SOUTH AFRICAN VETERINARY COUNCIL

Veterinary Facility Evaluated:

Rule 32: Animal Research Facilities

NAME OF THE FACILITY: _____

Please note:

32 (1) Application for facility registration must include a detailed description of the work that will be conducted and where indicated other Rules which may be applicable for certain procedures (for instance mobile facility for off-site work) or motivation for exemption from the minimum requirements referred to in Rule 31.

32 (2) Where prescribed minimum requirements are not met, an explanation with a motivation and a standard operating procedure (SOP) must be submitted to Council to indicate what procedures are in place to guarantee that the welfare of the patient is still accounted for. Such SOP must be re-submitted every five years, and signed by all veterinarians and relevant staff of that facility.

BY TICKING YES TO ANY RULE ON THIS CHECKLIST YOU AGREE THAT THE FACILITY ALREADY COMPLIES WITH THAT STANDARD.

Rule 32		**Research Animal Facilities**					**OFFICE USE**
					YES	**NO**	**CATEGORY A, B or C**
	(3)	**A research animal facility must:**					
		(a)		Be a permanent structure. (This is not intended to exclude buildings, which are factory produced and site assembled, e.g. a prefabricated building or a container as the word "permanent "relates to the materials used and not the building itself);			
		(b)		Have a source of good general lighting, which is also adequate to ensure the completion of a procedure in progress;			
		(c)		Have adequate ventilation;			
		(d)		Have a fire extinguishing apparatus in accordance with the requirements of the Occupational Health and Safety Act 1993, Act 85 of 1993, which meets the requirements of the relevant local authority;			
		(e)		Be so constructed as to minimise the escape of an animal and to ensure the effective and safe confinement of animals at all times; and			
		(f)		Be registered with the SAVC.			

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					YES	NO	CATEGORY A, B or C
	(4)	Subject to any requirements of a local or other authority, a research animal facility must consist of:					
		(a)		a reception and office area and area where suppliers / visitors can wait without direct access to animals;			
		(b)		one or more examination or procedure rooms;			
		(c)		animal housing rooms; and			
		(d)		isolation facility with adequate biosecurity measures, if needed.			
	(5)			The internal walls and floor surfaces, shelves and tables of a veterinary facility must be of such a nature that they can be properly cleaned and disinfected so as to maintain hygienic conditions.			
	(6)			The internal walls and floor surfaces, shelves and tables of a research animal facility must be of such a nature that they can be properly cleaned and disinfected so as to maintain hygienic conditions.			
	(7)			The drainage and washing water of a research animal facility must run into an adequate sewer and/or septic tank and/or collection tank and must comply with the requirements of local authorities.			
	(8)			Provision must be made at a research animal facility for the storage and disposal of carcasses and other waste in a manner, which will ensure that health risks are minimised.			
	(9)			Provision must be made at a research animal facility for a hygienic, insect, wild-bird and wild-rodent free environment within the facility as well as where therapeutic and nutritional or husbandry products are stored.			
	(10)			Adequate facilities must be available for the preparation of food and washing and cleaning of all equipment.			
	(11)	A research animal facility must comply with the following general procedural requirements:					
		(a)		Personnel must be trained in the basics of aseptic technique and such training must be relevant to the scope of practise;			
		(b)		Personnel responsible for the operation of sophisticated equipment and apparatus must be adequately trained within their scopes of practise;			
		(c)		Daily health-checks and welfare monitoring of animals housed at the research facility must be conducted by SAVC-registered or SAVC-authorised personnel, which must be followed up by weekly health and welfare monitoring by the veterinarian in charge;			
		(d)		All laboratory and diagnostic facilities must have a biosecurity program as well as an emergency/containment program and/or SOP for each designated area of the facility, these programs must be audited and records must be kept.			
	(12)	A research animal facility must comply with the following general requirements, where applicable:					
		(a)		Have equipment to determine the weight of animals accurately;			

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		(b)		an emergency service can be rendered to stabilise animals and/or for euthanasia;			
		(c)		resuscitative cardiopulmonary medicines as well as intravenous fluids and fluid administration sets must be readily available for emergencies;			
		(d)		suitable sterilising equipment, or access thereto, to be done adequately for the effective sterilisation of surgical packs and other equipment;			
		(e)		have adequate storage for sterilised packs and employ acceptable techniques to indicate the effectiveness and expiry of sterilisation;			
		(f)		routine laboratory equipment within the facility, or reasonable access to such a laboratory service must be available;			
		(g)		in the case of a research animal facility where invasive surgical procedures are performed, have an alternate power supply to allow the facility to function in the event of a power failure and to meet the requirements of local authorities;			
		(h)		post mortem examinations should be performed at the facility or reasonable access to such a service must be available;			
		(i)		have facilities and equipment or access thereto for the hygienic disposal of medical and biological waste and sharps to prevent the contamination of the research animal facility as well as the environment;			
		(j)		have facilities for the safe storage and use of relevant medicines for patient treatment and procedures in accordance with the medicines act; and			
		(k)		adequate biosecurity measures must be in place when dealing with contagious diseases or genetically modified organisms.			
	(13)			Only minor surgical procedures, excluding intra-abdominal, musculo-skeletal, intra-cranial, cardio-vascular or intra-thoracic surgery may be performed in a procedure room unless such procedure room complies with Rule 24.			
	(14)			Animals must, unless circumstance dictate otherwise, be euthanased in areas separate from animal housing areas, using appropriate euthanasia methods per species and life-stage. Where circumstance does not allow for the animal to be removed, appropriate measures must be in place (such as screens or sedation) to minimise the distress to any other animal in the housing area.			
	(15)	**The storage of medicine must comply with the following:**					
		(a)		light conditions, temperature and humidity must comply with the requirements for the storage of medicine, other pharmaceutical products, and packaging materials;			
		(b)		all medicines must be stored at the prescribed temperature;			
		(c)		schedule 5 and higher scheduled medicines must at all times be under direct supervision of a veterinary professional or para-veterinary			

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				professional, within the scope of practise of that para-veterinary professional, and locked away when the veterinary professional or para-veterinary professional is not on the premises;			
		(d)		storage areas must be large enough to allow orderly arrangement of stock and proper stock rotation;			
		(e)		refrigerator must be available and must be equipped with a suitable thermometer and capable of storing medicines at temperatures between 2°C and 8°C, if so indicated. The refrigerator must be cleaned, defrosted and checked periodically to ensure efficient running. This refrigerator must be used only for storing pharmaceutical products;			
		(f)		empty, time expired/or broken containers of medicines must be disposed of as legislated for dangerous substances in legislation controlling these substances; and			
		(g)		records of medicines purchased and prescribed or used need to be kept for a minimum period of 5 years.			
	(16)			If diagnostic imaging is done, the facility must comply with Rule 22.			
	(17)			Structural requirements for facilities where radiation equipment is installed, as well as user safety precautions for the use of this equipment thereto must comply with the relevant legislation.			
	(18)	**A research animal facility must comply with the following general requirements for anaesthesia:**					
		(a)		all animals must undergo a pre-anaesthetic clinical examination;			
		(b)		all persons administering anaesthesia must be registered or authorised by Council to do so and be competent in the efficient use of all anaesthetic facilities and equipment, provided that a veterinary para-veterinary professional, within his/her scope of practice may administer anaesthesia on the instructions of a veterinarian, with the exception of wildlife, which only a veterinarian personally may anaesthetise in accordance with Rule 10(2);			
		(c)		the monitoring, maintenance and recovery from anaesthesia must be effected under the direct supervision of a veterinary professional or veterinary para-veterinary professional, within his/her scope of practice who must be on the premises;			
		(d)		adequate facilities must be provided for the safe induction and recovery from anaesthesia.			
		(e)		the same person may not do surgery, monitoring and maintenance of general anaesthesia, unless circumstances dictate otherwise and appropriate vital signs monitoring equipment, such as a pulse oximeter or apalert is available;			
		(f)		equipment for anaesthesia, either inhalation or parenteral, and facilities adequate and appropriate for the needs of the research animal facility must be provided at all times;			

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		(g)		an appropriate range of clean, functional endotracheal tubes must be available for the relevant species;			
		(h)		medical oxygen must be available at all times for inhalation anaesthesia maintenance as well as to meet any other emergency situation;			
		(i)		storage for all explosives, such as gas or oxygen, must be provided for in accordance with the relevant legislation;			
		(j)		a means to provide artificial ventilation must be available;			
		(k)		lock-up facilities must be available for scheduled medicines in accordance with the relevant laws;			
		(l)		where applicable, equipment for the control of body temperature must be provided;			
		(m)		anaesthetic equipment must be adaptable for the variation in body weight and the species range in which it is intended for use;			
		(n)		active or passive anaesthetic gas scavenging equipment must be in use according to relevant legislation;			
		(o)		all anaesthetic equipment must be properly maintained and serviced at regular intervals; and			
		(p)		all animals must be monitored after surgery and not left unattended, unless adequately recovered from anaesthesia.			
	(19)	**A research animal facility must comply with the following general requirements for surgery, if invasive surgery is done:**					
		(a)		one or more rooms or areas for the treatment and pre-operative preparation of patients, which must be convenient to the operating room; and			
		(b)		a separate room or area appropriate to the species involved and the procedure performed which is equipped as an operating room and has:			
			(i)	an adequate light source;			
			(ii)	a surgical table with an impervious operating surface that can be easily cleansed and disinfected;			
			(iii)	a gas anaesthetic apparatus where relevant;			
			(iv)	an adequate supply of oxygen; and			
			(v)	adequate ventilation.			
	(20)			The operating room must be of adequate size and there must be an adequate supply of equipment, drapes and instruments at all times.			
	(21)			There may be no thoroughfare through an operating room.			
	(22)			The operating room may not be used as a storage room.			
	(23)			Patients should be prepared in a separate room or area convenient to the operating room but not in the same place as where surgery takes place.			

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	(24)			Only final preparation of the patient may be done in the operating room or area.			
	(25)			Aseptic conditions must be maintained in the operating room.			
	(26)			Have appropriate autoclave equipment or other suitable sterilising equipment, or access thereto, for the effective sterilisation of surgical packs and other equipment and have adequate storage for sterilised packs and employ acceptable techniques to indicate the effectiveness and expiry of sterilisation.			
	(27)			Suitable scrubbing up facilities must be available.			
	(28)			Animal housing rooms in which animals are kept must comply with appropriate animal housing, husbandry and environmental enrichment standards in accordance with the relevant SA National Standard (SANS) for the housing of laboratory animals, or, in the absence of a specific SANS, to the internationally accepted standard;			
	(29)	**Cages and/or enclosures must:**					
		(a)		be of adequate size for each animal or group of animals;			
		(b)		be of such a material so as to prevent self-injury of the animal;			
		(c)		favour maintenance of hygiene; and			
		(d)		be adequately ventilated and, if necessary, heated or cooled.			
	(30)			Appropriate environmental enrichment programmes for all species, including exercise where relevant must be available. exercise areas must be designed and constructed in a manner that will minimise escape and facilitate the maintenance of hygiene.			
	(31)	**A research animal facility must comply with the following ethical and additional standards:**					
		(a)		access control must be in place to restrict access to authorised personnel only;			
		(b)		adequate bio-exclusion and bio-containment protocols and standards must be in place;			
		(c)		all personnel performing procedures on animals must be registered or authorised by the Council, with sufficient registered veterinary and registered para-veterinary professionals to supervise all authorised personnel adequately;			
		(d)		animal welfare must be guaranteed in accordance with the relevant SANS, or in the absence of a specific SANS, the internationally accepted standard.			
		(e)		welfare inspections must be conducted at appropriate intervals by registered Animal Welfare Organisations with deficiencies addressed adequately and timeously, regular (at least weekly) veterinary health and welfare examination of animals, and at least daily welfare monitoring of experimental animals by registered or authorised persons with increased welfare monitoring frequencies as determined by Animal Ethics Committee depending on expected or known study severity;			

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		(f)		prior to initiating any scientific activities, approval must be obtained from an Animal Ethics Committee, which must conform to SANS 10386:2008 and if such activity could impact on human health, be registered with the National Health Research Ethics Council (NHREC).			
		(g)		DAFF compliance certification for Biosafety Level 3 or higher laboratories;			
		(h)		a permit in terms of Section 20 of Animal Diseases Act 1984, Act no 35 of 1984 must be obtained from the Department of Agriculture, Forestry and Fisheries where relevant;			
		(i)		nature Conservation and other permits where relevant; and			
		(j)		approvals in terms of the Genetically Modified Organisms Act 1997, Act no 15 of 1997 where relevant.			

Rule 6				Records at Veterinary Facilities			OFFICE USE
					YES	NO	CATEGORY A, B or C
	(1)			The attending veterinary professional (must) maintains records, including the records required in terms of the Medicines Act, for each animal **or** group of animals which are legible, accurate and permit prompt retrieval of information.			
	(2)			**Records must contain the following information for individual animals as applicable:**			
		(a)		the date or period of the examination or consultation;			
		(b)		name of the veterinarian who treated the patient;			
		(c)		client's identification;			
		(d)		patient name, other forms of identification, as well as the species, breed, gender and age;			
		(e)		clinical information for the purposes of continuous care and assessment;			
		(f)		vaccination record;			
		(g)		special procedures;			
		(h)		diagnosis;			
		(i)		treatment and scripts issued; and			
		(j)		discharge instructions.			
	(3)			**Records must contain the following information for production animals, including wildlife, as applicable:**			
		(a)		the date or period of the examination or consultation;			
		(b)		client's identification;			

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Rule 6		Records at Veterinary Facilities					OFFICE USE
					YES	NO	CATEGORY A, B or C
		(c)		species & breed; for wildlife species and sex, age group and/or colour if relevant;			
		(d)		procedures or treatment performed. For groups of animals a general description of the type of herd-work and bulk use of medicine is acceptable, but the use of schedule 5 and 6 wildlife capture medicines, must be recorded with care; and			
		(e)		instructions to client in general, if applicable and abnormal observations.			
	(4)			All records referred to in Rule 6(2), radiological images and the interpretation thereof, laboratory and pathology results must be retained by the principal of the veterinary facility for **a period of five years** from the patient's last visit, with the exception of ultrasound images where only the findings must be recorded.			
	(5)	**Records must contain the following information for diagnostic laboratory work (if) applicable:**					
		(a)		date sample was collected, date received, date completed, and date of release of results;			
		(b)		client information and geographical information;			
		(c)		animal identification as submitted, including species, breed, gender and age;			
		(d)		clinical history;			
		(e)		tests performed;			
		(f)		personnel doing the preparation and analysis;			
		(g)		method followed, deviations if any, reasons for deviation and reasons why results can still be accepted;			
		(h)		consumables and reagents including name, batch number, and expiry date;			
		(i)		results of quality control samples;			
		(j)		environmental conditions, if abnormal, or other critical information required by the standard operational procedure;			
		(k)		original findings; and			
		(l)		reports.			
	(6)			Records referred to in Rule 6(4) relating to a complaint, charge or allegation lodged with Council in terms of section 31(1) of the Act must be presented to Council within **seventy two (72) hours** of being requested to submit such records, or as otherwise arranged with Council.			
	(7)			Proper security arrangements must be made to protect medical and other clinical records from loss, fire, alterations, additions, supplements or unauthorised use; electronic records must be backed up on a daily basis and electronic backups should be stored off-site.			

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Rule 6		Records at Veterinary Facilities					OFFICE USE
					YES	NO	CATEGORY A, B or C
	(8)			Any alterations, additions and/or supplements to any records, clinical or otherwise, must be entered as a supplement to said record and must be clearly defined as such.			
	(9)	(a)		The principal of a veterinary facility will be responsible for confirming the identity of the attending veterinary professional to Council, where a complaint is lodged against his/her veterinary facility.			
		(b)		The principal of a veterinary facility will be responsible for providing the records referred to in Rule 6(5), should a complaint be lodged against a veterinarian no longer in the employ of the principal of the facility, subsequent to the date on which the complaint originated.			
		(c)		Should the principal of a facility fail to comply with the provisions of Rule 6(9)(a) he/she will be held accountable for any unprofessional conduct arising from such a complaint.			

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