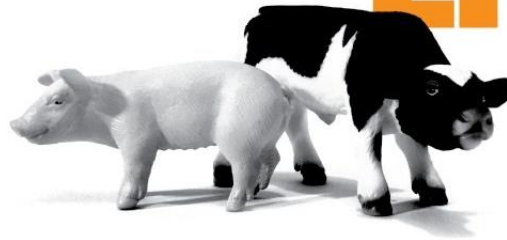


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LFA



8 May 2015

Project Officer – Review of guidelines for non-human primates
Ethics and Governance Section
Evidence, Advice and Governance Branch
National Health and Medical Research Council
GPO Box 1421
CANBERRA ACT 2601

Dear Sir/Madam,

SUBMISSION - DRAFT *PRINCIPLES AND GUIDELINES FOR THE CARE AND USE OF NON-HUMAN PRIMATES FOR SCIENTIFIC PURPOSES*

Lawyers for Animals Inc. (“**LFA**”) thanks the National Health and Medical Research Council (“**NHMRC**”) for the opportunity to comment on the draft *Principles and guidelines for the care and use of non-human primates for scientific purposes* (“**Principles**”). LFA has a keen interest in legal and regulatory standards that influence the treatment of animals, and provides the comments on the Principles below.

We understand the Principles present proposed revisions to the NHMRC’s existing *Policy on the care and use of non-human primates for scientific purposes* (2003) (“**Policy**”). In fact, it appears the NHMRC intends that the Principles, once finalised, will replace the Policy, rather than proposing amendments to the Policy. This submission has been prepared on that basis.

We note that compliance with the Principles, once finalised, is proposed to be included as a condition in funding agreements for research funded by NHMRC, in addition to compliance with the *Australian code for the care and use of animals for scientific purposes 8th edition* (2013) (“**Code**”) and applicable legislation. Unless the context suggests otherwise, references in this submission to activities conducted in the course of research refer to research funded by the NHMRC.

1. ABOUT LAWYERS FOR ANIMALS

LFA is a not-for-profit incorporated association run by a management committee of lawyers. Its objectives include:

- (a) alleviating the suffering of animals by engaging with those who create or administer laws in Australia to strengthen legal protection for animals;
- (b) promoting better animal welfare practices amongst animal-related industries in Australia; and
- (c) undertaking educational activities in an effort to dispel myths and increase awareness relating to animals and the law.

LFA also works in partnership with Fitzroy Legal Service to run the Animal Law Clinic in Melbourne. The Animal Law Clinic is a free legal advice service that operates with the primary objective of improving animal welfare.

LFA subscribes to the contemporary view that in all situations involving human guardianship or influence over animals, the following basic rights of animals (known as the “Five Freedoms”) must be upheld:

- (a) freedom from hunger and thirst;
- (b) freedom from discomfort;
- (c) freedom from pain, injury or disease;
- (d) freedom to express normal behaviour; and
- (e) freedom from fear and distress.

LFA considers that these five basic rights should guide the development, review and interpretation of all laws and policies that influence the treatment of animals at the hands of humans. This approach can be summarised by the application of one central question: “will the “Five Freedoms” be met?”

It will be difficult for many scientific studies involving non-human primates, particularly in medical research, to meet these basic criteria. Where they do not, LFA submits that such use of non-human primates cease and be replaced by human and/or cellular research, where both viable and ethical.

However, our principle of upholding The Five Freedoms does not preclude LFA from making suggestions to optimise the welfare of non-human primates (or other animals) whilst ever they remain lawfully subject to scientific studies which do not meet their basic rights.

2. NHMRC'S ROLE AS A STANDARD-SETTING AGENCY

As “Australia’s leading expert body promoting the development and maintenance of public and individual health standards”,¹ the role of the NHMRC as a best-practice setting body should not be underestimated. LFA acknowledges that legal regulation of the care and use of non-human primates rests largely with state and territory agencies. However, as a national leading expert

¹ See <https://www.nhmrc.gov.au/about>.

body, LFA considers the NHMRC should, as a matter of policy, lead the way in the development of best-practice standards regarding the treatment of animals associated with scientific research.

LFA acknowledges the Principles state that they are intended to outline “best practice guidance for the care and use of nonhuman primates for scientific purposes to assist investigators, teachers and animal carers” (at 1). However, overall the Principles emphasise that responsibility for animal welfare rests with State and Territory governments. LFA disagrees with the latter statement, and considers that responsibility for animal welfare is a civic responsibility shared by all members of the community, and particularly those with the capacity to influence the welfare of animals. It is that civic responsibility which is acknowledged and re-stated in State and Territory legal and regulatory requirements. The expression given to those requirements varies between States and Territories, and State/Territory bodies are vested with authority to enforce them. Responsibility for compliance with acceptable standards of animal welfare, however, rests with the individual.

LFA submits that, while State and Territory governments have enacted legal requirements in relation to animal welfare, the NHMRC has a responsibility to promote national standards of best practice that ensure animals are only used in scientific research as a last resort, that any animals used in scientific research are afforded the highest standards of care, and that individual researchers acknowledge their personal responsibility to procure and provide that care as the custodians of animals.

In this respect, LFA submits the Principles should be re-drafted, taking into account the further submissions below, to expressly identify “best practice standards” for the whole scientific community (and which shall be mandatory for research funded by the NHMRC).

The normative effect of such “best practice standards” would support consistent practices across institutional animal ethics committees, and State and Territory regulatory agencies and legislatures. While the Principles, as drafted, would contribute to that goal of national consistency, LFA considers the current drafting does not go far enough, and falls short of the leadership expected by the Australian community of its leading scientific standard setting body.

3. ARBITRARY DIFFERENTIATION BETWEEN GREAT APES AND OTHER NON-HUMAN PRIMATES

The Principles, and the Policy, differentiate between “great apes”, described as gorillas, orang-utans, chimpanzees and bonobos, and other non-human primates. The justification given for this differentiation (in the Principles) is that the use of great apes in scientific research raises additional ethical questions because they are the closest species to human beings with the most advanced social and behavioural skills (at [2]).

The Principles also state that the use of all non-human primates in scientific research raises ethical questions in addition to those that arise regarding the use of all sentient animals in scientific research because non-human primates have a “close phylogenetic relationship to humans” (at 1). However, the term “non-human primate” is not defined in the Principles, Policy, or the Code. Although the examples of macaques, marmosets and baboons are given in the Principles, the Principles also refer to “other primates” (at 2). Given the Principles apply exclusively to non-human primates, this term should be clearly and exhaustively defined to ensure the scope of the Principles is clear. To the extent that “great apes” are treated differently as a sub-set of non-human primates, the term “great apes” should also be clearly and exhaustively defined for the same reasons.

LFA submits that speciesist ideology has no place in public standards for the protection of animal welfare. The central question that should be front of mind when interfering with the liberty of

animals is “does this animal have a capacity for suffering?” The differing intellect, physical attributes (including gender, ethnic characteristics and disabilities) or behaviour of humans does not justify their discriminatory treatment. Yet the differentiation between great apes and other non-human primates in the Principles suggest that the central question for the NHMRC is “does this animal suffer in the same way or to a similar extent as an average human being?” This suggests the NHMRC has adopted the view that it is only average human suffering, and the suffering of animals who behave most like average humans, that is worthy of prohibition. If that were the case, then scientific experimentation upon humans with intellectual functioning equivalent to average macaques, marmosets and baboons would also be justified. Clearly, as the enlightenment philosopher Jeremy Bentham pointed out in 1789: *'The question is not, Can they reason? nor, Can they talk? but, Can they suffer?'*

While great apes and other non-human primates may experience suffering in ways particular to their relative physical, cognitive, social or emotional composition, all non-human primates – indeed, all animals with a nervous system - share the capacity for pain and suffering which evolved to increase their chance of survival. There is no reasonable justification for the assertion that great apes have a greater capacity for suffering, or that the suffering of great apes is more demonstrable than the suffering of other non-human primates (or other sentient beings), simply because they are more like the average human than other primates.

LFA submits that the use of all non-human primates, including great apes, in scientific research raises the same ethical concerns, contrary to the proposition in paragraph 2 of the Principles.

Given the NHMRC's acceptance that great apes should not be exposed to scientific research unless the research “will not have any appreciable negative impact on the animals involved” and “will potentially benefit the individual animal and/or their species” (at [5]), LFA submits that the ethical rationale for those requirements should apply equally to all non-human primates. The restrictions on the use of great apes in scientific research in paragraphs 2 to 7 of the Principles should apply to all non-human primates.

In the event NHMRC maintains a distinction between the treatment of great apes and other non-human primates in scientific research on the basis of “greater ethical concerns”, the normative basis of, and rationale for, those greater ethical concerns should be made explicit. The explanation given for the protection afforded to great apes as opposed to other non-human primates in the Principles (their genetic similarity to human beings and their relatively advanced social and behavioural skills compared to other non-human primates) is arbitrary and inadequate. The ‘great ape’ and ‘other non-human primate’ distinction ignores the equally advanced cognitive, social and behavioural skills of other non-human primates, and the potential for variations in the cognitive, social and behavioural skills between animals within the same primate species. Incontrovertible evidence of the advanced cognitive, social and behavioural skills of macaques, for instance, has been seen by a portion of the Australian public in the National Geographic television series 'Monkey Thieves' which aired on the ABC. Indeed, even the Principles acknowledge the “considerable species variation in social requirements” (at [6.2]).

If the different treatment of great apes and other non-human primates is based on ethical reasons, the Principles should explain why the suffering of animals with genes and cognitive, social and behavioural skills different to great apes for scientific purposes raises different or fewer ethical concerns.

4. USE OF NON-HUMAN PRIMATES FOR SCIENTIFIC PURPOSES AS A LAST RESORT

Subject to our submission in section 3 above, LFA commends the NHMRC's position in paragraph 1 of the Principles that the use of non-human primates in scientific research must be justified and only permitted when no alternative is suitable. However, LFA considers the drafting

of paragraph 1 introduces too many subjective elements in the assessment of the justification proposed for the use of non-human primates.

LFA considers the use of the words “suitable” and “potential” in paragraphs 1(i) and (ii) respectively introduce an unacceptable level of subjectivity and remoteness into the assessment called for under paragraph 1. For example, it is arguable that alternatives to the use of non-human primates are available, but may not be considered suitable for a range of practical, technical, financial, political, or professional reasons. For example, the alternatives might not be immediately available, may increase the costs of the project, may introduce additional variables, or may increase the potential for delay, while still providing the same scientific value. Similarly, justifying the use of non-human primates for scientific purposes based on potential, but unlikely or remote benefits is unacceptable. The potential benefits put forward as justification for the use of non-human primates for scientific purposes must be reasonably likely to accrue, and must not be remote or unlikely.

Taking an incrementalist approach, LFA submits the Principles should require that the use of non-human primates for scientific purposes should only be permitted where “no alternative is available to pursue the stated aims of the project” and the potential effects on the non-human primates are justified by “the reasonably likely” benefits of the project. In addition, any use of non-human primates that might reasonably cause “harm” or “distress” as defined in the Code should only be permitted in exceptional circumstances based on a consideration of specific criteria that ought to be listed in the Principles, and with an additional requirement that all options for pain relief (including anaesthesia) be administered.

LFA submits the NHMRC has little to lose and much to gain by introducing:

- (a) a standard of reasonableness into the test for assessing justifications put forward for the use of non-human primates for scientific purposes, and
- (b) clear, objective criteria for consideration in exceptional circumstances where harm or distress to the non-human primates involved is anticipated.

5. REMOVAL NHMRC NOTIFICATION REQUIREMENTS AND INSPECTION POWERS

The Principles propose to remove the following requirements currently imposed on projects funded by the NHMRC:

- (a) the requirement to seek and obtain an exemption from the NHMRC’s Animal Welfare Committee (“**AWC**”) to house non-human primates for periods longer than six weeks without access to an outside enclosure;
- (b) the requirement to notify the AWC of the importation of a non-human primate that is subject to Commonwealth regulation; and
- (c) the ability for the AWC to inspect facilities where non-human primates will be housed and used.

LFA is extremely concerned by the proposal to remove these oversight and accountability measures from the requirements applicable to scientific programs funded by the public, through the NHMRC. Broadly, we submit that these requirements should be included in the Principles.

5.1 The requirement to seek and obtain an exemption from the AWC to house non-human primates for periods longer than six weeks without access to an outside enclosure

Regarding the requirement described in paragraph (a) above, paragraph 5.10 of the Principles

provides that “Non-human primates must be provided with access to an outside enclosure if they are to be held for six weeks or longer unless specific approval is obtained from the [institutional Animal Ethics Committee]. Note: This requirement may not apply to non-human primates held in PC2, PC3 or PC4 conditions.”

It is unclear what constitutes “PC2, PC3 or PC4 conditions”, as these terms are not defined in the Principles, Policy or Code. LFA's research indicates that these terms refer to levels of physical containment intended to prevent the dissemination of biological hazards from scientific research facilities. LFA questions the implied inability of research facilities housing non-human primates in PC2, PC3 or PC4 conditions, to create conditions which provide a level of environmental enrichment to animals confined within such facilities. We contend that it is possible to provide large indoor enclosures with plant and other materials which may eventually require significant decontamination and disposal. The only likely inhibitor to providing such enriched environments is cost, and this cannot be used to justify the housing of non-human primates in conditions which fail to meet their most basic physical and behavioural needs, including the need to interact with members of their own species. The Australian public expects animals to be housed humanely, and this excludes cages without significant natural materials and/or involving solitary confinement.

LFA does not consider it is appropriate for the NHMRC to surrender its approval function in respect of the housing of non-human primates for longer than six weeks without access to an outside enclosure to an institutional Animal Ethics Committee (“AEC”). As the Principles acknowledge, non-human primates require a variety of stimuli and enrichment from the outside environment and that emphasis must be placed on appropriate and varied enrichment of the physical environment (see for example [5.11] and [6.3]). Furthermore, the Principles themselves are premised on the position that the “complex and highly social behaviour and advanced cognitive capacity of many non-human primates make it difficult to adequately provide for their needs in a captive environment or research setting” (at 1).

The confinement of non-human primates without access to large outside enclosures for any unnatural period of time, let alone a period of six weeks, has the potential to cause significant distress, emotional trauma, and psychological harm to the animals. Decisions to expose non-human primates to that risk should not be made by institutional AECs behind closed doors and without approval by the NHMRC. Surrendering this accountability function to institutional AECs would enliven the risk that such decisions may be made without due regard to the cumulative impacts on the individual animals involved; that such proposals for long-term indoors confinement may not be specifically considered in the context of the broader project proposal or given adequate consideration; and that decisions may be influenced by other factors supporting the approval of the project as proposed.

LFA submits that the NHMRC should maintain the requirement that an exemption be obtained from the AWC to house non-human primates for periods longer than six weeks without access to a large outside enclosure, that exemptions only be granted in exceptional circumstances and subject to rigorous welfare monitoring and reporting requirements, and that enriched indoor enclosures be required in all situations including PC2, PC3 and PC4 conditions.

5.2 The requirement to notify the AWC of the importation of a non-human primate that is subject to Commonwealth regulation

There does not appear to be any material administrative or economic rationale to justify the removal of this notification requirement.

In general, LFA supports the NHMRC playing an effective oversight and accountability role. Subject to any arguments that maintaining this notification requirement would place an

unreasonable administrative or economic burden on the NHMRC, LFA does not support its removal.

5.3 The ability for the AWC to inspect facilities where non-human primates will be housed

The Policy currently provides that researchers funded by the NHMRC “should be prepared to allow access to the AWC of the NHMRC to inspect the facilities where the animals will be housed and used” when new caging is required (at [15]).

The Principles propose to remove the AWC’s role in inspecting new caging for housing non-human primates proposed to be used in scientific research, and delegate that capacity to institutional AECs (at [5.3]).

LFA strongly opposes the proposal for the NHMRC to surrender its ability to inspect new caging for non-human primates proposed to be used in scientific research funded by the NHMRC. LFA considers the devolution of that role to institutional AECs undermines the objective of national uniformity in standards applicable to housing non-human primates by the scientific research community. This proposal also unjustifiably limits the NHMRC’s capacity to oversee the treatment of non-human primates in publicly-funded research, and to inspect facilities where non-human primates are being held at the tax payer’s expense (at least partially).

LFA does not oppose the additional requirement that caging for non-human primates in scientific research facilities be approved by institutional AECs according to the checklist in Part C of the Principles. However LFA considers it is essential that NHMRC, as the peak public standard-setting body, retain the ability to inspect facilities where non-human primates are housed for research funded by the NHMRC.

Furthermore, LFA considers NHMRC’s inspection ability should be expanded to allow inspections of research facilities where non-human primates are housed to be conducted by members of the AWC unannounced, and regardless of whether “new caging” is or was required for the research project. LFA submits that the relevance of the Principles is undermined if the NHMRC has no formal capacity to monitor their implementation. The ability for the AWC to inspect research projects funded by the NHMRC is an efficient accountability mechanism that is essential to the integrity of the Principles as a national standard of best practice.

Indeed, the variations in legal requirements, regulatory capacity and enforcement practices of state and territory animal welfare bodies may encourage institutional AECs to adopt standards that reflect the applicable State/Territory requirements. The abdication of the NHMRC’s inspection ability may encourage the fragmentation of non-human primate housing standards according to the prevailing State/Territory regulatory standards or policies. Indeed, in the absence of genuine oversight of the treatment of non-human primates in scientific research facilities, the risk that public funding for a research project may be withdrawn may present a greater incentive for compliance with animal welfare standards than the risk of regulatory penalties.

The Principles provide no justification for the NHMRC’s proposal to surrender its discretionary ability to inspect facilities for research projects funded by the NHMRC where non-human primates will or are being housed. On the contrary, LFA submits that the removal of the NHMRC’s ability to inspect facilities would undermine the integrity of the Principles as a national standard of best practice and unjustifiably remove an essential accountability mechanism for ensuring compliance with the Principles. As a matter of ensuring accountability for the use of public funds disbursed by the NHMRC according to the NHMRC’s own standards, the NHMRC should retain, at least, a discretionary ability to inspect scientific projects housing non-human

primates on an unannounced basis.

In addition, LFA considers the NHMRC's ability to inspect research facilities should be expanded to allow unannounced inspections and should not be limited to facilities where "new caging" is required.

In conclusion, LFA endorses the NHMRC's proposal to review and update the 2003 Policy, and to provide greater clarity around the NHMRC's expectations of best practice when it comes to the treatment and welfare of non-human primates in scientific research that the NHMRC funds.

The Principles provide a good starting point for that reform process, and LFA is pleased to have the opportunity to contribute to the reform process through public submission. However, LFA considers the draft Principles fall short of the public's expectations in several key respects, as outlined in the submissions above.

LFA would welcome the opportunity to be further involved in the NHMRC's Policy review and reform process, and to provide further comments on the Principles or revisions to them.

Yours faithfully

Lawyers for Animals Inc.

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