**Circular**

**21st March 2023**

Dear Investigators,

To enhance the research milieu and to facilitate review and approval of Dissertation / Theses protocols by the Institutional Ethics Committee's (IECs), in 2013 the IEC had suggested that each department should set up a Departmental Review Board (DRB) per the given DRB guidance document. This is to bring to your notice that there are some recurrent lacunae in submission of protocols for approval. In this regard, IEC would like to inform the following:

1. **Regarding DRB approval:**

   a) **Conflict Of Interest (COI) of DRB members**

      a. If you are a study team member/investigator, it is important to declare the COI at the time of decision making and establish appropriate mechanism to manage it.
      b. In the DRB approval letter, it should be clearly mentioned that "It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the DRB".
      c. When the study team member is also the chairperson, then please do not sign the DRB approval letter as chairperson.
      d. An alternative DRB member can sign for the chairperson for this project.

   b) **Revised DRB guidance document and sample format of DRB approval letter are attached.**

2. **Regarding protocol, these headings are very important:**

      a. Type of protocol (screening, survey, clinical trial, and phase)
      b. Rationale of doing the study
      c. Aims
      d. Objectives
      e. Study Methodology
      f. Inclusion/Exclusion Criteria/, Withdrawal, or discontinuation Criteria
      g. Sample size calculation
      h. Duration of the study
      i. Activity plan / Timeline
      j. Details of interventions, (please mention standard of care)
      k. Funding if applicable
      l. Schedule and Duration of Treatment, Modes of Treatment Studied, Procedures/ methodology,
      m. Efficacy or Evaluation Criteria (Response/Outcome),
      n. Safety Parameters Criteria (Toxicity),
      o. Statistical analysis (methods) with software details used if any (version no. /free/paid)
      p. Ethical considerations including CTRI registration.

      **In addition, please note:**

   ✓ It is preferable that an index be added to the submitted documents with pagination to help in locating documents.

   ✓ Don't put institute name in the protocol.

   ✓ Protocol summary - Brief introduction and methodology part should be added. It should describe the whole protocol in short.

   ✓ As per MUHS criteria, minimum 15 references are required and should be cited sequentially in the protocol (preferably latest).

   ✓ If caste and religion do not have any relevance to the study, please avoid using this part of demographic data.

3. Off-label use of drug if applicable – Please refer to ICMR 2017 guidelines (National ethical guidelines for Biomedical and Health research involving human participants, ICMR 2017-available online)

4. **Verbal and written assent age groups**

   Age 7 to 12 :- verbal / oral assent must be obtained in the presence of the parents /LAR and should be documented.

   Age 12 to 18 :- written assent.

   Document should be accompanied with parental consent.

5. **For collaborative studies, MOU should be tripartite.**

   1) Principal Investigator
   2) Head of the institution
   3) Director/Head of institute of collaborative site

   Memorandum of Understanding (MOU) between collaborative institutions (On Rs 100/- stamp paper, tripartite with terms of agreements specified clearly) sample format available on www.kem.edu

6. **Last date for submission of new projects is 20th of each month which will be taken up for next month full board meeting. Please follow the deadlines.**

7. **All investigators and study team members whose name are there in the protocol should submit their valid GCP training certificates, MMC for medical personnel, and short CV.**

8. **Students should follow the current guidelines given by MUHS for submission of dissertation likely to be completed by month / year as per MUHS stipulation.**

| | IEC-I | IEC-II | IEC-III |
|---|---|---|---|
| **Member Secretary** | Dr. Raakhi Tripathi<br>Associate Professor<br>Pharmacology & Therapeutics<br>**Intercom no. 7444, 7482, 7515**<br>**Mobile no. 9821724700**<br><br>**Signature** | Dr. Priyanka Prasad<br>Associate Professor<br>Microbiology<br>**Intercom no. 7552, 7515**<br>**Mobile no. 9930923115**<br><br>**Signature** | Dr. Swapna Kanade<br>Associate Professor<br>Microbiology<br>**Intercom no. 7827, 7515**<br>**Mobile no. 9004377725**<br><br>**Signature** |

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**Dr. Sangeeta Ravat,**
**Dean**
**Seth GSMC & KEMH.**

**Signature**
**Date:** 25/3/23

## Appendix 1.

## Sample Format of DRB Approval letter

Date _____

To,

Dr. _____, (name of the Guide)

Dr. _____ (Name of MD/MS/MSc/PhD student)

Dept. of _____.

Ref: The project entitled (Please put your department name / no of the protocol/year) "_____".

Sub: Departmental Review Board (DRB) approval

Dear Dr. _____,

The meeting of the Departmental Review Board (DRB) of _____ (name of the dept.) was held on _____ at _____ am / pm, in the _____ with Dr. _____ as Chairperson.

____ members attended the meeting held on _____. The list of members who attended the meeting is as follows.

| Name of Members | Position on DRB | Qualification |
|---|---|---|
| | | |
| | | |

**It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the DRB.**

It is understood that this study will be undertaken by _____ (name of the student) under your guidance during _____(period) and will follow the principle of Good Clinical Practices (GCP).

Dr._____ had been admitted to the _____course in the year_____. His/ Her title / synopsis will be registered in the Maharashtra University of Health Sciences (MUHS), Nashik in year_____. He/ She will submit the Dissertation on (approximate month and year) _____ to the MUHS, Nashik and appear for MD/MS Examination during (month and year) _____.

The DRB hereby approves the proposal entitled, "_____" at the meeting.

**Please submit the IEC approval letter to DRB within 6 months and if delayed please submit the reason to the chairperson of DRB for further course of action.**

Sincerely yours

_____

**Chairperson**
**DRB**
**(Signed and dated by the DRB Chairperson or Acting Chairperson or any one of the members who does not have a conflict of interest)**

## Appendix 2.

## Revised Departmental Review Board (DRB) Guidance Document dated 23rd February 2023

(for all MD/MS/Post graduate Theses /Dissertation)

**Purpose:**

To facilitate the review process for the investigators in term of time.

**Composition:**

- The DRB will be established by the **Head of the Department.**
- There will be one Chairperson, a Co-Chairperson who will be appointed from amongst the members (The Co-chairperson will perform the functions of Chairperson in his/her absence or at the time of Conflict of Interest).
- The DRB will be composed of at least 3 and a maximum of 7 members.

**Detailed instructions:**

The board should opine on the scientific aspects of the proposal. The Board should also consider the feasibility of the proposal and collaboration with any other department if required.

**Roles and responsibilities of the DRB members:**

- It is the responsibilities of the DRB members to read, understand, and follow the guidance document.
- The DRB will consist of members who collectively have the experience in research methodology and should have at least ≥ 5 years' experience or > 5 years PG teaching experience.
- **All Dissertations /** Theses (MD/MS/Post graduate thesis) will be reviewed and approved by the DRB before submission to Institutional Ethics Committee.
- The signature of the Chairperson/ Co-chairperson of the DRB will be mandatory on the DRB approval letter. Please note that the chairperson signing the DRB approval letter cannot be an investigator in that study.
- It is the responsibility of the DRB member to attend DRBC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- It is the responsibility of the DRB member to review, discuss and consider research proposals submitted for evaluation.
- It is the responsibility of the DRB member to carry out the work delegated by Chairperson.
- DRB should ask for submission of IEC approval letter within 6months of the DRB and if delayed should submit the reason to the chairperson of DRB.
- It is the responsibility of the DRB member to assist Chairperson in carrying out DRB work.