सत्यमेव जयते

Government of India
Ministry of Fisheries, Animal Husbandry and Dairying
Department of Animal Husbandry and Dairying

Guidelines of CPCSEA for Reuse/ Rehabilitation of Large Animals post experimentation 2020

Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)

CONTENTS

GUIDELINES OF CPCSEA FOR REHABILITATION/ REUSE OF LARGE ANIMALS POST-EXPERIMENTATION – 2020

[In conjunction with "Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules 2006, Section 9 (cc)]

These guidelines have been prepared to operationalise the rules amended in 2006, Section 9 (cc) for Rehab and Reuse of large animals:

A. Definitions:

(i) Large Animals: Animals above the phylogenetic level of rodents and lagomorpha are defined as large animals covered under the regulation of CPCSEA.

(ii) Reuse: "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 2001 and 2006) an animal is used again after a washout period, 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.

(iii) Rehabilitation: Rehabilitation of the large animals (mentioned in point C-ii)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 animal houses or breeding houses for the purpose of experimentation, for education, research and commercial purpose, 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".

B. Reuse of animals 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.

In case of dogs, any and all reuse 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 3 years. Hence all reuse within the 3 year period for studies/experiments, must be specifically authorized with a written consent of the CPCSEA. 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.

(i) Conditions for Reuse:

1. 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.

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

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

4. Health certificate for sound health and fitness of animals intended for reuse as per **Annexure-I** must be obtained and maintained at the establishment**.** The veterinarian should clearly certify that there has been no adverse effects, by way of the first experiment/caging and due to laboratory housing/procedures. Animals showing stereotypic behaviour, fear, freezing on human touch; genetic or physical defects; permanent implants, etc. should be declared unfit for reuse and recommended for proper rehabilitation.

5. The establishment must maintain records of reuse with detailed documentation up to a period of 10 years. Reusing 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 closely monitor end points and determine the suffering of animals before recommending reuse.

6. In case of Dogs used in toxicity studies, the animal 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 the data maintained as per **Annexure 1.** 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.

7. 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.

8. 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 3 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 3years.

C. Rehabilitation of large animals post-experimentation:

1. It is the responsibility of establishment conducting experiments on large animals to maintain them post-experimentation till their natural death at its own rehabilitation facility. In case the establishment is unable to rehabilitate the animals in its own facility, it will be responsible to rehabilitate them at an AWO (Animal Welfare Organisation) registered with AWBI and/or Government approved/registered AWOs for the animal species being proposed. The undertaking for adoption shall be submitted by the establishment to the AWO (Annexure II) duly signed by the Head of the organisation, Principal Investigator and the CPCSEA Main Nominee.

2. The table below gives the minimum costs (exclusive of government taxes) for rehabilitation of large animals at the AWOs.

Species	Minimum cost per day per animal (in INR)
Dogs	60
Cat	40
Sheep/Goats	50
Cattle	200
Horse	200
Pony/Mule	100
Monkey	100
Pig	120

3. In conjunction with *"Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules 2006, Section 9 (cc)"* a provision of an advance lump sum amount payable on monthly basis per animal as per above table needs to be transferred to AWO to meet the costs of rehabilitation. A 10% increase in the above cost should be added every year, in order to meet the cost index. This cost may be reviewed once in 5 years.

4. It will be the responsibility of the IAEC mainly CPCSEA Nominee to ensure (at least once in six months) that animals transferred with proper certification, permanent identification number/tag and a MoA (between the establishment and AWO) are kept under healthy conditions till their natural death. MoA should be duly signed by the Head of the establishments or any authorised representative.

5. Euthanasia, during rehabilitation, will only be permitted under any of the following conditions: (Euthanasia must always be carried out by administering overdose of Barbiturates).

a. the animal is not able to perform its natural functions and left in pain & suffering.
b. the animal encounters contagious/infectious diseases of zoonotic importance.

(Note: Ref. The Prevention and Control of Infectious and Contagious Disease in Animals Act 2009)

6. The health records of experimental animals shall be maintained at the establishment and AWO as per **Annexure-I.**

7. The information regarding the animals for rehabilitation (at establishment/ AWO)

should be made available to CPCSEA.

8. The animals used for routine nutritional studies and breeding experiments would be reused and utilised.

9. The animals used for challenge experiments if found fit after examination, may be included in the herd. For challenge study, the establishments can frame their own SOP.

10. The healthy and productive animals can also be given for adoption to the farmers, except for Cattle and its progenies.

(i) Rehabilitation through Adoption:

In case of non availability of registered AWOs for Sheep, Goat, Pig, Cat, Ponies and Mules, the animals may be adopted post experimentation. All the certificates and essential documents/records along with the undertaking has to be made available at the time of adoption. After adoption the animals should not be further sold.

The animals if given to AWO should not be sold. They can however, be given for adoption following due procedure like that of the establishments. The individuals adopting animals should never sell them further or give for adoption.

(ii) Rehabilitation in case of dogs:

Dogs that have completed the 3 year experimental term or if not permitted for reuse within the 3 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 establishments and ensure rehabilitation of the dogs not permitted for reuse and those whose 3 year experimental term is completed. Otherwise establishments 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.

Annexure-I

DETAILS/ RECORDS TO BE MAINTAINED WHILE REUSING/REHABILITATING ANIMALS

I. Instructions for reuse and rehabilitation of experimental Animals

The establishment should maintain record of all animals pertaining to admissions, treatment, health, experimentation for the purpose of reuse and rehabilitation.

The details as per the following forms have to be maintained and made available at any time for inspection for at least 10 years post experimentation.

1. **Pre-experimentation details of animal for reuse/rehabilitation:**

   Form is for maintaining records of animal's origin, treatment and tests performed during quarantine by the acquiring institution prior to experimentation signed by a veterinarian.

2. **Experimentation details**

   Form is for maintaining records pertaining to animal experimentation to know the kind of material handled during experimentation and protocols followed signed by principal investigator.

3. **Post-experimentation details of animal &suitability certification for reuse /rehabilitation**

   Form is for maintaining records of animals after performance of experimentation for its continuation either for reuse or for rehabilitation signed by veterinarian.

4. **Transfer certificate for rehabilitation**

   Form is for certifying suitability for rehabilitation authorized by a veterinarian.

II. Following forms/records should be maintained for supportive information

1. General health condition and body weight
2. Menstrual cycle (Species specific)
3. Tuberculin testing (in case of cattle, buffaloes and non-human primates).
4. Johnin testing (in case of cattle and buffaloes)
5. Brucellosis testing (in case of cattle, buffaloes, sheep and goats)
6. Mallein testing/ CFT/PCR (in case of equines)
7. X–Ray
8. Parasitological examinations
9. Microbiological examinations and screening records for seronegativity required for testing.
10. Hematology and biochemical tests.
11. Treatment record
12. Surgery
13. Research and experimentation methods

14. Volume of blood drawn/collected

III. These forms are to be filled only by designated persons and signed by competent authority (CA) or an officer appointed by CA for doing so.

IV. As an archival policy of the establishment, these forms should be available in the animal facilities for at least 10 years for inspection and data preservation.

V. Copies of the data pertaining to large animals at different phases need to be submitted to the IAEC for their review and the compiled data will be shared atleast once a year with CPCSEA along with information on acquiring source, completion of experiment and number of animal saved to meet objectives of 4R's.

VI. As per the current CPCSEA regulations, permission for experimentation on large animals is granted by CPCSEA with recommendation of a central sub-committee constituted for this purpose. The recommendation should be routed through IAEC of the institute and it is important to mention the reference number of the approval in these forms.

VII. Date of initiation and date of termination mentioned in the form is as per IAEC/ CPCSEA approval.

VIII. Forms such as post-mortem details and histopathology should be essentially maintained for all animals that have been sacrificed in experiments and/or died during rehabilitation.

IX. A unique identification number is followed in all the forms for uniformity in every establishment. The animal number to be placed in the appropriate box in the form will be derived as follows:

I	Species:	
	01	Buffalo
	02	Cat
	03	Cattle
	04	Dog
	05	Donkey
	06	Goat
	07	Horse
	08	Monkey
	09	Mule
	10	Pig
	11	Pony
	12	Sheep
	13	Any other (Please specify)

II	Sex	
	M	Male
	F	Female
	N	Neuter
III	Year of Birth	
	97	**1997**
	01	**2001**
IV	Establishment's CPCSEA Registration no.:	
	159/GO/ReRcBi-S/ReRcBi-L/01/CPCSEA **159**	
	401/PO/Bi-S/ Bi-L/01/CPCSEA **401**	
V	Individual number as per the establishment	
	002	
	009	
	019	

Example:

Species	**Gender**	**Year**	**Reg. No.**	**Individual No.**
6	**M**	**01**	**159**	**009**

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. The establishment should have this information/database for all dogs and which may be made available if required by CPCSEA. The establishment should update this information for each animal as and when an experiment is completed.

Pre-experimentation details of animal for Reuse /Rehabilitation

1. Name of the organization currently holding the animal/s

2. Details of the animals

a. Animal No:		b. DOB
c. Animals procured / Trapped from:		d. Date of procurement / trapping
e. Supplier / Source		f. Colony bred / Wild caught
g. Dam Number		h. Sire Number
i. Colour	j. Date of Induction	k. Body Weight and Date

3. Physical examination on arrival

a. Fore Limbs	b. Hind limbs
c. * Dental Formula: I C PM M	d. Teeth condition
e. Eyes	f. Nostrils
g. Mouth lesions if any	
h. External Body Coat	i. Abdominal palpation
j. Lymph nodes	
k. Chest auscultation	l. Body Temperature
m. Any injuries physical deformities	
n. Clinical Symptoms if any	
o. Health condition	

4. Quarantine period

a. Introduced on	b. Released from quarantine on

5. Microscopic examination for parasites

a. Fecal Examination for Endo parasites

b. Any Ectoparasites

c. Parasites on Blood smear examination

6. Any treatment given during quarantine

Date	Clinical Symptoms	Diagnosis	Treatment	Recovered on

7. Tuberculin testing:

Date	Source /Batch of Antigen	Result at each Observation		
		First (0h)	Second (48h)	Third (72 h)

8. Johnin testing:

Date	Source /Batch of Antigen	Result at each Observation		
		First (0h)	Second (48h)	Third (72 h)

9. Mallein testing:

Date	Source /Batch of Antigen	Result at each Observation	
		First (0h)	Second (48h)

10. Brucella testing:

Date	Source /Batch of Antigen	Antibody Titre

11. Chest X-Ray (as recommended)

a. Date	
b. Report contents	

12. Place of Rehabilitation/Name of the AWO animal being transferred for rehabilitation/experiment in which animal being proposed to be reused

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Experimentation details

[separate sheet for each experiment]

1. Animal No.	2. Age/Body weight/Date
3. Details of the experiments:	
a. Title(s) of the project	
b. Principal investigator	
c. Details of the protocol	
4. Age and weight at the time of termination of the experiment	
5. Experimental Endpoint Criteria	
6. Date of Termination of experiment as per CPCSEA approval	
7. Infectious agent used, if any give details	
8. Radioisotope used, if any give details	

Signature of the Principal Investigator

Name……
Designation……

Date:
Place:

Office Stamp

Post-experimentation details of animal & suitability certification for reuse /rehabilitation

1. Name of organization currently possessing the animal:				
2. Animal No.:				
3. Title of experiment:				
4. Investigators:				
5. Duration under experimentation:				
6. Body weight &date:				
7. Details of experimental procedures:				
8. Number of times anesthetized:		9. Number of times blood withdrawn:		
10. Infectious organisms involved:				
11. Radioactive substance used:				
12. Is the animal suffering from any Zoonotic disease:				
13. Physical abnormalities, if any furnish details:				
14. Any clinical symptoms:				
15. Any attention of a veterinarian required during rehabilitation and how long:				
16. Special nutritional requirements, if any during rehabilitation:				
Present condition of the animal [Mark √]:				
Excellent [Answers to 11-16 are No]		It can be retained		
Good [Answer to 11-15 are No]		It can be given for experimentation		
Satisfactory [Answers to 11-14 are No]		Fit for transfer to AWO for rehab		
Poor [Answers 11-13 are Yes]		Can be sent for Euthanasia		

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Transfer certificate for rehabilitation

[To be filled in for every animal separately]

1. Animal No.	2. Body weight/date:
3. Name & CPCSEA No. of organization handing over the animal(s):	
4. Name and address of the Rehabilitation Unit/AWO animals being sent to:	
5. CPCSEA/AWBI Registration No. of the Rehabilitation Unit/AWO:	
6. In case of emergencies contact person(s) details:	
Name:	Name:
Telephone No(s):	Telephone No(s):
Fax:	Fax:
7. Person handing over the animal:	8. Person under taking over the animal:
Signature	Signature
Name	Name
Designation	Designation
Date	Date

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Tuberculin Testing Record

Animal No						
Date	**Source & Batch number**	**Result of readings**			**Remarks**
		First (0h)	Second(48h)	Third(72 h)	

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Johnin Testing Record

Animal No				
Date	Source /Batch of Antigen	Result at each Observation		
		First (0h)	Second(48h)	Third(72 h)

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Mallein Testing Record

Animal No					
Date	Source /Batch of Antigen	Result at each Observation			
		First (0h)	Second(48h)		

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Brucella Testing Record

Animal No					
Date	Source /Batch of Antigen	Antibody Titre			

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

X – Ray Record

Animal No					
Date	**Organ/Site**	**Radiological Findings**			

Signature of Radiologist/Veterinary Surgeon

Name…….
Designation……..…….

Date:
Place:

Office Stamp

Details of Blood Drawn

Animal No					
Date	**Quantity**	**If any anaesthetic used & Quantity**	**Purpose**	**Name of the Person drawn the blood**	

Signature of Phlebotomist

Name……
Designation……

Date:
Place:

Office Stamp

Body Weight Record

Animal No.	
Date	Weight

Signature of Animal Technician

Name……
Designation……

Date:
Place:

Office Stamp

Microbiology Record

Animal No				
Date	**Test**	**Material**	**Organisms found**	**Remarks**

Signature of Microbiologist/Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Parasitology Record

Animal No					

Date	**Ectoparasites**	**Endoparasites**	**Remarks**

Signature of Parasitologist/Veterinarian
Name……
Designation……

Date:
Place:

Office Stamp

Record of Treatment provided

Animal No					

Date	**Clinical Symptoms**	**Diagnosis**	**Treatment**	**Remarks**

Signature of Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Haematology Records

Animal No											
Date	**Hb (g/l)**	**PCV (l/l)**	**RBC (10^{12}/l)**	**WBC (10^{9}/l)**	**Differential Leukocyte Count**					**ESR**
					N	**L**	**M**	**B**	**E**	

Signature of Pathologist/Veterinarian

Name……

Designation……

Date:
Place:

Office Stamp

Record of Surgeries conducted

Animal No					
Date	**Type of Surgery**	**Purpose**	**Treatment**	**Remarks**

Signature of Surgeon/Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

Post-mortem report

1. Animal Number					
2. Source					
3. Date of induction					
4. Was the animal sacrificed/died naturally					
5. Condition of the carcass					
6. Date of death					
7. History of animal					
8. External examination					
a. Head	b. Body	c. Limbs			
9. Discharges, if any					
a. Mouth	b. Eyes	c. Ears	d. Nose	e. Anus	f. Vagina /penis
g. Lesions in the buccal cavity	h. Teeth	i. Tongue			
10. Internal examination					
a. Lesions in Brain: c. Lungs: e. Liver: g. Spleen : i. Mesenteric Lymph nodes: k. Intestine m. Colon: o. Uterus			b. Lesions in Sinuses: d. Heart: f. Pancreas: h. Kidney/Ureter: j. Stomach l. Cecum: n. Rectum p. Ovaries/Testes		
11. Material Collected for Laboratory as deemed necessary by pathologist conducting PM					
Samples			**Findings**		
Samples for Microbiology					
Samples for Parasitology					
Samples for Histopathology					
12. Important Findings:					
13. Cause of Death:					

(Note: The information of the death of animal should be given to the establishment prior to the conduct of post mortem.)

Signature of Pathologist/Veterinarian

Name……

Designation……

Date:

Place:

Office Stamp:

Histopathology Record

Animal No.		
Date	**Material**	**Findings**

Signature of Pathologist/Veterinarian

Name……
Designation……

Date:
Place:

Office Stamp

D. Minimum Floor Area Per Animal:

Species	Cage size in feet			Floor area Sq. Ft.
	Width	Length	Height	
Dog/ Cat	3	5	4	15
Goat/ Sheep	4	6	5	24
Cattle-Calf	4	6	5	24
Cattle-Adult	6	10	6	60
Monkey	4	4	5	16
Horse	6	12	7	72
Pig	3	4	4	48

(Note: Above is the minimum floor areas required for specific species for each animal if individually housed. However, animal should have enough space to move around.)

E. Minimum ratio of animals to attendants for specific animals:

Dogs/Cats	Goat or Sheep	Cattle	Monkey	Horse
15:1	20:1	10:1	8:1	4:1

Annexure II

Undertaking for Rehabilitation

I hereby declare that the animal (species)..... Number..... being rehabilitated at ..... is fit for rehabilitation and is apparently healthy.

Signature of Principal Investigator

Name……
Designation……

Date:
Place:

Signature of Head of the organisation

Name……
Designation……

Date:
Place:

Office Stamp

Signature of Main Nominee of CPCSEA

Name……
Designation……

Date:
Place:

Office Stamp