THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL GUIDELINES ON THE RESPONSIBLE CONDUCT OF RESEARCH

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Document review and approval

Revision history

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1. Definitions

1.1	Anonymous data or specimen	Data or material without any overt identifying information or link to a specific participant or donor
1.2	Biohazard	Biological agent that pose risk to the health of living organisms.
1.3	Biological agent	Any micro-organism, cell culture or human endoparasite, including any which have been genetically modified, which may cause an infection, allergy or toxicity, or otherwise create a hazard to human health[1]
1.4	Conflict of Interest	A set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)[2].
1.5	Biological specimen	Human materials, including but not limited to blood and blood products, DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies, growth factors, saliva, urine semen and breast milk.
1.6	Biosafety	The discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials[3]
1.7	Broad consent:	The donor permits use of the specimen for current research, for storage and possible future research purposes[4], even though the precise nature of future research may be unclear at present. The nature of the further usage should be described as fully as possible and should stipulate that further prior ethics review of the new study is necessary. Permission may be sought to re-contact the person if intended future use is outside the scope of the current consent[5].
1.8	Coded data or specimen	A number, a symbol or other method provides a coded substitute for identifiers; and a key to the code exists so that the specimen can be linked to its original source
1.9	Donor	The person (living or deceased) from whose body a biological specimen has been removed or withdrawn

[1] Hazardous Biological Agents Regulations.
[2] Thompson, D.F. (1993). Understanding Financial Conflicts of Interest, *The New England Journal of Medicine*.
[3] Biosafety in Microbiological and Biomedical Laboratories 5th Edition. HHS Publication No. (CDC) 21-1112. 2009. https://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf
[4] World Health Organization. Informed Consent Templates. Consent for Storage and Future Use of Unused Samples http://www.who.int/rpc/research_ethics/informed_consent/en/
[5] Human Heredity and Health in Africa (H3Africa) Guidelines for Informed Consent. August 2013. http://h3africa.org/ethics/17-ethics/71-informed-consent

1.10	Genetics	The study of genes (human DNA), heredity and variation as well as how they affect inheritance of traits and conditions between generations of people, especially regarding human health and disease
1.11	Genomics	The study of all of a person's genes (the genome) and how they interact with each other and with the person's environment
1.12	Good Clinical Practice	An international and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. It also serves to protect the rights, integrity and confidentiality of trial subjects[6].
1.13	Good Laboratory Practice	A set of principles intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies. It is most commonly associated with the pharmaceutical industry and the required non-clinical testing that must be performed prior to approval of new drug products[7]
1.14	Health research	According to the National Health Act No 61 of 2003 it includes any research that contributes to knowledge of: the biological, clinical, psychological or social processes in human beings; improved methods for the provision of health services; human pathology; the causes of disease; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and related substances, and the development of applications of health technology
1.15	Identifier	Information such as a name, initials, address, folder number, or biometric identifier (e.g. finger print) that can identify a particular donor
1.16	Primary Use	Use of biological specimen for the purposes that it was originally collected for.
1.17	Principal Investigator	The lead researcher of a research project. He/she bears full responsibility for the scientific and ethical aspects of the study, and is the means of communication with the ethics committee while obtaining approval[8]. The principal investigator normally supervises and guides other scientists and team members.
1.18	Repository	Designated storage site for biological specimen.
1.19	Research	A systemic investigation, including research development, testing and evaluation, designed to develop or contribute to generalisable knowledge and new information.

[6]Vijayananthan, A. and Nawawi, O. Biomed Imaging Interv J. 2008 Jan-Mar; 4(1): e5.
[7]Teuscher, N. 2013. The Roundtable: Our thoughts about Model-Based Drug Development. What is GLP (Good Laboratory Practice)? https://www.certara.com/2013/12/09/what-is-glp-good-laboratory-practice/?
[8]Department of Health, Ethics in Health Research: Principles, Structures and Processes (2004)

1.20	Researcher	Any person conducting research under the umbrella of the SAMRC (including postgraduate students and Interns).
1.21	Research Data	The recorded factual material commonly accepted in the scientific community as necessary to validate research findings.[9]
1.22	Research Integrity	The quality of possessing and steadfastly adhering to high moral principles and professional standards as outlined by professional Organisations, research institutions and government and the public [10].
1.23	Responsible Conduct of Research	Research conduct that fulfils the professional responsibilities of researchers as defined by their professional Organisations, institutions as well as government[11]
1.24	Research misconduct	fabrication, falsification, or plagiarism
1.25	Secondary Use	Use of biological specimen for the purpose other than primary use.

2. Introduction

2.1 In terms of the South African Medical Research Council (SAMRC) Act No. 58 of 1991, SAMRC's objects are, through research, development and technology transfer, to promote the improvement of the health and the quality of life of the population of the Republic and to perform such other functions as may be assigned to the SAMRC by or under this Act.

2.2 Derived from these objects, are SAMRCs' vision and mission of building a healthy nation through research and innovation and to improve the nation's health and quality of life through promoting and conducting relevant and responsive health research respectively.

2.3 To ensure the achievement of its research goals and objectives it is critical that the SAMRC adheres to the highest ethical standards and professional conduct regulations, policies and ethics guidelines, such as the (National Health Act, 61 of 2003, Department of Health: Ethics in Health Research: Principles, Processes and Structures (2015), the SAMRC Act (1991), the Human Tissue Act (1983).

2.4 The SAMRC and its researchers, therefore, are required to conduct research ethically, responsibly as well as to ensure the conduct of research that is of high ethical standard and integrity. Respect for persons, fairness, competence, integrity, sensitivity, confidentiality and communication are values on which scientific research in the SAMRC is grounded[12].

[9] http://www.whitehouse.gov/omb/circulars.a110#36
[10] http://www.grants1.nih.gov/grants/guide/rfa-files/RFA-NR-06-001.htm1
[11] ORI, 2005 42 CFR, Section 93.103
[12] MRC Guidelines on Ethics for Medical Research: General principles (2000).

3. Purpose

3.1 To outline key principles that are central to the advancement of responsible conduct of research by all researchers including postgraduate students and interns under the auspices of the SAMRC and its partners.

3.2 To provide practical suggestions in order for researchers to maintain integrity and avoid departures from ethically accepted research practices that may lead to research misconduct.

3.3 To present a structure and Standard Operating Procedures (SOPs), for the advancement of scientific integrity and research that conforms to the highest ethical standards.

3.4 To entrench ethics and research integrity principles, processes, procedures and responsibilities for all research involving humans and animals.

3.5 To create awareness about potential research-related risks to society and the physical environment.

3.6 To endorse principles as set out in the Singapore Statement on Research Integrity[13] (see Annexure A).

3.6.1 To endorse the responsibilities as set out in the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations[14] (see Annexure B).

3.6.2 To provide principles and responsibilities for collaborative research, authorship, peer review, publication and dissemination of research findings, management of research data, materials and records, conflict of interest and mentorship.

3.6.3 To ensure compliance with National Guidelines on research ethics and relevant legislation and to International guidelines (where applicable).

4. Scope

4.1 These guidelines apply to all researchers, professional staff, technical staff (these include, fieldworkers, drivers and laboratory workers, etc.), students as well as visiting scientists including collaborating research partners who are involved in research funded (partly or wholly) or commissioned by the SAMRC.

4.2 All SAMRC researchers and staff members have an obligation to acquaint themselves with these guidelines and to ensure that the provisions thereof are respected and adhered to.

4.3 These guidelines shall be called the South African Medical Research Council's Guidelines on Responsible Conduct of Research.

5. Basic principles for health research

5.1 The Constitution of the Republic of South Africa Act, 1996 (Act 108 of 1996, as amended), Chapter 2-Bill of Rights state that everyone has inherent dignity and the right to have their dignity respected and protected s10, the right to life (s11), the right to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experiments without their informed consent (s12(2)(c)), the right

[13] www.singaporestatement.org

[14] www.researchintegrity.org/Statement/Montreal

to freedom of expression (s16), which includes freedom to receive or impart information or ideas s16(1)(b) and academic freedom and freedom of scientific research (s16)(d)) and the right of access to any information that is held by another person and that is required for the exercise or protection of any rights (s32(1)(b)).

5.2 The National Health Act (61 of 2003), Section 71(1)(2)(3) provides wide-ranging guidelines related to research on or experimentation with human participants. In keeping with the Act, health researchers must conform to the highest ethical principles and values, which must underscore all health research activities in South Africa[15].

5.3 The National Health Act (61 of 2003), Section 71(1)(2)(3) provides wide-ranging guidelines related to research on or experimentation with human participants. In keeping with the Act, health researchers must conform to the highest ethical principles and values, which must underscore all health research activities in South Africa[16].

5.4 The MRC promotes the four basic principles of biomedical ethics as follows:

5.4.1 Autonomy, which implies respect for the person and human dignity.

5.4.2 Beneficence, benefit to the research participant(s).

5.4.3 Non-maleficence, absence of harm to the research participant(s).

5.4.4 Justice, notably distributive justice – equal distribution of risks and benefits between communities[17].

5.5 To this end, the SAMRC expects all its researchers to –

5.5.1 Adhere to above principles which form the core of responsible and ethical conduct of research[18].

5.5.2 Act ethically and with integrity and professionalism in accordance with fundamental biomedical principles in all research involving humans and animals.

5.5.3 Promote the responsible conduct of research by being honest (in conveying research information truthfully and honoring commitments) accurate (in reporting findings precisely and taking care to avoid errors), efficient (i.e. using resources wisely and avoiding waste) and objective (by letting the facts speak for themselves and avoiding improper bias)[19].

5.5.4 Effectively and transparently declare and manage conflicts of interest or potential conflicts of interest.

5.5.5 Show sensitivity and respect for the sentience of non-human animals used in research[20].

5.5.6 Ensure that they obtain ethics approval for all research involving humans and animals, including approval for amendments to the original protocol. The SAMRC has research ethics committees for research involving humans and animals[21].

5.5.7 Communicate research results responsibly, including publications, media, community government and any other relevant stakeholders.

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[15] Department of Health, Ethics in Health Research: Principles, Structures and Processes (2004).
[16] Department of Health, Ethics in Health Research: Principles, Structures and Processes (2004).
[17] SAMRC Guidelines on Ethics for Medical Research: General Principles (2000).
[18] Department of Health, *Ethics in Health Research: Principles, Processes and Structures (2015).*
[19] ORI, 2005 42 CFR, Section 93.103.
[20] MRC Guidelines on ethics for Medical Research: Use of animals in research and training, Book 3 (2004)
[21] SAMRC Research Ethics Committee Policy.

5.5.8 Engage with the public and public and/or public representatives with regards to all research conducted within a particular community as far as is practically possible[22].

5.5.9 Reduce exposure of persons, animals and the outside environment to potentially hazardous agents in line with the MRC Guidelines on ethics for medical research: Use of biohazards and radiation, Book 4 (2002).

5.5.10 Embrace Good Laboratory Practice principles as provided for in the MRC Guidelines on ethics for medical research: Use of animals in research and training, Book 3 (2004), the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (19 of 2006), SANS 10386: 2008 Edition 1 – South African National Standard: The care and use of animals for scientific purposes and the World Health Organization Handbook: Good Laboratory Practice, 2nd Edition, (2010).

5.5.11 Submit progress and final reports to funders according to the timelines set out in the award letter.

5.5.12 To take note that research data, produced under jurisdiction of the SAMRC, including sponsored research awards, is property of the SAMRC and not the Principal Investigator or researcher

5.5.13 Authorize expenditure in line with the approved budget, review financial reports and should not incur irregular and/or fruitless and wasteful expenditure.

5.5.14 Where applicable, undergo training in Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and research ethics training.

6. Research Involving Human Participants

6.1 Protection of human participants in biomedical and humanities, social and behavioural sciences research is a shared responsibility between Principal Investigators (PIs), personnel involved in studies on human research, and the research ethics committee (REC).

6.2 SAMRC researchers shall not undertake research activity until the review of the study protocol and ethics approval has been granted by an REC which is registered with the National Health Research Ethics Council (NHREC).

6.3 Examples of research requiring ethics approval include but are not limited to the following:

6.3.1 Access to – personal information, documents, secondary data sets and social media (issues regarding potential unknown risks, privacy as well as confidentiality).

6.3.2 Collection and use of biological specimen.

6.4 The responsible conduct of research involving human participantsis not only about regulatory instruments *per se* but the spirit of the regulations and good science that require researchers to critically review what is known and give thoughtful consideration to what defines an acceptable study, i.e. the study must be relevant and necessary.

6.5 The benefits of the study to the community must outweigh the risks.

6.6 Participants' rights to protection of their privacy and confidentially must be respected and ensured by the research team. The use (actual or envisaged) of personal information of participants must be compliant to the Protection of Personal Information Act (Act, No. 4 of 2013).

6.7 The selection criteria for research participants must be fair and relevant to the various groups of the population as long as the study is relevant to their own situations, e.g. the issue of "vulnerable" people is sometimes used to exclude certain individuals unfairly from research leading to the creation of knowledge gaps.

7. Use of animals in research and training

7.1 The SAMRC recognises the ethical dilemma posed by using sentient animals (i.e. animals that have sensations and experience emotions) for research, teaching and testing. It subscribes to the ethics of supporting studies which promise to contribute to the understanding of biology and environmental principles and to the acquisition of knowledge that can reasonably be expected to benefit humans, animals or the environment[23].

7.2 Vertebrate animals are protected by several South Africa laws and regulations and international regulations, and in terms of the Animals Protection Act No. 71 of 1962 it may be an offence to kill or interfere with the well-being of an animal for scientific or educational purposes without justification which is approved by a formal process of ethical review.

7.3 The use of animals in research requires the "3 Rs" principles, namely refinement, reduction and replacement"[24] are applied during planning and execution of the studies.

7.4 The 3 Rs principles ensures that research involving animals is conducted in a humane manner in order to minimize pain, suffering and distress, the smallest number of animals that will permit valid scientific information are used in the study, and there is consideration of alternative methods which do not require use of animals.

7.5 Every situation in which sentient animals are used, either for research, for testing or for educational purposes must follow a formal of ethical review process by an the REC as outlined in the SAMRC REC Policy.

7.6 All SAMRC facilities using animals or insects (or both) must adhere to the following requirements:

7.6.1 The facility must be registered with the South African Veterinary Council (SAVC);

7.6.2 Specific protocols for the care and welfare of animals, and specific activities related to the facility must be developed and be available for inspection by any interested party such as the Society for the Prevention of Cruelty to Animals (SPCA).

7.6.3 The facility must comply with the regulatory statutes such as the Animals Protection Act No. 71 of 1962, Animal Disease Act No. 35 of 1984 and Veterinary and Para-Veterinary Act: SANS 10386SA.

8. Biohazards

8.1 Occupational Health and Safety Act, 85 of 1993 as amended, s8, states that every employer shall provide and maintain, as far as is reasonably practicable, a working environment that is safe and without risk to the health of his employees.

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[23] http://www.samrc.ac.za/ethics/ethics.htm

[24] Russel, WMS and Burch, RL. The Principles of Humane Experimental Technique. London, UK: Universities Federation for Animal Welfare; 1959.

8.2 The four groups of biological agents, i.e. Groups 1 to 4 Hazardous Biological Agents (HBA), are described in the regulations[25].

8.3 Biosafety is concerned with the containment methods required when managing parasites, infectious agents and infected or potentially infected animals, tissues or other materials, as well as radiation[26].

8.4 To reduce the risks associated with biohazards, researchers must adhere to biosafety measures, policies and procedures.

8.5 Research involving biohazards should first be considered by Ethics Committees – Human Research Ethics Committee (HREC) and Ethics Committee for Research on Animals (ECRA).

9. Biological Specimen/Data

9.1 Legislation:

9.1.1 The National Health Act (NHA) No 61 of 2003 permits removal of biological specimen from the living (s55) and deceased (s62) persons for the purposes of training students in health science, health research, advances of health sciences therapeutic purposes and production of a therapeutic, diagnostic or prophylactic substance (s64[1]) subject to written informed consent by the living person and will or written/oral statement in the presence of at least two competent witnesses oral statement in case of the deceased persons [27].

9.1.2 Notwithstanding an important role that biological specimen play in biomedical research, they may pose a risk to donors. Therefore, all stakeholders involved in research, including researchers, funders/sponsors and RECs must exercise great care and sensitivity in applying professional guidelines and applicable laws and regulations to protect donors.

9.2 Researcher Ethics Committees' obligations with respect to biological specimen:

9.2.1 Collection, use, sharing, transportation and storage of biological specimen for research purposes requires prior written approval/waiver by the SAMRC Human Research Ethics Committee (HREC) and/or any third-party REC as indicated in the SAMRC HREC policy.

9.2.2 Considering donor welfare, the HREC must determine implications of identifiability (identifier, coding or anonymization) of biological specimen and ensure that the proposed approach/planed usage and its implications are adequately disclosed and explained in the informed consent or the will or written/oral statement.

9.2.3 Although approval of blanket/unrestricted consent is not recommended, SAMRC HREC is however encouraged to considered H3Africa Initiative's and that consent should be 'broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health. The consent processes need to be appropriate for the cultural contexts in which the research takes place and tailored accordingly' [28].

9.2.4 In absence of a broad consent, secondary use of biological specimen should follow (expedited) review and approval/waiver procedure by the SAMRC HREC. SAMRC

[25] Hazardous Biological Agents Regulations.
[26] SAMRC Guideline on Ethics for Medical Research: Use of Biohazards and Radiation, 2002.
[27] National Health Act No. 63 of 2003.
[28] Human Heredity and Health in Africa (H3Africa) Initiative http://h3africa.org/

HREC may also consider reciprocal review and approval/waiver granted by a third-party REC as outlined in the SAMRC REC Policy.

9.2.5 In general, HREC's review must be in line with the NHA 61 of 2003, Guidelines on *'Ethics in Health Research: Principles, Processes and Structures* – 2015, SAMRC REC Policy and Procedures any applicable local/international legislation and/or ethical considerations regarding use of biological specimen.

9.3 **Researchers obligations with respect to biological specimen:**

9.3.1 Must ensure that the collection, storage, use, and distribution of biological specimens and associated data for research purposes adhere to national Acts and Regulations on the protection of human participants, including s68 of the NHA– "Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygote and gametes,", and the Protection of Personal Information (POPI) Act, (No. 4 of 2013) section 13.1 & 14.1(2).

9.3.2 Must ensure that biological specimen is collected using appropriate methodology for the specimen to be collected, and handled according to the applicable legislation, regulations, policies and standard operating procedures (SOP).

9.3.3 Researchers involved with handling biological samples must be appropriately trained.

9.3.4 No unauthorized disclosure of information occurs, whilst guaranteeing the traceability of donations[29].

9.3.5 Anonymity and privacy of donors are protected.

9.4 **Sharing/transfer of biological specimen**

9.4.1 Sharing and/or transfer of biological specimen to other institutions for research purposes requires a negotiated material transfer or license agreement with the recipient institution, and consideration of applicable legislation, international treaties, etc.

9.4.2 No biological samples may be shared with- or transferred to other institutions for purposes other than research-related.

9.5 **Repository and disposal of biological specimen/data**

9.5.1 Establishment of a biological specimen repository requires recommendation by the Biobanking Subcommittee of the HREC and approval by the SAMRC Executive Management Committee.

9.5.2 Repository must have effective SOP secure management of records and for receipting, handling, tracking, and disposal of biological specimen.

9.5.3 Stored biological samples must have unique identifier to facilitate removal and data management.

9.5.4 Labeling shall be clear, accurate and should withstand relevant transportation and storage conditions. Anonymized biological specimen should be labelled according to the repository's SOP.

9.5.5 All data, including genetic information, related to the biological specimen shall remain confidential all at times.

9.5.6 Data security measures shall be in place and there will be safeguards against any unauthorized data additions, deletions or modifications to donor files.

[29] Regulations issued in terms of s68 of the NHA. Regulations relating to tissue banks

9.5.7 All biological samples not utilized for research shall be destroyed in accordance with the relevant SOP.

10. Genetic and Genomic research

10.1 Most of genetic and genomic research projects share several common features that challenge the established norms of informed consent.[30]

10.2 Since information derived from genetic research provide wider information than the donor itself, it is important to safeguard donors' and their relatives from experiencing negative effects such as stigmatization, unfair discrimination, etc.

10.3 Similarly, donors involved in genomic research must receive special protection since study results may pose social, psychological, legal or economic implications for donors, their relatives or the community.

10.4 The informed consent must clearly demonstrate to donors on how data from the genetic/genomic research will be managed and provide give donors the right to receive results directly or be shared with their families.

10.5 In the case of anonymized specimen/data, researchers must not attempt to identify the donors by using genetic analysis technology.

10.6 Education and genetic counselling before and after testing must offered if results will be disclosed to the donors.

11. Data management and archiving

11.1 The SAMRC seeks to promote the highest standards in the management of research data and records since they are fundamental to both high quality research and scientific integrity.

11.2 The SAMRC recognises the value and importance of research data in generating new knowledge and, where necessary, verifying, justifying and defending the observations, findings, outputs and/or outcomes of research[31].

11.3 The SAMRC also recognises that research data may have broad and/or long-term value for research, teaching and for wider exploitation for public good both within and outside the SAMRC.

11.4 Researchers must avoid fabrication and falsification of research data.

11.5 The SAMRC research data and records should be:

11.5.1 Accurate, complete, authentic and reliable;

11.5.2 Identifiable[32], retrievable, and available when needed;

11.5.3 Secure (access-controlled) and safe (backed-up);

11.5.4 Stored, disseminated and used in a manner that is compliant with legal and regulatory obligations and, where applicable, the requirements of funders, sponsors, research participants and collaborators;

11.5.5 Subject to ethical, contractual and legal limitations, researchers are encouraged to make research data, records and materials available to other researchers for public benefit and use Section 10.2 (Data Sharing) below, discusses this in more detail with regard to conditions under which research data sharing would be encouraged and/or is appropriate.

11.6 Data collection, capture, storage, management, reporting and access must in all instances be in compliance with all applicable legislation, including but not limited to the Protection of Personal Information (POPI) Act (No. 4 of 2013), the Intellectual Property Rights from Publicly Financed Research and Development Act (Act No. 51 of

[30] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216676/. Accessed 1/9/2018

[31] MRC Draft Data Management Framework/Policy, October 2014.

[32] Identifiable does not refer to identifying participants – confidentiality of participants is to be maintained.

2008), the Promotion of Access to Information (PAIA), Act (Act No. 2 of 2000), and the National Health Act (Act No. 61 of 2003) and, where applicable, in compliance with Good Clinical Practice and Good Laboratory Practice requirements.

11.7 In the absence of an agreement to the contrary with a funder, sponsor or collaborator, or a prescription in law, the default position is that the MRC owns any data generated directly by its researchers including non-MRC researchers conducting research under the auspices of the MRC as well as students and visiting scientists.

11.8 Where research is supported by an agreement that includes specific provisions regarding ownership, retention of and access to data, the provisions of that agreement will, to the extent permissible by law, take precedence.

11.9 The lead SAMRC employee who was involved in generating the data is the custodian of that data set and is responsible for the protection, storage and management of the data in a manner compliant with POPI and any other data protection legislation applicable and enforce from time to time and the relevant research protocol.

11.10 Research data and records should be retained for as long as they are of continuing value to the researcher and the wider research community, and as long as specified by legislative and other regulatory requirements and, where applicable any funders, sponsors and/or collaborators, patent law, legislative and other regulatory requirements (see also the MRC Archive and Retrieval SOP for retention periods). The minimum retention period for research data and records in the SAMRC, however, is five (5) years[33] after publication or public release of the research findings. When researchers leave the SAMRC, the data becomes the property of the organisation, i.e. it will be kept within the Unit under which the researcher belonged within the SAMRC.

11.11 "It is difficult to predict when data collected sometime in the past could be useful. When a new disease emerges, such as AIDS, researchers use stored samples/data to pinpoint first occurrences and the likely course of development of the disease. Although the original data were not stored for this purpose, they nonetheless can be useful for tracking diseases years later. Stored data are also useful for understanding social questions. The Department of Energy committee that made recommendations on appropriate compensation for improper human radiation experiments conducted during the Cold War pulled together data collected as far back as the 1950's. Researchers also cannot predict when someone will challenge their work and ask to see the original data. Given the different reasons data could be useful over long periods of time, researchers should give some thought to retaining data longer than some minimum period required by specific regulations. How long is reasonable will vary from field to field and institution to institution"[34]

12. Data sharing

12.1 "Data sharing is valued across the research world, however, deciding when and with whom to share the data remains a challenge. Researchers are, for example, not expected to release preliminary data (data that have not been carefully checked and validated) but exception to the rule is that preliminary data that could potentially benefit the public can be shared with other researchers, for example, preliminary data that has indications

[34] Nicholas H Steneck. 2007. Introduction to the responsible conduct of research. Department of Health and Human Science. USA.

of a major threat to public health and/or policy makers, such as unexpected drug or an unrecognized environmental health problem (Steneck, 2007: 95).

12.2 Data that have no immediate public benefit/s is best held until the researcher is confident that the results will stand, e.g. the discovery of a basic scientific process that could eventually lead to public benefit/s (ibid).

12.3 Researchers can withhold confirmed or validated data until they have had time to establish their priority for their work through publication or a public announcement.

13. SAMRC Researchers obligations with respect to data management

13.1 According to Steneck (2007), researchers have been the most important component of responsible data management practices in the past and will likely remain so as long as the public feels the majority of researchers can be trusted.

13.2 SAMRC researchers are responsible for the effective, efficient and compliant management of that data in accordance with the principles and requirements articulated in this framework and, where applicable, any funder/sponsor/ research collaborator requirements set out in the agreement(s) governing the research.

13.3 SAMRC employees are responsible for all aspects of data management throughout the life cycle of the research, including:

13.3.1 Database design
- (a) Structure of database, data collection tools, skips, codes and range checks.
- (b) Queries, storage, confidentiality, security.

13.3.2 Data capture
- (a) Paper based - office edits, single/double entry.
- (b) Electronic data capture - administration, data checks.

13.3.3 Data evaluation
- (a) Ongoing field checks.
- (b) Final evaluation, data cleaning and edits.

13.3.4 Data analysis and reporting
- (a) Basic analysis, statistical modelling.

13.3.5 Data archiving
- (a) Metadata (i.e. protocol(s), questionnaires, training manuals, sampling plans, statistical analysis plans, interim monitoring plans, randomisation lists, informed consent forms).
- (b) Structured and labelled data files.

14. SAMRC obligations with respect to data management

14.1 The SAMRC is responsible for:

14.1.1 Providing a conducive environment and infrastructure for an organisation-wide Data Management System.

14.1.2 Providing access to services and facilities for the storage, backup, deposit and retention of research data and records that allow researchers to meet their requirements under the organizational practices and procedures and those of the funders of their research.

14.1.3 Providing researchers with access to training, support and advice in research data record management.

14.1.4 Providing the necessary resources for the provision of services, facilities and training.
14.1.5 The SAMRC is also responsible for the development and updating of Standard Operating Procedures for data management, archiving and curation.

15. Authorship

15.1 Researchers have a responsibility to communicate research results to the scientific community for external evaluation through publication in peer-reviewed scientific journals.
15.2 The International Committee of Medical Journal Editors (ICMJE) recommends four criteria on which authorship is to be based as follows:
15.2.1 "Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
15.2.2 Drafting the work or revising it critically for important intellectual content.
15.2.3 Final approval of the version to be published.
15.2.4 Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved"[35].
15.3 All authors, co-authors, contributors and co-investigators will be cited in publications in accordance with the criteria provided for by the ICMJE above. In this regard, researchers should keep in mind that authorship should be based on significant contributions to the work being published, the co-author must have been directly involved in the conceptualization, design, execution, or interpretation of the research, the drafting and writing or critically revising the intellectual content in the output.
15.4 Entities and individuals who have assisted the research by for example, providing some encouragement and advice or by providing infrastructure support services, space, financial support and reagents should be mentioned in the acknowledgement text of the publication in accordance with a format agreed to between the supporting entity and the researcher.

16. Publication and dissemination of research findings

16.1 Publication and dissemination of research findings and/or results is a vital component of research.
16.2 Research findings can be disseminated in many ways such as presentations at scientific meetings, publication in peer-reviewed scientific journals and media launches, which are appropriate mechanisms for the first public disclosure of new findings.
16.3 Research participants are entitled information about the outcomes of the research that they participated in. Therefore, it is a good practice for researcher to provide feedback to the research participants.
16.4 Researchers have a responsibility to avoid deliberate inclusions of inaccurate or misleading information relating to research processes and procedures in the research findings results in public statements.
16.5 Should the publication of the research material require translations into different languages, it would be prudent to acknowledge the original source from which translations are made,

[35] http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-rol... Accessed 7/11/2017

16.6 Confidentiality must be maintained where necessary (if information was given confidentially).

16.7 SAMRC policy governing intellectual property is applicable in case where this is a possibility for a copyright and patent application emerging from a project[36].

17. Mentorship and Supervision of Postgraduate Students including Interns

17.1 13.1 The key purpose of both mentoring and supervising junior scientists and student interns is to ensure that they become both successful and responsible researchers. All SAMRC senior scientists are expected to guide, advise and train up-coming scientists under their supervision, regarding specific guidelines on research and research ethics as well as key principles and fundamental values underscoring scientific integrity.

17.2 Junior researchers and student interns in turn have a duty to respect the authority and wisdom of seniors and others working with them.

17.2.1 It has to be noted that junior researchers and Interns have the right to point out any actions carried out by their seniors that may be unethical or questionable.

17.2.2 Junior researchers and Interns must strive to keep updated with all relevant pieces of legislations, rules and regulations including ethics guidelines applicable to the SAMRC.

17.3 The SAMRC as an organisation should provide a conducive environment for junior researchers and students alike. According to the University of Oxford, the research mentoring seeks to preserve the integrity of the research effort. It is a key means for experienced researchers to share their knowledge and values with those at an early stage of their career[37].

18. Conflicts of Interest

18.1 **"**Employee's duty is to act in the exclusive interests of the SAMRC and not for personal gain. A conflict of interest arises when the employee's personal activities and relationships interfere, or appear to interfere, with the employee's ability to act in the best interest of the SAMRC" [38].

18.2 An employee may not have a direct or indirect interest (financial or otherwise) in a supplier, customer, and distributor or in any organisation that could cause conflict of interest.

18.3 In research, conflicts of interest arise where researchers, research institutions, sponsors, research ethics committees, and policy-makers have other interests that can conflict with the ethical conduct of research. Such conflicts of interest may range from – financial to non-financial.

18.3.1 The conflicts in this regard may be real or perceived due to financial relationships with outside organisations and may not be apparent and/or obvious to others unless sufficient and specific information is provided on request. In such cases, it is important that researchers disclose such conflicts to the REC in their research proposals and to fellow researchers and/or collaborators. Financial interests include, but are not limited to:

(a) Ownership of stock or equity.
(b) Patents.
(c) Consulting arrangements.

[36] Management and Commercialization of Intellectual Property Policy (2013). http://innovation.mrc.ac.za/policy.htm
[37] http://www.admin.ox.ac.uk/researchsupport/integrity/mentoring.Accessed 3/22/2017
[38] SAMRC Code of Business Conduct Framework Policy (2016).

(d) Collaboration arrangements.
(e) Honoraria.
(f) Member of Board of Directors/Council.

18.3.2 Research funding within the SAMRC is obtained from both intramural grants and extramural grants. The extramural grants can be received from many sources, such as local organisations, governmental and non-governmental organisations, international organisations including donors and, multinational corporations.

18.3.3 Researchers should also be aware about ethical dilemmas (conflict of interest) that may arise due to receipt of corporate funding, including but not limited to receipt of incentives by researchers with the potential to bias outcome of the results, influence by the funding company on the conduct, analysis, or reporting of a study's findings, and funding companies requiring the right to approve publication of research outcomes

18.3.4 The SAMRC urges its researchers to always bear in mind that any questionable situation around funding has the potential to affect the credibility of the research and the entire organisation.

18.3.5 All SAMRC researchers are urged to be explicit and transparent about the resources that enabled their research in any of their publications.

18.3.6 Non-financial conflicts of interest are also equally important, and may include the following examples[39]:

(a) Personal relationships, e.g. a relative who works at the company whose product the researcher is evaluating.
(b) Strongly held personal beliefs that are in direct conflict with the topic that is being researched.
(c) Offers of honors from stakeholders, e.g. potential promotion and/or career advancement based on outcomes.
(d) Membership of a political party or special interest group whose interests may be affected by publication of the research findings.

18.3.7 Other examples of non-financial conflict could include unauthorised accessing of confidential information about friends or acquaintances who are participating in clinical research, or giving them preference for inclusion in such studies[40].

18.3.8 In all these instances, it is important for SAMRC researchers to understand that failure to disclose conflicts of interest can threaten the integrity of the organisation and compromise public trust in the standard of research conducted by the SAMRC. The SAMRC annual online declaration of interest by all staff required under the SAMRC Code of Business Conduct Framework Policy are aimed at avoiding conflicts of interest or escalation thereof into improper behavior and/or misconduct.

19. Peer review

[39] International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Conflicts of Interest. Available at: http://www.icmje.org/ethical_4conflicts.html. Accessed on April 13, 2017.
[40] National Institutes of Health, Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH, 5th Edition (2016).

19.1 Peer review is expert critique of research which is impartial and independent, it requires that the reviewer be an authority and/or specialist in the same or related field being reviewed and is an essential component of the conduct of responsible research.

19.2 Peer review can be in different forms, e.g. new proposal (scientific), grant manuscript, performance or personnel reviews. IT is not the intention of this document to deal with different forms of peer review but to provide a ethical guidelines around peer review process.

19.3 SAMRC envisaged and encourages employees to act as peer reviewers if they are requested to do so.

19.4 SAMRC personnel should recuse themselves from participating in the peer review process for which they have a conflict of interest or might be perceived to have a conflict of interest

19.5 Peer reviewers should be mindful of the public as well as the professional consequences of their evaluations and exercise special care when making these evaluations. In that regard, the peer review process must be conducted in a way that is timely, thorough, constructive, free from personal bias and respectful of the need for confidentiality[41].

19.6 If a SAMRC employee is not comfortable with the abovementioned way that the peer review process should be conducted, then he/she should decline request to be a peer reviewer.

20. Collaborative research

20.1.1 The SAMRC supports research collaboration locally and internationally. The complex scientific arena requires interdisciplinary or multidisciplinary approach. To be successful, collaborative research needs to be accompanied with a strong sense of commitment and communication strategies that are effective and efficient between the collaborators.

20.2 The SAMRC Collaborative Research Policy SAMRC provides specific criteria for selection of appropriate collaborating partners and collaborative research agreements as outlined below:

20.2.1 Activities of the proposed collaboration provide a close fit with the vision, mission, strategic plan and annual performance plan of the SAMRC;

20.2.2 Collaboration is a business / research unit objective to achieve the business / research unit's annual performance plan;

20.2.3 The discipline or subject area of the proposed collaboration falls within SAMRC's current or developing areas of expertise i.e. core business;

20.2.4 The collaborating partner's strategy is not in conflict with that of the SAMRC i.e. the SAMRC's mandate and ethical standards;

20.2.5 The collaborating partner and all researchers involved will comply with the SAMRC's ethical requirements that may be applicable to that research;

20.2.6 The partner should have illustrated financially stability and has complied with the financial due diligence requirements of the SAMRC;

20.2.7 The partner is in a position to contract legally with the SAMRC;

20.2.8 The partnering organisation has sufficient facilities to ensure the foundation, continuity and conclusion of collaboration; and

20.2.9 The collaborating partner will contribute positively to the SAMRC's reputation and uphold the SAMRC's values and Code of Business Conduct Framework Policy,

[41] Nicholas H Steneck. 2007. Introduction to the responsible conduct of research. Department of Health and Human Science. USA

including all research ethic requirements. Conflicts of interest declarations should be completed by all parties involved with the collaboration.

21. Guideline Authority

21.1 The Executive Management Committee (EMC) is responsible for the maintenance and review of this guideline.

Category:	Level XX
Risk:	Strategic
Effective Date:	1 March 2018
Review Date:	1 March 2019
Policy Owner:	Chief Research Operations Officer
Policy Manager / Cognisant Person:	Research Integrity Officer
Board Approval:	

Confirmation of Approval

..... ……..

Prof Glenda Gray Date

President

Annexure B: Singapore Statement on Research Integrity

Singapore Statement on Research Integrity

Preamble. The value and benefits of research are vitally dependent on the integrity of research. While there can be and are national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.

PRINCIPLES

Honesty in all aspects of research

Accountability in the conduct of research

Professional courtesy and fairness in working with others

Good stewardship of research on behalf of others

RESPONSIBILITIES

1. Integrity: Researchers should take responsibility for the trustworthiness of their research.

2. Adherence to Regulations: Researchers should be aware of and adhere to regulations and policies related to research.

3. Research Methods: Researchers should employ appropriate research methods, base conclusions on critical analysis of the evidence and report findings and interpretations fully and objectively.

4. Research Records: Researchers should keep clear, accurate records of all research in ways that will allow verification and replication of their work by others.

5. Research Findings: Researchers should share data and findings openly and promptly, as soon as they have had an opportunity to establish priority and ownership claims.

6. Authorship: Researchers should take responsibility for their contributions to all publications, funding applications, reports and other representations of their research. Lists of authors should include all those and only those who meet applicable authorship criteria.

7. Publication Acknowledgement: Researchers should acknowledge in publications the names and roles of those who made significant contributions to the research, including writers, funders, sponsors, and others, but do not meet authorship criteria.

8. Peer Review: Researchers should provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing others' work.

9. Conflict of Interest: Researchers should disclose financial and other conflicts of interest that could compromise the trustworthiness of their work in research proposals, publications and public communications as well as in all review activities.

10. Public Communication: Researchers should limit professional comments to their recognized expertise when engaged in public discussions about the application and importance of research findings and clearly distinguish professional comments from opinions based on personal views.

11. Reporting Irresponsible Research Practices: Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods.

12. Responding to Irresponsible Research Practices: Research institutions, as well as journals, professional organizations and agencies that have commitments to research, should have procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behavior in good faith. When misconduct or other irresponsible research practice is confirmed, appropriate actions should be taken promptly, including correcting the research record.

13. Research Environments: Research institutions should create and sustain environments that encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work environments that support research integrity.

14. Societal Considerations: Researchers and research institutions should recognize that they have an ethical obligation to weigh societal benefits against risks inherent in their work.

The Singapore Statement on Research Integrity was developed as part of the 2nd World Conference on Research Integrity, 21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries and organizations that funded and/or participated in the Conference. For official policies, guidance, and regulations relating to research integrity, appropriate national bodies and organizations should be consulted. Available at: www.singaporestatement.org

Annexure B: Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations

Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations

Preamble. Research collaborations that cross national, institutional, disciplinary and sector boundaries are important to the advancement of knowledge worldwide. Such collaborations present special challenges for the responsible conduct of research, because they may involve substantial differences in regulatory and legal systems, organizational and funding structures, research cultures, and approaches to training. It is critically important, therefore, that researchers be aware of and able to address such differences, as well as issues related to integrity that might arise in cross-boundary research collaborations. Researchers should adhere to the professional responsibilities set forth in the *Singapore Statement on Research Integrity*. In addition, the following responsibilities are particularly relevant to collaborating partners at the individual and institutional levels and fundamental to the integrity of collaborative research. Fostering the integrity of collaborative research is the responsibility of all individual and institutional partners.

Responsibilities of Individual and Institutional Partners in Cross-Boundary Research Collaborations

General Collaborative Responsibilities

1. Integrity. Collaborating partners should take collective responsibility for the trustworthiness of the overall collaborative research and individual responsibility for the trustworthiness of their own contributions.

2. Trust. The behavior of each collaborating partner should be worthy of the trust of all other partners. Responsibility for establishing and maintaining this level of trust lies with all collaborating partners.

3. Purpose. Collaborative research should be initiated and conducted for purposes that advance knowledge to the benefit of humankind.

4. Goals. Collaborating partners should agree at the outset on the goals of the research. Changes in goals should be negotiated and agreed to by all partners.

Responsibilities in Managing the Collaboration

5. Communication. Collaborating partners should communicate with each other as frequently and openly as necessary to foster full, mutual understanding of the research.

6. Agreements. Agreements that govern collaborative research should be understood and ratified by all collaborating partners. Agreements that unduly or unnecessarily restrict dissemination of data, findings or other research products should be avoided.

7. Compliance with Laws, Policies and Regulations. The collaboration as a whole should be in compliance with all laws, policies and regulations to which it is subject. Collaborating partners should promptly determine how to address conflicting laws, policies or regulations that apply to the research.

8. Costs and Rewards. The costs and rewards of collaborative research should be distributed fairly among collaborating partners.

9. Transparency. Collaborative research should be conducted and its results disseminated transparently and honestly, with as much openness as possible under existing agreements. Sources of funding should be fully and openly declared.

10. Resource Management. Collaborating partners should use human, animal, financial and other resources responsibly.

11. Monitoring. Collaborating partners should monitor the progress of research projects to foster the integrity and the timely completion and dissemination of the work.

Responsibilities in Collaborative Relationships

12. Roles and Responsibilities. Collaborating partners should come to mutual understandings about their roles and responsibilities in the planning, conduct and dissemination of research. Such understandings should be renegotiated when roles or responsibilities change.

13. Customary Practices and Assumptions. Collaborating partners should openly discuss their customary practices and assumptions related to the research. Diversity of perspectives, expertise and methods, and differences in customary practices, standards and assumptions that could compromise the integrity of the research should be addressed openly.

14. Conflict. Collaborating partners should seek prompt resolution of conflicts, disagreements and misunderstandings at the individual or institutional level.

15. Authority of Representation. Collaborating partners should come to agreement on who has authority to speak on behalf of the collaboration.

Responsibilities for Outcomes of Research

16. Data, Intellectual Property and Research Records. Collaborating partners should come to agreement, at the outset and later as needed, on the use, management, sharing and ownership of data, intellectual property, and research records.

17. Publication. Collaborating partners should come to agreement, at the outset and later as needed, on how publication and other dissemination decisions will be made.

18. Authorship and Acknowledgement. Collaborating partners should come to agreement, at the outset and later as needed, on standards for authorship and acknowledgement of joint research products. The contributions of all partners, especially junior partners, should receive full and appropriate recognition. Publications and other products should state the contributions of all contributing parties.

19. Responding to Irresponsible Research Practices. The collaboration as a whole should have procedures in place for responding to allegations of misconduct or other irresponsible research practice by any of its members. Collaborating partners should promptly take appropriate action when misconduct or other irresponsible research practice by any partner is suspected or confirmed.

20. Accountability. Collaborating partners should be accountable to each other, to funders and to other stakeholders in the accomplishment of the research.

The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations was developed as part of the 3rd World Conference on Research Integrity, 5-8 May 2013, in Montréal, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries or organizations that funded or participated in the Conference.

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