concerns here include distributive and social justice, respect to dignity, privacy, confidentiality, wellbeing and interests of safety. There is reference to the SAN Code of Research Ethics (2017) which emphasises the importance of respect, honesty, justice, fairness, care, and due process in the research context. These values are included in *Ubuntu*, together with social and health equity, distributive and social justice and reciprocity, all of which are drawn into informing public health approaches. The broad ethical principles give rise to key norms for ethical research with human participants, which are relevance and value, scientific integrity, stakeholder engagement, favourable risk-benefit ratio, fair selection of participants, informed consent, ongoing respect for enrolled participants and researcher competence and expertise.

The ethical basis for decision-making in the REC review process and health research ethics infrastructure are described in detail, as are vulnerability and incapacity. Special topics include novel, innovative unregistered and scientifically unproven therapies; insurance against research-related bodily injury; data science research; and artificial intelligence. The use of human biological material and data for research are also addressed in these Guidelines.

While not perfect, the Guidelines, are a significant improvement on the previous set. It highlights that it is not intended to be an instruction manual but provides binding normative guidance and best practices on how to think about and apply research ethics principles in practical contexts. Several engagements with RECs registered with NHREC, researchers, and consultation groups were undertaken, prior to the finalisation of the Guidelines.

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1. South African Department of Health. Ethics in Health Research Guidelines: Principles, Processes and Structures. https://www.health.gov.za/nhrec-guidelines/ (accessed 10 July 2024).