THE CPCSEA GUIDELINES FOR THE REUSE AND REHABILITATION OF DOGS

A. The Rationale and need

The Committee for the Purpose of Control and Supervision of Experimentation on Animals (CPCSEA), a statutory body of the Government of India, regulates the use of animals before, during and after use in experimentation. The CPCSEA, as mandated by law Rule 9 (c) of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 (which states that "animals intended for the performance of experiments are properly looked after both before and after experiments") finds it necessary to frame guidelines which limit the use of animals in testing /research and their care after use in experiments.

These guidelines define a time limit for which dogs can be tested and/or housed in laboratories. The guidelines are based on the premise that animals in laboratories undergo psychological, physiological and physical trauma, not just from the interventions made on them, but also from solitary confinement, lack of natural conditions, caging, handling and absence of appropriate social interaction. The concept of Rehabilitation has been recognised in India as the 4th R and evolved as an official policy of the CPCSEA in 2004.

Re-use of animals of higher phylogenetic order such as dogs is more common for several reasons, most often to save costs incurred in purchasing new animals. The advent of newer and less invasive methods of analysis, such as telemetry and imaging technologies, have also increased the possibility of re-using animals. Often, animals that have been used for a study and have not been subjected to an invasive procedure are used for a further scientific study. However, these animals are sometimes reused overlooking the physiological, psychological and physical trauma endured by them and hence these guidelines have been evolved to ensure the welfare of the animals before any repeat use in experimentation or prolonged housing in laboratories.

The effects on individual animals and their welfare must be considered on a case-by-case basis before reuse of laboratory animals can be advocated. Re-using animals as a reduction strategy must be promoted with extreme caution because reuse increases the potential of increased harm and trauma to individual animals and hence increases the quantum of an individual animals suffering. Re-use of animals for invasive procedures for reasons related to convenience and cost savings are never appropriate and cannot be approved for.

The point at which an animal should be rehabilitated or removed from experimentation/laboratory housing cannot be strictly defined, due to variations in study protocols, intensity of pain / distress an animal is subject to, inherent variations from animal to animal, degree of invasiveness of the study, volume of blood taken, repeated doses of toxic substances, age of animal, health of animal, handling, housing etc.

These guidelines define 'use' and 'rehabilitation' and sets time limits to the use of dogs in breeding and experimentation. Though special mention has been made on pharmacokinetic (PK), breeding, and telemetry studies, it is important to note that all and any re-use should have the special permission of the CPCSEA for every individual animal being considered for inclusion in a second/subsequent protocol of experimentation.

B. Definitions of 'Rehabilitation' and 'Reuse'of laboratory animals

(i) Rehabilitation of laboratory animals

The concept of 4th R "Rehabilitation" of laboratory animals is defined as "the aftercare rendered to animals that have been (i) bred for the purpose of experimentation (ii) subject to any form of experimentation (iii) retained in laboratory animal houses or breeding houses for the purpose of experimentation, both for education and research, with the sole intention of alleviating the pain/distress or suffering due to the physical, physiological and psychological trauma that the animals have been exposed to and to provide the animal a life distinctly different from laboratory housing and care , until the point of natural death".

Rehabilitation norms are elaborated in the "CPCSEA guidelines for rehabilitation and euthanasia of laboratory animals in the "REPORT OF THE CONSULTATIVE GROUP ON REVIEW OF THE NORMS AND PRACTICES FOR REGULATION OF ANIMAL EXPERIMENTATION - Sept 2004", Ministry of Environment and Forests, Government of India.

(ii) Reuse of laboratory animals

"Reuse" of laboratory animals is a term used where in, after completion of an experiment (experiment as defined in Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 and as amended in 2004) an animal is used again in the same or a different protocol, where an unused animal would have equally sufficed to meet the objectives of the second/or subsequent use.

C. Reuse of dogs in experiments

The CPCSEA's consent for reuse would be generally conditional upon the animal having suffered no significant adverse effects as a consequence of the first use, and the animal not having been subjected to any intervention which compromises its welfare and suitability on scientific terms, as a subject for the second or subsequent use. The CPCSEA reserves its right to make a decision on matters of reuse.

Any and all re-use of a dog after the completion of its use in an approved experimental protocol, must be further authorized/approved by the CPCSEA for each individual animal, limiting their reuse/stay in laboratory housing to a maximum period of three years. Hence all reuse or continued use within the three year period for studies/experiments, must be specifically authorized with a written consent of the CPCSEA.

1. The CPCSEA's consent for reuse will be conditional upon the animal having suffered no significant adverse effects as a consequence of the first use, and the animal not having been subjected to any intervention which compromises its welfare or suitability in scientific terms, to be used as a subject for the second or subsequent use.

2. The reuse of animals in an approved study may be reconsidered for second/repeated use when it may serve as a way to reduce the number of animals used, without causing any incremental pain/distress to the animal which results from second/repeat use.

3. When considering subsequent use of experimental animals- the physical and psychological health and wellbeing of the animal must be considered.

4. Before seeking permission with the CPCSEA for reusing an animal, the health of the animal and the opinion of the veterinarian and consent of IAEC must be in order.

5. Health certificate for sound health and fitness of animals intended for reuse must be obtained from a qualified veterinarian and should include a complete clinical examination, including vital signs (TPR), skin condition, behavior of animals, CBC, TPR, kidney (KFT) and liver function tests (LFT). The veterinarian should clearly certify that there has been no adverse effects including psychosomatic disorders, by way of the first experiment/caging and due to laboratory housing/procedures. Animals showing stereotypic behavior, fear, freezing on human touch; genetic or physical defects; permanent implants, etc. should be declared unfit for re-use and recommended for proper rehabilitation.

6. The laboratory must maintain records of re-use with detailed documentation.

7. Re-using animals as a reduction strategy can be promoted/considered by the IAEC only with extreme caution taking into consideration the potential of increased quantum and duration of pain and distress to individual animals caused by reuse. The IAEC should be asked to closely monitor end points and determine the suffering of animals before recommending reuse.

8. Dogs used in toxicity studies must be healthy and limit of use of individual dogs should be for a maximum period of 3 years for pharmacokinetic studies subject to the health status of the dog as reflected by general body condition, CBC, liver and kidney function tests. If the dog/s shows any liver or kidney impairment, within the three year period, the animal cannot be reused, even if within the 3 year period and must be rehabilitated with special care. Appropriate washout periods, with a minimum of three months, should be applied when studying the metabolism of a series of drugs to avoid confounding drug interactions and least physiological stress to the dog when repeatedly used within the 3 year period. LFT and KFT and blood profile should be done at the end of each wash out period and only if the animal is found healthy and normal, can the dog be reused.

9. Dogs used in breeding may be limited to 5 whelping cycles and must be rehabilitated on completion of this. Dogs used in toxicity studies should not be used for breeding.

10. In the case of telemetry studies, dogs from which the device has been explanted should not be used to implant another second device. Appropriate washout periods, with a minimum of three months time period should be adhered to, when studying the impact of several drugs to avoid drug interactions and least physiological stress to the dog. Telemetered dogs may be used till as such time the dogs shows normal physiological functions (TPR, liver, kidney) or until the device is no more functional and limited to a maximum period of three years.

11. The responsibility for all non-terminal research animals shall remain the responsibility of the PI and study veterinarian following the completion of the study

until final disposition is accomplished.To safeguard the animal's welfare through the study and until re-use / rehabilitation/ euthanasia, the Veterinary Surgeon named in the study should be actively involved, together with the PI and other named persons, ensuring the welfare of the animal.

D. Provision of identity number/s for individual dogs

In order to facilitate and ensure humane limits in reuse as per CPCSEA guidelines it is imperative to assign a unique number to each animal by way of micro chips. Once every animal is given a unique identity number this information should be made available in FORM B and the institute should have this information/database for all dogs and which may be made available if required by CPCSEA.The Institute should update this information for each animal as and when an experiment is completed.

E. Rehabilitation

Dogs that have completed the three year experimental term or if not permitted for reuse within the three year period should be promptly rehabilitated by the institute with information to the CPCSEA.

In the case of dogs there is immense possibility to be adopted by families. This may be encouraged, after the animals have been spayed/castrated by the institute and adoptions facilitated through trustworthy Animal Welfare Organization/s (AWO/s), after due approval of CPCSEA. Members / Representatives of the CPCSEA would be designated to liaise with institutes and ensure rehabilitation of the dogs not permitted for reuse and those whose three year experimental term is completed. Otherwise institutes should bear the costs of rehabilitation in their own facilities, until the natural death of the animal. AWOs may facilitate rehabilitation, if required by rehabilitator.