

## ETHICAL AND LEGAL ASPECTS OF RESEARCH INVOLVING ANIMAL SUBJECTS IN INDONESIA

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### Abstract

*Advances in science often benefit human health but can also involve sacrifices, particularly when animals are used as research subjects. This study explores the ethical and legal aspects of using animals in research, focusing on improving understanding and compliance with animal welfare regulations in Indonesia. The research aims to analyze laws and ethical principles such as the 3R and 5F to ensure humane treatment of animals. Utilizing a normative legal approach and library research methodology, this study evaluates various regulations, including laws, government policies, and institutional guidelines concerning animal welfare in research. The novelty of this research lies in its comprehensive analysis of how legal requirements intersect with ethical considerations, underscoring the need for ethics committees to oversee research practices. The findings emphasize that while animal research is essential for scientific progress, strict adherence to regulations is necessary to protect animals from abuse and ensure ethical research practices.*

*Keywords: Research ethics; Animal welfare; Normative law; 3R principles; Legal regulations.*

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### Abstrak

Kemajuan ilmu pengetahuan sering memberikan manfaat besar bagi kesehatan manusia, namun juga melibatkan pengorbanan, terutama saat hewan digunakan sebagai subjek penelitian. Penelitian ini mengeksplorasi aspek etika dan hukum dalam penggunaan hewan untuk penelitian, dengan tujuan meningkatkan pemahaman serta kepatuhan terhadap regulasi kesejahteraan hewan di Indonesia. Studi ini menganalisis undang-undang dan prinsip-prinsip etika seperti 3R (Replacement, Reduction, Refinement) dan 5F (Five Freedoms) untuk memastikan perlakuan manusiawi terhadap hewan. Menggunakan pendekatan hukum normatif dan metode penelitian kepustakaan, penelitian ini mengevaluasi berbagai regulasi yang berlaku, termasuk undang-undang, kebijakan pemerintah, serta pedoman institusional terkait kesejahteraan hewan. Kebaruan dari penelitian ini terletak pada analisis menyeluruh mengenai persyaratan hukum yang bersinggungan dengan pertimbangan etika, menekankan pentingnya peran komite etik dalam mengawasi praktik penelitian. Temuan ini menegaskan bahwa meskipun penelitian hewan penting untuk kemajuan ilmiah, kepatuhan terhadap regulasi yang ketat diperlukan guna melindungi hewan dari penyalahgunaan dan memastikan praktik penelitian yang etis.

*Kata Kunci: Etika penelitian; Kesejahteraan hewan; Hukum normatif; Prinsip 3R; Peraturan perundang-undangan.*

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## INTRODUCTION

Research is a systematic activity conducted based on scientific principles and methods to obtain information, data, and information from relevant subjects. This process involves understanding theories and testing assumptions or hypotheses through planned and controlled experiments.<sup>1</sup> The results obtained from this research may be in the form of conclusions that can be applied or serve as additional knowledge for the advancement of science.<sup>2</sup> For instance, in the biomedical field, research using animals as subjects has led to significant discoveries that aid in drug development and understanding of diseases. However, research must still respect the rights and dignity of the subjects involved, including animals. Research ethics demand that all living beings used in experiments be treated with great respect and care.<sup>3</sup> This includes efforts to minimize pain and suffering and providing adequate care for animals throughout the research. Additionally, legal regulations require researchers to obtain approval from the relevant ethical committee before conducting research involving animals, ensuring that all proposed procedures meet ethical and legal standards. Adhering to these principles is not only important for animal welfare but also for the validity and integrity of research outcomes.<sup>4</sup>

Scientific research, particularly in the biomedical field, plays a crucial role in the advancement of knowledge and medical innovation. Many significant discoveries in modern medicine, including the development of vaccines, drugs, and new therapies, depend on the use of animals as research subjects.<sup>5</sup> Experimental animals provide biological models that enable researchers to understand disease mechanisms and test the effectiveness and safety of interventions before they are applied to humans. However, the use of animals in research is accompanied by strict ethical and legal challenges.<sup>6</sup>

Advancements in science often bring great benefits to human health but also require sacrifices, especially when involving living beings like animals.<sup>7</sup> On one hand, research with animal subjects has resulted in medical breakthroughs that have saved countless lives. On the other hand, the use of animals for research purposes raises ethical dilemmas regarding their rights and welfare. Researchers are required to maintain a balance between scientific progress and respect for the rights of living beings involved. Therefore, ethical principles in research must be strictly applied to ensure that animals are used in a dignified and responsible manner. Research with animal subjects should only be conducted if the benefits far outweigh the potential suffering experienced by the animals.<sup>8</sup>

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<sup>1</sup> Nuria Reny Hariyati, *Metodologi Penelitian Karya Ilmiah* (Penerbit Graniti, 2020).

<sup>2</sup> H Rifa'i Abubakar, *Pengantar Metodologi Penelitian* (SUKA-Press UIN Sunan Kalijaga, 2021).

<sup>3</sup> M H Widyana Beta Arthanti et al., *Prinsip-Prinsip Dasar Bioetika* (Thalibul Ilmi Publishing & Education, 2024).

<sup>4</sup> Robert Patannang Borrong, "Etika Animalitas," *GEMA TEOLOGIKA: Jurnal Teologi Kontekstual Dan Filsafat Keilahian* 4, no. 2 (2019): 229–50.

<sup>5</sup> Danang Sugihardana and Wardah Yuspin, "Tinjauan Yuridis Tanggung Jawab Rumah Sakit Terhadap Kejadian Healthcare Associated Infections," *Media of Law and Sharia* 5, no. 4 (2024).

<sup>6</sup> Anindya Puspita Putri, "ILMU ALAMIAH DASAR," *Penerbit Tahta Media*, 2023.

<sup>7</sup> Christian Smith, *Moral, Believing Animals: Human Personhood and Culture* (Oxford University Press, 2003).

<sup>8</sup> Marc Bekoff and Jessica Pierce, *Wild Justice: The Moral Lives of Animals* (University of Chicago Press, 2009).

In recent decades, there has been a global demand to reduce the use of animals in research, in line with technological advancements that allow for the creation of more ethical alternatives. In vitro methods, such as cell cultures and computer simulations, have provided significant opportunities to reduce dependence on animals in research.<sup>9</sup> Nevertheless, these alternative methods still have limitations in replicating complex biological interactions that can only be observed in whole living organisms. Particularly in medical and pharmaceutical research, experimental animals continue to play a vital role as the "semi-final test tube" before clinical trials on humans are conducted. Nonetheless, efforts are ongoing to develop alternative models that can replace the role of animals while ensuring that researchers adhere to ethical principles.<sup>10</sup>

One way to guarantee the implementation of ethical standards in research involving animal subjects is through the role of ethical committees. Ethical committees are responsible for reviewing, supervising, and approving all research involving animals. They ensure that the proposed research complies with animal welfare principles and applicable regulations. Before the research is conducted, the ethical committee will evaluate whether the planned procedures can minimize pain, suffering, or stress on the animals. Additionally, they assess whether the use of animals in the research is truly necessary or if there are more humane alternatives that could be used. Thus, ethical committees serve as the front line in maintaining the balance between scientific demands and the protection of animal rights in research.

Based on the explanations above, the research problem can be formulated as follows: What ethical principles should be applied in research involving animal subjects? This inquiry aims to explore the fundamental ethical frameworks that govern the treatment and use of animals in scientific research.

## **METHOD**

This research employs a normative legal approach that focuses on norms and library research methods to analyze the legal aspects related to the use of animals in research.<sup>11</sup> Through this approach, the study aims to analyze and understand the legal regulations governing animal welfare, including applicable laws, regulations, and policies. The library research method involves an in-depth examination of various relevant sources, such as laws on animal welfare, related government regulations, and other scientific literature.<sup>12</sup> This study is descriptive-analytical in nature, aiming to provide a detailed overview of the regulations and ethical principles regarding the use of animals for research. Thus, this research not only contributes to understanding the ethical and legal aspects related to the use of animals in research but also serves as an important foundation for further development in the field of animal welfare law in Indonesia.<sup>13</sup>

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<sup>9</sup> Sam Harris, *The Moral Landscape: How Science Can Determine Human Values* (Simon and Schuster, 2011).

<sup>10</sup> Rachmat Hidayat and Patricia Wulandari, "Bioethical Principles of Use of Experimental Animals in Biomedical Research," *Biomedical Journal of Indonesia* 7, no. 1 (2021): 148–52.

<sup>11</sup> Danang Sugihardana et al., "TINJAUAN YURIDIS PERLINDUNGAN DATA PRIBADI DALAM MENGHADAPI TANTANGAN ERA DIGITAL," *Prosiding University Research Colloquium* 19, no. SE-Articles (March 7, 2024), <https://repository.urecol.org/index.php/proceeding/article/view/2774>.

<sup>12</sup> I Made Pasek Diantha and M S Sh, *Metodologi Penelitian Hukum Normatif Dalam Justifikasi Teori Hukum* (Prenada Media, 2016).

<sup>13</sup> Zainuddin Ali, *Metode Penelitian Hukum* (Sinar Grafika, 2021).

## RESULT AND DISCUSSION

Animal models play a critical role in biomedical research by helping scientists assess the efficacy and safety of new treatments and drugs. They allow researchers to simulate human disease processes and identify potential risks such as birth defects, infertility, toxicity, liver damage, and carcinogenic effects, ensuring early detection of dangerous side effects before human trials.<sup>14</sup> To minimize stress, pain, and secondary injury in laboratory animals, the use of anesthetic and sedative drugs must be carefully supervised. Addressing challenges in the teaching process is also crucial, requiring active participation from teachers and students in curriculum discussions. The Teaching and Research Office, alongside the Laboratory Animal Ethics Committee, should manage this process, promoting animal ethics training. Standardized experimental procedures can further improve the training of laboratory animal practitioners, emphasizing animal protection, welfare, and ethical awareness among educators and students.<sup>15</sup>

Animal welfare is a significant concern in any research activity involving animals as subjects, and it is crucial to ensure that their well-being is prioritized throughout the research process.<sup>16</sup> According to Law No. 18 of 2009 on Animal Husbandry and Animal Health, animal welfare encompasses all matters related to the physical and mental conditions of animals, ensuring that their needs align with their natural behaviors while safeguarding them from inhumane treatment by humans. In the context of research, this means that animal welfare must take precedence, particularly as research procedures can often have a profound impact on the health and comfort of the animals involved.<sup>17</sup> Researchers have a moral obligation to treat animals with dignity and respect, adhering to established principles of animal welfare. This includes providing appropriate housing, nutrition, and medical care to minimize stress and discomfort. Furthermore, researchers must ensure that the use of animals in their studies is justified, meaning that the scientific objectives must be clear and that the potential benefits to human or animal health outweigh any risks posed to the animals.

Several important considerations must be incorporated into research involving animal subjects. First, researchers should explore alternatives to animal use whenever feasible.<sup>18</sup> This may include employing in vitro models, computer simulations, or other innovative techniques that do not require live animals. When animals must be used, it is essential to follow the 3Rs principles: Replacement, Reduction, and Refinement. Replacement involves finding non-animal alternatives; Reduction focuses on minimizing the number of animals used in research; and Refinement aims to enhance the animal's

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<sup>14</sup> Aysha Karim Kiani et al., "Ethical Considerations Regarding Animal Experimentation.," *Journal of Preventive Medicine and Hygiene* 63, no. 2 Suppl 3 (June 2022): E255–66, <https://doi.org/10.15167/2421-4248/jpmh2022.63.2S3.2768>.

<sup>15</sup> Meili Kang et al., "A Review of the Ethical Use of Animals in Functional Experimental Research in China Based on the 'Four R' Principles of Reduction, Replacement, Refinement, and Responsibility.," *Medical Science Monitor : International Medical Journal of Experimental and Clinical Research* 28 (December 2022): e938807, <https://doi.org/10.12659/MSM.938807>.

<sup>16</sup> Sutiastuti Wahyuwardani, S M Noor, and B Bakrie, "Etika Kesejahteraan Hewan Dalam Penelitian Dan Pengujian: Implementasi Dan Kendalanya," *Jurnal Wartazoa* 30, no. 4 (2020): 211–20.

<sup>17</sup> Gaizka Ayu Satura, Amalia Putri Maharani, and Herbin Marulak Siahaan, "Reformasi Hukum Terhadap Budaya Penggunaan Hewan Sebagai Transportasi (Legal Reforms Against Animal Usage as Transportation)," *JURNAL USM LAW REVIEW* 7, no. 3 (2024).

<sup>18</sup> National Research Council et al., "Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research," 2003.

welfare by improving experimental procedures and environments to reduce pain and suffering.<sup>19</sup> Moreover, ethical review boards or committees should be established to evaluate research proposals involving animals, ensuring compliance with animal welfare regulations and standards. These committees play a vital role in overseeing research activities, guaranteeing that they meet the ethical criteria necessary to protect animal subjects while allowing for valuable scientific inquiry.<sup>20</sup> The commitment to animal welfare in research is not only a legal obligation but also a reflection of the values of compassion and responsibility that underpin the scientific community. By prioritizing animal welfare and implementing rigorous ethical standards, researchers can contribute to a more humane approach to scientific exploration that respects the intrinsic value of all living beings. This approach fosters public trust in research practices and underscores the importance of balancing scientific progress with ethical considerations.<sup>21</sup>

Research involving animals must be relevant to the goals of human or animal health, and its outcomes should have the potential to advance scientific knowledge or benefit the broader community. Before deciding to use animals, researchers must ensure that no alternatives exist that could replace animals, such as in vitro methods, computer simulations, or other feasible alternatives. However, in many cases, particularly those involving the testing of complex biological mechanisms, the use of animals is still necessary. Third, research involving animals must not duplicate previous studies unless there is a strong justification, such as biological heterogeneity and complexity or technological changes that require re-testing using animals.<sup>22</sup>

In the context of health research, the widely referenced ethical principles are guidelines from the World Medical Association, which include three main principles: respect, beneficence, and justice. The principle of respect emphasizes honoring the rights and dignity of living beings, including animals, and the obligation of researchers to protect the freedom and welfare of research subjects. Beneficence requires that the benefits derived from research must outweigh the risks faced by the animals. Justice refers to the fair treatment of animals, considering the proportion of risks and benefits involved.

Additionally, in research involving animal subjects, researchers are required to apply the 3R principles: Replacement, Reduction, and Refinement.<sup>23</sup>

Replacement refers to the use of alternative methods or models to replace animals in research whenever possible. This substitution can be relative, such as using animal tissues or organs from slaughterhouses, or absolute, such as using cell cultures or computer simulations.

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<sup>19</sup> Lynne U Sneddon, Lewis G Halsey, and Nic R Bury, "Considering Aspects of the 3Rs Principles within Experimental Animal Biology," *Journal of Experimental Biology* 220, no. 17 (2017): 3007–16.

<sup>20</sup> Francis L Macrina, *Scientific Integrity: Text and Cases in Responsible Conduct of Research* (John Wiley & Sons, 2014).

<sup>21</sup> National Research Council et al., "Guidelines for the Humane Transportation of Research Animals," 2006.

<sup>22</sup> Michael P Murtaugh et al., "The Science behind One Health: At the Interface of Humans, Animals, and the Environment" (Wiley Online Library, 2017).

<sup>23</sup> Matthias Eggel and Hanno Würbel, "Internal Consistency and Compatibility of the 3Rs and 3Vs Principles for Project Evaluation of Animal Research," *Laboratory Animals* 55, no. 3 (2021): 233–43.

2. Reduction emphasizes the importance of minimizing the number of animals used in research. Researchers should carefully design studies and use appropriate statistical techniques to ensure that the number of animals used is the least necessary without compromising the validity of the research results.

3. Refinement is the effort to minimize pain and suffering experienced by animals during research. This includes providing a suitable environment, proper care, and using procedures that minimize pain, such as anesthesia and analgesics

In addition to the 3R principles, the application of animal welfare is also regulated under the framework of the 5F (Five Freedoms), designed by the Farm Animal Welfare Council. The five freedoms include:

- a. Freedom from hunger and thirst, ensured by providing animals with sufficient access to clean water and food that meets their nutritional needs.
- b. Freedom from discomfort, fulfilled by providing a comfortable environment that meets the biological needs of animals, including adequate ventilation, temperature, and space to move.
- c. Freedom from pain, injury, and disease, guaranteed through disease prevention programs and appropriate and timely medical care when necessary.
- d. Freedom to express normal behavior, achieved by providing facilities that allow animals to behave naturally, such as social interactions and adequate space for movement.
- e. Freedom from fear and distress, ensuring that animals are treated in ways that do not cause undue stress or fear.

The implementation of these principles is a primary responsibility of researchers and research facility managers. Adhering to animal welfare principles is not only an ethical requirement but also essential for obtaining valid and reliable data. Research that mistreats animal subjects can produce biased or inaccurate data, ultimately harming scientific progress.

In Indonesia, several institutions have established ethical committees responsible for overseeing and approving the use of animals before research is conducted. These committees, often part of general research ethics committees, ensure that research complies with applicable regulations and animal welfare principles. For instance, institutions such as the Health Research Ethics Commission of the Health Research and Development Agency (KEPKBPPK), the Research Ethics Commission of the Faculty of Animal Husbandry at Gadjah Mada University, and the Research Ethics Commission of the Faculty of Veterinary Medicine at Airlangga University play crucial roles in maintaining animal welfare in research.<sup>24</sup>

Furthermore, regulations related to animal welfare in Indonesia are outlined in various regulations, such as the Head of LIPI Regulation No. 08/E/2013 on Guidelines for Research Ethics Clearance and Scientific Publication, as well as Law No. 41 of 2014 amending Law No. 18 of 2009. These regulations provide a strong legal foundation for the implementation of animal welfare principles across various research fields, both in biomedicine and non-biomedicine.<sup>25</sup>

<sup>24</sup> S Pi Seprianto, "MODUL MATA KULIAH BIOETIKA (IB113)," n.d.

<sup>25</sup> Azhara Devica Risnanda, "Perlindungan Hukum Dalam Klasifikasi Bentuk Kekerasan Terhadap Hewan Di Indonesia," *Res Nullius Law Journal* 5, no. 2 (2023): 123–34.

Animal models not only provide insights into the efficacy and safety of treatments but also serve as a foundation for understanding complex biological processes that cannot be replicated *in vitro*. As research evolves, so too must the ethical frameworks surrounding the use of animals. The integration of 3Rs principles (Replacement, Reduction, and Refinement) into research practices is essential for improving animal welfare while maintaining scientific integrity. Moreover, advancements in technology, such as organ-on-a-chip systems and computer modeling, offer promising alternatives that can complement or reduce reliance on animal models. Encouraging ethical reflection in the academic and research communities fosters a culture of responsibility, ensuring that laboratory animals are treated with respect and care while contributing to valuable scientific advancements.

By adhering to these ethical principles and regulations, research involving animals can proceed in a responsible, ethical, and scientific manner. This commitment enhances the integrity of the research process and fosters public trust in scientific endeavors. Ethical adherence ensures that researchers are aware of the moral implications of their work, recognizing that animals are sentient beings deserving of respect and humane treatment. This perspective encourages researchers to prioritize animal welfare, resulting in a more compassionate approach to scientific inquiry. Moreover, by implementing established guidelines like the 3Rs and 5Fs, researchers can contribute to developing innovative methodologies that reduce reliance on animal subjects while still yielding valuable data. This includes investing in advanced technologies such as *in vitro* models, computer simulations, and alternative testing methods, leading to breakthroughs in understanding complex biological processes without compromising animal welfare. Transparent communication regarding the ethical treatment of animal subjects is crucial for maintaining accountability within the scientific community. Researchers should engage with the public and stakeholders to explain the ethical considerations in their studies, addressing concerns and demonstrating their commitment to humane practices. This promotes a better understanding of the necessity of animal research in advancing medical and scientific knowledge and encourages collaborative efforts in developing ethical standards across various disciplines.

## CONCLUSION

Research involving animals must prioritize their welfare as a primary concern. The use of animals is only justified if the research is relevant, cannot be replaced by alternative methods, and does not duplicate previous studies. Ethical principles such as respect, beneficence, and justice must be applied to ensure that the rights and dignity of animals are upheld, and that the benefits of the research outweigh the risks faced by the animals. The 3Rs principle (Replacement, Reduction, and Refinement) serves as a guideline for minimizing the number of animals used, replacing them with alternative methods whenever possible, and treating animals humanely. The 5F (Five Freedoms) principle guarantees the basic freedoms of animals from suffering by ensuring they are kept in suitable conditions and provided with adequate care. Implementing animal welfare is also crucial for maintaining the validity and integrity of research results. In Indonesia, regulations and relevant institutions play a vital role in ensuring that the use of animals in research complies with strict regulations, ensuring that research not only generates valuable knowledge but is also conducted in an ethical and responsible manner.

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