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SOP 4.8 MANAGEMENT OF BIOSECURITY AND BIOSAFETY, AND STORAGE OF BIOLOGICAL MATERIALS OF HUMAN AND ANIMAL ORIGIN

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MANAGEMENT OF BIOSECURITY AND BIOSAFETY, AND STORAGE OF BIOLOGICAL MATERIALS OF HUMAN AND ANIMAL ORIGIN

1. Purpose

The purpose of these guidelines is to regulate the management of work with tissues and biological materials that could carry a risk of releasing pathogens or genetically modified tissues into the environment. It will define biosafety levels and formalise a procedure for the storage of biological samples of human and animal origin. Data is understood here as any information derived from experimental generation or information processing related to biological samples and materials which are subject of this SOP.

2. Preamble

2.1. Working with biological materials can lead to the accidental release of pathogens or biological tissue from the laboratory space at Rhodes University into the environment or it could result in contamination or exposure of Rhodes University staff or students to genetically modified organisms or to pathogen-containing materials.

2.2. This SOP is a common document for the Rhodes University Human Ethics Committee (RUHREC) and the Rhodes University Animal Research Ethics Committee (RUAREC).

2.3. The SOP is guided by the research policies and ethical standards of Rhodes University, as well as the following documents:

1.) Department of Agriculture, Forestry and Fisheries (DAFF) Procedure Manual for approval of veterinary laboratories. [1]

2.) Department of Health - REGULATIONS RELATING TO THE REGISTRATION OF MICROBIOLOGICAL LABORATORIES AND THE ACQUISITION, IMPORTATION, HANDLING, MAINTENANCE AND SUPPLY OF HUMAN PATHOGENS. [2]

3.) Chapter 4: Human and Animal Biological Material and Data for Research in the South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd ed. (the South African National Department of Health - NDoH 2024)[3].

4.) Department of Health – REGULATIONS FOR HAZARDOUS BIOLOGICAL AGENTS, OCCUPATIONAL HEALTH AND SAFETY ACT, 1993 (see for details; website accessed on 13th June 2024). [4]

5.) Townsend B.A. and Shozi B., *Altering the Human Genome: Mapping the Genome Editing Regulatory System in South Africa.*[5]

6.) Chapter 5 of the Genetically Modified Organism Act no. 15 of 1997. [6]

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[1] https://old.dalrrd.gov.za/vetweb/epidemiology/Laboratories/PM%202018%20Procedure%20Manual%20DAFF%20Approval%20of%20Laboratories.pdf

[2] https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon178.pdf

[3] https://www.health.gov.za/wp-content/uploads/2024/05/NDoH-2024-Health-Research-Guidelines-3rdEdition-v0.1.pdf

[4] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.labour.gov.za/DocumentCenter/Regulations%20and%20Notices/Regulations/Occupational%20Health%20and%20Safety/Regulations%20for%20Hazardous%20Biological%20Agents.pdf

[5] https://www.ajol.info/index.php/pelj/article/view/235587

[6] https://www.gov.za/documents/genetically-modified-organisms-act-0

7.) Cartagena Protocol on Biosafety and the text of the Genetically Modified Organisms Amendment Act no. 23 of 2006. [7]

8.) International Standardisation Organisation (ISO) Standards no. 17025 and the South African National Accreditation System (SANAS) accreditation of laboratories requirements. [8]

9.) List of Human Notifiable Disease in South Africa. [9]

3. Biosecurity at Rhodes University

3.1. Biosecurity or biosafety refers to the protection of Rhodes University staff and students from being exposed to harmful biological materials or pathogens.

3.2. Biosafety refers to the containment of all pathogens, microorganisms, and any biological material of human origin from being transferred out of a laboratory facility of Rhodes University. The severity of containment required is reflected in the biosafety level as defined below.

3.3. Only biosafety level 1 and 2 laboratories are available on the Rhodes University campus.

3.4. Dangerous material which are not of biological origin, e.g. chemicals or radioactive materials, are not subject of the current SOP. These considerations are addressed by adherence and compliance with the respective South African legislation.

4. Biosafety levels

4.1. Biosafety level 1: The level of containment required for biosafety level 1 is a regular laboratory where pathogens of no threat or limited and predictable threat to human health can be worked with. Such pathogens include bacteria such as probiotic species, i.e., Lactobacillus spp. species which are not known to cause disease in humans. Students and staff from particular departments are authorised to enter a biosafety level 1 laboratory while wearing basic protective personal equipment such as lab coats.

4.2. Biosafety level 2: This refers to a laboratory which has a self-closing door and where only authorised staff and students from Rhodes University can enter. Pathogens to be worked with for this biosafety level, would include analysis of water samples which might be contaminated with faecal matter, Escherichia coli, Salmonella spp. (DAFF or Department of Health authorisation is necessary to work with such pathogens) and/or microorganisms extracted and/or detected during a scat analysis. A quantifiable expression of the risk would be an infectious dose of the pathogen, and this would be 106 cells or spores/ova or less. Biosafety level 2 would also include work with human cancer and other cell lines.

4.3. Biosafety level 3 would include pathogens, which include *Brucella spp.* or other notifiable diseases or where the risk to the laboratory personnel of contracting infections from the inoculated pathogen is high. A quantifiable expression of the risk would be the infectious dose of the pathogen, and this would be 1000 cells or spores/ova or less. A special level 3 box or containment chamber needs to be procured/purchased for working with these types of pathogens. Such a box must be present in a controlled-access laboratory and biosecurity of any and all genetic/microbial cultures must be ensured by the cultures being stored in a locked fridge. Regular testing of the personnel for any symptoms or biological contamination

[7] https://www.gov.za/sites/default/files/gcis_document/201409/a23-060.pdf

[8] https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html#:~:text=ISO%2FIEC%2017025%20enables%20laboratories,nationally%20and%20around%20the%20world and https://www.sanas.co.za/Pages/index.aspx

[9] https://www.nicd.ac.za/wp-content/uploads/2017/06/NMC-list_2018.pdf

with the pathogen in question must be performed before, during and after the completion of the project. Isolating containment of the biosafety level 3 inoculation space must be demonstrated and recorded as outlined by DAFF.[10] Currently, Rhodes University does not operate any Biosafety 3 facility, but one might be established in the near future. The current SOP will be updated accordingly, once such a facility has been established.

4.4. Biosafety level 4: This involves containment in completely contained hazmat suits with their own air supply and these would normally be required for working with haemorrhagic fever pathogens such as Ebola Viral Disease (EVD) and Marburg viruses. These are not to be worked with at the Rhodes University campus.

5. Storage, management, and disposal of biological materials

5.1. At Rhodes University, staff and students do not perform or participate in clinical trials. However, it is noted that various departments conduct projects, which can be approved as non-clinical trial project by RUHEC and/or RUAREC and where biological samples of animal or human origin might be collected. Therefore, research applications reviewed by RUHREC, and/or RUAREC would apply to animal/human biological samples obtained for in-vitro or ex-vivo analysis or from commercial sources, e.g. cell cultures or human cells from volunteers (donors) or a traceable commercial supplier.

5.2. Research involving the "use of human biological material (e.g., human cell lines from a commercial source(s) or established cell lines falls under risk category 1: no ethical clearance required.[11] Such biological samples are from completely anonymised sources that cannot be traced back to human donors.

5.3. Research involving saliva or blood samples taken/obtained from human volunteers under professional oversight, e.g. by a nurse who takes the biological samples from human participants (for example monitoring of metabolic activity or measurement of concentration of important metabolites or homeostatic parameters, e.g. glucose levels in the blood from human volunteers). Such sample collections can only take place after all relevant ethical procedures, consent and engagement with human participants have been completed. Participant anonymity is protected by allocating each participant a participant identification code (PID). The sheet linking PIDs with participant names and research responses must be securely stored in a location separate from the research data and only accessible to the study team from Rhodes University such as students, academic staff members, research associates or postdoctoral fellows.

5.4. The departments of Biochemistry, Microbiology and Bioinformatics engage in research using recombinant organisms, and their GMO permits are in place.

5.5. All human and animal tissue samples must be traceable. This means that human cell lines or tissue samples must be procured from registered and (inter)nationally recognised and reputable suppliers.

5.6. Animal tissues must be collected during RUAREC-approved projects or only obtained under the material transfer agreements (MAT), which are concluded between Rhodes University academic staff and a reputable international or local supplier/academic or research

[10] https://www.dalrrd.gov.za/images/Branches/AgricProducHealthFoodSafety/animal-health/epidemiology/laboratory-approvals/laboratory-approval-procedures/checklist-biosafety-level-bsl-3.pdf, https://www.dalrrd.gov.za/images/Branches/AgricProducHealthFoodSafety/animal-health/epidemiology/laboratory-approvals/laboratory-approval-procedures/checklist-biosafety-level-bsl-3.pdf for details (website accessed on 31st May 2024).

[11] SOP 2.3 RU-HREC REVIEW PROCESSES, p2.

institutions. MATs must be run through the usual and standard contract vetting and signature procedures of Rhodes University.

5.7. Storage of animal tissues should be in fridges at 2-8 °C or at -80 °C in line with the best international standards. [12]

5.8. Each laboratory that works with samples mentioned in this protocol must have a waste disposal protocol and documents must be archived for at least 5 years for each project. Any extension to this period must be authorised by the RUHEC, RUAREC and the committee from point 6 of this SOP. Once the biological samples have reached the end of their useful stage, they are termed hazardous Biological Agents (HBAs). The biological waste includes any and all biological materials which are of no further practical use, e.g. in generating research or teaching-related data, they are considered biological waste. Such biological waste and all HBA waste is stored in identifiable biohazardous waste containers that can be sealed and collected by the HBA waste company that complies with the National Environmental Management Water Act, 2008 (Act No. 59 of 2008) for removal.

6. Monitoring of the SOP execution.

6.1. A committee is to be set up as soon as possible from the adoption of this SOP to oversee its implementation. The committee is to be composed of the following persons:

- DVC for Research, Innovation and Strategic Partnerships or their representative
- Chairperson of RUHREC
- Chairperson of RUAREC
- Health and Safety Representative (SHE Rep)
- Heads and Chief Technical Officers of the Departments of Zoology and Entomology, Ichthyology and Fisheries Science, Biochemistry and Microbiology and Biotechnology Innovation Centre

6.2. This committee is to meet at least twice a year to discuss the biosafety and biosecurity measures and needs on campus.

6.3. Ad-hoc meetings are to be held where deemed necessary. Communication may be via in-person meetings or technical means, such as email or Zoom, as the need arises.

6.4. At the same time, the committee will be notified and from time-to-time express opinions on the safety implications of research that has been approved by RUHEC and/or RUAREC.

7. Databases, registries, and repositories

Rhodes University has the capacity to freeze biological material up to -80°C, which is sufficient for the purposes required by Rhodes researchers.

8. Effective date of this SOP

20 July 2024 (RU-AREC) and 26 July 2024 (RU-HREC). The next revision date is July 2027, or as deemed necessary by a quorate meeting of RU-AREC and/or RU-HREC.

[12] Patel K, Chotai N. Documentation and Records: Harmonized GMP Requirements. J Young Pharm. 2011 Apr;3(2):138-50. doi: 10.4103/0975-1483.80303.