



저작자표시-비영리-변경금지 2.0 대한민국

이용자는 아래의 조건을 따르는 경우에 한하여 자유롭게

- 이 저작물을 복제, 배포, 전송, 전시, 공연 및 방송할 수 있습니다.

다음과 같은 조건을 따라야 합니다:



저작자표시. 귀하는 원저작자를 표시하여야 합니다.



비영리. 귀하는 이 저작물을 영리 목적으로 이용할 수 없습니다.



변경금지. 귀하는 이 저작물을 개작, 변형 또는 가공할 수 없습니다.

- 귀하는, 이 저작물의 재이용이나 배포의 경우, 이 저작물에 적용된 이용허락조건을 명확하게 나타내어야 합니다.
- 저작권자로부터 별도의 허가를 받으면 이러한 조건들은 적용되지 않습니다.

저작권법에 따른 이용자의 권리는 위의 내용에 의하여 영향을 받지 않습니다.

이것은 [이용허락규약\(Legal Code\)](#)을 이해하기 쉽게 요약한 것입니다.

[Disclaimer](#)

Ph.D. Dissertation of Veterinary Medicine

**Studies on the Institutional Animal Care and
Use Committee operation strategy in Korea**

한국의 동물실험윤리위원회 운영전략에 관한 연구

August 2022

**Graduate School of Veterinary Medicine
Seoul National University
Veterinary Pathology and Preventive Medicine Major
(Laboratory Animal Medicine)**

Na Ahn

Studies on the Institutional Animal Care and Use Committee operation strategy in Korea

Supervisor: Prof. Jaehak Park, D.V.M., Ph.D.

**Submitting a Ph.D. Dissertation of
Veterinary Medicine**

June 2022

**Graduate School of Veterinary Medicine
Seoul National University
Veterinary Pathology and Preventive Medicine Major
(Laboratory Animal Medicine)**

Na Ahn

Confirming the Ph.D. Dissertation written by

Na Ahn

July 2022

Chair Roh, Sangho (Seal)

Vice Chair Park, Jaehak (Seal)

Examiner Park, Se Chang (Seal)

Examiner Seok, Seung Hyeok (Seal)

Examiner Kim, C-Yoon (Seal)

Abstract

General Introduction: Laboratory animals are continuously used for biomedical research development despite the increasing availability of alternative methods to avoid animal experimentation. This study was undertaken to suggest the operational improvement of the Institutional Animal Care and Use Committee (IACUC). It focused on the case of Seoul National University (SNU), which conducts 5% of Korea's total animal protocol reviews and uses 10% of national laboratory animal usage. In addition, this study also outlines the current status and legal regulation issues with regard to the use and procurement of animals for research in Korea. The thesis is consists of four chapters as below.

Chapter 1. Use of laboratory animals and issues regarding the procurement of animals for research in Korea: This report outlines the current status of the use of laboratory animals in Korea. Compared with the UK, which uses a similar number of laboratory animals, the institutions in Korea tended to use more mammals such as rats and dogs. Alternatives should be implemented to avoid or replace the use of laboratory animals. Many animal experiment-related issues, including illegal animal supplies, recently discussed in Korea. Although animal activists claim to expand the

LAA regulation to most animal experiments which are currently under the APA regulation, if the type of animal experiment is out of the Laboratory Animal Act regulation, the scientific issues on the experiment should apply to the Animal Protection Act regulations. In addition, rather than regulating laboratory animal suppliers through legal means, enhancing education on ethical animal handling and treatment is more important for the researchers.

Chapter 2. The status of the IACUC of SNU (SNU-IACUC) – from its establishment to the present day: Here, as one of the pioneers of the IACUC in Korea, the author reported SNU-IACUC operations and activities including committee establishment and legal formulation, protocol review, and post-approval monitoring of protocols, which the IACUC has undertaken in the last decade. When compared with the national data, the scale of animal experimental protocols at SNU accounted for 5–7% of national data. The proportion of rodent use in the SNU was over 10% from 359 institutions operating IACUC nationwide. In addition, legal regulations and improvements were also discussed, and encompassed the limited number of committee members and the single IACUC policy in Korea. The author also emphasized the independent nature of the IACUC in protecting activities, including approval and monitoring animal experiments and its public role in narrowing the knowledge gap between society and scientists.

Chapter 3. Improvement plans on the operation of the Institutional Animal Care and Use Committee – focusing on the case of Seoul

National University: This study is focused on the grounded theory approach and sixty people were surveyed through purposeful sampling. Through this study, the author found that various practical educations are necessary such as: 1) Education for researchers on how to write a protocol 2) Standardization of screening criteria for various animal experiments by presenting various cases 3) Training on a detailed understanding of relevant laws and policies. The results of the surveys suggest that institutions that conduct animal experiments must continuously provide education to the researchers and the IACUC members. In addition, the institutions operating animal facilities and the IACUC must establish a unified/integrated management organization or consultative body with relevant committees for smoother operation of the IACUC. If greater levels of education and an integrated management system are established, it will be possible to enhance the excellence of researchers and to better manage the operation of the IACUC.

Chapter 4. Operational issues of the IACUC in Korea and suggestions for improvement: Korean 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 the review process in large institutions with a single IACUC. Here, the following three solutions are proposed to address above issues. 1) To review the application of controversial technology and/or multi-institution animal protocol, a public IACUC is required. 2) For clinical trials, the Veterinary Clinical Study Committee (VCSC), as an advisory body to the IACUC should be established. Owners of companion animals may provide informed consent to VCSC, which advises the IACUC. 3) The IACUC in large institutions should operate multiple committees of smaller members rather than increasing the number of members on a single committee.

Keywords: animal ethics, animal protocol review, animal welfare, the Institutional Animal Care and Use Committee (IACUC), laboratory animals, Seoul National University

Student Number: 2019-31521

Table of Contents

Abstract	1
Table of Contents	5
List of Figures	6
List of Tables	8
List of abbreviations.....	10
Chapter 1. Use of laboratory animals and issues regarding the procurement of animals for research in Korea.....	11
1.1. Introduction	12
1.2. Materials and Methods	17
1.3. Results and Discussion	19
Chapter 2. The status of the IACUC of Seoul National University – from its establishment to the present day.....	31
2.1. Introduction	32
2.2. Results	40
2.3. Discussion.....	60
Chapter 3. Improvement plans on the operation of the Institutional Animal Care and Use Committee – focusing on the case of Seoul National University.....	61
3.1. Introduction	62
3.2. Materials and Methods	65
3.3. Results	70
3.4. Discussion.....	88
Chapter 4. Operational issues of the IACUC in Korea and suggestions for improvement	91
4.1. Introduction	92
4.2. Opinions and Perspective	95
References.....	102
Abstract in Korean	111

LIST OF FIGURES

Fig. 1.1. A comparison of the total numbers of animals used for research and educational purposes nationwide from 2015 to 2020 -----	22
Fig. 1.2. A comparison of the numbers and ratios of mice for research and educational purposes in the UK and Korea in 2019 -----	23
Fig. 1.3. Comparisons of the numbers of various animal species for research and education purposes in the UK and Korea in 2019. A Primates, dogs, and reptiles/amphibians; B rats, birds, and fish -----	24
Fig. 1.4. The numbers of dogs and monkeys including primates used for research and education purposes nationwide from 2015 to 2020 -----	25
Fig. 2.1. The number of animal protocols reviewed by the SNU-IACUC from 2005–2019 -----	37
Fig. 2.2. Schematic of the protocol review process in the SNU-IACUC and the structure of SNU-IACUC -----	43
Fig. 2.3. A comparison of the total numbers of the representative animal species (mouse, rat, rabbit, dog, pig, and monkey) used for education and research purposes in the SNU and nationwide, from 2014–2019 -----	50

Fig. 2.4. The numbers and proportions of the representative animal species (mouse, rat, rabbit, dog, pig and monkey) in "full committee review" and "designated professional review" protocols approved by the SNU-IACUC, from 2013–2019 ----- 52

Fig. 2.5. Comparison of the four approval patterns of protocols reviewed by the SNU-IACUC and nationwide: averages from 2014–2019 ----- 54

Fig. 3.1. A Schematic diagram of an integrated management system for Seoul National University ----- 87

Fig. 4.1. The flow of the animal protocol review and approval for the clinical research, when both the Veterinary Clinical Studies Committee and the IACUC are present at the veterinary hospital or the institution ----- 98

LIST OF TABLES

Table 1.1. National report of Korea for animal use per institution operating the animal facility -----	14
Table 1.2. Recent issues related with the procurement of dogs and cats for research in Korea -----	26
Table 2.1. The operating bodies related to animal experimentation and facility in SNU and their roles over the years -----	34
Table 2.2. Animal facilities in Seoul National University -----	39
Table 2.3. National report of Korea for the animal protocol review from 2015-2019 -----	48
Table 2.4. Trend analyses of animal uses of six representative species in the SNU and nationwide -----	49
Table 3.1. Demographic characteristics of survey participants -----	69
Table 3.2. Status of protocol review in the IACUCs of various institutions	73
Table 3.3. Understanding of the process of animal protocol review when the protocol require approval by multiple committees -----	74
Table 3.4. Institution's supports and guarantee of autonomy to the IACUC	75

Table 3.5. Responses of researchers when protocol review was not approved
by the reviewer ----- 77

Table 3.6. Main opinions and suggestions of participants to their institutions
and government bodies about IACUC and animal experiments ----- 78

Table 4.1. The purpose and configurations of the Institutional Animal Care
and Use Committee as defined by the Laboratory Animal Act and the Animal
Protection Act ----- 94

LIST OF ABBREVIATIONS

APA: Animal Protection Act

APO: Animal Protection Organization

APQA: Animal and Plant Quarantine Agency

AV: Attending Veterinarian

DPR: designated professional review

FCR: full committee review

GLP: Good Laboratory Practice

IACUC: Institutional Animal Care and Use Committee

IBC: Institutional Biosafety Committee

IEPS: Institute of Environmental Protection & Safety

ILAR: Institute of Laboratory Animal Resources

IRB: Institutional Review Board

KLRI: Korea Legislation Research Institute

LAA: Laboratory Animal Act

LAMC: Laboratory Animal Management Committee

LMO: Living Modified Organism

PAM: post-approval monitoring

SNU: Seoul National University

VCSC: Veterinary Clinical Studies Committee

CHAPTER 1

Use of laboratory animals and issues
regarding the procurement of animals for
research in Korea

1.1. INTRODUCTION

Cell-based assay and computer simulation using big data have gradually started to replace animal studies although animal experimentation has contributed to biomedical sciences development, legal regulation increase, social perception change, and various alternative method suggestions. Despite the increasing availability of alternative methods to avoid animal experimentation, laboratory animals are continuously used for biomedical research development, including preclinical screening processes. Experiments on live animals often aim to acquire basic biological knowledge; discover and develop drugs, vaccines, and medical devices; safely test drugs, chemicals, and consumer products; research on the environment; and educate and train [1].

The use of animals for scientific purposes in Korea has been continuously increasing, similar to other countries. In addition, the number of institutions operating animal facilities has also increased (Table 1.1). The government operates the Animal Protection and Welfare Division (APWD) in the Animal and Plant Quarantine Agency (APQA) under the Ministry of Agriculture, Food and Rural Affairs (MAFRA) to manage and control the use of laboratory animals and animal facility operation at the national level

[2, 3]. APWD works together with the Animal Welfare Policy team of the MAFRA; it also operates the Institutional Animal Care and Use Committee (IACUC) portal website to support the IACUC operation nationwide and also offers information on the use, care, and welfare of animals to the scientists and public [4].

Any research institute that introduces animals must ensure that all processes, including the animal purchase process, are legal. Thus, the principal investigators must check whether their institute has appropriate facilities and specialized skills to manage the animals before purchasing it. Before purchasing animals, prior approval by the IACUC for the purpose and quantity of laboratory animals is required [5]. In Korea, animal uses are regulated by two laws; Laboratory Animal Act (LAA) and Animal Protection Act (APA). APA was primarily focused on preventing abuses of companion animals [6]; now, the policy objective and purpose were expanded to enhance public health, sentiment, and confidence, through an effective system minimizing animal cruelty and promoting animal welfare. On the other hand, LAA aims to contribute to life sciences development and public health improvement by enhancing the reliability of animal research and testing through appropriate regulation and oversight of institutions, laboratory animals, and animal testing [7].

Table 1.1. National report of Korea for animal use per institution operating the animal facility.

	2015	2016	2018	2019	2020
No. Institutions	351	333	362	380	413
Total animals use (nationwide)	2,507,157	2,878,907	3,727,163	3,712,380	4,141,433
Animal use per institution (Average)	7,142	8,645	10,296	9,769	10,277
- Public Research Institution	5,884	6,158	8,819	6,258	7,217
- University	7,322	8,996	9,642	10,028	9,691
- Medical Institute	6,327	7,610	8,648	10,352	10,619
- Private Company	7,848	9,871	11,886	11,011	11,776

Abstracted and translated from the annual reports posted in Institute of Animal Care and Use Committee Portal [4] operated by the Animal and Plant Quarantine Agency of Korea.

The data for 2017 are unavailable.

If the experiment is within the categories described in Article 3 of LAA [8], the animals may need to be obtained from registered laboratory animal suppliers. *“Article 3 (Object of Application): This Act shall apply to administration of animals used in testing required for any of the following subparagraphs and of animal testing facilities thereof or such: 1) development, safety control and quality control of foods, functional health foods, medical and pharmaceutical products, non-medical and pharmaceutical products, biomedicines, medical appliances, and cosmetics; 2) safety control and quality control of narcotics”*. The animals for testing or research defined in Article 3 of the LAA should be supplied by one of these three routes: (1) another animal facility, (2) a qualified laboratory animal production facility, and (3) a registered laboratory animal supplier. In addition, laboratory animals (e.g., rodents, beagles, and primates), managed by registered laboratory animal suppliers, must be handled by these suppliers. The registered laboratory animal supplier must regularly provide information to the animal facility of the institute regarding the animal breeding group and the genetic and microbiological status of the animals as well as the clinical history (e.g., vaccination or vermicides treatment records).

Although Article 3 of the LAA clearly defines the categories of animal experimentation regulated by the LAA, many experiments are complex and often border those categories. In this case, the institution

recommends the researchers to follow the LAA. However, researchers often cannot obtain the animals for animal experiments by one of those three routes in some instances. For example, obtaining wild animals, farm animals, and vertebrates other than mammals from a registered laboratory animal supplier, qualified laboratory animal production facility, or another animal facility is difficult. Students or researchers often visit private or public farms outside of their institution for training or research, where the animals are not obtained from the routes mentioned above. While scientists are making efforts to follow current regulations, the public often calls for stricter regulations. In particular, the animal rights movement has made its presence more known worldwide, and the difference in perspective between animal activists and animal research scientists has grown wider than before. Korea is not an exception to this. Although scientists are making efforts to reduce the use of laboratory animals, activists and even the public often call for stricter regulation to protect animals. Whilst some of the activists' claims appear acceptable, others often do not reflect science and reality [9].

This chapter outlines the current status of the use of laboratory animals in Korea and compares it with the status of the UK, which uses a similar number of laboratory animals in the world. In addition, it was discussed that animal procurement for research and education, as well as its legal regulation, by two legislative acts in Korea, the Animal Protection Act (APA) [10] and the LAA [8] with a few suggestions.

1.2. MATERIALS AND METHODS

Data collection

All national data for the use of animals from 2015 to 2020 were collected from the annual press release posted on the IACUC portal, which is open to the public for free use. APQA did not post the 2017 press release online; thus, this present study could not present data for 2017. The UK statistics for the use of animals in 2018 posted by the Understanding Animal Research (UAR) [11] were compared with the Korean statistics of the same year. UAR permitted the use of materials from its website. The UK government prefers to use the term “the number of procedures,” not “the number of animals,” because some animals may be used more than once, i.e., “re-used” in certain circumstances. Therefore, the number of procedures is usually slightly higher than the number of animals used. However, Korean statistics do not tell them apart, and the statistics posted in UAR were directly compared with Korean statistics.

All national legal information as regards the use of animals and supplies was obtained from the Korean Law Translation Center website, which is operated by the Korea Legislation Research Institute (KLRI) [12].

To obtain the interests and views of animal activists and the public about the issues regarding the use and supply of companion animals for research, the articles and editorials produced by various media were collected online and recent three cases were selected for discussion among the collected information.

1.3. RESULTS & DISCUSSION

The use of laboratory animals in Korea

APQA posted online the national animal usage data and statistics for 2015, 2016, 2018, 2019, and 2020 [4]. All information from the APQA is in Korean, and the authors translated and reformed it in English (Table 1.1). While the number of institutions operating animal facilities is gradually increasing annually, the number of animals used for education and research purposes was also noted to increase nationwide, from 2.5 to 4.1 million in 2015 and 2020, respectively. Although the increase in the use of animals per institution slowed down in 2019, a remarkable re-increase occurred in 2020.

As expected, rodents are the most widely used animals in studies, followed by fish and birds (Fig. 1.1). Of these rodents, 90% were mice. Most fish and birds used were zebrafish and chicken, respectively. The use of mammals other than rodents remarkably increased from 68,789 to 100,340 in 2016 and 2018, respectively. In a positive phenomenon, the number of animals in the same category decreased to 63,409 in 2019, although the use of rodents still increased in the same period. However, the decreasing trend did not last more than 1 year in Korea, unfortunately. In

2020, the use of most animal species, except for fish, has remarkably increased. In other country cases, such as the UK and Germany, the use of animals in research began to decline in 2015 and 2014, respectively [13]. This trend has not reversed in both countries. According to the UK statistics (except Northern Ireland), procedures increased after 2001, reaching a peak of 4.14 million in 2015, but it has decreased to 2.88 million in 2020. This is the lowest number of procedures carried out in a single year since 2004 [14]. In the UK, the scientific strategy for animal experiments is changing. In fact, Wellcome Sanger Institute, one of the world's top genomics centers, has decided to close its 13-year-old animal research facility which supplies mice for genetic scientists worldwide [15]. The UK government also explains that, in response to the coronavirus pandemic, restrictions such as lockdown which imposed strict limits on daily life may have affected research activity at establishments as well. However, no extra data were collected concerning the pandemic on its effect on the establishments. On the other hand, the pandemic did not affect animal experiments in Korea. The UK and Korea used a similar number of laboratory animals for research and education purposes, and over 70% of animals in experimental procedures were mice in both countries (Fig. 1.2). Interestingly, the institutions in Korea tended to use more rats and dogs, while the institutions in the UK used more fish, reptiles, and amphibians for animal experiments (Fig. 1.3A, B).

In Korea, the public is generally concerned about the use of companion animals and primates, and the Animal Protection Organizations has always kept their eyes on the laboratory use of dogs, including beagles. According to 2019 data, the institutions in Korea used more dogs thrice than the institutions in the UK (Fig. 1.3A). Primates, by the number of procedures, reached a peak of 3,600 in the UK in 2015 and 2016 [16], whereas animal experiments using primates are continuously increasing in Korea by 2020 (Fig. 1.4). Several facilities that can manage and breed primates were recently built and are in operation in Korea, and this may be one of main reasons for increase in the use of primates for research purposes.

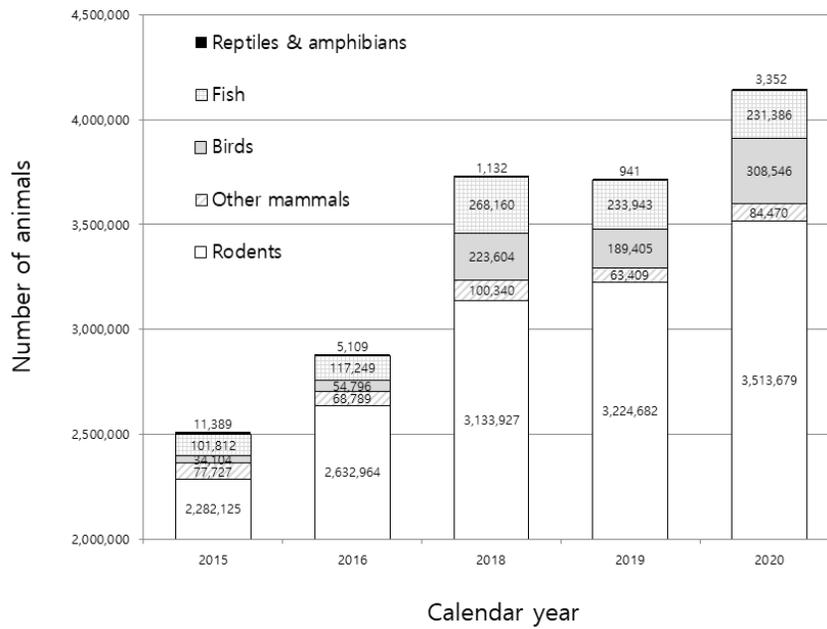


Fig. 1.1. A comparison of the total numbers of animals used for research and educational purposes nationwide from 2015 to 2020. Data were collected from the national Institutional Animal Care and Use Committee portal [4]. Data for 2017 are unavailable.

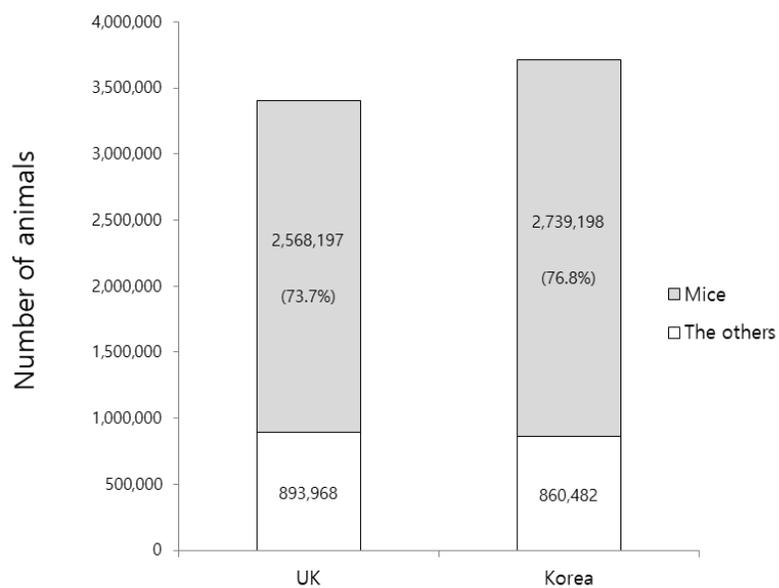


Fig. 1.2. A comparison of the numbers and ratios of mice for research and educational purposes in the UK and Korea in 2019. Data were collected from the national Institutional Animal Care and Use Committee portal [4] for Korean statistics and the Understanding Animal Research website [11] for the UK statistics.

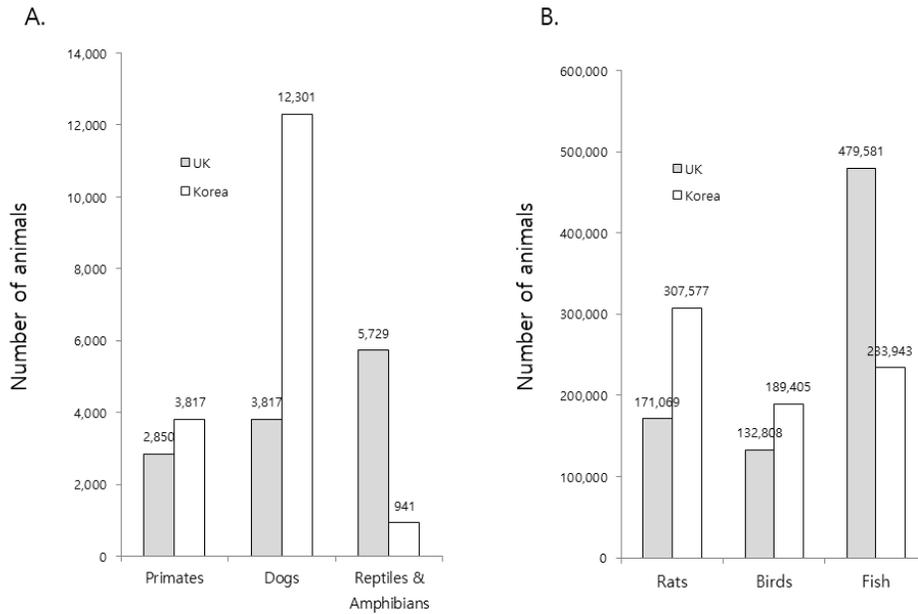


Fig. 1.3. Comparisons of the numbers of various animal species for research and education purposes in the UK and Korea in 2019. A Primates, dogs, and reptiles/amphibians; B rats, birds, and fish. Data were collected from the national Institutional Animal Care and Use Committee portal [4] for Korean statistics and the Understanding Animal Research website [11] for the UK statistics.

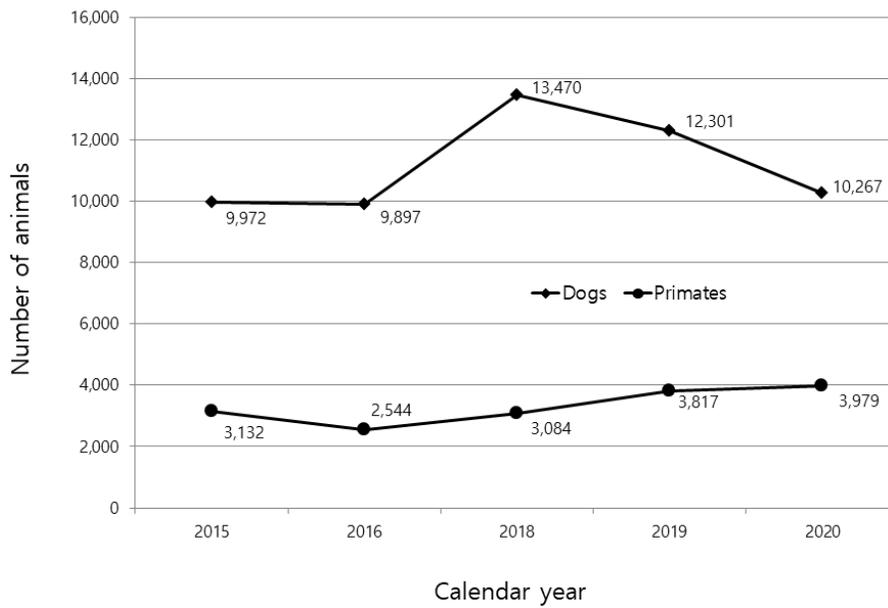


Fig. 1.4. The numbers of dogs and monkeys including primates used for research and education purposes nationwide from 2015 to 2020. Data were collected from the national Institutional Animal Care and Use Committee portal [4]. Data for 2017 are unavailable.

Table 1.2. Recent issues related with the procurement of dogs and cats for research in Korea.

Cases in point (year)	Summary of the contents*
<p>1. Purchase of dogs from unregistered animal supplier for a dog cloning project</p> <p>(December 2017)</p>	<p>KARA, an animal activist group, claimed that the dog cloning team [17] obtained the foster and oocyte donor dogs from a dog meat farm for the dog cloning program at a university [18]. However, according to the legal regulation in Korea, the dogs supplied to the cloning project were not included in the categories regulated by the LAA [8]; thus, enforcement of the law was not applicable. However, activists have claimed that all animal supplies for experiments, including dogs and cats, must be done by a registered laboratory animal supplier.</p>
<p>2. Illegal cat experiments using cats obtained from unauthorized routes</p> <p>(May 2020)</p>	<p>A general hospital and an affiliate professor were accused of animal abuse after allegations broke out that they had conducted unnecessary experiments on cats and euthanized them without proper anesthesia [19]. BRN had submitted a bill of indictment. BRN also claimed that they may have used some stray or abandoned cats taken from the streets in surgical experiments violating Article 24 of the APA [10]. However, the illegal animal supplies ended without prosecution, whereas improper use of drugs remains on trial.</p>

3. Purchase of dogs from an unclear source for veterinary education and training (March 2018)

A veterinary school had purchased dogs for education and training from an unclear source. The presumed source of dogs was a local dog meat shop, which could not be a registered animal supplier. Although the use of animals for veterinary education and training is out of the categories regulated by the LAA, the ALW accused a professor of this school, who is in charge of this training class, of the APA violation and so on [20]. According to the ALW's claim, the IACUC of the school failed to cross-check the address of the animal supplier, which was the same address as a local dog meat shop.

*KARA: Korea Animal Rights Advocates; LAA: Laboratory Animal Act; BRN: Beagle Rescue Network; APA: Animal Protection Act; ALW: Animal Liberation Wave; IACUC: Institutional Animal Care and Use Committee

Issues regarding the procurement of animals for research in Korea

Many animal experiment-related issues, including illegal animal supplies, recently discussed in Korea. Here the author introduces three examples of issues concerning animal supply which have recently occurred in Korea (Table 1.2).

Implementation of absolute or relative replacement

Korea tends to use more mammals including rats and dogs when compared with the UK. It should also be noted that the use of primates is continuously increased. Even excluding activists' calls for stricter regulation, the trend in animal use in Korea is far different from the other developed countries such as the UK and Germany. Following Russel and Burch's concept of the 3Rs (replacement, reduction and refinement) [21], replacement alternatives are being widely discussed to avoid or replace the use of laboratory animals. This includes both absolute replacements (i.e. replacing animals with computer models or microorganisms) and relative replacements (i.e. replacing animals with lower potential for pain perception). It may be impossible to replace every animal experiment with an absolute replacement. However, there are many relative replacement options. Although pain perception in fish or reptiles/amphibians is a matter of debate [22], the comparatively higher use of fish and reptiles/amphibians

in the UK can be seen as part of the effort to implement relative replacement. It is the time for researchers and government bodies to discuss this issue more seriously in Korea. In addition, the authority and autonomy of the IACUC must be ensured by institutions operating animal facilities to monitor the use of animals [23].

Legal regulations and suggestions for revision

Purchasing animals for laboratory uses from general animal shops or suppliers, also selling companion animals, is likely to be unscientific. Furthermore, these animals have a high possibility of spreading infectious diseases to humans. However, some animals (e.g., industrial animals), including chicken, are only available for purchase from registered general animal sales businesses, not from registered laboratory animal suppliers. Although most experiments or practices using industrial animals are not under the LAA regulation, some animal tests (e.g., testing of medical appliances) are included in this regulation. Purchasing those industrial animals from registered animal suppliers is hardly possible, and breeding all kinds of animals for specific experimentation purposes by the limited number of suppliers is also difficult. In addition, animal activists' claims to expand the LAA regulation to most animal experiments which are currently under the APA regulation is one of the major concerns to the researchers as described in Table 1.2. Such circumstance often makes some scientists

hesitate to initiate their animal research because they concern that they may not obtain the animals legally.

LAA application should continue only to the animal studies and tests which Good Laboratory Practice, generally known as GLP, requires. To avoid confusion and precise application of both acts, the reformation of the APA and the LAA is recommended in the future. For example, the LAA concentrates on the scientific reliability of animal experiments and the implementation of alternatives to animal testing, whereas the IACUC regulated by the APA covers all issues on animal welfare and ethics from the supply of animals to the completion of animal experiments. If the type of animal experiment is out of the LAA regulation, the scientific issues on the experiment also apply to the APA regulations. In addition, rather than regulating laboratory animal suppliers through legal means, enhancing education on ethical animal handling and treatment is more important for the researchers.

The suggestion(s) in this study can be a starting point to address the concerns of all parties to achieve a complete agreement for the proper use of laboratory animals. The author also hopes the information provided here will help animal researchers in global community understand the status of the animal experiment and the procurement of animals in Korea.

CHAPTER 2

The status of the IACUC of Seoul National
University: from its establishment to the
present day

2.1. INTRODUCTION

Despite growing public concern and increasing availability and diversity of alternative scientific methods, animals continue to be used for scientific purposes. The main purpose of scientific studies on live animals is: 1) to gain basic biological knowledge, 2) to investigate drug discovery and development, 3) to investigate vaccine and medical device research, 4) to assess safety testing of drugs, chemicals, and consumer products, 5) to perform environmental research, and 6) to assist with education and training [1]. The IACUC of Seoul National University (SNU) plays a key role in monitoring and managing the humane use of animals in research across the university campus, and by extension across Korea. This report outlines the activities undertaken by the IACUC of SNU (SNU-IACUC) over the last decade.

SNU-IACUC is one of the early established IACUCs in Korea, and advocates implementation of the 3Rs [6, 21], i.e., Replacement, Reduction and Refinement with respect to animal research, when university researchers propose experiments. In March 2005, the university first launched the Animal Experiment Committee of SNU (SNU-AEC) which later handed over its role to the SNU-IACUC. Three months later in June 2005, the

university also established the Institute of Laboratory Animal Resources of Seoul National University (SNU-ILAR) [24] to manage all animal facilities across the campus. The institute supported the operation of the SNU-AEC at that time. After launching of SNU-IACUC and SNU-ILAR, the university could collect and evaluate the data related to animal use in the campus, and also could manage animal facilities and train researchers and staffs more professionally. In 2007, the Korean government imposed requirements for an IACUC at all institutions running animal facilities [25], thus 2008, the SNU renamed the committee as the SNU-IACUC, and operation of the new committee was set apart from the SNU-ILAR to guarantee independence. SNU-IACUC specialize its roles to protocol reviews and the monitoring of approved animal experiments while SNU-ILAR is focusing the management of animal facilities and the education and training (Table 2.1). Although the official name in English is the IACUC, the Korean meaning is closer to “Committee on Animal Research and Ethics,” therefore reviewers focus more on ethical issues when they review a protocol. In October 2008, the SNU-IACUC was finally approved for legal operation by the APQA [2].

Table 2.1. The operating bodies related to animal experimentation and facility in Seoul National University (SNU) and their roles over the years.*

Roles Year(s)	~2005	2005-2008	2008~2020	2021~
Legal status of IACUC	N/A	Under preparation of IACUC by MAFRA	Operation of IACUC becomes compulsory to all institutions running animal facilities	
Animal protocol review	N/A	SNU-AEC** (ILAR support its operation including administration)	SNU-IACUC (Operation was set apart from the SNU-ILAR to guarantee independence and its administration is directly supported by Research Affairs)	
Post approval monitoring	N/A	None	SNU-IACUC	
Authority for animal facility management	Each college/facility	SNU-ILAR and each college/facility	SNU-ILAR: animal facilities registered to MFDS SNU-IACUC: all other animal facilities	SNU-ILAR

Education and training for researchers and animal facility staffs	Each college/facility	ILAR (Large facilities also operate their own program)	
		SNU-IACUC operates (re-) education programs for its own committee members	
Veterinary consulting	Each facility has own responsibility		ILAR supports consulting service to small facilities which cannot afford to employ veterinarian
	Large facilities generally employ their own attending veterinarian(s)		
Animal supply (purchase) and disposal	Each college/facility	SNU-ILAR	
Microorganism monitoring	Each college/facility		ILAR plans to integrate

N/A: not applicable; MAFRA: Ministry of Agriculture, Food and Rural Affairs; IACUC: the Institutional Animal Care and Use Committee; AEC: Animal Experiment Committee; ILAR: Institute of Laboratory Animal Resources; MFDS: Ministry of Food and Drug Safety

*The information here is based on the white paper of SNU-IACUC published in 2015 [26], and personal experiences and communications. Official opinion of SNU and organizations mentioned here may differ.

**SNU-AEC was launched by SNU Research Affairs in preparation of IACUC planned to be imposed by the government at that time. This committee is regulated by SNU bylaws, not by national laws.

Due to complicated legal limitations, the SNU only operates one IACUC. According to the APA in Korea [10], which regulate all types of animal use and correct animal experimental conduct, one corporation cannot operate multiple IACUCs, regardless of the scale of its animal use. In addition, the number of committee members who have voting rights is limited to 15. To avoid delays in the reviewing process, the SNU-IACUC has appointed 10 additional professional reviewers who are specialized in the animal study field; however these individuals do not have voting powers. Before reviewing a protocol, the professional secretary (administrator) pre-screens every protocol and conduct associated administrative processes. As a full-time employee, the professional secretary can either be a veterinarian or qualified individual (master's degree) with experience of animal experiments and/or animal ethics. In 2019, the committee reviewed more than 1,700 protocols, including protocol amendment requests (Fig. 2.1) [26]. In 2020, to expedite and shorten turn-around times for protocols, the university assigned additional staff to cover this administrative work. In addition to protocol review, committee functions also include regular and occasional post-approval monitoring (PAM). Regular PAM is generally performed in conjunction with the animal facility check, which is conducted by the SNU-ILAR every six months, which is the managing and regulatory body of the animal facilities in the SNU.

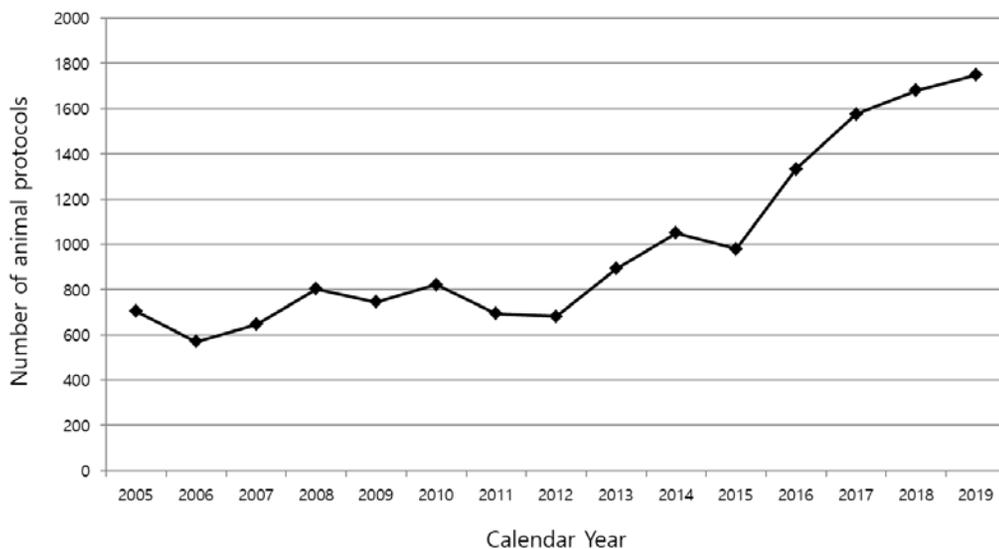


Fig. 2.1. The number of animal protocols reviewed by the Institutional Animal Care and Use Committee of Seoul National University (SNU-IACUC) from 2005–2019. Data from 2005–2014 were obtained from the SNU-IACUC white paper [26], and data from 2015–2019 were collected from the SNU-IACUC data archives.

From the medical school to the college of engineering, many researchers across the SNU have submitted animal experimental protocols to the SNU-IACUC. Thus, animal research activities at SNU are wide, and ranges from agriculture to translational medicine. To support those research activities, there are 15 animal facilities across the SNU, operated by six colleges and four institutes. Some facilities are located outside the main campus, i.e., medical and agricultural units (Table 2.2). With very few exceptions, most animal experiments in the SNU are performed at one of these animal facilities. In September 2020, the SNU completed a large centralized animal facility, directly operated by SNU-ILAR in Gwanak (main) campus. This facility is forecasted to take over animal housing from small or satellite animal facilities on the main campus, and will also offer several services including consulting by attending veterinarians, embryo preservation and transfer and purchasing of laboratory animals.

Table 2.2. Animal facilities in Seoul National University.

Campus*	Operating College or Institute	Name of animal facility
Gwanak	College of Agriculture and Life Sciences (CAL S)	CALS animal facility
Pyeongchang	Institute of Green BioScience & Technology	Designed Animal Resource Center
Gwanak	College of Veterinary Medicine (CVM)	CVM animal facility
Gwanak	CVM	Bio-MAX animal facility
Gwanak	CVM	Veterinary Medical Teaching Hospital animal facility
Gwanak	College of Pharmacy (CP)	Animal Center for Pharmaceutical Research
Gwanak	CP	CP satellite animal facility
Gwanak	Institute of Laboratory Animal Research (ILAR)	ILAR animal facility
Gwanak	College of Natural Sciences (CNS)	CNS animal facility
Gwanak	Institute of Molecular Biology & Genetics (IMBG)	IMBG animal facility
Yeongeon	College of Medicine (CM)	CM animal facility
Yeongeon	CM	Biomedical Center for Animal Resource Development
Hongcheon	Wide River Institute of Immunology (WRII)	WRII animal facility
Yeongeon	School of Dentistry (SD)	SD animal facility
Gwanak	SD	SD animal facility in Gwanak campus

*Gwanak: main; Yeongeon and Hongcheon: medical; Pyeongchang: agricultural.

2.2. RESULTS

Protocol review process of the SNU-IACUC

According to guidelines for the standard operations of the IACUC published by APQA and the Ministry of Drug and Food Safety (MDFS) [10], five pain levels (PLs) exist, and are categorized A to E. These pain categorizations are similar to the United States Department of Agriculture animal pain and distress categories [28]. The Korean guidelines by APQA and MDFS mostly refer to ‘Guide for the care and use of laboratory animals’ published by National Research Council of the United States of America [5] and only a specific difference is about the institutional-appointed Attending Veterinarian (AV) in animal facility. According to the Korean guidelines, AV is not compulsory while each animal facility must have an AV in the United States of America and the European Union by law.

A PL-A protocol is generally exempted from the reviewing process. Apart from PL-A protocol review, the SNU-IACUC engages with two types of review system: 1) designated professional review (DPR), and 2) full committee review (FCR). The DPR approach is generally applied to PL-B and -C protocols, while FCR is generally applied to PL-D and -E protocols. From 2020, for dogs, cats and monkeys including primates, FCR is applied to all protocols. Regardless of the type of review system, all committee

members regularly confirmed all protocols in committee meeting afterward. The general flow of a protocol review is described (Fig. 2.2). In the forthcoming paragraphs we introduce the FCR and DPR systems, respectively.

All protocol review procedures from submission to final decision including member voting are conducted online. When a researcher submit a protocol through the online submission system, the administrator pre-screens the protocol to sure all paperwork is correct, including experimental procedures and required animal numbers. Then, the protocol is assigned to a professional reviewer who is expert in that particular research area. The professional reviewer here includes some IACUC members who are experts in various fields of animal experiments and 10 additional reviewers who are not the IACUC members but experts in the fields not covered by the IACUC members. If a protocol involves a potential conflict of interest with a provisional reviewer, that individual is not assigned to that task. The professional reviewer is obligated to review all animal care and welfare issues and associated scientific animal studies. Once the protocol has been reviewed and approved, a report is delivered to all 15 committee members in order to conduct a general review and vote. The protocol is passed by a majority and is handed over to the IACUC chair for a final decision. At this stage, while most protocols are approved by the committee, if the chair determines any protocol issues, the protocol may be sent back to the

applicant, with comments. If the professional reviewer does not approve the protocol, the documents are returned to the applicant with one of the following two decisions, and some revision comments: 1) conditionally approved with a request for revision or 2) re-review after revision. For the former situation (1), the applicant must revise the protocol accordingly. Once the professional secretary receives the revised version and does not determine any further issues, the protocol goes to the chair. For the latter situation (2), the revised version of the protocol is sent to the same professional reviewer for re-reviewing then goes to the next place, general review and member voting.

In the DPR system, approval of a new or amended protocol may be directly finalized by the chair after professional review, without general review and member voting. The professional reviewing process reflects the FCR system however, if the chair, professional reviewer or professional secretary requests a general review and member voting for specific reasons, the protocol is referred to the FCR process for secure approval. Among the protocol amendment requests, simple modifications such as address change, replacement of technician, extension of the study period by less than three months, or increased animal numbers by less than 10% (rodents only) goes to the chair directly, regardless of protocol PL or the type of review system.

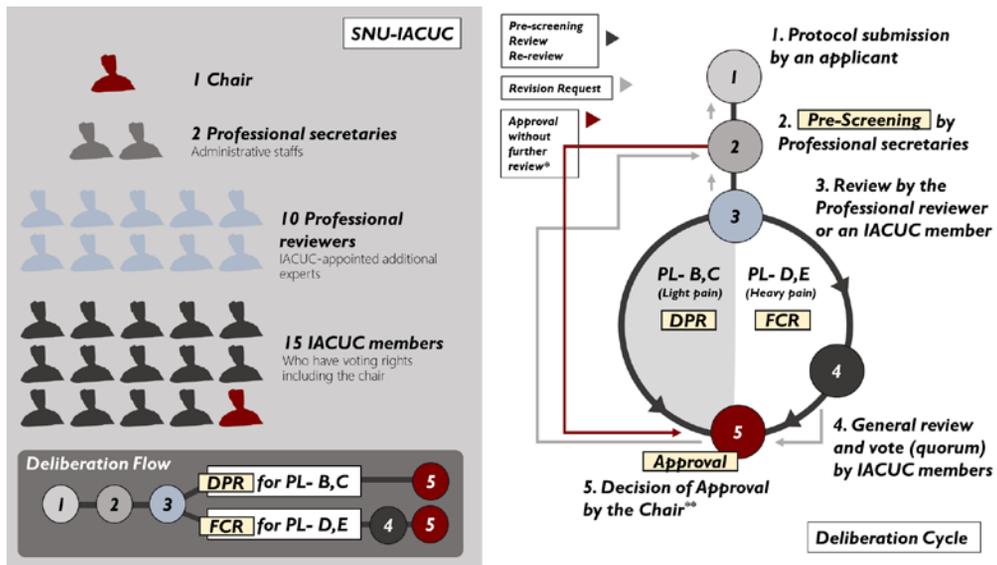


Fig. 2.2. Schematic of the protocol review process in the Institutional Animal Care and Use Committee of Seoul National University (SNU-IACUC) and the structure of SNU-IACUC. *1) The revised protocol without further issue after the decision of ‘conditionally approved with a request for revision’, 2) Simple modifications such as address change, replacement of technician, extension of the study period by less than three months, or increased animal numbers by less than 10% (rodents only). **Regardless of the type of review system, all committee members regularly confirmed all protocols in committee meeting afterward. DPR: designated professional review, FCR: full committee review, PL: pain levels.

Status of a protocol review by SNU-IACUC

Data collection

Although public concern regarding animal experiments is growing, the use of live animals for biomedical research is also increasing in Korea. This scenario at the SNU is no exception. In the next chapter, a decade of protocol reviews across the SNU was collated, and some results were compared with national data from APQA. The SNU-IACUC data were obtained either from the SNU-IACUC white paper published in 2015 [26] or from SNU-IACUC data archives. National data were collected from the national IACUC portal operated by APQA [24] which open to the public. SNU-IACUC permitted the use of data collected from its data archives as long as the data are in the range of annual report submitted to APQA. There was a limit to our report because the years of data obtained from SNU-IACUC and APQA varied from 2005 to 2015 depending on categories.

The scale of animal protocols

After launching the SNU-AEC in 2005, protocol review numbers increased considerably (Fig. 2.1). When compared with the national data (Table 2.3), the scale of animal experimental protocols at SNU accounted for 5-7% of national data. In 2019, the number of institutions registering

their own IACUC to APQA was 410, and the average number of protocols reviewed by each active (operative) IACUC was approximately 100. In contrast, SNU-IACUC reviewed over 1,700 protocols or protocol amendments in this period – approximately 20-fold greater than the national average.

Animal numbers, species, and PLs in submitted protocols

Of the approximate 20 animal species, from fish to horses used for animal experiments in SNU, the author selected six mammalian species; mouse, rat, rabbit, dog, pig and monkey (including primates), as representative animals for trend analyses of PLs and animal use. Importantly, these six species accounted for more than 90% of all animal experiments performed at SNU, and therefore adequately represented experimental studies and PLs.

As expected, most study animals were mice, followed by rats (Table 2.4). The numbers of the six representative animal species used for education and research purposes increased from 2.4 million in 2014 to 3.7 million in 2018, nationwide (Fig. 2.3). Use of the animals across the SNU also increased from 164,409 to 367,205 in the same period, and the proportion of animal use in the SNU has also increased up from 6.8% to 9.9%, when compared with national data during this period. In particular, the proportion of mice and rat use in the SNU was over 10% of total mice and rat use from 359 institutions operating IACUC nationwide in 2018 (Table 2.4). The increased use of the six representative animal species slowed down in 2019 (Fig. 2.3), whereas protocol reviews increased in both the SNU (Fig. 2.1) and nationwide (Table 2.3). This status reflected a reduction of animal numbers in protocols when compared with the

previous year. In the SNU, animal experimental protocols using pigs and dogs were also relatively high as well as mouse and rat protocols. This reason stemmed partly from xenotransplantation studies using mini-pigs [29] and dog cloning [30], respectively. Many scientists are involved in these projects as principal or collaborative investigators. In addition, as the SNU medical school has specific-pathogen-free mini-pig care and breeding facility in its “Biomedical Center for Animal Resource Development,” some protocols are taken over to obtain the permission of the distribution of those pigs and collaboration to share specific mini-pig with other institutions. Rabbits were primarily used for dental and orthopedic implant research in the SNU [31], whereas monkeys were generally used for xenotransplantation [32] or neuroscience [33] research.

Table 2.3. National report of Korea for the animal protocol review from 2015-2019.

Number of	2015	2016	2017	2018	2019
Total institutions registered IACUC	351	364	N/A	385	410
Total Institutions operating IACUC ^a	322	326	N/A	359	386
Total protocol review nationwide ^b	22,398	25,053	N/A	33,825	39,244
Protocol review per institution ^{b/a}	63.8	76.8	N/A	94.2	101.7

Abstracted and translated from the Institute of Animal Care and Use Committee Portal [4] operated by Animal and Plant Quarantine Agency of Korea.

Table 2.4. Trend analyses of animal uses of six representative species in the SNU and nationwide.

		2013	2014	2015	2016	2017	2018	2019
Mouse	National			1,893,493	2,212,357		2,739,198	2,851,898
	SNU	136,688	143,192	178,333	181,112	230,958	290,993	309,114
	SNU/National			9.42%	8.19%		10.62%	10.84%
Rat	National			319,519	351,821		320,896	307,577
	SNU	24,445	17,108	25,527	34,141	34,724	32,743	30,631
	SNU/National			7.99%	9.70%		10.20%	9.96%
Rabbit	National			37,178	37,373		34,952	27,001
	SNU	991	652	786	865	818	832	953
	SNU/National			2.11%	2.31%		2.38%	3.53%
Dog	National			9,972	9,897		13,470	12,301
	SNU	857	1,143	522	771	1,571	1,790	824
	SNU/National			5.23%	7.79%		13.29%	6.70%
Pig	National			11,636	11,354		11,808	9,323
	SNU	894	618	488	3,805	2,815	1,551	421
	SNU/National			4.19%	33.51%		13.14%	4.52%
Monkey	National			3,132	2,544		3,084	3,817
	SNU	0	60	127	175	197	110	116
	SNU/National			4.05%	6.88%		3.57%	3.04%

National data for this table were collected from the Institute of Animal Care and Use Committee Portal [4]. Only data from 2015, 2016, 2018 and 2019 were available.

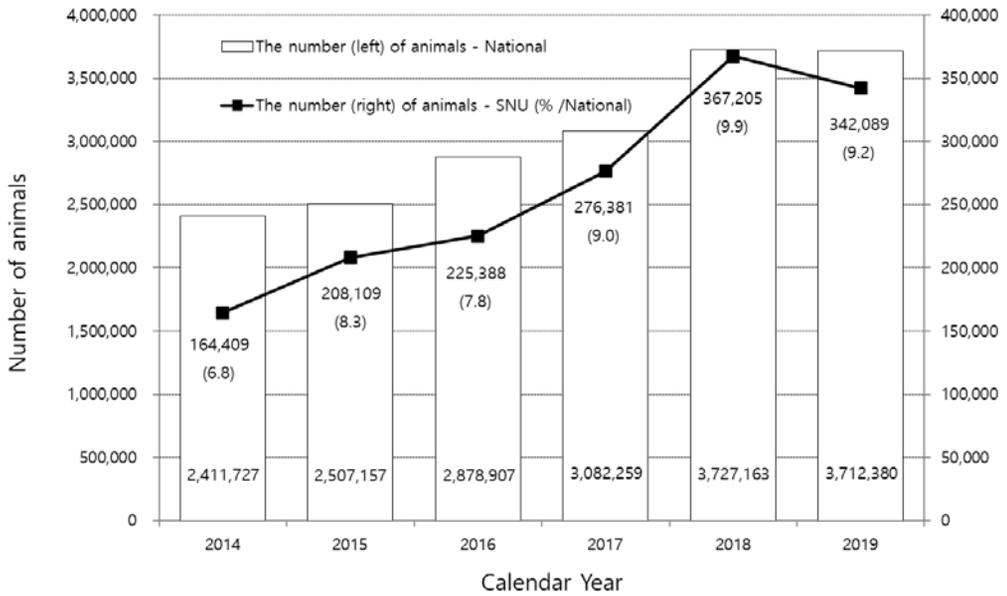


Fig. 2.3. A comparison of the total numbers of the representative animal species (mouse, rat, rabbit, dog, pig, and monkey) used for education and research purposes in the Seoul National University (SNU) and nationwide, from 2014–2019. SNU data were collected from the Institute of Animal Care and Use Committee (IACUC) of SNU data archives, and national data were collected from the national IACUC portal [4].

As mentioned previously, those protocols assigned to FCR were generally PL-D or -E status but there were exceptions. According to data from 2013 to 2019, the proportion of the representative animal species assigned to FCR review in the SNU-IACUC was 60-70% while the remainder was assigned to DPR (Fig. 2.4). The reason we compared the number and proportion of “the animals actually used in the protocols” assigned to FCR and DPR, instead of those of “the protocols”, is mainly because the numbers of animals in protocols varies from one to thousands, and the numbers of protocols and the animals in each protocol could be double counted as many researchers apply “Protocol amendment requests” in the same year as well. For instance, in the case of mice for FCR review, numerous protocols were related to cancer or neuroscience research, which traditionally induce high levels of animal pain, while toxicology-related protocols were mainly assigned to FCR review in rats (data not shown).

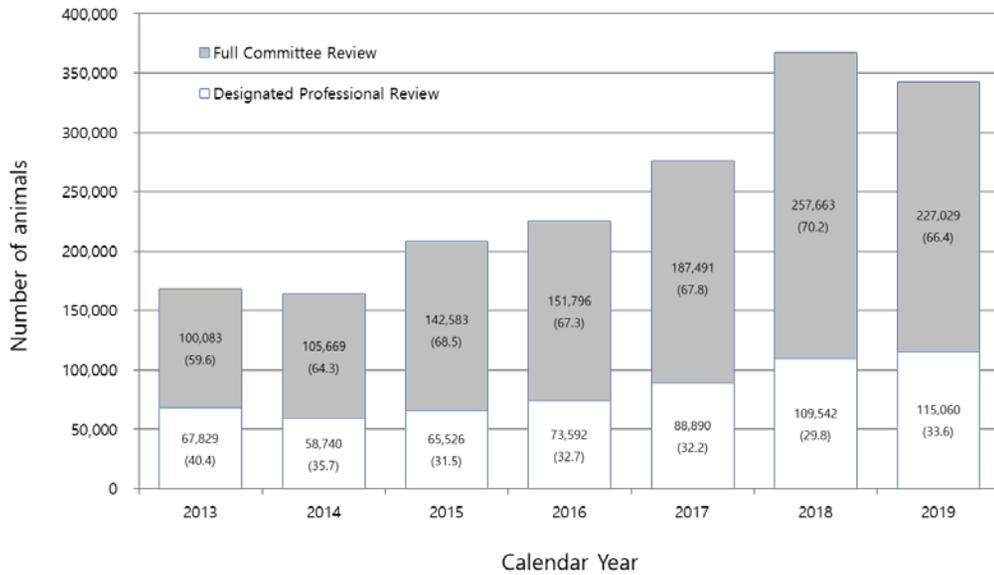


Fig. 2.4. The numbers and proportions of the representative animal species (mouse, rat, rabbit, dog, pig and monkey) in “full committee review” and “designated professional review” protocols approved by the Institutional Animal Care and Use Committee of Seoul National University (SNU-IACUC), from 2013–2019. The data were collected from the SNU-IACUC data archives.

Approved, conditionally approved with a request for revision, re-review after revision and rejected

Regardless of PLs, once a professional reviewer examined a protocol, they must assign a decision from the following four categories: 1) approved, 2) conditionally approved with a request for revision, 3) re-review after revision, and 4) rejected. As indicated (Fig. 2.5) protocol approval patterns were similar to national reports, although SNU-IACUC tended to impose more “re-review after revision” decisions to applicants, as the first decision. In contrast, “rejected” decisions were rare in the SNU-IACUC. This situation may have been partly reflected by SNU-IACUC strategy. Because some protocols were required to be twice revised to avoid “rejected”, there was a possibility of overlapped aggregation to count “re-review after revision”. Hence, the author only showed a tendency here, thus the precise number of original protocols could not be presented. In general, professional reviewers preferred to send back protocols with detailed comments if there were no severe ethical issues, instead of outright rejection.

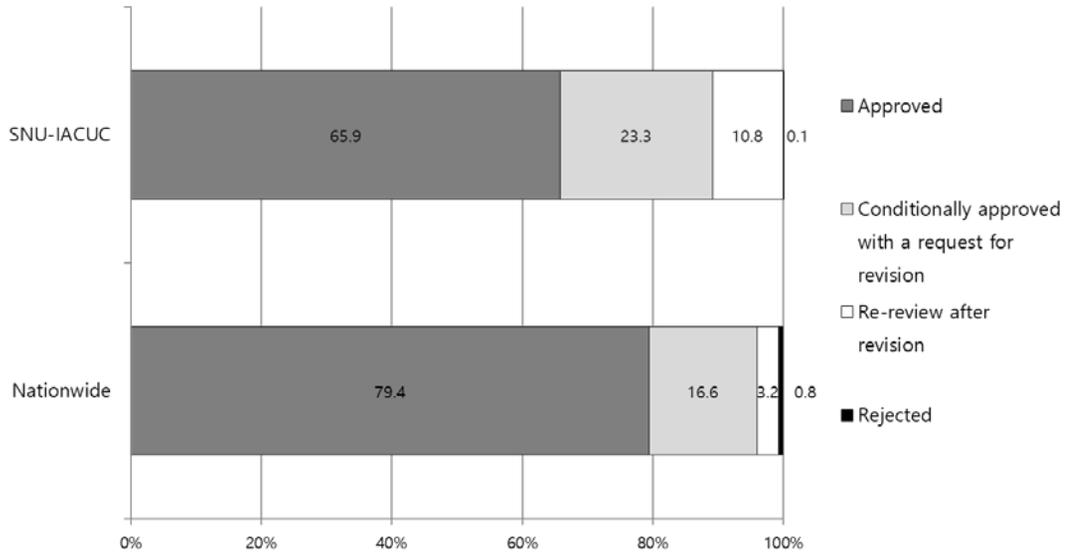


Fig. 2.5. Comparison of the four approval patterns of protocols reviewed by the Institutional Animal Care and Use Committee of Seoul National University (SNU-IACUC) and nationwide: averages from 2014–2019. SNU-IACUC data were collected from the SNU-IACUC data archives, and national data were collected from the national IACUC portal [4].

Issues with protocol PAM

PAM is an important service of the SNU-IACUC, and is just as vital as protocol review. In performing PAM, the committee ascertains whether researchers have followed all guidelines, and experiments were conducted as approved. In recent years, two important issues were directly observed from PAM activities; 1) overcrowded mouse housing, and 2) concerns related to dog reuse.

During a PAM review in an animal facility, committee members observed an overcrowded cage, which housed a nest of transgenic mice. Unfortunately, the facility had neglected to control mouse populations in cages; therefore, the SNU-IACUC reported this issue to the facility representative and requested a preventive action report. The facility was then listed in the next PAM schedule. When unsolicited visit was conducted later, the committee found no overcrowded cages.

When reviewing multiple protocols for period extensions by one research group, the professional reviewer observed that several physiological experiments were in progress, but the dog supply for experiments was limited. The reviewer was concerned about the duplicated use of some dogs for different experiments, and reported this issue to the committee followed by PAM. Fortunately no severe violations were observed against dog use; however, no information on “date of birth”,

“individual number/code”, and “protocol approval number” was observed on cage labels. This lack of vital information could potentially cause researchers to duplicate animal use, or promote incorrect animal use. Hence, the committee requested that researchers update all dog labels, including their respective names for future monitoring. After receiving the action report which was accompanied by the necessary documents, the committee confirmed all required corrections were completed.

Requirement of regulatory amendments

About 2,000 protocols, including protocol amendment requests, are currently under review of the SNU-IACUC. However, as the APA [10] requires that there be only a single committee and restricts it to consist of only 15 or fewer voting members, there are a lot of difficulties operating the IACUC, especially in large institutions such as SNU. In order to address this problem, as of December, 2020, efforts are being made at the National Assembly. Amendments, which would allow the active use of DPR and abolish the limit of the number of voting committee members, are currently on the table. Nonetheless, it remains that the single IACUC policy needs to be revised, and the double regulation imposed upon by the LAA [8] also poses a problem; as the LAA, which regulates animal experimentations for drug development, also limits the number of the committee members to 15

people or less, animal facilities at SNU, including the SNU-ILAR, are required to follow both laws.

APA was primarily focused on preventing abuses of companion animals [6], and now the policy objective and purpose is expanded to enhance public health, sentiment and confidence, through an effective system minimizing animal cruelty and promoting animal welfare, while the purpose of the LAA is to contribute to the development of life sciences and improvement in public health by enhancing the reliability of animal research and testing, through appropriate regulation and oversight of institutions, laboratory animals and animal testing [7]. The animals for testing or experimentation regulated by the LAA (Article 3) should be supplied either by another animal facility, a qualified laboratory animal production facility, or a registered laboratory animal supplier [8]. The categories defined by Article 3 of the LAA is limited to the specific animal testing or experimentation such as the safety and quality controls of foods, functional health foods, medical and pharmaceutical products, non-medical and pharmaceutical products, biomedicines, medical appliances, cosmetics, and narcotics. Although the other types of animal experiments just follow the regulation of the APA which does not limit the animal supply route, many institutions operating animal facilities are expanding this regulation to most animal experimentations as some experiments are complex and often border the categories. This often makes scientists abandon their animal research at

the planning stage because they cannot obtain the animals to use 'legally'. Reformation of APA and/or LAA including merging these two Acts should be considered instead of repeated amendments of each Act.

To achieve a seamless operation of the IACUC at SNU and in Korea, it seems that simply relying on the possible law reforms is not enough. The most important task seems to be acknowledging and expanding the authority and autonomy of the IACUC.

IACUC, institution and public

Despite ongoing alternative method development to avoid animal experimentation and growing public concern, animal use in scientific research cannot be completely avoided. Hence, it is incumbent that the scientific community communicates with the public to tolerate animal experimentation. This can be done by providing accurate information on animal welfare and clearly demonstrating efforts to reduce animal use in laboratories. In addition, the IACUC and its members should make efforts to narrow knowledge gaps in society, and this includes animal activists and scientists who conduct animal experiments. This strategy can be facilitated by alerting and studying public concerns on animal welfare issues. The IACUC is an autonomous body, and its right to approve and monitor animal experiments and related activities such as PAM are delegated by national

authorities. In addition, scientists and veterinarians work together with members or nominees of the Animal Protection Organization (APO) on this committee. Hence, institutions with IACUCs guarantee committee independence and protect their right to approve protocols and other activities. If IACUC decisions are interrupted or intervened by the APO, principal investigators, the national press or social media, then the committee cannot maintain its autonomy.

2.3. DISCUSSION

With 15 years' experience, the SNU-IACUC is facilitating humane animal research and carefully monitoring and controlling experimental animal use in Korea. In this study, as an IACUC pioneer in Korea, the author reviewed the SNU-IACUC operations and sought out areas that required improvement. Above all, the operation of a single IACUC policy must be changed for larger institutions, which operate multiple animal facilities e.g., SNU. Needless to say, the institution operating animal facility must secure the authority and autonomy of its IACUC. The authors hope the information provided here will help society understand the operational status of the IACUC in SNU.

CHAPTER 3

Improvement plans on the operation of the Institutional Animal Care and Use Committee – focusing on the case of Seoul National University

3.1. INTRODUCTION

The IACUC became compulsory in 2008 by the in Korea [25]. In particular, SNU first launched the SNU-AEC in 2005, and the SNU-AEC changed its name to the IACUC in 2008, following a government mandate [23]. Subsequently, SNU has been influential in the review of animal protocols and management of animal facilities. However, the administrative systems in SNU are divided into two sections: Research Affairs supporting the operation of the IACUC, and the ILAR managing the animal facilities. However, the governmental regulations related to animal experimentation are also controlled by two laws: the APA and the LAA [25]. Thus, there are overlapping areas and blind spots in the management system for animal experimentation.

As animal experiments with genetically modified organisms and human materials gradually increase in research, communication with relevant committees such as the Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC) is becoming essential. However, as the government departments managing these committees differ, the researchers, confused by complex regulations and guides, have raised dissatisfaction with the IACUC and the university. This is an issue faced by animal researchers, committee staff, and animal facility managers. Moreover, since the IACUC is an “institutional committee,” if it meets its

purpose and values, its way of operation significantly varies between institutions and countries. A number of studies have analyzed the status of animal experiments and related guidelines [1, 7, 25]; however, there has been limited research except a review paper reporting from the establishment of an institution IACUC to its current status in Korea [23]. To our best knowledge, there are limited studies that investigate and analyze problems and improvement measures in the operation of IACUC.

Grounded theory is often used to explain specific cases or provide a study framework. Grounded theory is a qualitative research methodology that explores practical fields in order to explain specific social phenomena or obtain a new understanding of existing social phenomena. Therefore, grounded theory is a qualitative research methodology useful in understanding the social, psychological, and structural phenomena of humans and societies that are difficult to capture through other research methodologies [34, 35]. Grounded theory provides researchers and readers with understanding about specific social phenomena and provides meaningful insight into human action and interaction by strengthening their understanding [36]. Therefore, grounded theory attempts abstract conceptualization and theorization of the process and trajectory surrounding human behavior and interaction, thereby developing both the substantive and formal theories of social reality [37]. Grounded theory methodology has become the most representative qualitative research methodology in social science fields such as education, nursing, business administration, family

studies, gerontology, social work, women's studies, and cultural research [38, 39, 40]. In addition, the coding method of the grounded theory method is widely used as a representative analysis technique in qualitative research.

This study was conducted by collecting opinions from related parties inside and outside the school regarding the operation of the IACUC at SNU (SNU-IACUC), which leads the animal experimentation-related field at national level and has an overwhelming scale in terms of quantity and analyzed respondents' opinions using the grounded theory methodology. The study was also undertaken to suggest the operational improvement of the IACUC and other relevant committees, in addition to related organizations. This is useful information for animal experimenters, researchers, practitioners in the SNU and Korea, and related parties globally.

3.2. MATERIALS & METHODS

The methodological framework consists of a qualitative approach. The study was conducted with the IRB approval from the SNU School of Dentistry (IRB approval number: S-D20210022). The survey was conducted by email and the participants provided informed consent.

Respondent Description

Theoretical Sampling

Theoretical sampling is purposeful sampling according to categories that we developed and these categories are based on theoretical concerns. Sixty people were surveyed through purposeful sampling. In the case of the SNU researchers, the main respondents, the target principal investigators, and graduate students/postdocs were selected to reflect the representativeness of each campus and major colleges. In addition, animal facility operators, administrators, and the IACUC members of each institution were selected as survey subjects from institutions that model IACUC according to the type of institution such as private company, university, and hospital.

SNU conducts 5% of Korea's total animal protocol reviews and also uses 10% of the national laboratory animal usage. It is a vast research institute that consumes approximately 350,000 experimental animals per

year, mainly rodents, at 15 official animal facilities located on four campuses [23]. This is close to the total annual use of laboratory animals in the Netherlands or Israel [13]. In addition, being a university, the types of animal experiments performed and the affiliation of researchers vary and it is possible to collect a variety of samples and cases—unlike institutions that only conduct research on specific animal species or specific fields.

Therefore, the questionnaire was designed for the principal investigators and researchers who submit animal protocols which will be reviewed by the IACUC and the animal facility operators who manage the laboratory animals. However, for the analyses related to the operation of the IACUC, comparative analyses must be performed according to the type and size of institution including university, public institution, and private company. Therefore, in the case of the IACUC members and administrators, a survey was conducted targeting the IACUC members and administrators in universities (national and private), public institutions, and private companies that operate the IACUC in Korea.

Demographic characteristics of the respondents

The frequency and proportion of participants according to their majors, careers, and their roles within the IACUC are presented in Table 3.1. Many of the survey respondents had majored in veterinary and animal sciences because both the principal investigator and researchers, and also a

significant number of animal facility operators and the IACUC members and administrators, had majored in the relevant fields. Since the College of Medicine has animal facilities on three campuses (Yeongeon, Pyeongchang, and Hongcheon) within SNU, and the College of Pharmacy also operates large-scale animal facilities in Gwanak campus to conduct animal research, the ratio of principal investigators and researchers who majored in these two colleges is second highest after veterinary and animal sciences. Consequently, the survey request to the researchers was calculated at an appropriate rate.

As a result of examining the period during which the respondents conducted activities related to animal experiments such as research, facility management, protocol review, committee administration, etc., most of the reviewers and the principal investigators were classified as having over 10 years of experience in animal experiment-related experiences. If the respondents had performed research for over 10 years as a researcher and acted as a reviewer for the last five years, they were classified as those with over 10 years of experience in relation to animal experiments.

Questionnaire composition of the survey

The questionnaire was composed of items necessary for improving the operation of IACUC based on the opinions of experts in the field, such as animal facility operators and administrative personnel, referring to

various suggestions of SNU animal researchers posted over the past several years. The survey targets were classified as the IACUC members, administrators, animal facility operators, principal investigators, and researchers (postdocs and graduate students). In addition, the questionnaire contents were divided into the IACUC members, administrators, animal facility operators, and research personnel (principal investigators, postdocs and graduate students) according to their duties.

Data Analyses

The survey was conducted and analyzed as follows. First, similar answers were grouped in the data, categorized, and open coding was performed to suggest response rates for each item. Subsequently, items (topics) showing significant results were extracted, and among them, the key issues necessary for operational improvement of the IACUC were selected and survey results were derived through an axial coding process. Subsequently, the study was conducted through the process of searching for alternatives through selective coding, which analyzes the questionnaires asking about differences in opinions by groups.

Table 3.1. Demographic characteristics of survey participants.

Items	Classification	Frequency (%)	Remarks
Roles in animal experiment-related activities	Committee member (=Protocol reviewer) (CP)	19 (31.7)	Internal member: 12 External member: 7
	Administrator (AD)	7 (11.7)	
	Facility operator (FO)*	7 (11.7)	
	Principal Investigator (PI)*	15 (25.0)	
	Postdoc or Student (PS)*	12 (20.0)	
Specialty	Natural Sciences (Biology, Chemistry, Ecology etc)	10 (16.7)	
	Medical and Pharmaceutical Sciences	17 (28.3)	
	Veterinary Sciences	21 (35.0)	
	Others (Engineering, Education, Humanities, Theology etc)	8 (13.3)	
	Unverifiable	4 (6.7)	
Affiliation	Seoul National University	45 (75.0)	
	Other Universities	8 (13.3)	Public: 4; Private: 4
	Institution other than University	7 (11.7)	Public: 4; Private: 3
Experience of animal experiment-related activities	Less than 1 year	2 (3.3)	AD: 2
	1-10 years	19 (31.7)	CP: 4, AD: 1 FO: 2, PS: 12
	Over 10 years	36 (60.0)	CP: 15, AD: 3 FO: 3, PI: 15
	Unverifiable	3 (5.0)	AD: 1, FO: 2

*Surveys on FO, PI and PS were performed only to participants of Seoul National University.

3.3. RESULTS

Open coding

All responses to the questions were summarized, while similar answers from the raw data were grouped into one item for the questionnaires voluntarily described by the respondents. Subsequently, the response rate for each item was summarized in the tables below.

Status of animal protocol review

The results of a questionnaire surveyed to the administrators of each institution's IACUC about the scale of each institution's animal protocol reviews are shown in Table 3.2. Excluding one private company and SNU-IACUC, the IACUC of each institution and the IBC of SNU review 200–300 new protocols a year. In addition, the number of reviewers is approximately 10, except for one public institution specializing in animal testing.

These results show that in order to achieve a seamless protocol review while satisfying both the APA (which is currently limited to 15 members) and the LAA (which require a majority vote of all enrolled members for protocol approval), it is more realistic for SNU to operate at least three or more IACUCs. Although the restriction on the reviewer number in APA will be abolished soon, the majority vote of all enrolled

members policy in the LAA remains unchanged. In the case of the IRB, SNU operates three committees in the Research affair, and the College of Medicine and the School of Dentistry each operate their own IRB.

Understanding of the process of animal protocol review

When performing animal experiments using human or transformed cells, approval from the IRB or the IBC and the IACUC is required. For smooth animal experiments, it is necessary to submit an animal protocol with prior approval from the IRB or the IBC in order for cells to be used. When the approval from multiple committees is required for an animal experiment, four out of six institutes (private company, general hospital, public institution, and SNU) required the pre-approval from the IRB and/or the IBC prior to protocol submission for review by the IACUC. In addition, the other two institutions (national university and private university) responded that all necessary committee approvals were required at the time of actual animal testing or experiments without any specific order.

In the US, when multiple committee approvals are required for the application of genetically modified organisms to humans or animals, there is no national-level guideline. However, each institution has its own guidelines. Some institutions require prior approval from the IBC for research involving animal experiment [41, 42], but conversely, there are cases where simultaneous or prior approval from the IRB or the IACUC is required during the IBC approval procedure [43]. Although there is no

unified guideline, it is recommended that the committees of institutions maintain a close relationship and agree on procedures [44].

Table 3.3 presents the responses of the principal investigator, postdoc/graduate students, and reviewers as to whether researchers or reviewers are aware of the process when multiple committee approvals are required when writing or reviewing an animal protocol. When multiple committee deliberation was required, reviewers generally understood this and stated that the guidance of the institution was sufficient. However, over half of the principal investigators and postdoc/graduate students responded that they were unaware and did not receive adequate guidance from the institution. This suggests that researchers who write animal protocols require education about the content.

Institution's supports and guarantee of autonomy to the IACUC

In the operation of the IACUC, support from institutions is important, but autonomy and independence from institutions are also essential [23]. In order to evaluate this, 1) institutional support, 2) a guarantee of independency, and 3) a reflection of the external committee members' opinions were asked. The responses of the IACUC members are shown in Table 3.4. Approximately 70% of the IACUC members stated that the support and autonomy from the institution were secured, and over 80% of the members responded that the opinions of external members were well reflected.

Table 3.2. Status of protocol review in the IACUCs* of various institutions.

Type of institution	Number of		
	protocol review per year	Committee member (additional reviewer)	Administrative staff
Private company	25	8	0.5**
General hospital	240	10	1
Public institution	310	5	1
University A (national)	193	13	1
University B (private)	269	12	1
SNU-IACUC*	1,000 (approx.)	15 (9)***	2
SNU-IBC* (for reference)	200	12	1

*SNU: Seoul National University; IACUC: Institutional Animal Care and Use Committee; IBC: Institutional Biosafety Committee

** One person in the company works as the staff of IACUC and IBC together.

*** In addition to fifteen official committee members, nine professional reviewers perform the protocol review in SNU-IACUC.

Table 3.3. Understanding of the process of animal protocol review when the protocol require approval by multiple committees.

	Committee member (reviewer)	Principal investigator	Postdoc/student
Notified and understood	14 (73.7)	5 (33.3)	1 (8.3)
Notified but not understood	1 (5.3)	0 (0.0)	3 (25.0)
Not notified but understood	2 (10.5)	2 (13.3)	1 (8.3)
Not notified and not understood	2 (10.5)	8 (53.3)	7 (58.3)
Total	19 (100.0)	15 (100.0)	12 (100.0)

Table 3.4. Institution's supports and guarantee of autonomy to the IACUC.

Items	Evaluation index					
	Supportive		Additional support required			
Support on IACUC operation			Financial	Manpower (staff)		
		13 (68.4)		2 (10.5)	4 (21.1)	
Guarantee of autonomy	Fully guaranteed		Partially guaranteed	Not guaranteed		
	14 (73.7)		2 (10.5)	3 (15.8)		
Reflection of the external committee members' opinions	Agree	Partially agree	Neutral	Partially disagree	Disagree	Refusal to answer
	16 (84.2)	1 (5.3)	1 (5.3)	0 (0.0)	0 (0.0)	1 (5.3)

Axial coding

Several noteworthy items were identified as requiring improvement in the operation of the IACUC through the survey. These are classified and summarized as follows.

Complaint to reviewers

When the protocol was not approved, the researchers were asked to write whether they agreed with the review results, if they disagreed, they were required to state the reason, and their complaints and suggestions about the protocol writing and review procedure. The researchers commonly highlighted the inconsistency of the review and complained that the reviewer failed to provide a valid rationale when requesting that the number of animals be reduced (Table 3.5). The former derives from the lack of the presentation of educational materials for the principal investigators and postdoc/graduate students who write the animal protocol, and the latter derives from the lack of education for reviewers.

Table 3.5. Responses of researchers when protocol review was not approved by the reviewer.

List of reasons not to agree	Number of responses	
	PI (8)	PS (7)
After submission of amended protocol upon request, the reviewer pointed out other items not notified previously	3 (20.0)	1 (6.7)
Reviewers' requesting reduction in the number of animals to use without reasonable evidence	2 (13.3)	3 (20.0)
Reviewers' requesting to amend the previously approved protocol with no valid rationale	1 (6.7)	3 (20.0)
Others	2 (13.3)	0
Researchers' complaints and requests about animal protocol preparation and review process	Number of responses	
	PI (15)	PS (12)
Providing researchers with good examples of various animal protocols along with specific feedback is required	6 (40.0)	6 (50.0)
Shortening approval delays is required	4 (26.7)	1 (8.3)
Intervening processes such as extension and repetition without any other protocol change need to be simplified	2 (13.3)	0 (0.0)
Amendment request from reviewer is hard to understand	1 (6.7)	3 (25.0)
Integrated management system for IRB, IBC and IACUC is required	2 (13.3)	2 (16.7)

PI: principal investigator; PS: postdoc/student

Table 3.6. Main opinions and suggestions of participants to their institutions and government bodies about IACUC and animal experiments.

To	Structured answers	CP	AD	FO	PI	PS
Institution	Providing education for reviewers and researchers including online classes	1	1	2		1
	Reducing the number of protocols to review	3				
	Reduction of protocol submissions through integrated review of similar protocols				2	
	Additional staff and/or financial support	1	1			
	Improving the notice method to researchers		1			1
	Strengthening post-approval monitoring activity			1		
	Integrated management of IRB, IBC and IACUC	1	1	4	2	1
	Standardization of checking in and out of animals			1	1	
	Providing consulting and technical support by professionals such as attending veterinarians				2	1
	Communication among IACUC, animal facility, and other related committees and institutions				1	1
Government	Legal guarantees of the independency and autonomy of the IACUC	2	1			
	IACUC regulatory amendments based upon the size of institution	1				
	Reinforcement of animal experiment alternatives through legal means	1			1	
	Minimum education requirement for reviewers and researchers		1	1		
	Mandatory hiring attending veterinarian		2	1		

CP: committee member; AD: administrator; FO: facility operator; PI: principal investigator; PS: postdoc/student

Case-oriented education with professional advice

The researchers basically accepted and respected the opinions and comments of the reviewers. However, as shown in Table 3.5, researchers emphasized the need for case-oriented education for researchers with professional advice. This opinion is also well expressed in Table 3.6, where many of the parties involved in animal experiments emphasized the education for reviewers and researchers.

Manpower support

In the open coding process, over 30% of the IACUC member respondents stated that the institution's support was insufficient (Table 3.4). Regarding the lack of support for the IACUC, the demand for manpower support was predominantly high. This suggests that human resource support is more important than financial support in the operation of the committee. In addition, this is consistently shown in Table 3.6, which deals with recommendations to institutions and governments that emphasize human resource support such as attending veterinarians.

Opinions and suggestions by the respondents

The results were collected by allowing each survey respondent to freely describe their suggestions for their affiliated institutions and related government ministries. These are shown in Table 3.6. Suggestions for the provision or reinforcement of education for reviewers and researchers and

requests for the integrated management of various committees were evenly distributed regardless of the respondents' categories. As a request to the government, the IACUC members and administrators had opinions on legal guarantees of the independency and autonomy of the IACUC. In addition, in the case of administrators and animal facility operators, there were requests for educating IACUC reviewers and researchers and making it mandatory to hire attending veterinarians. Proposing these issues to the government rather than the affiliated institution, proves that the affiliated institution's interest and support for those issues are limited.

Therefore, for seamless animal experiments through the improvement of the IACUC operation, we propose two topics: 1) reinforcing the education for researchers and reviewers, and 2) preparing an integrated management system for the relevant committees (IRB, IBC, and IACUC).

Reinforcement of the education for researchers and reviewers

Various forms of case-oriented education for researchers and reviewers are necessary. In particular, since the acceptance of online lectures by institutional members has increased, it is necessary to create online lectures of various cases at the national or institutional level and share the contents. Rather than complaining about the related regulations, researchers want education to develop their understanding of procedures and regulations to accept the relevant points. Therefore, education support that

reflects this is required, and considering that it is difficult for each institution to bear this independently, support, such as the development of curriculum by the relevant government bodies, is required.

Preparation of an integrated management system for the relevant committees

Administrators and animal facility operators are complaining about difficulties in managing the APA, the LAA, the Bioethics and Safety Act, and the Living Modified Organism (LMO)-related laws simultaneously, so that researchers find out if there are any illegalities in the contents stipulated in multiple laws. Consequently, researchers must be aware of this and prepare for it. However, in reality, researchers are unaware of this. To make this possible, it is necessary to prepare an integrated management system for the relevant committees such as the IRB and IBC.

Selective coding-storyline

This study categorizes key issues based on “Grounded Theory” by collecting opinions from researchers, reviewers, administrators, and facility operators on the operating conditions of animal experiments and the IACUC in institutions equipped with animal facilities. Based on these results, we compare the merits of each in the case of maintaining the current status and pursuing an effective step-by-step change. In addition, the author suggests a desirable improvement plan for the operation of the IACUC and related organizations by analyzing the opinions from the respondents.

Maintaining the Current Status

If the current procedure is maintained, there is a high possibility of preparing an animal protocol in a situation where proper information is lacking, as highlighted by those involved in animal experiments. Animal protocols that require amendment are subject to judgment such as “conditionally approved with a request for revision” or “re-review after revision,” so the protocol applicant reflects the reviewer's comments and understands their errors through the revision and gradually writes a high-quality animal protocol. However, researchers believe that most of the items highlighted by reviewers (errors or mistakes in writing) can be avoided if there is prior education and training, which can shorten the time from submission to approval.

Researchers are often dissatisfied with the reviewer's review criteria, mainly because the reviewers make new comments about the protocol approved by other reviewers in the past and reject it. Not all IACUC members who conduct reviews are experts in animal experiments; therefore, it is important to educate reviewers to enable consistent reviews. In addition, the laws related to animal experiments (APA and LAA) are also being periodically revised, and even if the administrator of each institution is notified of this, the relevant information cannot be delivered to researchers in a timely manner or reviewers cannot recognize it. Therefore, it cannot be reflected in the protocol review. Regarding these legal changes, each institution should periodically educate reviewers and researchers in order to avoid future difficulties.

Attempt to Partial or Total Change

The results of this study indicate that changes are inevitable to improve the management of animal experiment procedures based on the IACUC, including ethical perspective. Above all, various forms of practical education are necessary for all participants related to animal experiments, including researchers and reviewers (IACUC members). Consequently, three suggestions have been proposed in this study: 1) Education for researchers on how to write a protocol according to the type of animal experiment, 2) Standardization of screening criteria for various animal experiments by presenting various cases for the IACUC members who

review the protocol, and 3) Training on a detailed understanding of relevant laws and policies for administrators and animal facility operators. The reasons for each proposal are as follows.

1) Education for researchers on how to write a protocol according to the type of animal experiment: As experimental techniques using animals are diverse and advanced, prerequisites for planning are increasing, and there are cases in which researchers fail to prepare a complete protocol because they are not well aware of it. If education in this regard is effective, researchers can easily determine what type of animal experiment is included by writing the protocol according to the research purpose. Therefore, unnecessary re-review will be reduced.

2) Standardization of screening criteria for various animal experiments by presenting various cases for the IACUC members who review the protocol: Since not all IACUC members who review the protocol are experts in the relevant animal experiments, it is occasionally difficult to decide what kind of decision suits each type of experiment. Each member has a variety of perspectives depending on their position (e.g., animal researchers, animal activists, religious people, lawyers, and researchers on alternative methods of animal testing). In addition, there may be differences of opinion between members with long-term review experience and new members. However, from the researcher's perspective, since the least consistent decision is expected for the same animal experiment, each institution regularly educates reviewers using typical cases for each type of experiment as an example

based on the protocol deliberation results previously accumulated. Consequently, it is necessary to help those who review the criteria to make a decision in a state of mutual agreement on some basic matters.

3) Training on a detailed understanding of relevant laws and policies for administrators and animal facility operators: Administrators and facility operators are in the position of receiving the most complaints from researchers. However, are also obliged to deliver the most recent and relevant information to researchers. In accordance with changes in society's perception of companion animals, related laws are also periodically strengthened or revised; therefore, each institution needs to frequent communicate this to researchers. In addition, it is necessary to support them to receive the education provided by experts, or to attend public hearings on government policies and events of related societies and civil society organizations.

In addition to providing various forms of education, taking SNU as an example, the author proposes an integrated management system improvement plan for the relevant committees as shown in the schematic diagram below (Fig. 3.1). As a result of the survey and online search, there are many cases where the IACUC and the IBC are jointly operated and managed in Korea and international cases. However, in the case of SNU, as described in Fig. 3.1, the Research ethics team is in charge of administration of the IRB and the IACUC, while ILAR manages technical support and

facility management related to animal experiments separately. However, for the IBC, the Institute of Environmental Protection & Safety (IEPS) provides administrative and technical support.

However, as research using genetically modified organisms or translational research becomes active, the need for information sharing between the IBC, the IACUC, and the IRB increases and researchers' demands for an integrated organization to seamlessly manage them are also increasing. Therefore, the Research ethics team is continuously focusing on the Office of Research Integrity, which involves its original tasks such as publication ethics and conflict of interest in research and separately forms an integrated management organization or consultative body that manages mutual communication by overseeing the IRB, the IACUC, and the IBC. Furthermore, administrative and educational support for each committee will be provided by the IEPS for the IBC and by the ILAR, which is currently unconnected with the IACUC, for the IACUC. In the case of the IRB, it is proposed that the administrative and education support team will manage a total of five subcommittees (1st, 2nd, 3rd, Medical, and Dental), which are separately operated by Research Affairs, as depicted in Fig. 3.1. Unlike SNU, in a small institution, administrative and educational support can be operated by an integrated administrative team.



Fig. 3.1. A Schematic diagram of an integrated management system for Seoul National University.

3.4. DISCUSSION

It will be difficult for each individual institution to conduct all these trainings independently. As with the public IRB education program operated by the National Institute for Bioethics Policy [45] and the research safety education program of the National Research Safety Headquarters [46], it is necessary to consider operating a public IACUC. This manages the IACUC of each institution and supports education for administrators, animal facility operators, researchers and IACUC members who review animal protocols, along with various curriculum developments by government-related ministries, directly or through related organizations. Currently, in Korea, the Korean Association for IACUC [47] and the Bioethics Information Center [48] are providing the IACUC education programs, and some institutions are providing their own education programs. However, there are many differences in the scale, content, and scope of education. In the US the majority of institutions use the Collaborative Institutional Training Initiative (CITI) Program [49] to provide training programs for researchers and reviewers on the IRB, the IACUC, and the IBC. Therefore, the establishment of an integrated educational support organization in Korea may be considered in the future. For reference, in Korea, the US CITI program is provided in connection with BIC Study.

The IRB, which reviews human research, and the IBC, which reviews the use of cells and tissues and LMOs, are managed and supervised

by a government department different from the IACUC. As animal experiments become increasingly sophisticated, studies that require approval from both the IACUC and the relevant committee are increasing. Consequently, rather than prescribing prerequisites for the deliberation of a specific committee, it is desirable to create an integrated management body for the relevant committees within the institution that effectively communicate when researchers conduct animal experiments. This will ensure that the animal facility operator or members of each committee conducting a review can more easily verify the relevant protocols with each other. Such a system can support researchers to conduct more ethical and rational animal experiments while complying with the relevant laws. In addition, the integrated management body must focus on the education of the researchers. Many institutions in the US have various educational service programs in their division or office of research compliance [50, 51]. Therefore, the government should also check whether there are any contradictions between the relevant regulations of each committee. If certain areas require change, they should be actively improved from a researcher-centered perspective.

Conclusion

The results of the surveys suggest that institutions that conduct animal experiments must continuously provide education related to their duties for

researchers and the IACUC members. In addition, they must establish a unified/integrated management organization or consultative body with relevant committees such as the IRB and the IBC. If greater levels of education and an integrated management system are established, it will be possible to enhance the excellence of researchers and to better manage the operation of the IACUC.

CHAPTER 4

Operational issues of the IACUC in Korea and suggestions for improvement

4.1. INTRODUCTION

The APA [10] and the LAA [8] 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 IACUC by the APA [7]. 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 from each other (Table 4.1), 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 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 [52].

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 years since

2008, I would like to share my thoughts on the three issues listed below, which I believe that important. Some of the issues discussed here may be unique to Korea; however, I believe that majority of them are worldwide.

Table 4.1. The purpose and configurations of the Institutional Animal Care and Use Committee 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	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Veterinarian or Ph.D. with experience in animal experiments 2. Person referred by Animal Protection Organization 	<ol style="list-style-type: none"> 1. Veterinarian

The information here is based on the “Guidelines for the Standard Operations of the IACUC (in Korean)” published in 2018 [52].

4.2. OPINIONS & PERSPECTIVE

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 [45].

Veterinary Clinical Studies Committee (VCSC)

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 [53]. 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 [54]. 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 [55, 56]. 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 [57]. 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. 4.1 depicts an example of the action of the VCSC and its relationship with the IACUC.

Animal protocols for clinical research submitted to VCSC or IACUC

Scientifically and/or clinically justified for using naïve animals instead of patient animals for this clinical study?

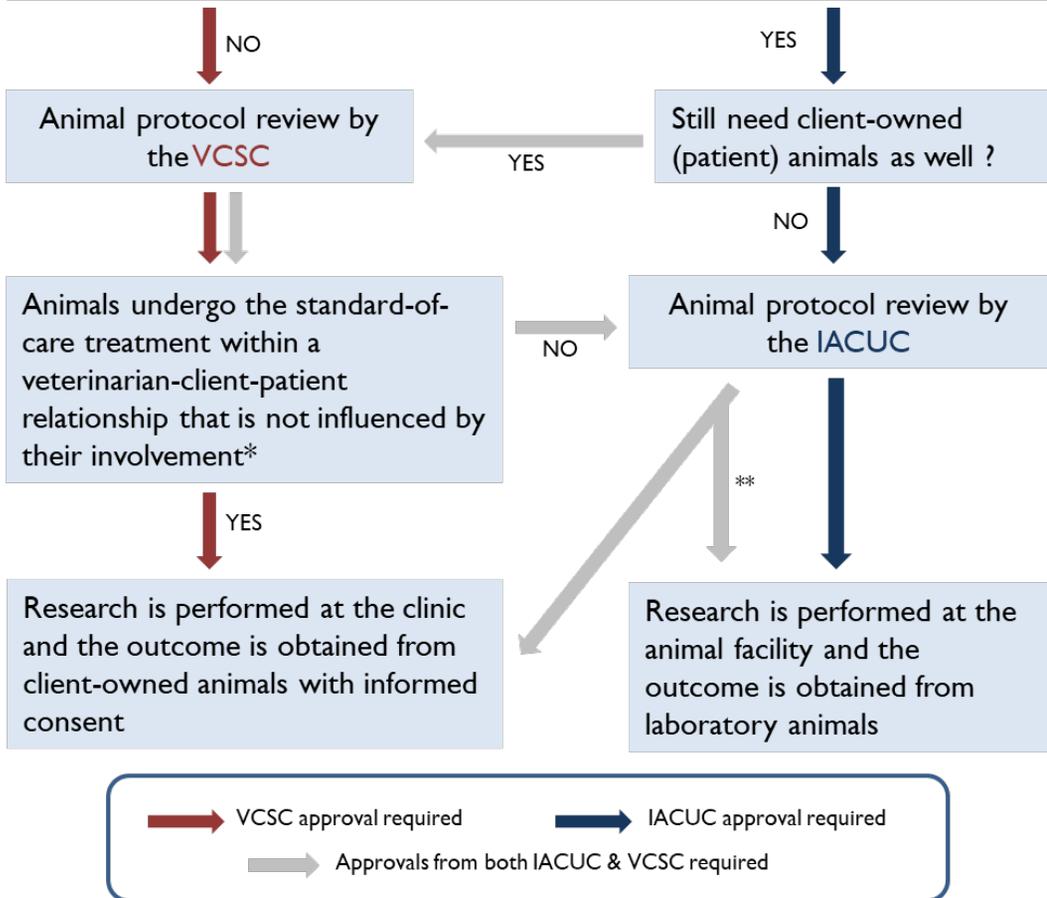


Fig. 4.1. The flow of the animal protocol review and approval for the clinical research, when both the Veterinary Clinical Studies Committee (VCSC) and the Institutional Animal Care and Use Committee (IACUC) are present at the veterinary hospital or the institution. Once the VCSC determines that the protocol will influence the management of the animal patient, the protocol is transferred to the IACUC for additional review.

*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.

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 [8]. 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) [8].

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 [23]. 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.

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.

REFERENCES

1. Taylor K, Alvarez LR. An estimate of the number of animals used for scientific purposes worldwide in 2015. *Altern Lab Anim* 2019; 47: 196-213.
2. Animal and Plant Quarantine Agency of Korea (APQA) [Internet]. APQA English website [cited 29 March 2021]. Available from:
<https://www.qia.go.kr/english/html/indexqiaEngNoticeWebAction.do?clear=1>
3. Kurosawa TM, Park J-H, Hong C-C. Chapter 10, Laws, Regulations, Guidelines, and Principles Pertaining to Laboratory Animals in Far East Asia. In: Guillén J, editor. *Laboratory Animals*. 2nd ed. Amsterdam (Netherlands): Elsevier Academic Press; 2018, 293-317.
4. National IACUC Portal. [Internet]. In Animal and Plant Quarantine Agency of Korea [cited 29 September 2020]. Available from:
<https://www.animal.go.kr/aec/index.do> (in Korean)
5. Guide for the care and use of laboratory animals, 8th ed. [Internet]. National Research Council, National Academies Press: Washington, DC, U.S.A., 2011 [cited 19 April 2021]. Available from:
<https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>
6. Choe BI, Lee GH. Individual and collective responsibility to enhance regulatory compliance of the Three Rs. *BMB Rep* 2014; 47: 179–183.

7. Ogden BE, Pang William W, Agui T, Lee BH. Laboratory Animal Laws, Regulations, Guidelines and Standards in China Mainland, Japan, and Korea. *ILAR J* 2016; 57: 301–311.
8. Laboratory Animal Act and Enforcement decree of the Act. [Internet]. The Korean Law Information Center English website [cited 29 March 2021]. Available from:
<https://law.go.kr/LSW/eng/engLsSc.do?menuId=2§ion=lawNm&query=laboratory+animal+act&x=0&y=0#liBgcolor0>
9. Ahn, N., Park, J. and Roh, S. Ethics in animal research – a focus on animal procurement and the Institutional Animal Care and Use Committee. *J. Periodontal Implant Sci.* 2022; 52: 1-2.
10. Animal Protection Act and Enforcement decree of the Act. [Internet]. The Korean Law Information Center English website [cited 29 March 2021]. Available from:
<https://law.go.kr/LSW/eng/engLsSc.do?menuId=2§ion=lawNm&query=animal+protection+act&x=37&y=22#liBgcolor0>
11. Understanding Animal Research (UAR). [Internet]. Animal Research Numbers in 2018, UAR website (Category: Communications & media) [cited 21 July 2021]. Available from:
<https://www.understandinganimalresearch.org.uk/news/communications-media/animal-research-numbers-in-2018>

12. Korean Law Translation Center of Korea Legislation Research Institute (KLRI). [Internet]. KLRI English website [cited 19 April 2021]. Available from: https://elaw.klri.re.kr/eng_service/main.do
13. Worldwide Animal Research Statistics: Speaking of research [Internet]. Speaking of research website [cited 28 February 2022]. Available from: <https://speakingofresearch.com/facts/animal-research-statistics/>
14. UK Government Home Office. [Internet]. 2020 Annual Statistics of Scientific Procedures on Living Animals. [cited 21 July, 2021]. Available from: <https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2020>
15. Else H. Genomics institute to close world-leading animal facility. *Nature* 2019; **569**: 612.
16. Understanding Animal Research (UAR). [Internet]. Animal Research Numbers in 2016, UAR website (Category: Communications & media) [cited 21 July, 2021]. Available from: <https://www.understandinganimalresearch.org.uk/news/communications-media/number-of-animals-used-in-research-in-2016/>
17. Lee BC, Kim MK, Jang G, Oh HJ, Yuda F, Kim HJ, Shamim MH, Kim JJ, Kang SK, Schatten G, Hwang WS. Dogs cloned from adult somatic cells. *Nature* 2005. **436**: 641.
18. Koreandogs. [Internet]. Seoul National University's Dark Connection with Dog Meat Farms: We Demand the Truth from SNU! (Press Conference)

Koreandogs English website [cited 21 July, 2021]. Available from:

<https://koreandogs.org/snu/>

19. Shim E. [Internet]. Professor experimented with cats illegally, South Korea animal activists say. United Press International, Inc. [cited 21 July, 2021]. Available from: https://www.upi.com/Top_News/World-News/2020/05/20/Professor-experimented-with-cats-illegally-South-Korea-animal-activists-say/4011589958877
20. Kim J. [Internet]. The dogs for veterinary education and training had been purchased from an unclear source in a veterinary medical school (News article in Korean). Hankyoreh Newspaper. [accessed on July 21, 2021]. Available from: http://www.hani.co.kr/arti/animalpeople/companion_animal/921786.html
21. Russell WMS, Burch RL. Chapter 4. The sources, incidence, and removal of inhumanity. In: Russell WMS, Burch RL, editors. The principles of humane experimental technique. London: Methuen & Co Ltd; 1959.
22. Redmond C. Chapter 27, When is an alternative not an alternative? Supporting progress for absolute replacement of animals in science. In: Animal Experimentation: Working towards a paradigm change. Series: Human-Animal Studies, Vol.22. (Hermann, K. and Jayne, K. eds.), 2019; BRILL Press, Leiden.
23. Ahn N, Roh S, Park J. The status and issues of the Institutional Animal Care and Use Committee of Seoul National University: From its establishment to the present day. *Exp Anim* 2021; 70: 532-40.

24. Institute of Laboratory Animal Resources (ILAR) [Internet]. ILAR of Seoul National University [cited 29 March 2021]. Available from: <https://ilar.snu.ac.kr/> (in Korean)
25. Lee GH, Choe BI, Kim JS, Hart LA, Han JS. The Current Status of Animal Use and Alternatives in Korean Veterinary Medical Schools. *Altern Lab Anim* 2010; 38: 221–230.
26. Protocol review and other activities (2015). In: White paper of Institutional Animal Care and Use Committee of Seoul National University; 2015. p. 111–179. (in Korean)
27. Pain and distress management and evaluation, In: Guidelines for the standard operations of the IACUC; 2017. p. 37–45. Available from: http://ebook.qia.go.kr/20180621_173152/ (in Korean)
28. USDA Pain & Distress Categories. [Internet]. Division of Laboratory Animal Resources, University of Kentucky [cited 29 March 2021]. Available from: <https://www.research.uky.edu/division-laboratory-animal-resources/usda-pain-distress-categories>
29. Choi HJ, Yoon CH, Kim MK. Updates on corneal xenotransplantation. *Curr Ophthalmol Rep* 2019; 7: 30–36.
30. Kim MJ, Oh HJ, Kim GA, Setyawan EMN, Choi YB, Lee SH, et al. Birth of clones of the world's first cloned dog. *Sci Rep* 2017; 7: 15235.
31. Choi J-Y, Sim J-H, Yeo I-SL. Characteristics of contact and distance osteogenesis around modified implant surfaces in rabbit tibiae. *J Periodontal Implant Sci* 2017; 47: 182–191.

32. Shin JS, Kim JM, Min B-H, Yoon IH, Kim HJ, Kim J-S, et al. Pre-clinical results in pig-to-nonhuman primate islet xenotransplantation using anti-CD40 antibody (2C10R4)-based immunosuppression. *Xenotransplantation* 2017; 25: e12356.
33. Yun JW, Ahn J-B, Kang B-C. Modeling Parkinson's disease in the common marmoset (*Callithrix jacchus*): overview of models, methods, and animal care. *Lab Anim Res* 2015; 31: 155–165.
34. Glaser BG. Basic social processes. *Grounded Theory Rev* 2005; 4: 1-28.
35. Morse JM. Situating grounded theory within qualitative inquiry. In Schreiber RS, Stern PN editors. *Using grounded theory in nursing*. New York: Springer; 2001. pp. 1– 15.
36. Corbin J, Strauss A. *Basics of qualitative research: Techniques and procedures for developing grounded theory*. London: SAGE Publications; 1998. pp. 10-11.
37. Priya A. Grounded theory as a strategy of qualitative research: An attempt at demystifying its intricacies. *Sociol Bull* 2016; 65: 50-68.
38. Strauss A, Corbin J. editors. *Grounded theory in practice*. Thousand Oaks: SAGE Publications. 1997.
39. Bryant A, Charmaz, K. Introduction. In Bryant A, Charmaz K editors. *The SAGE handbook of grounded theory*. Thousand Oaks: SAGE Publications. 2007. pp. 1– 28.

40. Morse JM. Tussles, tensions, and resolutions. In Morse JM, Stern P, Corbin J, Bowers B, Charmaz K, Clarke A editors. *Developing grounded theory: The second generation*. Left Coast Press; 2009. pp. 13–19.
41. Institutional Biosafety Committee (IBC) Laboratory Research [Internet] Weill Cornell Medicine website [cited 8 April 2022]. Available from: <https://research.weill.cornell.edu/integrity-compliance/human-subjects-research/institutional-biosafety-committee-ibc-laboratory>
42. Institutional Biosafety Committee (IBC) [Internet] Research at Brown, Brown University website [cited 8 April 2022]. Available from: <https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/institutional-biosafety-committee-ibc>
43. IBC Review Process [Internet] Florida International University Research website [cited 15 April 2022]. Available from: <https://research.fiu.edu/ibc/review-process/>
44. Dobos KM, Johnson CM. Keeping the Intersections of IBCs, IACUCs, and IRBs from Turning into Roadblocks [Internet] Ampersand, The Public Responsibility in Medicine and Research (PRIM&R) blog [cited 8 April 2022]. Available from: <https://blog.primr.org/ibcs-iacucs-and-irbs/>
45. Public IRB [Internet] Korea National Institute for Bioethics Policy website [cited 8 April 2022]. Available from: <http://www.nibp.kr/xe/irb>

46. National Research Safety Information System (NRSIS) [Internet] NRSIS website [cited 8 April 2022]. Available from:
<https://www.labs.go.kr/contents/siteMain.do>
47. Korean Association for IACUC (KAIACUC) [Internet] KAIACUC website [cited 8 April 2022]. Available from: <https://kaiacuc.org/>
48. Bioethics Information Center Study (BICStudy) [Internet] BICStudy website [cited 8 April 2022]. Available from: <https://bicstudy.org/>
49. Collaborative Institutional Training Initiative (CITI) program [Internet] CITI program website [cited 8 April 2022]. Available from:
<https://about.citiprogram.org/>
50. Research Ethics & Integrity [Internet] Research at Brown, Brown University website [cited 8 April 2022]. Available from:
<https://www.brown.edu/research/ori>
51. Scholarly Integrity and Research Compliance [Internet] Research and Innovation, Virginia Tech website [cited 8 April 2022]. Available from:
<https://www.research.vt.edu/sirc.html>
52. Guidelines for the standard operations of the IACUC (in Korean): Animal and Plant Quarantine Agency; 2017. [Internet].
http://ebook.qia.go.kr/20180621_173152/. Updated 2018, Accessed 2021 Aug 03
53. Park S-Y, An J-H, Kwon H, Choi S-Y, Lim K-Y, Kwak H-H, Hussein KH, Woo H-M, Park K-M. Custom-made artificial eyes using 3D printing for dogs: A preliminary study. 2020; PLoS ONE 15: e0242274.

54. Establishment and Use of Veterinary Clinical Studies Committees.
[Internet]. American Veterinary Medical Association website [cited 26 March 2022]. Available from: <https://www.avma.org/resources-tools/avma-policies/establishment-and-use-veterinary-clinical-studies-committees>.
55. VMTH Clinical Trials: Clinical Trial Review Board. [Internet]. UC Davis Office of Research website [cited 26 March 2022]. Available from: <https://research.ucdavis.edu/policiescompliance/animal-care-use/iacuc/vmth-clinical-trials/>
56. Clinical Review Board. [Internet]. Colorado State University Research Integrity & Compliance Review Office website [cited 26 March 2022]. Available from: <https://www.research.colostate.edu/ricro/crb/>
57. Bertout JA, Baneux PJR, Robertson-Plouch CK. Recommendations for Ethical Review of Veterinary Clinical Trials. 2021; Front Vet Sci 8: 715926.

국문초록

개요: 동물실험 대체법의 활용가능성이 증가함에도 불구하고 의생명과학의 연구발전을 위해 연구자들은 실험동물을 지속적으로 사용하고 있다. 본 연구는 각 연구기관의 실험동물시설 관리 및 동물실험윤리위원회(IACUC) 운영방안 개선을 제안하기 위해 수행되었다. 이를 위해 한국 전체 동물실험계획서 심의의 5%를 수행하고 국가전체 실험동물 사용량의 10%를 소모하는 서울대학교에 초점을 맞춰 연구를 진행하였다. 또한, 본 연구는 국내 연구용 동물의 사용 및 조달에 관한 현황 및 법적 규제 문제에 대해서도 다루고 있다. 논문은 아래와 같이 총 4 개의 장으로 구성되어 있다.

제 1 장. 한국의 실험동물의 사용현황 및 동물 조달에 관한 현안: 이 장에서는 한국의 실험동물 사용현황을 보고하였다. 비슷한 수의 실험동물을 사용하는 영국에 비해 한국의 동물실험기관은 설치류와 개를 포함, 포유류를 더 많이 사용하는 경향이 있다. 따라서 실험동물의 사용을 줄이거나 대체하기 위한 대안을 강구해야 한다. 최근 국내에서 위법한 동물 공급을 비롯, 동물실험과 관련된 많은 문제가 논의되고 있다. 동물보호단체 활동가들은 현재 동물보호법 규정이 적용되는 대부분의 동물실험에 대해 보다 엄격한 실험동물에 관한

법률(실험동물법)로 확대 적용해야 한다고 주장하고 있지만, 동물실험의 종류가 실험동물법 규정에 명시된 것이 아닌 경우 실험과 관련한 과학적 문제는 동물보호법의 규정을 적용하는 것이 타당하다. 또한, 법적 수단을 통해 실험동물 공급업체를 규제하는 것보다 윤리적인 동물 취급 및 처치에 대한 교육을 강화하는 것이 연구자에게 보다 더 중요하다.

제 2 장. 서울대학교 동물실험윤리위원회의 현황 - 설립에서 현재까지:

저자는 한국 동물실험윤리위원회(IACUC)의 선구자 중 하나인 서울대학교 IACUC 가 지난 10 여년 동안 수행한 위원회 구성 및 규정 제정, 동물실험계획서 심사 및 계획서 승인 후 모니터링(PAM)을 포함한 운영 및 활동을 다음과 같이 보고하였다. 국가 발간자료와 비교할 때 서울대학교 동물실험계획서의 규모는 국가 전체의 5~7%를 차지하고 있다. 서울대에서 설치류를 실험에 사용하는 비율은 IACUC 가 운영되고 있는 전국 359 개 기관 총 사용량의 10% 이상이었다. 위원수 제한과 단일 IACUC 정책을 포괄하는 법적 규제 및 개선사항에 대한 기술과 함께 동물실험 승인 및 승인 후 모니터링을 포함한 IACUC 의 활동에 대한 독립성과 사회와 과학자 사이의 지식 격차를 줄이는 데 있어 IACUC 의 공적 역할이 중요함을 강조하였다.

제 3 장. 서울대학교의 사례를 중심으로 한 동물실험윤리위원회 운영

개선안: 이 연구는 근거이론 접근에 초점을 맞추어 60명의 의도적 표본 추출을 통해 조사연구를 수행하였다. 본 연구를 통해 1) 연구자를 위한 동물실험계획서 작성법 교육 2) 다양한 사례를 제시하여 각종 동물실험에 대한 선별 표준화 3) 관련 법규에 대한 상세한 이해를 위한 교육 등, 다양한 실천적 교육이 필요함을 알 수 있었다. 또한, IACUC의 원활한 운영을 위해서는 유관 위원회의 통합관리시스템 개선방안도 필요하다. 다양한 수준의 교육과 통합관리시스템이 구축된다면 연구자의 우수성을 높이고 IACUC의 운영을 보다 잘 관리할 수 있을 것이다. 설문 결과에 따르면 동물실험을 수행하는 기관은 연구자와 IACUC 회원에게 지속적으로 교육을 제공해야 한다. 또한, 동물시설을 운영하는 기관과 IACUC는 IACUC의 원활한 운영을 위해 관련 위원회와 통합/통합 관리 조직 또는 협의체를 구성해야 한다. 더 높은 수준의 교육과 통합관리체계가 구축된다면 연구자의 역량을 높이고 IACUC의 운영을 보다 잘 관리할 수 있을 것이다.

제 4 장. 한국의 IACUC 운영 현안 및 개선안 제언: 한국에서는 IACUC

운영과 관련된 다음과 같은 당면한 문제들이 있다. 1) 논란의 여지가 있는 기술을 포함한 동물실험계획서 심의. 2) 복수의 기관이 참여하는 동물실험계획서 심의. 3) 보호자가 있는 환자동물에 대한 수의임상시험 심의. 4) 단일 IACUC 를 운영하는 대형 연구기관에서의 심의지연 문제.

위의 문제를 해결하기 위해 다음과 같은 세 가지 해결방안을 제안한다.

1) 논란의 여지가 있는 실험기법을 적용하거나 복수의 기관이 관여하는 동물실험계획서 심사를 위한 공공 IACUC 를 설치한다. 2) 수의임상시험을 위해 IACUC 의 자문기관으로 수의임상연구위원회 (Veterinary Clinical Study Committee; VCSC) 설치한다. VCSC 는 임상시험 전 동물 보호자로부터 사전동의를 받고 IACUC 에 조언하는 역할을 할 수 있다. 3) 관계법령이 개정될 경우, 대형 동물실험 연구기관의 경우 하나의 IACUC 에 심사위원 수를 늘리는 것보다는 적정 규모를 가진 여러 개의 위원회를 운영하는 것이 바람직하다.

주요어: 동물윤리, 동물실험계획서심사, 동물복지, 동물실험윤리위원회, 실험동물, 서울대학교

학번: 2019-31521

Studies on the Institutional Animal Care and Use Committee operation strategy in Korea

Supervisor: Prof. Jaehak Park, D.V.M., Ph.D.

Submitting a Ph.D. Dissertation of
Veterinary Medicine

June 2022

Graduate School of Veterinary Medicine
Seoul National University
Veterinary Pathology and Preventive Medicine Major
(Laboratory Animal Medicine)

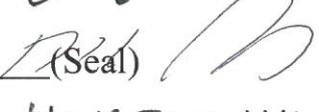
Na Ahn

Confirming the Ph.D. Dissertation written by
Na Ahn
July 2022

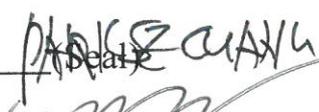
Chair Roh, Sangho

(Seal) 

Vice Chair Park, Jaehak

(Seal) 

Examiner Park, Se Chang

(Seal) 

Examiner Seok, Seung Hyeok

(Seal) 

Examiner Kim, C-Yoon

(Seal) 