



Desh Bhagat University

Mandi Gobindgarh

Standard Operating Procedures (SOP) For Institutional Ethics Committee for Life/ Medical Science Research

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About Institutional Human Ethics Committee (IHEC)

The need for Institutional Ethics Committee (IECs) in medical Science and life science research establishments resulted from the realization that affirms human rights or any life as a prerogative of all members of society. This has been emphasized under the Statement of General Principles in Biomedical research involving human participants (http://icmr.nic.in/human_ethics.htm#Guidelines) pertaining to precaution and risk minimization. It is mandatory that all proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC), also referred to as Institutional Review Board (IRB). Desh Bhagat University, Mandi Gobindgarh in accordance with the ICMR and UGC guidelines, has established such an Institutional Ethical Committee.

RESPONSIBILITY: The responsibilities of IHEC are:-

1. To protect the dignity, rights and well being of the potential research participants.
2. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
3. To assist in the development and the education of a research community responsive to local health care requirements.

The Chairman and Member Secretary are responsible for implementing these SOPs.

COMPOSITION OF IHEC: IECs should be multidisciplinary and multisectorial in composition.

The Chairperson of the Committee should preferably a senior faculty who is involved in research. The Member Secretary, who generally belongs to the same Institution, should conduct the business of the Committee. Other members should be a mix of medical / non-medical, scientific and non-scientific persons including at least one representative of common man to reflect the differed viewpoints.

The composition is as follows:-

1. Chairperson
2. 3-4 basic medical scientists,
3. Clinicians from various Institutes
4. One legal expert or retired judge
5. Representative of non-governmental voluntary agency



6. One lay person from the community
7. Member-Secretary

The tenure of the committee is for 02 years.

IEC MEETINGS The Chairperson will conduct all meetings of the IEC. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

SUBMISSION OF APPLICATION

- All investigators are also responsible for implementing this SOP.
- The Principal Investigator has to submit an application (2 copies & soft copy) in a prescribed format (form A & B or A & C) along with study protocol and other related documents necessary for review of the IHEC.
- All research proposals must be submitted in English language only.
- Application can be submitted to the office of the Member Secretary, on any working day.
- PhD research – only registered candidates are eligible to apply.
- Sponsored projects - Only approved projects are eligible for clearance by the committee. However, a no objection letter for the purpose of seeking funds from various funding sources will be issued by the Sub-committee.
- All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting.
- Copies of informed consent form to be enclosed.
- Incomplete applications will be rejected.

SCRUTINY OF PROPOSALS

- All members of IHEC are responsible for reviewing the proposals.
- The Member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved, categorize them into three types, namely, exemption from review, expedited review and full review.
- They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research.
- All the Members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
- The IHEC review will be done through formal meetings and will not resort to decision through circulation of proposal. The investigators shall make a presentation before the committee.
- Expert opinion of additional members would be obtained, if necessary.



- A decision of the IHEC will be communicated to the applicant in writing, within 15 days of the meeting at which the decision was taken in the specified format.
- A certificate of approval will be issued to the applicant.
- All the approvals will be valid for only 3 years or for the duration of the project, whichever is less. Investigator has to get his or her project re-approved after three years, if necessary.

DECISION MAKING

- Members will discuss the various issues before arriving at a consensus decision.
- A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the Minutes.
- Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- Modified proposals may be reviewed by an expedited review through identified members.

COMMUNICATING THE DECISION

Decision will be communicated by the Member Secretary in writing. Suggestions for modifications, if any, should be sent by IEC. Reasons for rejection should be informed to the Researchers. Member Secretary to send the details to research cell so as for further processing .



Research Advisory Committee

Desh Bhagat University, Mandi Gobindgarh introduced MPhil and Doctorate Programme in various faculties in Dec 2012. For the smooth functioning of the research cell and as per the rules and regulations, University established its various committees for research.

THE UNIVERSITY RESEARCH BOARD

There shall be a University Research Board comprising the following members:

(i)	The Vice-Chancellor	Chairperson
(ii)	The Pro Vice-Chancellor	Member
(iii)	Registrar	Member Secretary
(iv)	The Dean Academic Affairs	Member
(v)	The Dean Research & Development	Member
(vi)	The Dean of Faculty / Director of School	Member
(vii)	All Professors and Heads of University teaching departments in the Faculty; provided further that Professors/ Heads from only such Departments as are engaged in imparting Post-Graduate instruction and doing research work shall be eligible for appointment as members.	Member
(viii)	Two experts from outside the University to be nominated by the Vice-Chancellor for a period of two Years	Member
(ix)	The supervisor of a candidate whose synopsis is to be considered for Approval in the meeting of University Research Board (URB) should be Present in the concerned meeting of URB, if he is not a member of URB.	Member

FUNCTIONS OF UNIVERSITY RESEARCH BOARD

- (i) To establish the standards/ qualifications of teachers for M.Phil, Ph.D or Post Ph.D work and for acting as research supervisors for Research students.
- (ii) To prescribe requirements for entrance, course work, major and minor, language and thesis for research degrees.
- (iii) To establish the standards for the scholastic performance of research degree students.
- (iv) Keep adequate records of all research students so that both the Dean and the students know at all times their status towards fulfilling the requirements of the Post Graduate degree.



- (v) Consider the recommendation of Departmental Research Committee and approve the registration of candidates for M.Phil/P.hD degree.
- (vi) Review the progress of research work of the candidates and approve extension of time for completion of research work wherever required.
- (vii) Consider and accept the report of the Departmental Research Committee on the Six-Monthly progress of work of Research Scholars recommended by the faculty concerned.
- (viii) The University research Board shall meet as per the discretion of the Chairperson. The quorum for the meeting shall be three members.
- (ix) The Chancellor shall have the power to co-opt any other person(s) on the Board of Management, their tenure and conditions shall be as prescribed by the Chancellor.

THE DEPARTMENTAL RESEARCH BOARD

University Research Board has its own departmental Research Board in each department of the University. Any changes in the Departmental Research Board can be recommended by the University Research Board with the approval of the Governing Body/ Chancellor.

The following shall be members of Departmental Research Board:

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| (i) Head of the Department who holds the Ph.D degree or senior most teacher with Ph.D degree. | Chairperson |
| (ii) Deputy Registrar or any other official to the nominated by the Registrar | Member Secretary |
| (iii) All Professors in the subject, employed in the University | Member |
| (iv) Readers/Associate Professors and Lecturers/ Assistant Professors who hold Ph.D. Degree. | Member |
| (v) One/two teachers from allied/supporting departments to be nominated by the Vice-Chancellor | Member |
| (vi) One nominee of the Vice-Chancellor from within or Outside the University. | Member |

***(The nominee of the Vice-Chancellor and the teachers nominated by Dean Academic Affairs should hold Ph.D Degree)**



FUNCTIONS OF DEPARTMENTAL RESEARCH BOARD (DRB)

1. To consider the proposals of the research students in the faculty at the initial stage.
2. The DRB may desire the student to make a presentation on the research synopsis to which all faculty members of the Department/ School may be invited.
3. The DRB will review the progress of the research work of the students on the basis of progress reports and annual seminars/ Presentation and report the same to University Research Board.
4. All cases which are rejected by the Departmental Research Board (DRB) must be reported to the University Research Board giving reasons/ Justification for rejection.
5. Quorum: three members.

EXAMINERS PANEL COMMITTEE (EPC)

- (a) The Head of the Department (Chairperson) who holds a Ph.D degree/ senior most faculty member holding Ph.D degree.
- (b) All Professors in the Department
- (c) If there is no Professor other than Head of the Department or the Head of the Department is a Reader/Associate Professor, a Professor from an allied Subject/Department to be nominated by Vice-Chancellor
- (d) Supervisor of the Candidate/ Co-Supervisor if any.
- (e) Where the quorum is incomplete, Vice-Chancellor may nominate one or two Professors from allied subject/department.

Responsibility:

1. The committee is concerned with the formation of the panel of External Examiners of MPhil/PhD thesis/Dissertation.
2. Meeting regarding the panel is held and submitted to the vice chancellor for approval of one Examiner from outside the region and done from inside the region in case of PhD thesis and one examiner in case of MPhil Dissertations
3. The approved panel list is submitted to examination branch for further processing of the work.

SCREENING COMMITTEE

- (a) The Dean of the Faculty (Chairperson)
- (b) The Head of the Department who holds a Ph.D degree/ senior most faculty member holding Ph.D degree.
- (c) The Supervisor of the Candidate / Co-Supervisor if any.
- (d) One or Two Professors from within the Faculty to be nominated by the Vice - Chancellor
- (e) Where quorum is incomplete, the Vice-Chancellor may nominate one or two Professors from relevant/allied subjects



Responsibility:

1. The committee is concerned with the opening of reports of External Examiners
2. Screening committee approval is seek from Vice chancellor before opening of the reports of the Examiners

VIVA VOCE COMMITTEE :

1. Dean Research (Chairperson)
2. Director of concerned Faculty
3. Guide of the Scholar
4. External Examiner
5. Subject Expert from concerned Dept.
6. Allied Field Subject Expert

Responsibility:

1. The Concerned committee is concerned with conducting the final open Viva voce of the Scholar

RESEARCH AWARD COMMITTEE (RAC)

1. Vice-Chancellor (Chairperson)
2. Dean, Academic Affairs
3. Dean Research
4. Dean of the Faculty / Director of the School
5. All Heads of the Departments in the Faculty and one Professor from each department in the Faculty by rotation according to seniority for a term of two years.
6. Concerned supervisor / Co-Supervisor if any of the candidate

Responsibility:

The RAC is concerned with final notification release approval in case of MPhil/PhD research of scholars

