

ANNEXURE -11

Version 01, Dated 18 Feb 2013	Policy on fee structure and reviewing of per protocol documents	Page 1 of 2
-------------------------------------	---	----------------

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
Chartered Accountant

Mrs. UpmaPareek
Ex. President AWWA

Policy on fee structure and reviewing

Of per protocol documents

1. Institutional Ethics Committee (IEC) shall meet in every 3 months' time for reviewing and approval. Committee's opinion shall be available in 3 weeks' time to the applicant / presenter of study in the schedule Y compliant document format.
2. Institutional Ethics Committee (IEC) fees structure for reviewing of per study documents is INR 100,000/-
Or
An option is available to pay one time Institutional Ethics Committee (IEC) fees of INR 200,000/- for reviewing per study documents including amendments or new safety information etc (inclusive of point no:3). This one- time fee shall be valid for reviewing of per study documents, from its inception till completion of the study.
3. Institutional Ethics Committee fees structure shall be INR 50000/- for reviewing of the following :-
 - a. Changes /amendment made in the submitted documents for re-submission and re-approval.
 - b. New patient safety information / additional information for reviewing and approval.
 - c. Changes or amendment made in ICF/Inclusion Exclusion criteria/ Protocol including administrative or patient safety.
 - d. Any other document other than the previously approved documents.
 - e. Payee name : BhagwanMahaveer Cancer Hospital & Research Centre, J.L.N.Marg, Jaipur-302017

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
Chartered Accountant

Mrs. UpmaPareek
Ex. President AWWA

Version 01, Dated 18 Feb 2013	Policy on fee structure and reviewing of per protocol documents	Page 2 of 2
-------------------------------------	--	----------------

4. Institutional Ethics Committee shall give conditional approval for the study in the absence of DCGI approval and shall be valid for 9 months till DCGI approval is obtained. In case presenter of the study fails to obtained DCGI approval in the stipulated time lines of 9 months, IEC shall charge a renewal fee of INR 50000/-
5. Institutional Ethics Committee (IEC) shall charge a sum of INR 150000/- for the "expedited" reviewing of the study protocol, inclusive of scheduled IEC meeting fee.
6. Clinical Trial and Research department shall levy a fee of INR 5000/ per document for Institutional Ethics Committee (IEC) notification i.e. CIOMS or SUSAR's after the study close- out.
7. The Applicant/Presenter should submit all documents required, at least 15 days prior to the meeting for a thorough and complete review of the ethics of the proposed research.
8. All records must be safety maintained after the completion/termination of the study for not less than 15 years from the date of completion or termination of the study, therefore applicant & presenter should submit an archival fee of INR 30000/- for maintaining the records.
9. Please review annexure- 3 for Initial submission of proposed study documents for reviewing and approval
10. Payee name: Institutional Ethics Committee, Bhagwan Mahaveer Cancer Hospital & Research Centre.