

27 June 2014 Dear Researcher

Animal research compliance

This communication is intended to bring your attention to a set of requirements associated with animal use for scientific purposes (i.e. research, teaching or testing) under South African law and regulations. The requirements relate to:

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- 1. The administration of Scheduled drugs to animals; and
- 2. Performing procedures on animals (including anaesthesia or chemical immobilisation, surgery, perianaesthetic monitoring, euthanasia, administration of scheduled or experimental substances, collection of fluid/tissue samples, and other scientific procedures). Some of these procedures may only be performed by registered veterinarians, while others may also be performed by registered para-veterinary professionals (i.e. laboratory animal technologists, veterinary nurses, animal health technicians, or veterinary technologists) or by non-SAVC-registered persons who have been authorized by the South African Veterinary Council (SAVC) to perform these specific procedures.

Ensuring that current and future uses of animals for scientific purposes may be conducted at UCT requires institution-wide compliance with these regulations. The FHS Deanery has met with UCT Legal Services and the Office of Research Integrity and determined that a systematic approach to full compliance will best serve the interests of both researchers and the Faculty.

BACKGROUND:

Rule 2 Relating to the Practicing of Veterinary Professions, as published in the Government Gazette on 12 April 2013, provides in regard to the Veterinary and Para-Veterinary Professions Act (No. 19 of 1982) that the following are deemed to be services/procedures which pertain specially to the veterinary profession (i.e. a veterinarian or veterinary specialist):

- a) The diagnosis, treatment, prevention of, or advice on a disease, physiological or pathological condition in an animal;
- b) chemical restraint of an animal, which includes general, standing, and/or regional anaesthesia, as well as chemical immobilisation of an animal;
- c) a surgical or dental operation or procedure on an animal; and
- d) the prescribing or administration of medicine to an animal.

Rule 10, as published in the Government Gazette on 8 June 2012, further requires that "[t]o tranquilize, sedate, chemically immobilize or anaesthetize wildlife, any schedule 5 or 6 substance must be administered by a veterinary professional personally."

The Rules Relating to the Practising of the Para-Veterinary Profession of Laboratory Animal Technologist (GN 1445 of 3 October 1997) stipulate that the following services/procedures (amongst others) pertain to the profession of laboratory animal technologists:

- a) Care of experimental animals;
- b) oral and parenteral administration and administration by inhalation of scheduled and experimental substances;

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- c) administration of scheduled substances for anaesthesia and euthanasia;
- d) collection of body fluids including blood, urine by free flow and ascites, and the collection of tissues including smears, faeces, post mortal samples and bacterial swabs for diagnostic and experimental purposes;
- e) clinical observation;
- f) preparation of animals for surgery;
- g) monitoring of animals before, during and after an operation;
- h) performance of minor surgical procedures such as lancing of abscesses and suturing of superficial wounds:
- i) assisting with experimental surgical procedures;
- j) use of the tranquilliser dart gun and blow pipe;
- k) capture of wild animals for the purpose of research;
- l) transportation of experimental animals;
- m) training and examination of trainee laboratory animal technologists; and
- n) teaching of students or researchers who require training in any specific aspect of laboratory animal technology.
- o) conducting of experiments with experimental animals

Section 23(1)(a) of the Veterinary and Para-Veterinary Professions Act prohibits any persons who are not registered with the SAVC to perform, in any way whatsoever, any of the services or procedures which are deemed in terms of the Rules to pertain specially to the veterinary or para-veterinary professions. Section 23(1)(c) of the Act makes provision that the SAVC may authorize persons who are not registered with the SAVC (e.g. researchers) to perform some of these procedures, following suitable training, the confirmation of practical competency in the procedures by a registered veterinarian, a formal application process, and subject to such conditions as the SAVC may determine per person and procedure.

The Veterinary and Para-Veterinary Professions Act and the Medicines and Related Substances Control Act (No. 101 of 1965) are available at:

- <u>http://www.savc.org.za/pdf_docs/act_19_of_1982.pdf</u>
- http://www.saflii.org/za/legis/consol_reg/marsa10101965rangnr510723/

COMPLIANCE:

In order to achieve compliance in the FHS, the following actions will take place over the coming weeks. More precise information in terms of timelines, venues, and sequence will be forthcoming.

- The FHS Deanery will recall all existing prescriptions for Schedule 5 and 6 drugs for studies that do not presently employ registered veterinarians, registered para-veterinary professionals, or SAVC-authorised personnel to administer all of these drugs to animals. Drugs will be reissued under new prescriptions when once all such drug administration is performed only by appropriate SAVC-registered or SAVC-authorised personnel.
- FHS will employ additional veterinary and para-veterinary professionals to provide support for scientific studies on an interim basis, affording a period for researchers to ensure that:
 - 1) Scheduled drug administration can be done in full compliance; and
 - 2) Only appropriate SAVC-registered or SAVC-authorized personnel perform any veterinary or paraveterinary procedures on animals.
- Researchers will be invited to informational meetings on the topic of compliance with laws and regulations applicable to animal use.



- A frequently-asked-questions (FAQs) document will be posted to UCT websites in order to answer common significant questions.
- The Office of Research Integrity (ORI) will create a roster of personnel who require training and practical competency assessment for the purpose of application to the SAVC for authorizations of non-SAVC-registered study participants to perform animal procedures.
- The Research Animal Facility (RAF) will work with the FHS Deanery and the ORI to establish a program for training and competency assessment of personnel across the range of animal procedures for which SAVC-authorizations may be available.
- ORI and the FHS Deanery will track SAVC authorization applications, authorization expiration/renewal dates, and SAVC-imposed supervision requirements for SAVC-authorised staff.
- Researchers remain fully responsible to ensure that the conduct of all animal procedures is consistent with applicable laws and regulations.

These actions will elevate the compliance and quality of animal research at UCT as well as animal welfare. At present, however, they will pose challenges and unavoidable disruptions to current research and scientific practices, though this may be offset to a large extent by the employment of additional SAVC-registered professionals in the interim period. I appeal to you for your understanding, patience and flexibility, and remind you that these are not new standards but rather ones that may implicate liabilities including reputational and professional harms to institutions, their veterinary and para-veterinary professionals, and to principal investigators and study participants individually, professionally, and personally.

We will endeavour to proceed towards full compliance with promptness and efficiency. Questions may be directed to the Dean's Office (via nikki.henry@uct.ac.za), which will draw on the support of UCT Legal Services, the Office of Research Integrity, and the RAF as appropriate. Please mark questions with the subject line, "Animal Research-SA Compliance." Please also anticipate group-level responses either through informational activities or other communications.

Sincerely

WILLEM DE VILLIERS PROFESSOR AND DEAN