



Animal Research Forum

MINUTES

Forum to Discuss Legal Requirements and Streamlining of Animal Research Compliance Processes, held on 13 September 2017 at 15:00 in the Postgraduate Room 1, Barnard Fuller Building, Medical School

1. Background and objective

The Forum was arranged at the request of the Deputy-Dean for Research, Prof Karen Sliwa, to facilitate discussion between animal research stakeholders in the Faculty of Health Sciences (FHS).

The objective was to provide an opportunity for the animal research community to clarify the South African regulatory framework related to animal research and accompanying processes; to air related grievances; and to address misperceptions and miscommunications.

2. Welcome

The Chair of the Forum, Prof Sliwa, welcomed all animal researchers and stakeholders present and provided an overview of the agenda (attached – “**Addendum A**”).

Prof Sliwa acknowledged the important work of researchers who use experimental animals.

The meeting was alerted to the letters (Aug/Sept 2017) from the UCT Legal Office, Office of Research Integrity and Senate Animal Ethics Committee (attached – “**Addendum B**”), which provides an overview of the applicable South African laws and standards governing research that involves animals. The letters were circulated to all animal research principal investigators in the Faculty prior to this meeting.

3. Present and apologies

3.1 Present

Chair: Prof Karen Sliwa (FHS Deputy-Dean: Research)

Emeritus Prof Patrick Commerford (FHS Animal Ethics Committee (AEC) Chairperson)

Profs: Frank Brombacher, Muazzam Jacobs, Anna-Lise Williamson, Justiaan Swanevelder, Marianne Vanderschuren and Peter Zilla

A/Prof: Neil Davies

Drs: Ros Chapman, Gerald Chege, Susan Cunningham, Liezl Gibhard, Asfree Gwanyanya, Nkanyiso Hadebe, Sabelo Hadebe, Inga Hitzeroth, Jennifer Hoving, Fleur Howells, Ramona

Hurdayal, Tertius Kohn, Antoinette Labuschagne, Bert Mohr, Suray Parihar, Joseph Raimondo, Claire Spottiswoode, Dale Taylor, Elizabeth van der Merwe

Ms: Carlette Hlungwani, Eliza Hui, Paula Saner

Mr: Daniel Doetz, Sidney Engelbrecht, Rodney Lucas, Jabu Magagula, Jakobus Visser,

Sr: Janet McCallum, Stephanie Struwig

3.2 Apologies

Dr Lyn Horn

4. Presentations

4.1 Overview of regulations (DAFF, NHREC, SAVC)

The ORI Senior Manager, and the UCT Legal Services Director could not attend the meeting.

Dr Bert Mohr (Director, UCT-RAF and Veterinary Scientific Services) spoke to this agenda item.

Dr Mohr referred to the letter of 31 August 2017, a joint letter from the UCT Legal Services, Office of Research Integrity (ORI) and Chairperson of the Senate Animal Ethics Committee (SAEC), addressed to the Deputy Vice-Chancellor for Research and Internationalisation, Prof M Phakeng, which provides an overview of the South African legal framework applicable to animal research. The follow-up letter of 7 September 2017 from the SAEC Chairperson, Prof Marianne Vanderschuren, to the Deanery of the Faculty of Health Sciences, was mentioned.

The letters emphasised the expectation for compliance, with the request to identify gaps in compliance and strategies to close these. The communications highlighted ORI's commitment to continue facilitating compliance relating to, *inter alia*, SAVC authorisation and DAFF Section 20 permits. E.g., the recent engagement between UCT stakeholders and DAFF - the meeting, facilitated by ORI, was held on Tuesday, 22 August 2017 at the offices of DAFF in Pretoria. The aim of the meeting was, *inter alia*, streamlining of processes relating to DAFF Section 20 permit applications and laboratory audits. The meeting outcome was reportedly very positive.

The DAFF meeting was a good example of constructive engagements with regulatory bodies. Going forward, the ORI proposed similar engagement with SAVC regarding the streamlining of authorisation processes for personnel performing procedures on live animals, to clarify certain requirements, and to discuss the concerns raised by UCT animal researchers and this Forum.

4.2 Implementation of regulations (UCT-RAF and Veterinary scientific services)

Dr Mohr provided an overview of the implementation of compliance processes in the FHS, UCT-RAF and veterinary services, which enable the animal research and teaching enterprise.

Dr Mohr overviewed the following aspects, which were established over the past few years:

- a. Scheduled drugs: The use and storage of highly scheduled drugs are closely controlled, including quarterly audits of scheduled drug registers, as per regulatory requirements.
- b. Registration of Research Animal Facilities: The FHS Research Animal Facilities, including the core UCT-RAF and satellite laboratories, are registered with SAVC. The facilities will

undergo SAVC audits in October 2017 to establish compliance with minimum standards. The UCT-RAF animal biosafety level 3 (ABSL-3) laboratory is also formally DAFF certified.

- c. Teaching: The UCT-RAF & veterinary services present the 40-hour biannual introductory course in laboratory animal science and ethics. The course is CPD accredited by the SAVC; European accreditation (FELASA) is being sought. The AEC requires new animal researchers to attend the course. However, the AEC permits personnel to start animal work before they attend the course, as long as they attend the next available course.
- d. Training in veterinary and para-veterinary animal procedures: Veterinary services have established training & competence assessment programmes in basic to advanced procedures for relevant species and techniques. This enables the SAVC authorisation of personnel (academic and professional) who perform regulated procedures on animals. Training can be performed at any time throughout the year with prior appointment, so does not need to be done immediately before applications for authorisation of personnel are submitted to the SAVC.
- e. The requirement to reconfirm the competence of authorised personnel in regulated animal procedures on an annual basis is being further pursued, resource and systems constraints are challenging.

The cumbersome nature of the SAVC authorisation application processes was considered with specific reference to turn-around time for applications, inconsistencies of outcomes, clarity of which procedures require authorisation (e.g. welfare monitoring, transport, killing animals). A detailed list of queries and concerns should be produced in order to engage constructively with the SAVC to streamline processes and clarify requirements, mediated by the ORI.

In the Faculty of Health Sciences and UCT, We need to consider the most appropriate models for research and teaching, when considering configuration of systems, processes, oversight and resources. The Deputy Dean of Research requested an overview of alternative models or scenarios that could be considered. Dr Mohr elaborated on the following main components:

- a. In terms of delays experienced after submitting SAVC authorisation applications: FHS students/researchers could begin performing procedures on animals, immediately after their competence has been confirmed for SAVC authorisation application, as long as they were directly supervised in their procedures by a registered veterinary or para-veterinary professional (depending of nature of procedure). This would form part of competence-based training and deeper learning. The student could then perform procedures while awaiting authorisation confirmation from SAVC. The primary limitation for most research groups might be funding for professional fees / salaries. There could e.g. be funds made available for this by UCT or Faculty. Dr Mohr overviewed the user charges for veterinary and para-veterinary professional time (i.e. services), for the next 3 years (attached – “**Addendum C**”) – in comparison to the cost of e.g. a rat or mouse.
- b. In terms of who performs procedures: RSA universities and research institutions differ widely in their models of who performs animal procedures (attached – “**Addendum D**”):
 - i. *Researcher Model*: on the one extreme, in some South African institutions (e.g. UCT), animal procedures are mainly performed by researchers/students.
 - ii. *Professional Model*: on the other extreme, in some South African institutions, veterinary or para-veterinary professionals mainly or solely perform procedures.

- iii. *Hybrid Model*: A hybrid model may be considered, i.e. where procedures are performed by a combination of researchers / students on the one hand; and veterinary / para-veterinary professionals on the other. In such a hybrid model, not all students who do entry-level animal projects (e.g. Honours), necessarily perform all of their animal procedures themselves. Students still get exposure by assisting in procedures and/or animal projects in the animal labs. Hybrid models could decrease authorisation costs; as well as impact of delays in applications.
- iv. In all above models, health professionals may also perform specialised procedures (e.g. cardiovascular surgery; neurosurgery), within their scope of practice.
- c. The above models could be further explored, e.g. a research group where one person (or few persons) is authorised to perform procedures for the group, *in lieu* of all students in the group applying for SAVC authorisation; this could limit costs and impact of delays.

Clarity is required in terms of requirements for the involvement of health professionals who conduct procedures on animals, e.g. regulations surrounding scheduled drug use; performing procedures on animal species not included in the scope of practice for their profession; the distinction between the specialised procedure itself (i.e. where the health professional should be responsible for their own competence) vs. veterinary aspects (e.g. anatomy, physiology, peri-operative management, species-specific complications, pharmacology, etc.) where the veterinary professional would be working within the scope of practice for their profession.

4.3 Implementation of regulations (animal ethics): Mr Sidney Engelbrecht

Mr Engelbrecht presented on the current issues and potential way forward relating SAVC and DAFF submissions as facilitated by the ORI. Reference was made to a successful meeting held between the ORI and DAFF. The outcome of the meeting will be communicated to relevant researchers via the Compliance Vula site.

Mr Engelbrecht emphasised the recent work done by the ORI and Legal Office by assessing the current legal framework. As a result the letter was drafted and jointly signed by the UCT Legal Office, ORI and SAEC.

It was highlighted that the ORI, under the leadership of Dr Lyn Horn, is actively working to establish a good working relationship between the University and the SAVC.

Mr Engelbrecht highlighted changes related to DAFF Section 20 applications; i.e.:

- a. Simultaneous submission to DAFF and AEC – in the past there was separated submissions and the DAFF submission required AEC approval; and
- b. DAFF now accepts a 2-page summary of a study whereas a full protocol was required in the past.

In addition, Mr Engelbrecht referred to an audit of the FHS AEC conducted by the National Health Research Ethics Council (NHREC). The NHREC audited the FHS AEC and highlighted a deficiency, i.e. the absence of a post-approval monitoring system. The audit recommended that the FHS AEC implemented a post-approval monitoring system to audit approved studies.

Mr Engelbrecht cautioned that compliance with the recommendation is critical as the FHS AEC is registered with the NHREC. The FHS AEC could lose its registration status, if found not to be compliant with the NHREC recommendation to implement a post-approval monitoring system.

5. Concerns of research community: All users of FHS animal facilities

Dr Joseph Raimondo acknowledged the recognition of the legal framework, but questioned the context; i.e. whether the laws are written understanding operations of research in an international competitive environment. In some international systems/guidelines, researchers can be the oversight authority. The current SAVC Rules do not make provision for such a system. Dr Raimondo proposed that the SAVC issues new Rules to “legalise” such a system. Dr Raimondo stated that it is not required to change the applicable laws as it is a lengthy process in parliament and needs sign-off by the President. However, Rules do not require parliamentary processes and requires sign-off by the applicable Minister. The process of introducing new Rules are less cumbersome than changing or promulgating an act.

Dr Raimondo stressed the drop in animal research in the Faculty. He mentioned that there is a 48% drop of AEC application numbers. He stated that hiring more staff in the Research Animal Facility (RAF) will bankrupt the Faculty.

In response, Prof Sliwa, indicated that to enable research, within the legal framework of this highly regulated field, requires reassessment of models. To do animal research at a high standard, not all students should necessarily do all their own procedures, e.g. in small studies.

Dr Mohr mentioned that the question of supervision could be addressed to the SAVC. There are costs involved e.g. to have a lab animal technologist supervise students before they receive SAVC authorisation.

Dr Raimondo is worried about flexible lab practices by using a Lab Animal Technologist; it is not always possible for one person to service multiple research groups, especially after-hours.

Prof Anna-Lise Williamson stated that the Faculty should comply with the applicable laws, i.e. the Veterinary Act, not only the Rules made under the Act. Dr Raimondo emphasised that it is not the law that requires changes, but Rules that are friendly to the animal research context.

The chairperson of the FHS AEC, Prof Patrick Commerford, referred to the UCT Code of Animal Research. In this regard, Prof Commerford noted that UCT has committed to follow the relevant laws, SANS Code (10386:2008) and the Veterinary Act, including SAVC authorisations.

In this regard, the SAEC chairperson, Prof Marianne Vanderschuren, stated that the SAEC supports animal research at UCT by UCT researchers, but it must be compliant with the legal framework. The SAEC comprises of a variety of people; and is not trying to prevent animal research at UCT.

In response, Prof Williamson mentioned that there should be more animal researchers on the SAEC and requires more animal expertise on the Committee. In response, Prof Sliwa posed the question whether the SAEC can expand its membership to include more animal researchers.

Prof Peter Zilla voiced his concern about the interpretation of the law. Prof Zilla held the view that some interpretation of the law can be hostile. He cautioned that one should stick to the spirit of the law.

Prof Sliwa indicated that one should investigate different practices at other institutions.

Dr Nkanyiso Hadebe stated that research is unique and innovative. In this regard, veterinarians may not be competent in the context of all animal procedures performed in research.

Furthermore, Dr Hadebe questioned the authority of the SAVC in relation to specialised service; e.g. stereotaxic surgery. Dr Hadebe referred to the delays in sequences of events and roles/responsibility as a direct result of applying of SAVC authorisation. He referred to his research project, which was delayed by seven months owing to SAVC authorisation and building works. He stressed that if one sticks to the law, then research will perish. He posed the question whether the Rules make a difference when one weighs-up the time and money to perform animal research under the current legal framework.

Prof Muazzam Jacobs voiced his frustration with reference to a similar Forum held five years ago on 22 March 2012. All the issues experienced and mentioned in 2012 has been voiced many times previously and again at this Forum. It was previously asked for a University mandate to do SAVC authorisations, but nothing came from it.

Prof Sliwa responded that regulations need to be questioned in terms of exemptions; e.g. highly specialised procedures. In this regard, Prof Sliwa recommended a Working Group to propose rewording of processes and regulations. These need to be more flexible to research.

Dr Mohr mentioned that the law makes provision for health professionals to work together with veterinarians. E.g. in clinical practice, veterinarians take responsibility for veterinary aspects, while a health professional (e.g. surgeon) may perform a specialised procedure on the animal (e.g. heart valve replacement). Here, there is a clear division of responsibility / accountability, between the veterinary vs. health professionals. What is less clear is e.g. where medical professionals perform all components of the procedure, with no veterinary involvement.

Prof Sliwa responded that a Hybrid model for research may be required.

Prof Commerford noted that professional protection should be considered. The SAVC is also protecting the veterinarian profession. The Health Professions Council is the governing body that protects the healthcare/medical profession. It was noted that only a healthcare professional may perform a procedure on a human. The same principle applies in the context of the veterinarian profession, whereby the SAVC protects the veterinarian profession and only a veterinarian may perform a procedure on an animal.

A/Prof Neil Davies voiced his concerns by stating that the SAVC authorisation process is a bureaucratic nightmare. A/Prof Davies referred to the SAVC inaccuracies in Annexure A. In addition, he referred dissatisfaction with the SAVC invoice process, there are apparent errors.

Dr Sabelo Hadebe voiced the view that the delays for SAVC authorisation is unnecessary.

Prof Deon Bezuidenhout posed the question whether the ORI/UCT could ask the SAVC to increase the frequency of Council meetings, to have authorisation applications processed more frequently.

Dr Inga Hitzeroth raised the question whether UCT has approached the SAVC with concerns from researcher relating to; e.g. delays in authorisation process. In this regard, Mr Engelbrecht responded that formal communication and numerous email communications were sent to the SAVC, but no formal meeting was held to address concerns from animal researchers. In some instances, the SAVC responded well to requests from the ORI. He indicated that part of the next steps is to set-up a meeting with the SAVC and bring the concerns to the SAVC attention.

Dr Susie Cunningham raised issues related to research on animals in the wild. Dr Cunningham stated that if researchers in wildlife animals are unable to perform procedures, then they cannot do conservation and train students. Fundamental techniques and talented Post-doctoral students/fellows, are no longer able to answer research questions. It is therefore important the Rules are updated line with the research context.

Regarding wildlife research, Dr Mohr proposed that the conservation group approach the SAVC to address issues related to SAVC authorisation in the context of wildlife research.

Dr Antoinette Labuschagne proposed that the SAVC should make provision for a "sub-category" for researchers. It was not clear why sterile gloves should be work during abdominal surgery in animals.

Dr Tertius Kohn indicated that one should investigate what the status is at other universities. He proposed that all universities should be approached to band together to get the laws changed. He is particularly frustrated with the DAFF Section 20 permit requirements.

6. Efficiency of the RAF, streamlining of processes: Mr Daniel Doetz

Mr Daniel Doetz presented a talk on the financial sustainability of animal research in the Faculty of Health Sciences with a reference to the operation of the Research Animal Facility. Mr Doetz stated that animal research is highly subsidised by the Faculty. He posed the question how the Faculty prepare to finance animal research for the next five to ten years. He stressed the source of funding over the period, researchers should let him or the RAF know if there are external sources of equipment funding or contract research opportunities. Mr Doetz indicated that one should consider an appropriate model to support animal research in the Faculty.

7. Budgets for the Faculty and RAF: Mrs Eliza Hui

Mrs Hui referred to a Provincial Agreement that supports animal research. The Research Animal Facility costs approximately R10 million per annum. Mrs Hui indicated that an increased GOB budget has been requested to meet compliance. She stressed that maintenance of infrastructure is a real concern especially replacement of out-dated infrastructure.

In this regard, Dr Fleur Howells posed the question how is UCT addressing a more suitable animal research structure/facility. The university must commit to new animal research building.

8. Next steps:

A FHS Committee was formed to streamline animal research processes: tasked to investigate international models of animal research oversight (in order to evaluate RSA model vs. international norms); and establish list of concerns to raise with the SAVC. Members: Bert Mohr (chairperson), Joe Raimondo, Neil Davies, Nkanyiso Hadebe, Jabu Magagula. Prof Sliwa requested that anyone involved in animal research is welcome to volunteer to join the Committee. Interested parties to join the Committee should contact Mr Sidney Engelbrecht per email at sidney.engelbrecht@uct.ac.za.

Investigate the *hybrid model* of animal research, including the supervision period required in-between SAVC authorisation application, i.e. feasibility to appoint a Lab Animal Technologist to

supervise researchers/students while awaiting outcome from SAVC authorisation period. Explore models at other universities.

Investigate the option to have the UCT-RAF training course in laboratory animal science, including in practical research procedures, formally accredited and recognised by SAVC.

A united voice is required in UCT (SF representatives were advised to have similar process to FHS process) for engagement with SAVC; mediated by the Office of Research Integrity (ORI).

Establish a UCT delegation to meet with the SAVC. This should be mediated by the ORI. It was proposed that Profs Williamson and Zilla be included in the UCT delegation.

The SAEC Chairperson, Prof Vanderschuren, proposed that the ORI and Legal Services are included in further discussions; and that internal processes should be dealt with before the ORI approach the SAVC. It was reiterate that the ORI is willing to assist.

9. Closure

The Forum meeting closed at 16:30.

10. Next meeting

The follow-up forum to discuss streamlining of animal research will take place in February 2018.

Abbreviations:

AEC – Animal Ethics committee

DAFF – Department of Agriculture, Forestry and Fisheries

FHS – Faculty of Health Sciences

NHREC – National Health Research Ethics Council

ORI – Office of Research Integrity

RAF – UCT Research Animal Facility

SAVC – South African Veterinary Council

SAEC – Senate Animal Ethics Committee

UCT – University of Cape Town

Addendum A

AGENDA FOR THE FORUM TO DISCUSS LEGAL REQUIREMENTS & STREAMLINING PROCESSES FOR ANIMAL RESEARCH IN THE FACULTY OF HEALTH SCIENCES

Venue: Post-graduate room 1, Barnard Fuller building

Date: Wednesday 13 September 2017, 15H00 to 16H30

Agenda

15h00-15h05 Welcome: Prof Karen Sliwa-Hahnle

15h05-15h15 Overview of regulations (DAFF, NHREC, SAVC): Dr Lyn Horn

15h15-15h20 Implementation of regulations (veterinary services): Dr Bert Mohr

15h20-15h25 Implementation of regulations (animal ethics): Mr Sidney Engelbrecht

15h25-16h00 Concerns of research community: All users of FHS animal facilities

16h00-16h05 Efficiency of the RAF, streamlining of processes: Mr Daniel Doetz

16h05-16h10 Budgets for the Faculty and RAF: Mrs Eliza Hui

16h10-16h15 Scenario planning: Karen Sliwa-Hahnle & Bert Mohr

16h15-16h25 Discussion: Proposal for next steps: All

16h25-16h30 Summary: Prof Karen Sliwa-Hahnle

**RESEARCH OFFICE**

Senate Animal Ethics Committee
Office of Research Integrity

Allan Cormack House
2 Rhodes Avenue (Cnr. Rhodes Ave. and Main Road)
Mowbray
7700
South Africa
Tel: +27 (0) 21 650 2593
E-mail: Marianne.vanderschuren@uct.ac.za

Internet: www.research.uct.ac.za

7 September 2017

Prof Bongani Mayosi, Prof Karen Sliwa,
Dean and Deputy Dean: Research
Faculty of Health Sciences

RE: Animal Research Regulations, Compliance and Implementation at UCT

Dear Profs Mayosi and Sliwa,

I write to you today to inform you of recent updates on the subject of regulations relating to animal research, compliance and the implementation of the regulations at UCT. The attached letter, sent to Prof Phakeng, DVC: Research and Internationalisation refers.

The letter addressed to Prof Phakeng is a result of recent reassessment and reconsideration of the legal framework that surrounds animal research. Discussions were held between the ORI Senior Manager, Dr Lyn Horn; the Director of Legal Services, Mr Claude Bassuday and myself in order to identify and unpack the applicable laws, guidelines, regulations and standards on this topic. The letter specifically outlines all of the acts, regulations and subsequent rules that relate specifically to animal-based research. The discussion was triggered and the letter compiled as a result of growing discontent, particularly in the Faculty of Health Sciences, regarding what is perceived to be "over-regulation" of researchers and is intended to provide a clearly articulated perspective of the landscape pertaining to this topic. The letter was considered by SEC on the 4th of September; SEC will be supplying the ORI, Legal Services Department and myself, as the SAEC Chairperson, with steps which need to be taken to support the issues contained therein.

The laws applicable to animal research are clearly outlined in the letter, it is now important that the efforts of the RAF, ORI, FHS Ethics Office and AEC, SAEC and animal researchers in the FHS are focused on complying with the regulations. The support offices (both administrative and veterinary) will need to assess which requirements are being met and if the mechanisms currently in place are sufficient in order to facilitate compliance. Furthermore it is important to identify any gaps, which may be present in the processes and propose and implement measures to mitigate these gaps. It may well be the case that additional staffing capacity is needed in certain offices in order to facilitate compliance efforts. Lastly, it is important that internal monitoring, quality assurance and auditing processes are put in place in order to ensure that the efforts outlined above are running efficiently and meeting the needs of the compliance processes.

It should be noted that the ORI, in collaboration with the affected parties and offices will be playing a key role in facilitating compliance processes. They will engage with the SAVC in an attempt to further streamline the authorisation process, and will continue to build positive relationships with SAVC colleagues in order to ensure the best possible outcome for UCT's applications.

As the SAEC Chair, I would like to encourage the meeting on the 13th of September to be a forum for constructive engagement, specifically on the topic of SAVC compliance, but more broadly on compliance with regard to animal research, including topics such as DAFF Section 20 approvals, post-approval monitoring and continued training efforts to support proficiency. Consideration of the items identified in paragraph 3, above, should form part of the discussion at the meeting.

I thank Prof Sliwa and her team for opening up the forum of discussion on the 13th of September. I look forward to a constructive session of engagement with the animal users, management, ethics office staff and veterinary staff of the Faculty of Health Sciences.

Yours sincerely,



A/Prof Marianne Vanderschuren
Chair: Senate Animal Ethics Committee

CC:

Prof Mamokgethi Phakeng	DVC: Research & Internationalisation
Dr Marilet Sienaert	ED: Research
Mrs Christina Pather	Acting ED: Research
Mr Claude Bassuday	Director: Legal Services
Dr Bert Mohr	Director: RAF
Dr Lyn Horn	ORI Senior Manager
Prof Patrick Commerford	FHS AEC Chair
Dr Arjun Amar	SCI AEC Chair



RESEARCH OFFICE

Senior Manager, Office of Research Integrity
Dr Lyn Horn

Allan Cormack House
2 Rhodes Avenue (Cnr. Rhodes Ave. and Main Road)
Mowbray
7700
South Africa
Tel: +27 (0) 21 650 1287
E-mail: lyn.horn@uct.ac.za Internet: www.research.uct.ac.za

31 August 2017

Prof M Phakeng
Deputy Vice Chancellor:
Research and Internationalisation

Dear Prof Phakeng

Re: Animal Research Compliance: Researcher concerns with the South African Veterinary Council (SAVC) authorisation processes.

The SAVC requires all personnel (staff and students) who perform research procedures on animals to be authorised by the Council. The authorisation process involves training and certification of competency (by a UCT veterinarian) for each type of procedure and for each animal species. Researchers may not commence research procedures on animals or have access to the highly scheduled drugs until this authorisation has been approved by the SAVC. Recently, many researchers, particularly at the Faculty of Health Sciences have expressed concern and resistance to this process. An unauthorised survey of animal users has been conducted by Joseph Raimondo who has also petitioned the Deputy Dean at the Faculty, Prof Sliwa to hold a meeting to discuss matters relating to the perceived over-regulation of animal research at UCT. The results of this survey can be accessed here: <http://goo.gl/hmPnyy>.

The suggested meeting is scheduled to take place on Wednesday 13th September 2017. Furthermore, it has been stated, in correspondence around this issue, that *"There is currently no specific legal framework to regulate the use of animals for scientific purposes in South Africa. The Veterinary and Para-veterinary Professions Act No 19 of 1982 (upon which the SAVC derives its mandate) does not address the use of animals for scientific and medical research. I, therefore, believe a thorough analysis of the legal basis for SAVC authorisation by researchers should be re-visited by UCT leadership"*.

The above statement is inaccurate. It is essential in our view, that Senior Management at UCT understands the current legal framework for animal research in South Africa. It is our opinion that UCT has no choice but to comply with the regulatory framework, which is outlined below. Failure to do so places the institution at risk on several accounts, including reputational risk, risk of prosecution, risk to funding and international legal assurances (such as between UCT and the NIH) and risk to the careers of the veterinary and para-veterinary staff, who form the foundation of the professional staffing support for the animal research platform at UCT and can be held "personally liable" for irregularities.

The following Acts, Laws, Rules and Regulations, South African National Standards and Guideline documents form the relevant regulatory framework for animal research in South Africa. Of particular relevance to this discussion are points 1, 4, 5, 6, 7 and 10 below:

1. **SANS 10386: 2008 The care and use of animals for scientific purposes.** This document is referenced by both the National Health Research Ethics Council 2015 Guidelines, as well as by the SAVC Rules (See especially Rule 32 below) published in the Government Gazette 9 November 2015.
2. **The National Health Act No. 61 of 2003.** Which in Section 72 gives a mandate to the National Health Research Ethics Council (NHREC) to "set norms and standards for health research involving humans and animals" and to "audit animal health research ethics committees".

3. **Ethics in Health Research: Principles, Processes and Structures. 2015. Department of Health South Africa.** This document was drafted by the NHREC (as per the mandate provided by the National Health Act) and is signed by the Minister of Health, who states in the forward that these guidelines “*contain national policy for conducting research responsibly and ethically.... And describe the regulatory framework in South Africa*”. Section 1.5 Research using Animals states at 1.5.4 that SANS 10386:2008 or the latest version provide the minimum benchmark to ensure the ethical and humane care of animals used for scientific purposes”
4. **The Veterinary and Para-veterinary Professions Act 19 of 1982.** Particularly Section 23(1)(c) 23.
 - a. *Unregistered persons shall not practice veterinary or para-veterinary professions.—(1)
No person shall in any manner whatsoever practise a veterinary profession or a para-veterinary profession unless he or she is registered or deemed to be registered in terms of this Act to practise the profession concerned.....*
 - b. *(c)The council may, after consideration of an application by a person not registered or deemed to be registered in terms of this Act, authorize him or her in writing to render subject to such conditions as the council may determine, for gain a particular service deemed in terms of the rules to pertain specially to a veterinary profession or a para-veterinary profession.*
 - c. The SAVC state the following: Section 23 of the Veterinary and Para-Veterinary Professions Act (Act 19 of 1982) prohibits unregistered persons from practicing any of the professions referred to in the Act or performing any of the procedures referred to in the Act. Whereas the Council would prefer all services rendered and/or procedures performed in terms of the Act to be rendered/performed by registered individuals, it recognises the need for such services to be rendered/procedures to be performed by other individuals under specific circumstances from time to time.
5. **The Veterinary and Para-veterinary Professions Act 19 of 1982, as amended. Rules relating to the Practice of Veterinary Professions. Rule 32. Research Animal Facilities.** These new rules were published in the Government gazette on the 9 November 2015 and came into force with publication. They pertain specifically to research animal facilities. Rule 32 contains 31 subsections that determine how animal research facilities should operate and include rules that relate directly to the authorisation of persons conducting procedures on animals in a research context.
 - a. 11(c) states that daily health checks and welfare monitoring of animals must be conducted by authorized or registered personnel
 - b. 15(c) states that scheduled 5 and above medicines must always be under the direct supervision of registered professionals
 - c. 18(b, c) Anaesthesia (as well as the monitoring, maintenance and recovery processes) must only be administered by registered or authorized persons with the exception of wildlife which must be administered by a veterinarian.
 - d. 31(c) states that all persons performing procedures in animals must be registered or authorized by the Council, with sufficient registered Veterinary and Para-veterinary staff to supervise all authorized personnel adequately
 - e. 31(d) States that animal welfare must be guaranteed in accordance with the relevant SANS and in the absence of a SANS then with internationally accepted standards
 - f. 31(e) States that welfare inspections must be conducted at appropriate intervals by registered Animal Welfare Organizations.
6. **The Veterinary and Para-veterinary Professions Act 19 of 1982, as amended. Rules Relating to the Practising of the Para-Veterinary Profession of Laboratory Animal Technologist.** Government Notice No 1445 of 3 October 1997
7. **The Veterinary and Para-veterinary Professions Act 19 of 1982, as amended. Rules Relating to the Practising of the Profession of Veterinary Nurse.** 1991, Government Notice No R1065 of 17 May 1991
8. **Animal Diseases Act 35 of 1984.** Section 20 permit requirements and laboratory certification by DAFF
9. **Genetically Modified Organisms Act 15 of 1997**
10. **Medicines and related substances control Act 101 of 1965.**

Hence, it can be seen from the above that South Africa does in fact have a clearly articulated and relatively current regulatory framework for animal research that must be adhered to.

The Office for Research Integrity (ORI) and the Senate Animal Ethics Committee (SAEC) do wish to provide an environment that supports animal research at UCT, on condition that such research is conducted responsibly according to high ethical standards and is compliant with current legislation.

We acknowledge that recently SAVC authorisation processes have become increasingly cumbersome and time consuming, outcomes of authorisation decisions have been inconsistent requiring the need for appeals and turnaround time has been prolonged, in some instances between four and six months.

We recommend that constructive engagement with the SAVC is needed to attempt to address current shortfalls in processes and to possibly explore areas where streamlining of authorisation applications and approvals can occur. For example, it has been suggested that once a person has been certified competent by a UCT veterinarian, and an application for authorisation has been made, that the person works under close direct supervision of registered personnel so that research may proceed without delays. This option may require additional supervision and, therefore, the employment of additional registered para-veterinary staff. Such an operational model could be suggested and implemented, if accepted.

Recently, the ORI has facilitated a meeting between a small delegation of scientists and staff with DAFF to discuss the Section 20 permit process. This meeting was very successful. The ORI is willing to attempt to facilitate a similar process with the SAVC, once stakeholders have decided what issues could reasonably be put forward for negotiation with the SAVC.

We, the signatories of this letter, do not believe that any form of non-compliance is an option. We also believe that compliance with the South African animal research regulatory framework should be implemented uniformly throughout UCT and not be implemented only at Faculty level, which has been the case in the past (See SAVC implementation letter of 2014 by Dean of FHS in 2014). We look to Senior UCT management to support this standpoint.

Yours sincerely,



Prof Marianne Vanderschuren
Chairperson:
Senate Animal Ethics Committee



Dr Lyn Horn
Senior Manager:
Office of Research Integrity



Mr Claude Bassuday
Director:
Legal Services

Scenario Planning (User Fees)

Service / Product (UCT-RAF)	2017 (ZAR)	2018 (ZAR) *	2019 (ZAR) *
Professional Fees (per hour)			
Lab animal technologist / vet nurse – training / supervision	127	273	443
Lab animal technologist / vet nurse	380	410	443
Veterinarian – training / supervision	202	437	708
Veterinarian	607	656	708
Comparative costs (Animals)			
Rat supply (adult)	211	232	255
Rat maintenance (per cage per week, IVC)	104	115	126
Mouse supply (adult, SPF)	88	97	107
Mouse maintenance (per cage per week, SPF)	59	64	71
Health screen (standard panel, per rodent)	6 762	7 438	8 182

* Illustrative rates are shown, assuming 8% increase in salaries and 10% increase in animal-related fees on annual basis.

Scenario Planning (Health Sciences) – Models

Details	Researcher model ↔	Hybrid model ↔	Professional model
Model description	Researchers perform all own procedures	Researchers, techs & vets do procedures	Technologists or vets perform procedures*
Students performing procedures	+++++	+++	+
Student exposure to procedures	+++++	+++(++)	+(++++)
Authorised persons (student/researchers)	+++++	+++	+
Impact of delays in authorisation	+++	++	+
Registered persons (vets/technologists)	++	++(+)	+++
Salary fees (UCT-RAF)	++	++(+)	+++
Authorisation fees	+++	++	+

* Professional model: Researchers may still perform specialized procedures, e.g. cardio-vascular surgeons.