NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

Faculty of Health Sciences Ethics Office for Research, Training and Support
health-sciences.nwu.ac.za/healthethics

AnimCare Ethics Committee on Animal Care, Health and Safety in Research *(AREC-130913-015)*

Guidelines for Bi- or Multilateral Agreements

to be submitted by the **Applicant**, as approved by the **NWU Legal Office** when such agreements involve animals or animal products

AnimCare 08-02a, Version 4.10 (May 2017)

These guidelines refer to several legal documents and guidelines, including the SANS 10386: 2008, Animal Protection Act (1962), Animal Health Act (2002) and the Animal Diseases Act (1984), as mentioned or included in Addenda A to C below.

1 Guidelines

The following guidelines should be followed by applicants, and compliance verified by AnimCare reviewers and eventually by the AnimCare committee before any ethics approval be granted:

1. Whenever there is a **bilateral of multilateral cooperation agreement**, contact the NWU Legal Office at the following address:

Yolandi Calitz (Legal Advisor)
Room 332, Building C1, Potchefstroom Campus, North-West University, Potchefstroom, 2531
Tel: 018 299 4954
E-mail: Yolandi.Calitz@nwu.ac.za

2. Request the Legal Office to facilitate the bi-or multilateral cooperation agreement, including a contract or memorandum of understanding (MOU). The following authorisation levels and signatures (as available from the Dean's Office) would typically apply:
   2.1. Any national and/or international contractual agreements related to research or training will have to be signed by institutional management (deputy vice chancellor)
   2.2. Any confidentiality agreement related to MTA will have to be signed by the research director and institutional management (deputy vice chancellor)
   2.3. Any contractual agreement related to intellectual property (or commercialisation thereof) will have to be signed by the institutional management (deputy vice chancellor)
3. Whenever any live animals or physical material (i.e. any biological sample of human, animal or plant origin, microorganism or genetic material) is transferred from the facility of one institution to another, a materials transfer agreement (MTA) , in addition to the abovementioned agreement is applicable (MTA should preferably be separate from the cooperation agreement).
4. Transport of the said animals or physical material is not included in the MTA and separate shipping agreements should be put into place where applicable.
5. Purpose of the MTA: The MTA should ensure that the objectives, intellectual property (IP) and other ownership rights, responsibilities and liabilities, and what the receiver is entitled to do (or not) are clearly stipulated and protected. Usually the sender remains the owner, and the receiver has custodianship with clear understanding of what its role is regarding the materials or any derivatives thereof.
6. Permits: Department of Health will not grant any permits as required without a proper MTA plus ethics approval.

2 Addendum A: Communication from DoH

In a communication from DoH, dated 14 October 2016, the following was stated:

From: *HealthSciences-Ethics*
To: *HealthSciences-Ethics*
Date: *2016/10/14 08:58 AM*
Subject: *HS Ethics Office Notice: Material Transfer Agreement requirements*

Email from the Department of Health:
Dear Applicants

This serves as a reminder to all Principal Investigators to make sure they should submit three documents when applying for an export permit. These are: Ethical Clearance, Material Transfer Agreement (MTA) and an application form. All these documents should show the name of the PI(s) and their signatures where necessary. It is our understanding that when you submit your protocol for ethical review you submit the protocol; consent form and the MTA? If the MTA was not submitted in the initial application then one can be created and signed and submitted to the Research Ethics Committee that approved the trial to sign/stamp the MTA to show approval.

Please bear in mind that the MTA is:

1. *A legally binding document;*
2. *The information on the MTA should be a summary of your protocol showing what substances are going to be exported; the quantities, number of participants and visits/frequency of exporting samples; and lastly and most important whether the substances will be stored overseas or destroyed - the latter being the norm for most Health Research Ethics Committees;*
3. *The MTA should specify the collaborator;*
4. *The MTA should be signed by the PI(s) locally and the collaborator if it's a grant (e.g. foreign sponsors such as NIH, ECDP, WHO, etc.) type of research/Investigator Initiated Research (IIR) with collaboration or Sponsor representative if it's a pharmaceutical sponsored trial e.g. Sponsor clinician or medical officer/ Biobank representing the sponsor; and*
5. *Therefore, an export application form will be signed by the PI(s) and the address (on the export application form) where the substances are being exported to should be the same address on the MTA.*

We have encountered applications that have MTA signed between laboratories, which is unacceptable mainly because the Laboratory Manager/Project Manager(s) are not researcher(s)/PI(s), nor are they on the ethical clearance or MTA. We expect that the MTA signed by the PI(s) and collaborator or pharma company (sponsor) clinician/custodian/ Biobank representing the sponsor will have the information on the local laboratory and an overseas laboratory. We believe that this information is covered in other documents relevant to the study logistics which are part of the submission to the ethics committee.

We do hope this message clarifies the matter of MTA between laboratories and we can move to what is legally and ethically acceptable.

Warm regards
Lineo Motopi
0123958366; motopl@health.gov.za

AnimCare discussed this at the committee meeting on 27 October 2016, when it was requested that legal advice be sought to better understand how this pertains to the transfer of animal products. Sr Erica Vercuiel, NSPCA, forwarded a section from the Animal Diseases Act (no 9152 of 1984), whereby permits are required for research using animal products. Clarification was necessary.

The Ethics Office, Health Sciences, NWU, approached attorney Mr Francois Bloem for legal advice. Examples of how NWU use animal products in health-related research was sought and is discussed below.

The points of departure with regard to this document are:

1. Animal testing is legal in South Africa;
2. There are no current legislation specifically directed at the protection and monitoring of animals used in research in South Africa;
3. Protection and monitoring of laboratory/research animals are regulated by codes of conduct/South African National Standard(2008);
4. SANS is to be read together with The Animal Protection Act and related animal health legislation;
5. Animal research aimed at/impacting on human health is regulated by the National Health Act and is excluded from this document.

3 Addendum B: Legal advice by Mr Francois Bloem

Translated from feedback via e-mail

3.1 New drugs from Pharmaceutical Chemistry for testing on animals elsewhere **Example**

In our department we synthesize compounds and these compounds are then send to other researchers/collaborators overseas to be tested for antimalarial activity, monoamine oxidase inhibition, etc. These tests involve either enzyme inhibition studies or cell line studies

Response

Translated from Afrikaans: Following is a quote from the Animal Diseases Act and upon your request, I did some research on legislation regarding the "transport and export / import of animal products for research in general". I studied the following documents jointly and separately, namely: SANS 10386: 2008 Animal Protection Act (1962), Animal Health Act (2002) and the Animal Diseases Act (1984) and interpret it as follows *(this is my interpretation and may differ from another, and I trust my interpretation of your question is correct)*:

- In general, the documents mentioned are vague about specific transportation and import / export of animal material ("bio-samples") for research. I looked at the purpose / objective of SANS and the available legislation to provide more context (of course there is more legislation in question as above). There is much reference to the transport and import / export of animals. So I went to look at the definitions of "animals" in order to gain an understanding of all in includes.
- In my opinion the Animal Health Act 2002 provides the best basis for interpretation with regard to your question. One of the objectives of this law is to regulate the import and export of animals and things. The definition of animals and things include animal products. The definition of animal products include *"… any part or portion-derived or yielded from ANY animal"*. To the best of my understanding, the latter quote creates room that "bio-material" could also be read here. Sections 8 and 9 of the said Act refers to the requirement of an export / import health certificate issued by the National Executive Officer, and that no export / import may take place without this. Furthermore, Article 30 refers to the following conjecture: *"…it is presumed that any sample, taken from an animal or thing in terms of this act, is representative of that animal or thing from which it was taken and that such animal or thing possesses the same properties as that sample"*. Section 20 of the Animal Diseases Act as quoted by you, aims to prevent the spread of animal diseases and parasites, and to control, and is very specific and mandatory. When reading these two laws together (both actually aims at preventing the spread of diseases and parasites), I therefore interpret that animal material ("bio-samples") falls under the definition of *"animals or things"* and, consequently, import / export certificates would be required. (Note that I am out here on the assumption that a certificate and permit has the same meaning, if not, the requirement of a certificate would, in my opinion, also implies a permit as requirement).

I trust that the above-mentioned makes sense. I would like to hear how the Research Ethics Council interprets the above-mentioned, as well as at international level

3.2 Formulations for animal testing at PCDDP

Example

For the PCDDP we typically may transfer formulations, whole rodent (rats or mice) and organs or biological fluids from rodents. In terms of receipt, we may receive the same and in addition, organs and biological fluids from non-rodent species

Response

See response to the previous example above.

3.3 Environmental Sciences

Example

It sounds from the letter that only human health research requires this document, or was environmental research deliberately or for some reason not mentioned? In our field there are as many possibilities for tissue exports as there are projects (not for human health related research). I try and list a few here:

- whole specimen/tissue/DNA for archiving in natural history museums or other collections
- return of specimens/tissue/DNA that were on loan from natural history museums or other collections
- samples for analysis (e.g. for molecular, toxicological, pathological purposes)

Response

Where research is done using animals with the aim of “human health development”, permits are required in every case, according to the National Health Act. This type of research is therefore excluded from my opinion expressed to you before.

4 Addendum C: Excerpt from the Animal Disease Act

for purposes of this section or, where no compensation has been so prescribed, any amount fixed by him in accordance with any criterion deemed applicable by him;

(b) the value of any thing which has in connection with the animal or thing been returned to the owner;

(c) any amount which is due by the owner pursuant to any provision of this Act in respect of the animal or thing to the State; and

(d) any amount which may accrue to the owner from any insurance thereof,

fix a fair amount as compensation.

(3) Notwithstanding the provisions of subsection (2), the director shall, in the case where a carcass has been disposed of in terms of section 17 (5), fix the nett income accruing from such disposal, against which any amount payable by the owner concerned by virtue of any provision of this Act in respect of the carcass to the State is to be set off, as compensation in respect of the carcass, if—

(a) the owner is otherwise entitled in terms of this section to compensation; and

(b) that nett income exceeds the amount prescribed in respect of any such carcass.

Limitations on investigations, experiments and research with, and manufacture and evaluation of, certain products.

20. 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 *(a)*; 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.

General provisions regarding applications, claims and requests.

21. (1) Subject to the provisions of this Act regarding any particular application, claim or request, any application, claim or request which is under this Act required or permitted to be lodged with or directed to the director, shall—

(a) be made or submitted in the prescribed manner;

(b) contain the prescribed particulars and information;

(c) be made or submitted within the prescribed time; and