

Annexure 11
AX 11/SOP 05-A/V7

Departmental Review Board (DRB) Guidance Document & sample format of DRB approval letter
(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.

Note: *If there is a delay in submission (12 months after joining the MD/MS course) of thesis proposal to IEC, then a letter with reason for delayed submission needs to be submitted to IEC with signature of HOD, PI (guide) and student.*

Sample Format of DRB Approval letter

Date _____ (mandatory)

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.

Sincerely yours

Signature of 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)

Note: *If there is a delay in submission (12 months after joining the MD/MS course) of thesis proposal to IEC, then a letter with reason for delayed submission needs to be submitted to IEC with signature of HOD, PI (guide) and student.*