

Frequently Asked Questions DAFF¹² Processes @ UCT

Office of Research Integrity (ORI) Contacts

Mr Werner van der Ross Senior Admin Officer: Animal & Biosafety Compliance
werner.vanderross@uct.ac.za **Role:** Initial queries, review and comment on DAFF applications, escalation of applications for institutional signature, maintenance of ORI DAFF-based database and documents, external liaison with DAFF, submission of completed DAFF applications, post-submission assistance with project queries.

Mrs Paula Saner Research Integrity Co-ordinator
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Question 1: I am using (xyz) pathogen/virus/disease/reagent/antibody, do I need to apply for a Section 20 permit?

Attached (**APPENDIX B**) is a brief list of items which WILL ALWAYS require a Section 20 application. Please note that this list is not comprehensive. If you are uncertain, please contact Werner with a brief description of the project (including details on handling, storing and disposing of the material). The ORI will liaise with DAFF on your behalf to establish whether a Section 20 permit will be needed. DAFF take a number of factors into account when addressing queries including overall risk; what the pathogen/virus/disease/reagent/antibody is; its origin; its intended use and, how it will be stored and/or destroyed at the end of the project. Thus, we cannot give you a simple yes/no answer without contacting our colleagues at DAFF. (Please see the Animal Diseases Act, Act 35 of 1984, for full information.) Please also refer to “Scope of Section 20” in the notification document.

Question 2: Is there a list of approved/recognised suppliers of animal products?

No, DAFF has indicated that they cannot give us such a list. Please see the answer to question 1 above.

Question 3: I need to apply for a DAFF Section 20 permit, how do I do this?

In order to make an application you will need to submit the following to Werner:

1. Completed DAFF Section 20 application form (leave out section 11, Werner will obtain the institutional signature on your behalf), forms can be obtained from Werner or the “Compliance: Animal Rsch” Vula Site
2. Short summary of the project (1-2 pages)
3. SOPs mentioned in the application
4. Product specification sheets for material used in the project

It is important to note that high quality applications, which address as many of DAFF’s (likely) queries and supply the necessary information are likely to progress through the process with fewer bumps along the way. DAFF are interested in topics like containment, storage, transport and waste disposal, it is therefore important to adequately address these topics in the application form.

Once submitted to Werner, the application undergoes an internal check for completeness and consistency. If the application requires additional information or amendments, Werner will alert the applicant and request the necessary changes. Once satisfied with the application, Werner submits for institutional signature. Once

¹ DAFF applications included in this document: Section 20 and Import Permits, GMO licenses

² Following the 2019 National Elections, DAFF have become the Department of Agriculture, Land Reform and Rural Development (DALRRD), we still refer to them, colloquially, as DAFF.

the institutional signature has been obtained Werner then submits the application to DAFF. When the application is submitted to DAFF, Werner will cc the applicant/PI/supervisor, as a means to confirm submission.

Question 4: How will I know if DAFF have any queries? How will I know if the permit has been approved?

In an effort to ensure that the correct messages are reaching the correct people, the ORI will, as a matter of course, include Werner's contact details on the application form (in addition to the member of the research team listed as the contact person). This is done with the aim of limiting miscommunications and ensuring the questions/permits reach the correct people.

It is strongly advised that all communications regarding DAFF matters are channelled through the ORI. We have developed strong working relationships with our DAFF colleagues over the past few years and are in a good position to advocate for UCT applications and limit misunderstandings. DAFF prefer to communicate through our offices and will use this method as a first attempt.

Question 5: When should I submit my DAFF Section 20 application?

You must make your application to DAFF **BEFORE** your project starts, DAFF **do not consider 'retrospective' applications**. You should not start your project until you have received your Section 20 permit. It is possible to make a simultaneous submission to your local AEC and DAFF, and let the processes run in parallel.

Question 6: How long does the DAFF Section 20 application process take?

On average applications take 4 weeks from the date of submission to DAFF. Some applications have been approved in a shorter timeframe, these were high quality applications where DAFF did not need to further interrogate any aspects of the projects. Some applications have taken longer than 4 weeks, this is usually because applications are incomplete; do not sufficiently address the points in the application form; do not supply supporting information or, applicants are slow in responding to DAFF's queries. The turnaround process depends on synergy between the applicant, the ORI and DAFF.

Question 7: I have a DAFF Section 20 Permit, but want to make changes to my project, what should I do?

DAFF consider amendments, using processes similar to UCT AEC practices, please contact Werner further assistance. You will need to supply Werner with a copy of the original permit and a document outlining which parts of the approved project are no longer taking place and what is replacing them. This should take the form of the initial application form using track changes to illustrate the requested amendments.

Question 8: Are there any costs associated with a DAFF application?

Section 20 applications: No

GMO applications: Yes, a nominal fee, as per the application form

Import permit applications: Yes, a nominal fee, as per the application form

Please note that DAFF are not vendors on UCT's payments system, please take this into account when factoring in any payments associated with GMO or Import Permit applications. Because so few payments are currently made to DAFF offices it is easiest to either do an EFT to them and claim a reimbursement from UCT or to do a direct deposit using petty cash. We frequently review this decision to ensure that it is still a feasible option.

Question 9: What guarantees do I have that the information contained in my application will not get into the wrong hands/be used by government (or other researchers) for to conduct their own research?

The DAFF Section 20 team are conscious of the concerns regarding the confidentiality and privacy of the applications we submit. They are bound by the Public Servants Act and also the Animal Diseases Act, all

information is treated as confidential and is protected by these acts. Section 25 of the Animal Diseases Act (Act 35 of 1984) states the following:

1. No person shall, except for the purpose of the performance of his duties under this Act, or for the purpose of legal proceedings thereunder, or when required to do so by any competent court, excluding a civil court, or under any law, or with the written consent of the Minister, disclose to any other person any information acquired by him in the performance of his duties under this Act, and which relates to the business or affairs of a person.
2. No person shall, except with the written consent of the Minister, give access to any person other than the director, an officer, or any other person entitled thereto in terms of any law, to any records or registers kept in terms of this Act.

The Section 20 team have reviewed the application process and taken UCT researchers into account during the review process. **Please note:** DAFF will not communicate with anyone who makes a project enquiry who is not (a) the researcher/applicant, (b) listed on the application as the 'contact person' or (c) is a staff member in the ORI. This is to ensure that confidentiality is maintained.

Question 10: Who is eligible to apply for DAFF Permits?

All researchers at UCT, planning to conduct projects that will need either GMO, Section 20 or an Import Permit must make applications. **Please note:** If you are a RSA PERMANENT RESIDENT, and making an application for an import permit, you will need to supply a copy of your permanent residency document when submitting your application forms.

APPENDIX A

Animal Diseases Act, 1984 (Act No. 35 of 1984)

Section 20. Limitations on investigations, experiments and research with, and manufacture and evaluation of, certain products

No person shall, except under a permit and in compliance with the conditions which are prescribed or, in any particular case, determined by the director —

- a. conduct any investigation, experiment or research with any vaccine, serum, toxin, anti-toxin, antigen or other biological product which consists or originates wholly or partially of, or from, any micro-organism, or of or from the glands, organs, fluids, or any other part, of an animal or parasite: Provided that the foregoing provisions of this paragraph shall not apply to any substance in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);
- b. for the manufacture or evaluation of a product or remedy used for or intended to be used at or for the testing, diagnosis, prevention, treatment or cure of any animal disease or parasite, or for the maintenance or improvement of the health, growth, production or working capacity of an animal, use any vaccine, serum, toxin, anti-toxin, antigen or other biological product referred to in paragraph (a); or
- c. for the purposes of any investigation, experiment or research referred to in paragraph (a), or for the manufacture or evaluation of a product or remedy referred to in paragraph (b) —
 - i. infect or contaminate any animal or any other thing with any animal disease or parasite; or
 - ii. introduce into or collect in the Republic, or have in his possession, or remove or transport from the place where it is normally found or kept, any controlled animal or thing, or any protozoon, bacterium, virus, fungus, parasite, other organism or agent which is capable of spreading any animal disease or parasite.

https://www.acts.co.za/animal-diseases-act-1984/20_limitations_on_investigati

Application cycle: DAFF Section 20

