CODE OF CONDUCT FOR RESEARCHERS

1. General

1.1. The SANBS expects all scientists, both clinical and non-clinical, SANBS employees, visiting workers in SANBS establishments, staff employed through research grants or contracts administered by SANBS, recipients of SANBS grants and any other individuals making use of any SANBS resources to adopt the highest achievable standards in the conduct of their research. This means exhibiting impeccable scientific integrity and following the principles of good research practice. This guide is about ensuring that scientific and ethical principles underpinning the conduct of research are achieved in practice.

2. External References and Internal References

2.1. Constitution of The Republic of South Africa No. 108 of 1996;
2.2. The National Health Act of Act 61 of 2003 and its regulations;
2.3. Protection of Personal Information Act 4 of 2013 and its regulations;
2.4. Material Transfer of Human Biological Materials (National Health Act, 2003 - Act No. 61 of 2003);
2.5. Ethics in health research: principles, processes and structures, second edition, 2015.
2.6. South African Good Clinical Practice: Clinical Trial Guidelines (SA DOH, 3ed 2020)
2.7. National Regulations Relating to Research with Human Participants R719 of 2014, Gazette No 38000, 19 September 2014, Vol 591 No 10268;
2.8. Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes and gametes, R181 of 2012, Gazette No 35099, 2 March 2012;
2.9. Ethical principles for medical research involving human subjects: Declaration of Helsinki (WMA, 2013);
2.10. International Ethical Guidelines for Health-related Research Involving Humans, 2016, CIOMS.
2.11. International Conference on Harmonization Good Clinical Practice Guideline, (10 November 2016);
2.12. International Committee of Medical Journal Editors (ICMJE) guidelines for authorship (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html); and
2.13. Other relevant legislation, company documents and policies.

3. Definitions

3.1. **Research misconduct** is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
3.2. **Fabrication** is making up data or results and recording or reporting them.
3.3. **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
3.4. **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

4. Compliance

4.1. It is the responsibility of the Translational Research Cellular Therapy Senior Manager to ensure the document is applied, reviewed and revised.
4.2. It will result in the researcher not being approved for future research within the organization
4.3. An individual conducting research is requested to sign the "Code of Conduct for research in the SANBS Statement of Agreement" form.

5. General principles

5.1. Good research practice (GRP) is essentially an attitude of mind, that becomes an attitude to work. It is about the manner in which research is planned and conducted, the results are recorded and reported, and the fruits of research are disseminated, applied, and exploited. GRP will allow ready verification of the quality and integrity of research data, provide a transparent basis for investigating allegations of bad practice or fraud, and lead to better

research. While the integrity and responsibility of individual researchers are of the utmost importance, research institutions, research funders, and the research community in general also share responsibility for promoting and verifying good practice, especially through their arrangements for training and supervision and through the ethos they create.

5.2. In clinical studies, the rights, safety, and well-being of participants must be safeguarded. Issues of consent and confidentiality, benefits outweighing risks and harms, benefit sharing, post-trial access and other justice considerations are paramount.

5.3. The POPIA must be complied with.

5.4. For near-market projects sponsored by industry and some other funders, the more rigorous requirements of Good Laboratory Practice is be mandatory. There must be adequate resources to accommodate these requirements and further advice should be sought from those with relevant expertise.

5.5. Investigational therapeutic products should be manufactured, handled, and stored in accordance with Good Manufacturing Practice or other appropriate guidelines for the manufacture of medicinal products.

5.6. GRP can only be achieved if the staff at all levels are trained and supervised properly by research team leaders in a research culture that encourages frank discussion and debate. Research team leaders are responsible for seeing that a constructive atmosphere prevails and must ensure that staff have the appropriate training and experience to carry out duties as required by the research protocol; this is especially important for new staff. To ensure the quality of research practice, supervision and checking is an integral part of the process; a senior

5.7. of each research group should take personal responsibility for this.

5.8. The steps that may be needed to supervise GRP include monitoring of training and supervision of new staff and of continuing professional development, regular checks on data recording and notebooks, and occasional checks on the day-to-day conduct of experiments. From time to time and randomly, experiments should be tracked back from conclusion to conception to ensure that all necessary paper/electronic “trails" are in place.

6. Conflicts of interest

6.1. Conflicts of interest may occur in all walks of life; medical research is no exception. A conflict arises when a person's judgement concerning a primary interest, such as scientific knowledge or participant protection, could be unduly influenced by a secondary interest, such as financial gain or personal advancement. There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required is to recognize the conflict and deal with it accordingly. Researchers must pay as much attention to perceived and potential conflicts of interest as well as to actual conflicts. How one is perceived to act influences the attitudes and actions of others, and the credibility of scientific research overall.

6.2. Conflicts of interest can occur at any stage of the research process– from planning the research to disseminating and exploiting the results – and can occur in many forms. Apart from financial interests, conflicts might, for example, be personal, academic, or political.

6.3. Researchers should automatically ask themselves "Would I feel comfortable if others learnt about my secondary interest in this matter or perceived that I had one?" If the answer is no, the interest must be disclosed and addressed appropriately, for example, according to the policy of an employer, a peer-review body, or a journal.

6.4. Where there is the possibility of a perception of conflict of interest, albeit no real conflict, this must be declared as well.

7. Planning the research

7.1. All research projects, both clinical and non-clinical, should be conceived, designed, and implemented according to the highest standards, including:

7.2. The rationale for the study. Subsequent modifications should be well documented with an audit trail where relevant. There should be evidence of approval be it for original documents or amendments. Each key document and any changes should be signed and dated by the researcher responsible to establish the provenance of the study and protect intellectual property rights.

7.3. Adherence to current safety practices, ethical standards, and legal regulations.

7.4. Securing all necessary ethical reviews and regulatory approvals in good time, for example from the Research Ethics Committees.

7.5. In clinical studies, identifying a health professional who will take overall responsibility for the well-being and interests of patients or healthy volunteers involved and for ensuring that their rights (e.g., in terms of consent and confidentiality) are protected.
7.6. Identifying the individual or group that will take ultimate responsibility for overseeing the scientific and ethical conduct of the study as the scientific plans are put into practice. This is especially important in projects affecting patients or volunteers and in other complex and collaborative programs.
7.7. Consultation with patients or beneficiaries/donors wherever appropriate, especially in clinical and applied research.
7.8. Consultation with statisticians at the planning stage, where relevant. The statistical power of a study should be an early consideration, and researchers should draw on professional statistical advice if needed. This is especially important for studies involving people or animals to avoid unnecessary or unproductive experiments.
7.9. Ensuring that organizations responsible for the care of any patients involved are aware that the research is being planned.
7.10. Assessment of resources needed (e.g., space, staff, funding, biological resources, facilities, and clinical support) to ensure the study is viable within the available means and economy in the use of resources.
7.11. Regular review of progress so that new findings can be taken into account and the project plan modified accordingly, especially if plans involve any risk to participants or use of animals.
7.12. Agreement in advance on who will be writing any planned publications and the authorization required to publish Acknowledgement of formal or informal contributions to the work, including sponsoring organizations and scientific collaborators.

8. Conducting the research

8.1. RESEARCH INVOLVING HUMAN PARTICIPANTS CAN ONLY BE CONDUCTED WITH PRIOR RESEARCH ETHICS COMMITTEE APPROVAL. THIS INCLUDES BOTH PROSPECTIVE AND RETROSPECTIVE STUDIES.

8.2. **Information and Organization:**

i. The legal and ethical requirements relating to human participants, animals, and personal information should be known and understood by each person involved in the study, and they should know to whom to direct questions regarding the research (study). Since ethical issues, guidance, or requirements often change, research teams and centers must have an effective communication plan for disseminating knowledge and documents. The protocol should state the process (change request process) in case of deviations from the protocol which should include ethical/regulatory approval requirements.

8.3. **Use, calibration, and maintenance of equipment:**

i. Equipment used to generate data should be appropriately located, safe, suitable for the purpose, of appropriate design, and of adequate capacity. It should be calibrated and serviced regularly by trained staff so that performance is optimal and the results reliable. A designated person should be responsible for ensuring the proper use and maintenance of equipment and, where appropriate, for training staff in its use; when this is not possible, the users themselves should take on the responsibility. Records should be kept of calibration, servicing, faults, breakdowns, and misuse of equipment.

ii. A standard operating procedure or usage instructions should be maintained for each piece of equipment; in some cases, this might be the manufacturer's instruction manual. There should be easily accessible instructions for the safe shutdown of equipment in case of emergency.

8.4. **Risks of research misuse**

i. In progressing their scientific investigations, researchers should actively consider any risks that their research will generate outcomes that could be misused for harmful purposes. Where such risks exist, they should seek advice from their Head of Department or Institution and take active steps to minimize them. Departmental units should have in place mechanisms to ensure that risks of misuse associated with ongoing research programmes are identified and managed and to provide advice to the researchers on these issues.

8.5. **Hazardous processes and materials**

i. Experiments should be conducted in accordance with SANBS and/or local policies on health and safety regulations and guidelines. Where appropriate, risk assessments complying with the regulations on Control of Substances Hazardous to Health (COSHH)

should be prepared before the work is carried out. Staff should be properly trained and monitored so as not to endanger themselves, others, or the environment.

8.6. **Standard operating procedures**

i. Standard operating procedures (SOPs) should be documented for all routine methods and for individual items of equipment to ensure that data are collected consistently and accurately. When there is more than one approved technique for any given procedure, all should be covered by SOPs. SOPs should be written in simple language, readily accessible, and ideally in a standardized format. The SOPs should be updated as necessary, and only the current version should be available.

ii. Standard written protocols should also be available covering the process of seeking informed consent from donors, patients or volunteers including minors/vulnerable populations, to ensure clarity and consistency.

8.7. **Recording Data**

i. Gathering and Storing data**:** A Research Ethics Committee or other appropriate ethics committee must approve all research involving identifiable personal or anonymized data. All personal data must be encoded or anonymized as far as possible and consistent with the needs of the study, and as soon as possible/relevant possible after collection cyphers (codes), questionnaires, audiotapes, etc. must be stored separately. This applies to both paper and electronic records.

ii. Data should be stored in a way that permits a complete retrospective audit if necessary.

iii. Data should be stored safely, with appropriate contingency plans.

iv. Data records should be monitored regularly to ensure their completeness and accuracy. Raw (original) data/images should be recorded and retained; this is especially important where data/images are subsequently enhanced. If possible, both original features should be stored.

v. Any sharing of data must comply with POPIA and a data sharing agreement needs to be in place (if applicable)

8.8. **Retention of accurately recorded and retrievable results is essential for research:**

i. Primary research data (and where possible/relevant specimens, samples, questionnaires, audiotapes, etc.,) must be retained in their original form within the research establishment that generated them for a minimum of ten years from completion of the project.

ii. Work that is aimed to inform national policy should be archived.

iii. Research records relating to clinical or public health studies should be retained for 20 years to provide scope for longer follow-up if necessary.

iv. Researchers that are leaving the establishment that generate the data and who wish to retain data/copies of data for personal use must get permission from their team leader or head of the department to do so. Where personal data are involved, the request should be refused unless it is clear that future use will be consistent with the terms of the consent.

v. Publication of the data (including in Master/Doctoral theses) does not negate the need to retain source data.

8.9. **Notebooks and electronic records.**

i. The following basic policies apply: All raw data should be recorded and retained in indexed laboratory notebooks with permanent binding and numbered pages or in an electronic notebook dedicated to that purpose. Machine print-outs, questionnaires, chart recordings, autoradiographs, etc. which cannot be attached to the main record should be retained in a separate ring binder/folder that is cross-indexed with the main record.

ii. Records in notebooks should be entered as soon as possible after the data are collected.

iii. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should also be clearly identified and dated.

iv. Special attention should be paid to recording accurately the use of potentially hazardous substances (e.g., radioactive materials) in both laboratory notebooks and any central logbooks.

v. In clinical studies, consent forms should be kept securely with the raw data, and normally for the same period of time.

vi. Supervisors should regularly (monthly or as appropriate to the nature of the work) review and sign off notebooks of researchers to signify that records are complete and accurate. Queries should be discussed immediately with the individual who recorded the data and

any resultant changes to the records should be signed by both. Authentication of data collected and recorded electronically requires special consideration.

8.10. **Computer-generated data.**

i. Special procedures are necessary for electronically generated data: Data should be backed-up regularly; duplicate copies should be held on an alternative device such as an external drive or in the cloud in a secure but readily accessible archive.
ii. Where feasible, a hard copy should be made of particularly important data.
iii. Copies of relevant software, particularly the version used to process electronic data, must be retained along with the raw data to ensure future access. Software updates must be logged and stored as new formats and media are adopted.
iv. Special attention should be paid to guaranteeing the security of electronic data.

8.11. **Reporting the results**

i. The SANBS is committed to transparency in research. The data on which published research is based must be available for evaluation by the broader research community.
ii. Once all issues of confidentiality and ownership have been addressed, research findings should be disseminated so that they can be assessed bythe scientific community. Accordingly, researchers should publish their data in a timely fashion in a peer-reviewed journal or in other equally reputable publications and/or present their results at scientific meetings.
iii. It is equally unethical not to report results, or to exaggerate the importance of results for medical practice or policy. Both are areas in which a researcher's desire for advancement or recognition may conflict directly with the public interest in a complete, balanced, and rigorous account of the scientific evidence.

8.12. **Publication policy**

i. Publication of articles for internal SANBS staff should be in accordance with the SANBS Publication Policy
ii. The person with overall responsibility for the research programme should authorize the publication of results; authorization should cover both the content of the paper (integrity of results, adequacy of internal peer review, appropriate protection of intellectual property rights, appropriate authorship) and the intended place of publication.
iii. Research findings with substantial implications for clinical practice or which are likely to attract strong public interest should be drawn to the attention of the SANBS HREC through the Translational Research office and/or other research funders before publication.
iv. A written agreement should be negotiated with external sponsors before the research is initiated to cover the free dissemination of research findings; this is especially important where funding has been secured from industry.
v. Published reports should normally contain basic information about the ethical acceptability of the work and/or its legality, as well as information about the scientific method.
vi. The leader of the research team should authorize any release of the results on the Internet.
vii. Releasing information in this way may well compromise intellectual property rights, so there should be a suitable mechanism to monitor information placed on the web.

8.13. **Authorship**

i. Authorship of articles must be in line with the ICJME criteria https://www.icmje.org/recommendations/
ii. Authorship of papers should include those individuals who have made a major contribution to the work and who are familiar with the entire contents of the paper.
iii. Authors should have participated sufficiently in the research to take public responsibility for the content.
iv. Other contributions to the work should be acknowledged formally, as should financial support from sponsors. Authors are responsible for obtaining written permission from persons acknowledged by name.

8.14. **Methods of publication**

i. Work should preferably be published as a coherent entity rather than a series of small parts unless there is a legitimate need to demonstrate first discovery by publishing preliminary data. Quality rather than quantity is paramount; the proliferation of multi-author papers to increase quantity should be discouraged.
ii. Authors must not publish the same data in different journals.

8.15. **Correction of errors and retraction of published findings**

i. If an error is found that degrades the worth of published findings, the principal author must immediately discuss the matter with the research leader, with a view to notifying co-authors and publishing a correction as soon as possible setting out the basis of the reservations.
ii. Where the findings are found to be in serious doubt, a retraction should be published speedily.
iii. In all cases the HREC must be notified as soon as reasonably possible.

8.16. **Applying and exploiting the results**

i. SANBS's mission can only be fulfilled if the results of research are communicated effectively. SANBS, therefore, expects those it supports to play their part in disseminating balanced information on scientific advances and their potential implications for society to the health professionals and policymakers who will be involved in applying them, and to the wider public.

8.17. **Commercial exploitation.**

i. Since part of SANBS's mission is to improve quality of life and economic competitiveness, SANBS-funded researchers are expected to maximize the prospects of research being taken into practice through the commercial route by protecting Intellectual Property Rights (IPR).
ii. Intellectual property can only be protected adequately if researchers keep thorough, accurate, and contemporaneous research records.
iii. Researchers who collaborate with industry should take special care to keep detailed records of their research.
iv. IPR should be considered before data are submitted for publication or presented at meetings.
v. All intellectual property, know-how, reagents, or materials generated by SANBS employees while on SANBS premises, or in connection with SANBS research activities, is the property of the SANBS. This is usually also the case for visiting workers who use SANBS research facilities.
vi. Data placed on the web are considered to be in the public domain and cannot be protected.
vii. Material transfer agreements (MTAs), Data Transfer Agreements (DTAs) and confidentiality agreements are important for protecting resources that may potentially have great value. MTAs and DTAs are agreements between the sender (e.g., SANBS) and recipient organizations regarding the provision of research materials and data; they set out the terms on which the provider is prepared to release its material / data to the recipient. MTAs must be in line with the NDoH gazettet MTA requirements.
viii. Confidentiality agreements recognize the need for tentative research and/or development partners to share proprietary research findings and/or commercial technologies before making a formal commitment to a partnership; they, therefore, bind and protect the parties by limiting the use of exchanged information to the discussions in hand. Researchers should generally seek expert guidance before entering into these agreements.

9. Research misconduct

9.1. Dealing with research misconduct

i. Research misconduct is rare. Most researchers operate according to the highest standards, and, as a consequence, there is generally a high level of trust between them. Individuals are naturally reluctant to entertain any suspicion about the activities of a colleague. A serious case of research misconduct may lead to the end of a research career and may reflect badly on colleagues and on SANBS. If suspicion does arise it can lead to considerable distress on the part of a potential whistle-blower in deciding how to proceed. It is important, therefore, to emphasize that the SANBS is committed to the following principles:
ii. Any allegation of research misconduct must be dealt with expeditiously. If such misconduct is established there is an absolute responsibility to expose it.
iii. A finding that research misconduct has occurred will be dealt with openly, and all steps to correct its effects will be taken.

9.2. Findings of Research Misconduct

i. This is when a significant departure from accepted practices of the relevant research community.
ii. The misconduct is committed intentionally, or knowingly, or recklessly; and
iii. The allegation be proven by a preponderance of evidence

9.3. The rights of any researcher accused of misconduct must be protected.

9.4. The rights of any individual reporting suspicions of such misconduct in good faith must be protected.

9.5. An individual who suspects that research misconduct may have occurred is strongly encouraged to discuss the problem in confidence, with the chairperson of the ethics committee.

9.6. Because the consequences of research misconduct are so severe, there are several stages in the process of investigating it:

i. Should an individual believe that research misconduct may have occurred the facts should be reported to the SANBS Human Research Ethics Committee (HREC) chairperson and Medical Director.

ii. In consultation with any other research ethics committee involved, Human Resource Division (SANBS employee), Internal Audit or the SANBS legal advisor, the HREC chairperson shall, without delay, appoint a committee to establish the facts of the matter and to recommend whether there is a *prima facie* case to be answered. The committee shall:

iii. Inform, in confidence, those directly affected by the investigation of its nature. This will include the appropriate ethics committee where relevant, line manager, or supervisor of the individual/institution involved.

iv. Conduct an investigation to establish the facts.

v. Report to the CEO within one month of establishment of the committee. This should either be a final report or a motivation to extend the investigation for a limited period.

vi. The final report shall recommend:

vii. Whether there is a *prima facie* case for disciplinary action.

viii. What immediate action, if any, must be taken to rectify any irregularity. Full details of such action shall be made available to all interested parties inside and outside SANBS , either immediately, or, if necessary, after the completion of a disciplinary case.

ix. On receiving the report, the CEO will, without delay, take appropriate action, based on the recommendations of the committee, referring the matter for disciplinary action, if necessary.

x. After the completion of any disciplinary case, a full report of the facts of the case and the actions that have been taken to rectify the situation will be documented. The decision to make these findings public will rest with CEO.

xi. All steps should be taken to protect the interest of *bona fide* individuals reporting misconduct.

10. Revision Summary

VERSION NUMBER	REVISION DETAILS
0	New document.