Research-related import/export permits: A brief update

Blessing Silaigwana
FHS Research Diligence Manager

OUTLINE

- Distinguish between Department of Health (DOH) vs DALRRD import/export permits
- Challenges faced by researchers w.r.t DOH import/export permits
- Faculty approach in dealing with these challenges.
- New Faculty SOPs for applying for DALRRD permits.

OVERVIEW

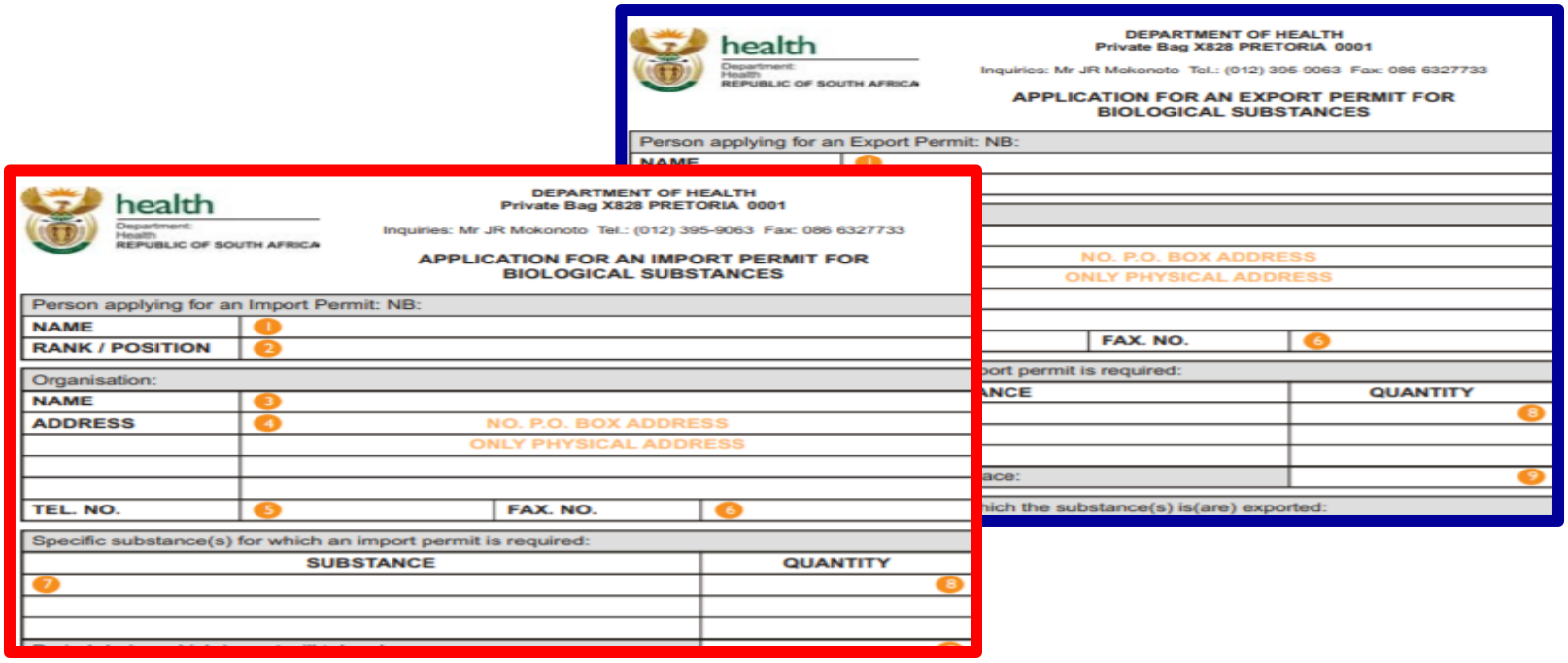
- Legislation obliges researchers to obtain certain permits/approvals from Government authorities before commencing research!

- Researchers must be aware that it remains their responsibility to apply for such permits and familiarize themselves with the permit issue process.

- Researchers often confused about the different permit processes that must be followed; and which permits to apply.

DoH Import/Export Permits

- Required in terms of the National Health Act (61 of 2003) regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, zygotes and gametes.



health
Department:
Health
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH
Private Bag X828 PRETORIA 0001

Inquiries: Mr JR Mokonoto Tel.: (012) 395-9063 Fax: 086 6327733

APPLICATION FOR AN IMPORT PERMIT FOR BIOLOGICAL SUBSTANCES

Person applying for an Import Permit: NB:

NAME	1
RANK / POSITION	2

Organisation:

NAME	3		
ADDRESS	4	NO. P.O. BOX ADDRESS ONLY PHYSICAL ADDRESS	
TEL. NO.	5	FAX. NO.	6

Specific substance(s) for which an import permit is required:

SUBSTANCE	QUANTITY
7	8

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APPLICATION FOR AN EXPORT PERMIT FOR BIOLOGICAL SUBSTANCES

Person applying for an Export Permit: NB:

NAME 1

NO. P.O. BOX ADDRESS
ONLY PHYSICAL ADDRESS

FAX. NO. 6

ort permit is required:

ANCE	QUANTITY
	8

ace: 9

hich the substance(s) is(are) exported:

Note

A material transfer agreement (MTA) between the two parties exchanging human biological samples is needed (a legal requirement)

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FAQs: DOH Import & Export Permits

1. What is the DOH export / import permit application process?

- The applicant (usually Principal Investigator) completes application form AND emails : importexportpermit@health.gov.za

2. If an investigator site is running multiple clinical trial studies going to the same destination, would they need to make application for separate export permits?

- YES, A separate export / import permit is required per study / protocol

3. Can an organisation / institution make application for the export / import permit on behalf of the investigator?

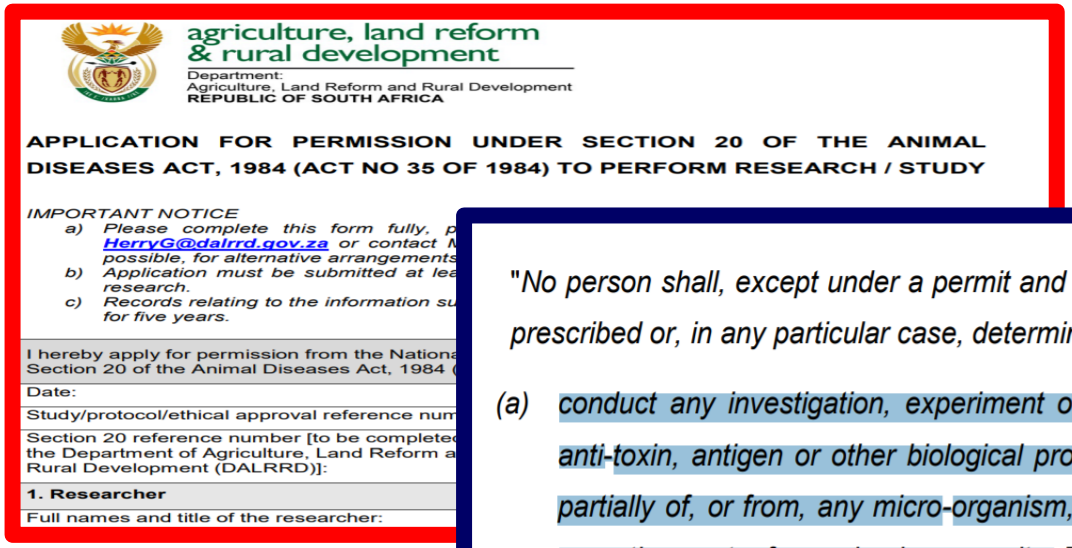
- NO, The investigator is responsible for applying for the permit.
- Organizations / institutions can assist with the export/import permit issue follow-up process

For more FAQs on DoH import/export permits, please see link below:

https://vula.uct.ac.za/access/content/group/25f04c1d-1bf4-497a-bdb5-e12357b066ef/test/FAQs%20%20PERMIT%20PROGRAMME%20MARCH%202015.pdf

DALRRD permits

- SECTION 20 permit
  - Required for any animal research in terms of Section 20 of the Animal Diseases Act (35 of 1984)



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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, p
HerryG@dalrrd.gov.za or contact N
possible, for alternative arrangements
b) Application must be submitted at lea
research.
c) Records relating to the information su
for five years.

I hereby apply for permission from the Nationa
Section 20 of the Animal Diseases Act, 1984 (

Date:

Study/protocol/ethical approval reference num

Section 20 reference number [to be completed
the Department of Agriculture, Land Reform a
Rural Development (DALRRD)]:

1. Researcher

Full names and title of the researcher:

"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);

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DALRRD permits

- ## Veterinary import/export permit

  Required in terms of the Animal Diseases Act (35 of 1984) to import animals/ and or animal-derived materials such as:

  – blood or serum from animals
  – test kits for diagnosing animal diseases
  – bacteria, viruses or any pathogens of animals to be used for research
  – antigen or other product which is either derived from animals or derived from organisms infectious to animals

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APPLICATION REFERENCE NUMBER:

Less than 10 digits

DIRECTORATE: FOOD IMPORT & EXPORTS STANDARDS
Private Bag X138, Pretoria, (Tshwane) 0001
Delpen Building, Cnr Annie Botha & Union Street, Riviera, 0084
Enquiries: Tel: +27 12 319 7514/7632/7633/7503/7461/7510/7500
Fax: +27 12 329 8292/ 319 7644
Email: Vetpermits@daff.gov.za

APPLICATION TO IMPORT DIAGNOSTIC KITS AND PHARMACEUTICALS (EXCLUDING VACCINES) INTO THE REPUBLIC OF SOUTH AFRICA

IMPORTANT NOTICE

1. Please complete this form fully, in **PRINT**, prior to the return thereof.
2. Import permits are valid for a limited period and one consignment only.
3. Imports may only be authorized in writing by issuing a veterinary import permit.
4. Application for a permit must be made at least four weeks but not longer than eight weeks prior

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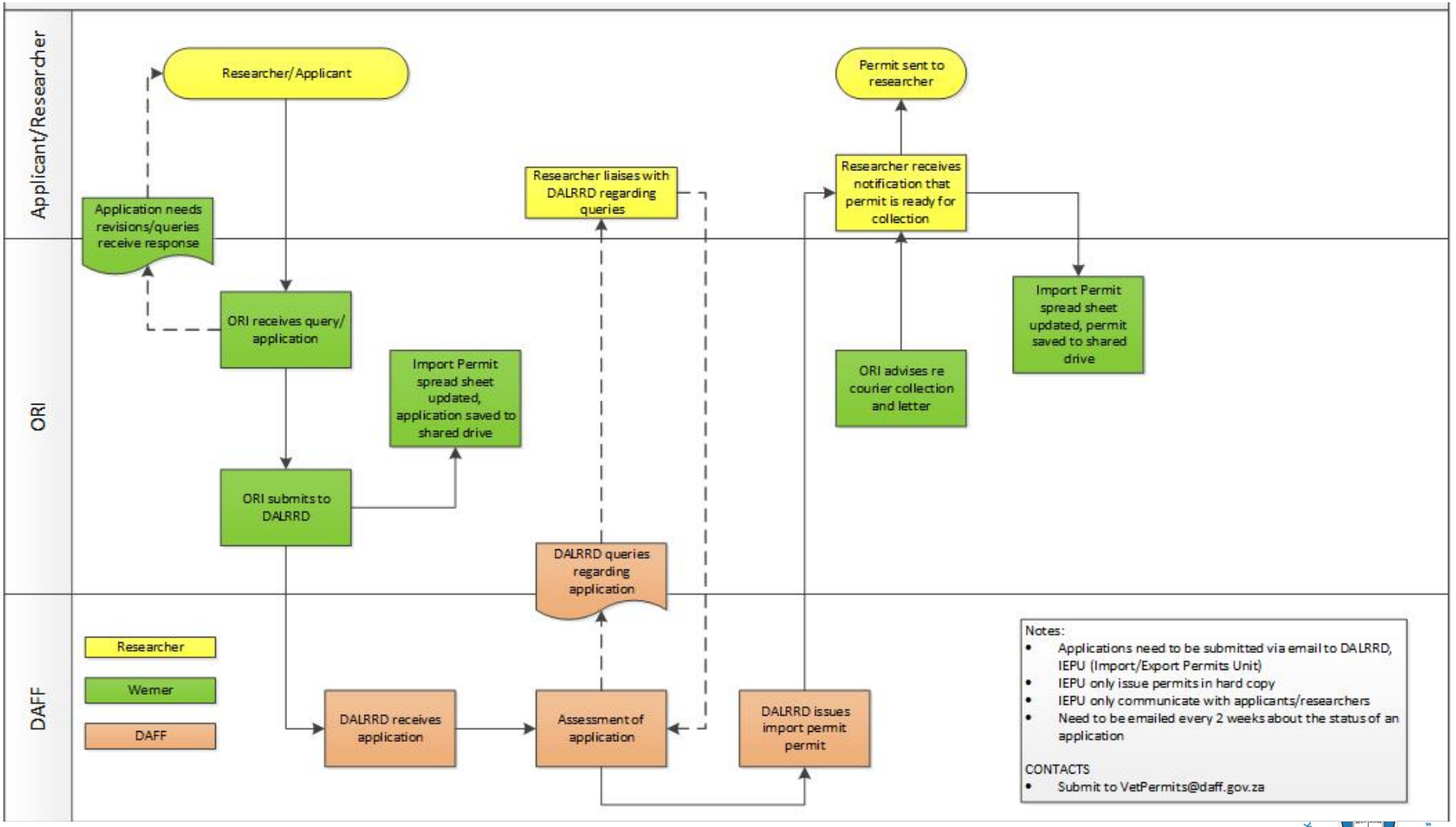
Current application process - DALRRD permits



– Acknowledgement

ORI (Werner van der Ross & Paula Saner)

Challenges in obtaining permits

The South African clinical trial industry: Implications of problems with the issuing of human tissue export permits

L J Burgess, D Pretorius

Lesley Burgess represents Tread Research CC, which is affiliated to the Cardiology Unit of Department of Internal Medicine at Tygerberg Hospital, and Stellenbosch University, Cape Town, South Africa. Deodanda Pretorius represents Andurihl Medical Writing CC, in Brackenfell in Cape Town.

Corresponding author: *D Pretorius (deodanda@andurihl.com)*

The National Health Act requires a valid permit before human biological tissue samples are exported from South Africa. However, delays in issuing export permits make it difficult for many researchers and pharmaceutical companies to comply. There are misconceptions about who is responsible for obtaining such a permit. Delays have caused many new trials to start without a permit, and biological samples from ongoing trials have been exported using expired permits. This could have detrimental consequences for the South African trial industry, especially with the country's history of vulnerable populations in developing areas. Medicine Control Council inspections have listed findings related to export permits for several trial sites. Researchers must be aware that it remains their responsibility to apply for such a permit. The most important steps to ensure a smoother approval process are for applicants to (*i*) familiarise themselves with the permit issue process and (*ii*) recognise the importance of correctly completing and signing application forms.

S Afr J BL 2013;6(1):13-15. DOI:10.7196/SAJBL.228

- Delays in issuing permits
- Incorrect permits issued
- No response to queries on permits from authorities
- Impact on research collaborations

Faculty approach in dealing with DOH permit challenges

Multipronged approach from Acting Deputy Dean, FHS Research Office & members of Faculty

- Compiled a list of outstanding import/export permits, which was sent to the DOH for follow-up.
- Engaged a senior person at Department of Science and Innovation to push DOH.
- Formal UCT letter drafted and given to DVC to sign and send to DG of DOH (and to raise the issue at the DVC's Forum)
- Engaged with SACRA for assistance in finding a solution with DOH permits
- Engaged with the Provincial Health Research Committee (other WC institutions face same challenge and support coordinated approach)
- Southern African Research & Innovation Management Association is also attempting to assist with the issue.

New FHS SOPs for compliance permits

- SOP on applying for Section 20 & import permits from DALRRD
- SOP on applying for GMO facility certifications from DALRRD

Some useful links on permits

- https://www.gov.za/documents/national-health-act-material-transfer-agreement-human-biological-materials-15-aug-2018
- https://vula.uct.ac.za/access/content/group/25f04c1d-1bf4-497a-bdb5-e12357b066ef/test/FAQs%20%20PERMIT%20PROGRAMME%20MARCH%202015.pdf
- https://www.dalrrd.gov.za/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/importexport

Thank you

- For any questions feel free to email blessing.silaigwana@uct.ac.za
- Or pop into office E48 in the Old Main Building – we're here to help!