

# Etika Penelitian Menggunakan Hewan Percobaan

Komisi Etik Penelitian Kesehatan  
Badan Penelitian dan Pengembangan Kesehatan

**Hewan BUKAN Manusia**

**Tidak Memanusiakan Hewan**

# Prinsip Dasar Etik Pelaksanaan Penelitian Biomedis menggunakan Hewan Percobaan

- Prinsip Etik Penelitian:
  - Respect, Beneficiary, Justice.
- Prinsip Etik Penggunaan Hewan: 3R
  - Reduction, Replacement, Refinement
- Prinsip Etik Pemeliharaan/ Perlakukan terhadap Hewan: 5F ( 5 Freedoms)
  - F from hunger & thirst
  - F from pain
  - F from distress & discomfort
  - F from injury & diseases
  - F to express normal behaviour

# Prinsip Etik Penelitian:

- Respect:  
Menghormati makhluk hidup (Hewan Percobaan)
- Beneficiary:  
Bermanfaat bagi manusia & makhluk lain
- Justice:  
Bersikap adil dalam memanfaatkan hewan percobaan  
Contoh sikap tidak adil:
  1. Hewan di suntik/ dibedah berulang ulang untuk menghemat jumlah hewan
  2. Memakai obat ethanasia yang menimbulkan rasa nyeri karena harganya lebih murah.

# Prinsip Etik Penggunaan Hewan Percobaan

- Reduction

Memanfaatkan hewan dalam jumlah sekecil mungkin yang dapat memberikan hasil penelitian yang sah.

- Replacement

- Relatif : mengganti hewan percobaan dengan memakai organ/jaringan hewan dari rumah potong, hewan dari ordo lebih rendah.
- Absolut: mengganti hewan percobaan dengan memakai kultur sel/jaringan, program komputer.

- Refinement

- Mengurangi rasa nyeri/distress dengan memakai obat analgesik, sedativa, anestesi.
- Mengurangi rasa nyeri/distress dengan melakukan prosedur secara benar oleh orang yang terlatih.

# 5 Freedoms

- **Freedom:**

- from **hunger and thirst** (Rasa lapar & haus) memberikan akses makanan & air minum yang sesuai & memadai untuk kesehatannya
- from **discomfort** (Ketidak nyamanan) menyediakan lingkungan yang paling sesuai
- from **pain, injury, and disease** (Rasa sakit & penyakit) dengan program kesehatan, pencegahan, mengurangi rasa sakit & pengobatan
- from **fear and distress** (Ketakutan dan stress jangka panjang) memberi kondisi untuk mencegah stress
- to **express natural behavior** (Mengekspresikan tingkah laku alami) memberikan ruang dan fasilitas yang sesuai

# Freedom from Hunger and thirst

Bebas dari rasa lapar & haus

- Memberikan akses makanan & air minum yang sesuai & memadai untuk kesehatannya (jumlah dan komposisi nutrisi)
- Makanan dan air minum memadai dari kualitas, dibuktikan melalui analisa proximate makanan, analisa mutu air minum, dan uji adanya kontaminasi secara berkala

## Animal Welfare Act

### Feeding

22-40 g dry  
food/kg body  
weight for dogs

150 g food/day  
for cats





# Freedoms from Discomfort

Bebas dari rasa tidak nyaman

- Menyediakan lingkungan bersih, dan yang paling sesuai dengan biologi species (siklus cahaya, suhu & kelembaban lingkungan; fasilitas fisik).
- Ukuran kandang (*Guide for the Care and Use of Laboratory Animals*) dan komposisi kelompok (*social vs solitaire; hierarchy*)



Group housing  
when ever possible



Enrichment devices for  
rodents: Igloo, nest etc.

Nesting materials

Human interactions



Enrichment  
Devices for NHP



# Freedoms from Pain, injury, & disease



Bebas dari rasa nyeri,  
trauma & penyakit

- Program kesehatan, pencegahan penyakit, pengobatan, dan meminimalkan/ meniadakan rasa sakit
- Pemilihan prosedur dengan pertimbangan meminimalkan rasa sakit (*non-invasive*)
- Penggunaan anesthesia dan analgesia apabila diperlukan
- Euthanasia dengan metoda yang “*humane*” untuk meminimalkan/ meniadakan penderitaan hewan





TABLE 3.1 Recommended Dry-Bulb Macroenvironmental Temperatures for Common Laboratory Animals

Animal	Dry-Bulb Temperature	
	°C	°F
Mouse, rat, hamster, gerbil, guinea pig <sup>a</sup>	20-26	68-79
Rabbit	16-22	61-72
Cat, dog, nonhuman primate	18-29	64-84
Farm animals, poultry	16-27	61-81

<sup>a</sup>Dry-bulb room temperature settings for rodents are typically set below the animals' LCT to avoid heat stress, and should reflect different species-specific LCT values. Animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress.

TABLE 3.2 Recommended Minimum Space for Commonly Used Laboratory Rodents Housed in Groups\*

Animals	Weight, g	Floor Area/Animal, <sup>a</sup> in. <sup>2</sup> (cm <sup>2</sup> )	Height, <sup>b</sup> in. (cm)	Comments
Mice in groups <sup>c</sup>	<10	6 (38.7)	5 (12.7)	Larger animals may require more space to meet the performance standards.
	Up to 15	8 (51.6)	5 (12.7)	
	Up to 25	12 (77.4)	5 (12.7)	
	>25	≥15 (≥96.7)	5 (12.7)	
Female + litter		51 (330) (recommended space for the housing group)	5 (12.7)	Other breeding configurations may require more space and will depend on considerations such as number of adults and litters, and size and age of litters. <sup>d</sup>

Animals	Weight, g	Floor Area/Animal, <sup>a</sup> in. <sup>2</sup> (cm <sup>2</sup> )	Height, <sup>b</sup> in. (cm)	Comments
Rats in groups <sup>c</sup>	<100	17 (109.6)	7 (17.8)	Larger animals may require more space to meet the performance standards.
	Up to 200	23 (148.35)	7 (17.8)	
	Up to 300	29 (187.05)	7 (17.8)	
	Up to 400	40 (258.0)	7 (17.8)	
	Up to 500	60 (387.0)	7 (17.8)	
	>500	≥70 (≥451.5)	7 (17.8)	
Female + litter		124 (800) (recommended space for the housing group)	7 (17.8)	Other breeding configurations may require more space and will depend on considerations such as number of adults and litters, and size and age of litters. <sup>d</sup>
Hamsters <sup>c</sup>	<60	10 (64.5)	6 (15.2)	Larger animals may require more space to meet the performance standards.
	Up to 80	13 (83.8)	6 (15.2)	
	Up to 100	16 (103.2)	6 (15.2)	
	>100	≥19 (≥122.5)	6 (15.2)	
Guinea pigs <sup>c</sup>	Up to 350	60 (387.0)	7 (17.8)	Larger animals may require more space to meet the performance standards.
	>350	≥101 (≥651.5)	7 (17.8)	

\*The interpretation of this table should take into consideration the performance indices described in the text beginning on page 55.

<sup>a</sup>Singly housed animals and small groups may require more than the applicable multiple of the indicated floor space per animal.

<sup>b</sup>From cage floor to cage top.

<sup>c</sup>Consideration should be given to the growth characteristics of the stock or strain as well as the sex of the animal. Weight gain may be sufficiently rapid that it may be preferable to provide greater space in anticipation of the animal's future size. In addition, juvenile rodents are highly active and show increased play behavior.

<sup>d</sup>Other considerations may include culling of litters or separation of litters from the breeding group, as well as other methods of more intensive management of available space to allow for the safety and well-being of the breeding group. Sufficient space should be allocated for mothers with litters to allow the pups to develop to weaning without detrimental effects for the mother or the litter.



**TABLE 3.3 Recommended Minimum Space for Rabbits, Cats, and Dogs Housed in Pairs or Groups\***

Animals	Weight, <sup>a</sup> kg	Floor Area/ Animal, <sup>b</sup> ft <sup>2</sup> (m <sup>2</sup> )	Height, <sup>c</sup> in. (cm)	Comments
Rabbits	<2	1.5 (0.14)	16 (40.5)	Larger rabbits may require more cage height to allow animals to sit up.
	Up to 4	3.0 (0.28)	16 (40.5)	
	Up to 5.4	4.0 (0.37)	16 (40.5)	
	>5.4 <sup>c</sup>	≥5.0 (≥0.46)	16 (40.5)	
Cats	≤4	3.0 (0.28)	24 (60.8)	Vertical space with perches is preferred and may require additional cage height.
	>4 <sup>d</sup>	≥4.0 (≥0.37)	24 (60.8)	
Dogs <sup>e</sup>	<15	8.0 (0.74)	— <sup>f</sup>	Cage height should be sufficient for the animals to comfortably stand erect with their feet on the floor.
	Up to 30	12.0 (1.2)	— <sup>f</sup>	
	>30 <sup>d</sup>	≥24.0 (≥2.4)	— <sup>f</sup>	

\*The interpretation of this table should take into consideration the performance indices described in the text beginning on page 55.

<sup>a</sup>To convert kilograms to pounds, multiply by 2.2.

<sup>b</sup>Singly housed animals may require more space per animal than recommended for pair- or group-housed animals.

<sup>c</sup>From cage floor to cage top.

<sup>d</sup>Larger animals may require more space to meet performance standards (see text).

<sup>e</sup>These recommendations may require modification according to body conformation of individual animals and breeds. Some dogs, especially those toward the upper limit of each weight range, may require additional space to ensure compliance with the regulations of the Animal Welfare Act. These regulations (USDA 1985) mandate that the height of each cage be sufficient to allow the occupant to stand in a "comfortable position" and that the minimal square feet of floor space be equal to the "mathematical square of the sum of the length of the dog in inches (measured from the tip of its nose to the base of its tail) plus 6 inches; then divide the product by 144."

<sup>f</sup>Enclosures that allow greater freedom of movement and unrestricted height (i.e., pens, runs, or kennels) are preferable.

# Pain Assessments

- In human studies – the gold standard of pain assessment is by “self reporting”
- In animal studies – pain assessment tools are necessary

## **In animal studies:**

- Pain Scoring
- Pain Scale

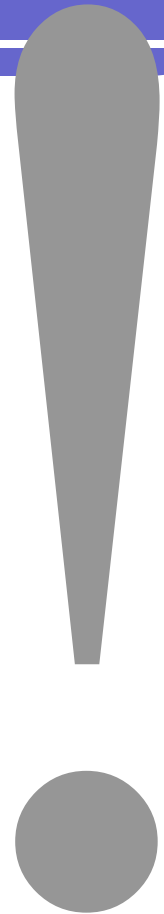
Signs of pain can be species-specific.

Pain scoring system should be developed to quantify the degree of pain experienced by an animal.

Scoring system is based on clinical signs, behavior, and action to be taken based on the score.

Pentingnya Aspek Kesejahteraan Hewan  
Yang Digunakan Dalam Penelitian

Keadaan Hewan Yang  
Tidak Sejahtera Akan  
Mengakibatkan Bias  
Pada Hasil Penelitian



# Examples of Pain Assessment in Animal Research

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RECOGNITION AND ALLEVIATION OF PAIN IN LABORATORY ANIMALS

TABLE 3-1 Behavioral Signs of Persistent Pain

Sign	Explanation
Guarding	The animal alters its posture to avoid moving or causing contact to a body part, or to avoid the handling of that body area.
Abnormal appearance	Different species show different changes in their external appearance, but obvious lack of grooming, changed posture, and a changed profile of the body are all observable signs. In species capable of some degree of facial expression, the normal expression may be altered.
Altered behavior	Behavior may be depressed; animals may remain immobile, or be reluctant to stand or move even when disturbed. They may also exhibit restlessness (e.g., lying down and getting up, shifting weight, circling, or pacing) or disturbed sleeping patterns. Large animal species may grunt, grind their teeth, flag their tail, stomp, or curl their lips (especially sheep and goats). Primates in pain often roll their eyes. Animals in pain may also show altered social interactions with others in their group.
Vocalization	An animal may vocalize when approached or handled or when a specific body area is touched or palpated. It may also vocalize when moving to avoid being handled.
Mutilation	Animals may lick, bite, scratch, shake, or rub a painful area.
Sweating	In species that sweat (horses), excessive sweating is often associated with some types of pain (e.g., colic).
Inappetence	Animals in pain frequently stop eating and drinking, or markedly reduce their intake, resulting in rapid weight loss.

Not present  
0



Moderate  
1



Severe  
2



Orbital tightening



Nose bulge



Cheek bulge



Ear position







# Freedoms from Fear and distress

Bebas dari ketakutan dan stress jangka panjang

- Memberi kondisi (lingkungan, perlakuan) yang mencegah/ meminimalkan stress (aspek *husbandry*, *care*, penelitian)
- Memberikan masa adaptasi dan pengkondisian (misalnya *training*) bagi hewan terhadap prosedur penelitian, lingkungan baru, dan personnel
- Semua prosedur pada hewan dilakukan oleh *personnel* yang *qualified*, dan terlatih





# Freedoms To Express Natural Behavior

## Mengekspresikan tingkah laku alami

- Memberikan ruang dan fasilitas yang sesuai (pengayaan lingkungan yang sesuai dengan biologi dan tingkah laku species): Food searching, foraging, dll
- Memberikan sarana untuk kontak sosial (bagi species yang bersifat sosial): Pengandungan berpasangan atau berkelompok. Memberikan kesempatan untuk grooming, mating, dan bermain, dll
- Program pengayaan lingkungan (Environmental Enrichment)



# Natural Habitat of Nonhuman Primates





Gang cages are designed closed to natural habitat

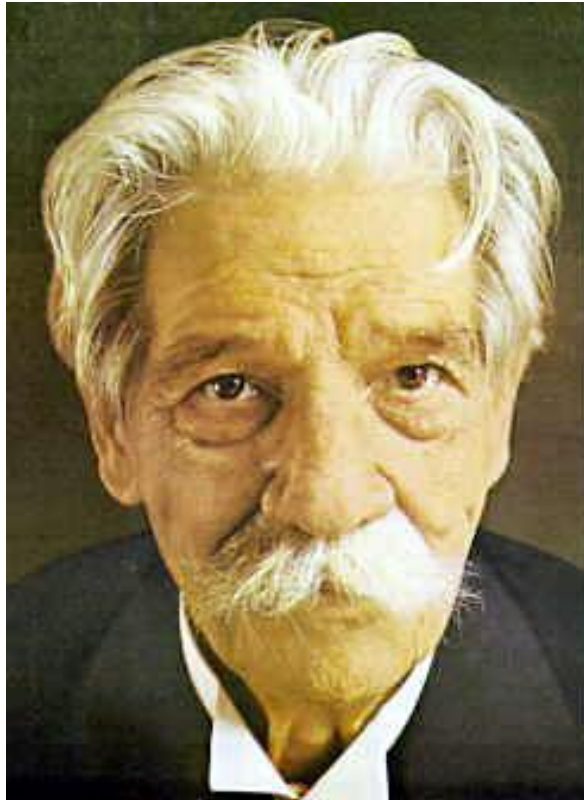




# Natural Behavior of burrowing & hiding



# Moral Status of Animals



Albert Schweitzer (1875-1965)

- In general, the more mentally complex an animal, the greater the moral value and the higher the burden that must be met before it can be used in research or killed.
- Some animals gain enhanced moral status because of their interaction with human beings.

# LEGISLASI KESEJAHTERAAN HEWAN

- Regulasi/ Undang undang
- Kebijakan
- Pedoman

# REGULASI

## Nasional:

Undang-undang RI No. 18 Tahun 2009  
Tentang Peternakan dan Kesejahteraan  
Hewan

Bab VI. Kesejahteraan Hewan,  
Pasal 66 & 67.



# REGULASI

Luar negri:

- AS:

Code of Federal Regulation:  
Title 9 C.F.R. Chapter 1,  
Subchapter A – Animal Welfare,  
Parts 1, 2, and 3.

**FOR MORE INFO...**

<http://www.nal.usda.gov/awic/legislat/awabrief.htm>

# REGULASI

- AS:

The Animal Welfare Act (AWA) in 1966.

- Amendemen AWA th 2002 mengecualikan unggas, mencit dari genus *Mus*, dan tikus dari genus *Rattus* yang dibiakkan untuk kepentingan penelitian.
- AWA tidak mengatur pemakaian hewan untuk pendidikan maupun hewan ternak untuk penelitian.

# REGULATIONS

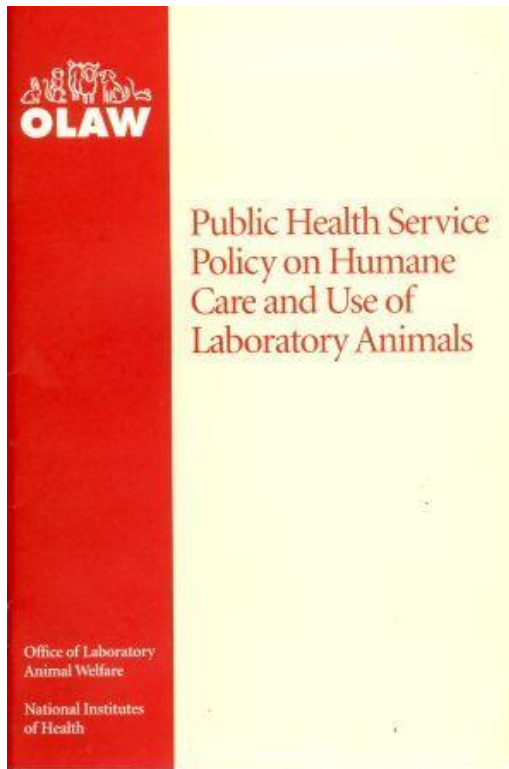
- Eropa:

European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, ETS 123 Appendix A.

FOR MORE INFO...

<http://conventions.coe.int/en/Treaties/Html/123.htm>

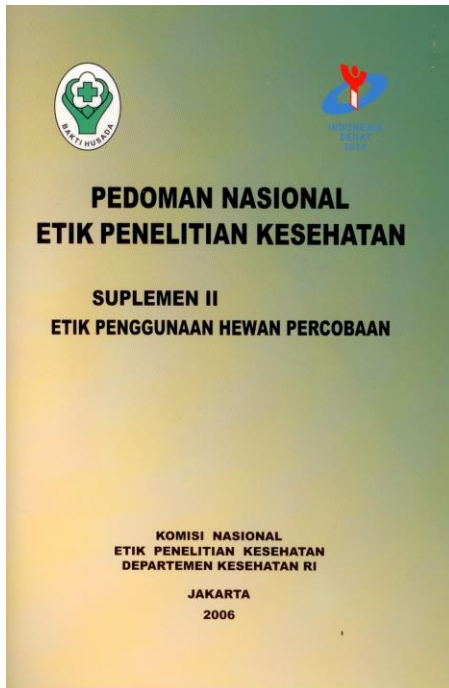
# KEBIJAKAN



US:

Public Health Service  
Policy on Humane Care  
and Use of Laboratory  
Animals. National  
Institutes of Health.  
Revised 2002

# PEDOMAN



Nasional:  
Pedoman Nasional Etik Penelitian Kesehatan. Suplemen II Etik Penggunaan Hewan Percobaan. Komisi Nasional Etik Penelitian Kesehatan, Departemen Kesehatan RI. Jakarta. 2006

# PEDOMAN

Internasional:

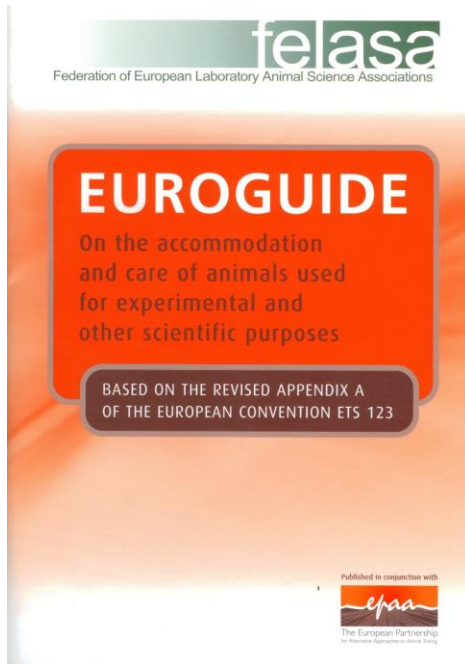
International Guiding Principles for Biomedical Research Involving Animals, Council for International Organizations of Medical Sciences (CIOMS), WHO, 1985.

# PEDOMAN



*US:*  
*The Guide for the Care and Use of Laboratory Animals*  
(National Research Council, National Academy of Sciences, 2010)

# PEDOMAN



*Eropa:  
Euroguide on the  
accommodation and care of  
animals used for experimental  
and other scientific purpopaoses*  
(based on the Revised Appendix  
A of The European Convention  
ETS 123)



# LEGISLASI DI ASIA

- **Guidelines for Proper Conduct of Animal Experiments  
June 1, 2006 Science Council of Japan**  
<http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-20-k16-2e.pdf>
- **Institute for Animal Experimentation (Japan)**  
[www.anex.med.tokushima-u.ac.jp](http://www.anex.med.tokushima-u.ac.jp)
- **Japanese Association for Laboratory Animal Science  
(English)**  
[http://www.soc.nii.ac.jp/jalas/index\\_e.html](http://www.soc.nii.ac.jp/jalas/index_e.html)
- **Act on Welfare and Management of Animals – Japan  
(English Translation)**  
<http://www.cas.go.jp/jp/seisaku/hourei/data/AWMA.pdf>

# LEGISLASI DI ASIA

## **Korean Animal Protection Law**

[www.koreananimals.org/animals/apl/2007apl.htm](http://www.koreananimals.org/animals/apl/2007apl.htm)

## **Hong Kong - Code of Practice Care and Use of Animals for Experimental Purposes**

[Download PDF file](#)

## **Philippines Animal Welfare Act**

[www.angelfire.com/ok2/animalwelfare/welfareact.html](http://www.angelfire.com/ok2/animalwelfare/welfareact.html)

## **Regulations in China—Updates**

<http://losangeles.china-consulate.org/eng/news/topnews/t127829.htm>

[www.chinadaily.com.cn/english/doc/2004-05/17/content\\_331357.htm](http://www.chinadaily.com.cn/english/doc/2004-05/17/content_331357.htm)

## **Taiwan Animal Protection Act**

<http://eng.coa.gov.tw/./content.php?catid=8998>

# LEGISLASI DI ASIA

- **The Animal Welfare Act Of 1998: Republic Act 8485 - An Act To Promote Animal Welfare In The Philippines**  
[http://www.congress.gov.ph/download/ra\\_10/RA08485.pdf](http://www.congress.gov.ph/download/ra_10/RA08485.pdf)
- **Ethical Principles and Guidelines for the Use of Animals for Scientific Purposes, NRC of Thailand (1999)**  
<http://labanimals.net/image/Ethics/Ethics%20on%20Animals%20.pdf>
- **NACLAR Guidelines: [http://www.ava.gov.sg/NR/rdonlyres/C64255C0-3933-4EBC-B869-84621A9BF682/13557/Attach3\\_AnimalsforScientificPurposes.PDF](http://www.ava.gov.sg/NR/rdonlyres/C64255C0-3933-4EBC-B869-84621A9BF682/13557/Attach3_AnimalsforScientificPurposes.PDF) (Singapore)**
- **AVA Regulations for "Care and Use of Animals for Scientific Purposes" is : [http://www.ava.gov.sg/NR/rdonlyres/C64255C0-3933-4EBC-B869-84621A9BF682/8337/Attach24\\_legislation\\_AB\\_CareandUse\\_rules.pdf](http://www.ava.gov.sg/NR/rdonlyres/C64255C0-3933-4EBC-B869-84621A9BF682/8337/Attach24_legislation_AB_CareandUse_rules.pdf) (Singapore)**

# LEGISLASI

## **Canada:**

- **Guide to the Care and Use of Experimental Animals Volume 1.** Canadian Council on Animal Care. Volume 1 (2nd. Edition), 1993. (Adopted May 1999) Canadian Council on Animal Care, 315-350 Albert St., Ottawa, Ontario, Canada, K1R 1B1.  
[http://www.ccac.ca/en/CCAC\\_Programs/Guidelines\\_Policies/GUIDES/ENGLISH/toc\\_v1.htm](http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/GUIDES/ENGLISH/toc_v1.htm)
- **Guide to the Care and Use of Experimental Animals Volume 2.** Canadian Council on Animal Care. Volume 2, 1984. (Adopted May 1999) Canadian Council on Animal Care, 315-350 Albert St., Ottawa, Ontario, Canada, K1R 1B1.  
[http://www.ccac.ca/en/CCAC\\_Programs/Guidelines\\_Policies/GUIDES/ENGLISH/TOC\\_V2.HTM](http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/GUIDES/ENGLISH/TOC_V2.HTM)

# LEGISLASI

Australia:

Australian Code Of Practice For The  
Care And Use Of Animals For Scientific  
Purposes, National Health And Medical  
Research Council, Australia

# LEGISLASI

New Zealand:

The Good Practice Guide For The Use  
Of Animals In Research, Testing And  
Teaching, National Animal Ethics  
Advisory Committee, New Zealand

# TERIMA KASIH

