Best Practice for the Care and Use of Animals in Experimentation: A Malaysian Perspective

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Abstract

Passing federal laws and national guidelines is one of the best revenues to protect animals used in experimentation. The laws can establish standards of care for animals in scientific research such as housing standards and treatment for the animals. At international level, animal ethics and law for the care and use of animal in experimentation have been widely discussed for decades ago. There are several well-known international documents and

guidelines that have been referred by many countries when constructing their own federal laws governing the subject matter. They are Terrestrial Code, European Directives, and International Guiding Principles for Biomedical Research Involving Animals. In Malaysia, the Animal Welfare Act 2015 finally has been enforced on 18th July 2017 where the Act among others will regulate the use of animal for scientific purposes in the country. Besides, it will validate the practice of Institutional Animal Care and Use Committee (IACUC) which was based on self-regulation before the enactment of the Act and the Act is significant of having legal enforcement in order to give better protection to the animals subjected to experimentation. Thus, the law has taken its role in enhancing the animal ethics for the care and use of animal in science in Malaysia. This paper aims to analyses the provisions of law in several international documents governing the subject matter that reflect the international practice. Then it will look into the practice of research institutions in Malaysia, applying the existing animal ethics and law in the subject matter. This paper adopts doctrinal approach considering primary and secondary sources of law. Relevant to this, Animal Welfare Act 2015 (AWA) and Malaysian Code of Practice for the Care and Use of Animals for Scientific Purposes (My Code) are analysed. Besides, it also employed empirical study by way of interviews and observation. This paper is significant to inform the practice of animal ethics at international level to be learned by Malaysia as the country is still at an early stage of having the new Act.

Keywords: *Animal Ethics, Animal Experimentation, Animal Law, Animal Research, Scientific Purposes.*

1. Introduction

Animals have been subjected to experimentation and widely used in research and educational purposes around the world including in Malaysia. Despite the advancement of new technology today offering alternative test models such as 'in vitro' and 'in vivo' testing, we cannot deny that the use of animal in experiments is still relevant and as necessity to human and animal benefits. Plus, scientists have been eager to protect their right to use animals by pronouncing numerous unpredictable medical discoveries that came about during animal experiments (Theodorou, 2005). Accordingly, use of animals in experimentation is permissible taking into moral, scientific, and legal consideration. The law will regulate the use of animal for the scientific purposes as well as outline humane treatment of animal before, during and after the scientific procedures. The law did not give absolute rights to human to use animals for their own purposes rather it gives permission to use the animals only if animal welfare is taken care of.

Although there is no international treaty or declaration yet which sets out the principles for the use of animals in research, there are several principles could be viewed as norms or 'best practice standard' as they appear in a number of international, regional and national legislative instruments and guidelines (Sharman, 2006). Thus, this paper will discuss the international principles for the protection of animals in scientific research that appear in

international documents. Then, it will see how far Malaysia has conformed to the international standards on the use of animal for scientific purposes. As Malaysia is still new in having the federal law regulating the subject matter, thus lessons from nations with already established laboratory animal laws and regulations offer several models to follows (Vasbinder & Locke, 2016).

2. Methodology

This paper is based on two approaches. First, a doctrinal legal research is employed to analyses the international law and Malaysian law that regulate the animal experimentation. It involves reference to and analysis of primary and secondary materials i.e. international documents, federal laws and policies. At international level, the relevant documents are the Terrestrial Code, EU Directive 2010/63 and Universal Declaration on Animal Welfare (UDAW). Meanwhile, in Malaysia, Animal Welfare Act 2015, Wildlife Conservation Act 2010, Malaysian Code of Practice for the Care and Use of Animals for Scientific Purposes (MyCode); pending the Animal Welfare (Animals Used in Research, Testing or Teaching) Regulations 2015 to be gazzetted and policies of research institutions will be referred. Besides that, the relevant literatures were also been referred to explore the basic principles underlying the law, regulations and standards on animal care and use for scientific purposes in the country.

Second, empirical method is employed to collect data from interview. Under this approach two interviews were conducted involving stakeholders from two institutions to understand the implementation of the laws and gather their views and perspectives on the law. They were officials from Department of Veterinary Service (RP1) and Institute of Medical Research (IMR), Kuala Lumpur (RP2). Besides, an observation also was conducted to one of laboratory of research institutions conducting the animal experimentation.

3. Discussion

(a) International Documents

At international level, there are several documents and guidelines outlining the care and ethics for the use of animals in experimentation. Some of the documents have been adopted and referred by many countries in constructing national laws governing the use of animal for scientific purposes. Follows are the international documents that regulate the subject matter:

(i) Terrestrial Code

OIE members realized that the use of live animals in research and education provides advancement of scientific knowledge in protecting human and animal health and life particularly in the field of medicine and veterinary science. That advancement is crucially

important while at the same time animal welfare should be respected (World Organization for Animal Health). For this reason, OIE developed and published a Terrestrial Code outlining the standards for the welfare of animal. The development of the standards and recommendations in the Code was the result of the continuous work since 1960 of one of the OIE's Specialist Commission, the OIE Terrestrial Animal Health Standards Commission. Then, it was first published in 1968. Since 2005, the OIE has adopted ten animal welfare standards in the Terrestrial Code addressing various areas of animal welfare including the use of animals for the research and education purposes (World Organization for Animal Health). It can be said as the most important document regulating the use of animal in science as it has been referred by many countries in developing their law regulating the subject matter including Malaysia.

(ii) European Union

European Union is extensively regarded as an international leader on animal welfare issues. The EU has two documents concerning the use of animal in research i.e. EU Directive 2010/63 and European Convention for the Protection of Vertebrate Animals Used for Experimental and other Scientific Purposes (Whittaker, 2014). The contents in the Directive and the Convention are considerably overlapped but they are two different documents and have different legal status. The former requires the State Members to incorporate the document into their domestic legislation in order to take effect in their countries whereas the latter is only legally binding to the ratified parties.

(iii) Universal Declaration on Animal Welfare (UDAW)

Animal suffering is an issue of worldwide concern and is precisely the reason it should be the subject of universal declaration. In line with this, WSPA initiated a draft of the Universal Declaration of Animal Welfare (UDAW) due to the absence of multilateral agreements concerning animal welfare. It is said as the WSPA's effort to secure international legal recognition for animal welfare principle (Gibson, 2011). UDAW was drawn after the failure of the Universal Declaration of Animal Right (UDAR) where the support for the latter waned and the draft was put on the shelf. WSPA opted for the term of welfare of animals after knowing the use of the term "rights" of animals will not attract the support of states at international plane (Stojanovic, 2016). After some periods, the UDAR been retitled, amended, and then presented by WSPA as UDAW. The draft of UDAW has gone through several processes and amendments where its first draft was revealed at the Animal 2000 World Congress. Then, it was followed by an Intergovernmental Conference on Animal Welfare in Manila in 2003 which resulted in a redraft of the UDAW. The new draft made a specific mention to the 'Five Freedoms' of animal welfare and 'Three R's' relating to the use of animals in science. Now, WSPA focuses to gain official status for the UDAW within the UN and eventually convert it into a convention on animal welfare. The organization is hoping to present the document to the United Nations by 2020, or sooner if

they feel they have enough pre-emptive support from signing nations (Hugo, 2017). If enacted, countries would agree to consider animal welfare in their policymaking and to make an effort to improve the state of animal care in their countries (Hugo, 2017).

(iv) International Guiding Principles for Biomedical Research Involving Animals

International Guiding Principles for Biomedical Research Involving Animals was published by Council for International Organizations of Medical Science (CIOMS) in 1985. CIOMS is a non-governmental and non-profit international organization established jointly by WHO and UNESCO. The International Guiding Principles for Biomedical Research Involving Animals provides criteria for establishing codes of practice or legislation concerning the use of animals in scientific research, therefore has been the framework for the development of laws, policies, and guidelines for over 25 years (Council for International Organization of Medical Sciences and The International Council for Laboratory Animal Science, 2012). The document lists 10 guiding principles which should be used by the international scientific community to guide the responsible use of vertebrae animals in scientific or educational activities. These include the decisions regarding the welfare, care, and use of animals should be guided by scientific knowledge and professional judgment, reflect ethical and societal values, and consider the potential benefits and the impact on the well-being of the animals involved.

(b) International Best Standards for the Use of Animal in Science

Even though animal law is varies from countries to countries, and there is no international treaty or declaration that sets out the principles for the use of animals in research, there are several principles could be viewed as norms or best practice. Follows are several important international principles that reflect international best practice for the use of animals in experiments:

(i) Animal Welfare Concept

Animal welfare and its supporting concepts is the best available and most acceptable concept to be used in animal experimentation in most countries like the United Kingdom, Australia including in Malaysia. The concept upholds that the use of animals for scientific purposes is morally justified as long as their welfare is taken care of.

It focuses on regulating animal use instead of abolishing it in total and at the same time maintains that humans have an obligation to treat animal 'humanely' (Ibrahim, 2006). Therefore, most of the law are based on the animal welfare concept and numerous laws regulating these uses of animals are designed to avoid "unnecessary pain and suffering" or the like.

Three Rules principle and Five Freedoms are the two basic principles underlying the animal welfare concept in the use of animal in experimentation. The Three R' proposed by Russel and Burch in 1959 as they do not seek to abolish the animal experimentation, but they only proposed to remove the element of inhumanity inflicted towards the subject of the experimentation. This is being done through the implementation of the Three R's which is a goal consistent with the animal welfare approach.

The concept serves as a main guideline for the responsible use of live animals. These principles encourage researches to work to reduce the number of animals used in experiments to the minimum considered necessary, refine or limit the pain and distress to which animals are exposed and replace the use of animals with non-animal alternatives when possible (Ferdowsian & Beck, 2011).

Meanwhile, the Five Freedoms highlighted five basic freedoms of animals to ensure their welfare. They are;

(i) *freedom from hunger, thirst and malnutrition,* by providing ready access to fresh water and a diet to maintain full health and vigor

(ii) *freedom from physical and thermal discomfort,* by providing a suitable environment including shelter and a comfortable resting area

(iii) *freedom from pain, injury and disease,* by prevention or rapid diagnosis and treatment

(iv) *freedom from fear and distress,* by providing sufficient space, proper facilities and company of the animal's own kind, and;

(v) *freedom to express normal pattern of behavior*, by ensuring conditions that avoid mental suffering (Webster, 2016).

Therefore, all experiments shall be designed to avoid distress and unnecessary suffering to the experimental experiments. It cannot be denied that animal is never likely to be completely free of the stipulated negative experience or states of thirst, hunger, discomfort, pain, fear, distress, malnutrition and injury. Nevertheless, a major strength of the Five Freedoms paradigm was that it very effectively directed intention towards the need to understand, identify and minimize negative welfare states (Mellor, 2016).

Both principles are internationally well-known principles governing the use of animal for scientific purposes. The Five Freedoms are now well recognized as highly influential in the animal welfare while the Three R's are a benchmark and well-accepted guiding principle underlying specifically the humane use of animal in experimentation. They have often been and still are referenced in the process of outlining the basic features of animal

wellbeing in policy statements and authoritative treaties. The two principles are widely incorporated in many animal research regulations of many countries as well as been recognized in various international documents. For example, Article 7.1.2 of Terrestrial Code outlines the guiding principle for animal welfare; among others are the Five Freedoms that provides valuable guidance on animal welfare Three R's that provides valuable guidance for the use of animals in science. Meanwhile, European Directive 2010 in article 4 highlighted the principle of Three R's.

(vi) Justification for Research

Animals may be legitimately be used for the purposes of scientific research where such research can be said to contribute and improved human and animal health (Sharman, 2006). Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge to be gained or lead to enhancement in human and/or animal well-being (Perry, 2007). The third principle of International Guiding Principle for Biomedical Research Involving Animals provides that animals should be used only when necessary and only when their use is scientifically and ethically justified. Article 7.8.1 of Terrestrial Code provides that such experiment is justified for the scientific or educational aim as well as important to human and animal health, environment, or the advancement of biomedical knowledge.

(vii) Definition of Animal

The protection offered by animal legislation should be extended to all living creatures, or at least to all vertebrate animals (Sharman, 2006). It is noted that the EU Directives in article 2(a) cover all vertebrates including free living larval and/or reproducing larval forms but excluding foetal or embryonic forms. Moreover, it also appears in international guidelines where some species of animals are prohibited to be used. In European Directive, there are number of articles restrict the use of particular animals such as endangered species (Article 7), non-human primates (Article 8) animals taken from the wild (Article 9) and stray or feral animals of domestic species (Article 11) (Ollson, Da Silva, Townend & Sandoe, 2016). These articles state that such animals cannot be used in procedures unless provided with scientific justification.

(viii) Qualifications and Training

The competence of the research personnel carrying out the procedure is an important element in promotion of animal welfare during research procedures (Whittaker, 2014). Thus, it is agreed that scientific procedures must always be carried out by qualified persons with formal training and appropriate experience in conducting procedures on

animals. Training in humane animal care should be provided to both animal researchers and personnel on on-going bases (Sharman, 2006).

The ninth principle of International Guiding Principles states that institution is responsible to ensure that the research personnel is qualified and competence by providing adequate on-going treatment and education on humane treatment of animals. Article 23 of the European Directive and Article 26 of the European Convention provide that the research staffs shall be adequately educated and trained before they can perform out any procedures on animals. European model is relatively advanced when the Directive requires a person on site with responsibility for 'ensuring that staffs are educated, competent and continuous trained' and the investigators should be supervised until they have demonstrated the requisite competence (Directive 2010/63/EU, Article 24.1(c)). Besides that, EU Directive requires that member states publish their minimum requirements with respect to education and training and their requirements for obtaining, maintaining and demonstrating competence (Directive 2010/63/EU, Article 23.3). A list of topics for inclusion as part of educational programs is also provided (Directive 2010/63/EU, Annex V).

Other than that, Article 7.8.5 of Terrestrial Code mentions that continuous professional and paraprofessional educational opportunities should be made to all relevant laboratory staffs. The provision further outline in detail and provide various scope of knowledge for all research personnel i.e. scientific staffs, veterinarians, animal care staffs, students and members of the local oversight committee or others involved in oversight. Besides that, occupational health and safety for research animal related risks should be provided as part of the assurance of training and competency for personnel.

    (ix)   Animal Ethics Committee

A competent authority needs to be established in order to implement a system for verification of compliance by institutions. Institutions may utilize a local committee i.e. Animal Ethics Committee (AEC) or Animal Care and Use Committee (ACUC) to do the oversight framework (Article 7.8.4, Terrestrial Code). AEC with clearly defined powers should be established at institutional, local, regional or national levels to approve proposals for animal research on the basis of their scientific merit and ethical acceptability (Sharman, 2006). Moreover, AEC should include equal numbers of research, veterinarians, animal welfare advocates and lay persons (Sharman, 2006).

    (x)   Unlawful research

Each nation should at a very minimum ensure that its animal research legislation prohibits certain types of animal tests (Sharman, 2006). This can be including tests where the animal is likely to experience severe or on-going pain, draize test, LD50 toxicity test where aims to determine the toxicity of a cosmetic and household products (Sharman, 2006). If

governments are not willing to prohibit such tests, they must ensure that a separate process for authorizing such research has been established, to ensure greater scrutiny for the tests and the conditions in which they are to be conducted (Sharman, 2006).

(c) *Malaysian Perspective: Adherence to International Best Standards for the Care and Use of Animals in Experimentation*

The use of animal for scientific purposes in Malaysia is governs by federal law i.e. Animal Welfare Act 2015 and Wildlife Conservation Act 2010 as well as policies of each research institution. The new legislation of Animal Welfare Act 2015 came with a significance of regulating the use of animals in research, testing and teaching where the subject matter was in form of self-regulation before the enactment. The law is based on the concept of animal welfare where it permits the use of animal for the scientific purposes. The welfare concept is incorporated in section 24(1)(a) of the AWA where it states that every owner or licensee has a duty to take reasonable steps to ensure that the welfare of animals in possession are fulfilled. This include its need to suitable diet and environment, its need of protection from pain and suffering, housing with or apart from other animals and to be able to exhibit its normal behaviour. These requirements are in line with the Five Freedoms principle mentioned above.

Further, section 26 of the Act outlines that no person shall use the animals in research, testing and teaching unless all reasonable steps must be taken to ensure good care of the physical, health and behavioural needs of the animals in accordance to both good practice and scientific knowledge. Besides, the animals shall be provided with treatment when they are ill or injured that will alleviate any unreasonable or unnecessary pain or distress. If the needs of the animals cannot be met or the treatment cannot be given due to the nature of the research, the pain or distress must be reduced into minimum possible in the circumstances. In another hand, the Three R's principle is upheld to justify the use of animals in scientific and teaching activities. It is stated in section 1 of MyCode that each activity need to consider the replacement of animals with other alternative methods, the reduction of number of animals used and the refinement of techniques used to reduce the adverse impact on animals. The rules also been incorporated in policy of all research institutions in Malaysia.

Furthermore, section 26 animals may only be used in research, testing and teaching. MyCode provides that scientific and teaching activities using animals may be performed only when they are essential such as *'to obtain and establish significant information relevant to the understanding of humans and animals; for the maintenance and improvement of human and/or animal health and welfare; for the improvement of animal management or production; to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment; or for the achievement of educational objectives.'* The code also requires a balancing of the

predicted scientific or educational value of a project with its effects on animal welfare. The benefit of the project must outweigh the suffering or death of the animals as well as non-availability of non-animal alternatives (MyCode). It shows that animals may only be used if the researcher can give valid justification.

Animal Welfare Act 2015 covers all animal species other than wildlife as section 2 of the Act defines animals as any living creatures other than humans. They include beast, bird, aquatic animal, reptile, and insect. Thus, with the provision, all species of animals, vertebrate and invertebrate are guaranteed for protection of their welfare under the Act. In the meantime, some policies of research institution in Malaysia cover definition of animal to be used in science to both vertebrate and invertebrate. For example, UKMAEC guidelines in section 4 refers animal as invertebrate and non-human vertebrate. Meanwhile, some policies like UM guideline excluded the invertebrate species to be used in research, teaching, biological testing and other related purposes.

Even though AWA clearly states that it does not cover the use of wildlife animal for scientific purposes, the subject matter is governed under the Wildlife Conservation Act 2010 (WCA). Besides, MyCode has a special provision detailing procedures for the use of wildlife for scientific purposes. In Malaysia, wildlife is also subjected to be used for scientific purposes in Malaysia such as protected species of crocodile, elephant and birds. Besides, the law is silent whether to include of live pre-natal or pre-hatched creatures in the last half of gestation, such as (i) mammalian or reptilian foetus (ii) pre-hatched avian, mammalian or reptilian young (eggs) and (iii) live marsupial young as animal. For the time being, it is under grey area and will be determined later when there are cases brought before court (RP1, 2018). There is also no provision of law that prohibits certain type of animals to be used as subject of experiments. In practice, researchers may use any types of animals including domestic animal such as cat as long as they can provide with justification (RP2, 2018).

Then, it is appeared that in Malaysia, there is requirement to establish AEC or IACUC where Section 2.1 of MyCode requires any institutions that use animals for scientific purposes to establish one or more IACUC to ensure that all care and use of animals is conducted in compliance of the Code and relevant legislation. IACUC is comprises at least 4 persons from 4 categories which are (i) a person who has qualification in veterinary service, (ii) a qualified person with substantial recent experience in the use of animals in scientific or teaching activities, (iii) a person who is not employed by the institution with commitment and established experience in welfare of animals and (iv) a layman who has never been involved in the use of animals. The main responsibility of the Institutional Animal Care and Use (IACUC) is to administer the care and use of animal for scientific purposes on behalf of the institution as to ensure that it is done humanely and ethically and in compliance with the Guide. The committee also responsible in reviewing the research proposals and evaluate the harm and benefits of the research project and ensures that the

use of animals for research is justified, and incorporates the principles of Replacement, Reduction and Refinement. The IACUC need to be satisfied with these three conditions before the use of animals is allowed i.e. (i) the research is vital, (ii) high quality of research with aim to publish in reputable journal and (iii) the Three Rules Principle is applied (RP2, 2018). They are also responsible for the training and annual monitoring or inspection of the facilities, as well as submit a written submission annually to the institutions on its activities.

The IACUCs in each of the respective institutions in Malaysia adhered to what is suggested by MyCode where some institutions have created effective organizations of training, monitoring and inspection while some efforts are still fledging. Currently, some institutions established multiple IACUCs and some ministries created centralized IACUCs to oversee multiple institutions within that ministry (Retnam et al, 2016). Therefore, there is a need to standardize and streamline the functions of various IACUCs and align them to the current laws i.e. AWA 2015 and its Animal Welfare (Animals Used in Research, Testing or Teaching) Regulations 2015. With the enactment of the AWA 2015, its subsidiary legislation i.e. the Animal Welfare (Animals Used in Research, Testing or Teaching) Regulations 2015 will regulate the IACUC which brings legal effect to the organization as they are now bound to the provisions in the Act and Regulations. Any inconsistencies or non-compliances to the prescribed laws and regulations, they can be sued and will be held liable under the AWA 2015.

Besides that, the competence of the research personnel carrying out the procedure is an important element in promotion of animal welfare during research procedures. MyCode addressed that an essential factor contributing to high standards of animal care is the number of well-trained committed personnel and the animal facilities need to be supervised by persons with appropriate veterinary or animal care qualifications. However, the Code is silent on the meaning of well-trained and the term appropriate is vague. In practice, a series of training are provided by the Institution as to produce competent and well-trained personnel. This is due to the responsibility of the Institution to provide educational programs, continuing training and workshop to the investigators. Institution should encourage and promote formal training and in animal science and technology. The training includes basic knowledge on laboratory animal science, animal handling and restraining, humane care and use of animals, the ethics of animal use in research and teaching, health and safety issues as well as regulations governing animal care and use. The training is a requirement for the investigator as a proof that he or she is qualified to perform specific procedures on animals.

Research institutions in Malaysia continuously give the required trainings to their researchers and personnel as to improve their skills. Among the relevant trainings and education are animal handling, ethics in the use of animal in research and occupational safety while conducting the scientific procedures (RP2, 2018). It is believed that every

research institution in Malaysia is aware of this requirement of having competent researchers and personnel. This is because even before the enactment of the AWA 2015, they already have their own policy which require of the well-trained researchers to conduct the project. For example, UM policy stated that all academicians, staffs, researchers, and students are required to undergo appropriate competency training on basic laboratory animal science and animal handling courses conducted by Laboratory Animal Committee (LAC) and/or other relevant bodies. In addition to relevant training on Occupational Safety and Health conducted by the University's Occupational Safety and Health Unit. Meanwhile, UKM policy requires all researchers to attend short courses on laboratory animal techniques and handling.

Despite the provision on the responsibility of the institution to provide adequate training to their personnel, the competency of the student or researchers is still an issue (RP1, 2018). From an observation to a laboratory of one of higher learning institute, students seem to be incompetent to carry out the procedure. Plus, the conductor and laboratory staffs failed to convey adequate knowledge on the needs and welfare of the animal as required in the policy of their institutions. As to this problem, there must be a set of standards to measure the competency of personnel. Besides, as suggested, there should be an active effort to collaborate with global peers with extensive experience and resources to advance care and use of animals in research (Retnam et al, 2016). Therefore, another area that requires continual improvement will be education for the researcher and personnel involved in animal research.

Finally, regarding the unlawful research, there is no provision of law restricting certain type of research to be prohibited in the country. For instance, toxicity test is still relevant in Malaysia as research on Malaysian herbs is still in demand and necessary (RP2, 2018). Thus, there must be a separate process for authorising such research to ensure greater scrutiny of the justification the tests and the conditions in which they are to be conducted.

4. Conclusion

The discussion has shown that Malaysian regulation has adhered to the most of international best standards on the use of animals for scientific purposes. Through the new legislation of Animal Welfare Act 2015, animal welfare concept is recognized along with its longstanding principle of Five Freedoms. MyCode in the other hand uphold the Three R's principle to be applied in every research activity. Besides that, AWA provides wide definition of animals which includes all species, vertebrae, and invertebrate except wildlife. Animal may only be used in research, testing, and teaching with a valid justification. IACUC is established at each research institutions among others to review the project proposal and give authorization to the researchers to use animals in scientific and educational purposes. However, there are some principles appear to be international standards in regulating the animal use in subject matter did not found in Malaysian

regulation for instance prohibition of certain species of animals to be used for experimental purposes and restriction of unlawful researches. To be highlighted here, the principles discussed above are not compulsory to be followed as there is not yet international treaty or convention that set the international best standards on the subject matter. At least by adhering to what have been appear in most of international documents show that Malaysia is now at par with international level in governing the animal use for scientific purposes.

All in all, Malaysia has taken serious effort to regulate the use of animals for scientific purposes by passing federal law which has legal effect. Nevertheless, it cannot be denied that law need to be effectively implemented and enforced.

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