BIOSAFETY & BIOSECURITY NEWSLETTER



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Section 20 permits and permit amendments

Researchers are reminded that Section 20 of the Animal Diseases Act (Act 35 of 1984) requires research using animals, animal biological samples and animal pathogens to obtain a Section 20 permit BEFORE their research commences. These permits applications must be submitted through the Office of Research Integrity (ORI), in order to obtain institutional sign-off. <u>Researchers MAY submit</u> <u>Section 20 permits in parallel with their applications to the Faculty of Health Sciences Animal Ethics Committee (FHS AEC) to reduce waiting times.</u>

Amendments

In addition, when submitting an amendment to your FHS AEC-approved project, the AEC will flag if you need to submit an amendment to your Section 20 permit based on whether there is a change in the BIOSAFETY risk or scope of your project. Circumstances that WILL trigger an amendment include:

- Change in Pl
- If you are collecting samples 'in the field' (i.e., in the wild), and you want to change the location of your sample collection
- Extension of the duration of your study
- Addition of experimental procedures not covered in the original permit
- Change in experimental animals (e.g., from pigs to sheep)
- Changes to your research which affect the BIOSAFETY risk of a project (e.g., change from handling a hazard group 2 organism to handling a hazard group 3 organism, adding aerosol-generating procedures while handling pathogens, etc.)
- Changes in the facility where your research is being conducted (e.g., moving from the lab approved in your project to a different lab, especially if you are moving to a different biosafety level lab (from BSL3 to BSL2)
- Additional products, reagents etc that require an import permit (an import permit will not be issued by the relevant Department of Agriculture (DoA) office, if it is not covered by your Section 20 permit).

The FHS AEC will flag projects that are likely to require an amendment to their Section 20 permits. Please contact Ms Lisa Williams (<u>lisa.williams@uct.ac.za</u>), in the ORI, who will facilitate the submission of your permit to the DoA.

Going forward, Dr. Sarita Groenewald, the ORI's Biosafety and Biosecurity Specialist, will collaborate with researchers to prepare initial Section 20 applications that address the overall needs of their research projects and carefully consider biosafety risks. The aim is to describe projects in a way that covers the need for future Section 20 amendments, while still ensuring that applications meet the biosafety requirements of the Section 20 permit process.







Internal Facility Audits

As a part of the new integrated biorisk at management programme UCT, the biosafety and environmental risk specialists (Sarita Groenewald and Kim van Reenen) must conduct internal facility audits and inspections of all life sciences research and teaching facilities on and off campus. The scope of the inspections will include infrastructural and engineering controls, compliance with national legislation, regulations and guidelines for the use, handling and disposal of potentially biohazardous organisms and materials, genetically modified organisms (including genome-edited organisms) and chemicals. We will also engage with the laboratory managers, H&S reps, Scientific Officers, to give feedback on our activities and gather specific information regarding biosafety, biosecurity and environmental safety training needs, specific challenges they face, and other biosafety-related concerns/issues.

We will engage with the relevant departments to find suitable dates for these visits. The first facility inspections have been scheduled for June 2025.



Improved Resources Page

We are excited to announce that the Biosafety and Biosecurity Resource Website has been improved, and users can now easily access relevant information via the direct links on the page. Click on the "Biosafety and Biosecurity resources" link on the OHSE <u>Biosafety | Staff</u> page.

The resources are grouped into specific categories, including general biosafety and biosecurity manuals, the South African biosafety and biosecurity-related legislation, biological risk assessment, and other relevant publications.

Please refer to the **SA Guidelines: Biosafety and biosecurity** compliance in research, teaching and testing facilities in **SA** to help you navigate the national regulatory framework.

If you need guidance when completing Section 20 and Veterinary import permits, please see the **Guideline for Applying for Section 20 and Veterinary Import Permits under the Animal Diseases Act** under the heading "Animal Health".

New resources and updated guidelines will be uploaded regularly. Please share any relevant biosafety-related literature that will be useful for the UCT research community.

Successful training sessions!

The ORI hosted 3 Biosafety and Biosecurity Workshops in March and April. The first was a basic introduction to integrated biorisk management and the South African regulatory framework aimed at students (13 participants), the second a more advanced session which also included biosafety and biosecurity risk assessments, aimed at staff (25 participants) and the third focused on "Mastering Biosafety and Biosecurity Forms" (13 participants).



In addition to receiving helpful training, the sessions also served as a networking opportunity for participants to build relationships with colleagues working in different departments at UCT. Here is some feedback from the community:

"The enthusiasm of the instructor made the session engaging and interesting" "I liked the case study at the end"

"The promise of support from UCT is very nice. This workshop is proof of that support in effect." "I got to understand the difference between biosafety and biosecurity." "Learning about the researcher's responsibility"

"This was a great introduction to Section 20 applications. I liked that context was given for why we need to do them and the perspective we should keep in mind when tackling Section 20 applications. I also like that I could ask very specific questions and that they were well received."



Updates to the F/IBC application form

Funder requirements necessitated updates to the Faculty/Institutional Biosafety Committee application form. The changes are as follows:

- IBC meeting minutes need to be publicly available on an institutional website. In section 1 of the form, we have provided an opportunity for researchers to *provide an alternative title for their research project*. We are aware that there may be sensitive, confidential or proprietary information in the project title as well as other sections of your applications to the F/IBC. The IBC has undertaken to make publicly available only the necessary information outlined by the US Office for Science Policy (OSP) requirements, and will treat sensitive, confidential and proprietary information with the due care that it requires. The minutes will be published starting from 25 June 2025, no back-dated minutes will be published. Please rest assured that the IBC and ORI are working hard to ensure necessary protections are in place to ensure the integrity of the committee's work, while meeting funder requirements.
- Research involving **gene drive modified organisms (GDMOs)** may necessitate risk assessments with a broader scope of considerations due to greater uncertainty of the technology and potential uncertainty of the impact of the GDMO. In the new section F2 of the F/IBC form, researchers can indicate that their research involves the use of GDMOs.
- Dual-use research of concern (DURC) and research activities involving the creation and/or use of pathogens with enhanced pandemic potential (PEPP) require additional IBC review and oversight. The new section 3 of the F/IBC form contains a checklist of questions to flag DURC and PEPP research.



Contacts

Please feel free to contact us in the ORI should you have queries related to biosafety and biosecurity. Your queries can be directed as follows:

• Dr Sarita Groenewald

(<u>sarita.groenewald@uct.ac.za</u>) for GMO facility registrations and imports, biosafety audit responses, the South African biosafety and biosecurity regulatory framework and questions about biosafety compliance.

• Mrs Suraya Azam

(<u>suraya.azam@uct.ac.za</u>) for submission of Section 20 permits applications and queries related to the IBC.

• Ms Lisa Williams

(<u>lisa.williams@uct.ac.za</u>) for submission of Section 20 amendments.

If you want to enquire about import permits relating to the Department of Health, please contact Dr Blessing Silaigwana (blessing.silaigwana@uct.ac.za)



APPLICATION FORM

What you can do

Share this newsletter with colleagues and students in your department.

Visit our revamped webpages and let us know if they are useful, or missing something.

Share resources with us. Please let us know if you have come across a useful resource that improves, simplifies, or provides scientific evidence for your own biosafety and biosecurity management so we may add it to our repository.

Remember to submit Section 20 permit and amendment applications to the ORI for review and final signature (the Department of Agriculture (DOA) won't process an application without our signoff!).

