Policy – Applications for Scientific Purposes-Related Authorisation

A. Background

The Veterinary and Para-Veterinary Professions Act, Act 19 of 1982, provides for the authorisation of unregistered persons to render the procedures, functions or services pertaining to the profession of a veterinarian or para-veterinary professional, subject to such conditions as the South African Veterinary Council [SAVC] may determine from time to time and in each individual case.

Authorisation granted in terms of section 23[1][c] of Act 19 of 1982 may be granted on application, where a need for such authorisation is appropriately motivated, and in addition, the competence of the person for whom the application is made, including qualifications, expertise, knowledge and skills, including practical competence in procedures, has been formally confirmed.

Requests have been received from the research community in South Africa for the streamlining of applications for authorisation of persons involved in the care and use of animals for scientific purposes, in order to ensure that persons who perform veterinary or para-veterinary procedures, functions or services for scientific purposes may do so legally. The SAVC supports a faster, administratively simpler and more cost-effective authorisation process for such persons.

The SAVC has additionally created the voluntary option for Institutions to be formally recognised as SAVC-Accredited Animal Research Institutions, which recognises and rewards confirmed good practice standards. [Note: This is distinct from the registration of Research Animal Facilities with the SAVC]. Benefits of formal Institutional Accreditation by the SAVC include significantly more frequent and faster review and approval processes for authorisation applications; simplified and administratively lighter application requirements for multiple persons in batch form; the option for select senior researchers to play a formal role in the oversight of authorised persons to ensure maintained competence; and a significantly reduced requirement for annual submission of status reports to the SAVC by institutions to confirm that authorised persons remain competent.

The process and conditions for the future authorisation of persons involved in the care and use of animals for scientific purposes, are defined and described as follows:

B. Definitions
1. **Authorisation**: A special dispensation granted by the SAVC in terms of section 23[1][c] of Act 19 of 1982, to legitimise all relevant functions, procedures and services that are not performed by registered veterinarians or registered veterinary para-professionals. In all cases, authorisation for veterinary or para-veterinary procedures, services or functions, will be based on confirmed competency by a SAVC-registered veterinarian, sound knowledge, experience and training.

2. **Confirmation of competence**: Confirmation of practical competence in procedures and functions, should be based on direct observation of procedural skill, according to current best practice standards. Appropriate records should be maintained, to establish a clear audit trail of competency assessments that have been performed and the objectivity of assessments.

3. **Authorisation applications**: Applications for section 23[1][c] authorisation of unregistered persons, as submitted by institutions, organisations or research animal facilities to the SAVC’s Registration & Authorisation (R&A) committee for evaluation:
   
i. **In cases where animals are used for scientific purposes by SAVC-Accredited Animal Research Institutions** (see definition below), the quality-assurance provided by the institutional accreditation process, allows for a streamlined, administratively efficient and rapid processing of authorisation applications, including the potential for the electronic review of applications in batches (i.e. for groups of persons), where most applications may also be processed electronically between scheduled full R&A committee meetings. For such SAVC-Accredited Animal Research Institutions, applications will be processed eight (8) times per year (electronic and at full R&A committee meetings – for Categories A, B and E) with turnaround times of twenty (20) working days from the submission deadline date; or four (4) times per year (at full R&A committee meetings – for Categories C, D and F) with turnaround times of forty (40) working days from the submission deadline date. SAVC-Accredited Animal Research Institutions enjoy additional benefit in that submission of satisfactory status reports to the SAVC, which confirm the sustained competence of all authorised persons in authorised procedures, is only required once per year in batch form.
   
   ii. **In cases where animals are used for scientific purposes but not by SAVC-Accredited Animal Research Institutions**, authorisation applications must be submitted per person (i.e. individually per scientist / student / employee); have to be administratively significantly more comprehensive, in order to demonstrate how appropriate standards will
be maintained outside of an SAVC-accredited environment (i.e. by addressing all of the requirements as for definition 4, below, with appropriate supporting evidence for each applicant); and requiring detailed review of individual applications (i.e. not in batches) in full R&A committee meetings, thus impacting unavoidably on turnaround times. These applications will take at least three months to process, but potentially significantly longer depending on the comprehensiveness of the application submitted. Institutions that are not Accredited by the SAVC have to submit satisfactory status reports to the SAVC, which confirm the sustained competence of all authorised persons in authorised procedures, twice per year on an individual basis, i.e. a separate report for each authorised person.

4. **SAVC-Accredited Animal Research Institution:** An institution, organisation or entity that meets all of the following criteria:

   i. Formal accreditation may be awarded to an institution, organisation or entity by the SAVC following a successful Institutional Accreditation application;

   ii. Research animal facilities (or other relevant veterinary facilities) that comply with the minimum standards for research animal facilities (or other veterinary facilities) as defined by the SAVC in the Rules for the practising of veterinary professions; registered with the SAVC as research animal facilities (or other veterinary facilities); and for which only a registered veterinarian as the principal of the facilities takes responsibility for minimum standards.

   iii. For SAVC-registered research animal facilities, a positive inspection report by a registered veterinarian or veterinary para-professional (SAVC-appointed Inspector), confirming acceptable compliance with the relevant minimum standards for research animal facilities and with the relevant legislation and national standards for the care and use of animals for scientific purposes;

   iv. A registered veterinarian in its employment or have contracted a registered veterinarian to assess and supervise the work of the SAVC-authorised persons [as well as of the registered veterinary para-professionals].

   v. For registered research animal facilities, a registered veterinarian must take responsibility for the health and welfare of the animals at the facility on at least a weekly basis;

   vi. Sufficient presence of registered veterinary and registered para-veterinary professionals, to supervise the work of all authorised persons adequately, in their role as the SAVC-appointed supervisors in the SAVC-defined conditions of authorisation, with consideration
that registered professionals may only supervise procedures and functions that fall within the SAVC-defined Scope of Practice of the registered professional;

vii. Scheduled medicine prescription and control by a registered veterinarian;

viii. Minimum training in animal ethics, the care and use of animals for scientific purposes, and animal welfare for SAVC-authorised persons as recommended by SANS 10386 (South African National Standard for the Care and Use of Animals for Scientific Purposes, SANS 10386: 1st ed. 2008 or latest version);

ix. A registered veterinary professional performs the formal assessment and confirmation of competence in veterinary and para-veterinary procedures, functions and services, for the purpose of applying for Section 23[1][c] authorisation;

x. A Standard Operating Procedure (SOP) – evaluated and approved by the SAVC – for the monitoring of animal health and welfare in the institution, including all relevant activities of authorised persons, as well as of registered veterinary and para-veterinary professionals. The SOP must be approved by the registered veterinarian who acts as the principal of the registered facilities and takes responsibility for minimum standards;

xi. A Standard Operating Procedure (SOP) – evaluated and approved by the SAVC – for the system of oversight used to ensure the maintained competence of authorised persons in veterinary and para-veterinary procedures, functions or services, so that good veterinary practice standards are maintained, and the minimum fear, pain, suffering, distress or lasting harm is caused to animals. The system should include consideration of the level of supervision (i.e. direct and continuous; indirect; or by direction) until initial competence is attained and then deepened and maintained; and increased levels of supervision following prolonged periods of not performing a procedure. Depending on the scope and scale of authorisation, the SOP may include the oversight of the competence of authorised persons by a combination of (1) the SAVC-appointed supervisors; (2) experienced and confirmed-competent persons who are specified by and report to the SAVC-appointed supervisors; and (3) independent competent auditors who are registered with the SAVC. The level of supervision, frequency of competence assessments, independence of oversight and record-keeping are critical elements [Refer supervision agreement]. The SOP must be approved by the relevant SAVC-appointed supervisor(s), as well as by the registered veterinarian who acts as the principal of the registered facilities and takes responsibility for minimum standards;

xii. A system to formally reconfirm the competence of authorised persons in authorised procedures, services and functions, by the SAVC-appointed supervisor(s), at least every
five [5] years (for Categories A, B & E), at least every three [3] years (for Categories C and F); and at frequencies specified by the SAVC depending on the severity of the specific procedure but at least every five [5] years (for Category D);

xiii. An Animal Ethics Committee (AEC) that is registered with the National Health Research Ethics Council (NHREC) approves all protocols, projects, studies, animal care and use procedures, as well as SOPs for animal care and use; the AEC has effective oversight of the entire animal care and use programme in the institution; the composition and operation of the AEC complies with The South African National Standard for the Care and Use of Animals for Scientific Purposes (SANS 10386: 1st ed. 2008 or latest version) and Ethics in Health Research: Principles, Processes and Structures (National Department of Health; 2nd ed. 2015 or latest version); there is representation on the AEC of independent Animal Welfare Organisations as required by SANS 10386, who are knowledgeable on animal welfare, care and use for scientific purposes of applicable animal species; as well as a registered veterinarian who attends all AEC meetings and is knowledgeable on the health, welfare, care and clinical procedures of all applicable animal species. While it is recognised that not all AECs may be legally obligated to register with the NHREC, this statutory body represents the only formal South African quality-assurance system for the operation of AECs. Since voluntary registration with the NHREC is possible for AECs that meet the registration requirements, any AEC may use this mechanism to demonstrate that the required quality standards are being met, since the requirements for best practice, ethical standards and principles are independent of which species are used or the exact nature of the scientific animal use;

xiv. The governance and management of the AEC adheres to good governance principles, including independence of reporting lines; appropriate management of potential conflicts of interest; confidentiality; adherence to its terms of reference; appropriate authority within the institution to ensure assured adherence to AEC policies and decisions; and adequate resourcing to enable the AEC to fulfil its mandate as per the SANS 10386;

xv. Appropriate oversight of animal welfare, including inspections of all animal care and use facilities and areas by independent Animal Welfare Organisations, conducted at regular intervals as recommended by SANS 10386 (but at least once per year), with identified deficiencies addressed adequately and timeously; as well as at least once daily welfare monitoring of animals by SAVC-registered or SAVC-authorised persons, with increased monitoring frequencies as required by AECs depending on expected or known severity;
xvi. AEC performs regular onsite inspection of the execution of protocols and procedures, i.e. active post-approval monitoring (PAM), in order to ensure compliance with the approved AEC protocol and related conditions, including personnel competence and animal welfare;

xvii. AEC inspects all animal care and use areas as recommended by SANS 10386 (but at least annually);

xviii. For distant study sites, in terms of the above-mentioned (xv - xvii) oversight requirements, where it may be difficult to meet requirements, other mechanisms of AEC oversight should be in place, e.g. regular self-evaluation reports from investigators; audio-visual recordings of animal care and procedures; inspection of higher-risk studies by independent auditors; etc., depending on the level of known, expected or potential harms to the animals;

xix. The competence of authorised persons in authorised procedures, functions and services, may be assessed by SAVC-appointed independent auditors, as determined by the SAVC;

xx. A system to ensure compliance with all relevant legislation (as amended), regulations made thereunder, and national standards, including:

- Animal Diseases Act [Act No 35 of 1982]
- Animal Health Act [Act No 7 of 2002]
- Animal Identification Act [Act No 6 of 2002]
- Animal Improvement Act [Act No 62 of 1998]
- Animal Matters Amendment Act [Act No 42 of 1993]
- Animals Protection Act [Act No 71 of 1962]
- Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act [Act No 36 of 1947]
- Genetically Modified Organisms Act [Act No 15 of 1997]
- Hazardous Substances Act [Act No 15 of 1973]
- Meat Safety Act [Act No 40 of 2000]
- Medicines and Related Substances Control Act [Act No 101 of 1965]
- National Environmental Management: Biodiversity Act [Act No 10 of 2004]
- National Health Act [Act No 61 of 2003]
- Occupational Health and Safety Act [Act No 85 of 1993]
- Performing Animals Protection Act [Act No 24 of 1935]
- Societies for the Prevention of Cruelty to Animals Act [Act No 169 of 1993]
- Veterinary and Para-Veterinary Professions Act [Act No 19 of 1982]
- Any other relevant legislation, Nature Conservation ordinances and bylaws
SANS 10386 (The South African National Standard for the Care and Use of Animals for Scientific Purposes, SANS 10386: 1st ed. 2008 or latest version)

5. **Authorisation fees**: Reduced authorisation fees (initial and maintenance fees) will apply to persons who are authorised for Categories A to E procedures; full authorisation fees (initial and maintenance fees) will apply to persons who are authorised for Category F functions.

6. **Institutional Accreditation application**: An application made to the SAVC for the accreditation of an institution, organisation or entity as an SAVC-Accredited Animal Research Institution. Once accreditation is granted, (re-)application for renewal of accreditation only needs to be applied for every three years.

7. **Categories**: Describes the groupings of veterinary and para-veterinary procedures, functions or services, for which authorisation for scientific purposes may be applied for, as follows:
   i. **Category A**: Minor, minimally invasive, or killing procedures, that do not involve sedation, analgesia or general anaesthesia;
   ii. **Category B**: Minor or minimally invasive procedures involving sedation, analgesia or brief (< 15 minutes duration) general anaesthesia, with no residual pain on recovery; or surgical procedures conducted under brief non-recovery general anaesthesia;
   iii. **Category C**: Surgical procedures involving general anaesthesia; the administration and maintenance of balanced or more prolonged (≥ 15 minutes duration) general anaesthesia; or use of neuromuscular blocking agents;
   iv. **Category D**: Other procedures or techniques that do not fall into any of the other Categories [Note: This Category should only be used in exceptional cases];
   v. **Category E**: Health practitioners registered with the Health Professions Council of South Africa (HPCSA) who perform Category A to C procedures, in cases where the procedures on humans are included in the health practitioner’s Scope of Practice;
   vi. **Category F**: Persons who perform, on a professional or employment level, *inter alia* some of the services, functions or procedures of veterinarians, laboratory animal technologists or other para-veterinary professionals.

8. **Employee**: A person who is employed (whether in permanent employment, on contract, or on *ad hoc* basis), to *inter alia* render services, functions or procedures that include veterinary
or para-veterinary services, procedures or functions. Authorisation is considered for duration of employment, limited to animal care and use for scientific purposes.

9. **Inspector**: A trained, SAVC-registered veterinarian or veterinary para-professional who is up to date with all relevant legislation and standards, including legislation pertaining to animal welfare and the requirements for Accredited Animal Research Institutions; appointed by the SAVC.

10. **Long-term scientist**: A qualified scientist who is involved in animal use for scientific purposes for a period longer than three years, and whose involvement includes performing veterinary or para-veterinary services, functions or procedures. Authorisation is considered for the duration of projects or teaching activities, whether on contract or in employment of the SAVC-Accredited Animal Research Institution, with authorisation being limited to animal care and use for scientific purposes.

11. **Post-graduate student**: A student enrolled for a post-graduate qualification for which the completion of a scientific project or study is a requirement, and whose involvement includes performing veterinary or para-veterinary procedures or functions. Authorisation is considered for the duration of the scientific project, limited to animal care and use for scientific purposes.

12. **Registered veterinary or para-veterinary professional**: A person who is registered with the SAVC in terms of the Veterinary and Para-Veterinary Professions Act (No 19 of 1982).

13. **Scientific purposes**: Pertains to all live non-human animals (including their fertilised eggs, fetuses and embryos), incorporating domesticated, purpose-bred, agricultural or farm animals as well as wildlife, that are used for research, testing, education or validation; including activities performed for any of the following purposes: the advancement of knowledge; to test a hypothesis; to supply a product or produce a biological substance; to provide organs, tissues, cells, gametes, blood or serum; to act as a host; to impart or demonstrate existing knowledge; to test or collect data on any substance or product, including to comply with statutory requirements; clinical trials; safety or efficacy testing of vaccines, medicines, medical devices or other substances; to validate facts or existing knowledge; to learn surgical or other procedures or techniques on animals; to observe or study animals; to make audio and/or visual recordings of any of the above; including creative work, expansion on previous work,
procedures or experiments as part of research, past, current or future projects and maintenance of projects.

14. **Supervision agreement**: Signing of a supervision agreement between the SAVC-appointed supervisor (registered veterinary or para-veterinary professional), the authorised person, and the responsible head of the institution (i.e. employer), at the time of the submission of the authorisation application, confirming that all parties will adhere to the SAVC-defined conditions of the authorisation, should it be granted. The agreement includes the requirement for regular submission of satisfactory status reports [including any changes to the conditions of authorisation and the end of projects] to the SAVC for all authorised persons, confirming their sustained competence, and the conditions of authorisation will specify the intervals at which the reports would have to be submitted as well as the detail required in such reports. SAVC-Accredited Animal Research Institutions have to submit status reports to the SAVC once per year in batch form; while Institutions that are not SAVC-Accredited have to submit reports twice per year on an individual basis, i.e. a separate report for each authorised person.

C. **Authorisation Application – Required Information Per Category (for SAVC-Accredited Animal Research Institutions)**

Note: In cases where authorisation applications are submitted for institutions that are not SAVC-Accredited Animal Research Institutions, authorisation applications have to be administratively much more comprehensive, i.e. in addition to the information required below, such applications additionally need to demonstrate how appropriate standards will be maintained, outside of an SAVC-accredited environment, i.e. by addressing all of the requirements as for definition 4, above, with appropriate supporting evidence for each applicant.

1. **Category A**
   i. Applications processed eight (8) times per year (electronic and scheduled meetings).
   ii. Twenty (20) working days for approval from submission deadline to response.
   iii. Confirmation of status of person (scientist/employee/student).
   iv. Positive identification and payment of authorisation fee.
   v. Confirmation by registered veterinarian of the list of procedures for which the applicant is confirmed competent, per animal species.
   vi. Supervision by registered veterinary / para-veterinary professional within their Scope of Practice.
vii. **Curriculum vitae** (qualifications, education and training in animal science / animal ethics, animal experience).

viii. Description of level and frequency of supervision as required to ensure authorised persons remain competent to perform procedures to cause the minimum fear, pain, suffering, distress or lasting harm, with supervision as needed until such competence is attained and maintained (if not already adequately covered by the relevant SOP that is submitted as part of the Institutional Accreditation application).

ix. Signed SAVC supervision agreement.

2. **Category B**

   i. Applications processed eight (8) times per year (electronic and scheduled meetings).

   ii. Twenty (20) working days for approval from submission deadline to response.

   iii. Confirmation of status of person (scientist/employee/student).

   iv. Positive identification and payment of authorisation fee.

   v. Confirmation by registered veterinarian of the list of procedures for which the applicant is confirmed competent, per animal species.

   vi. Supervision by registered veterinary / para-veterinary professional within their Scope of Practice.

   vii. **Curriculum vitae** (qualifications, education and training in animal science / animal ethics, animal experience).

   viii. Description of level and frequency of supervision as required to ensure authorised persons remain competent to perform procedures to cause the minimum fear, pain, suffering, distress or lasting harm, with supervision as needed until such competence is attained and maintained (if not already adequately covered by the relevant SOP that is submitted as part of the Institutional Accreditation application).

ix. Signed SAVC supervision agreement.

3. **Category C**

   i. Applications processed four (4) times per year (at scheduled meeting dates).

   ii. Forty (40) working days for approval from submission deadline to response.

   iii. Confirmation by registered veterinarian of the list of procedures for which the applicant is confirmed competent, per animal species, with detailed veterinary description of procedures.

   iv. Confirmation of status of person (scientist/employee/student).

   v. Positive identification and payment of authorisation fee.

   vi. **Curriculum vitae** (qualifications, education and training in animal science / animal ethics, animal experience).

   vii. Supervision by registered veterinary professional only.

   viii. Description of level and frequency of supervision as required to ensure authorised persons remain competent to perform procedures to cause the minimum fear, pain, suffering, distress or lasting harm, with supervision as needed until such competence is attained and maintained (if not already adequately covered by the relevant SOP that is submitted as part of the Institutional Accreditation application).
ix. Signed SAVC supervision agreement.

4. **Category D**
   
i. Applications processed four (4) times per year (at scheduled meeting dates).
   
ii. Forty (40) working days for approval from submission deadline to response.
   
iii. Confirmation by registered veterinarian of the list of procedures for which the applicant is confirmed competent, per animal species, with detailed veterinary description of procedures.
   
iv. Confirmation of status of person (scientist/employee/student).
   
v. Positive identification and payment of authorisation fee.
   
   
vn. Supervision by registered veterinary / para-veterinary professional within their Scope of Practice.
   
iv. Description of level and frequency of supervision as required to ensure authorised persons remain competent to perform procedures to cause the minimum fear, pain, suffering, distress or lasting harm, with supervision as needed until such competence is attained and maintained (if not already adequately covered by the relevant SOP that is submitted as part of the Institutional Accreditation application).
   
ix. Signed SAVC supervision agreement.

5. **Category E**
   
i. Applications processed eight (8) times per year (electronic and scheduled meetings).
   
ii. Twenty (20) working days for approval from submission deadline to response.
   
iii. Confirmation by registered veterinarian of the list of procedures for which the applicant is confirmed competent, per animal species; with detailed veterinary description of procedures (for Category C procedures).
   
iv. Confirmation of status of person (scientist/employee/student).
   
v. Positive identification and payment of authorisation fee.
   
   
vn. Supervision by registered veterinary / para-veterinary professional within their Scope of Practice.
   
iv. Note: For Category E, competence assessment and confirmation, as well as veterinary supervision, relates only to **veterinary aspects**, including veterinary-related or species-specific anatomy, physiology, biology, ethology, husbandry, handling, restraint, clinical examination, health and welfare monitoring, pharmacology, peri-surgical management, anaesthesia-related complications, maintenance of good veterinary practice, etc.
   
ix. Description of level and frequency of supervision as required to ensure authorised persons remain competent to perform procedures to cause the minimum fear, pain, suffering, distress or lasting harm, with supervision as needed until such competence is attained and maintained (if not already adequately covered by the relevant SOP that is submitted as part of the Institutional Accreditation application).
x. Signed SAVC supervision agreement.

6. **Category F**
   
i. Applications processed four (4) times per year (at scheduled meeting dates).
   
ii. Forty (40) working days for approval from submission deadline to response.
   
iii. Confirmation by registered veterinarian of the list of procedures, functions and services for which the applicant is confirmed competent, per animal species.
   
iv. Motivation for employment or professional service and proof why a registered veterinary or para-veterinary professional could not be employed, including advertisement and list of applicants for position with qualifications and SAVC registration status.
   
v. Positive identification and payment of authorisation fee.
   
vi. Curriculum vitae (qualifications, education and training in animal science / animal ethics, animal experience).
   
vii. Supervision by registered veterinary / para-veterinary professional within their Scope of Practice.
   
viii. Description of level and frequency of supervision as required to ensure authorised persons remain competent to perform procedures to cause the minimum fear, pain, suffering, distress or lasting harm, with supervision as needed until such competence is attained and maintained (if not already adequately covered by the relevant SOP that is submitted as part of the Institutional Accreditation application).
   
ix. Signed SAVC supervision agreement.
   
x. May be required by the SAVC to complete training and examination for registration with the SAVC; or other specified education or training for purposes of authorisation.

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AUTH.RESEARCH