



**NWU Guidelines for the
Animal Care and Use Programme**
(NWU-ACUP:2024 1st ed.)

Senate Committee for Research Ethics (SCRE)
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NWU Office for Research Support

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1 INTRODUCTION

1.1 Scope of the Guidelines

These **Guidelines** are stemming from the NWU's **Policy on the Animal Care and Use Programme** (9P_9.1.5_AnimCare of 9 Sep 2021 – [\[pdf\]](#)), and pertains to the care and use of animals for scientific purposes on all of its campuses. It has been developed and approved, and is maintained by the North-West University (NWU) Senate Committee for Research Ethics (SCRE).

Stakeholders

- a) These Guidelines *assist university management* (e.g. the deputy vice chancellor of research and innovation (DVC-R&I) and the NWU Research Office), relevant Deans and/or Deputy Deans R&I of Faculties involved in the use of animals for scientific purposes.
- b) The provisions of the Guidelines *apply to various animal custodians, professionals and scientists*, including animal research ethics committees, all relevant line managers of research animal facilities (RAFs), attending and supervising veterinarians and paraveterinary and supporting staff at RAFs, as well as all researchers, educators and postgraduate students using animals for scientific purposes (*i.e. for research, field trials, testing, diagnosis, teaching and/or training activities*)– as per SANS 10386:2021 2nd ed. §1.1).
- c) These guidelines *exclude* the care and management of *wild and feral animals* living on NWU property, or animals receiving *veterinary clinical healthcare services at NWU animal health facilities* for the purpose of community service, all of which are also included in the NWU's Policy on the Animal Care and Use Programme. Rather all matters pertaining to the care of these animals are the responsibility of the NWU's University Management Committee (UMC), who has to put separate measures in place for that purpose.

1.2 Purpose of the Guidelines

The current NWU **Guidelines for the NWU Animal Care and Use Programme** aims to harmonise institutional policies and procedures to attain the highest standards as per its own norms and values, as well as to align with international best practices. Importantly, it also aligns its own policies and procedures with national legislative provisions, as described in the SANS 10386:2021, clause 5.9.4.1 and the NDoH 2024. It outlines minimum requirements and standards for the scope and activities mentioned in §1.1 above, and are to be implemented at the respective entities and its programmes (such as described in §3 and illustrated in Figure 4 below). The document also aims to harmonise and align the implementation of the NWU Animal Care and use Programme as it pertains specifically to the use of animals for scientific purposes.

These Guidelines therefore set the collective principles and minimum norms and standards of the NWU Animal Care and Use Programme, also outlining responsibilities and functions of the authorised institutional official (AIO), management structures and the aforementioned senior management and line managers, animal research ethics committees (ARECs), research animal facilities (RAFs) and its staff, researchers, including postgraduate students, using animals for scientific purposes, occupational health and safety, and biological safety.

Furthermore the Guidelines assist the NWU to promote the culture of care, responsible management of the care and use of animals, and to prepare for annual external review and quadrennial independent external audit of institutional animal care and use programme, as required by the SANS 10386:2021 and supported by the NDoH 2024 Guidelines (see §2.1 below).

1.3 Context of the Guidelines

The relationship between the Policy, Guidelines and Directory documents on the Animal Care and Use Programme is explained in **Figure 1** below.



Figure 1: A Birds-eye view of the relationship between the Policy, Guidelines and Directory document, being the main documents describing and governing the NWU Animal Care and Use programme.

As a separate addendum document, the **Directory of structures, facilities and documents within the NWU Animal Care and Use Programme**, is an informative document that outlines existing compliance with the **Guidelines** (e.g. *list of structures and applicable documents and where they can be accessed*), as well as gaps and recommendations for aspects still to be developed and/or to be made available by the respective entities. As such it will be constantly updated (as a work in progress document) to guide stake holders and to demonstrate progress regarding improved compliance to the Animal Care and Use Programme, for monitoring by the Senate Committee for Research Ethics (SCRE).

1.4 Abbreviations and/or Definitions

Term, acronym or abbreviation	Description
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care International
AIO	Authorised institutional official, typically the Deputy Vice Chancellor for Research and Innovation
AREC	Animal Research Ethics Committee
CIOMS	Council for International Organizations of Medical Sciences
DAFF	(National) Department of Agriculture, Forestry & Fisheries (<i>former name, now known as DALRRD – see below</i>)
DALRRD	(National) Department of Agriculture, Land Reform and Rural Development (<i>formerly known as DAFF - see above</i>)
NDoH 2024	National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3 rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH. 137 p. ISBN 978-0-621-52027-9
DSI	(National) Department of Science and Innovation (<i>formerly known as DST – “Technology”</i>)

Term, acronym or abbreviation	Description
Ethics	<p>The term “ethics” refers to standards of research conduct, which indicate how a person should behave based on moral duties and virtues arising from the principles of right and wrong. Ethics therefore involve two aspects:</p> <ol style="list-style-type: none"> 1) the ability to distinguish right from wrong; and 2) The commitment to do what is right as articulated in various pieces of legislation and guidelines regulating the execution of research. <p>Of importance for these Guidelines is Animal Research Ethics, or the ethics of the use of animals for scientific purposes.</p>
ICLAS	International Council for Laboratory Animal Sciences
Integrity	Refers to the quality or state of being of sound moral principle, uprightness, honesty and sincerity.
NABF	National Aquatic Bioassay Facility
NDoH	National Department of Health
NHA	National Health Act, 2003 (Act No. 61 of 2003)
NHREC	National Health Research Ethics Council
NSPCA	National Council of Societies for the Prevention of Cruelty to Animals
NWU	North-West University
NWU-AnimCareREC	North-West University Animal Care, Health and Safety in Research Ethics Committee
NWU-AnimProdREC	North-West University Animal Production Research Ethics Committee
OIE	World Organisation for Animal Health (<i>i.e., still using the historical acronym for the former name “Office International des Epizooties”</i>)
PAWS	Potchefstroom Animal Welfare Society
PCDDP	Pre-Clinical drug Development Platform of the DSI/NWU
Policy	Principle of action adopted by the NWU or relevant unit
SAALAS	South African Association for Laboratory Animal Sciences
SABS	South African Bureau of Standards
SACNASP	South African Council for Natural Scientific Professions
SAE	Serious adverse event (<i>related to a study intervention, for example due to a research procedure on an animal</i>)
SI	Serious incident (<i>unrelated to a study intervention, for example due to a facility failure or accident</i>)
SANS 10386	South African National Standard: The Care and Use of Animals for Scientific Purposes, with the latest version used in these Guidelines being the SANS 10386:2021 2nd ed.)
SAVC	South African Veterinary Council

Term, acronym or abbreviation	Description
Scientific purposes	The 'use of animals for scientific purposes' refers to their involvement in research, field trials, testing, diagnosis, teaching and/or training activities (see SANS 10386:2021 2 nd ed., clause 1.1)
SCRE	Senate Committee for Research Ethics (i.e., NWU committee)
SOP	Standards Operating Procedure
ToR	Terms of Reference
UESM	Unit for Environmental Sciences and Management
Values	Refers to beliefs of a person or social group in which they have an emotional investment either for or against something
DVC-R&I	Deputy Vice-Chancellor: Research and Innovation

2 PRINCIPLES

2.1 Authoritative documentation

The NWU recognises the following authoritative documentation:

- **South African** legislation, guidelines & standards
 - RSA Constitution & relevant legislation (as outlined in the NWU Policy on the Animal Care and Use Programme)
 - National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH. 137 p. ISBN 978-0-621-52027-9. (**NDoH 2024** or latest version) ([link](#)).
 - South African National Standard: The Care and Use of Animals for Scientific Purposes (**SANS 10386:2021** 2nd ed. or latest version) (*available to NWU staff and students via the NWU Library services*).
- General **NWU** institutional policy documents & ToR

Key documents related to research ethics of the NWU can be accessed from the website, with links to the portals provided for your convenience. Nevertheless, the links below may expire at some point, at which time these documents will have to be searched for on the NWU website.

- NWU Policy on the Animal Care and Use Programme ([portal](#))
- NWU Research Ethics Policy ([portal](#))
- NWU Code of Conduct for Researchers ([portal](#))
- NWU Policy on Academic Integrity ([portal](#))
- NWU Scope of North-West University Scientific- and Research Ethics Committees ([pdf](#))
- Terms of Reference for respective Research Ethics Committees ([portal](#))

- Important **international** principles & codes

- Brink CB* & Lewis DI. (2023) The **12 Rs Framework** as a comprehensive, unifying construct for principles guiding animal research ethics. *Animals*,13(7):1128. <https://doi.org/10.3390/ani13071128>.
- **CIOMS-ICLAS Principles**. (2012) International Guiding Principles for Biomedical Research Involving Animals [[pdf](#)]
- Osborne N, Avey MT, Anestidou L, Ritskes-Hoitinga M & Griffin G. 2018) Improving animal research reporting standards: **HARRP**, the first step of a unified approach by ICLAS to improve animal research reporting standards worldwide. *EMBO Reports*, 19:e46069. <https://doi.org/10.15252/embr.201846069>.
- **OIE** terrestrial animal health code, 2012, World Organisation for Animal Health. [[pdf](#)], of which South Africa is a member
- Nerocopa. (2022) **PREPARE** Guidelines [[portal](#)]
- NC3Rs. (2020) **ARRIVE** Guidelines 2.0. [[pdf](#)]
- AAALAC (2011) **Guide** for the Care and Use of Laboratory Animals, 8th ed. National Academy Press:Washington DC. ([link](#))
- Hartung, T. (2010) “Comparative analysis of the revised **Directive 2010/6106/EU** for the protection of laboratory animals with its predecessor 86/609/EEEC – a t4 report”, *ALTEX - Alternatives to animal experimentation*, 27(4), pp. 285–303. doi: 10.14573/altex.2010.4.285. ([link](#))
- Other international standards as recognised by the SANS 10386:2021 2nd ed and the NDoH 2024 3rd ed.

2.2 Principles

2.2.1 NWU ethical point of departure

The NWU ascribe to the following 3 overarching principles¹ as ethical point of departure for the care and use of animals for scientific purposes.

Principle 1. The NWU cultivates the respect for the dignity of animals in research, as live and sentient beings
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In this regard the North-West University recognises the moral dilemma of using animals for experimentation. Firstly, animals are sentient beings with sensations and emotions, and therefore the ability to experience suffering. At the same time, we accept that experimentation with animals is essential to advance biomedical (and veterinary, natural or agricultural) sciences, ultimately reducing suffering (to humans or animals, or harm to the environment) and enhancing life and wellbeing:

- This will be sought within a pro-actively cultivated culture of care that fosters effective training, communication and respect.
- In all instances sound motivation, justification and attempts for implementing mitigating measures must be provided for the use of animals and associated procedures in research, including a proper harm-benefit analysis (i.e. demonstration that benefit outweighs harm).

¹ Adopted and expanded from the ethical points of departure for research using animals, as approved by the Senate Committee for Research Ethics, Oct 2020. These replace the previously approved principles of the ethical point of departure.

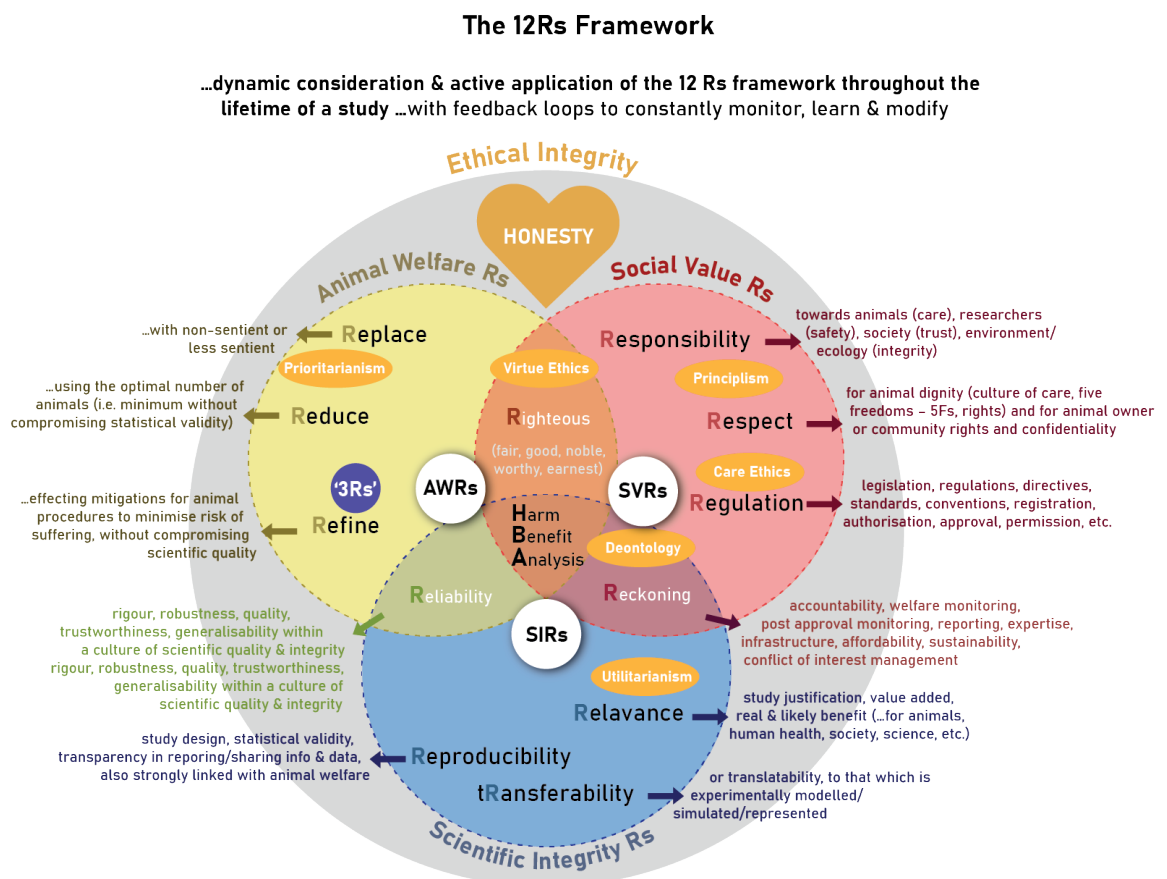
<ul style="list-style-type: none"> • Ethical reflection will consider <u>human / researcher safety</u>, <u>animal wellbeing</u> and <u>environmental integrity</u>. • The <u>wellbeing of animals will remain of utmost importance</u>, firstly by ensuring humane treatment of animals at all times, and by recognising undue stress, pain or discomfort and making relief thereof a priority above the scientific / experimental interests. • The <u>repetition</u> of previously performed research experiments with animals will not be considered, unless it can be motivated to be necessary and shown to contribute to new knowledge.
<p>Principle 2. The NWU endorses the universal 4Rs ethical principles pertaining to the use of animals for scientific purposes</p>
<p>The principle of the 4Rs will be applied at all times:</p> <ul style="list-style-type: none"> • <u>Replace</u>: to replace animals with alternatives (where possible and sensible) • <u>Reduce</u>: to reduce the number of animals used (to the minimum that will still provide scientifically verifiable answers) • <u>Refine</u>: to refine experimental design and procedures (i.e. implementation of best procedures to minimise suffering of animals, selection of the optimal animal models, ensuring the finest experimental design, and ensuring the maximal usefulness & trustworthiness of experimental data) • <u>Responsibility</u>: to consider and value the rights of animals and their wellbeing (consideration and active promotion of the ‘5 Freedoms’: Freedom (1) from hunger or thirst, (2) from discomfort, (3) from pain, injury or disease, (4) to express (most) normal behaviour, and (5) from fear and distress). In addition, it entails responsibility towards fellow researchers and the community at large, as well as the environment.
<p>Principle 3. The NWU endorses the universal 12Rs framework pertaining to the ethical use of animals for scientific purposes</p>
<p>The 12Rs framework (see 2.2.2 below) guides the comprehensive approach to ethical integrity regarding the use of animals for scientific purposes. This framework unfolds in different overlapping domains:</p> <ul style="list-style-type: none"> • Animal welfare Rs: Replace, Reduce, Refine, Responsibility (see Principle 2 above) • Social integrity Rs: Respect, Responsibility, Regulation • Scientific integrity Rs: Reproducibility, Translatability, Relevance • Domain overlapping Rs: Reliability, Reckoning, Righteous <p>The domains and their R principles overlap and are interdependent. Furthermore, ethical integrity requires consideration throughout the cycle of a study, from conceptualisation through planning, review & approval, execution, monitoring, reporting, conclusion and record keeping. Regular feedback loops and independent review & monitoring, professional & expert consultation, and revision as indicated are necessary.</p>
<p>Principle 4. The NWU upholds accountability and the highest ethical conduct in research using animals</p>
<p>All use of animals for research or training purposes at the North-West University will stand the test of scientific integrity and ethical conduct.</p> <ul style="list-style-type: none"> • All projects must be <u>reviewed</u> and <u>approved</u> by an appropriate scientific committee, and reviewed, approved (ethically sound, compliant & benefit outweighs harm) and monitored (overseen) by a registered animal research ethics committee of the NWU (i.e. according to scope the NWU-AnimCareREC or the NWU-AnimProdREC) • The NWU subscribes to <u>quality assurance</u> in the keeping and use of animals in research. All keeping, handling, and experimentation with animals must be done according to well-designed experimental protocols and with appropriate safety measures in place. These must be performed in appropriate, approved, maintained and monitored facilities and by appropriately qualified, trained and competent researchers and technicians, under the supervision of appropriately qualified and registered professionals. In addition, regular internal and external inspections and audits are implemented.

- The NWU accepts its duty to be accountable and responsive towards community context and values. The unique context and diverse perspectives and values of the South African community will be considered in the care of animals and the planning and execution of all research using animals. Care and use of animals will actively foster public responsibility and accountability via access to important information, education and overall transparency, as well as service to society with expertise and promotion of public engagement.

Ultimately, all use of animals must be managed within the NWU's Animal Care and Use Programme, as governed by the NWU Policy in this regard. In this regard, the Guidelines endorses the 12Rs Framework (see §2.2.2 below) as comprehensive guidance tool for striving towards optimal ethical integrity regarding the use of animals for scientific purposes, and as also endorsed by the NDoH 2024 3rd ed..

2.2.2 The 12Rs framework

The NWU Guidelines for its Animal Care and Use Programme and the NDoH 2024 endorse the 12Rs framework (see full reference in §2.1 above). This is briefly outlines in **Figure 2** below).



This comprehensive framework for the ethical use of animals for scientific purposes provides three primary domains for ethical principles, including animal welfare, social values and scientific integrity. Importantly, the framework also emphasises that the three primary domains are interdependent and interlinked, and that they do not function in silos. The 12 ethical principles feed into a final harm-benefit analysis. In addition, the framework should be applied from the start of a study (conceptualisation, planning, review & approval), right through execution (conducting experiments, reporting, amendment) to the end (research

reporting and storage of data). Lastly, the framework caters for various prominent moral ethical theories, and is applicable across cultural differences. Detailed explanation can be found in the original publication (see §2.1).

The framework can also be viewed as a monumental building depicted in **Figure 3** below:

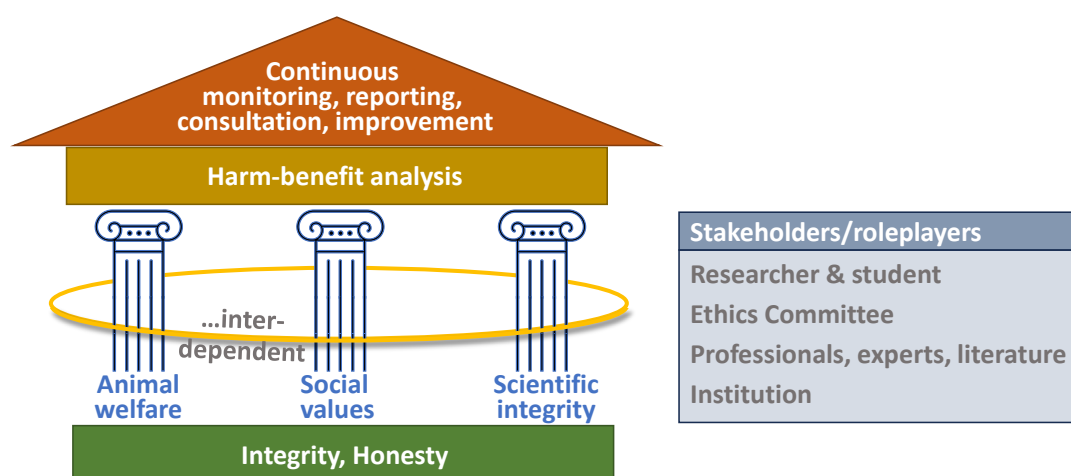


Figure 3: The 12Rs Framework. An alternative way of comprehending the framework.

You will see in this monumental building of ethical integrity the elements of:

1. the foundation as integrity and honesty;
2. and then three pillars of animal welfare, social values and scientific integrity, with interdependency;
3. the capstone as the harm-benefit analysis, taking all of these into account, and employing various moral theories of ethics;
4. all taken forward by continuous monitoring, reporting, consultation and improvements to be implemented.

The stakeholders & role-players that is needed to make this ethical framework work include the researcher and student, the ethics committee, various professionals (veterinary and other), experts (specialists in relevant fields), literature, and the structures, policies, support and environment created and provided by the institution.

2.2.3 The NWU's understanding of a culture of care

Definition: *"The term Culture of Care is used in the laboratory animal community to indicate a commitment to improving animal welfare, scientific quality, care of the staff and transparency for the stakeholders"*². A culture of care is about caring from the heart, and not merely driven by law, rules and standards.

Figure 3 below outlines how the North-West University views a "culture of care" within a research institution, environment and community, as should be intentionally and pro-actively driven, supported and cultivated by institutional management and fostered by its staff.

² Norecopa. 2016. <https://norecopa.no/more-resources/culture-of-care>.



Figure 4: Understanding a culture of care within a research institution, environment and community (Christiaan B Brink, NWU. 2020). *Self-created, based on principles outlined in: Norecopa. 2016. <https://norecopa.no/more-resources/culture-of-care> Brown M. 2014. NC3Rs: Creating a culture of care. <https://www.nc3rs.org.uk/news/creating-culture-care>, and Brown et al. 2018. Chapter 2 Culture of Care: Organizational Responsibilities, in *Management of Animal Care and Use Programs in Research, Education, and Testing*. 2nd edition. <https://www.ncbi.nlm.nih.gov/books/NBK500402/>.*

All management, staff, researchers and students are expected to actively foster and conduct within a culture of care within the Animal Care and Use Programme.

3 LINE OF AUTHORITY, REPORTING & COMMUNICATION

The SANS 10386:2021 2nd ed. (or latest version) §5.2 & §5.3 and their respective sub-clauses stipulate in detail the extensive responsibilities of the institution (and per implication its management) regarding the care and use of animals for scientific purposes. In addition, the NDoH 2024 (or latest version) §5.2ff adds responsibilities along the same lines, whereas many of the institutional responsibilities are implied in the specified requirements for research ethics committees.

Some of these responsibilities of institutional management include, but are not limited to, the overall oversight of the animal care and use programme and structures, the establishment and internal audit of research ethics committees (with independent decision-making authority regarding ethical matters), the appointment of specialised staff for the care of animals, training and empowerment of all staff using animals for scientific purposes and the provision of all necessary support and infrastructure to enable compliance. Certain responsibilities of institutions are met in close collaboration with the research ethics committees and animal facility management (compare SANS 10386:2021 2nd ed., §5.2.3.5.3). Some of these responsibilities are also outlined in par. 3.3 below.

The NWU and its line managers are committed to the highest standard of animal care and assurance of welfare, including proper management, high quality animal facilities, competent staff, the implementation of sound ethical principles and integrity. In addition, the NWU management actively promotes a “culture of care” (see §2.2.2).

As per the **Policy on the Animal Care and Use Programme of the North-West University**, **Figure 4** below outlines the management structures and lines of communication within the Animal Care and Use Programme. In line with the scope of these guidelines (see par. 1.1) it is important to note that, whereas the care and use of animals for scientific purposes falls under the authority of the Deputy Vice Chancellor Research and Innovation (DVC R&I – see also par. 3.1

below), the care of feral and wild animals falls under the authority of the University Management Committee (UMC) and is accordingly **not** covered by the current guidelines and hence these are merely referred to in **Figure 4**.

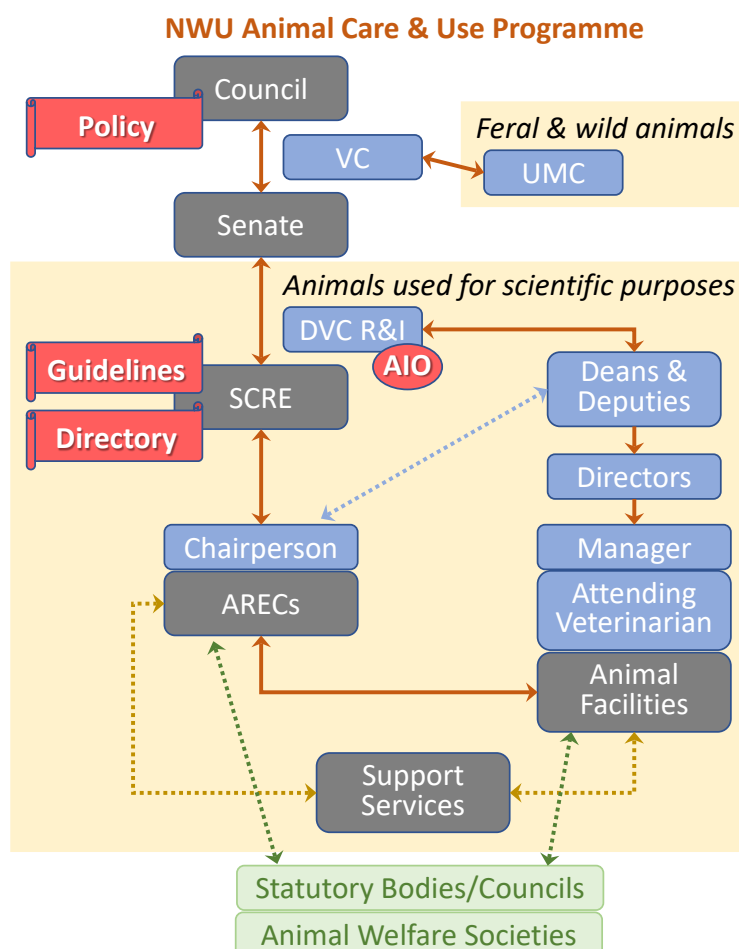


Figure 5: A Birds-eye view of the Management structures and reporting lines of the NWU Animal Care and Use programme, including external role players (*i.e. statutory bodies/councils and animal welfare societies*). UMC = University Management Committee ; VC = Vice Chancellor ; DVC R&I = Deputy VC Research and Innovation; UMC = University Management Committee; AIO = authorized Institutional Official; SCRE = Senate Committee for Research Ethics; AREC = Animal Ethics Committee (e.g. NWU-AnimCareREC & NWU-AnimProdREC) ; Statutory Bodies/Councils include the National Health Research Ethics Committee (NHREC), South African Veterinary Council (SAVC), South African Council for Natural Sciences Professions (SACNASP) etc. ; Animal Welfare Societies include the National Council of Societies for the Prevention of Cruelty to Animals (NSPCA).

The role of the lines of authority and structures in **Figure 4** as it pertains to the care and use of animals for scientific purposes are discussed in the sections below.

3.1 Authorised Institutional Official

As per the **NWU Policy on the Animal Care and Use Programme**, the Deputy Vice Chancellor for Research and Innovation is the Authorised Institutional Official (AIO) who takes final responsibility for the Animal Care and Used Programme and its management (compare also SANS 10386:2021 2nd ed., §5.2.3.5.1; NDoH 2024 3rd ed. §5.5.2e), as this relates to the use of animals for scientific purposes.

3.2 Responsibilities of the NWU

The responsibilities of institutions, overseen by the AIO (see 3.1 above), are stipulated in the SANS 10386:2021 2nd ed. and the NDoH 2024 3rd ed., specifically to safeguarding support to the Animal Facilities and ARECs to fulfil their respective duties (see SANS 10386:2021 §4 & §5). Special reference is made to the following aspects that the NWU is required to comply with:

- a) The NWU governance structures are required to understand and accept responsibilities, as well as the need to ensure compliance with standards and to establish clear lines of responsibility, communication and accountability (§4.7.4.1, §5.2.3.1, §5.2.3.3 & §5.2.3.5).
 - In this regard the NWU is required to provide the infrastructure, powers and resources required (SANS 10386:2021, §5.2.3.1.2e, §5.2.3.3b, §5.2.3.5.2, §5.2.3.1c, §5.3.3.2.5 & §5.3.3.4). This includes, but is not limited to the provision of finance, guidance, staff, facilities, expertise and veterinary care, training, etc.), in close collaboration with the animal research ethics committees (ARECs) and research animal facilities (RAFs), to ensure that compliance with the National Standard and Guidelines is possible.
 - The NWU must also empower the ARECs and recognise their authority and independence regarding ethical oversight processes, respond to recommendations of the AREC, seek advice from the AREC on matters related to the care and use of animals for scientific purposes (SANS 10386:2021, §5.4.3.5), and provide indemnity against personal liability of AREC members.
 - The NWU must also establish clear lines of responsibility, communication and accountability, ensure compliance, have procedures for handling complaints and non-compliance, manage multi-institutional national and international studies, monitor its animal care and use programme (see below) and promote public relations and transparency.
- b) The NWU must ensure that all scientific activities using animals are subjected to ethical review and approval, as well as post-approval monitoring and other ethical oversight of, for example, serious adverse events, by the AREC (SANS 10386:2021, §4.2.2 & §5.3.2). AREC members, as well as researchers, postgraduate students and international collaborators using animals for scientific purposes must also have the required animal research ethics education, training in relevant animal procedures and competency certification, as required by and specified in both the SANS 10386:2021 and the NDoH 2024, as well as by the South African Veterinary Council (SAVC) and the South African Council for Natural Scientific Professions (SACNASP, as per the Natural Professions Act of 2003).
- c) The NWU must require that all of its Research Animal Facilities (RAFs) are registered at the South African Veterinary Council (SAVC), that all RAFs (i.e., animal facilities that capture, breed, house and test animals for research purposes) have Biological Safety Level accreditation (BSL2 or BSL3 as necessary) from the Department of Agriculture, Land Reform and Rural development(DALRRD), that permits are available for capturing, housing and/or keeping any animal species for which this is required, that the necessary expertise and veterinary oversight is available, that the required standard operating procedures (SOPs) for RAFs are in place and operational, and that all activities comply with national legislation.
- d) The NWU must require that all of its laboratories that store, analyse, test or otherwise animal biological materials and derivatives (e.g. vaccines) have Biological Safety Level

accreditation (BSL2 or BSL3 as necessary) from the Department of Agriculture, Land Reform and Rural development (DALRRD).

- e) The NWU must require that each research study (or other scientific use) using live animals, animal biological materials or derivatives thereof, have unique Section 20 permits from the Department of Agriculture, Land Reform and Rural development(DALRRD).
- f) The NWU must ensure that a qualified, competent and authorised Biological Safety Officer(s) and Biological and Environmental Safety Committee is available to advise and manage activities related to biological and environmental safety of relevant animal and laboratory facilities, as well as of research studies using animals, animal biological materials and derivatives thereof and facilities (see SANS 10386:2021, clause 5.2.3.1.2f and several other relevant clauses; NDoH 2024, section 4.1.7).
- g) An annual review of the ethical oversight activities of the NWU's animal research ethics committees (ARECs) as per provisions of the SANS 10386:2021 2nd ed. (§5.3.6.6) must be conducted by a panel including at least the AIO (or delegated individual from senior management), the AREC chairperson and an external reviewer. In this regard, the National Health Research Ethics Council (NHREC) -registered ARECs may regard annual reporting to the NHREC as a process that will allow adequate external review and feedback.
- h) Quadrennial (i.e., every four years) independent external review of the animal care and use programme of the North-West University, as per provisions of the SANS 10386:2021 2nd ed. (§ 9.1), must be performed.
 - This review includes all of the NWU's activities related to the use of animals for scientific purposes, including all governance and related documentation, record keeping, the fostering of a culture of care, all studies using animals for any scientific purpose, ethical oversight by the animal research ethics committees (ARECs), the management, activities and documentation at research animal facilities (RAFs), care of animals on NWU property not for scientific purposes, etc.
 - It implies that the University have approved processes in place and makes available finances for the audits, appoints external auditors, arranges for meetings between the auditors and NWU management and other relevant NWU stakeholders, arranges for access of the auditors to all relevant documentation and processes, ARECs, RAFs, staff, researchers and any other relevant request from the auditors, to perform a proper independent external audit of the NWU's animal care and use programme.
 - The NWU must ensure that the independent external review process is educational in nature, and an opportunity for self-assessment. The NWU should consider to make the review report, or an executive summary thereof, publicly available.
- i) The Authorised Institutional Official (AIO) must arrange for an annual discussion with the chairpersons of each AREC, discussing its effective functioning and challenges to ensure compliance with the SANS 10386:2021 2nd ed. This meeting may be considered taking place during the meetings of the Senate Committee for Research Ethics (SCRE – see §3.2 below), but individual discussions may also be required if deemed necessary.

3.3 NWU oversight body (SCRE)

As per the **Policy on the Animal Care and Use Programme of the North-West University**, the Senate Committee for Research Ethics (SCRE) monitors the Animal Care and Use Programme, as this relates to the use of animals for scientific purposes (compare also SANS 10386:2021 2nd ed., §5.2.3.1.1), and to advise the Authorised Institutional Officer in this regard:

- SCRE must assist the AIO to fulfil the responsibilities of the Institution, as indicated in §3.1 above.
- SCRE must receive, discuss and approve annual reports as part of its oversight of the AREC activities. If the AREC is a National Health Research Ethics Council- (NHREC-) registered committee, the same annual report as for the NHREC may serve and the annual report to the SCRE.

3.4 Line Management

The AIO and SCRE (see §3.1 & §3.2 above) delegates certain functions along management structures and lines. As **Policy on the Animal Care and Use Programme of the North-West University**, the relevant Deans (*i.e. of Faculties where researchers use animals for research purposes*) must ensure within the Animal Care and Use Programme (compare a full list of responsibilities in the SANS 10386:2021 § 5.9.7):

- effective management structures;
- sufficient resources and funding (budget) for effective operation, including but not limited to:
 - empowerment, independence in decision-making and adequate administrative support for Animal Research Ethics Committees (ARECs) to fulfil its extensive legal obligations regarding effective ethical oversight of research, including review and approval processes, post-approval ethical oversight and other responsibilities;
 - suitable animal research facilities and maintenance thereof, including appointed managerial and professional officials, administrative support, competent staff for animal research facilities, infrastructure and equipment;
 - training and empowerment of all staff and researchers;
 - compliance with the authoritative documentation listed in §2.1, with special reference to the NDoH 2024 and SANS 10386:2021 2nd ed., or latest versions;
 - compliance any other relevant legislation, regulations, and standards.

As per own arrangements within faculties, the Deputy Deans for Research and Innovation and the respective Directors of Research Entities are responsible to assist the Executive Deans with managerial matters to enable an effective Animal Care and use Programme. In this regard, the following apply:

- The Managers of **Animal Research Facilities** are responsible to oversee the proper overall management of their respective facilities as per these regulations (see §4), and to advise the line management in this regard.
- Chairpersons of the **ARECs** are responsible to oversee the overall management and steering of their respective ARECs, who's ultimate responsibility is to oversee the ethical conduct of the care and use of animals used for scientific purposes (see §5), and to advise the line management, SCRE and the AIO in this regard.

- **Supporting services**, including the Biological Safety Officer(s)³, or individuals with necessary expertise and authority, and the Institutional Biological Safety Committee⁴ (IBSC, as per SANS 10386:2021 2nd ed. and the NDoH 2024 §4.4.2.4), Occupational Health and Safety Coordinators(s), Medical Services, Legal Office, Protection Services, Facilities Department and other relevant service departments are responsible to advise line management on any matters related to their respective scope and fields of expertise, as it relates to the Animal Care and Use Programme.
- The relevant **Statutory Councils** regulate, within their respective scopes, the standards for professionals and practices within the Animal Care and Use Programme. This may include the National Health Research Ethics Council (NHREC) of South Africa, The South African Veterinary Council (SAVC), and the South African Council for Natural Scientific Professions (SACNASP).
- The relevant **national Governmental Departments** regulate, within their respective scopes, compliance with national legislation and regulations. This may include the National Department of Health (NDoH), the Department of Research and Innovation (DRI) and the Department of Agriculture, Land Reform and Rural Development (DALRRD).
- The **Animal Welfare Societies** (via appointed/contracted participation in Animal Facilities, the AEC and ARECs) advises on animal welfare matters related to the Animal Care and Use Programme.

4 RESEARCH ANIMAL FACILITIES

Research Animal Facility (RAF) here implies all facilities where animals are housed or kept (permanent or temporary), where these animals are used for scientific purposes. This may be a single facility site, or a cluster of premises/units that are managed collectively.

When RAFs are rented from private or other owners, that facility becomes the responsibility of the NWU, so that a clear Memorandum of Agreement (MoA) and Service Level Agreement (SLA) must be in place. All requirements for RAFs as explained below would apply, except that management reporting lines may be adjusted as needed, without compromising proper NWU ethico-legal and professional veterinary/para-veterinary oversight.

When the NWU collaborates with another institution with its own RAF and NHREC-registered animal research ethics committee (AREC), a Memorandum of Agreement must be in place, providing for all matters as stipulated in the SANS 10386:2021 and NDoH 2024 (in particular Appendix A3.2 as illustrative example of considerations).

4.1 Principles

The following principles are applicable to all Research Animal Facilities:

- In all cases animal welfare and associated professional care will always take precedence over scientific interest.

³ ...or individuals with the necessary expertise and authority

⁴ ...or committee structure with the necessary expertise and authority

- Cost implications will never be a valid reason not to provide proper care, and when best care is not possible due to budgetary constraints, the animals will not be kept, housed or used.
- Prioritisation of animal welfare is not only a moral issue, but we acknowledge the well-described array of scientific evidence that healthy animals also yield more reliable research results, and hence that healthy animals lead to higher scientific quality (including enhanced repeatability of results, data reliability, translatability, trustworthiness of result and scientific integrity). To the contrary, unwell conditions of animals add confounding factors, which ultimately has a negative on scientific quality. Compare also the 12Rs Framework (§2.2.2).

More detail is available in the listed authoritative documentation in §2.1 and as explained in the content of §2.2.

4.2 Management

Management of Animal Research Facilities is responsible for the proper management of animal welfare and use, facility maintenance and personnel management, and crisis management.

4.2.1 Manager

All Animal Research Facilities will have a formally appointed manager who takes responsibility of the over management of the facility infrastructure, staff, researchers and students, compliance and safety, and SOPs (compare SANS 10386:2021 2nd ed., §5.6.4). This should be a staff member formally appointed to perform management duties and responsibilities of the facility manager, being countability, competent, and with appropriate qualifications and professional authorisation to perform these duties. Such an individual needs sufficient experience, seniority, leadership skills and delegated powers to effectively manage the RAF, and clear reporting lines must be established with the attending veterinarian and management.

4.2.2 Attending veterinarian

All Animal Research Facilities will have a formally appointed *“attending veterinarian”*, taking overall responsibility of the veterinary care of animals (compare SANS 10386:2021 2nd ed., §5.9). There may be multiple *“supervising veterinarians”* for studies, who will report to the attending veterinarian.

If the attending veterinarian is also the facility manager, proper measures shall be in place to manage any real or perceived conflict of interest between veterinary care (e.g. animal welfare) on the one side, and the interest of the facility (e.g. finances, staff, research and other activities and responsibilities).

4.2.3 Animal facility staff management

The Manager of the Animal Research Facility, with the assistance of the attending veterinarian, are responsible to ensure the following:

- Continued training and education, maintenance of registration, competence assurance and empowerment of all facility staff members, including the supervising veterinarian(s), laboratory animal technician(s) (LATs), veterinary nurse(s), animal caretaker(s), administrative and supporting staff, etc.

- Management of the wellbeing of the facility staff members, including the management of compassion fatigue.
- Management and maintenance of biological safety matters, including of all staff, researchers and students, and all prescribed safety procedures, in close collaboration and under the guidance of the biological safety officer and institutional biological safety committee (IBSC – see SANS 10386:2021 2nd §3.17 & §5.2.3.1.3, and the NDoH 2024 §4.4.2.4).
- Occupational health and safety and general personnel security, in close collaboration with indicated experts.
- Pro-active promotion of animal welfare and the management and reporting of animal welfare concerns by any personnel, or via any other means.
- Ensuring adequate resources to comply with SANS 10386:2021 2nd and NDoH 2024 3rd ed, as well as to perform duties as per professional mandate and task agreement.

4.3 Animal caretakers

Competent animal caretakers must oversee the daily care of animals (compare SANS 10386:2021 2nd ed., §5.6).

4.4 Researcher and student support, and oversight

All Animal Research Facilities must provide or ensure access control, appropriate training, supervision and support to researchers and students using animals for scientific purposes. This includes assurance of compliance with biosafety and occupational health and safety measures, and compliance with any other accreditation requirements as applicable.

After hour work by staff of students should be regulated, including that no individual may work alone in the facility at any time (*due to safety concerns and risk management*).

4.5 Minimum standards

Minimum requirements are specified in the SANS 10386:2021 2nd ed. and the NDoH 2024 3rd ed.

All Animal Research Facilities that house animals will meet the requirements where and as applicable, as indicated below.

4.5.1 Compliance

All Animal Research Facilities will implement appropriate quality assurance measures, including that they will, where and as applicable, be registered with relevant statutory bodies, or otherwise comply with legal or regulatory requirements, including:

- Registration with the South African Veterinary Council (SAVC) to provide any veterinary and/or para-veterinary care, or SAVC authorisation of researchers (including postgraduate students) to perform procedures within the scope of veterinary and/or para-veterinary professionals.

- SAVC registration of all NWU research animal facilities (RAFs), as well as Biosafety Level (BSL 2/3) clearance from the Department of Agriculture, Land Reform and Rural Development (DALRRD)⁵.
- Biosafety level (BSL) certification of any laboratory storing, analysing or otherwise using animal biological materials for any scientific purpose, including for research, testing and teaching purposes.
- Section 20 approval, or at minimum written clearance from DALRRD if not required, for any study using live animals or animal biological products.
- Legal compliance when working with genetically modified animals (Genetically Modified Organisms Act 15 of 1997) or when genetically modifying animal biological materials.
- Compliance with all minimum standards set out in the South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2021 2nd ed., or latest version, with special reference to §10 and Annexures A, P, Q and T⁶).
- Compliance with all minimum norms and standards set out in the South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd ed. (NDoH 2024).
- Ethical oversight, ethical approvals, inspection reports and recommendations of the overseeing animal research ethics committee (AREC – compare §4.2.2 & §5 below).
- Welfare oversight and inspection reports and recommendations of the National Council of Societies for the Prevention of Cruelty to Animals (NSPCA – compare §4.2.2 below).
- Rules of the NWU Institutional Biological Safety Committee (IBSC), as per SANS 10386:2021 2nd §3.17 & §5.2.3.1.3 and other relevant §and regulations.

4.5.2 Oversight and reporting

The following will apply to all Animal Research Facilities:

- Regular reporting about all animal welfare matters and the use of animals to the overseeing animal research ethics committee (AREC) prior to each meeting of the AREC (typically monthly, or as per meeting schedule). Immediate notification is required with any Serious Adverse Event (SAE) or Serious Incident (SI), followed by a SAE/SI report when resolved and upon conclusion.
- The AREC may require inspection of the premises on an ad hoc basis and/or request a meeting with the manager, attending veterinarian or other staff as per SOP, when required.
- The animal research facility will assist the overseeing AREC with any information required for the AREC's annual reporting to the NWU Senate Committee for Research Ethics (SCRE) and, if applicable, to the National Health Research Ethics Council (NHREC).
- At least annually the animal research facility will be inspected by the overseeing Animal Research Ethics Committee (AREC). The Animal research facility will comply with report findings and recommendations by the AREC.

⁵ DALRRD, previously known as the Department of Agriculture, Forestry & Fisheries (DAFF).

⁶ In addition, the governing principles for wild-life research, the use of animals on farms, or the use of animals for teaching and training are outlined in the SANS 10386:2021 2nd ed., §10 to 13. Furthermore, the care of specific species is explained in Annexures B to O.

- The animal research facility will allow inspections by the National Council of Societies for the Prevention of Cruelty to Animals (NSPCA). This may coincide with the inspection by the AREC. The Animal research facility will comply with report findings and recommendations by the NSPCA.
- If and as applicable, the animal research facility will register with the South African Veterinary Council (SAVC) and the Department of Agriculture, Land Reform and Rural Development (DALRRD) – see par. 4.5.1 above), or any other statutory body as required by legislation and regulations. In addition, if and as applicable, the animal research facility will allow inspections and comply with report findings and recommendations by such bodies.

4.5.3 Access control & biosecurity

All animal research facilities will ensure:

- that appropriate access security to the facility and its animals are in place and managed (see also par. 3.2f));
- appropriate biosafety measures are in place and maintained (compare §4.5.1 above, as well as the SANS 10386:2021 2nd ed. §3.17 & §5.2.3.1.3);
- emergency procedures, including for serious adverse events (SAEs) or serious incidents (Sis), are in place and clearly visible or otherwise accessible and available to all staff and researchers;
- a proper disaster plan, including, but not limited to worst-case scenarios and pointers, levels of concern (human, animal, facility), types of disasters, responsibilities, etc. (compare §4.5.4 and §6.2 below).

4.5.4 Policies, ToRs, SOPs and related documents

All animal research facilities must have the following in place and accessible onsite and via a secure website:

- Authoritative documentation as listed in par. 2.1 of these regulations above.
- Terms of Reference of the research animal facility, in a single document at least covering the following aspects:
 - Describing statutory and institutional requirements, management structures, accountability and lines of communication, administration, finances and other relevant matters.
- Standard Operating Procedures (SOPs) of the animal facility, in multiple documents, at least covering the following aspects:
 - Staff management, training and competence assurance.
 - Access control and biosecurity.
 - Safety, Health and Environment Department manages biological and other safety procedures via its NWU SHE S360E system.
 - Housing environment control and facility maintenance and cleaning.
 - Species-specific...

- management of physiological, behavioural and social needs, husbandry, breeding and population management, routine welfare monitoring;
- euthanasia and any end-of-study procedures (*for example reintegration into breeding programmes, or if applicable, reintegration into the natural habitat or selling of agricultural animals, etc.*);
- clinical management of animal health and disease, pain and distress, and other emergency procedures;
- transport of animals.
- Waste management (including biological).
- Reporting of problems, whistleblowing and complaints.
- Record keeping, data management and archiving.
- Sample management, including the obtaining, preparation, storage and disposal of (mostly biological) samples.
- Disaster management plan (compare §4.5.3 above and 6.2 below).
- Record keeping, as per NWU Policy on Archives, Museums and Special Collections ([link](#)) and as per NWU File Plan ([link](#)):
 - Records of facility access and maintenance, service records, apparatus/instrument calibration, and related records.
 - Records of staff management documents (CVs, job description, professional registration as applicable, proof of training & competency).
 - Records of all animal health/welfare monitoring, including routine welfare monitoring by staff, veterinary reports, welfare monitoring by researchers, and any other report related to the welfare of animals
 - Records of the animal facility inspection reports from the South African Veterinary Council (SAVC), the overseeing animal research ethics committee (AREC) and the National Council of Societies for the Prevention of Cruelty to Animals (NSPCA).
 - Records of animals produced, used, euthanised, overproduced, acquired or distributed, imported or exported, and/or transported.
 - Records of any and all adverse events, incidents, post-mortem reports, as well as related feedback from the animal research ethics committee and action plans.
 - Records of any and all animal samples collected, storage, use and distribution and waste management.
 - Records of any and all biological safety inspections, recommendations, reports and action plans.
 - Records of all ethical oversight, including the ethical approval letters of all studies conducted in the animal facility.
 - Any other records of safekeeping and management.

4.5.5 Training

Competence of all staff, researchers and students will be assured by means of appropriate registration at statutory bodies (where and as applicable), continuous training and competence confirmation, clear communication and reporting lines, pro-active and active fostering of a culture of care and attention to staff wellbeing, including matters such as potential compassion fatigue.

The animal research facility will:

- ascertain appropriate training, competence, ethical clearance and authorisation for any and all staff, researchers and students handling or using animals, before they are allowed to handle or use any animals;
- provide training to ensure that staff, researchers and students are familiar with the facility's operations and rules, as well as that competence is species-specific and as required by the study-specific animal procedures at the animal research facility;
- ensure that planned studies can indeed be performed at the animal research facility, considering appropriateness of the facility and infrastructure for the species and study, the capacity and availability of professional staff, as well as pertaining to applicable equipment and its maintenance status (validation, calibration, access records), etc. (compare SANS 10386:2021 2nd ed., including its applicable appendices);
- provide the necessary supervision by competent and authorised staff.

4.5.6 Quality assurance

Quality assurance implies compliance with the SANS 10386:2021 2nd ed., applicable ethical approval by the overseeing AREC (which should be checked and kept on record), competence of researchers and students, as well as knowledge and compliance with facility rules and procedures. When such compliance or proof thereof is not apparent, the animal facility shall deny the right of access to the facility.

When affordability and cost-benefit ratio allow (i.e., optional), the University will support the implementation of quality assurance measures, including, but not limited to:

- good laboratory practice (GLP) accreditation (*for example via the South African National Accreditation System (SANAS)*);
- other appropriate quality assurance (*for example International Organization for Standardization ISO 17025, and ISO 9001*);
- international accreditation (*for example the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)*).

5 MANAGEMENT & REGULATION OF ANIMAL RESEARCH ETHICS COMMITTEES

All NWU animal research ethics committees (**ARECs**) are registered with the NWU Senate Committee for Research Ethics and oversees all ethical aspects related to the use of animals for scientific purposes, as per their respective approved scopes. Relevant authoritative documentation is specified in par. 5.1 below.

Responsibilities (in close collaboration with their administrative support) include, but are not limited to the review, approval and post-approval monitoring of studies using animals, training of researchers and students in the ethical principles of the use of animals for scientific purposes,

ethical review and approval of studies, post-approval monitoring, as well as handling of serious adverse events (SAEs), serious incidents (SIs) and complaints.

The relevant Executive Deans (*i.e. where researchers use animals for research purposes*) must ensure sufficient resources for ARECs, including administrative support and other responsibilities as per SANS-10386:2021 2nd ed. (compare §3.1, §3.2 & §3.3 above).

A list of the applicable Terms of Reference (ToR) and Standard operating Procedures (SOPs) are listed in the “*Directory of NWU Animal Care Management Structures and Procedures*”.

5.1 Purpose & scope

The ARECs advise the AIO and SCRE (see par. 3) on all matters related to the responsible management, care and protection of feral animals. This ARECs are governed and regulated by:

- The National Department of Health’s guidelines on the Ethics in Health Research: Principles, Processes and Structures (DoH 2015 or latest version) ([link](#)) - *applicable only when registered with the National Health Research Ethics Council (NHREC)*.
- South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2021 2nd ed. or latest version) ([link](#) - via NWU intranet, search SANS 10386). Particular reference to §5.4.
- NWU Research Ethics Policy ([link](#))
- NWU Policy on the Animal Care and Use Programme ([link](#)).

All ARECs overseeing health and health-related research shall be registered with the National Health Research Ethics Council (NHREC), whereas any AREC overseeing non-health research may choose to be registered. Registration at the NHREC is strongly encouraged for all ARECs to promote the highest ethical standards, ensure rigorous audits and assist with sound benchmarking.

5.2 Composition

The composition of ARECs is determined by both the DoH 2015 (or latest version) and the SANS 10386:2021 2nd ed (or latest version), §5.3.3.2. The committee must comprise of a minimum of nine (9) members and ensure appropriate expertise, diversity, and non-affiliated membership (*i.e. entirely independent of the NWU*). In brief, membership composition has the following representation:

- Chairperson (no category)
- Veterinarian(s) (category A)
- Scientist(s) working experienced in using animals in research (category B)
- Animal welfare society representative(s) (category C), including from the NSPCA
- Layperson (category D), including at least one member entirely independent of the NWU
- A member involved in the daily care of animals (additional members, no category)

In addition, the following typically applies:

- At least 33% of membership must be from categories C & D

- Junior staff should be included in membership for the purpose of capacity building.
- Appointment of *ad hoc* members from scarce categories (e.g. category C) may facilitate quorate meetings when the full member is not available.
- Expertise, such as a human health professional (as applicable for health research), a translational scientist, an expert in quantitative methodologies, a biostatistician and a legal expert, as per NDoH 2024 3rd ed. or latest version, must be represented amongst the membership, within an appropriate category.

5.3 Functioning

Meeting and decision-making requirements are governed by the SANS 10386:2021 2nd ed. and NDoH 2024 3rd ed. (or latest versions), with special reference to SANS 10386:2021 §5.4.3.2.9 &10.

- Quorate meetings comprise of the following members present (in person or via interactive electronic link such as video conferencing):
 - the chairperson or acting chairperson
 - at least one member from each category (i.e. A, B, C & D)
 - either the simple majority of members when membership is <15 or 33% of members when membership is 15 or more
 - 33% of members present being from categories C & D
- Minutes should capture the deliberations and eventual decisions.

5.4 Required support from the University

As per SANS 10386:2021 2nd ed., §5.3.3.4, the following shall be provided by the University, via its management structures:

- adequate staffing and administrative support
- financial resources and facilities
- orientation and training of AREC members
- powers (i.e. authority enforce compliance with national legislation and regulations and to make uncoerced decisions on matters related to the use of animals for scientific purposes)
- other resources needed for fulfil its duties

5.5 Documentation

The applicable documents must be in place, including:

- Terms of Reference (ToR)
- Standard operating procedures (SOPs) as applicable, including, but not limited to those related to:
 - selection, appointment and functioning of the AEC (*including meetings, decision making & record keeping*);

- ethics applications and approval, including expedited processes
- emergencies (adverse events and incidents);
- inquiries, complaints, concerns & requests;
- whistleblowing & complaints;
- human safety, animal welfare promotion, environmental protection and risk management.

6 RESPONSIBILITIES OF INDIVIDUALS USING ANIMALS FOR SCIENTIFIC PURPOSES

The responsibilities of researchers, teacher and students using animal for scientific purposes, as well as any professional and support staff assisting with associated scientific activities, are clearly outlines in the SANS 10386:2021 2nd ed., §6.

6.1 The responsible researcher

The principal investigator (PI) or module co-ordinator (in case of education and training) or any other responsible scientist for other scientific activities, shall retain the ultimate responsibility to ensure that the study complies with National legislation, guidelines and standards. The PI shall properly manage all activities by the scientific team, from conceptualisation until conclusion, thereby to ensure the welfare of animals, compliance with what was approved by the scientific and ethical committee and the associated responsibilities of amending studies and regular or timely reporting (including monitoring and final post-approval reports, as well as any adverse events or incident reports).

The PI shall also ensure that expert and professional advice is timely sought, veterinary oversight is in place where and as applicable, that approval by an appropriate animal research ethics committee (AREC) is obtained and conditions adhered to, that all approvals, licences, permits, permissions, etc. by animal facilities, sites or other owner properties are obtained and rules adhered to.

In case of multi-institutional collaborative work, the necessary memorandum of agreement and material transfer agreement (as applicable) shall be in place and maintained.

6.2 Scientific team members

Scientific team members (research co-workers) shall embrace a culture of care towards animals and be familiar with the approved proposal and approved documentation, their own role and responsibilities, and ensure sound and timely communication with the PI on all matters that may affect the scientific activity. No scientific activity prior to approval, or outside of what has been approved, by the AREC will be undertaken.

All team members working in animal research facilities or sites, shall adhere to the rules of that facility or site, and collaborate with the applicable management.

All members shall have received appropriate animal research ethics training, to be updated every 3 years. Furthermore, all members handling animals shall be signed off as competent by the attending or supervising veterinarian and have South African Veterinary Council (SAVC) authorisation, or applicable registration with the South African Council for Natural Scientific Professions (SACNASP) for field work not involving veterinary procedures, as applicable for the scientific activity. It shall be assured that competence is maintained and, where necessary, re-

assessed, over the duration of the scientific activity. Welfare of animals shall be monitored as approved, and when an intervention is warranted, the necessary steps as approved shall be taken in close collaboration with the supervising veterinary or paraveterinary professionals.

All research notes and raw results shall remain the property of the NWU, will not leave the NWU premises and will be stored in electronic or hard copy format as per approved file storage plan.

7 PLANS FOR HANDLING OF CHALLENGES

7.1 Risk management, assessments & plans

As per SANS 10386:2021 2nd ed., §10.6, the design, management and functioning and animal facilities should:

- facilitate access control and general sound functioning;
- promote species-specific animal safety and wellbeing, housing & husbandry, environmental enrichment, acquisition and transport;
- ensure biological safety management and support appropriate environmental control and record keeping;
- enable all activities of staff, researchers and students related to the daily and health care and scientific use and procedures;

All animal facilities must do a risk analysis on a regular basis, at least every 3 years.

All animal facilities must have plans in place, and support from management, to:

- address any concerns identified during analyses;
- manage identified risk.

7.2 Disaster management

All Research Animal Facilities must have a formal disaster management plan in place (compare §4.5.3 & §4.5.4 above), covering the management of worst-case scenarios, including, but not limited to, for at least the following potential risks:

- Power failure, water shortage and failure of other life support systems
- Disease outbreak in the animal facility
- Infrastructure catastrophe, for example fire or emergency evacuation of staff and animals (aligned with the NWU Emergency Plan)
- Supplier shortages of critical supplies, for example of food or medicines
- Security or other risks that require access limitation to campuses and facilities, including riots and demonstrations or national disasters
- Any other foreseeable risk

7.3 Biological safety

The Biological Safety Officer(s), or individuals with necessary expertise and authority, and the Institutional Biological Safety Committee (IBSC, as per SANS 10386:2021 2nd ed. and the NDoH 2024 §4.4.2.4) must oversee biological safety associated with research activities.

The following are key points from the national standards:

- The IBSC reviews and approves any proposed use of biohazardous agents, nano-materials, human material, and recombinant deoxyribonucleic acid (DNA) molecules (compare SANS 10386:2021 2nd ed., §3.17), thereby to ensure compliance with applicable regulatory guideline and the safety of researchers, animals and the environment.
- In this regard, if and as necessary, the researcher, educator or other person intending to use animals for scientific purposes shall consult with the Biological Safety Officer already during the planning phase.
- For review and approval of any proposal prior to ethical review, the researcher, educator or other person intending to use animals for scientific purposes, shall make available to the IBSC and biological safety officer, as per SOPs of the IBSC, the study proposal (as approved by the scientific committee), study guide and/or any other proposal document and supporting documentation, or any other information as requested.
- During the execution of any study or other use of animals, the researcher, teacher, student, facility staff and/or team shall apply the necessary approved biosafety measures. When and if the IBSC or biological safety officer request information or inspections to ensure legal compliance and safety, and the applicable researcher, teacher, student, facility staff or team shall comply with any such requests and all recommendations in a timely manner.
- The biosafety officer or IBSC shall approve the onsite disposal and storage of animal carcasses and waste material (compare §4.5.3 above, as well as SANS 10386:2021 2nd ed., §5.2.3.1.3f).
- The IBSC shall keep records of proposals, reviews, rebuttals, supporting documentation and approvals for a minimum of 5 years (compare SANS 10386:2021 2nd ed., §5.2.3.1.3j). These records shall be kept, as per NWU Policy on Archives, Museums and Special Collections ([link](#)) and as per NWU File Plan ([link](#)).
- Any failure to comply with recommendations of the biosafety officer or IBSC, or with conditions of approval, will be viewed as non-compliance or misconduct (whichever is appropriate), and may lead to prescribed remedial or disciplinary steps, and/or immediate withdrawal of the approval of a study.

7.4 Pest Control

All Animal Research Facilities must have SOPs for pest control in place. These SOPs must indicate how these procedures and measures will:

- ensure effective control with no suffering of the animals considered as pests;
- protect humans, non-targeted animals and the environment against any harmful consequences of the pest control measures.

7.5 Occupational health and safety

Occupational Health and Safety at South African workplaces (excluding the mining industry) is mandated by the Occupational Health and Safety Act (Act 85 of 1993) and its Regulations. The cornerstone of the NWU's approach to health and safety is its Health and Safety Policy and Occupational Health and Safety Management System. The policy shows the NWU's commitment to comply with all legislation pertaining to health and safety, while the management system provides the specific procedures. The NWU Occupational Health and

Safety Management System, as also applicable to the Animal Care and Use Programme, consists of the following nine elements:

1. Legislation and Policy
2. Organisational Structure and Reporting
3. Responsibilities and Appointments
4. Meeting Structures
5. Training
6. Risk Management
7. Emergency Management, including emergency evacuation control
8. Incident Management, and
9. Operational Control (*which include, among others, the physical infrastructure-related matters such as electricity, illumination, ventilation, fume cabinets and biological safety cabinets, and use of hazardous chemicals, pressure equipment, storage of flammable substances and protective equipment*).

7.6 Research & professional integrity

All Animal Research Facilities and ARECs must have standard operating procedures (SOPs) in place for at least the following:

- Whistleblowing and complaints
- Violation of good research practice & research misconduct, including when to refer to the NWU Research Integrity Office or applicable disciplinary processes not handled by the Animal Research Facility or AREC.
- Reporting and immediate management of any neglect of the sound care of animals, including daily animal care, professional/veterinary care and/or care by any users of animals for scientific purposes

8 QUALITY ASSURANCE OF THE PROGRAMME

Quality assurance measures should be implemented for all Animal Research Facilities and Animal Research Ethics Committees (ARECs), as specified below.

8.1 Internal assessments

Regular internal assessments should at least include the following:

- Annual inspections of all respective Animal Research Facilities by the overseeing AREC, as per SANS 10386:2021 2nd ed., §5.4.3.3.
- Any other required statutory inspection or inspection by an accreditation body where and as applicable.
- Annual report of the Animal Ethics Committee (AEC) to the Deputy Vice Chancellor (as Authorised Institutional Official) and the Senate Committee for Research Ethics (SCRE).

- Internal self-assessments of the AEC and ARECs every 4-5 years (*synchronised in-between external audits*), which may include an exploratory and advisory visit by another committee.

8.2 External assessments

Regular external assessments should at least include the following:

- Annual inspections of all respective Animal Research Facilities by the Animal facility the National Council of Societies for the Prevention of Cruelty to Animals (NSPCA).
- Scheduled inspections of all SAVC-registered Animal Research Facilities by the South African Veterinary Council (SAVC).
- Scheduled audits of all NHREC-registered Animal Research Ethics Committees (ARECs) by the National Health Research Ethics Council (NHREC).
- Annual review of all Animal Research Ethics Committees (ARECs) and independent external every four years by an appointed external panel (compare §3.2d&e).
- Scheduled other external audits and/or inspections as required by accreditation, authorisation or registration of an Animal Research Facility of AREC.

8.3 Continuous empowerment

Continues empowerment of staff, researchers and students working with animals, should include:

- Continuous education in animal research ethics;
- Continuous training and competence assurance in animal care, handling and procedures;
- Attendance of training and networking opportunities by Animal Research Facility staff and Animal Research Ethics Committees (ARECs) members, such as congresses, seminars, workshops and training courses, as required.
- Bench-marking visits by Animal Research Facility staff and Animal Research Ethics Committees (ARECs) members as required.

9 REFERENCE DOCUMENTS

- Regulatory documents as listed in §2.1 above.

10 ABOUT THE ACUP DIRECTORY

The Animal Care and Use Programme (ACUP) Directory of structures, facilities and documents within the NWU Animal Care and Use Programme is a loose-standing working document, as addendum to this Guidelines document. It describes the status of structures, facilities and documents within the NWU Animal Care and Use Programme, assisting the AIO and SCRE to monitor gaps and progress to them, as to comply with the guidelines.