	DEPARTMENT OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT (DALRRD) DIRECTORATE ANIMAL HEALTH
	GUIDELINES FOR APPLICATION FOR A PERMIT UNDER SECTION 20 OF THE ANIMAL DISEASES ACT 1984 (ACT NO 35 OF 84)
THIS VERSION:	**Version 22/2**
APPROVED BY:	**Director Animal Health**
SIGNATURE:	
APPROVAL DATE:	2022 -08- 31
NO OF PAGES:	**13**

CONTENTS

1. Purpose

1.1. The purpose of this document is to provide guidelines for the application procedure for permission to conduct research under Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84).

1.2. These are guidelines only and do not absolve the researcher from compliance with any other legislation within the Republic of South Africa, or from providing any further information that may be requested during the evaluation process of the Section 20 application.

1.3. If you are unsure if you require a Section 20 permit or not, please send a written enquiry to the Section 20 Secretariat, which should include a summary of the study methodology:

Miss Marna Laing
Section 20 Secretariat
Directorate: Animal Health
Department of Agriculture, Land Reform and Rural Development
Tel: 012 319 7442
Fax: 012 319 7470
Email: MarnaL@dalrrd.gov.za
Courier/ hand delivery: Attention Miss M Laing, Office G80, Delpen building, 130 Annie Botha Ave, Gezina, Pretoria.

The enquiry will be assigned to a Section 20 official who will liaise with you further regarding the need for a Section 20 permit. If a permit is not required, you will be informed of this in writing (via an official letter or email). You may not assume that a Section 20 permit is not required unless this has been confirmed in writing;

If you have not received any feedback from either the Secretariat or a Section 20 official after 14 working days, kindly contact the Secretariat.

1.4. A Section 20 permit will contain the conditions approved for the research project based on the information provided in the application form as well as any further additions, changes and/ or alterations or other information received in writing during the evaluation and processing of the application.

2. Applicable legislation

2.1. The Animal Diseases Act 1984 (Act no 35 of 84) and the Animal Diseases Regulations (R.2026 of 1986).

Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) *"Limitations on investigations, experiments and research with, and manufacture and evaluation of, certain products"* states that:

"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 9a); 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."

2.2. Any other relevant Veterinary Procedural Notice and Standard Operating Procedure.

2.3. Any other applicable South African legislation.

This document does not supersede any other relevant legislation. You may be required to apply for other permissions under other relevant South African Acts.

3. Obtaining the application form

3.1. Please ensure that the correct, updated application form for permission under Section 20 of the Animal Diseases Act (Act 35 of 1984) to perform research/study is completed.

3.2. Application forms may be obtained from the Department of Agriculture, Land Reform and Rural Development (DALRRD) website (www.dalrrd.gov.za) or from the Section 20 Secretariat at the following address:

Miss Marna Laing
Section 20 Secretariat
Directorate: Animal Health
Department of Agriculture, Land Reform and Rural Development
Tel: 012 319 7442
Fax: 012 319 7470
Email: MarnaL@dalrrd.gov.za

3.3 The following has to be taken into account:

- It is advised that application forms and supporting documentation are submitted at least three months prior to the planned start of the research/study. No part of the research/study (including collection of samples) may commence without a Section 20 permit or an exemption.
- We kindly request that only one application is included per email.
- If you have not received any feedback from either the Secretariat or a Section 20 official after 14 working days, kindly contact the Secretariat to ensure the application has been delivered.
- Please include the title of your research project with every enquiry and clearly indicate that it is not a new application but only enquiry.

4. Completion of the application form and attachments

4.1. It is the responsibility of the researcher as named in the application form to ensure that all supplied information is correct and true;

4.2. Please ensure that the contact details provided are correct and that the contact person is available during the Section 20 evaluation process;

4.3. The application must be signed by the supervisor of the student, as well as the person responsible for the main laboratory(ies)/ facility(ies) where the research is to be conducted.

4.4. Please provide a summary (maximum 1-2 pages) of the research/study methodology focussing on the proposed handling, testing, distribution, facilities and storage of biological materials, in section 9 of the application form or as a separate attachment;

4.5. Please ensure that the required level of containment corresponds with the biosafety level (BSL) of the proposed nature of work to be conducted. For biosafety levels of pathogens, refer to the standards set by the World Organisation of Animal Health (OIE) within the OIE Terrestrial Manual at www.woah.org;

4.6. The Director: Animal Health (DAH) may determine that the biosafety and biosecurity measures, including vector protection where relevant, of laboratories, biobanks and other relevant facilities to be used for the research project require a physical inspection, or evaluation in another manner determined suitable by the DAH, in order to ascertain their suitability for the project. If a DAH recommendation report for any of the abovementioned facilities is already available, please ensure that it is attached to the Section 20 application form;

4.7. The BSL-3 status of a laboratory will only be accepted if the laboratory has been officially inspected and is in possession of a valid Directorate Animal Health compliance certificate. Please attach this to the application form if applicable.

4.8. Diagnostic tests for controlled and notifiable diseases in terms of the Animal Diseases Act, 1984 (Act No 35 of 1984), must be performed using a validated test at a DAH approved and South African National Accreditation System (SANAS) accredited facility with the relevant diagnostic method listed on the facility's schedule;

4.8.1. If any non-validated tests for controlled or notifiable diseases are to be conducted as part of the research/study, this must be clearly indicated. If a test for a controlled/notifiable animal disease is not performed with a SANAS accredited and DAH approved test, the results are not considered diagnostic results and may not be distributed, verbally or in writing. All positive results must be sent immediately to the DAH at the epidemiology@dalrrd.gov.za for consideration. The researcher should be instructed to include the Section 20 reference number and research project title with the test results. If the DAH determines it is necessary, these results may be forwarded by the Directorate to the state veterinarian of the area concerned for further investigation or action as directed by the DAH. The DAH may require that positive results have to be sent to a SANAS accredited and DAH approved laboratory for confirmation at the cost of the researcher;

4.8.2. If samples are to be obtained from a laboratory or bio-banking facility, the researcher must obtain a letter from the laboratory or biobank manager stating it is aware of the study/ research and gives permission for the samples to be removed and used by the researcher. Information on the geographical origin and species of the samples should be included. The letter must also specify exactly what types and quantities of samples will be shared, as well as the storage or preservation medium the samples are kept and/or will be transferred in. This letter should be attached to the application;

4.9. If samples are to be inactivated or treated at an external facility, the researcher must obtain a letter from the facility to state that it is aware of the relevant risks and is capable and willing to handle and inactivate the samples as required. The method and parameters of inactivation should also be specified. This letter should be attached to the application;

4.10. For transportation by road, all samples must be packaged and transported in accordance with the Regulations of the National Road Traffic Act, 1996 (Act No. 93 of 1996). For transportation by air, samples must be packaged in accordance with IATA requirements;

4.11. Only waste disposal companies and facilities that are registered to handle the relevant biohazard level of the waste generated by the study may be used for the removal of waste generated during or by the research/study. The evaluating official may request a copy of the valid registration certificate of the waste disposal company;

4.12. For vector-borne animal diseases and/ or the maintenance of relevant vectors, ensure that precautionary measures with regards to vector protection are taken into account and described in the application form. Examples of SOPs may be found on the departmental website: https://www.dalrrd.gov.za/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/Epidemiology/researchapproval. A vector protected checklist is also available at: https://www.dalrrd.gov.za/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/Epidemiology. These SOPs may be utilised or equivalent internal SOPs for vector protection may be provided as attachments. As per 4.6 above, also provide a copy of the vector protection recommendation report from DALRRD if one has been issued;

4.13. With regard to any investigation, experiment, research or evaluation with any unregistered medicine or with a registered medicine used outside of its registered conditions (e.g., clinical trials, safety trials, residue studies, proof of concept studies etc):

4.13.1. If a field trial or any investigation, experiment, research or evaluation deemed by the Director: Animal Health to be "conducted under uncontrolled conditions" is to be conducted in a target specie, the applicant must attach proof of Clinical Trial Approval or exemption issued by the South African Health Products Regulatory Authority (SAHPRA) to the Section 20 application form;

4.13.2. If a any investigation, experiment, research or evaluation deemed by the Director: Animal Health to be "conducted under controlled conditions" is to be conducted in a target specie, the applicant must attach proof that they have contacted SAHPRA with regard to the requirement for Clinical Trial Approval to the Section 20 application form;

4.13.3. If a trial, investigation, experiment, research or evaluation is to be conducted in non-target animals (e.g. laboratory rodents, rabbits etc.) in a laboratory under controlled conditions, the animal disease control risk will be evaluated by the DAH and the conditions for such approval will be set by the Director: Animal Health;

4.13.4. Where an unregistered medicine, vaccine, feed additive or other product is to be used and animals are to be slaughtered for human consumption at the completion of such a study, the withdrawal period for the substance utilised must be determined by SAHPRA. It is the responsibility of the researcher to obtain this withdrawal period from SAHPRA and attach it to the Section 20 application form;

4.13.5. "Controlled conditions" are those in which the acquiring, movement, keeping and release of study animals and material will be conducted in a manner that mitigates potential disease transmission opportunities and all relevant safety aspects, to the satisfaction of the Director: Animal Health. Depending on the disease risk and relevant safety risks of the study, "controlled conditions" may require the use of a DAH approved facility of appropriate biosecurity standards (e.g. a BSL 2+, vector-protected facility or BSL 3) and safe removal or disposal of the animals and material at the end of the study.

4.14. If the research or study involves any activities which require a state veterinary letter, as identified in section 5 below, this must be clearly noted in the application form.

4.15. A Section 20 permit may have a maximum validity of 3 years, where after the researcher must apply for an extension and/or amendment if required (see section 7).

5. State Veterinary Letters

5.1. An official letter from the responsible state veterinarian of the area concerned must be obtained by the researcher in the case of the following:

5.1.1. If any field samples are to be collected from any animal, parasite or vector of animal disease;

5.1.2. If any animals are to be obtained from any property other than the facility where the research will be conducted itself;

5.1.3. If the research is to be conducted on a property not belonging to the research facility and may involve any potentially infectious agent; parasite or vector of any animal disease;

5.1.4. If any material that is not passed as fit for human consumption will be removed from an abattoir. In this case the letter must be obtained from the state veterinarian responsible for the abattoir. (Note that permission is required from the responsible state veterinarian and abattoir owner to enter the abattoir premises for any purpose).

5.2. The letter from the responsible state veterinarian must be addressed to the Director: Animal Health and state the following (as applicable):

5.2.1. Whether the property/holding/farm/reserve etc. or specified area is under official quarantine for the suspicion or incidence of any controlled or notifiable disease; and

5.2.2. That the state veterinarian is aware of the research, sampling or use of animals from the area and either has no objection or provides reasons for any objection to this; and

5.2.3. Any other information or control measures the state veterinarian deems necessary, useful or relevant to the research project.

5.3. Contact details for the relevant state veterinarians may be found on the departmental website (https://www.dalrrd.gov.za/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/contacts/provincialveterinary) or on the relevant provincial veterinary services' websites.

6. Submission of the completed application form and the evaluation process

6.1. The following documents must be submitted at least 3 months prior to the proposed starting date of the research/study:

6.1.1. Fully completed application form for permission under Section 20 of the Animal Diseases Act (Act 35 of 1984) to perform research/study, including a brief summary of the methodology of the research. If insufficient space is available on the application form (section 9), kindly provide the additional information as an attachment to the application form;

Supporting documents as applicable:

6.1.2. Letter from the responsible state veterinarian for the area of the province or provinces as outlined in section 5.

6.1.3. Letter from biobank or laboratory that samples will be sourced from as described in point 4.7.2.

6.1.4. If applicable, calibration certificates and service records of critical equipment utilised as part of the research study (e.g. incinerator, biosafety cabinet, autoclave, etc.).

6.1.5. Communication from SAHPRA regarding clinical trials as described in point 4.12 above.

6.1.6. If animals are destined for slaughter for human consumption upon completion of the research/study, please attach the following, as relevant to the study:

6.1.6.1. If the animals are treated with a substance, the withdrawal period approved by SAHPRA if an unregistered product is used, or the package insert if a registered product is used;

6.1.6.2. If the animals are to be infected with any disease, a testing protocol to confirm that the animals are negative for the disease in question and may be safely moved to the abattoir and slaughtered. Such testing should preferably be conducted at an independent laboratory;

6.1.6.3. The certificate of registration of the abattoir;

6.1.6.4. Letter of permission from the state veterinarian responsible for the abattoir if any material not passed as fit for human consumption is to be removed from an abattoir for the research/study.

6.2. Please submit the completed application form and all relevant attachments to the Section 20 Secretariat at the following address:

Miss Marna Laing
Section 20 Secretariat
Directorate: Animal Health
Department of Agriculture, Land Reform and Rural Development
Tel: 012 319 7442
Fax: 012 319 7470
Email: MarnaL@dalrrd.gov.za
Courier/ hand delivery: Attention Miss M Laing, Office G80, Delpen building, 130 Annie Botha Ave, Gezina, Pretoria.

6.3. The application will be allocated to a Section 20 official for evaluation and processing. Following evaluation of the application and information supplied:

6.3.1. No further information may be required; or

6.3.2. Additional information or proof may be required; and/or

6.3.3. Alternate handling or treatment of certain materials or processes or facilities may be required; and/or

6.3.4. A full and signed copy of the entire protocol may be required; and/or

6.3.5. An inspection visit by the DAH audit/compliance team may be requested.

6.4. The applicant will be notified of any further requirements in writing. If you have not received any feedback from either the Secretariat or a Section 20 official after 14 working days, kindly contact the Secretariat to ensure the application has been delivered.

6.5. If permission under the Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) is granted by the Director: Animal Health it will be in the form of a signed letter, on the DALRRD letterhead, entitled "*PERMISSION TO DO RESEARCH IN TERMS OF*

SECTION 20 OF THE ANIMAL DISEASES ACT, 1984 (ACT NO. 35 OF 1984)". No other communication may be considered to be a Section 20 permit.

6.6. If it is decided that a permit under Section 20 of the Animal Diseases Act 1984 (Act no. 35 of 84) is not required for the research/study, the applicant will be informed of this in writing by the evaluating official or the Section 20 secretariat. You may not assume that a Section 20 permit is not required unless this has been confirmed in writing.

6.7. Note that a thoroughly completed application form containing all relevant supporting documentation will allow for quicker processing.

6.8. All information received as part of the Section 20 application is treated confidentially, as per Section 25 (Secrecy) of the Animal Diseases Act (Act No. 35 of 1984).

7. Amendments and extensions

7.1. Written permission from the Director: Animal Health must be obtained prior to any deviation from the conditions approved under a Section 20 permit, and the conditions specified and disclosed within the Section 20 application, for the research/study as described under section 1.4 above. This includes when the responsible researcher or supervisor has changed. This is also relevant for when the expiry date of the Section 20 permit will be reached and an extension to continue with the research project is required.

7.2. An amendment must be applied for by completing the following form: "Request to amend existing permit for research under Section 20 of the Animal Diseases Act, 1984 (Act No 35 of 1984)". This form is available on the departmental website (https://www.dalrrd.gov.za/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/Epidemiology/researchapproval) or from the Section 20 Secretariat. The amendment application form should be sent to the Section 20 Secretariat and must include any relevant supporting attachments as specified on the application form.

7.3. The application for an amendment will be allocated to a Section 20 official for evaluation and processing in the same manner as for an application for a Section 20 permit;

7.4. The amendment, if granted, will be forwarded to the applicant in writing. If the amendment is not granted or is determined to be unnecessary, the researcher will be informed of this in writing. You may not assume that an amendment to a Section 20 permit is not required or has been granted unless this has been confirmed in writing;

8. Dispute resolution:

8.1. In the event of an appeal against the evaluation process that is still in progress, the appeal must be addressed in writing to the Deputy Director: Epidemiology. Send your appeal to epidemiology@dalrrd.gov.za, clearly note the addressee and copy the responsible official that has been processing the application;

8.2. An objection against the decision taken by the Director Animal Health with regards to the Section 20 application upon completion of the evaluation process, should follow the provisions of Section 23 of the Animal Diseases Act 1984 (Act no 35 of 84).

9. Other

9.1. A copy of the Animal Diseases Act, 1984 (Act No 35 of 1984) is obtainable from the DALRRD website.

9.2. Section 20 applications may be submitted to DALRRD prior to the issuing of research ethics approval however, no part of a study may commence until valid ethical approval has been obtained from the relevant South African authority as applicable;

9.3. For any research where a veterinary import permit is required for the importation of any animal, animal derived product, parasite or contaminated or infectious thing into the Republic as per Section 6 of the Animal Diseases Act, 1984 (Act No 35 of 1984), you are requested to apply for a veterinary import permit after obtaining a Section 20 permit. When submitting an application for a veterinary import permit, please attach your Section 20 permit.

9.4. If the research/study involves pathogens listed in the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), the research/study must also be conducted in compliance with this Act.

9.5. Any proposed research/study involving any unregistered pharmaceutical or biological product is also subject to either Section 21 approval obtained from the South African Health Products Regulatory Authority (SAHPRA) in terms of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), and/or approval from Act 36 in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

9.6. Any proposed research/study involving any activity or procedure defined as a veterinary or para-veterinary activity or procedure, must be conducted in compliance with the Veterinary and Para-Veterinary Professions Act 1982 (Act No. 19 of 82);

9.7. Any proposed research/study involving genetically modified organisms (GMO) is also subject to approval from the Directorate: Biosafety under Genetically Modified Organisms Act, 1997 (Act No.15 of 1997).

9.8. For any research conducted with regard to wildlife species, threatened species and/or endangered species, relevant nature conservation permits may be required.

END