#### **Revision of IAEC**

If any establishment desires to replace of their any internal IAEC member, they are required to send the request for revision along with the biodata and consent letter of the proposed member(s) and the Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal of revision of IAEC has been recommended for approval by the IAEC, in a single PDF file.

### Procedure for applying online:

Step 1: The user is required to login through User Login Window at Home Page by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

Step 2: Click on the Revision of IAEC tab.

Step 3: Click on edit button in front of the IAEC member to whom the establishment wants to change/revise and then click on update to save the changes. (Ensure that all the details of each IAEC members are filled in complete manner).

Step 4: Furnish the reason for Revision of IAEC, date of the IAEC meeting, Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal of revision of IAEC has been recommended for approval by the IAEC, in a single PDF file (Maximum file size: 1MB) and the Remarks related to Minutes of IAEC meetings.

Step 5: Click on Submit; After submit, payment detail page will display; Click on Make Payment and pay the requisite fee through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

### **Change of Nominee Request**

If any establishment desires to replace of their IAEC nominee nominated by CPCSEA, they are required to send the request for Change Nominee and the Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal of Change Nominee has been recommended for approval by the IAEC, in a single PDF file.

## Procedure for applying online:

Step 1: The user is required to login through User Login Window at Home Page by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

### Step2: Click on the Change Nominee tab.

Step 3: Tick the checkbox in front of the IAEC Nominee for whom the establishment wants to submit the request to change; furnish the reason for Change of Nominee in the Text Area displaying in from the ticked nominee

Step 4: Furnish the date of the IAEC meeting, Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal to change the nominee has been discussed and recommended to CPCSEA by all the IAEC members.

Step 5: Click on Submit.



A-nav NARAYANA COLLEGE OF NURSING

Chinthareddypalem, NELLORE - 524 003. 34

### **Submission of Minutes of IAEC meeting**

For renewal of registration, it is required to upload the Minutes of IAEC meeting regularly throughonline panel.

### Procedure for applying online:

**Step 1:** The user is required to login through User Login Window at Home Page by selecting *'Establishment Login'* in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

**Step 2:** Click on the tab viz. **Upload Minutes;** furnish the details such as Date of Minutes of IAEC meeting, copy of the Minutes of IAEC meeting with the signed attendance sheet and Remarks related to Minutes of IAEC meetings; Click on **Submit** Button.

**Step 3:** The establishment can see the status / submit the reply in response to the clarification soughtby CPCSEA on click on View Minutes Tab in reference to the Minutes of IAEC meeting submitted by the establishment.

Note: The meeting must be conducted with the required quorum as per the CPCSEA guidelines and the minutes must be signed by all the approved members of IAEC who have attended the meeting.

#### Submission of Research Protocol (s) on Large Animals

Any establishment conducting experiments on large animals is required to send the protocols to O/o CPCSEA for their approval.

Note: The establishments are required to get their Animal House Facilities approved and registered/renewed for housing large animals before commencing any research on them.

### List of requisite documents for protocol:

1. Checklist of the Protocol (Completely filled and duly signed by the Principal Investigator).

2. Completely filled form 'B' (Section I & II) duly signed by the Principal Investigator alongwith Investigator's declaration and Certificate (signed by Main Nominee of CPCSEA and Chairman of IAEC).

3. Minutes of the IAEC meeting with the signed attendance sheet, wherein the protocol has been recommended by the IAEC and forwarded to CPCSEA for approval. The IAECmeeting should be conducted with all the approved IAEC members, wherein the presence of CPCSEA nominee and Socially Aware Nominee is mandatory. In case the Main Nominee conveys his/ her unavailability, Link Nominee may be invited in place of Main Nominee.

4. Rodent Study Data (wherever required).

5. The establishments are required to deposit the fee for Research Protocol through 'online payment gateway' as per revised fee (Rs. 1000/-for educational Protocols and Rs. 5000/-for non-educational Protocols) in the prescribed column at the time of the submission of Research Protocol (s) online.

#### Note:

> No Hard Copies of any of the above documents are to be submitted until asked for.

> All the formats (Checklist, Form B, format of Investigator's declaration and Certificate, Format of Rat Study Data) are available on the website: http://cpcsea.nic.in/Content/53\_1\_FORMS.aspx.



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### **Fees Payable to CPCSEA:**

S. No.	Purpose	Code	Fee to be charged in INR	
			Small animals	Large animals
1.	Registration for the purpose of Research for education	Re	10,000	10,000
2.	Registration for the purpose of Research for commercial		10,000	10,000
3.	Registration for the purpose of Research	R	10,000	10,000
4.	Registration for the purpose of Non- Research Commercial (i.e. Production of Hyper immune Plasma and Serum)	NRc	-	10,000
5.	Registration for Breeding for in-house use	Bi	15,000	25,000
6.	Registration for Breeding for the purpose of Trade	Bt	25,000	25,000
7.	Renewal for the purpose of Research for education	Re	2,500*	2,500*
8.	Renewal for the purpose of Research for commercial	Rc	2,500*	2,500*
9.	Renewal for the purpose of Research	R	2,500*	2,500*
10.	Renewal for the purpose of Non- Research Commercial (i.e. Production of Hyper immune Plasma and Serum)	NRc	-	2,500*
11.	Renewal for Breeding for in-house use	Bi	2,500*	2,500*
12.	Renewal for Breeding for the purpose of Trade	Bt	2,500*	2,500*
13.	Revision of IAEC	-	1,000	
14.	Protocol on Large Animals (educational) where the Joint Director (Research) or Dean (Research) or competent authority equivalent to Joint Director (Research) or Dean (Research) would certify that the particular protocol under this category is a thesis project (per protocol)	-	1,000	
15.	Protocol on Large Animals (educational other than thesis project) (per protocol)	-	5,000	
16.	Protocol on Large Animals (non- educational) (per protocol)	-	5,000	

The establishments which are not doing efforts to renew their Animal House Facilities before the date of expiry of the registration, they shall be charged registration fee for the respective purpose as per fee structure (enclosed) in place of renewal fee.

### Note:

- The establishments which are applying for registration with CPCSEA, for different purposes are required to submit the fee(s) as per their purpose(s). If the purpose is more than one, the fee is to be added accordingly.
- The establishments already registered with CPCSEA and applying for renewal of registration are required to submit the renewal fee(s) as per their purpose(s) (as mentioned in the table above). If the purpose is more than one, the fee is to be added accordingly.

### All communications must be addressed to:

Member Secretary (CPCSEA), Office of the CPCSEA, Animal Welfare Division, 5th Floor, Vayu Block, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi – 110003. Phone: 011-24695232, 24695424, E-mail: cpcsea-mef@gov.in, Website: http://cpcsea.nic.in

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## **Renewal of Registration & Reconstitution of IAEC**

As per the guidelines of CPCSEA, every establishment registered with CPCSEA is required to be renewed. The IAEC of the establishment(s) is valid up to the validity of renewal of registration. Therefore, IAEC must be reconstituted at the time of renewal of registration. The term for renewal of registration and reconstitution of the IAEC of the establishment is 5 Years as per extant guidelines.

### List of requisite documents:

1. The biodata and consent letters of Five (5) IAEC members (all from science background including one Veterinarian having at least BVSc degree). At least half of the internal members are required to be replaced at the time of Reconstitution of IAEC.

2. The minutes of IAEC meetings of the previous five years, bearing the signature (with date) of all the IAEC members. The minimum of 6 members are required to compose a quorum.

3. The Annual Inspection Report of the Animal House Facility and Annual statement of large animals use of the previous five years duly signed (with date) by the Main Nominee / Link Nominee (if Main Nominee is not available).

4. The establishments are required to deposit the renewal fee through 'online payment gateway' as per revised fee in the prescribed column at the time of the submission of online application for renewal of registration (http://cpcsea.nic.in/WriteReadData/LnPdf/Fee Structure order.pdf)

### Procedure for applying online:

**Step 1:** The user is required to login through User Login Window at Home Page of Website of CPCSEA (http://cpcsea.nic.in) by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

**Step 2:** The establishment is required to upload the biodata and consent letters of each existing IAEC members (in a single PDF file; Maximum file size: 1 MB) on click on the tab IAEC members.

**Step 3:** The establishment is required to click on tab viz. Renewal Reconstitution request; and fill the details of proposed Five (5) IAEC members for reconstitution of IAEC, Upload their biodata and consent letters along with the details in a single PDF file (Maximum file size: 1MB).

**Step 4:** After furnishing the above details, the establishment is required to click on Final Submit button; payment detail page will display; click on Make Payment; pay the renewal fee through 'online payment mode i.e. Debit Card, Credit Card and Internet Banking.

### Note:

- 1. The establishment shall apply in advance (40 days) for renewal of registration & reconstitution of IAEC before the expiry date.
- 2. The fees which have already been paid through DD for renewal of registration for the same period will display to the establishment and will be adjusted at the time of online payment.
- 3. Adherence to the Guidelines of CPCSEA issued from time to time. Establishments not adhering to the Guidelines of CPCSEA are liable for action as per Rules.
- 4. Submission of annual inspection reports and annual statement of Large Animal Use by the Main Nominee regularly.
- 5. The animal house facility of the establishment will also be inspected by external nominees / Members of CPCSEA at any time / within the span of renewal.



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# Biodata and consent format for IAEC members

Name:			Sex:	
Date of Birth (dd/mm/yy):				
Professional Mailing Addres	s(Include insti	tutional name	e)	
Telephone (Office) :	Mobile Number :			
Telephone (Residence):	E-Mail:			
Academic Qualifications (Mo	st current qual	ification first	):	
Degree / Certificate	Subject	Year	Institution, Country	
Professional Experience:				
Month and Year	Title		Institution / Company, Country	
Experience in animal handlir	ng/ research:			
Month and Year	Month and Year Area of Specialization		Institution / Company, Country	
Consent: I hereby give my consent to i I undertake to follow all the r				
Signature: Date:				



Law:

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**Note:** "The research protocols dealing with withdrawal of or **below 0.6ml/kg body wt.** of blood from large animals on weekly basis for the purposes of the experimentation on feeding trials, breeding experiments and live-stock management studies which require blood collection from the experimental animals to further study the clinical parameters and forthe purpose of clinical disease diagnosis, field studies or thesis studies, may be approved by the IAEC. This will be applicable for ICMR, ICAR, Veterinary and Agriculture Universities and Government funded institutions handling large animals."

### **Procedure for Submission of online Protocol:**

**Step1:** The user is required to login through User Login Window at Home Page by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

**Step 2:** Click on the Tab Viz. **New Research Protocol**; a form will display wherein requisite details to be filled for submission of Research Protocol such as title of the protocol, details of species etc.

**Step 3:** Upload the requisite files in the above form such as Checklist, Form B, Investigator Declaration, Certificate, Minutes of IAEC meeting, Rodent Study data (if applicable) and Guidelines/ References related to your research protocol. (*The maximum size of each file is displaying in front of the column*)

**Step 4:** Tick in front of the IAEC members who have attended the IAEC meeting and recommended the research protocol to CPCSEA for approval (*Ensure the required quorum of the IAEC meeting as per the CPCSEA guidelines and the presence of CPCSEA nominee and Socially Aware Nominee*).

**Step 5:** Click on **Submit Button**, after submit, payment detail page will display; Click on **Make Payment** and pay the requisite fee through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

### **Amendment of Registration**

Any establishment registered with CPCSEA can amend the Name, Address of the Animal House Facility, Purpose of registration and expand their Animal House Facility (Small / Large) through Amendment process.

# Procedure for applying online:

**Step 1:** The user is required to login through User Login Window at Home Page by selecting *'Establishment Login'* in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

**Step 2:** Click on the tab viz. **Amendment of registration**; Select the type of Amendment from thefollowing:

- i. Amendment in the Name of the establishment.
- ii. Amendment in the Address of the establishment (Location of the Animal House Facility).
- iii. Amendment in the Purpose of registration with CPCSEA.
- iv. Amendment in the Type of Animal House Facility (Small / Large).

**Step 3:** After selection of Type of Amendment, the establishment is required to fill up the requisite details and upload the requisite documents.

**Step 4:** After furnishing the above details, click on **Submit** Button. In case of Amendment in the Purpose of registration with CPCSEA and Amendment in the Type of Animal House Facility



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(Small / Large), requisite fee will be applicable and will be pay through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

### Submission of Inspection Report(s) by the Nominee of CPCSEA

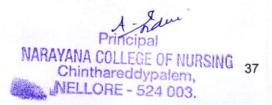
- i. Inspection Reports / Annual Inspection Reports will be filled online by the concerned Nominee of the establishment. CPCSEA have provided the User ID and password to Nominees of CPCSEA for online processing. Therefore, Nominees are requested to visit their online panel to fill up the Inspection Reports / Annual Inspection Report of the Animal House Facility (s) of all
- ii. the establishments allotted as and when required. Annual statement of large animal's use will also be uploaded by the Nominees.
- iii. Annual Inspection Reports and Annual statement of large animals use of the previous five years are must for considering the renewal of registration of the establishments.
- iv. In case of Small and Large animal House Facility, the concerned Nominee of the establishment required to upload the Inspection Reports / Annual Inspection Reports of Both the facilities (Small and Large).
- v. The Main Nominee of the concerned establishment is required to ensure conduct of the IAEC meetings as stipulated in the guidelines of CPCSEA and to upload the Annual Inspection Report of the Animal House Facility in the prescribed format regularly to the O/o CPCSEA.
- vi. While filling up the online Inspection reports, nominees need to specify each column as per the CPCSEA Guidelines for Laboratory Animal Facility 2015. Nominees must avoid to write "as per guidelines or satisfactory or as per norms" in the columns of inspection report.
- vii. Nominees need to clearly indicate in the concerned column whether the Animal House Facility of the concerned establishment is recommended for consideration of Registration / Renewal.
- viii. Nominees will not upload the minutes of IAEC meetings as the same will be uploaded by the establishments.

### Procedure for Submission of online:

**Step 1:** The user is required to login through User Login Window at Home Page by selecting 'Nominee Login' in User type and put the User Name & Password which is given to each Nominee(s) of CPCSEA.

**Step 2:** Nominee can see the details of Inspection ordered to him/her in three separate tabs viz. Inspection ordered for New Registration, Inspection ordered as an external nominee and CPCSEA Nominee in the IAEC of the establishments.





**Step 3:** The nominee can submit the Inspection Report(s) of the establishment(s) allotted to him/her from the above mentioned two tabs and submit the Annual Inspection Report(s) of any establishment(s) allotted to him/her through the third tab viz. CPCSEA Nominee in the IAEC of the establishment. The Annual Statement of Large Animal Use will also be submitted from this tab.

**Step 4:** The nomine can see the details/ status/ remarks of CPCSEA in reference to the any of the Annual Inspection report(s) submitted by him/her in the tab Annual Inspection Report and can also the details/ status/ remarks of CPCSEA in reference to the any Annual Statement of Large Animal Use submitted by him/her in the tab Annual Statement of Large Animal Use.

**Step 5:** The Nominee can view the remarks / send the reply in reference to the any online request(s) of any establishment(s) allotted to him/her from the tab Remark Window.

**Step 6:** For submission of Inspection Reports/ Annual Inspection Reports, the nominee(s) need to specify the details in each column as per the CPCSEA Guidelines and upload him/her signature and photographs of Animal House Facility at the time of Inspection in a single PDF file (*Maximum File Size: 1 MB*).

**Step 7:** The Nominee can also save the details before submission the Inspection Reports / Annual Inspection Reports to CPCSEA on click on Save Button.

**Step 8:** For final submission of Inspection Report(s) / Annual Inspection Report(s) to CPCSEA, click on **Submit** Button.



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# **Review of Projects in the IAEC Meeting**

- 1. Date of IAEC meeting:
- 2. Name of the projects:
- 3. Name of the PI:
- 4. Duration of the project:
- 5. No. of animals approved in the IAEC:
- 6. No. of animals used till date:
- 7. Project status: completed/ongoing
- 8. Brief progress report:
- 9. Remarks:

Signature of the PI & Date



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