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Operational issues of the Institutional Animal Care and Use Committee in Korea

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ABSTRACT

Korean Institutional Animal Care and Use Committee (IACUC) is currently facing some operational pressing issues. 1) Review of the animal protocol containing controversial technology. 2) Review of the multi-institution animal protocol. 3) Review of veterinary clinical trials for client-owned animals. 4) Delay in the review process in large institutions with a single IACUC. Here, the following three solutions are proposed to address the above issues. 1) Establishment of public IACUC. 2) Establishment of the Veterinary Clinical Study Committee as an advisory body to the IACUC. 3) Operating multiple committees rather than increasing the number of committee members on a single committee.

Keywords: Animal ethics; animal protocol review; animal welfare; clinical trial; Institutional Animal Care and Use Committee

INTRODUCTION

The Animal Protection Act (APA) [1] and the Laboratory Animal Act (LAA) [2] are two important laws in Korea that govern animal experiments and laboratory animal treatment [3]. In 2007, the Korean government mandated that all institutions with animal facilities should review each animal experiment protocol through their respective Institutional Animal Care and Use Committee (IACUC) by the APA [4]. In 2009, the government also enacted, in conjunction with the LAA, the establishment of the Laboratory Animal Management Committee (LAMC). Although the purpose and composition of each committee differ (**Table 1**), it is difficult to manage both committees simultaneously. Therefore, the IACUC is considered an LAMC if it meets the requirements of both the APA and the LAA. This was accomplished by recognizing the authority of a committee established by an institution, which is referred to as an "Integrated IACUC." The government published "The Guidelines for the Standard Operations of the IACUC," a document that describes the operation of an integrated IACUC, to allow for more flexibility in the IACUC operations [5]. Although certain sections in the integrated IACUC are contradictory, most institutions that operate animal facilities have an integrated IACUC, and the government generally approves these committees. However, there are still gaps present in the IACUC's operation, and the operating system could be improved. Although several issues have been raised in the integrated IACUC operations over the past 14 yr since 2008, we would

Table 1. The purpose and configurations of the IACUC as defined by the Laboratory Animal Act and the Animal Protection Act

Categories	Laboratory Animal Act	Animal Protection Act
Official name of committee	Laboratory Animal Management Committee	Institutional Animal Care and Use Committee
Main purpose	Scientific reliability of animal experiments	Ethical management and protection of animals
Roles of committee	1. Review and approval of ethical and scientific reliability of animal experiments 2. Confirmation and evaluation of supply, management, experiment, post-processing of laboratory animals 3. Confirmation and evaluation of animal facility management 4. Review of animal experiments using hazardous substances	4. Confirmation and evaluation of education and training program for animal facility manager and employees
Configuration	One committee per facility	One committee per institution
Number of committee members	4–15 persons	3–15 persons
Essential members	1. Veterinarian or Ph.D. with experience in animal experiments 2. Person referred by Animal Protection Organization	1. Veterinarian

The information here is based on the "Guidelines for the Standard Operations of the IACUC (in Korean)" published in 2018 [5].
IACUC, Institutional Animal Care and Use Committee.

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Conflict of Interest

The authors declare no conflicts of interest.

like to share our thoughts on the three issues listed below, which we believe that important. Some of the issues discussed here may be unique to Korea; however, we believe that majority of them, such as veterinary clinical trials, are worldwide issue [6].

PUBLIC IACUC

Due to their small size or budget, some institutions such as startup companies or small private research centers may have difficulty establishing IACUCs. Although small institutions can work together to build an IACUC, they may have difficulty on designing a set of rules. An institution that requires animal experiments to be conducted for pharmaceutical researches should follow the LAA; however, other institutions may disagree because the LAA regulations are generally stricter than the APA.

If multiple institutions are involved in a single animal protocol across multiple locations, or if controversial technologies, such as human-animal chimeric embryo generation, are used in animal experiments, an individual committee at an institution may be unable to approve the animal protocol. In such cases, a third-party committee may be required address the issues. Fortunately, an amendment to the APA on the establishment of the public IACUC passed the National Assembly plenary session in April 2022. However, if the public IACUC decision is not accepted by the institution, the decision is futile. Furthermore, animal researchers in each institution should not use the public IACUC to avoid IACUC animal protocol review from their institutions. As a result, if the government establishes a public IACUC or an organization to run it, it should clarify its legal authority so that the institution can follow the decision. Other roles of the public IACUC may include standardization of the review process and post-approval monitoring, education for researchers and institutions, and improvement of animal welfare by minimizing blind spots related to animal experiments, as in the case of public Institutional Review Boards in Korea operated by the National Institute for Bioethics Policy [7].

VETERINARY CLINICAL STUDIES COMMITTEE

In November 2020, an ignominious research article was published in which the surgery team excised one side of the eyeball from two normal beagle dogs and implanted artificial eyes created using three-dimensional printing technology [8]. Although the university's IACUC approved the animal protocol and the journal accepted the manuscript after peer review, the

journal's editorial team later posted an "Expression of Concern" in this article. Two concerns were raised and the following questions were asked: 1) Would the study provide clinical benefits for dogs over conventional eye removal procedures? 2) Could the study's use of naïve dogs instead of clinical cases be scientifically and/or clinically justified? Nobody could imagine an ocular surgeon applying a new artificial eye implantation technology in the same way. If this application is accepted for a clinical trial, the surgery will be only performed on voluntary patients with informed consent signed by the animal owner.

To protect animals from conflict of interest issues, the American Veterinary Medical Association suggests that if the protocol falls under the category of standard clinical treatment, it can be monitored by the Veterinary Clinical Studies Committee (VCSC) after receiving informed consent from the animal owner before undertaking clinical trials [9]. The protocol out of this category, of course, must also be approved by the IACUC. In this case, the VCSC obtains informed consent from the animal owner, forwards the proposal for IACUC review, and gives professional advice to the IACUC. Generally, IACUC review and approval are required for all teaching and research activities at most academic institutions, including clinical trials in the standard clinical treatment category [10]. Furthermore, the VCSC should have at least one member who is a member of the IACUC to act as a liaison between the two entities. The VCSC can be implemented in Korean veterinary clinics.

In many countries, including Korea, access to the IACUC or the VCSC in private veterinary clinics is difficult [6]. As with the public IACUC described above, the Korean Veterinary Medical Association or Korean Society of Veterinary Science may operate a public VCSC to manage the clinical trials for small local clinics, other than academic institutions and/or veterinary teaching hospitals. **Fig. 1** depicts an example of the action of the VCSC and its relationship with the IACUC.

However, whether clinical trials should be classified as a type of animal experiment or not is still debated, particularly when pharmaceutical products or biomedicine are used in the categories of testing regulated by the LAA [2]. If the clinical trial is considered an animal experiment regulated by the LAA, it should not be performed due to the violation of obtaining the experimental animal because the patient coming to the hospital is not included among the supply routes defined by the LAA: 1) another animal facility, 2) a qualified laboratory animal production facility, and 3) a registered laboratory animal supplier (Article 9, Use of Laboratory Animals) [2]. Therefore, all interested parties, including veterinary clinics, research institutions, government bodies, pharmaceutical companies, and even animal activists, should collaborate to reach agreements on the proper application of clinical research.

OPERATION OF MULTIPLE IACUCS

Since the number of IACUC members is currently limited to 15, a single integrated IACUC can delay the review process of animal protocols in large institutions with multiple animal facilities [11]. Increasing the number of committee members reviewing animal protocols could be one solution to expedite the reviews. However, it is debatable whether the actual process should be expedited because the protocol review is completed by the vote of all committee members, rather than by a reviewer's decision. As the number of voters increases, it takes longer to schedule meetings and make decisions on animal protocol reviews.

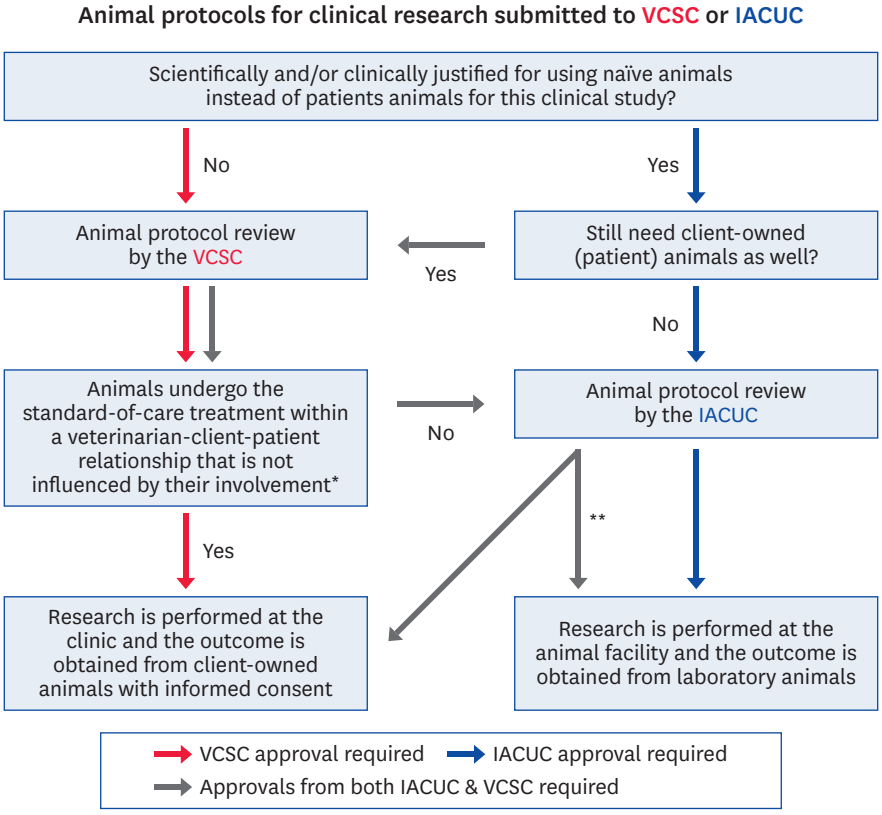

Fig. 1. The flow of the animal protocol review and approval for the clinical research, when both the VCSC and the IACUC are present at the veterinary hospital or the institution. Once the VCSC determines that the protocol will influence the management of the animal patient, the protocol is transferred to the IACUC for additional review.
VCSC, Veterinary Clinical Studies Committee; IACUC, Institutional Animal Care and Use Committee.
*Procedures must be within the categories of standard veterinary medical treatments. For example, testing the food supplement without specific change in the taste of dog or cat food, monitoring the interactions between the client and the patient, and application of medically approved new materials in surgery *etc*.
**When control animal monitoring is required at the animal facility.

Hence, for large institutions operating multiple animal facilities, limiting the number of animal protocols to be reviewed per each IACUC and establishing an additional mandatory IACUC may successfully achieve a prompt review process rather than increasing the number of the committee members in a single integrated IACUC. When formally asked, the Ministry of Agriculture, Food and Rural Affairs confirmed that one institution needs to operate a single IACUC. Therefore, the government must actively consider the operation of multiple committees.

CONCLUSION

Although the operation of the IACUC has significantly advanced animal experimentation in terms of ethical treatment of animals and raised the scientific standards since 2008, the IACUC operating system should be revised continuously. Although there may be other issues that need to be solved, the three suggestions above will help resolve the major issues in the current IACUC operations in Korea.

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