

MINUTES OF THE XVII MEETING OF COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA) HELD ON 22.1.2007 AT 3.00 P.M. UNDER THE CHAIRMANSHIP OF SHRI B.S. PARSHEERA, CHAIRMAN, CPCSEA AND ADDITIONAL SECRETARY, MINISTRY OF ENVIRONMENT & FORESTS

A List of Participants in the meeting and list of Members granted leave of absence are enclosed.

Chairman, CPCSEA, welcomed the members and agenda items were taken up as follows:

17.1 CONFIRMATION OF THE MINUTES OF THE XVI MEETING OF CPCSEA HELD ON 16TH NOVEMBER, 2006.

The Committee for the Purpose of Control and Supervision of Experiments on Animals confirmed the Minutes of the XVI Meeting held on 16th November, 2006.

17.2 TO REVIEW THE ACTION TAKEN ON THE MINUTES OF THE XVITH MEETING AND PENDING POINTS OF PREVIOUS MEETINGS OF CPCSEA.

9.2-3.1.2: To review of experiments using animals in case of traditional medicine

9.2-3.2.5 Funding of projects on traditional systems of medicine and proper scientific review with regard to the scope and purpose of research.

In view of the fact that the representative of Department of AYUSH had been unable to attend successive meetings of CPCSEA, it was decided that the matter would be taken up by Chairman, CPCSEA with the Secretary, Department of AYUSH.

12.5 Stopping of redundant experiments in Medical and Veterinary Colleges

Members deliberated over the responses received from the three experts who had been assigned the task of scrutiny of the syllabus of PCI, MCI and VCI. It was agreed that CPCSEA would impress upon these apex bodies that there must be continuous efforts to reduce use of animals in redundant experimentation. They would also be requested to inform CPCSEA about the steps already taken in this regard over the last three years. In addition, it was agreed that an Annual Report may be called for from these bodies so as to set in place a mechanism for continuous monitoring. Action would be taken by Member-Secretary, CPCSEA with approval of Chairman, CPCSEA.

The matter would accordingly be removed from the agenda of the next meeting.

12.6 Proposal for one day training to CPCSEA nominees.

The Committee noted that a five day training module had been prepared by Dr. P. Balakrishnamurthy and Dr. K. Nachimuthu, Members CPCSEA in consultation with Expert Consultant (CPCSEA). It was observed that there was need for some modifications in the proposed programme in light of the logistical arrangements at NIAW, though the subject area had been comprehensively covered. Dr. P. Balakrishnamurthy and Expert Consultant (CPCSEA) would develop the detailed syllabus and also suggest faculty for conducting the courses so that with approval of Chairman CPCSEA the matter could be coordinated with Ed.CIL for scheduling the first training in March, 2007, if possible.

13.6 Deposit of the amount collected as Registration / Renewal Fee.

The Committee was informed that the matter was under process in the Ministry. Member-Secretary CPCSEA also informed that in light of the requirements of the current financial year, the available funds would be drawn upon, in addition to the funds provided as grants-in-aid.

13.7 Meeting of the Sub-Committee on Rehabilitation of Animals after their Experimentation

Since comments had not been received from any CPCSEA Member, it was agreed that the matter would be taken up in the next meeting of CPCSEA. Members would be requested to give their comments at the earliest.

16.6.2 Action to be taken on the basis of Report of Consultative Group on Review of the Norms and Practices for Regulation of Animal Experimentation.

Dr. P. Balakrishnamurthy, Member, CPCSEA, mentioned that some more time was required to discuss and examine the issue and it was agreed that the matter would be taken up in the next meeting of CPCSEA.

16.8 Approval of Animal House Facility by CPCSEA.

The Committee noted that approval of Animal House facilities had been conveyed and desired that names of animals for which approval had been provided should also be conveyed. In respect of M/s. Ranbaxy Laboratories Ltd., it was agreed that Expert Consultant (CPCSEA) would clarify to the institution the specific improvements required to be carried out in the old Kennel facility.

In respect of M/s. VEL's College of Pharmacy, Chennai and MMM Heart Foundation, Chennai, since compliance report had not been received, the proposals were not approved.

16.9 Regarding Inspection of Animal House Facilities

The Committee examined the suggestions made by Dr. A.J. Rao and Dr. P. Balakrishnamurthy. After deliberation it was agreed that the frequency of the inspection by the concerned CPCSEA nominee should be prescribed as once per year, regardless of whether any IAEC meeting had been scheduled by the institution. Instructions would be issued accordingly by Member Secretary, CPCSEA, with approval of Chairman CPCSEA.

17.3 REGISTRATION OF INSTITUTES WITH CPCSEA.

It was noted by the Committee that while there had been an increase in the number of institutes registered, the total number was only 1020, which appeared to be on the lower side. It was therefore agreed that CPCSEA would address the apex councils concerned as well as the relevant Ministries, bringing to their notice the statutory requirement for registration of institutions using animals and also forward to them a list of institutions already registered by CPCSEA. CPCSEA would request these bodies to ensure that all institutions using animals for the purpose of teaching/breeding/experimentation are duly registered with CPCSEA, and to send a report in this regard.

Chairman, CPCSEA, further desired that a copy of relevant rules/guidelines including the report of the Consultative Group on Use of Animals in Experimentation be forwarded to Dr. Ranjani Warriar, Director, MEF, since proposals considered by GAEC also involve use of animals.

AGENDA ITEM NO.17.4 : CONSIDERATION OF PROPOSALS RELATING TO ANIMAL EXPERIMENTATION.

17.4.1: Update regarding proposals submitted earlier.

During the last meetings of SCLA, certain project proposals were deferred for want of details of the project and for other reasons. In one such proposal of Sun Pharma Advanced Research Center, clarifications had been received and were considered by CPCSEA as follows:

S. No.	Name of the institute/ Name of the Investigator	Project Title	Decision of the XVI CPCSEA meeting	Action Taken/ updated Status/ development/ latest position	Decision of CPCSEA
1.	Sun Pharma Advanced Research Center (SPARC), Tandalija . Baroda. 390020 (Gujarat)	Regulatory / DRF metabolic studies in dogs.	The Committee sought details regarding the source of procurement of beagle dogs and desired that NCE's identification code may be provided so that the matter could be considered.	The Institute has submitted the details regarding the source of procurement of beagle dogs and NCE's project identification code: 10711131	Approved

17.4.2: Consideration of New Proposals :

Thirty one new proposals where-in the animal house facilities of the concerned establishments had been approved by CPCSEA, were considered as below:

S. No	Name of the institute/Name of the Investigator	Project Title	Decision of CPCSEA
1.	M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, Ahmedabad-380 015. /Dr. Girish Joshi	Repeated dose chronic toxicity & toxicokinetic (9-12 months) studies of ZYO1 in beagle dogs.	Approved
2.	M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, Ahmedabad-380 015. /Dr. Girish Joshi	Four-week repeated dose oral toxicity & toxicokinetic studies of new molecules (ZYH4 and ZYD1) in beagle dogs with 2 week recovery.	Approved

3.	M/s. Cadila Health Care Ltd. Zydus Tower, Satellite Road, Ahmedabad-380 015. / Dr. Girish Joshi	Repeated dose chronic toxicity & toxicokinetic (12 months) study of ZYH1 in beagle dogs.	Approved
4.	Sree Chitra Tirunal Institute for Medical Science and Technology, Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Biofunctional evaluation of low dose Paclitaxel eluting endovascular stents-Preclinical evaluation in Porcine model.	Approved
5.	Sree Chitra Tirunal Institute for Medical Science and Technology, Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Biofunctional evaluation of V-Concepts drug eluting endovascular stents- Preclinical evaluation in Porcine model.	Approved
6.	Sree Chitra Tirunal Institute for Medical Science and Technology, Poojapura, Thiruvananthapuram-695 012, Kerala /Dr. Manoj Komath	“Endodontic Usage Test of Calcium Phosphate Bone Cement” (Internal Project).	Approved
7.	Sree Chitra Tirunal Institute for Medical Science and Technology, Poojapura, Thiruvananthapuram-695 012 Kerala / Dr. Annie John	Ultrastructural study of the interface between bone and bioactive ceramics-a pre-clinical evaluation.	Approved

8.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. Annie John	Bone regeneration in large segmental defects using tissue engineered new generation bioceramic scaffold.	Approved
9.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Biofunctional evaluation of Sirolimus eluting coronary stent-Preclinical evaluation in Porcine model.	Approved
10.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. V. Kalliyana Krishnan	Pulp and Dentine Test for Single solution Bonding Agent.	Approved

11.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. V. Kalliyana Krishnan	Pulp and Dentine Test for Indigenously Developed dual Cure Flowable Resin Cement.	Approved
12.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Development of porcine models of Cerebral and Myocardial Ischemic diseases.	Approved
13.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. Annie John	Bone regeneration in large segmental defects using tissue engineered new generation bioceramic scaffold.	Approved

14.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. D.S. Nagesh	Ex-vivo evaluation of Haemoconcentrator in porcine model.	Approved
15.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. Muraleedharan CV	Development of improved tilting disc heart valve prosthesis.	Approved
16.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. D.S. Nagesh	Ex-vivo evaluation of Haemoconcentrator in sheep model.	Approved

17.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Biofunctional evaluation of SS316L and L605CoCr coronary stents in porcine coronary artery over-stretch injury model.	Approved
18.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. V. Kalliyana Krishnan	Pulp and Dentine Test for Indigenously Developed Dual Cure Flowable Resin Cement.	Approved
19.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Biofunctional evaluation of electrophysiology catheter in porcine heart model.	Approved

20.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Preclinical evaluation of heart valve substitute in pig model.	Approved
21.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Preclinical evaluation of heart valve substitute in sheep model.	Approved
22.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. P.R. Umashankar	Feasibility trial on NTU ureteric stent.	Approved

23.	Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Biomedical Technology Wing (BMT), Poojapura, Thiruvananthapuram-695 012, Kerala / Dr. CC Kartha	Adult human cardiac stem cells and endothelial progenitor cells; detection of optimum conditions for their therapeutic use.	Approved
24.	National Brain Research Centre NH-8, Jaipur Highway, Nainwal Model, Manesar, Gurgaon (District), Haryana. / Dr. Aditya Murthy	The role of basal ganglia and frontal cortex in control.	Approved
25.	National Institute of Immunology, Aruna Asaf Ali Marg, New Delhi-110 067./ Dr. Subeer S. Majumdar	An attempt to restore fertility following testicular germ cell depletion due to chemotherapy.	Approved
26.	Indian Veterinary Research Institute Izatnagar (Bareilly) / Dr. V.P. Singh	Vaccination trails against Caprine Pleuropneumonia by using Mycoplasma mycoides subsp capri (M. capri)	Approved, subject to the condition that the form B duly signed by IAEC members should be forwarded to CPCSEA.
27.	Indian Veterinary Research Institute Izatnagar (Bareilly) / Dr. D.B. Mondal	Development of Herbo-Mineral Drug Formulation as a component of Integrated Tick Control Measures in Bovines.	Approved, subject to the condition that the form B duly signed by IAEC members should be forwarded to CPCSEA.

28.	Indian Veterinary Research Institute Izatnagar (Bareilly) / Dr. M. Haque Received on 4.1.2007	Studies on alternate cost effective contrast agents for imaging gastrointestinal and urinary tract in small animals.	Approved, subject to the condition that the form B duly signed by IAEC members should be forwarded to CPCSEA.
29.	National Dairy Development Board, Anand-388001, Gujarat / Dr. A.K. Srivastava	Estimation of Metabolisable Energy (ME) values of various feeds and fodder using in vitro gas production technique.	Approved
30.	Advinus Therapeutics Pvt. Ltd., Plot Nos. 21 & 22, Phase-II, Peenya Industrial Area, Bangalore-560 058 Karnataka. / Dr. Rashmi Barbhaiya	Evaluating the diuretic potential of test item in Beagle dogs Project code : ATL/SP-D/Diuretic:1-4/2006	Approved
31.	Advinus Therapeutics Pvt. Ltd., Plot Nos. 21 & 22, Phase-II, Peenya Industrial Area, Bangalore-560 058 Karnataka. / Dr. Rashmi Barbhaiya	Optimization of condition for evaluating cardiovascular parameters in dogs Project code : ATL/SP-D/Surgery: 1-8/2006	Approved

In all cases approved by CPCSEA, the Committee stipulated that the animals were to be procured from legal sources.

17.5: Approval of Animal House facility by CPCSEA

The Animal House Facility of the following 10 institutions were considered by CPCSEA.

(a) Christian Medical College, Bagayam, Vellore - 632, Tamil Nadu.

The Animal House Facility of the institute was approved for the purpose of breeding and experimentation of the following animals namely Rat, Mice, Guinea Pig and Rabbit.

(b) Medical Education Department, Stanley Medical College, Chennai, Tamil Nadu

The inspection report was considered and it was decided that the institute be requested for reporting the compliance in respect of the following suggestions within a month.

- (i) Rabbits were found to be sick with hair loss and found lethargic and they are fed only with Bengal gram, Carrots and Cabbage. It is advisable to include Luccine grass to maintain them in healthy condition. As the animals were very sickly looking, further usage is not advisable and it was necessary to procure healthy rabbits. The sick animals need rehabilitation.
- (ii) Bedding in the mice and rat cages was found to be not clean.
- (iii) Record maintenance needs more clarity and details.
- (iv) The unskilled helper in the animal facility needs training.
- (v) The visiting veterinarian Dr. Uma Maheswari's guidelines to be taken up immediately.

(c) Southern Regional Research Centre, Central Sheep and Wool Research Institute, Mannavanoor - PO, Kodaikanal - 624 103, Tamil Nadu.

The inspection report was considered and it was decided that Member Secretary, CPCSEA would write to Director of the institute requesting for reporting the compliance in respect of the following suggestions, within two months.

- (i) All the Animal House Facilities (Sheds) should be renovated as per the CPCSEA guidelines.
- (ii) All the rabbit cages should be changed as per the standard.
- (iii) Proper ventilation and temperature maintenance should be followed in all sheds.
- (iv) Records available but not upto the standard, the past records were not made available during the inspection.
- (v) Only four veterinarians are available, all others are contract labourers and they should be trained for the Animal House Facilities.
- (vi) The surroundings of the animal house was not maintained neat and clean, it should be hygienic.
- (vii) A revamping of the system is required.
- (viii) Feeding can be done in a separate shed during rainy days.

(d) Reliance Life Science PVT LTD, Dhirubhai Ambani Life Science Centre, Thane-Belapur Road, Rabale, Navi, Mumbai – 400 701, Maharashtra.

The Animal House Facility of the institute was approved for the purpose of breeding and experimentation of the following animals namely Rat, Mice, Guinea Pig and Rabbit.

(e) Jai Research Foundation, Vapi - 396 195, Gujarat.

The Animal House Facility of the institute was approved for the purpose of breeding and experimentation of the following animals namely Rat, Mice, Guinea Pig, Rabbit and Duck.

(f) National Institute of Virology, 20-A, Dr. Ambedkar Road, P.B. No.11, Pune - 411 001, Maharashtra.

The Animal House Facility of the institute was approved for the purpose of breeding and experimentation of the following animals namely Rat, Mice, Guinea Pig, Rabbit, Monkey, Sheep, Geese and Fowls.

(g) Institute of Veterinary Biology Products, Department of Animal Husbandary, Pune -411 007, Maharashtra.

The inspection report was considered and it was decided that the institute be requested for reporting the compliance in respect of the following suggestions within a month.

- (i) Records available, but not in the standard format, all the records to be maintained as per the guidelines.
- (ii) Proper label in the individual cages are not available. Proper labels should be provided for all cages.
- (iii) Mice and rat feed to be given in containers.
- (iv) Reasons indicated for not conducting IAEC meetings after 21.5.2003.

(h) Nicholas Piramal India Limited, Nicholas Piramal Research Centre, 1 Nirlon Compled, Off Western Express Highway, Near NSE Complex, Goregaon (East), Mumbai - 400 063, Maharashtra.

The Animal House Facility of the institute was approved for the purpose of breeding and experimentation of the following animals namely Rat, Mice, Guinea Pig and Rabbit.

(i) J.S.S. College, of Pharmacy, Sri Shivarathreshwara Nagar, Mysore - 570 015, Karnataka.

The Animal House Facility of the institute was approved for the purpose of experimentation of the following animals namely Rat, Mice, Guinea Pig and Rabbit.

(j) International Institute for Biotechnology & Toxicology, Padappai, Kancheepuram Dist, Tamil Nadu.

The Animal House Facility of the institute was approved for the purpose of breeding and experimentation of the following animals namely Rat, Mice, Guinea Pig, Rabbit, Dog and Goat.

17.6 PROPOSAL OF FOREST DEPARTMENT, GOVT. OF NCT OF DELHI FOR USE OF COMMENSAL MONKEYS BEING REHABILITATED AT THEIR MONKEY SHELTER AT RAJOKARI FOR RESEARCH PURPOSES.

The Committee examined the proposal and agreed that use of such monkeys in animal experimentation was feasible and would also assist the institutions who were seeking primates for use in their research. All such proposals would be submitted to CPCSEA after ensuring requisite clearance. It was agreed that details of the nodal officer in the Forest Department of Government of NCT of Delhi would be circulated and these details would also be brought to the notice of institutions whose proposals for use of primates had already been approved by CPCSEA.

17.7 SUB-COMMITTEE FOR SELECTION OF CPCSEA NOMINEES ON INSTITUTIONAL ANIMALS ETHICS COMMITTEES.

The Committee agreed that since there was no major backlog in appointment of nominees, it would be appropriate if guidelines for selection of CPCSEA nominees could be formulated so that proposals could be scrutinized by Expert Consultant CPCSEA and decisions taken in light of the guidelines. Dr. Vasantha Muthuswamy and Dr. A.J. Rao, were nominated for formulation of these guidelines and were requested to finalize by them by February, 2007.

In this regard, it was also desired that in all cases where an alternative CPCSEA nominee had not been provided to institutions, this should be done at the earliest by Expert Consultant (CPCSEA).

17.8 ANY OTHER ITEM WITH THE PERMISSION OF CHAIR

Nil