1. Objective:

The objective of the of Institutional Ethics Committee (IEC) of Bhagwan Mahaveer Cancer Hospital and Research Centre (BMCHC) is to contribute to its effective functioning so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as 'prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR.

2. Role of IEC

This IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. The goals of research, however important, will never be permitted to override the health and wellbeing of the research subjects.

It will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee wills also examine compliance with all regulatory requirements, applicable guidelines and laws.

Its mandate will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency. The role of IEC can be modified according to the requirement of the BMCHRC.

3. Composition of IEC

IEC of BMCHRC is multidisciplinary and multi-sectoral in composition. Independence and competence of its functioning as per the applicable rules and regulation are the two hall-marks qualities:

Chairman

Dr. ArunChougule

Member Secretary

Dr. Anjali Sharma
Member Clinician

Basic Medical Scientist

Dr. Shashi Bansal

Member Clinician

Dr. Naresh Kumar Soni
Consultant Surgeon

Dr. Divesh Goyal
Medical Oncologist

Member Legal Expert

Mr.Devendra Mohan Mathur
High Court Advocate

Member Social Scientist

Dr. Jyoti Joshi
Consultant Psychologist

Mr. Manish Yadav
Assistant Prof. Sociology

Member Lay Person

Mr. Krishan Pal Dheer
Charted Accountant

Mrs. UpmaPareek
Ex. President AWWA

COMPOSITION OF INSTITUTIONAL ETHICS COMMITTEE BMCHRC-JAIPUR

S. No.	1	2	3	4	5
Name	Dr. Arun Chougule	Dr. Anjali Sharma	Dr Naresh Kumar Soni	Dr Jyoti Joshi	Dr. Shashi Bansal
Address	Department of Radiotherapy SMS Medical College Jaipur	Bhagwan Mahaveer Cancer Hospital and Research Centre, J.L.N. Marg, Jaipur -302017	Senior Consultant Surgical Oncology, Fortis - Escorts Hospital, Jaipur	22- A, Jhalana Dungari,Jaipur-302004	Department of Pathology, BMCHRC, J.L.N. Marg,Jaipur-302017
Qualification	M.Sc. (Physics &) PhD (Radiology)/ FUICC	M.B.B.S, MD (Pathology	MBBS, MS,	M.A. Sociology, Doctor of Philosophy	M.D. Pathology, DNB Pathology, Registration No. 01247 DMC,24106 MCI
Organization Title	Dean, Faculty of Paramedical Sciences & Prof. Radiation Physics	Sr. Consultant Department of Pathology BMCHRC Jaipur	Senior Consultant Surgical Oncology	Coordinator, RajasthanRajyaPatthya,Pustak Mandal	Consultant Pathologist
Ethics Committee Position	Chairman	Member Secretary	Member Clinician	Member Social Scientist	Basic Medical Scientist
Telephone Number	0141-2700357	0141-2700107 (Ext 256,) 9314516162	91-9799495275,	9414112902	9868426153, 9350345289
E-mail/ Fax Number	arunchougule11@gmail.com	anjalisharma04061970@gmail.com, Fax no: 0141-2709716	nareshsoni@yahoo.com, bmchrcethicscommittee@gmail.com, Fax No. 0141-2709716	jyotijoshi566@gmail.com, Fax No. 0141-2709716	drshashi12@gmail.com, Fax No. 0141-2709716
Mailing Address	II/38 Gandhi Nagar Govt. Quarters Gandinagar Jaipur	160Vidyut Nagar Ajmer Road Jaipur-302017	81, Suraj Path, Behind Ridhi-Sidhi Sweets, GopalpuraByepass Road, Jaipur-302018	III/63 Gandhi Nagar Jaipur-302015, Land Line No. 0141-2702255	30/415 Varun Path Mansarover Jaipur 302020

Chairman

Dr. ArunChougule

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Dr. Anjali Sharma
Member Clinician

Basic Medical Scientist

Dr. Shashi Bansal

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Dr. Naresh Kumar Soni
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Dr. Divesh Goyal
Medical Oncologist

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High Court Advocate

Member Social Scientist

Dr. Jyoti Joshi
Consultant Psychologist

Mr. Manish Yadav
Assistant Prof. Sociology

Member Lay Person

Mr. Krishan Pal Dheer
Charted Accountant

Mrs. UpmaPareek
Ex. President AWWA

COMPOSITION OF INSTITUTIONAL ETHICS COMMITTEE BMCHRC-JAIPUR

S. No.	6	7	8	9	10
Name	Mrs. Upma Pareek	Mr. Krishan Pal Dheer	Mr. Devendra Mohan Mathur	Dr. Divesh Goyal	Mr. Manish Yadav
Address	AWWA, Military Hospital Jaipur	LBS Pharmacy College	Jaipur High Court Bhagwandas Road, Ashok Nagar Jaipur, Rajasthan 302015	Fortis Escorts Hospital, Malviya Nagar, Jaipur	Department of Sociology University of Rajasthan Jaipur-302017
Qualification	Commerce Graduate (Social Activist)	B.A. & P.G. Charted Accountant	LLB, LLM	M.D; DM Gujarat Cancer & Research Centre	M.A. Sociology
Organization Title	Ex- President AWWA Command Hospital Lucknow	Nominated State consumer's rights Activist	High Court Advocate	Senior Consultant Medical &Hemato-Oncologist,	Assistant Professor
Ethics Committee Position	Member Lay Person	Member Lay Person	Member Legal Expert	Member Clinician	Member Social Scientist
Telephone Number	91-9352568305, 91-141-4013826	9829133186	0141- 2705201 0141-2710968 +91-9414050984	9462748680, 9426748680	9983234848
E-mail/ Fax Number	pareekupma@gmail.com , Fax No. 0141-2709716	bmchrcethicscommittee@gmail.com, Fax No. 0141-2709716	bmchrcethicscommittee@gmail.com, Fax No. 0141-2709716	diveshgoyal123@gmail.com,diveshgoyal123@rediffmail.com	manishyadav88@hotmail.com
Mailing Address	164, Vidhyut Nagar "C" Jaipur - 302021(Raj)	J-130, Adarsh Nagar, Jaipur-302004	C-144, Behind UCO Bank, Mangal Marg, Bapu Nagar, Jaipur -302015	108, VivekVihar,oppositeDainikBhaskar office, J.L.N.Marg, Jaipur 302015	Assistant Professor Department of Sociology University of Rajasthan Jaipur

Chairman

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The Chairperson of the Committee is from outside the Institution to maintain the independence of the Committee. The Member Secretary belongs to the same Institution to conduct the business of the Committee. Other members are a mix of medical / non- medical scientific and non-scientific persons including lay public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson
2. Basic medical scientists.
3. Clinicians from various Institutes
4. Legal expert or retired judge
5. Social scientist / representative of non-governmental voluntary agency
6. Philosopher / ethicist / theologian
7. Person from the community
8. Member-Secretary
9. Secretarial staff

The ethical committee at any institution can have as its members, individuals from other institutions or communities if required. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The membership of IEC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s), Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s) etc They should be appointed by the Head of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.

IEC will be constituted in the following pattern:

1. A Chairperson
2. A Member Secretary,
3. Nine members from different Departments / Specialties / disciplines or community representative etc.

Members' role and Responsibilities:

Chairman

Dr. ArunChougule

Member Secretary

Dr. Anjali Sharma
Member Clinician

Basic Medical Scientist

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Member Lay Person

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Charted Accountant

Mrs. UpmaPareek
Ex. President AWWA

Chairperson: Non – affiliated well respected personaptly qualified and experienced in clinical research & Ethics:

- Conduct EC meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations
- Ratify minutes of the previous meetings
- In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

Member secretary Affiliated aptly qualified and experienced in clinical research & Ethics and can devote adequate time for committee activities under institutional protection:

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication and archiving
- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required
- Ensure adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.

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- Assess the need for expedited review/ exemption from review or full review.
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

Basic Medical scientist(s): Affiliated / Non- Affiliated aptly qualified (preferably pharmacologist) and experienced in clinical research & Ethics:

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

Clinician (s): Affiliated / Non- Affiliated aptly qualified (Recognized medical qualification, expertise and training) and experienced in clinical research & Ethics:

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Legal expert(s): Affiliated / Non- Affiliated aptly qualified (having basic recognized degree in law and or desirable training in medical law) and experienced in clinical research & Ethics:

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions,

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such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any.

Social scientist / Philosopher / Ethicist / Theologian: Affiliated / Non- Affiliated aptly qualified (Literate social behavioral science and expert in health related activities or a member of an NGO and knowledgeable of local, cultural community issue) and experienced in clinical research & Ethics:

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

Lay person (s): Non- Affiliated aptly qualified (Literate community representative, aware of local language, cultural and moral values and involve in social and community welfare activities) and experienced in clinical research & Ethics:

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

4. Authority under which IEC is constituted:

Major General S.C. Pareek, Retired, Executive Director, Head of The Institute constituted the Institutional Ethics Committee (IEC).

5. Membership requirements:

a. The duration of appointment is initially for a period of 3 years

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b. At the end of 3 years, as the case may be, the committee may be extended or reconstituted, and 50% of the members may be replaced by a defined procedure by the member of the IEC.
c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
d. A member can tender resignation from the committee with proper reasons to do so. Or committee may terminate or initiate a IEC membership disqualification procedure if member fail to attend more than 3 consecutive IEC meetings without prior intimation. Chairperson may recommend such case to Executive Director for necessary action.
e. All members will maintain absolute confidentiality of all discussions during the meeting.
f. Conflict of interest if any, will be declared by the member of the IEC
g. Member having interest in clinical trial shall not participate in voting.

6. Quorum requirements:

The minimum of 5 members are required for the quorum.

1. One basic medical scientist (preferably one pharmacologist)
2. One clinician
3. One legal expert or retired judge
4. One social scientist / representative of nongovernmental organization / philosopher / ethicist / theologian or a similar person
5. One layperson from the community
6. All decisions should be taken in meetings and not by circulationof project proposals

7. Offices& Administrative Support

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. 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.

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The committee will be assisted by Secretarial Staff namely Secretarial Assistant & Steno Typist. There shall always be financial transparency of committee activities and functioning.

8. Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC.

9. Application Procedures:

a. All proposals for Clinical Research/Trial will be submitted in the prescribed application form, the details of which are given under Documentation
b. All relevant documents should be enclosed with application form
c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators will be forwarded by the Head of the Departments / Institution to the ethics committee.
d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
f. Prescribed fee if any should be remitted along with the application.

10. Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted.
3. Approval of the Head of the Department / Institution
4. Protocol of the proposed research
5. Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like Performa,
7. Case report forms, questionnaires, follow - up cards, etc.
8. Informed consent process, including patient information sheet and informed consent form in local language(s).
9. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.
10. Curriculum vitae of all the investigators with relevant publications in last five years.
11. Any regulatory clearances required.
12. Source of funding and financial requirements for the project.
13. Other financial issues including those related to insurance
14. An agreement to report only Serious Adverse Events (SAE) to IEC.
15. Statement of conflicts of interest, if any.
16. Agreement to comply with the relevant national and applicable international guidelines.
17. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
18. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
19. Any other information relevant to thestudy

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11. Review procedures:

a. The meeting of the IEC will be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review. The proposals will be sent to members well in advance.
b. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
c. Researchers will be invited to offer clarifications if need be.
d. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
e. Review of Ethics Committee SOP would be prior to effective date of re-registration or as per conditional requirement with Chairman's permission.
f. The decisions will be minuted and Chairperson's approval taken in writing.

12. **The terms of reference for the IEC are as follows:**

a. Scientific design and conduct of the study.
b. Approval of appropriate scientific review committees.
c. Examination of predictable risks/harms.
d. Examination of potential benefits.
e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
f. Management of research related injuries, adverse events.
g. Compensation provisions.
h. Justification for placebo in control arm, if any.
i. Availability of products after the study, if applicable.
j. Patient information sheet and informed consent form in local language.
k. Recruitment strategies within specific study and in general
l. Protection of privacy and confidentiality.
m. Involvement of the community, wherever necessary.
n. Plans for data analysis and reporting
o. Adherence to all regulatory requirements and applicable guidelines
p. Competence of investigators, research and supporting staff
q. Facilities and infrastructure of study sites
r. Criteria for withdrawal of patients, suspending or terminating the study

13. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified.

14. Decision-making

a. Members will discuss the various issues before arriving at a consensus decision.
b. 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.
c. Decisions will be made only in meetings where quorum is complete.
d. Only members can make the decision. The expert consultants will only offer their opinions.
e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
g. Modified proposals may be reviewed by an expedited review through identified members.
h. Procedures for appeal by the researchers should be clearly defined.

a) Communicating the decision

a. Decision will be communicated by the Member Secretary in writing.
b. Suggestions for modifications, if any, should be sent by IEC.
c. Reasons for rejection should be informed to the researchers.
d. The schedule / plan of ongoing review by the IEC should be communicated to the PI.

b) Follow up procedures

a. Reports will be submitted at prescribed (annual) intervals for review.
b. Final report will be submitted at the end of study.
c. All SAEs and the interventions undertaken will be intimated.
d. Protocol deviation, if any, will be informed with adequate justifications.
e. Any amendment to the protocol will be resubmitted for renewed approval.
f. Any new information related to the study will be communicated.
g. Premature termination of study will be notified with reasons along with summary of the data obtained so far.
h. Change of investigators / sites will be informed.

c) Record keeping and Archiving

a. The constitution and composition of the ethics Committee.
b. The Curriculum vitae of all the committee members.
c. Standard Operating Procedures followed by the committee.
d. National and international guidelines
e. Copies of the Protocol, data collection formats, Case Report Forms, investigational brochures etc. submitted for review.
f. All correspondence with committee members and investigators regarding application decision and follow up.
g. Agenda of all ethics committee meetings.
h. Minutes of all ethics committee meeting with signature of the Chairperson
i. Copies of decisions communicated to the applicants.
j. Record of all notification issued for premature termination of a study with a summary of the reasons.
k. Final report of the study including microfilms, Compact Disks and/ or Video-recordings.
l. All records must be safely maintained after the completion/termination of the study for not less than 15 years from the date of completion or termination of the trial. Periodic Archival Documents Checks are performed with log entries.
m. All SAE Gr V / Death records are safely archived for life time (i.e. 21 years)

d) Updating IEC members

a. All relevant new guidelines will be brought to the attention of the members.

b. Members will be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

19. List of Annexure of applicable Documents

a. Institutional Ethics Committee member's list. BMCHRC, Jaipur (Annexure – 1)
b. Institutional Ethics Committee, member's curriculum vitae BMCHRC, Jaipur. (Annexure – 2)
c. SOP on Management of Research study Submission and Review of Post Approval Amended Protocol / Protocol related Documents.(Annexure – 3)
d. Details of clinical trials conducted at BMCHRC under Institutional Ethics Committee since last registration (Mar 2013) (Annexure -4)
e. Minutes of meeting of Institutional Ethics Committee since last registration (Mar 2013) (Annexure -5)
f. Details of supporting staff at Clinical Trial & Research Department, BMCHRC, Jaipur (Annexure -6)
g. Institutional Ethics Committee, BMCHRC, Jaipur "under – taking" (Annexure - 7)

20. List of Annexure of applicable SOP's

a. SOP for 'Vulnerable Population in Clinical Research" (Annexure – 8)
b. SOP on 'Disclosure of Financial Interest and Management of Conflict of Interest' in a private sponsored clinical research (Annexure – 9)
c. SOP on new & Existing Institution Committee member training (Annexure – 10)
d. SOP on Institutional Ethics Committee Fee structure and reviewing of per protocol document (Annexure – 11)
e. SOP on Narcotic and Psychotropic substance / handling in clinical trials, BMCHRC, Jaipur (Annexure – 12)
f. SOP on Audio / Video / Photographic Recording of Informed Consent Process of Human Research Participant in clinical research, BMCHRC, Jaipur (Annexure – 13)

g. SOP on Drug / Study drug destruction, BMCHRC, Jaipur (Annexure – 14)
h. SOP on SAE reporting time lines, BMCHRC – Jaipur (Annexure – 15)
i. SOP on Review of Protocol / Deviation / Violation / waiver / non-compliance. (Annexure – 16)
j. SOP on Handling of participant's / Patient's queries, requests and complaints (Annexure – 17)
k. SOP on Preparing Standard Operating Procedures (SOP's): writing, reviewing, distributing, amending Control of SOP's for the Institutional Ethics Committee.