



National Institutes of Health
Health Research Institute
National Bioethics Committee for Research (NBC-R)



**ADVISORY FOR DATA SAFETY AND MONITORING BOARDS FOR
CLINICAL TRIALS**

The National Bioethics Committee for Research (NBC-R) strongly urges that all the clinical trials submitted for approval must also be under the oversight of a Data Safety and Monitoring Board (DSMB) besides the approval of IRBs from each participating institutes.

The Data Safety Monitoring Board (DSMB) in principle is an independent group of experts that maintains an oversight on trials to ensure the safety and integrity of the human subjects as well as the data.

The members of the DSMB serve in their individual capacity and provide their expertise and recommendations. The primary responsibilities of the DSMBs are to:

1. Periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy,
2. Make recommendations concerning the continuation, modification, or termination of the trial.
3. Should review each protocol for any major concern prior to implementation.
4. Should review cumulative study data to evaluate safety, study conduct, and scientific validity and integrity of the trial.
5. In case of an adverse event, investigate and determine the nature of it and provide detailed guidance to the trial team along with mandatory reporting to the regulatory bodies.

No member of the DSMB should have direct involvement in the conduct of the study or be the employee of the funding agency and must not have financial, proprietary, professional, or other interests that may affect impartial, independent decision-making by the DSMB.

The DSMB should, through the Principal Investigator, provide feedback at regular and defined intervals to the IRBs and NBC. The investigator is required to transmit the report to his/her local IRB and NBC-R.

This issues with the approval of chairperson NBC-R for compliance by all clinical trials.

Yours sincerely

(Prof. Dr. Saima Perwaiz Iqbal)
Chairperson
NBC-Research Ethics Committee



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