

Annexure 11

AX 11/SOP 05/V6



Departmental Review Board (DRB) Guidance Document

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

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 may be appointed amongst the members (The Co-chairperson will perform the functions of Chairperson in his/her absence).
- The DRB will be composed of at least 3 and a maximum of 7 members.

Details instructions:

The board should give opinion 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, 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 yrs PG teaching experience.
- It is the responsibility of Chairperson of the DRB to send the names of the DRB members to the IEC before 31st August 2013.
- **All thesis** (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. In case DRB approval letter is being issued to the chairperson who is also a principal investigator for the study then the signature of the co-chairperson / any of the DRB member can be obtained on DRB approval letter.
- It is the responsibility of the DRB member to attend DRB 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.
- It is the responsibility of the DRB member to assist Chairperson in carrying out DRB work.