

Attitudes to severity assessment in Japan

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Abstract

In Japan, it is stipulated that the institutional animal care and use committee (IACUC) be established at each research organization in "The Basic Policy on Animal Experimentation" (The Ministry of Education, Culture, Sports, Science and Technology, 2006) and so forth. The investigators are required to submit a protocol to the IACUC before the commencement of animal experiments. IACUC reviews and approves protocols in compliance with the applicable national and international laws and regulations and also with the institutional guidelines on animal experimentation based on the 3R tenet proposed by Russell and Burch (1959). It should be noted that the concept of the 3R tenet is clearly specified in the revised Japanese law "The Law Concerning Humane Treatment and Management of Animals" (2005). In assessing the severity imposed on animals, SCAW's* "Categories of Biomedical Experiments Based on Increasing Ethical Concerns for Non-human Species" (1987) has been widely utilized throughout Japan. During the course of protocol review, humane endpoints should also be taken into consideration. Furthermore, with the explosive increase of the use of genetically modified animal models in recent years, it is imperative for both IACUC and investigators to assess the adverse effects of genetic modification on animal welfare. Thus, IACUC should take various factors into consideration in reviewing/approving protocols. There is no doubt that regulations and guidelines concerning animal experimentation are of importance, but at the same time implementation of humane experiments greatly depends on each investigator's efforts or responsibilities.

*SCAW: Scientists' Center for Animal Welfare

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Introduction

In Japan "The Law Concerning Humane Treatment and Management of Animals" (the Law) was revised in 2005, and the revised Law went into operation as of June 1, 2006. It should be noted that the concept of the 3R tenet proposed by Russell and Burch (1959) is clearly specified in the revised Japanese Law. With the revision of the Law, the Ministry of the Environment (MOE) revised "The Standard for Care and Management of Laboratory Animals" in 2006 whereby the revised standard is called "The Standard for Care and Management of Laboratory Animals and Alleviation of Pain" (the Standard). Also the Ministry of Education, Culture, Sports, Science and Technology (MEXT), the Ministry of Health, Labor and Welfare (MHLW), and the Ministry of Agriculture, Forestry and Fisheries (MAFF) have each established "The Basic Policy on Animal Experimentation Performed at Research Organizations etc." in the same year. It is stipulated that the institutional animal care and use committee (IACUC) be established at each research organization in "The Basic Policy on Animal Experimentation" and

that the investigators are required to submit a protocol to the IACUC before the commencement of animal experiments. During the course of protocol review, it is imperative for both IACUC and investigators to assess the severity (pain and distress) imposed on animals. Here in the present paper, I will describe the severity assessment in Japan.

Results and Discussion

In 1987, it was required in Japan to stipulate the guidelines on animal experimentation at universities and other organizations by "The Notice on Animal Experimentation" issued by the Ministry of Education. In the same year, the Japanese Association for Laboratory Animal Science (JALAS) also established "The Guidelines on Animal Experimentation". The Notice and the Guidelines required that the institutional animal care and use committee (IACUC) should be established at each research organization and that the investigators should submit a protocol to the IACUC before the commencement of animal experiments. During the course of protocol review, it is imperative for both IACUC and investigators

to assess the severity (pain and distress) imposed on animals. In 1988, I introduced for the first time to Japan (Kuhara, 1988, 1990, 1992) SCAW's "Categories of Biomedical Experiments Based on Increasing Ethical Concerns for Non-human Species" ("Categories") that was published in *Laboratory Animal Science* (Anonymous, 1987). The Japanese translation of SCAW's "Categories" has since been widely utilized all over Japan up to today as a basis for assessing pain and distress imposed on laboratory animals. Later in 2002, Kurosawa *et al.* published "Categories of Biomedical Experiments Based on Pains and Distress Imposed upon Laboratory Animals" (Kurosawa, 2002). More recently, it was recommended that SCAW's "Categories" should be utilized in preparing/reviewing protocols in "The Guidelines on Animal Experimentation" that was published by the Science Council of Japan (SCJ) in 2006.

In reviewing protocols, humane endpoints should also be taken into consideration. In this respect, it is of great benefit for us Japanese to have available the translation (Nakai, 2006) of "Humane Endpoints for Animals Used in Biomedical Research and Testing" that was originally published in *ILAR Journal* (Stokes, 2000). I don't think that the concept of humane endpoints is well disseminated at present in Japan, therefore I am sure that the above translation would help disseminating the concept of humane endpoints in our country.

Furthermore, with the explosive increase of the use of genetically modified (GM) animal models in recent years, it is imperative for both IACUC and investigators to assess the adverse effects of genetic modification on animal welfare. The production of GM animals presents us very difficult ethical problems. Careful discussion would be needed with regard to the welfare of GM animals. There are several useful references regarding the welfare of GM animals (Robinson and Jennings, 2003, Canadian Council on Animal Care, 1997), and one of the references, i.e., "Refinement and Reduction in the Production of Genetically Modified Mice" that was originally published in *Laboratory Animals* (Robinson and Jennings, 2003), was translated into Japanese by myself (2006) and the published translation has contributed to the advancement of the welfare of GM animals in Japan. But I am strongly wishing that the guidelines for the welfare of GM animals would be established in Japan in the near future, considering that the number of GM animals used in biomedical researches is increasing explosively in Japan as well as overseas and that genetic modification might cause adverse effects on the welfare of GM animals.

Finally, it goes without saying that laws and regulations concerning animal welfare are of great significance, but at the same time it is more important for investigators and/or laboratory animal technicians to realize that laboratory animals are suffering pain and distress, and for all those who receive benefit from animal experimentation to feel gratitude for animals. For that purpose, education and training for investigators and/or laboratory animal technicians are needed. In Japan, the qualifying examination for laboratory animal technicians is in place. The qualifying examinations for laboratory animal technicians are carried out every year by the Japanese Society for Laboratory Animal Resources (JSLAR). The education and training for investigators and laboratory animal technicians are performed at each research organization as well as by JSLAR according to the "Basic Policy on Animal Experimentation". I strongly hope that animal welfare will be further promoted here in Japan.

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