NOTIFICATION: Addressing common challenges associated with animal research and the Department of Agriculture, Forestry and Fisheries (DAFF)

UCT's Office of Research Integrity (ORI) recently led a delegation of UCT staff to the DAFF Animal Health Unit to discuss various topics relating to laboratory and section 20 approvals. This meeting was held as a result of an initial written request for clarification from DAFF on a number of issues, some of which were satisfactorily resolved in writing; others required further discussion. Below are some of the outcomes of the letter and meeting which affect the UCT animal research community.

Scope of Section 20 of the Animal Diseases Act (Act 35 of 1984)

Section 20 (c) (ii) refers to "*any agent which is capable of spreading any animal disease or parasite*". Therefore, any animal product or material may be considered an agent capable of spreading diseases or parasites. This extends to other, non-animal, materials that may be capable of spreading any animal disease or parasite (e.g. human tissues contaminated with possibly zoonotic diseases, contaminated environmental samples, vector samples etc…).

If research involves diseases or parasites only capable of infecting humans and is conducted solely on humans then the study may be considered exempt from the Section 20 requirements. However, if the research involves the use of animals or animal products/materials (e.g. antisera, antibodies or serum derived from animals or animal products) regardless of the topic, then a Section 20 permit may be needed as the animal materials used may be capable of transmitting animal diseases or parasites.

All Section 20 applications are evaluated on a case-by-case basis due to the varied and unique circumstances and conditions of the research. The evaluation is performed in such a manner so as to ensure an acceptable standard of risk mitigation for the research.

Approval for laboratory-based projects

DAFF are willing to consider inspecting and auditing laboratories in which certain projects and groups of projects take place. Having a clear understanding of the environment in which the projects will occur, and developing a register of 'trusted/approved facilities' will result in a streamlined process for applications.

When working with a disease or pathogen that is not known to be in South Africa DAFF may require a higher BSL level than what might be considered the standard requirement from an international perspective

ACTION: UCT needs to inform DAFF which laboratories will form part of this 'trusted/approved facilities' grouping. Researchers are invited to nominate their laboratories to form part of this group. For further information, please contact Paula Saner: paula.saner@uct.ac.za.

Approval for research programmes versus projects

From UCT's perspective, certain research projects can be regarded as umbrella projects (i.e. with the same methodology applying for several projects, except for a change in one very specific aspect e.g. the gene that is isolated or a type of anti-sera to be used). Although DAFF does not generally approve 'umbrella' research programmes it may be possible to have a 'baseline' approval; amendment requests could then be made with a reference back to the approved project i.e. so that a full new application does not have to be submitted. Such amendments could undergo an 'expedited' or fairly rapid review process. It would also be crucial for DAFF to know who the PI is for such project i.e. the person taking overall responsibility especially when students are involved.

Annual reports

DAFF have asked us to submit annual reports for projects which have received Section 20 permits.

ACTION: The ORI will start following up on annual reports in line with the AEC reporting cycle, early in 2018. We await confirmation of the content requirement for the annual report, before sending out a formal notification/reminder.

Wildlife research

A Cape Nature or SANParks permit does not exempt the requirement for a Section 20 permit for relevant research in any context that could result in the inadvertent transmission of an animal disease. During the Section 20 permit application DAFF may require that the local state veterinarian assess certain aspects of a given project.

> **Research versus diagnosis:** Diagnostic specimens, imply that a diagnostic test is performed on the specimen, there is a result which is used for some purpose and the specimen is destroyed. Collection of diagnostic specimens (if treated as described above) does not require a Section 20 permit. If the sample is positive for a notifiable or controlled animal disease the state veterinarian should be notified. For example, DNA samples collected from Rhino by SAN parks are generally regarded as 'diagnostic' and a Section 20 permit is not needed. *If many diagnostic specimens are collected and the results published this would be considered research and a Section 20 permit required. If samples are to be stored in a repository or biobank this would also require a permit. If in doubt ask the ORI to consult DAFF.*
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> **Marine research**, including research on fish and marine mammals is not handled by DAFF, i.e. Section 20 permits are not required. However some level of permission may be required and queries in this regard must be directed to the Department of Environmental Affairs and Tourism.