Version: 20/1

agriculture, land reform & rural development

Department:
Agriculture, Land Reform and Rural Development
REPUBLIC OF SOUTH AFRICA

APPLICATION FOR PERMISSION UNDER SECTION 20 OF THE ANIMAL DISEASES ACT, 1984 (ACT NO 35 OF 1984) TO PERFORM RESEARCH / STUDY

IMPORTANT NOTICE

a) *Please complete this form fully, preferably typed in text, and email to Mr Gololo at HerryG@dalrrd.gov.za or contact Mr Gololo at 012 319 7532 if email submission is not possible, for alternative arrangements.*
b) *Application must be submitted at least 3 months prior to the proposed starting date of the research.*
c) *Records relating to the information supplied in this section must be kept for auditing purposes for five years.*

I hereby apply for permission from the National Director of Animal Health, South Africa, to do research under Section 20 of the Animal Diseases Act, 1984 (Act No 35 of 1984):	
Date:	
Study/protocol/ethical approval reference number:	
Section 20 reference number [to be completed by the Department of Agriculture, Land Reform and Rural Development (DALRRD)]:	
1. Researcher	
Full names and title of the researcher:	
Institution/ work address of the researcher:	
Contact details of relevant person for correspondence regarding application	
Name:	
Tel:	
E-mail:	
2. Project	
Title of research project:	
Aim/ objectives of research project:	

Proposed starting date:	
Proposed date of completion: (Note: Maximum permit validity of 3 years, where after the researcher must apply for an extension and/or amendment if required – see guidelines)	
3. Institution(s) involved in the research project (Details of <u>all</u> research institutions or laboratories where any part of the research will be done. Kindly expand table if more space is needed)	
Name of institution:	
Physical address:	
Relevant department/ sub-section of institution:	
Laboratory name:	
4. General	
4.1. Pathogen/disease/vector to which study relates:	
4.2. Micro-organism, parasite or animal material (including vaccine, serum, test kit, toxin, anti-toxin, antigen, biological product which consists or originates from a microorganism animal or parasite) to be used in study:	
4.3. Does the study involve the importation of the material mentioned in 4.2 above and/or unregistered pharmaceutical products? Please list these products and the exporting country. Please include specification sheets for all products to be imported.	<u>Importation involved:</u> Yes ☐ No ☐ <u>If yes, list the products and country(ies) involved:</u> <u>Specification sheet(s) of product(s):</u> Attached: Yes ☐ No ☐ Not applicable ☐
4.4. Biological origin of the micro-organism, parasite and/or animal material:	
4.5.1 As part of the study, will: (a) field samples be collected? (b) samples be utilised from a biobank or laboratory? 4.5.2 If yes to (a) or (b) in 4.5.1, please specify: (i) The location details (ii) provide a list of all the samples including species of origin for each	<u>(a) Field samples will be collected:</u> Yes ☐ No ☐ (b) Bio-banked samples will be utilised: Yes ☐ No ☐ (i) Location details: (ii) Sample list (include species origin):
4.6. Please attach a letter from the relevant state veterinarian of the research/ sampling area stating whether it is under any disease restrictions and/or a letter of permission from the biobank or laboratory concerned. (complete only if "Yes" to 4.5)	<u>SV letter:</u> Attached: Yes ☐ No ☐ Not applicable ☐ <u>Biobank/laboratory letter</u> Attached: Yes ☐ No ☐ Not applicable ☐

4.7. If samples are to be collected at an abattoir, please supply: (a) the registration certificate (in terms of the Meat Safety Act, 2000 (Act No. 40 of 2000) and name of the abattoir, (b) written permission from the abattoir owner and (c) written permission from the relevant authorised state veterinarian responsible for the abattoir.	Registration certificate of abattoir: Attached: Yes ☐ No ☐ Not applicable ☐ Permission from abattoir owner: Attached: Yes ☐ No ☐ Not applicable ☐ Permission from authorised state veterinarian Attached: Yes ☐ No ☐ Not applicable ☐
4.8 Will samples be packaged and transported in accordance with International Air Transport Association (IATA) requirements and/or the National Road Traffic Act, 1996 (Act No. 93 of 1996);	Yes ☐ No ☐ Not applicable ☐ If no, please describe alternative method/SOP:
4.9. Does the study involve genetically modified organisms/material?	Yes ☐ No ☐
5. Facilities	
5.1. Indicate the Biosafety level (BSL) of each facility involved in the handling of samples/animals for this study. If working with vectors or vector-borne pathogens, please indicate if the facility is vector protected.	
5.2. Are these facilities Directorate Animal Health (DAH) approved/ compliant? If yes, supply a copy of the DAH certificate (BSL-3) or a copy of the DAH recommendation report for other biosafety and biosecurity, or other purpose (e.g. vector protection), if available. If not DAH approved for a specific BSL or vector protection, provide a short description of BSL or vector protection related precautions in place:	DAH certificate or recommendation report: Attached: Yes ☐ No ☐
5.3. Describe the containment of the pathogen/ vector/ material at facilities in detail (includes storage, processing, testing activities, any handling, etc.) or provide/refer to relevant SOP:	
6. Live Animals	
6.1. Will live animals be used in study? If yes, list which species and approximate number:	
6.2. If live animals will be used, specify origin of animals:	
6.3. In reference to 6.2. above, please attach a letter from the relevant state veterinarian of the sourcing area stating whether it is under any disease restrictions.	SV letter: Attached: Yes ☐ No ☐ Not applicable ☐
6.4. Describe containment and handling of live animals with regard to the biosecurity of the facility in detail:	

6.5. Fate of live animals after completion of the study: *(Refer to guideline document if entering the human food chain)*	
6.6 For clinical trials, please refer to the guidelines and attach approval, exemption or proof of communication sent to SAHPRA, as applicable.	SAHPRA approval, exemption or proof of communication that was sent: Attached: Yes ☐ No ☐ Not applicable ☐
7. Disposal of materials and/or animals	
7.1. Describe the disposal of all biological/contaminated/potentially infectious waste at end of study (this includes carcasses and contaminated consumables utilised, solid waste and liquid waste):	
7.2. Method of disposal/ destruction used:	
7.3. If this function is outsourced provide the name and valid registration certificate of the waste contractor: The waste contractor must be registered to move and handle the relevant level of biohazardous waste generated.	
7.4. If incinerated on the premises, supply valid calibration certificate for the incinerator and discuss disposal process from study site to incinerator:	
8. Storage and/or distribution	
8.1. Will any vaccine, serum, toxin, anti-toxin, antigen, biological product which consists or originates from any microorganism, animal or parasite be stored beyond the completion of the study? If yes, specify in detail: which samples, how they will be stored, access control and exactly where they will be stored.	
8.2. Will any vaccine, serum, toxin, anti-toxin, antigen, biological product which consists or originates from any microorganism, animal or parasite be distributed? If yes, specify where and for what purpose.	
9. Kindly provide a summary of the <u>methodology</u> of the study in the space below (materials and methods as well as objective):	

If insufficient space, please provide additional information as attachment/annex to the application form (maximum 2 pages) This information must be signed off as true and complete and representing complete disclosure.

10. Details of person responsible for research	
Name:	
ID/Passport number:	
Physical address:	

I hereby confirm that the summary and the information of the research/study as provided with this application, is true and correct and represent a complete disclosure. I further confirm that, where applicable, the following conditions will be adhered to:

1. No part of the study will commence until valid ethical approval has been obtained from the relevant South African authority as applicable;
2. Approval under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No 36 of 1947) and/or the Medicines and Related Substances Control Act, 1965 (Act No 101 of 1965) will be obtained prior to the commencement of the study if applicable;
3. Any suspicion of a controlled/notifiable disease in terms of the Animal Diseases Act, 1984 (Act No 35 of 84), will be reported immediately to the responsible State Veterinarian;
4. If a test for a controlled/notifiable disease was not performed in a DAH approved laboratory for the specific 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 epidemiology@dalrrd.gov.za for consideration;
5. Consent from the owners of animals to be used in the study will be obtained in writing prior to the commencement of the study, if applicable;
6. Should there be any deviations to the descriptions, specifications or conditions described in this Section 20 application and/or Section 20 permit approved by the Director: Animal Health for the research/study; the Director: Animal Health will be informed immediately.

Signature: _____ Date: _____

11. Details of supervisor of the person responsible for research:	
Name:	
ID/Passport number:	
Physical address:	
Email address:	
Designation:	

I am aware of the research referred to on this application form and take responsibility for this project to be done according to the research/study summary provided, at the above mentioned institution. Should there be any descriptions, specifications or conditions described in this Section 20 application and/or Section 20 permit approved by the Director: Animal Health for the research/study, the Director: Animal Health will be informed immediately.

Signature: _____	Date: _____
12. Details of person(s) responsible for the main laboratory(ies)/ facility(ies) where the research will be conducted (kindly expand table if more space is needed):	
Name:	
ID/Passport number:	
Physical address:	
Postal address:	
Email address:	
Designation:	
I am aware of the research referred to on this application form and take responsibility for this project to be done according to the research/study summary provided, at the above mentioned institution. Should there be any descriptions, specifications or conditions described in this Section 20 application and/or Section 20 permit approved by the Director: Animal Health for the research/study, the Director: Animal Health will be informed immediately. Signature: _____ Date: _____	