



INSTITUTIONAL ANIMAL ETHICAL COMMITTEE MEETING

Purpose

This SOP describes the protocol to conduct Institutional Animal Ethics Committee (IAEC) meetings.

Scope

This SOP provides guidelines to the Chairperson and Member Secretary of IAEC, CMC, Vellore, to conduct IAEC meetings as per the guidelines given in the Compendium of the CPCSEA – 2018 and subsequent guidelines issued by the CPCSEA.

Pre-meeting procedures

- The IAEC meeting in CMC, Vellore, will be held 3 times in a year (February, June and October). As a general rule, requests for expedited IAEC meetings will not be entertained. Under exceptional circumstances, an expedited IAEC meeting may be conducted if:
 - the matter is urgent AND important
 - ALL IAEC members agree to it
 - all the rules, as applicable to regular IAEC meetings are followed
 - the PI requesting the expedited meeting agrees to bear ALL the meeting-related expenditure.
- After consultation with all members of IAEC, the date of meeting will be finalized and then broadcasted on the official CMC broadcast e-mail from the Principal's Office.
- All Principal Investigators (PIs) who would like to submit proposals for discussion at the IAEC meeting may download the appropriate forms from the CMC Research Website (<http://www.cmch-vellore.edu/SITES/research/Index.html#>)
- In general, only those projects that have obtained final approval from the Institutional Review Board (IRB) will be taken up for discussion for IAEC approval. In cases where the project has been submitted for IRB approval, but approval letter is awaited, then the PI will be allowed to submit the proposal for the IAEC meeting. However, IAEC approval letter will be issued only after receiving the final IRB approval.
- PIs will initially submit soft-copies of the required forms to animaethics@cmcvellore.ac.in by the designated date.

- These will be screened by the co-ordinator using a checklist to ensure that all the necessary information has been provided and documents submitted.
- A screening report will be sent to the Principal Investigator (PI) within one week of receipt of the proposal for screening.
- The PI will be given at least 4 days to make all necessary corrections as per screening report and submit 4 hardcopies (including original) of the corrected documents to the Research Office, Carman Block, CMC, Bagayam. All relevant documents as per checklist should be enclosed with the application. Documents to be submitted are given below:

New proposals:

- a. Covering letter from the PI
- b. Form B
- c. IRB approval letter
- d. Sanction letter from external funding agency (if applicable/available)

Progress reports (continuation of project / request for sanction of the next year's allotment of animals)

- a. Covering letter from the PI
- b. Progress Report
- c. IAEC approval letter
- d. Up-to-date Form D

Amendment of approved protocol

- a. Covering letter from PI with justification for the proposed amendment.
- b. Revised Form B (with modified parts highlighted)
- c. IAEC approval letter
- d. IRB approval of the proposed amendment

Extension of duration of sanctioned project (no additional animals required)

Requirements are the same as for submission of progress reports (item 2 above).

Final reports

- a. Covering letter from the PI
 - b. Final report
 - c. Original IAEC approval letter
 - d. Up-to-date Form D
- All submitted proposals along with the agenda for meeting will be sent to all the members of the IAEC (by post or by email as per preference of the IAEC member) at least 15 days prior to the meeting.

- Official invitation letters to attend the IAEC meeting on the specified date will be sent to the external members of IAEC as per their institutional norms.
- A timetable will be prepared and sent to the PIs informing them the tentative time at which they will have to be present to make a brief presentation of their project proposal. Instructions for preparation for the presentation will be included in this email (details given below).
- The external members of the IAEC are entitled to a sitting fee of Rs. 5000 per IAEC meeting. In addition, travel expenses will be reimbursed as per institutional rules and current guidelines of the CPCSEA. Arrangements for accommodation will be considered on request.

Conduct of the meeting

- The IAEC meeting will be conducted as prescribed in the Compendium of the CPCSEA 2018.
- In case of research protocols on small animals, the IAEC will grant approval for experiment on animals after considering all aspects of the project including the welfare of the animals.
- For carrying out the experiment on large animals, approval of CPCSEA is a must and IAEC will only recommend the research protocol for consideration of CPCSEA. Such applications will be submitted to the CPCSEA online by the Member Secretary after obtaining approval of the IAEC.
- The current members of the IAEC as given below (June 2017 – May 2022)
 - Dr. Anna B. Pulimood, Principal of CMC and Chairperson, IAEC
 - Dr. A. Yasotha, CPCSEA Main Nominee (external member)
 - Dr. D. Sivaraman, Scientist from outside the institute (external member)
 - Dr. B.R. Senthilkumar, Socially aware member (external member)
 - Dr. M.R. Srinivasan, Link Nominee (external member)
 - Dr. Christhunesa Christudass, Scientist from different discipline
 - Dr. Biju George (replaced by Dr. Suceena Alexander in June 2020), Vice-Principal (Research), CMC, Scientist from different discipline
 - Dr. Imayarasi K, Veterinarian
 - Dr. Joe Varghese, Member Secretary, IAEC
- Quorum requirements: The minimum of six members is required to form quorum of the IAEC meetings.
- Presence of all the 3 nominees of CPCSEA (main nominee, socially aware member and scientist from outside institution) is a must at every meeting. The Link nominee should be present in at least one meeting in a year.
- All decisions will be undertaken in the meetings of IAEC and not by the method of circulation of project proposals, e-mail etc.

- Conduct of business: The Chairperson of the IAEC shall be responsible for conducting the meeting with the help of the Member Secretary of IAEC. If for reasons beyond control, the Chairperson is not available, or has a conflict of interest, an ad-hoc Chairperson will be elected from amongst the present members, who will conduct the business of the meeting.
- The Member Secretary of IAEC is responsible for organizing the meetings, maintaining the records and communicating with all concerned.
- The IAEC will discuss all proposals submitted including new proposals, progress reports, requests for extension of time and final reports. The presence of the PI or co-PI at the meeting is required for all proposals except for final reports.
- PIs or Co-PIs must present their project proposals (new projects and progress reports) with the help of a MS PowerPoint presentation of not more than 7 – 10 slides explaining the:
 - a. background, aim and objectives of the study (1 – 2 slides),
 - b. number of animals requested / used (clearly presented in tables or as appropriate) and justification for the same (1 – 2 slides)
 - c. procedures to be carried out (for new proposals) OR major results obtained in brief (for progress reports) - 1 – 2 slides
- Participation by Investigators / experts in IAEC: IAEC may call upon subject experts who may provide special inputs of selected research protocols, if need be. They are required to give their specialized views but not to take part in the decision-making process which will be made by the members of the IAEC only.
- Members will discuss all the related issues concerning the welfare of animals before arriving at a consensus decision. Negative viewpoints will be recorded in the minutes. In case consensus is not arrived at and the case merits special attention of CPCSEA, such cases will be forwarded to CPCSEA.
- In case a conflict of interest arises, such a member should withdraw from the meeting during the decision-making process. This should be informed to the chairperson prior to the review of the application and the same should be recorded in the minutes.
- Suggestions for modifications in the research protocol, or reasons for rejection, should be clearly stated at the IAEC meeting. These will be recorded in the minutes.
- In cases of conditional decisions on research protocol, suggestions for subsequent review and the procedure for having the application reviewed (including the timelines for re-submission) will be clearly informed to the PI at the meeting. Modified proposals will be reviewed by an expedited review through identified members. This may be done over e-mail.
- For all new projects, the IAEC, after discussion, may approve the project after considering all aspects of the project. However, allotment of animals will be approved only for the first year of the project. Therefore, the approval given by the IAEC will have a maximum validity of 1 year from the date of the IAEC meeting. A progress report must be submitted for approval of animals for every subsequent year.

- In cases where PI requires IAEC approval for submission of grant applications to funding agencies, the IAEC will tentatively approve such proposals after due consideration. However, animals will not be allotted for such proposals. If the grant proposal is funded, the PI will have to re-submit the project proposal to the IAEC prior to initiation of the study for allotment of animals for the project. These will then be considered as new proposals.
- All decisions of the IAEC will be considered final.
- The Member Secretary will prepare the minutes of the meetings. The minutes will be approved and signed by all the members of the IAEC.

Post-meeting procedures

- A scanned copy of minutes will be uploaded by the Member Secretary in the CPCSEA website within 15 days of the meeting.
- The Member Secretary will inform the PIs the final decision made regarding their project proposal within 2 working days of the IAEC meeting. In case of proposals requiring modification and re-submission, clear details of the modifications required will be communicated by e-mail. The timelines for re-submission will also be clearly stated.
- The IAEC approval certificate (in the prescribed format) will be prepared by the Member Secretary and signed by the Chairperson, Member Secretary and the Main Nominee of the CPCSEA. The certificate will be issued to the PI within 14 days after the IAEC meeting. In case of delays related to re-submission of proposals requiring modification, issue of certificate may also be delayed proportionately. The certificate will have a validity of 1 year from the date of IAEC meeting.
- The PIs will be informed about their duties and responsibilities which include the following:
 - a. Progress Report / Project completion report should be submitted for consideration of IAEC at prescribed intervals for review and it should not exceed the timeline of the research as mentioned in the Form B / IAEC approval certificate
 - b. Final report should be submitted to the IAEC of the establishment at the end of study.
 - c. All Serious Adverse Events (SAEs) and the interventions undertaken should be intimated to IAEC.
 - d. Protocol deviation, if any, should be informed with adequate justifications to IAEC and in case of large animals, it should be intimated to CPCSEA immediately for consideration of CPCSEA.
 - e. The procedural deviations in research protocol shall be treated as a fresh research protocol by CPCSEA.
 - f. Any new information related to the study should be communicated to IAEC immediately.

- g. Premature termination of study should be notified to the IAEC with reasons along with summary of the data obtained so far.
- h. Change of investigators / sites should be informed and approval of IAEC should be undertaken first.
- The original copy of the Form B and minutes of the IAEC meeting will be filed by the Member Secretary.

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Version 2 (Sep 2021) prepared by Dr. Joe Varghese and checked by Dr. Christunesa Christudoss

New updates:

- Rules for submission of amendment requests for approved and ongoing projects
- Rules for expedited IAEC meeting