

VETERINARY/PARA-VETERINARY VS NON-VETERINARY PROCEDURES

Preamble

The following table lists those procedures that require registration or authorisation with the South African Veterinary Council (SAVC). The intention of the guideline is to in the main control biomedical research and veterinary procedures restricted according to the veterinary act. The guideline seeks to clarify in which cases authorisation with SAVC is required. This will be in line with the specific procedure and competencies in line with the Veterinary and Para-Veterinary Professions Act 19 of 1982 and Medicines and Related Substances Act 101 of 1965

Definitions:

“Animal” means any vertebrate other than man

“Scientific purposes” means using an experimental animal for any scientific reason, including for research, testing, teaching, validation, production or observation, test a hypothesis or demonstrate existing knowledge; and includes all aspects of housing, care and monitoring of animals.

“ Biomedical purposes: Biomedical research examines the effects of drugs, vaccines, medical devices, test compounds, stimuli, diseases and medical techniques on the biological systems of living creatures, including animals. Biomedical research can include wild species when their use is intended for biomedical purposes;

Basic biomedical research, which addresses mechanisms that underlie the formation and function of living organisms, ranging from the study of single molecules to complex integrated functions of humans, contributes profoundly to our knowledge of how disease, trauma, or genetic defects alter normal physiological and behavioural processes. Recent advances in molecular biology techniques and characterization of the human genome, as well as the genomes of an increasing number of model organisms, have provided basic biomedical researchers with the tools to elucidate molecular-, cellular-, and systems-level processes at an unprecedented depth and rate.

Thus, basic biomedical research affects clinical research and vice versa. Biomedical researchers supply many of the new ideas that can be translated into potential therapies and subsequently tested in clinical studies, while clinical researchers may suggest novel mechanisms of disease that can then be tested in basic studies using animal models.

General footnotes to all tables:

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- 2. In all cases, mention of a registered facility does not imply that all procedures necessarily need to be done in the facility (e.g., field work is performed in the field); but the SAVC-authorized/registered person must be associated with a SAVC-registered facility.*

Table 1. Ecological, conservation, behavioural work and nutritional research		
Category	Examples (others may be applicable)	Authorisation / Registration required from the SAVC
Monitoring of animals in their natural habitat (Excluding Biomedical Scientific Purposes)	<ul style="list-style-type: none"> a) Pure observation studies evaluating animals in the field for behaviour, and observational research in other zoological studies b) Observation of breeding and other related parameters c) Census and related activities d) Metabolic (excluding Biomedical Scientific Purposes) and respirometer related studies e) Mechanical capture and/or restraint of animals f) Tagging of animals (excluding invasive/surgical tagging) g) Non-invasive collection of genetic material, i.e. <ul style="list-style-type: none"> 1. Hair; 2. Faeces; and 3. Dart Biopsy 	Not Required**
Stress research (Excluding Biomedical Scientific Purposes)	<ul style="list-style-type: none"> a) Tagging of animals (excluding invasive/surgical tagging) b) Collection of faecal samples c) Experiments grouping of animals (excluding all biomedical research) t to study behaviour d) Modifications in the animals' natural habitat including the introduction of external stimulus (e.g., predator noises) e) Thermal studies (for the surgical implant of loggers see Biomedical Scientific Purposes) f) Simple maze testing 	Not Required** (See table 2 when medication is being administered)

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Table 1. Ecological, conservation, behavioural work and nutritional research		
Category	Examples (others may be applicable)	Authorisation / Registration required from the SAVC
	g) Simple memory/recognition testing	
Reproductive research (Excluding Biomedical Scientific Purposes)	a) Observational studies b) Tagging and monitoring (excluding invasive/surgical tagging) c) Evaluation of changes in reproductive behaviour with only post-mortal sampling	Not Required (See table 2 when medication is being administered)
Nutritional studies (Excluding Biomedical Scientific Purposes)	a) Administration of registered/unregistered nutrients or food/feed supplements in the food/feed that would be defined as farm foods or zootechnical remedies in terms of the Act 36 of 1947 when registered (and not scheduled in terms of Act 101/1965) b) Tagging of animals (excluding invasive/surgical tagging) c) Growth curve monitoring with change in fed diets (for tubing/gavage see Biomedical Scientific Purposes) d) Rumen sampling including by tubing or from already implanted fistulas (for the implantation of fistula, see Biomedical Scientific Purposes) e) Evaluation of faecal or rumen samples (not for the purposes of diagnosis)	Not required
The surgical implantation of any device will be considered a veterinary procedure	a) Surgical implantation of any device (excluding devices administered by simple needle application such as Passive Integrated Transponders (PIT) tags which are considered non-invasive tagging and thus do not require authorisation)	Person and Facility
Non-chemical termination of animals^{\$}	b) Non-chemical termination of animals	Person and Facility
**Since some studies may induce significant stress and can impact on animal welfare, these studies should have veterinary oversight as per SANS 10386 (2021) and this aspect should be included in the ethics application and falls under the control of the Animal Ethics Committee.		

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Table 1. Ecological, conservation, behavioural work and nutritional research		
Category	Examples <u>(others may be applicable)</u>	Authorisation / Registration required from the SAVC
<p>§ For non-chemical euthanasia, The South African Council for Natural Scientific Professions SACNASP and the SAVC will be required to collaboratively set working guidelines and standards for competence-based training in procedures, which will apply to the veterinary profession as well – for research in predators, termination of the prey species should be according to a species-specific protocol according to best practice guidelines.</p> <p>If a veterinary procedure is required, a SAVC registered veterinarian or para-veterinary professional from a registered veterinary facility may assist in a research project, without the facility being SAVC-registered, on condition that the facilitated procedure does not convert to common or routine practice.</p>		

Table 2. Administration of Medication		
Category	Examples <u>(others may be applicable)</u>	Authorisation / Registration required from the SAVC
Anaesthesia and Tranquilisation	<ul style="list-style-type: none"> a) To allow animal handling and restraint b) To allow tagging of animals c) To allow the fitting of tracking devices d) To perform a surgical procedure e) To perform the implantation of monitoring devices f) To allow for the collection of genetic material 	Person and Facility [#]

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Table 2. Administration of Medication		
Category	Examples <u>(others may be applicable)</u>	Authorisation / Registration required from the SAVC
	g) Overdose of an anaesthetic or chemical agent for resultant euthanasia for any purpose [#]	
Chemical wildlife immobilization	a) Darting of wildlife to facilitate a procedure b) Translocation of animals c) Sampling any data from animals	Person and Facility
Scheduled parenteral medication	d) Intravenous medication e) Infusions f) Extravascular administrations (excluding oral without assistance) g) Gavage, or tubing h) Injections	Person and Facility
Prescribed medication from Schedule 1 to 6 after consultation with a veterinarian (Excluding medication that is required to be administered by a veterinarian according to the Veterinary Rules e.g., anaesthesia and also excluding items indicated for Biomedical Scientific Purposes)	a) Prescribed for use by a veterinarian	Person and Facility
Over-the-counter medication (Excluding as for Biomedical Scientific Purposes)	a) Use of a registered stock remedy as indicated on the package insert e.g., tubing of cattle for bloat	Not required
Chemicals not registered as medicines and used solely for monitoring purposes (Excluding Biomedical Scientific Purposes)	a) Labelled water b) Isotope administration c) Non-controlled chemical substances as marker substances	Not Required (the process of administering the medicine must be authorised)

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Table 2. Administration of Medication		
Category	Examples <u>(others may be applicable)</u>	Authorisation / Registration required from the SAVC
β The administration of medication by the parenteral route in general will require SAVC authorisation or registration.		

Table 3. Sampling of animals		
Category	Examples <u>(others may be applicable)</u>	Authorisation / Registration required from the SAVC
Sampling post-mortem after euthanasia	a) As listed for behavioural and nutritional research (Table 1)	Not required
Blood sampling (Peripheral vein or needle stick sampling only) (Excluding Biomedical Scientific Purposes)	a) Sampling from a peripheral vein b) Needle stick sampling	Person and Facility
Blood sampling (other methods which are invasive)	a) Cardiac puncture b) Large venous puncture c) Arterial puncture d) Peri-orbital bleeding e) Vascular catheterization	Person and Facility
Invasive sampling	a) CSF (cerebrospinal fluid) sampling b) Stereotactic sampling c) Bone marrow sampling d) Biopsies (excluding dart biopsy)	Person and Facility

Table 4. Biomedical Scientific Purposes α		
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Table 4. Biomedical Scientific Purposes ^α		
<p>Using an animal to study changes in physiology or other phenotypes after administration of a substance, or performing a medical or veterinary technique including the application of external stimuli, and/or when the result has a direct impact on human/animal health, understanding of a human/animal disease (or condition) or pathophysiology/treatment/management thereof, and/or involves surgery, including the termination (i.e., euthanasia) of the animals involved</p>	<ul style="list-style-type: none"> a) Testing of a new medicine/substance for any effect (as defined by the Medicines Act) by any route b) Implantation of a medical device e.g., fistulas, loggers, trackers (excluding per needle administered devices) c) Surgery or surgical procedure on an animal d) Invasive embryo transfer or trans-abdominal artificial insemination e) Memory testing for e.g., Alzheimer's research f) Water maze testing, and depression testing g) Teaching towards facilitation of a) to g) above h) Any such research on classical laboratory-bred, or purpose-bred animals, that as a species or strain (breed) are used for these purposes 	<p>Person* and Facility[£]</p>
<p>Using an animal to assess or demonstrate the safety and/or efficacy of a substance, medicine, chemical, product or medical device, including the termination of the animals involved</p>	<ul style="list-style-type: none"> a) <u>Non</u>-clinical toxicity or safety testing b) Dose-finding studies c) Placebo-controlled studies d) Discovery studies e) Assessing the safety or efficacy of medical devices f) Studies required to register a substance or product as a stock remedy or medicine g) Testing of vaccines or other biological agents 	<p>Person* and Facility[£]</p>

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Using an animal for the production of biological substances, e.g., antibody production, antigen propagation, blood, or serum/plasma harvest, including the termination of the animals involved	<ul style="list-style-type: none"> a) Vaccinating an animal to monitor the antibody response. b) Using an animal to propagate an antigen c) Collection of serum/plasma for further testing or to facilitate laboratory models 	Person* and Facility [£]
Using an animal to make a diagnosis in another animal or human, including the termination of the animals involved	<ul style="list-style-type: none"> a) As a last resort for testing for overt toxicity such as botulism or rabies 	Person* and Facility [£]
Implantation/infestation studies, including the termination of the animals involved	<ul style="list-style-type: none"> a) Xenograft models b) Parasite infestations c) Autotransplant models d) Implantation of any physiological monitor (excluding microchipping) e) Fistula for rumen sampling 	Person* and Facility [£]
Infectious studies, including the termination of the animals involved	<ul style="list-style-type: none"> a) To determine the effect of a disease in an animal for the study of the disease directly or for establishing the effect of a therapeutic agent b) Using an animal as a host to propagate the lifecycle of a micro- or macro-organism. 	Person* and Facility [£]
Administration of medication (as per Table 2) or sampling of animals (as per Table 3) when intended for Biomedical Scientific Purposes	<ul style="list-style-type: none"> a) Administration of medication for biomedical scientific purposes b) Sampling of animals for Biomedical Scientific Purposes 	Person* and Facility [£]
Monitoring of animals and basic handling, Specific to Biomedical Research.	<ul style="list-style-type: none"> a) Routine monitoring of habitus b) Monitoring for change in behaviour 	Registered Facility

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	c) Handling animals outside of its cage or enclosure d) Weighing animals e) Cage changing	A person trained and certified competent by a veterinarian or para-veterinarian who is registered and competent to facilitate said procedures.
HPCSA registered qualified medical professionals involved in the care or use of animals for Biomedical Scientific Purposes:	When the person performing a procedure is a medical doctor, dentist or medical specialist who is currently actively registered with the Health Professions Council of South Africa (HPCSA) (or other international medical speciality board) to undertake the same procedure in humans (in cases where this professional does not need to be supervised by another HPCSA-registered professional when performing the procedure on humans) performs veterinary procedures such as anaesthesiology, advising on species-specific aspects, monitoring animal wellbeing and ensuring that current good veterinary practice standards are maintained.	No SAVC authorization is required as long as the person is working under the direct supervision of a SAVC registered veterinarian The veterinarian's role is that of direct and continuous supervision of the animal's welfare.
	1) When a medical doctor, dentist or medical specialist is performing a procedure and is currently actively registered with the HPCSA (or other international medical speciality board) to undertake the same procedure in humans (in cases where this	Person* and Facility ^ε SAVC authorisation is required in all cases where there is no SAVC-registered veterinarian present throughout the duration of the procedure.

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Table 4. Biomedical Scientific Purposes ^α

	professional does not need to be supervised by another HPCSA-registered professional when performing the procedure on humans).	
<p>1) However, in all cases there must still be a registered veterinarian linked to the project and animal, in order to appropriately attend to the animal's health and welfare and emergencies.</p> <p>2) All other persons will require authorisation from the SAVC.</p> <p>3) SACNASP-registered professionals will require SAVC authorisation if they are involved in Biomedical Scientific Purposes in any animal species.</p> <p>* For a person involved in the care or use of animals for Biomedical Scientific Purposes:</p> <p>£ For Registration of Facilities, the following shall apply</p> <ol style="list-style-type: none">1) Facilities that are used for any of the purposes contemplated as biomedical will require SAVC registration .2) SAVC-authorized persons and HPCSA-registered persons may only operate in a registered veterinary facility.3) If the Facility is not SAVC registered, the animal needs to be relocated to a registered veterinary facility for the facilitation of veterinary procedures.		

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