



TEERTHANKER MAHAVEER UNIVERSITY

(Established under Govt. of U. P. Act No. 30, 2008)

Delhi Road, Moradabad (U.P)

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Ref. : TMU/R.O./2020-21/Ethics Committee/001

Date : 05.04.2021

Circular

Subject: Constitution of University Level Research Ethics Committee (for experimentation on Human beings & Animals)

This is for the information of all the concerned that the University Level Research Ethics Committee for experimentation on Human beings & Animals has been re-constituted and approved by the competent authority as below:

1	Chairperson	: Dr. Najmul Huda Department of Pediatric Orthopaedics, KGMU, Lucknow (Mob: 09837119336)
2	Basic Medical scientist	: Dr. Sangeeta Kapoor Prof. & HOD, Biochemistry, TMMC&RC, Moradabad (Mob: 9411874572) : Dr. (Mrs.) Shyamoli Dutta Prof. & HOD Pathology, TMMC&RC, Moradabad (Mob: 08958961880) : Dr. Meghanand Nayak Prof. & HOD, Oral Pathology & Microbiology, TMMC&RC, Moradabad (Mob: 09571222081) : Dr. Anurag Verma, Principal, College of Pharmacy, TMU, Moradabad (Mob: 09690237514)
3	Clinicians	: Dr. Gurdeep Singh Jheetay, Prof. & HOD, Anesthesiology, TMMC&RC (Mob: 07500592693) : Dr. Ajay Pant Medical superintendent & Prof. HOD, Orthopaedics, TMMC&RC Moradabad (Mob: 9897147983) : Dr. D.S. Gupta, Reader Oral Maxillofacial Surgery, TMDC&RC, Moradabad (Mob: 09411696393)
4	Legal Expert	: Dr. H.B. Dixit Principal, MHPG College, Moradabad (Mob: 09412389967)
5	Social Scientist/ NGO	: Dr. Alok Mishra Head, Department of Social Welfare, TMU (Mob: 09415834996)
6	Educated Person from the community	: Shri. A.K. Kapoor PCS Retired, 1/69, Bahar Sahara Estates, Jankipuram, Lucknow (Mob: 09389692009)
7	Ex-officio member	: Dr. Prithpal Singh Matreja, Member Secretary-CRC-TMMC&RC Professor, Dept. of Pharmacology, TMMC&RC, Moradabad (Mob: 9855001847)
8	Member Secretary	: Dr. Rohit Varshney Professor, Dept. of Anesthesia, TMMC&RC, Moradabad (Mob: 09897490444)

Dr. Aditya Sharma
(Registrar)

Copy to:

1. P.S. to Hon'ble Vice Chancellor
2. Associate Dean (Academics)
3. Director (Administration)
4. Members as above
5. Guard file



**TEERTHANKRE MAHAVEER MEDICAL COLLEGE AND RESEARCH CENTRE
INSTITUTIONAL ETHICS COMMITTEE (IEC)**

IEC should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.

IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IEC will ensure that all the cardinal principles of research ethics viz. autonomy, beneficence, non-maleficence and justice are taken care of in planning, conduct and reporting of a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/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 periodic reports, final report and site visits etc. The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

CONSTITUTION OF IEC

The Principal & Dean, TMMC&RC, Moradabad shall constitute the IEC, in consultation with the Academic Board in the following pattern:

1. Chairperson
2. Member Secretary from Institute
3. Dean
4. 5-7 members from different specialties as specified above, some of them should be from the Faculty of the Institute.

The committee will be normally reconstituted every 3 years

Membership Duration and Responsibilities

1. The duration of the membership will be 3 years
2. There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
3. A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Director.
4. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
5. Conflict of interest if any shall be declared by members of the IEC at the beginning of every meeting.



Quorum Requirements

A minimum of 5 members including at least three outside members is required for quorum. All decisions should be taken in meetings and **not by circulation of project proposals.**

Offices/Conduct of the Meeting

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available; an alternate Chairperson will be elected by the members present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.

Review Procedure

1. Meetings of IEC shall be held on scheduled intervals as prescribed (once in 3 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
6. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

Independent Consultants

IEC may call upon subject experts as consultants for review of selected research protocols. 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 will not take part in the decision making process.

Element of Review

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Justification for placebo in control arm, if any.
7. Availability of products to the trial subjects after the study, if applicable.



8. Patient information sheet and informed consent form in English/Hindi and local language.
9. Protection of privacy and confidentiality of subjects.
10. Involvement of the community, wherever necessary.
11. Protocol and proforma of the study including the consent form.
12. Plans for data analysis and reporting.
13. Adherence to all regulatory requirements and applicable guidelines.
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure.

Expedited Review

Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the IEC for clearance and approved by the Chairperson. The approvals will be reported in the next IEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.

Decisions Making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.
5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC.
 - (i) PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.
 - (ii) The final report of the completed study should be submitted by PI.
 - (iii) The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC.

Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

Follow up Procedures

1. Annual report should be submitted by the PI on prescribed format along with comments.



2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
3. All SAEs and the interventions undertaken should be intimated immediately to IEC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study.
4. Protocol deviation, if any, should be informed with adequate justifications.
5. Any amendment to the protocol should be submitted for approval.
6. Any new information related to the study should be communicated to IEC.
7. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
8. Change of investigators should be done with the approval of IEC.

Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of IEC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.
5. Final report of the approved projects.



Standard Operating Procedure (SOP) for Institutional Ethics Committee

1. Objective

The objective of Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.

2. Functions of Institutional Ethics Committee (IEC)

IEC should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies. IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IEC will ensure that all the cardinal principles of research ethics viz, autonomy, beneficence, non-maleficence and justice are taken care of in planning, conduct and reporting of a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/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 periodic reports, final report and site visits etc. The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

3. Composition of IEC

IECs shall be multidisciplinary and multi sectorial in composition. The number of members in the committee shall be kept small (7-11 members) as a large committee makes it difficult in reaching consensus and in having the presence of all the members. The external members shall be in majority to ensure the independence of the committee. The Chairperson of the committee shall be from outside the institution and not Head/former Head of this institution. The Member Secretary, drawn from institution itself, shall conduct the business of the Committee. Other members will be a mix of medical and non-medical scientific and non-scientific persons including general public to reflect the differed viewpoints.

The composition may be as follows:

1. Chairperson
2. Basic medical scientists
3. Clinicians
4. Legal expert
5. Social scientist/representative of non-governmental voluntary agency
6. Educated person from the community
7. Member-Secretary

IEC shall have majority of its members from other institutions. They could be drawn from any public or private institute from anywhere in the country. There shall be adequate representation of age, gender, community etc. in the Committee to safeguard the interests and welfare of all sections of the society. The Committee cannot consist entirely of men or entirely of women.



4. Constitution of IEC

The Principal & Dean, TMMC&RC, Moradabad shall constitute the IEC, in consultation with the Academic Board in the following pattern:

1. Chairperson
2. Member Secretary from Institute
3. Dean
4. 5-7 members from different specialties as specified above, some of them should be from the Faculty of the Institute.

The committee will be normally reconstituted every 3 years

5. Membership Duration and Responsibilities

1. The duration of the membership will be 3 years
2. There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
3. A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Director.
4. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
5. Conflict of interest if any shall be declared by members of the IEC at the beginning of every meeting.

6. Quorum Requirements

A minimum of 5 members including at least three outside members is required for quorum. All decisions should be taken in meetings and not by circulation of project proposals.

7. Offices/Conduct of the Meeting

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.

8. Independent Consultants

IEC may call upon subject experts as consultants for review of selected research protocols. 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 will not take part in the decision making process.

9. Application Procedure

1. All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
2. All relevant documents should be enclosed with application.
3. The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators should be forwarded by the Head of the Department.



4. The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.
5. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
6. The decision of IEC 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.

10. Documentation

All research proposals should be submitted with the following documents:

1. Title of the project
2. Names of the PI and Co-investigators with designation.
3. Name of any other Institute/Hospital/Field area where research will be conducted.
4. Approval of the Head of the Department.
5. Protocol of the proposed research.
6. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant annexure like proforma, case report forms, questionnaires, follow-up cards, etc. to be used in the study.
8. Patient information sheet and informed consent form in English/Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).
9. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.
10. Any regulatory clearances required. Copy of clearances if obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
11. Source of funding and Budget along with the supporting documents.
12. Indemnity issues including insurance for the compensation to the participants etc.
13. An undertaking to immediately report Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any.
15. Plans for publication of results—positive or negative—while maintaining the privacy and confidentiality of the study participants.
16. Any other information relevant to the study.
17. Agreement to submit annual progress report and final report at the end of study.
18. The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).

11. Review Procedure

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3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.



6. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

12. Element of Review

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Justification for placebo in control arm, if any.
7. Availability of products to the trial subjects after the study, if applicable.
8. Patient information sheet and informed consent form in English/Hindi and local language.
9. Protection of privacy and confidentiality of subjects.
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13. Expedited Review

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14. Decisions Making

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 - (i) PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.
 - (ii) The final report of the completed study should be submitted by PI.
 - (iii) The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC.



15. Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

16. Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/ Device/ Collaborative Trials

After the approval from IEC, the sponsor/CRO will submit the clinical trial agreement/ Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Dean, TMMC&RC, with the counter signature of PI. As per existing policy of the Institute, there will be 25% overhead charges to the total cost of the trial/per patient cost. The drug trial shall be started by the PI after the agreement is signed by both the parties as well as DCGI and required regulatory approvals are available for the concerned trial.

17. Follow up Procedures

1. Annual report should be submitted by the PI on prescribed format along with comments.
2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
3. All SAEs and the interventions undertaken should be intimated immediately to IEC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study.
4. Protocol deviation, if any, should be informed with adequate justifications.
5. Any amendment to the protocol should be submitted for approval.
6. Any new information related to the study should be communicated to IEC.
7. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
8. Change of investigators should be done with the approval of IEC.

18. Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of IEC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.
5. Final report of the approved projects.

19. Updating IEC Members

1. All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary.
2. Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.



TEERTHANKER MAHAVEER MEDICAL COLLEGE & RESEARCH CENTER

Delhi Road, Moradabad - 244001 (U.P.)

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC) (for attachment to each copy of the proposal)

***Code No. of IEC:**

*** To be filled by IEC Member Secretary**

Proposal Title:

Name, Designation & Qualifications :

Departmental Tel Nos. :

Email ID :

Signature :

PI :

Co-PI/ Collaborators

- 1.
- 2.
- 3.

Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at TMMC&RC. The investigators should sign their CV.



Sponsor Information

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐
b) Private ☐
2. International Government ☐ Private ☐ UN Agencies ☐
3. Industry National ☐ Multinational ☐
4. Contact address of sponsor

5. Budget

Details of the study proposed

1. Type of study Epidemiological ☐ Basic Sciences ☐ Behavioral ☐
Clinical ☐ Single Centre ☐ Multicentric ☐
2. Status of review New ☐ Revised ☐
3. Clinical trials
Drug/Vaccines/Device/Herbal Remedies
i. Does the study involve use of
Drugs ☐ Devices ☐ Vaccines ☐
Indian Systems ☐ Any Other ☐ None ☐
of Medicines/
Alternate systems of Medicine
ii. Is it approved and marketed
In India ☐ UK & Europe ☐ USA ☐
Other Countries, Specify
iii. Does it involve a change in use, dosage, route of administration? Yes ☐ No ☐
If yes, whether DCGI's/Any other Regulatory Authority's
Permission is obtained? Yes ☐ No ☐
If yes, copy of permission attached Yes ☐ No ☐
iv. Is it an Investigational New Drug? Yes ☐ No ☐
If yes
a. Investigator's Brochure enclosed Yes ☐ No ☐
b. Preclinical studies data available (If yes, provide summary) Yes ☐ No ☐
c. Clinical studies data available (If yes, provide summary) Yes ☐ No ☐
d. Clinical study is Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ NA ☐
e. DCGI's permission obtained Yes ☐ No ☐
If yes, copy of letter enclosed Yes ☐ No ☐

4. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words)

5. Subject selection

- i. Number of subjects
 - ii. Duration of (a) Study: (b) Subject participation:
 - iii. Will subjects from both sexes be recruited Yes ☐ No ☐
 - iv. Inclusion/exclusion criteria given Yes ☐ No ☐
 - v. Type of subjects Volunteers ☐ Patients ☐
 - vi. Vulnerable subjects Yes ☐ No ☐
- (Tick the appropriate boxes)
Pregnant Women ☐ Children ☐ Elderly ☐



Fetus ☐ Illiterate ☐ Handicapped ☐
Terminally ill ☐ Seriously ill ☐ Mentally Challenged ☐
Economically & socially backward ☐ Any other ☐
vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)
Captives ☐ Institutionalized ☐ Employees ☐
Students ☐ Nurses/Dependent ☐ Armed Forces ☐
Any Other ☐ Staff ☐

6. Privacy and confidentiality

i. Study Involves Direct Identifiers ☐ Indirect Identifiers/Coded ☐
Completely Anonymised /Delinked ☐
ii. Confidential handling of data by staff Yes ☐ No ☐

7. Use of biological/hazardous materials

i. Use of fetal tissue or abortus. If yes provide details Yes ☐ No ☐
ii. Use of organs or body fluids. If yes provide details Yes ☐ No ☐
iii. Use of recombinant/gene therapy products Yes ☐ No ☐
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained? Yes ☐ No ☐
iv. Use of pre-existing/stored/left over samples Yes ☐ No ☐
v. Collection for banking/future research Yes ☐ No ☐
vi. Use of ionizing radiation/radioisotopes Yes ☐ No ☐
If yes, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? Yes ☐ No ☐
vii. Use of Infectious/biohazardous specimens Yes ☐ No ☐
viii. Proper disposal of material Yes ☐ No ☐

ix. Will any sample collected from the patients be sent abroad? Yes ☐ No ☐

If yes, give details and address of collaborators

a. Sample will be sent abroad because (Tick appropriate box)

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed ☐

If so, reasons

b. Has necessary clearance been obtained Yes ☐ No ☐

8. Consent *Written ☐ Oral ☐ Audio-Visual ☐

i. Patient Information Sheet attached : (Tick the included elements) Yes ☐ No ☐

Understandable language ☐ Alternatives to participation ☐
Statement that study involves research ☐ Confidentiality of records ☐
Sponsor of study ☐ Contact information ☐
Purpose and procedures ☐ Statement that consent is voluntary ☐
Risks & discomforts ☐ Right to withdraw ☐
Benefits ☐ Consent for future use of biological material ☐
Compensation for participation ☐ Benefits if any on future commercialization e.g. Genetic basis for drug development ☐
Compensation for study related injury ☐
Translation of information sheet in local Language ☐
ii. If healthy volunteers will be included, information sheet for them attached Yes ☐ No ☐



- iii. Consent form in English ☐ Local Languages ☐
iv. Who will obtain consent? PI-Co-PI ☐ Nurse/Counsellor ☐
Research Staff ☐ Any Other ☐

*If written consent is not obtained, give reasons

9. Will any advertising be done for recruitment of Subjects?

(Posters, flyers, brochure, websites – if so attach a copy) Yes ☐ No ☐

10. Risks & benefits

i. Is the risk reasonable compared to the anticipated benefits to subjects/community/country? Yes ☐ No ☐

ii. Is there physical/social/psychological risk/discomfort? Yes ☐ No ☐
If yes, Minimal or no risk ☐ More than minimum risk ☐ High risk ☐

iii. Is there benefit a) to the subject? Yes ☐ No ☐

Direct ☐ Indirect ☐

b) to the society Yes ☐ No ☐

11. Data monitoring

i. Is there a data & safety monitoring committee/Board (DSMB)? Yes ☐ No ☐

ii. Is there a plan for reporting of adverse events? Yes ☐ No ☐

If yes, reporting will be done to

Sponsor ☐ IEC ☐ DSMB ☐

iii. Is there a plan for interim analysis of data? Yes ☐ No ☐

12. Is there compensation for injury? Yes ☐ No ☐

If yes, by Sponsor ☐ Investigator ☐ Insurance Company ☐ Any Other ☐

13. Do you have conflict of interest? Yes ☐ No ☐

(Financial/Non financial) If yes, specify

Check list for attached documents:

- Project proposal-11 copies ☐
Curriculum Vitae of non TMMC&RC Investigators ☐
Brief description of proposal/summary ☐
Copy of the Protocol/Project and questionnaire (if any) ☐
Investigator's Brochure ☐
Copy of Patient information sheet & Consent form in local language ☐
Copy of Advertisements/Information brochures ☐
DCGI/DBT/BARC clearance if obtained ☐
Copy of Insurance Policy ☐
Copy of Clinical trial agreement ☐
Copy of IEC proforma ☐
Copy of PI undertaking ☐
Copy of Case Report Form ☐
Signature of PI
Date Signature of HOD



TEERTHANKER MAHAVEER MEDICAL COLLEGE & RESEARCH CENTER
Delhi Road, Moradabad - 244001 (U.P.)

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1. NAME AND CODE NUMBER OF THE PROJECT
 2. NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR
 3. OTHER MEMBERS OF THE RESEARCH TEAM
 4. NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE
 - 5.
 6. NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE PI.
-
1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
 2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
 3. I confirm that the CO PI and other members of the study team have been informed about their obligations and are qualified to meet them
 4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
 5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, Regulatory authorities, Sponsors or their authorized representatives.
 6. I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence
 7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
 8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
 9. I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Signature of Principal Investigator Date



ONE PAGE CV*

Last Name First Name Middle Initial

Date of Birth (dd/mm/yy): Sex

Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)

Professional Mailing Address

(Include institution name)

Study Sited Address

(Include institution name)

Telephone (Office):

Mobile Number:

Telephone (Residence):

E-Mail:

Academic Qualifications (Most current qualification first)

Degree/Certificate Year Institution, Country

Current and Previous 4 Relevant Positions Including Academic Appointments

(Most current position first)

Month and Year Title Institution/Company, Country

Brief Summary of Relevant Clinical Research Experience:

Signature:

(Signature Required)

Date:

*For Non-TMMC&RC Investigator



Teerthanker Mahaveer Medical College & Research Center

Delhi Road, Moradabad - 244001 (U.P.)

**FORMAT FOR COMMUNICATION TO THE PRINCIPAL INVESTIGATOR BY THE
MEMBER SECRETARY, INSTITUTIONAL ETHICS COMMITTEE**

No. _____ Dated: _____
To, _____
Prof./Dr. _____

Dear Prof./Dr. _____

The Institutional Ethics Committee in its meeting held on _____, has reviewed and discussed your application to conduct the clinical trial/project entitled

" _____ "

_____ sponsored by _____ Code no. _____

The following documents were reviewed:

- a. Trial Protocol (including protocol amendments)/project, dated _____ Version no (s). _____
- b. Investigator's Brochure, dated _____, Version no. _____
- c. Patient Information Sheet and Informed Consent Form (including updates if any) in Hindi, English and/or vernacular language.
- d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
- e. Current CV of investigator from outside TMMC&RC.
- f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
- g. Investigator's Agreement with the Sponsor.
- h. Investigator's Undertaking.
- i. Ethics Committee Proforma.
- j. DCGI approval letter/submission letter.
- k. Case Report Form.
- l. Any other/additional documents

Decision of Committee: Institutional Ethics Committee Member Secretary



Teerthanker Mahaveer Medical College & Research Center,
Delhi Road, Moradabad - 244001 (U.P.)

INTIMATION OF START OF STUDY

1. Project/Trial Code Number
2. Title of the drug/multicentric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start

Date: (Signature of Principal Investigator)



Teerthanker Mahaveer Medical College & Research Center,
Delhi Road, Moradabad - 244001 (U.P.)

PROGRESS REPORT (Annual)/FINAL REPORT

1. Project/Trial Code Number
2. Title of the drug/multicentric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start
8. Objectives of the study
9. Progress report as per objectives (attach separate sheet)
10. Serious Adverse Events if any with details (in summary form)
11. Protocol deviation if any with reasons/justifications
12. Report/publications/conference presentation
13. Awards/recognition

Date: (Signature of Principal Investigator)
(Signature of Head of the Department)



Teerthanker Mahaveer Medical College & Research Center,

Delhi Road, Moradabad - 244001 (U.P.)

GUIDELINES FOR PATIENT INFORMATION SHEET

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. Study Title

Is the title self explanatory to a lay person? If not, an additional simplified title may also be included.

2. Invitation Paragraph

You should explain that the patient is being asked to take part in a research/trial study. The following is an example: "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part."

3. What is the purpose of the study?

The background and aim of the study should be given here

4. Why have I been chosen?

You should explain how and why the patient was chosen and how many other patients will be studied.

5. Do I have to take part?

You should explain that taking part in the research/trial is entirely voluntary. You could use the following paragraph: "It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. What will happen to me if I take part?

You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc? Whenever possible you



should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use – the following simple definitions may help:-

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual – i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

Placebo: A placebo is a dummy treatment such as a pill, which looks like the real thing but is not. It contains no active drug, chemical or ingredient.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

8. What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identity card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research/trial the patient should be told what other treatment options are available.

10. What are the side effects of taking part?

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case



of emergency. The known side effects should be listed in terms the patient will clearly understand (e.g. 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For any relatively new drug it should be explained that there may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said: "It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator. Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy. There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage. If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance. You should clearly state what will happen if you detect or find a condition of which the patient was unaware. Is it treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly. It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

"We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better".

13. What if new information becomes available?

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. You could use the following:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."



14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

16. Will my taking part in this study be kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research/trial is:

"If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

The answer should include the organization or company sponsoring or funding the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution). The patient should be told whether the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.

19. Who has reviewed the study?

You may wish to mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).



20. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. (Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers)

Remember to thank your patient for taking part in the study!

The patient information sheet should be dated and given a version number.

The Patient Information Sheet should state that the patient will be given a copy of the information sheet and the signed consent form.

Date:

Signature of PI



Teerthanker Mahaveer Medical College & Research Center

Delhi Road, Moradabad - 244001 (U.P.)

INFORMED CONSENT FORM

Study Title _____
Study Number _____
Subject's Full Name _____
Date of Birth/Age _____
Address _____

1. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.

OR

I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the clinical trial/project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)
5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable

Representative: _____

Signatory's Name _____ Date _____

Signature of the Investigator _____ Date _____

Study Investigator's Name _____

Signature of the Witness _____ Date _____

Name of the Witness _____



तीर्थकर महावीर मेडिकल कालेज एवं शोध केन्द्र, मुरादाबाद

सूचित सहमति पत्र

अध्ययन शीर्षक.....
अध्ययन नम्बर.....
सहभागी का पूरा नाम.....
जन्मतिथि/उम्र.....
पता.....

1. मेरी पुष्टि है कि मैंने उपरोक्त परिक्षण हेतु जानकारी पत्र दिनांक..... को पढ़ व समझ लिया है, तथा मुझे प्रश्न पूछने के अवसर प्रदान किये गये।

अथवा

मुझे अध्ययन अन्वेषक ने विस्तार से सब तथ्यों को समझा दिया है तथा मुझे प्रश्न पूछने का अवसर प्रदान किया।

2. मैंने समझ लिया है कि इस अध्ययन में मेरी प्रतिभागिता स्वेच्छिक है, तथा यह कि मैं बिना कोई कारण बताए किसी भी समय अपनी चिकित्सीय देखभाल या कानूनी अधिकारों पर प्रभाव पड़े बिना हट जाने के लिए स्वतंत्र हूँ।
3. मैंने समझ लिया है कि चिकित्सीय प्रायोजक की ओर से काम करने वाले अन्य, नेतिकता समिति तथा विनियामक प्राधिकारियों का चालू अध्ययन तथा इससे सम्बन्धित हो सकने वाले किसी अनुसंधान से सम्बन्धित मेरे स्वास्थ्य अभिलेखों को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, नले ही मैं इस परीक्षण से हट ही क्यों न जाऊँ। तथापि मैंने समझ लिया है कि तृतीय पक्ष को दी गई या प्रकाशित की गई किसी जानकारी में मेरी पहचान को उजागर नहीं किया जाएगा।
4. इस अध्ययन में प्राप्त किन्हीं आकड़ों या परिक्षणों के प्रयोग पर पाबंदी न लगाने के लिये मैं सहमत हूँ, बशर्ते कि ऐसे प्रयोग मात्र वैज्ञानिक प्रयोजन/नों के लिये ही हों।
5. उपर्युक्त अध्ययन में भाग लेने के लिये मैं सहमत हूँ।

सहभागी के हस्ताक्षर या अंगूठे का निधान/कानूनी रूप से स्वीकार्य प्रतिनिधि.....

हस्ताक्षर करने वाले का नाम..... दिनांक.....

अध्ययन अन्वेषक के हस्ताक्षर..... दिनांक.....

अध्ययन अन्वेषक का नाम.....

गवाह के हस्ताक्षर..... दिनांक.....

गवाह का नाम.....





TEERTHANKER MAHAVEER UNIVERSITY

Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/20-21/167

Dated : 19/08/2021

Subject: Minutes of "Institutional Ethics Committee" Meeting (held on 16/08/2021 to 18/08/2021)

A meeting of Institutional Ethics Committee was held on 16/08/2021 to 18/08/2021 at 06:00 PM through virtual platform, Teerthanker Mahaveer University, and Moradabad.

Following members were present in the meeting:

S. No.	Name	Designation
1.	Dr. Najmul Huda	Chairperson
2.	Dr. Rohit K. Varshney	Member Secretary
3.	Dr. Ajay Pant	Member
4.	Dr. Anurag Verma	Member
5.	Dr. Sangeeta Kapoor	Member
6.	Dr. G.S. Jheetay	Member
7.	Dr. Meghanand Nayak	Member
8.	Dr. Seema Awasthi	Member
9.	Dr. D.S. Gupta	Member
10.	Dr. Prithapi Singh Matreja	Member Secretary (CRC)

Agenda: The protocols of the following research projects (including theses protocol/dissertation of PG/Faculty and M.Sc. Students were discussed regarding suitability for ethical clearance:





INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/20-21/167

Dated : 19/08/2021

S.No	Department	Candidate Name	Guide	Title	Remarks
1	Chest & TB	Dr. Vikrant Solanki	Dr. M. Maqsood	Occurrence of diabetes mellitus with rifampicin resistance in patients of pulmonary tuberculosis	- Mention phone Number in Participant Information Sheet. - Revise consent form.
2	Ophthalmology	Dr. Mukta Tiwari	Dr. Ashish Chander	Association of serum lipid levels and glycosylated hemoglobin (HbA1c) with severity of diabetic retinopathy	Revise Participant information Sheet & informed consent form (Hindi version)
3	Ophthalmology	Dr. Palak Jain	Dr. P S Rastogi	A comparative study to evaluate the efficacy of subtenon's block with peribulbar block in cases of phacoemulsification	Literature evidence is required regarding the advocacy of peribulbar block & subtenon's block
4	Ophthalmology	Dr. Aishwarya Tyagi	Dr. Ashish Chander	A Comparative Study To Analyse The Changes In Central Macular Thickness In Diabetes With Different Stages Of Diabetic Retinopathy	Approved
5	Obstetrics & Gynecology	Dr. Berkha Garg	Dr. Archana Agarwal	A Study on association of maternal prepregnancy BMI according to WHO Asian Guidelines and gestational weight gain in pregnancy outcome	Revise consent form





TEERTHANKER MAHAVEER UNIVERSITY

Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/20-21/167

Dated : 19/08/2021

6	Obstetrics & Gynecology	Dr. Ratna Tejaswi	Dr. Shubhra Agarwal	role of prophylactic add on tranexamic acid in active management of third stage of labour, a prospective randomized Study	Literature evidence is required regarding the prophylactic use of tranexamic acid in active management of third stage of labour.
7	Obstetrics & Gynecology	Dr. Priyanka Chaudhary	Dr. Prachi Singh	A study to evaluate association between hyperprolactinemia and thyroid hormone disorder in Abnormal Uterine bleeding due to ovulatory disorders". A Prospective Observational study	Modify Participant information sheet.
8	Obstetrics & Gynecology	Dr. Jyoti Khatri	Dr. Rehana Najam	A comparative study of the impact of client centred structured contraceptive counselling versus conventional counselling techniques among postpartum and postabortal females	Approved
9	Pediatrics	Dr. Brij Bhushan	Dr. Baljeet Maini	Assessment of Platelet Indices as a biomarker for diagnosing Neonatal Sepsis.	Approved
10	Pediatrics	Dr. Animesh Indu	Dr. Baljeet Maini	Red Cell Distribution Width As A Biomarker For Predicting Mortality In Critically Ill Children	Approved





TEERTHANKER MAHAVEER UNIVERSITY

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INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/20-21/167

Dated : 19/08/2021

11	Pediatrics	Dr. Rufaida Mazahir		Caffeine Citrate Administration and Risk Of Acute Kidney Injury In Preterm Neonates	- Revise Aim & objectives. - Revise Methodology - Modify Participant Information Sheet
12	General Medicine	Dr. Achintya Agrawal	Dr. Krishan Gopal	Effect of decontamination of oral cavity on the frequency of ventilator associated pneumonia	Literature Evidence is required for support of the use for 2% chlorhexidine for decontamination of oral cavity in patients on Ventilator.
13	General Medicine	Dr. Priya Singh	Dr. Vishvanayak	The Clinico-etiological profile of elderly patients presenting with heart failure at a tertiary care hospital	Revise Consent form
14	General Medicine	Dr. Himanshu Goel	Dr. Bajrang lal Banthia	Role of Vitamin-D3, D-dimer and serum ferritin levels in assessing the severity of Covid-19 patients: A retrospective cum prospective study	Revise Consent form and mention "Permission to be taken from Medical Superintendent" in Methodology.
15	General Medicine	Dr. Pinki	Dr. Vishvanayak	Clinical profile and outcome of hypertensive emergencies at a tertiary care hospital	- Mention phone number Participant information sheet. - Revise consent form.





TEERTHANKER MAHAVEER UNIVERSITY

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INSTITUTIONAL ETHICS COMMITTEE

Ref. No.

TMMC&RC/IEC MOM/20-21/167

Dated : 19/08/2021

16	Orthopedics	Dr. Hamza Habib	Dr. Amit Saraf	A Triple Blind Randomized Study to Compare the Effects of Platelet Rich Plasma Versus Growth Factor Concentrate in Patients of Osteoarthritis Knee.	• Revise consent form. • Modify Participant information sheet.
17	Orthopedics	Dr. Vaneet Arora	Dr. Manmohan Sharma	Comparison of Intrarticular Autologous Platelet-Rich Plasma with Corticosteroid (Methyl Prednisolone Acetate) Injection in Osteoarthritis of Knee: A Prospective Randomized Study.	• Subject to clearance from CRC.
18	Orthopedics	Dr. Krishna Dev	Dr. Manmohan Sharma	Estimation of vitamin D deficiency in fragility fractures: A case control study.	• Revise Participant information sheet (Hindi Version)
19	Orthopedics	Dr. Rajat Khanna	Dr. Sudhir Singh	Role of serum CTX-II (Carboxy terminal cross linking telopeptide fragments of type II collagen) levels in diagnosis of knee osteoarthritis.	• Subject to clearance from CRC.
20	Orthopedics	Dr. Divyam Jindal	Dr. Sudhir Singh	Role of serum MMP-3 (matrix metalloproteinase 3) in diagnosis of knee osteoarthritis.	• Subject to clearance from CRC.





TEERTHANKER MAHAVEER UNIVERSITY

Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/20-21/167

Dated : 19/08/2021

21	Pathology	Dr. Ariba Nasir	Dr. Shyamoli Dutta	Role of Haematobiochemical Parameters as Predictors of Early Microvascular Complications in Type 2 Diabetes.	Revise Participant information sheet.
22	Pathology	Dr. Gunjita Singh	Dr. Shyamoli Dutta	Assessment Of Hematological Parameters And Coagulation Profile In Pregnancy Induced Hypertension.	Revise consent form.
23	General Surgery	Dr. Kritika Soni	Dr. Sarita Kanth	A clinic-etiological study to observe changing pattern in patients of breast lump.	- Revise consent form. - Modify Participant information sheet.
24	General Surgery	Dr. Ashutosh K Pradhan	Dr. Sanjay Sharma	A prospective study to assess the effectiveness of conservative management for FISSURE-IN-ANO	- Revise consent form. - Literature evidence including Meta-analysis is required regarding the thesis topic in evidence of use of conservative management for chronic fissure – in – ANO.
25	General Surgery	Dr. Shah Nawaz Ahmad	Dr. Sarita Kanth	Comparative study of modified negative pressure wound therapy with conventional povidone iodine wound dressing	Subject to clearance by CRC





TEERTHANKER MAHAVEER UNIVERSITY

Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No.

TMMC&RC/IEC MOM/20-21/167

Dated :

19/08/2021

26	General Surgery	Dr. Anuradha Rani	Dr. S. C. Sharma	A study of ligation of the intersphincteric fistula tract (LIFT): A sphincter saving technique for Fistula-In-ANO	• Revise consent form. • Modify Participant information sheet.
27	General Surgery	Dr. Shah Ojas Mahesh	Dr. Vipin Kumar	A study of various clinical presentation and outcomes in patients of chest injury attending Teerthanker Mahaveer Medical College and Research Center	• Approved
28	General Surgery	Dr. Vivek Kumar	Dr. Nitin K Rastogi	A comparative study of topical phenytoin versus conventional dressing (5% povidone iodine) in the management of diabetic ulcer.	• Revise consent form.
29	Psychiatry	Dr. Sahil Goyal	Dr. S Nagendran	Association of parameters of the marital life with depressive disorders	• Revise consent form. • Modify Participant information sheet.
30	Biochemistry	Bushra	Dr. Sangeeta Kapoor	Study of serum mineral profile in patients with hypothyroidism.	• Revise consent form. • Mention what amount of blood will be withdrawn from the patients during study in the Consent form and Methodology.



TEERTHANKER MAHAVEER UNIVERSITY

Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/20-21/167

Dated : 19/08/2021

31	Microbiology	Seejal Jain	Dr. Vasundhra Sharma	Study on bacteriological profile and antibiogram of blood stream infection in patients admitted in intensive care unit.	Revise consent form & mention regarding the signature of patient or blood relative in the form.
32	Microbiology	Rinki Kumari Singh	Dr. Shweta R Sharma	Occurrence and antimicrobial susceptibility pattern of Pseudomonas aeruginosa isolated from surgical site infections and wound infections at tertiary care center.	- Include a Co- guide from surgical specialty. - Revise consent form
33	Microbiology	Shivani Gour	Dr. Vasundhra Sharma	Study on bacteriological causes of urinary tract infection in pregnant women and their current resistant pattern	Revise consent form

The meeting ended with thanks to the chair.

Dr. Najmul Huda
Chairperson I.E.C.,
TMU, Moradabad

Copy to:

- Director Admin (TMU)
- Principal, TMMC&RC, Moradabad

Dr. Rohit K. Varshney
Member Secretary
I.E.C, TMU, Moradabad

- All members of I.E.C.
- All HODs, TMMC&RC, Moradabad



TEERTHANKER MAHAVEER UNIVERSITY

Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

Subject: Minutes of Ethics Committee Meeting (held on 25/11/2019 & 26/11/2019)

A meeting of Institutional Ethics Committee was held on 25/11/2019 & 26/11/2019 at 09:15 AM in the conference Room, Teerthanker Mahaveer Hospital & Research Centre, TMU, Moradabad.

Following members were present in the meeting:

S. No.	Name	Designation
1.	Dr. Anil Kumar Tripathi	Chairperson
2.	Dr. Najmul Huda	Member Secretary
3.	Dr. Sunitha J D	Member Secretary
4.	Dr. Ajay Pant	Member
5.	Dr. Sangeeta Kapoor	Member
6.	Dr. G.S. Jheetay	Member
7.	Dr. Meghanand Nayak	Member
8.	Dr. Shyamoli Dutta	Member
9.	Dr. D.S. Gupta	Member
10.	Dr. Prithap Singh Matreja	Member Secretary (CRC)

Agenda: The protocols of the following research projects (including theses protocol/dissertation of PG/Pharma D. and M.Sc. Students were discussed regarding suitability for ethical clearance:



**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No.

TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

S.No	Department	Candidate Name	Guide	Title	Remarks
1	Anesthesiology	Dr. Isha N Bhagat	Dr. G S Jheetay	Clinical evaluation of intubating conditions and hemodynamic effects using two doses of rocuronium bromide: A prospective comparative study	Assessment by a single anaesthetist not below the grade of SRs
2	Anesthesiology	Dr. Nikhita Juneja	Dr. G S Jheetay	Comparison of hemodynamic changes in patients undergoing laparoscopic cholecystectomy using rocuronium and vecuronium for intubation and maintenance under general anesthesia	Modify informed consent from (Hindi version)
3	Anesthesiology	Dr. PE Ricky Paul	Dr. G S Jheetay	A comparative study of lactated ringer solution and 6% hetastarch for pre loading before spinal anesthesia in elective cesarean section	Modify inclusion criteria
4	Anesthesiology	Dr. Uday Kiran	Dr. Pallavi Ahluwalia	Comparison of intravenous dexmedetomidine and clonidine in preventing postspinal shivering in patients undergoing lower limb orthopedic surgeries	Approved
5	Anesthesiology	Dr. Naveen Baloda	Dr. Pallavi Ahluwalia	Effect of different volumes of normal saline for epidural volume expansion on spinal anesthesia in patients undergoing infra-umbilical surgeries	Approved
6	Anesthesiology	Dr. Saurav Mondal	Dr. Rohit K Varshney	A prospective randomized comparative study between intrathecal clonidine and dexmedetomidine as an adjuvant to hyperbaric bupivacaine in the subarachnoid block for inguinal hernia surgeries	Approved





INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

7	Obstetrics & Gynecology	Dr. Amita Azad	Dr. Nupur Nandi	Randomized control trial on systemic use of itraconazole versus terbinafine in vulvovaginal candidiasis	Modify title/methodology.
8	Obstetrics & Gynecology	Dr. Shreya Gupta	Dr. Nupur Nandi	Randomized control trial on intravaginal use of low dose misoprostol versus dinoprostone gel for induction of labor at term pregnancy	Modify title
9	Obstetrics & Gynecology	Dr. Rekha Yadav	Dr. Kanchan Rani	Risk factor analysis for isthmocele after cesarean section.	Approved
10	Obstetrics & Gynecology	Dr. Jyoti Yadav	Dr. Shubhra Agarwal	Comparison of visual inspection methods with PAP smear as screening test for pre malignant lesions of cervix	Approved
11	Obstetrics & Gynecology	Dr. Radhika Anand	Dr. Poonam Singh	Association of life style and dietary habits on the level of anti mullerian hormone (AMH) and follicle count in the patients of infertility	Approved
12	Obstetrics & Gynecology	Dr. Prachi Dahiya	Dr. Renu Garg	A comparative study of obstetrics outcome among women with previous spontaneous or induced abortion and live births	Modify exclusion criteria, modify title
13	Obstetrics & Gynecology	Dr. Yugantika Tomar	Dr. Rehana Najam	To study the effectiveness of mifepristone versus balloon catheter in induction of labor in women with previous 1 caesarean section: A randomized comparative study	Approved
14	Obstetrics & Gynecology	Dr. Saima Siddique	Dr. Rehana Najam	To study the pregnancy outcomes with metformin versus insulin in women with gestational diabetes	Modify CRF





INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

				mellitus: a randomized comparative study	
15	Obstetrics & Gynaecology	Dr. Puja	Dr. Renu Garg	Comparison of Doppler and non-stress test in assessment of perinatal outcome beyond 34 weeks	Approved
16	Obstetrics & Gynaecology	Dr. Kazi R Rahaman	Dr. Poonam Singh	Impact of sildenafil on endometrial and sub endometrial blood flow as measured by color doppler in patients of infertility	Approved
17	Psychiatry	Dr. Shally Mittal	Dr. S Nagendran	Predictors of severity in patients with first episode of psychosis: A cross sectional study	Approved
18	Psychiatry	Dr. Gajal Gupta	Dr. S Nagendran	Effect of risperidone and olanzapine on the metabolic profile of drug naive bipolar disorder patients	Approved
19	Psychiatry	Dr. Sonam Saxena	Dr. Seema Singh	Association of stress, depression and anxiety in patients presenting with primary headache	Include also patients of headache reporting to Medicine, Ophthalmology & Neurology
20	Psychiatry	Dr. Arnav Puri	Dr. Prerana Gupta	Treatment outcome and quality of life in patients of bipolar affective disorder treated with adjuvant electroconvulsive therapy	Approved
21	ENT	Dr. Somya Choudhary	Dr. Probal Chaterji	A clinico-pathological study of thyroid swelling in tertiary center in U.P (West)	Approved
22	ENT	Dr. Shantanu Narain	Dr. Probal Chaterji,	A clinico-radiological study of complications of chronic otitis media	Approved



**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

23	ENT	Dr. Shreesh Sharma	Dr. KVK Sudhakar	Assessment of ossicular necrosis in mucosal type of chronic otitis media	Approved
24	ENT	Dr. Saood Nafees	Dr. S M Tripathy	A study of impact of allergic rhinitis on quality of life of people in western UP	Approved
25	Ophthalmology	Dr. Gunjan Tomar	Dr. P S Rastogi	Etiological profile and predisposing risk factors in patients with suppurative keratitis	Approved
26	Ophthalmology	Dr. Radha Mathur	Dr. Ashish Chander	Evaluation of changes in tear film and meibomian gland in patients with primary pterygium	Approved
27	Ophthalmology	Dr. Puneet Devi	Dr. Gopesh Mehrotra	Evaluation of anatomical and functional outcome of external dacryocystorhinostomy in patient with chronic dacryocystitis	Approved
28	Ophthalmology	Dr. Rajdeep Kaur	Dr. Ashish Chander	Association of visual field loss with vision related quality of life in patients of primary open angle glaucoma	Approved
29	Dermatology	Dr. Garima Singh	Dr. K S Dhillon	Nail disorders and its association with various dermatological and systemic diseases: A clinical study	Approved
30	Dermatology	Dr. Kamalpreet Kaur	Dr. K S Dhillon	Clinical profile of cutaneous manifestation in diabetes mellitus in a tertiary care hospital in western Uttar Pradesh	Approved
31	Dermatology	Dr. Sneha Singh	Dr. Sanath Aithal	Dermatophytic infection among pediatric age group: A clinical and epidemiological study	Approved



**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

32	Dermatology	Dr. Pratika Goyal	Dr. Sanath Aithal	Assessment of the metabolic syndrome, lipid profile and quality of life in patients of xanthelasma palpebrarum: An observational study at a tertiary care center in Western Uttar Pradesh	Methodology flow chart to be corrected
33	Pathology	Dr. Anamika Rawat	Dr. Seema Awasthi	Role of HER/neu and Ki67 in urothelial tumor	Approved
34	Pathology	Dr. Nishant Mishra	Dr. Shyamoli Dutta	Comparative study of modified ultrafast papanicolaou and standard papanicolaou staining technique for the assessment of cervical smear	Approved
35	Surgery	Dr. Alok Maurya	Dr. R K Kaul	Study of association of H pylori with peptic ulcer perforation in Teerthanker Mahaveer Medical College & Research Center	Approved
36	Surgery	Dr. Reena Singh	Dr. Vipin Kumar	A clinical study and outcome in patients of blunt injury abdomen, attending emergency department in Teerthanker Mahaveer Medical College & Research Center	Approved
37	Surgery	Dr. Radha Krishna Singh	Dr. M S Chahal	To study the conservative treatment versus operative management of uncomplicated acute appendicitis	Approved
38	Surgery	Dr. Pragya Singh	Dr. S C Sharma	A study of intraoperative peritoneal lavage with adjunct usage of superoxidized solution in cases of perforation peritonitis	Approved
39	Surgery	Dr. Chakraborty Neelanjana	Dr. Sanjay Sharma	A study of risk factors and clinical presentation of ureteric calculi in patients presenting in Teerthanker	Approved

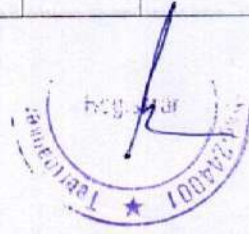




INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

				Mahaveer Medical College & Research Center	
40	Surgery	Dr. Vipul Goel	Dr. N K Singh	A study of risk factors contributing to complications in enteral ostomy patients	Approved
41	Surgery	Dr. Lalit G Vadhver	Dr. S P Sinha	A study of intra peritoneal access by closed versus open method in laparoscopic abdominal surgeries to create pneumo peritoneum	Approved
42	Surgery	Dr. Rishabh Jain	Dr. S P Sinha	A study of clinical presentation and management of complicated liver abscess in patients presenting in Teerthanker Mahaveer Medical College and Research Center	Approved
43	Surgery	Dr. Anmol A Dobriyal	Dr. S P Sinha	A study to observe the outcome of low pressure vs. standard pressure pneumo peritoneum in laparoscopic cholecystectomy	Approved
44	Surgery	Dr. Priyanka Yadav	Dr. N K Singh	An observational study for causes of surgical jaundice at tertiary care hospital	Approved
45	Surgery	Dr. Agrawal Parth	Dr. Sanjay Sharma	Association of International prostate symptom score (IPSS Score) with transurethral prostatectomy (TURP) outcome in patients of benign prostate hyperplasia	Approved
46	Surgery	Dr. Abhishek Dhawan	Dr. N K Singh	An observational study of necrotizing fasciitis in relation to clinical spectrum and bacteriological pattern	Modify objectives, Modify methodology



**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

47	Surgery	Dr. Anshul Jasuja	Dr. Sarita Kanth	A study of early enteral feeding after surgical treatment of bowel perforation	Approved
48	Surgery	Dr. Harsh Darshan	Dr. Sarita Kanth	A study of occurrence and severity of pancreatitis in case of gall stone disease admitted in Teerthanker Mahaveer Medical College & Research Center	Approved
49	Surgery	Dr. Yatish Sharma	Dr. M S Chahal	An interventional study to see the analgesic effect of 0.5% bupivacaine instillation in gall bladder fossa and trocar incision site following laparoscopic cholecystectomy	Approved
50	Surgery	Dr. Virender Chaurasia	Dr. Harpreet Singh	A study of occurrence on incidental carcinoma of gall bladder in operated cases of gall stone disease	Approved
51	Orthopaedics	Dr. Najmul Huda		Evaluation of the effect of platelet rich plasma combined with core decompression as a strategy to conserve the hip joint in femoral head osteonecrosis	Approved
52	Medicine	Dr. Geetesh Manik Dr. Bhumesht Tyagi		Predictors of premature coronary artery disease in young patients presenting with acute coronary syndrome (ACS) in the Indian population	Approved
53	Forensic Medicine	Dr. Anuj Gupta		Profile of autopsies conducted at mortuary of TMMC&RC, TMU, Moradabad	Approved



**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

54	Anatomy	Dr. Hina Nafees	Unraveling the role of vascular endothelial growth factor (VEGF), placental growth factor (PIGF), soluble membrane bound fms-like tyrosine kinase 1 (sFlt1), soluble endoglin (sEng), placental protein 13 (PP13) in the development of preeclampsia	Modify Methodology
55	Anatomy	Dr. Rohin Garg	Analysis of lung function and respiratory symptoms in brass/metal industrial workers of Moradabad, Uttar Pradesh	Approved
56	Pediatrics	Dr. Deepika Agarwal	Use of pediatric early warning score (PEWS) to predict the outcome in children admitted in PICU and its association with mortality and morbidity	Approved
57	Pediatrics	Dr. Sakshi Karia	To study exposure and use of media devices among young children aged 6 months to 8 years in Moradabad region	Approved
58	Pediatrics	Dr. Shweta Gupta	Study of clinic-etiological profile of nutritional anemia in children admitted in tertiary care center, Teerthanker Mahaveer Medical College & Research Center	Modify exclusion criteria
59	Pediatrics	Dr. Divya RS	Study of congenital hypothyroidism newborns at a tertiary care center	Approved
60	Pediatrics	Dr. Divya Agrawal	Assessment of fetal nutrition at birth in a Western UP tertiary care hospital using Clinical assessment of nutritional status (CAN) score and other anthropometric measures	Approved





INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

61	Pediatrics	Dr. Aafrin Bari	Dr. Baljeet Maini	A study of clinic-etiological profile of respiratory distress in children	Modify inclusion & exclusion criteria
62	Pediatrics	Dr. Richa Danda	Dr. Santosh Bhalke	To study the clinic-etiological profile of first episode of seizures in children between 6 months – 12 years of age in a tertiary care center	Approved
63	Pediatrics	Dr. Sangeeta Khatwani	Dr. Baljeet Maini	Comparative study of early neonatal morbidities of late preterm and term neonates.	Modify consent form (Hindi Version)
64	Pediatrics	Dr. Yash Jain	Dr. Atul Goel	A clinicoetiological study of febrile thrombocytopenia: A hospital based retrospective study	Approved
65	Pulmonary Medicine	Dr. Pratayaksha	Dr. G Ramakrishna	Association of bronchial asthma severity with sputum eosinophil count and serum IgE level	Modify exclusion criteria
66	Pulmonary Medicine	Dr. Richa Arora	Dr. G Ramakrishna	To assess the levels of serum magnesium in diagnosed cases of chronic obstructive pulmonary disease at tertiary care center	Approved
67	Pulmonary Medicine	Dr. Devashish Verma	Dr. Mazher Maqsood	To assess the diagnostic role of pleural fluid cholesterol in categorizing type of pleural effusion	Modify methodology
68	Pulmonary Medicine	Dr. Aarif	Dr. Mazher Maqsood	The bacteriological profile and antibiotic sensitivity pattern in acute exacerbation of chronic obstructive pulmonary disease patients	Approved





INSTITUTIONAL ETHICS COMMITTEE

Ref. No.

TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

69	Orthopaedics	Dr. Vinish K Verma	Dr. Manmohan Sharma	Assessment and treatment of chronic low back pain with psychological impact: A prospective study	Approved
70	Orthopaedics	Dr. Divesh Singh	Dr. Manmohan Sharma	Assessment of disease activity score with respect to Vitamin D in rheumatoid arthritis: A observational study	Modify exclusion criteria
71	Orthopaedics	Dr. Aijaz A Ganai	Dr. Najmul Huda	Association between the clinical and MRI based outcome in patients of osteoarthritic knee treated with platelet rich plasma: A prospective study	Approved
72	Orthopaedics	Dr. Aditya Jha	Dr. Najmul Huda	Assessment of role of platelet rich plasma for healing of diaphyseal long bone fracture: A randomized control trial	Approved
73	Orthopaedics	Dr. Chetan Verma	Dr. Sudhir Singh	Association of serum COMP (cartilage oligomeric matrix protein) levels with various grades of knee osteoarthritis: A case-control study.	Approved
74	Orthopaedics	Dr. Lal Shrikant Kaushik	Dr. Sudhir Singh	Association of serum CTX-1 (carboxy terminal telopeptide 1) levels with various grades of knee osteoarthritis: A case-control study	Approved
75	Orthopaedics	Dr. Goushal Azam	: Dr. Ajay Pant,	Evaluation of platelet rich plasma as a therapeutic strategy in Kellgren and Lawrence grade IV osteoarthritis of knee	Approved
76	Orthopaedics	Dr. Ayush Singhal	: Dr. Ajay Pant,	To assess the association of age, body mass index (BMI), gender, duration of disease with functional improvement in patients of osteoarthritis knee treated with	Approved



**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

				platelet rich plasma: A prospective study	
77	Orthopaedics	Dr. Kapil Yadav	Dr. Amit Saraf	Occurrence of modifiable and non-modifiable risk factors of osteoporosis in adult population reporting to a tertiary health center: An interventional study	Approved
78	Orthopaedics	Dr. Nishank	Dr. Amit Saraf	To evaluate the neck disability in relation to physical activity among young adults with chronic neck pain reporting to a tertiary care hospital	Approved
79	Medicine	Dr. Aashima Walia	Dr. Vishvanayak	Association between non-alcoholic fatty liver disease and coronary artery disease	Approved
80	Medicine	Dr. Gaurav Singh Raghuvanshi	Dr. Jigar Haria,	Study of prognostic significance of terminal QRS complex distortion in acute ST elevated myocardial infarction(STEMI) at a tertiary care center	Approved
81	Medicine	: Dr. Aravind Sharma	Dr. Alok Singhal	To compare the effectiveness and safety of teneligliptin vs. glimepiride in patients with type 2 diabetes mellitus	Approved
82	Medicine	Dr. Aakrati Bansal	Dr. Bajrang Lal	To study the risk predictors in young patients presenting with acute coronary syndrome	Approved
83	Medicine	Dr. Anubhav Lalit	Dr. Soubhagya M,	Neck circumference as a marker for obesity and its association with metabolic syndrome	Update Exclusion criteria





INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

84	Medicine	Dr. Kajal	: Dr. Vishvanayak	Thyroid function abnormalities in critically ill patients	Approved
85	Medicine	Dr. Singam Sumeet K	Dr. Ajay Kumar	Study of thyroid profile abnormalities in patients with chronic kidney disease	Approved
86	Medicine	Dr. Jiwan Kumar	: Dr. Alok Singhal	Association between high density lipoprotein (HDL) and glycosylated hemoglobin (HbA1c) in type 2 diabetes mellitus patients undergoing angiography with acute coronary syndrome	Approved
87	Medicine	Dr. Sandhya Chauhan	Dr. Anand Dev	Assessment of dapagliflozin effectiveness as add-on therapy for the treatment of type 2 diabetes mellitus	Approved
88	Medicine	Dr. Sukriti Azad	Dr. Krishan Gopal	Comparison of acute physiological and chronic health evaluation score II (APACHE II) and Sequential organ failure assessment (SOFA) score as predictive tools in patients of sepsis	Approved
89	Medicine	Dr. Satyam Leekha	Dr. V K Singh	Association between serum uric acid level and angiographic severity of coronary artery disease using GENSINI score in patients undergoing coronary angiography	Revise exclusion criteria
90	Medicine	Dr. Anmol Gera	Dr. V K Singh	To evaluate the effectiveness of teneligliptin as an add-on therapy in type 2 diabetes mellitus (T2DM) patients inadequately controlled with a stable dose of metformin and glimepiride	Approved





INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

91	Medicine	Dr. Gaurav Kaushik	Dr. Jigar M Haria,	Estimation of serum zinc levels in patients of decompensated liver disease and its association with stages of hepatic encephalopathy	Approved
92	Medicine	Dr. Sushrut Gupta	Dr. Ajay Kumar	The outcome of direct-acting antiviral in treatment-naïve non-cirrhotic, chronic hepatitis-C infected patients in tertiary care center	Approved
93	Medicine	: Dr. Veeresh Kumar Dhanni	Dr. Krishan Gopal	Nucleated red blood cells: predictor of prognosis and mortality risk in critically ill patients	Approved
94	Radiodiagnosis	Dr. Mudit Jain	Dr. Sunil Kumar	Sonoelastographic evaluation of pelvic adnexal masses and its association with clinic-pathological findings	Approved
95	Radiodiagnosis	Dr. Akul Mohan	Dr. Vijai Pratap	Role of ultrasonography in diabetic nephropathy in patients with diabetes mellitus type II	Modify title, methodology
96	Radiodiagnosis	Dr. Soham Kapoor	Dr. Vijai Pratap	Role of ultrasound elastography in evaluation of quadriceps and patellar tendons in patients with knee pain with magnetic resonance imaging comparison	Modify title
97	Radiodiagnosis	Dr. Ayushi Chhabra	Dr. Ankur Malhotra,	Comparative evaluation of placental elasticity in normal pregnancy and pregnancy induced hypertension in second trimester and its association with uterine artery pulsatility index and fetal outcome	Approved





INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

98	Radiodiagnosis	Dr. Mrigank Amber	Dr. Ankur Malhotra	Comparative evaluation of Balthazar Index, Morte Index and revised Atlanta Classification in predicting severity of acute pancreatitis and their association with	Approved
99	Radiodiagnosis	Dr. Gaurav Patnayak	Dr. Rajul Rastogi	Comparative study of non-enhanced computed tomography (NECT) brain in acute cerebral venous sinus thrombosis (CSVT)	Approved
100	Radiodiagnosis	Dr. Sheetal Dhanda	Dr. Sunil Kumar	Role of first trimester uterine artery Doppler combined with mean arterial pressure in prediction of risk of pre-eclampsia and intrauterine growth retardation	Approved
101	Radiodiagnosis	Dr. Tanu	Dr. Shruti Chandak	Role of high resolution ultrasonography in evaluation of tibial and median nerve in diabetic peripheral neuropathy	Modify Methodology
102	Radiodiagnosis	Dr. Kirti	Dr. Madhu Sharma	Evaluation of gall bladder wall thickness with magnetic resonance imaging and ultrasonography for early detection of gall bladder malignancy	Approved
103	Radiodiagnosis	Dr. Yogendra	Dr. Shruti Chandak	Association of shear wave elastography values with grey scale ultrasonography grades for quantitative grading of nonalcoholic fatty liver disease	Modify Title
104	Radiodiagnosis	Dr. Anshul Jain	Dr. Madhu Sharma	Association of high resolution ultrasonography with magnetic resonance imaging in rheumatoid arthritis	Modify Title





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Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

105	Radiodiagnosis	Dr. Kush Dugad	Dr. Rajul Rastogi	Role of high resolution ultrasonography (HRUS) in Leprosy	Approved
106	Pharmacy	Purna Atray, Hina Parveen	Prof. Piyush Mittal	Utilization of inhalers in respiratory disease patients in tertiary care hospital- An observational study.	Approved
107	Pharmacy	Abhishek Jain, Gourav Jain, Divyanshi Rastogi, Raju	Sarita Jangra Bhyan	To study the prescribing pattern of antibiotics in patients of Septicemia and their correlation with culture sensitivity test in tertiary care hospital	Modify objectives
108	Pharmacy	Kartikey Pathak, Prakhar Jain, Saqib Rehan, Shubham Sarkar	Sarita Jangra Bhyan	An observational study on response to Fluvoxamine and Sertraline on patients with OCD at tertiary care teaching hospital in western U.P.	Approved
109	Pharmacy	Shraddha Tiwari, Nidhila Saji	Prof. Piyush Mittal	Study of Adverse events following immunization in children receiving vaccination at tertiary care hospital.	Approved
110	Pharmacy	Sadaf Saifi, Trishya Mishra	Prof. Piyush Mittal	Study of medication adherence " Self efficacy and medicine taking behavior of stroke patients	Approved
111	Pharmacy	Indradeep Yadav, Shubham Gangawat, Paluck, Pankaj Negi	Sarita Jangra Bhyan	Occurrence study of safety of antiepileptic drugs at tertiary care teaching hospital. An observational study	Modify title
112	Pharmacy	Snigdha Banerjee, Dishant Pawar	Mr. Rishi Kapoor Poddar	Study of Prescription pattern of antidepressants at tertiary care teaching hospital	Modify outcome measures

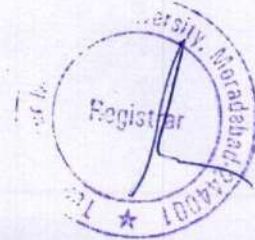


**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

113	Pharmacy	Anjali, Vibhor Aggarwal, Mohd Tousib	Dr. Ashish Akshay Bedi	Drug Utilization study of antidiabetic drugs and extend of usage of newer antidiabetic drugs in a tertiary care hospital	Approved
114	Pharmacy	Shree Ram Yadav, Rajkumar, Laxman Thapa, Abdul Malik	Prof. Piyush Mittal	Drug Utilization evaluation of antibiotics at Surgery department in tertiary care hospital	Approved
115	Pharmacy	Kaivalya R. Pillai, Pankhuri Jain, Hashim Khan	Dr. Ashish Akshay Bedi	Drug utilization study of antitubercular drugs and role of newer agents in tuberculosis at tertiary care	Approved
116	Anatomy	Saurabh Chaudhary	Dr. Supriti Bhatnagar	Relationship between quadriceps angle (Q Angle) with body parameters in sedentaries and sportspersons	Modify case definitions
117	Physiology	Bhavna	Dr. Ritu Adhana	Immediate effect of short duration of slow deep breathing on autonomic parameters in healthy young adults	Approved
118	Physiology	Rovins Kumar	Dr. Jayballabh Kumar	To study the association of body mass index with sympathetic function in young male adults.	Approved
119	Microbiology	Ayushi Jain	Dr. Umar Farooq	Frequency of candida infection among intensive care unit patients and their susceptibility profile	Approved
120	Microbiology	Lalman	Dr. Sudhir Singh	Study of viral markers (human immunodeficiency virus, HBsAg, and anti-HCV) among pregnant women attending the antenatal clinica	Approved
121	Microbiology	Manisha	Dr. Sudhir Singh	Occurrence of dengue infected patients in a tertiary care center	Approved



**INSTITUTIONAL ETHICS COMMITTEE**

Ref. No. TMMC&RC/IEC MOM/19-20/167

Dated : 09/12/2019

122	Microbiology	Mohd Junaid	Dr. Sudhir Singh	Bacterial profile of diabetic foot infection in a tertiary care center	Approved
123	Microbiology	Mohd Zulfikar	Dr. Shweta R Sharma	Speciation of candida species isolated from patients with esophageal candidiasis and their antifungal susceptibility test to flucanazole	Approved
124	Microbiology	Navdeep Singh	Dr. Shweta R Sharma	Frequency of hepatitis E virus infection in patients with acute hepatitis	Approved
125	Microbiology	Rounak Chahal	Dr. Shweta R Sharma	Determination of anti-streptolysin O titer in suspected cases of streptococcal infection in pediatric population	Approved
126	Microbiology	Somya Shukla	Dr. Vasundhra S	Comparison of bacterial urinary tract infection in non-catheterized and catheterized patients and their antibiogram	Approved
127	Microbiology	Versha	Dr. Vasundhra S	To determine the resistance pattern of Staphylococcus aureus in pus samples	Approved
128	Microbiology	Pallavi Chitrans	Dr. Vasundhra S,	Bacterial profile and their antibiogram from endotracheal aspirate and bronchoalveolar lavage fluid samples from intensive care unit patients	Approved





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Ref. No. TMMC&RC/IEC MOM/19-20/167 Dated : 09/12/2019

129	Obstetrics & Gynaecology	Dr. Poonam Singh	Ovarian rejuvenation with injections of PRP in ovary in women with poor ovarian reserve	Include tumour markers consent modify
130	Pharmacy	Mr. Bhupinder Singh	Plasma level – Time study of prepared double layer sublingual films containing piroxicam and zolmitriptan in healthy human volunteers.	Approved

The meeting ended with thanks to the chair.

Dr. Dr. Anil Kumar Tripathi
Chairperson I.E.C,
TMMC&RC, Moradabad

Dr. Najmul Huda
Additional Dean Academics & Member Secretary
I.E.C, TMMC&RC, Moradabad

Copy to:

- Director Admin (TMU)
- Principal, TMMC&RC, Moradabad
- All HODs, TMMC&RC, Moradabad
- All members of I.E.C.





TEERTHANKER MAHAVEER MEDICAL COLLEGE & RESEARCH CENTRE

Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No. TMMC&RC/IEC MOM/18-19/48

Dated : 27/12/2018

Subject: Minutes of Ethics Committee Meeting (held on 21/12/2018 & 22/12/2018)

A meeting of Institutional Ethics Committee was held on 21/12/2018 & 22/12/2018 at 09:15 AM in the conference Room, Teerthanker Mahaveer Hospital & Research Centre, TMU, Moradabad.

Following members were present in the meeting:

S. No.	Name	Designation
1.	Dr. Anil Kumar Tripathi	Chairperson
2.	Dr. Najmul Huda	Member Secretary
3.	Dr. Ajay Pant	Member
4.	Dr. Sangeeta Kapoor	Member
5.	Dr. G.S. Jheetay	Member
6.	Dr. Meghanand Nayak	Member
7.	Dr. D.S. Gupta	Member

Agenda: The protocols of the following research projects (including theses protocol/dissertation of PG/Ph.D. and M.Sc. Students were discussed regarding suitability for ethical clearance:





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Dated :

27/12/2018

S. No	Department	Candidate Name	Title	Guide	Suggestions	Remarks of Ethical Committee
1.	Anaesthesia	Dr. Niranjan Reddy	"COMPARISON OF TWO DIFFERENT CONCENTRATIONS OF ROPIVACAINE 0.25% AND 0.5% FOR POST OPERATIVE ANALGESIA IN INGUINAL HERNIA REPAIR-A PROSPECTIVE RANDOMIZED STUDY"	Dr. Mukesh Prasad, Assoc. Prof. Department Of Anaesthesia		Approved
2.	Anaesthesia	Dr. Shristi Srivastava	"A PROSPECTIVE RANDOMISED STUDY COMPARING I-GEL AND PROSEAL LARYNGEAL MASK AIRWAY BY FIBEROPTIC BRONCHOSCOPY IN ANAESTHETISED ADULTS UNDERGOING ELECTIVE SURGERY"	Dr. Pramod Kumar Professor, Department Of Anaesthesia	• Modify title	
3.	Anaesthesia	Dr. Razi Shahid	"A PROSPECTIVE RANDOMIZED STUDY TO COMPARE LEVOBUPIVACAINE AND ROPIVACAINE IN PATIENTS UNDERGOING FOREARM ORTHOPAEDIC SURGERIES UNDER ULTRA SOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK"	Dr G.S. Jeetay Prof. & HOD Department Of Anaesthesia	• Modify Participant information sheet.	
4.	Anaesthesia	Dr. Aditya Samudrala	"A COMPARATIVE STUDY OF MEDICAL GRADE AIR-OXYGEN PROPOFOL AND NITROUS OXIDE-OXYGEN PROPOFOL IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY UNDER GENERAL ANAESTHESIA."	Dr G.S. Jeetay Prof. & HOD Department Of Anaesthesia	• Modify Participant information sheet.	
5.	Anaesthesia	Dr. Vikramaditya.N	"COMPARISON OF TRANSVERSUS ABDOMINIS PLANE BLOCK WITH ILIOINGUINAL AND ILIOHYPOGASTRIC NERVE BLOCKS 'USG GUIDED IN HERNIORRAPHY FOR POSTOPERATIVE ANALGESIA"	Dr. Pallavi Ahluwalia Professor, Department Of Anaesthesia	• Modify Participant information sheet.	
6.	Anaesthesia	Dr. Sangeeth.S	"A COMPARATIVE STUDY OF INFRAINGUINAL VERSUS SUPRAINGUINAL APPROACH OF FASCIA ILIACA COMPARTMENT BLOCK FOR POSTOPERATIVE ANALGESIA IN HIP SURGERIES."	Dr. Pallavi Ahluwalia Professor, Department Of Anaesthesia	• Sample size calculation to be done.	
7.	Obstetrics & Gynecology	Dr. Pavitra Singh	CLINICAL ASSOCIATION OF CASES OF ABNORMAL UTERINE BLEEDING(AUB) ACCORDING TO PALM – COEIN CLASSIFICATION	Dr. Nupur Nandi Professor Department Of Obstetrics & Gynaecology		Approved





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8.	Obstetrics & Gynecology	Dr. Priyanka Rathore	ASSOCIATION OF VAGINAL INFECTION IN PRETERM LABOR AND PRETERM PREMATURE RUPTURE OF MEMBRANES	Dr. Nupur Nandi Professor Department Of Obstetrics & Gynaecology	• Replace patient Information Sheet	
9.	Obstetrics & Gynecology	Dr. Nivedita Chawla	COMPARATIVE STUDY OF ORMELOXIFENE VERSUS MEDROXYPROGESTERONE ACETATE IN ABNORMAL UTERINE BLEEDING IN PERIMENOPAUSAL WOMEN.	Dr. Rehana Najam Professor Department Of Obstetrics & Gynaecology	• Tests of Significance to be applied.	
10.	Obstetrics & Gynecology	Dr. Swati Jain	COMPARATIVE STUDY OF METFORMIN VERSUS MYOINOSITOL IN POLYCYSTIC OVARIAN SYNDROME'	Dr. Rehana Najam Professor Department Of Obstetrics & Gynaecology	• Tests of Significance to be applied.	
11.	Obstetrics & Gynecology	Dr. Bishakha Chamua	PLACENTATION AND INTRAOPERATIVE COMPLICATIONS IN WOMEN WITH 2 OR MORE PREVIOUS CAESAREAN SECTIONS UNDERGOING REPEAT CAESAREAN SECTION	Dr. Hema Dhumale Professor & HOD Department Of Obst.& Gynaecology		Approved
12.	Obstetrics & Gynecology	Dr. Charu Gupta	"TO ASSESS THE ASSOCIATION OF HYPOTHYROIDISM WITH PREGNANCY INDUCED HYPERTENSION (PIH)."	Dr. Hema Dhumale Professor & HOD Department Of Obst.& Gynaecology	• Modify exclusion criteria • Test of significance.	
13.	Paediatrics	Dr. Neeraj	CLINICAL AND BACTERIOLOGICAL PROFILE IN SEPSIS IN LOW BIRTH WEIGHT NEONATES	Dr. K.P. Dutta Professor, Department Of Paediatrics		Approved
14.	Paediatrics	Dr. Sambhav Jain	OCCURRENCE OF THROMBOCYTOPENIA AND ITS ASSOCIATED MATERNAL AND NEONATAL RISK FACTORS AND OUTCOME AMONGST NEONATES ADMITTED TO NEONATAL INTENSIVE CARE UNIT(NICU) AT A TERTIARY CARE CENTRE	Dr. K.P. Dutta Professor, Department Of Paediatrics	• Modify title.	
15.	Paediatrics	Dr. Venkatesh Badugu	STUDY OF CLINICAL PROFILE AND SEVERITY OF MALARIA IN HOSPITALISED CHILDREN	Dr. Santosh Bhalke Department Of Paediatrics	• Modify exclusion criteria	
16.	Paediatrics	Dr. Keshawati	TO STUDY THE CLINICAL SPECTRUM AND FREQUENCY OF GLUCOSE 6 PHOSPHATE DEHYDROGENASE DEFICIENCY IN NEONATES WITH HYPERBILIRUBINEMIA.	Dr. Santosh Bhalke Department Of Paediatrics		Approved





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17.	Paediatrics	Dr. Abhishek Yadav	FACTORS AFFECTING REBOUND INCREASE IN BILIRUBIN LEVELS AFTER STOPPING PHOTOTHERAPY IN NEONATAL HYPERBILIRUBINEMIA	Dr. (BRIG) Ashok Saxena Professor Department Of Paediatrics		Approved
18.	Paediatrics	Dr. Jivesh Loona	TO ASSESS THE IMMUNIZATION STATUS AS REGARDS BCG,OPV,DPT AND MEASLES AND FACTORS AFFECTING IT IN CHILDREN (9MONTHS— 6YEARS) ATTENDING OPD/IPD SERVICES OF PAEDIATRIC DEPARTMENT AT TMMC&RC, MORADABAD	Dr. (BRIG) Ashok Saxena Professor Department Of Paediatrics		Approved
19.	Paediatrics	Dr. Monika Khari	TO STUDY THE OCCURRENCE OF CHILDHOOD HYPERTENSION IN SCHOOL GOING CHILDREN ATTENDING PEDIATRICS OPD IN TEERTHANKER MAHAVEER MEDICAL COLLEGE & RESEARCH CENTRE MORADABAD	Dr. Anshuman Srivastava Associate, Professor Department Of Paediatrics		Approved
20.	Pathology	Dr. Ina Garg	CORRELATION OF SERUM ADA LEVELS IN CYTOLOGICALLY SUGGESTED CASES OF TUBERCULAR LYMPHADENITIS.	Dr. Seema Awasthi Professor Department Of Pathology	• Include details of exclusion criteria.	
21.	Pathology	Dr. Vivek Mohan	HEMATOLOGICAL AND BIOCHEMICAL PARAMETERS IN PRE AND POST PLATELETPHERESIS DONORS	Dr. Shyamoli Dutta Professor & Hod	• Modify the inclusion criteria. • Information sheet and consent form not accrding to the study.	
22.	Pathology	Dr.Apexa Suman	CLINICOPATHOLOGICAL ASSOCIATION OF GASTRODUODENAL DISEASES BY GASTRODUODENOSCOPY AND BIOPSY	Dr. Shyamoli Dutta Professor & Hod	• Modify title • Informed consent form	
23.	Pathology	Dr. Kanika Kapoor	TO STUDY OF EFFECT OF GLYCEMIC CONTROL ON PLATELET INDICES IN PATIENTS OF TYPE 2 DIABETES MELLITUS.	Dr. Seema Awasthi Professor Department Of Pathology	• Modify title, objectives and methodology	
24.	Otorhinolaryngology	Dr. Rajat Kumar	"A CLINICOPATHOLOGICAL CO-RELATION OF LUDWIG'S ANGINA IN A TERTIARY CARE CENTRE"	Dr.KVK Sudhankar Associate Professor Of ENT Department Of Otorhinolaryngology		Approved





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25.	Otorhinolaryngology	Dr. Akanksha Ken	"COMPARATIVE STUDY OF ENDOSCOPE ASSISTED ADENOIDECTOMY BY MICRODEBRIDER AND CURETTE METHOD"	Dr.S.M. Tripathy Associate Professor, Department Of Otorhinolaryngology		Approved
26.	Otorhinolaryngology	Dr. Mohini Tyagi	ASSOCIATION BETWEEN REFLUX SYMPTOM INDEX AND REFLUX FINDING SCORE IN PATIENTS WITH LARYNGOPHARYNGEAL REFLUX	Dr. Probal Chatterji Professor & Head Of Department Of Otorhinolaryngology		Approved
27.	Otorhinolaryngology	Dr. Moumita Sen	SCREENING OF HIGH RISK INFANTS FOR HEARING LOSS IN A TERTIARY CARE HOSPITAL IN WESTERN U.P.	Dr. Probal Chatterji Professor & Head Of Department Of Otorhinolaryngology		Approved
28.	General Medicine	Dr. Aarish Gujar	STUDY OF THE OCCURRENCE AND PROGNOSTIC SIGNIFICANCE OF HYPONATREMIA IN ACUTE MYOCARDIAL INFARCTION	Dr.Vishvanayak Professor, Department Of General Medicine		Approved
29.	General Medicine	Dr. Rahul Roy	EVALUATION OF THYROID PROFILE IN PATIENTS WITH CIRRHOSIS OF LIVER	Dr. A.J. Dhumale Professor, Department Of General Medicine		Approved
30.	General Medicine	Dr. Mohd. Zishan Khan	"STUDY ON THE ASSOCIATION BETWEEN HYPERURICEMIA AND ALBUMINURIA IN PATIENTS WITH TYPE-2 DIABETES MELLITUS"	Dr. V.K. Singh Professor & HOD, Department Of General Medicine		Approved
31.	General Medicine	Dr. Sumit Verma	"COMPARISON OF BLOOD PRESSURE VARIABILITY AND SAFETY OF TELMISARTAN VS AMLODIPINE IN NEWLY DIAGNOSED HYPERTENSIVES"	Dr. V.K. Singh Professor & HOD, Department Of General Medicine	• Only new patients to be included.	
32.	General Medicine	Dr. Kamal Mavi	"ESTIMATION OF VITAMIN D LEVEL IN PATIENTS OF CHRONIC LIVER DISEASE & ITS ASSOCIATION WITH CHILD TURCOTTE PUGH'S SCORE"	Dr. Ajay Kumar Professor, Department Of General Medicine	• Statistical test to be included	
33.	General Medicine	Dr. Shubhankit Arya	TO STUDY THE ASSOCIATION OF NON ALCOHOLIC FATTY LIVER DISEASE (NAFLD) WITH DIASTOLIC DYSFUNCTION IN TYPE 2 DIABETES MELLITUS PATIENTS	Dr. Mukesh Aggarwal Professor, Department Of General Medicine	• Modify participant's information sheet.	





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34.	General Medicine	Dr. Abhishek Singh	STUDY OF MICROVASCULAR COMPLICATIONS IN PATIENTS WITH NEWLY DIAGNOSED TYPE II DIABETES MELLITUS	Dr. Vishvanayak Professor, Department Of General Medicine	Should know the details of all investigations.	
35.	General Medicine	Dr. Husna Shamim	TO STUDY THE CORRELATION OF QTC DISPERSION WITH THE SEVERITY OF CORONARY ARTERY DISEASE DETECTED BY SYNTAX SCORE IN PATIENTS WITH ACUTE ST ELEVATION MYOCARDIAL INFARCTION.	Dr. Alok Singhal Professor, Department Of General Medicine		Approved
36.	General Medicine	Dr. Deepanker Shivam	TO PREDICT THE OCCURRENCE OF ESOPHAGEAL VARICES IN CLD PATIENTS USING TRANSIENT ELASTOGRAPHY [FIBROSCAN].	Dr. Jigar M. Haria Professor, Department Of General Medicine		Approved
37.	General Surgery	Dr. Vishnu Sanker	A STUDY OF SINGLE-LAYER CONTINUOUS VERSUS TWO-LAYER INTERRUPTED INTESTINAL ANASTOMOSIS	Dr. N.K. Singh Professor, Department Of General Surgery	Statistical test to be included.	
38.	General Surgery	Dr. Sunil Kumar Tiwari	COMPARISON OF CONTINUOUS VERSUS INTERRUPTED ABDOMINAL FASCIA CLOSURE IN PATIENT OF PERFORATION PERITONITIS USING NON-ABSORBABLE SUTURE	Dr. N.K. Singh Professor, Department Of General Surgery	Participant's information sheet & consent form to be modified as per the study.	
39.	General Surgery	Dr. Aviral Gupta	A STUDY OF FACTORS AFFECTING CONVERSION OF LAPAROSCOPIC CHOLECYSTECTOMY INTO OPEN CHOLECYSTECTOMY.	Dr. S.P. Sinha Prof. & Head, Dept. Of General Surgery	Modify patients information sheet & consent form	
40.	General Surgery	Dr. Vibhor Agarwal	CLINICO-RADIOLOGICAL PRESENTATION AND MANAGEMENT OF VARICOSE VEINS OF LOWER LIMB	Dr. P.D. Poonekar Professor		Approved
41.	General Surgery	Dr. Vikram Singh Yadav	TO STUDY OCCURENCES OF INTRA OPERATIVE DIFFICULTIES IN LAPAROSCOPIC CHOLECYSTECTOMY & THEIR POST OPERATIVE OUTCOMES	Dr. Col. M.S. Chahal (Vsm)	- Methodology to be modified. - No Grading /Scaling.	
42.	General Surgery	Dr. Shakshi Jaiswal	"A COMPARATIVE STUDY BETWEEN TRANS-ABDOMINAL PRE PERITONEAL REPAIR (TAPP) AND OPEN INGUINAL HERNIA REPAIR (LICHENSTEIN) IN TEERTHANKER MAHAVEER MEDICAL COLLEGE AND RESEARCH CENTER"	Dr. S.C. Sharma Asst. Professor Department Of General Surgery	Modify patients information sheet & consent form	





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27/12/2018

43.	General Surgery	Dr. Richa	ASSESSMENT OF SURGICAL SITE INFECTIONS IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY IN TEERTHANKER MAHAVEER MEDICAL COLLEGE & RESEARCH CENTRE	Dr. S.P. Sinha HOD & Professor Department Of Surgery		Approved
44.	General Surgery	Dr. Abdul Qadir	TO STUDY THE OCCURRENCE OF COMMON BILE DUCT STONES IN PATIENTS OF CHOLELITHIASIS AND THEIR COMPLICATIONS	Dr. Desh Diwaker Mittal Professor Department Of Surgery		Approved
45.	General Surgery	Dr. Sunil Kumar Singh	ASSOCIATION OF ACUTE PHYSIOLOGY AND CHRONIC HEALTH EVALUATION (APACHE II) SCORE WITH SURGICAL OUTCOME IN THE PATIENTS OF PERFORATION PERITONITIS.	Dr. Sanjay Sharma Professor, Mbbs, Ms (General Surgery)		Approved
46.	Ophthalmology	Dr. Priyadarshini	TO STUDY GLAUCOMA – AWARENESS, KNOWLEDGE AND ATTITUDE TO SCREENING IN PATIENTS OF WESTERN UTTAR PRADESH	Dr. Jaya Devendra Professor And Head Department Of Ophthalmology		Approved
47.	Ophthalmology	Dr. Ranjot Kour	"EVALUATION OF MACULAR AND RETINAL NERVE FIBRE LAYER THICKNESS IN UNILATERAL AMBLYOPIC PATIENTS USING OPTICAL COHERENCE TOMOGRAPHY"	Dr. Jaya Devendra Professor And Head Department Of Ophthalmology		Approved
48.	Ophthalmology	Dr. Prachi Rathore	"EFFECT OF CATARACT SURGERY ON MACULAR THICKNESS IN DIABETIC PATIENTS"	Dr. Jaya Devendra Professor And Head Department Of Ophthalmology		Approved
49.	Ophthalmology	Dr. Vineet Choudhary	TO STUDY THE PATTERN OF OCULAR MORBIDITY IN SCHOOL GOING CHILDREN IN WESTERN UTTAR PRADESH	Dr. Ashish Chander Professor Of Ophthalmology		Approved
50.	Psychiatry	Dr. Tarun Yadav	A STUDY ON ATTEMPTED SUICIDE : CORRELATES WITH STRESS , PSYCHIATRIC COMORBIDITY AND SUBSEQUENT SUICIDAL RISK	Dr. Prerana Gupta Md Psychiatry	• Modify the inclusion criteria.	
51.	Psychiatry	Dr. Shweta Singh	A STUDY OF VITAMIN B12 LEVELS IN PATIENTS SUFFERING FROM BIPOLAR DISORDER AND OBSESSIVE COMPULSIVE DISORDER. .	Dr. S.Nagendran/Dr. Prerana Gupta	• Include Co-guide from Biochemistry department.	





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Dated : 27/12/2018

52.	Psychiatry	Dr. Kashypi Garg	TO ASSESS THE ATTITUDE OF EMERGENCY HEALTHCARE PROFESSIONAL TOWARDS THE PATIENTS OF PSYCHIATRIC ILLNESS, AND ITS IMPACT AS PERCEIVED BY THE SERVICE USERS: AN ANALYSIS OF SOCIO-CULTURAL TRENDS	Dr.S Nagendran MD, H.O.D, Department Of Psychiatry		Approved
53.	Psychiatry	Dr. Ishan Koushal	ESTIMATION OF C-REACTIVE PROTEIN LEVELS AND STUDY OF THEIR SIGNIFICANCE IN PATIENTS OF BIPOLAR DISORDERS	Dr. S Nagendran MD, H.O.D, Department Of Psychiatry		Approved
54.	DVL	Dr.Harshita Jain	A STUDY OF CLINICO - EPIDEMIOLOGICAL PROFILE OF FACIAL DERMATOSES IN A TERTIARY CARE HOSPITAL IN WESTERN UP	Dr.(LT Col) K S Dhillon Professor, Department Of DVL		Approved
55.	DVL	Dr.Deepak	A STUDY OF CLINICAL PROFILE OF CUTANEOUS MANIFESTATIONS IN GERIATRIC POPULATION IN A TERTIARY CARE HOSPITAL IN WESTERN UP	Dr.(LT Col) K S Dhillon Professor, Department Of DVL		Approved
56.	DVL	Dr. Abhyuday Tiwari	STERIOD MODIFIED TINEA CORPORIS : A CLINICAL STUDY OF UNUSUAL/ATYPICAL PATTERNS	Dr.Sanath Aithal Professor, Department Of DVL	• Modify inclusion criteria.	
57.	DVL	Dr. Naina	GLYCOLIC ACID PEEL (35%) AND SALICYLIC ACID PEEL (30%) IN MELASMA: A COMPARATIVE EVALUATION AND IMPACT ON QUALITY OF LIFE	Dr.Sanath Aithal Professor, Department Of DVL		Approved
58.	Pulmonary Medicine	Dr.Tushar	TO STUDY THE DIAGNOSTIC PROFILE OF COMMUNITY ACQUIRED PNEUMONIA IN HOSPITALIZED PATIENT IN TERTIARY CARE CENTRE AT TMMC & RC	Dr. Mazher Maqsood Associate Professor, Department Of Pulmonary Medicine		Approved
59.	Pulmonary Medicine	Dr. Kunal Kumar	TO EVALUATE THE DIAGNOSTIC YIELD OF CARTRIDGE BASED NUCLEIC ACID AMPLIFICATION TEST (CB NAAT) COMPARED TO OTHER METHODS FOR DIAGNOSIS OF TUBERCULOUS LYMPHADENITIS	Dr. Sanjay Sahay Department Of Pulmonary Medicine		Approved
60.	Pulmonary Medicine	Dr. Sanchit Periwal	TO STUDY THE DIAGNOSTIC YIELD OF PLEURAL FLUID ADENOSINE DEAMINASE (ADA) COMBINED WITH LYMPHOCYTIC/NEUTROPHIL (L/N) RATIO IN TUBERCULAR PLEURAL	Dr. G Ramakrishna, Professor & HOD Department Of Pulmonary		Approved





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			EFFUSION AT TERTIARY CARE CENTER	Medicine		
61.	Pulmonary Medicine	Dr. Saurabh Tomar	THE ASSESSMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE SEVERITY BY USING MULTIDIMENSIONAL GRADING SYSTEM (BODE INDEX) AS A PREDICTOR IN A TERTIARY CARE HOSPITAL	Dr. G Ramakrishna, Professor & HOD Department Of Pulmonary Medicine		Approved
62.	Orthopaedics	Dr. Ankur Agarwal	AGE AND GENDER DIFFERENCES IN MODIFIED FEMORAL NECK-SHAFT ANGLE: AN MRI BASED OBSERVATIONAL STUDY.	Dr. (LT GEN) B.K. Copra Department Of Orthopaedics	- Elaborate in rationale the advantages of knowing the angle. - Modify consent form and include Hindi form also with details of objectives of study.	
63.	Orthopaedics	Dr. Shubham Aggarwal	TO ASSESS THE FUNCTIONAL AND RADIOLOGICAL OUTCOMES IN PATIENTS OF MEDIAL COMPARTMENT OSTEOARTHRITIS OF KNEE UNDERGOING MEDIAL OPEN WEDGE HIGH TIBIAL OSTEOTOMY.	Dr. Najmul Huda Professor, Department Of Orthopaedics	Highlight the importance of technique to patient in patient information sheet.	
64.	Orthopaedics	Dr. Aashish	ASSESSMENT OF FUNCTIONAL AND RADIOLOGICAL OUTCOME IN PATIENTS WITH PROXIMAL HUMERUS FRACTURE MANAGED BY PROXIMAL HUMERUS LOCKING COMPRESSION PLATE	Dr. Amit Saraf Department Of Orthopaedics	Modify exclusion criteria.	
65.	Orthopaedics	Dr. Ravi Dholariya	CLINICO-RADIOLOGICAL OUTCOME OF DISPLACED INTRACAPSULAR FRACTURE NECK OF FEMUR IN ADULTS MANAGED BY OSTEOSYNTHESIS AND PRIMARY VALGUS INTERTROCHANTERIC OSTEOTOMY: A PROSPECTIVE STUDY	Dr. Ajay Pant HOD, Department Of Orthopaedics		Approved
66.	Orthopaedics	Dr. Sudhir Bheri	TO ASSESS THE AGE AND GENDER DIFFERENCE IN TIBIO-FEMORAL ANGLE IN CHILDREN BETWEEN 2-10 YEARS OF AGE: AN OBSERVATIONAL STUDY.	Dr. Najmul Huda Professor, Department Of Orthopaedics	Modify source of data, modify informed consent form.	
67.	Orthopaedics	Dr. Vikas Verma	CLINICO-RADIOLOGICAL ASSESSMENT OF DISTAL END RADIUS FRACTURES: A PROSPECTIVE STUDY	Dr. Man Mohan Sharma Associate Professor Department Of Orthopaedics		Approved





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68.	Orthopaedics	Dr. Abhinav Bhardwaj	CLINICORADIOLOGICAL OUTCOME OF PATIENT WITH TRANSVERSE PATELLA FRACTURE MANAGED BY MODIFIED TENSION BAND WIRING USING CANNULATED CANCELLOUS SCREW: A PROSPECTIVE STUDY	Dr. (LT GEN) B.K. Copra Department Of Orthopaedics	Calculate Sample size	
69.	Orthopaedics	Dr. Aditya Jain	COMPARISON OF THE CLINIC RADIOLOGICAL OUTCOME OF INTRAMEDULLARY NAILING VERSUS PLATING IN DISPLACED MID CLAVICULAR FRACTURE: A RANDOMIZED PROSPECTIVE STUDY	Dr. Ajay Pant HOD, Department Of Orthopaedics	- Modify rationale - Modify consent form	
70.	Orthopaedics	Dr. Manish Singhal	CLINIC-RADIOLOGICAL OUTCOME AFTER SURGICAL INTERVENTION IN BIMALLEOLAR ANKLE FRACTURE: A PROSPECTIVE ON RETROSPECTIVE STUDY.	Dr.Amit Saraf Department Of Orthopaedics	Modify title	
71.	Radiodiagnosi s	Dr.Nitya Verma	COMPARATIVE ROLE OF COMPUTED TOMOGRAPHY AND MAGNETIC RESONANCE IMAGING IN UROLOGICAL CONDITION	Dr.Vijay Pratap Professor &Head Department Of Radiodiagnosis	Include phone number in consent form.	
72.	Radiodiagnosi s	Dr. Abhishek Kumar Singh	COMPARISON OF HIGH RESOLUTION ULTRASONOGRAPHY AND MAGNETIC RESONANCE IMAGING IN PAINFUL WRIST JOINT	Dr.Vijay Pratap Professor &Head Department Of Radiodiagnosis	- Include the list of indications for MRI - Calculate sample size	
73.	Radiodiagnosi s	Dr. Neha	ROLE OF SPLENIC STIFFNESS IN PREDICTING ESOPHAGEAL VARICES IN PORTAL HYPERTENSION	Dr.Rajul Rastogi Associate Professor Department Of Radiodiagnosis	- To consider acute hematemesis in patient proforma (as it affects the splenic size) subgroup - Hepatic - Extra hepatic	
74.	Radiodiagnosi s	Dr. Vivak Bhandari	"COMPARATIVE EVALUATION OF COMPUTED TOMOGRAPHY (CT) AND MAGNETIC RESONANCE IMAGING (MRI) THORAX IN EVALUATION OF PULMONARY AIRSPACE DISEASE."	Yeslawath Professor, Department Of Radiodiagnosis	Inclusion criteria may restricted. Including the indications. Both modalities in each patient.	
75.	Radiodiagnosi s	Dr. Sumit Kaushik	ROLE OF SONOGRAPHY & SONOELASTOGRAPHY IN CHARACTERISATION OF CERVICAL LYMPHADENOPATHY WITH PATHOLOGICAL ASSOCIATION	Dr. Abhishek Aggarwal Professor Department Of Radiodiagnosis	Modify rationale of the study	





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Delhi Road, Moradabad (U.P)

INSTITUTIONAL ETHICS COMMITTEE

Ref. No.

TMMC&RC/IEC MOM/18-19/48

Dated :

27/12/2018

76.	Radiodiagnosi s	Dr. Deepak Singla	CT ENTEROGRAPHY USING DIFFERENT ENDOLUMINAL CONTRAST AGENTS : A COMPARATIVE STUDY	Dr. Shruti Chandak Profesor Department Of Radiodiagnosis		Approved
77.	M.D. Radiodiagnosi s	Dr. Vaibhav Khare	" COMPARATIVE STUDY OF MAGNETIC RESONANCE IMAGING (MRI) & COLONOSCOPY IN EVALUATION OF COLORECTAL DISEASES"	Dr. Nitish Kumar Yeslawath Professor, Department Of Radiodiagnosis		Approved
78.	Radiodiagnosi s	Dr. Atul Pratap Singh	ROLE OF HIGH RESOLUTION ULTRASONOGRAPHY IN EVALUATION OF KNEE JOINT PATHOLOGIES WITH MAGNETIC RESONANCE IMAGING ASSOCIATION	Dr. Shruti Chandak Profesor Department Of Radiodiagnosis	• Rewrite the aim.	
79.	Radiodiagnosi s	Dr. Ashwani Jain	A PROSPECTIVE STUDY TO ASSESS DISEASE ACTIVITY IN PATIENTS OF PULMONARY TUBERCULOSIS BY HIGH RESOLUTION COMPUTED TOMOGRAPHY..	Dr. Abhishek Aggarwal Professor Department Of Radiodiagnosis	• Modify study titles and AIMS.	
80.	M.Sc. Microbiology	Pradeep Kumar	OCCURRENCE OF BRUCELLOSIS IN PATIENTS OF PYREXIA OF UNKNOWN ORIGIN (PUO)	Dr. Shweta R. Sharma, Dr. Jigar Haria Dr. Vasundhara Sharma		Approved
81.	M.Sc. Microbiology	Sanil Yadav	OCCURRENCE OF INTESTINAL PARASITIC INFESTATION IN PATIENTS SUFFERING FROM GASTRO-INTESTINAL DISTURBANCES.	Dr. Sudhir Singh Dr. Jigar Haria Dr. Vasundhara Sharma		Approved
82.	M.Sc. Microbiology	Ashu Rajput	STUDY OF MICROBIAL CONTAMINATION OF MOBILE PHONES OF HEALTH CARE WORKERS	Dr. Umar Farooq Dr. Nitali Arun		Approved
83.	M.Sc. Microbiology	Anas Altaf	OCCURRENCE OF DERMATOPHYTES AND OTHER FUNGAL AGENTS IN CLINICALLY SUSPECTED CASES OF SUPERFICIAL MYCOSIS.	Dr. Umar Farooq Dr. Vasundhara Sharma Dr. Dilip Meena		Approved
84.	M.Sc. Microbiology	Pravendra Kumar	OCCURRENCE OF MALARIA POSITIVE CASES AND THEIR ASSOCIATION WITH KIDNEY FUNCTION TEST IN DIFFERENT AGE GROUPS	Dr. Shwetank Goel		Approved





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85.	M.Sc. Microbiology	Mush Bar Fatma	SPECTRUM OF ORGANISMS ISOLATED FROM SURGICAL SITE INFECTION AND THEIR ANTIMICROBIAL SUSCEPTIBILITY PROFILE.	Dr. Sudhir Singh Dr. S.C. Sharma Dr. Nitali Arun		Approved
86.	M.Sc. Microbiology	Sunil Gautam	OCCURRENCE AND PATTERN OF HEPATITIS A AMONG PATIENTS WITH SUGGESTIVE SYMPTOMS OF HEPATITIS	Dr. Sudhir Singh Dr. Amit Mishra Dr. Nitali Arun		Approved
87.	M.Sc. Microbiology	Chaman Parveen	STUDY OF RICKETTSIA INFECTION IN PATIENTS SUFFERING FROM FEVER OF UNKNOWN ORIGIN.	Dr. Shweta R. Sharma Dr. V.K. Singh Dr. Vasundhara Sharma		Approved
88.	M.Sc. Microbiology	Pragati Devi	STUDY OF OCCURRENCE OF ENVELOPE ANTIGEN AMONG HEPATITIS B SURFACE ANTIGEN POSITIVE CASES	Dr. Shweta R. Sharma Dr. Amit Mishra Dr. Nitali Arun		Approved
89.	M.Sc. Biochemistry	Ruchira Dubey	STUDY OF BIOCHEMICAL MARKERS OF MYOPATHY IN HYPOTHYROID PATIENTS	Dr. Sangeeta Kapoor, Dr. V. K. Singh	• Check role of uric acid in myopathy.	
90.	M.Sc. Biochemistry	Surbhi Chaudhary	STUDY OF SERUM PROLACTIN LEVELS IN TYPE 2 DIABETES MELLITUS.	Dr. Sangeeta Kapoor, Dr. V. K. Singh	• Controls not to be included.	
91.	M.Sc. Biochemistry	Alok Kumar Maurya	ESTIMATION OF SERUM ELECTROLYTES LEVEL IN HYPOTHYROID PATIENTS	Dr. Anil Kumar Dr. Harekrishna Sharma	• Modify consent form	
92.	M.Sc. Biochemistry	Harjeet Singh	STUDY OF BIOCHEMICAL MARKERS (SERUM VITAMIN D, SERUM CALCIUM, SERUM PHOSPHORUS AND SERUM ALKALINE PHOSPHATASE (ALP)) IN TYPE 2 DIABETES MELLITUS PATIENTS.	Dr. Anil Kumar Dr. Harekrishna Sharma	• Controls not to be included.	
93.	M.Sc. Anatomy	Neha Chaudhary	MORPHOMETRY OF ARTICULAR SURFACES OF UPPER END OF ULNA ON THE BASIS OF DIGITAL IMAGE ANALYSIS & FRACTAL GEOMETRY IN NORTH WEST INDIAN POPULATION	Dr. Nidhi Sharma		Approved





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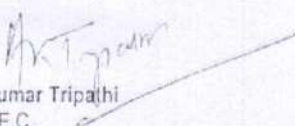
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TMMC&RC/IEC MOM/18-19/48

Dated : 27/12/2018

94.	M.Sc. Anatomy	Aleeza Muneer Siddiqui	STEREOLOGICAL ESTIMATION OF BRAIN VOLUME USING CAVALIERI PRINCIPLE IN NORMAL POPULATION AND PATIENTS SUFFERING FROM NEUROLOGICAL DISEASES BY RADIOLOGICAL IMAGES	Dr. Rohin Garg Dr. Rajendra Pandey Dr. Rajul Rastogi	Approved
95.	M.Sc. Pharmacology	Chitranshi	EVALUATION OF TREATMENT ADHERENCE AMONG ASTHMA PATIENT IN A TERTIARY CARE HOSPITAL	Dr. Prithpal Singh Matreja	Approved
96.	Ph.D. Physiology	Dr Sanket Jheetay	A STUDY OF SERUM DIHYDROTESTOSTERONE LEVEL AND LIPID PROFILE IN TYPE II DIABETIC MELLITUS PATIENTS.	Dr. Rinku Garg Dr. Ritu Adhana	Approved

The meeting ended with thanks to the chair.


Dr. Dr. Anil Kumar Tripathi
Chairperson I.E.C.,
TMMC&RC, Moradabad


Dr. Najmul Huda
Additional Dean Academics & Member Secretary
I.E.C, TMMC&RC, Moradabad

Copy to:

- Director Admin (TMU)
- Principal, TMMC&RC, Moradabad
- All HODs, TMMC&RC, Moradabad
- All members of I.E.C.





**TEERTHANKER MAHAVEER MEDICAL COLLEGE
& RESEARCH CENTER
DELHI ROAD, MORADABAD-244001**

TMMC/IEC/2017/03

Dated-13-02-2017

Subject: Minutes of Ethics Committee Meeting (held on 11-02-2017 & 12-02-2017)

A meeting of Institutional Ethics Committee was held on 11-02-2017 & 12-02-2017 at 9:30 AM in the Conference Room, 5th Floor, Hospital Building of TMMC&RC, Moradabad.

Following members were present in the meeting-

S.N.	Name	Designation
1	Dr. S.K. Sharma	Chairperson
2	Dr. Sangeeta Kapoor	Member
3	Dr. (Mrs.) Shyamoli Dutta	Member
4	Dr. G.L. Garg	Member
5	Dr. Alok Mishra	Member
6	Dr. (Mrs.)Ranjana.Mohan	Member
7	Dr.D.S. Gupta	Member
8	Dr. Jayballabh Kumar	Member Secretary

Agenda: The protocols of the following research projects (including theses protocols of PG/ Ph.D. students, and protocols of the faculty research projects) were discussed regarding suitability for ethical clearance:

S.N.	Title of study	Dept.	Principal investigator	Guide, co-guide & co-investigators	Suggestion	Remarks of ethical committee
1	"Evaluation of thyroid dysfunction in type2 diabetes mellitus"	Medicine	Dr. Rajiv Ranjan Tiwari	Dr V K Singh Dr Ajay Kumar Dr Sangeeta Kapoor	1.Classify latent/overt/subclinical hypothyroidism 2.Elaborate objective 3.Add tertiary hospital setting in western U.P 4. cross sectional observational study 5.Written informed consent 6. patient information sheet- amount of blood to be collected 7..Specify statistical analysis	Approved



2	"Study of Association Between metabolic syndromes and acute myocardial infraction"	Medicine	Dr. Rohit Jain	Dr Vishvnayak Dr Geetesh Manik Dr Harekrishna Sharma	1. Consecutive word to be omitted 2. Cross sectional study	Approved
3	"Study of clinical, hematological, biochemical profile & complications in plasmodium Vivax malaria at tertiary care centre in western UP"	Medicine	Dr. Rohit Pratap Singh Tomar	Dr V K Singh Dr. J. M. Haria Dr Umar Farooq	1.Modify/shorten Title 2. Elaborate objective-Correlation 3. Comment on No of patients	Approved
4	"Evaluation of diastolic dysfunction in patients of type2 diabetes mellitus without cardiac symptoms at a tertiary care Centre, Moradabad, UP, India	Medicine	Dr. Chinky Sharma	Dr. J. M. Haria Dr Ajay Kumar Dr Geetesh Manik	1. Shorten the Title 2. Remove asymptomatic 3Objective Evaluate frequency 4. Age upper limit to be specified 5. Elaborate Statistical analysis	Approved
5	Study of factors affecting early termination of breast feeding in infants up to 6 months	Pediatric	Dr. Nilay Anand	Dr. Utkarsh Sharma Dr Shweta Yadav	1.Modify Title 2.Comment on no. of subjects/patients (Clarify sample size)	Approved



6	" Study of morbidity patterns in patients getting admitted to neonatal intensive care unit of TMMC & RC , Moradabad	Pediatric	Dr. Shruti Jain	Dr. Utkarsh Sharma Dr Arti Sharma	1.Modify Title (simplify) 2.100 subjects 3.Aims & objectives to be reframed	Approved
7	"To Assess the practices and factors affecting the knowledge and attitude of parents /caregiver on optional vaccine for infants"	Pediatric	Dr. Manisha Kumari	Dr Deepak Seth Dr Anshuman Shrivastava	1.Modify Title 2.Reframe & improve objectives 3.Sample size 100	Approved
8	To determine the Time of initiation of Breast Feeding in Neonates Admitted in Postnatal Ward and Factors Associated with Delay in Initiation of Breastfeeding	Pediatric	Shubhangini Soni (MBBS)	Dr Utkarsh Sharma Dr VP Giri Dr Prithpal Singh Matreja	1.Modify Title 2.Aims & objectives to be reframed	Approved
9	"Comparative role of various Doppler parameters in predicting perinatal outcome in fetal growth restriction (FGR)"	Obst & Gyne	Dr Komal Rathore	Prof. (Dr.) Rehana Najam Dr. Rajul Rastogi Dr. Anshuman Shrivastava	1.Change Title 2.Sample size 60 3. change study design	Approved
10	" A clinic pathological study of endometrium in abnormal uterine bleeding cases by Hysteroscopy and its histopathological Co-Relation	Obst & Gyne	Dr Shruti Uniyal	Dr. Shweta Yadav Dr Ashutosh Kumar	1.Title – Using Hysteroscopy 2.Exclusion criteria – systemic disorder, bleeding disorder, aspirin etc. to be recognised	Approved
11	" To study the pattern and clinic pathological correlation of adnexal masses	Obst & Gyne	Dr Sonakshi Pandey	Dr Arti Sharma Dr Semma Awasthi Dr Arjit Agarwal	1.Title – Study of the patterns and clinic pathological correlation of adnexal mass 2.Aim – Study of spectrum of adnexal masses	Approved



12	"To correlate the findings of papsmear, colposcopy & cervix biopsy (Histopathological examination) in detection of cervical cytological abnormalities of cervix	Obst & Gyne	Dr Shavika Mehta	Dr. Arti Sharma Dr Ashutosh Kumar	1. Modify Title 2. Modify Aim 3. Exclusion criteria – Pregnancy & Puerperium 3. Statistical analysis detail (sensitivity & Specificity)	Approved
13	Feto Maternal Outcome in Obstructed Labor	Obst & Gyne	Vidushi Chandra (MBBS)	Dr Rehana Najam	1.Title-Modify 2.Aim- modify	Approved
14	Evaluation of Intraspinal Space Occupying lesion using MR Spectroscopy and Diffusion Weighted imaging	Radiodiagnosis	Dr Manish Raj	Dr. Arvind Shukla Dr Arjit Agarwal Dr Narendra Kumar	1. Study period	Approved
15	Correlation between conventional MRI spine and Diffusion Tensor imaging scores in Patients with Spinal Trauma	Radiodiagnosis	Dr Mohini Choudhary	Dr. Shruti Chandak Dr. Shalini Saraswat Dr Narendra Kumar	1.Elaborate statistical analysis	Approved
16	"comparative study of high resolution ultrasonography & magnetic resonance imaging in diagnosis of ankle pathologies	Radiodiagnosis	Dr Ratish kumar Raman	Dr. Vijay Pratap Singh Dr. Rajul Rastogi Dr Ajay Pant	1. Aims 2.Define age limits 3. in place of ankle it should be Ankle Joint 3. Exclusion criteria – Implants incompatible with MRI 4.Elaborate statistical analysis	Approved
17	"Comparative evaluation of carotid Doppler & coronary CT angiography as predictors of coronary artery disease in patients of acute stroke"	Radiodiagnosis	Dr Pragya Sinha	Dr. Vijay Pratap Singh Dr. Rajul Rastogi Dr VK Singh Dr Anurag Srivastava	1. Details of statistical analysis	Approved
18	Comparative study of Laproscopic versus open cholecystectomy	Surgery	Dr. Bharat Pratap Singh	Dr N K Singh Dr A K Singh	1. Elaborate objectives 2. Selection bias removal	Approved



19	"To study the outcome of early laparoscopic cholecystectomy for acute calculus cholecystitis"	Surgery	Dr. Ghulam Nabi	Dr Sunesh Kumar Dr N K Singh	1.Exclusion criteria – pancreatitis to be ruled out both by imaging and amylase 2. specify age group in Inclusion criteria	Approved
20	"To Study the various management Modalities for ileal perforation"	Surgery	Dr. Shekhar Varshney	Dr D.D. Deka Dr Ashok Kumar Singh	1. Revise inclusion criteria-include Crohn's disease etc.	Approved
21	"Comparison of open versus laparoscopic appendectomy"	Surgery	Dr. Udit Patel	Dr S.P Sinha Dr S Srinivasan	1. elimination of selection bias 2. elaborate objectives –factors etc	Approved
22	"A Comparative study of different types of nutritional support in surgical patients"	Surgery	Dr. Piyush Kumar	Dr S.P.Sinha Dr.M.S.Chahal	1. age -18-65 yeears 2. Study group – number increases to 30 3. Elaborate statistical analysis	Approved
23	Comparison Between Laparoscopic Cholecystectomy & Open Cholecystectomy	Surgery	Latika Mittal (MBBS).	Dr Mohd. Atif Khan Dr Prithpal Singh Matreja Dr Kirti Vishwakarma	No suggestion has been given by any member	Approved
24	"Real-time ultrasound-guided catheterization of the internal jugular vein: A prospective comparison with the landmark technique"	Anesthesia	Dr Aditya Garg	Dr. G. L. Garg Dr. Rohit Varshney	1. Rephrase Title 2.Age limit-18-65 years	Approved
25	" A Comparative Study on the Stylet and the Gum Elastic Bougie for Endotracheal Intubation in a Simulated Difficult Airway	Anesthesia	Dr Ravi Kumar Keshri	Dr. G.L.Garg & Dr. Rohit Varshney	1. Revise study age group (18-65 years) 2. Revise exclusion criteria 3. Include ASA grade III & IV	Approved



26	Clinical evaluation of intubating conditions and hemodynamic effects using Rocuronium Bromide and Succinyl choline-A Prospective comparative study	Anesthesia	Dr Yashovardhan	Dr. Pallavi Ahluwalia Dr. G.S.Jheetay	No suggestion has been given by any member	Approved
27	"A prospective randomized study to compare Ambu-Laryngeal mask Airway & air-Q with l-LMA as an intubation conduit for patient undergoing elective surgery"	Anesthesia	Dr Vinod Kumar Yadav	Dr. G.S.Jheetay Dr. Md.Shahbaz Alam	1. Classify statistical analysis method	Approved
28	"A study of quality of life, Correlates and psychiatric comorbidities in patients diagnosed with obsessive compulsive disorder	Psychiatry	Dr. Sunny Dua	Prof. A. Q. Siddiqui Dr. Prerna Gupta Dr. Seema Singh	1. Reframe Aim 2. number of patients to be mentioned 3. duration of study	Approved
29	"Study of psychiatric morbidity in patients suffering from chronic dermatological disease	Psychiatry	Dr. Sumitabh Gupta	Prof. A. Q. Siddiqui Dr. Prerna Gupta Dr. Seema Singh Dr RR Reddy	1. Sound justification for inclusion of skin disease	Approved
30	" A Study of Frequency of dry eye in type 2 diabetes mellitus patients"	Ophthalmology	Dr. Tushar Singh Chauhan	Dr JayaDevendra Dr P.S.Rastogi Dr Gopesh Mehrotra	No suggestion has been given by any member.	Approved



31	"Effects of ND-YAG laser capsulotomy on macular thickness and intraocular pressure"	Ophthalmology	Dr. Vaishli Budhwar	Dr. Jaya Devendra Dr. Ashish Chander Dr. Farhat Abrar	1.type of study- prospective longitudinal study 2. Elaborate statistical analysis	Approved
32	Study to Detemine Concurrent Changes in Corneal Thicness, Intra Ocular Pressure & Corneal Curvature Measurements During Pregnancy	Ophthalmology	Dr Priye Suman Rastogi (FACULTY)	Dr Astha Lalwani Dr Vaishali Budhvar	1. Modify Title 2. reframe Aims 3. elaborate objectives 4. increase the time duration of study	Approved
33	"A study of clinical variants in patient with acne	Dermatology, Venerology & Leprology	Dr. Arjun Singh	Prof. D. R. Reddy Dr Dhillon	1. modify Title 2. Clarify – Aims & objectives (irrespective of HIV status) 3. In setting – write Tertiary care centre 4. Cut down age to 12 years in Exclusion criteria	Approved
34	"Isolation and speciation of candida with antifungal susceptibility patterns from various clinical samples"	Microbiology	Dr Imran Ahamad	Dr. Umar Farooq	1. Reframe Title 2. include all catheter type 3. Include Mycafungin & Caspofungin	Approved
35	Isolation & Speciation of Candida with Antifungal Susceptibility Patterns from Various Clinical Samples	Microbiology	Bhavya Jain(MBBS)	Dr Vasundhara sharma Dr Sudhir Singh Dr Naitali Arun	No suggestion has been given by any member	Approved
36	Incidence of Enterococcal Urinary Tract Infection and its Sensitivity Pattern Among Patients Attending TMMC & RC	Microbiology	Umang Agarwal (MBBS)	Dr Umar Farooq Dr sudhir Singh Dr Nitali Arun	1.Clinical co guide must be involved 2.Changes required in Exclusion criteria	Approved



37	"Evaluation of diabetic neuropathy changes in newly diagnosed patients of type II diabetes mellitus (T2DM)"	Physiology	Dr. Jaspreet Kaur Jaura	Dr. Jayballabh Kumar Dr VK Singh Dr. Gaurav Kumar Dr Ritu Adhana	1. Increase subjects with nerve conduction studies 2. include vitamin B12 in exclusion criteria 3. How to exclude Arsenic, Opium exposure, Fluoride & Lead exposure(i.e. any alternative cause of peripheral neuropathy)	Approved
38	"Correlation of High Resolution Computed Tomography (HRCT) findings with Clinical Severity in COPD patients	Pulmonary Medicine	Dr Ankit Agarwal	Prof. Mukesh Gupta Dr. Mazhar Maqusood Dr.Rangnath TG Dr Rajul Rastogi Dr Anurag	1.Revise Title 2.Revise Aim & Objective 3.Revise age limit	Approved
39	Role of Xenobiotic Metabolizing Enzyme Gene Polymorphism, and its Association with Cytokines Signaling in the Etiology of Bronchial Asthma	Ph.D (Biotechnology) IFTM Univesity Pulmonary Medicine	Mr. Ankit Kumar	Dr. Tanzeel Ahmed Dr Mazher Maqusood	1.No of subjects to be increased 2. Major modification required 3. Molecular statistician to be consulted	Approved
40	To Evaluate the Outcome of Use of Different inhalers and their techniques in patient with chronic obstructive pulmonary disease	Pulmonary Medicine	Ms. Shailee Shail	Dr Mazher Maqusood Dr Prithpal Singh Matreja	1. modify Title	Approved
41	"A study of clinico-radiological and operative findings in childhood acquired cholesteatoma"	ENT	Nitish Agarwal	Dr Probal Chatterji Dr Arvind Shukla	Modify Aim & objective	Approved



42	A clinical study of neck swelling and their pathological correlations	ENT	Dr Anupama Rai	Dr Probal Chatterji Dr.(Mrs.) Shyamoli Dutta	1.Modify Title & Aim 2. Reframe objective 3. Exclusion criteria – reframe 2 nd point	Approved
43	“Role of Histochemical Stains in Detection of Helicobacter Pylori in Gastric Endoscopic Biopsy with Special Reference to Immunohistochemistry”	Pathology	Dr Chitra Chauhan	Dr Semma Awasthi Dr Ashutosh Kumar	1. Shorten the Title 2.Modify Aim 3. Total cases- give number,50 4. Modify Exclusion criteria-Other causes of dyspepsia like Cholelithiasis	Approved
44	“Histopathological Spectrum of urinary bladder biopsies-A Tertiary care center study”	Pathology	Dr Somya Agarwal	Prof. (Dr.) Shyamoli Dutta Dr Seema Awasthi Dr Ashutosh Kumar	1. Reframe Inclusion criteria 2. include co guide as Urologist 3. age specifications 4.Elaborate exclusion criteria	Approved
45	“Pattern of Histopathological changes of placenta in toxemia of pregnancy”	Pathology	Dr Mahima Choudhary	Dr Ashutosh Kumar Dr Rehana Nazam Hudda Dr Faiyaz Ahmad	1. Modify Title, Aim & Objective 2. Reframe Exclusion criteria –Hypertension Other long standing disease 3. Mention number of patients	Approved



46	"Study of cervical lymph nodes by FNAC with special stains & clinical Correlation- A clinically beneficial and cost effective modality"	Pathology	Dr Vivek Singh	Dr Ashutosh Kumar Dr Seema Awasthi	1.Limit age group 2.Radiological finding added 3. Modify Exclusion criteria 4. Inclusion criteria – inclusion of HIV status	Approved
47	To Study the Pattern of Histopathology of Gall Bladder of Patients Undergoing Cholecystectomy	Pathology	Ms. Ruchir Taneja (MBBS)	Dr Ashutosh Kumar Dr Prithpal Singh Matreja		Approved
48	"Quality of life assessment in patients of chronic obstructive pulmonary disease in rural and urban Moradabad- A cross-sectional study"	Community medicine	Dr Vaibhav Rastogi	Dr. Anurag Srivastava Dr Bhaskar Watode Dr Mazher Maqusood	1.Aim should be reframed 2.Inclusion of cold stage criteria Or put some intervention part (some comparator group must be introduced) 3. Community based in Title 4. Sampling strategy should be made clear 5. Back translation of questionnaire & validation to be done	Approved
49	"An epidemiological study of stress, Anxiety and depression among adolescents in urban and rural Moradabad"	Community medicine	Dr Nawaid Arif	Dr. Anurag Srivastava Dr Bhaskar Watode Dr Sachin Singh Yadav	1.Include Co guide from psychiatry department	Approved



50	'An Epidemiological study of postpartum depression in rural Amroha: A community based study'	Community medicine	Dr. Neelam Jaiswal	Dr. Mukesh sharma Dr. Sadhana Singh Dr. Anish Prabakar	Include Co guide from psychiatry department	Approved
51	Study of violent asphyxia deaths in associated mortuary of TMMC & RC Hospital/ Amroha & its Medicolegal importance	Forensic Medicine & Toxicology	Dr. Kirti Vardhan Singh	Dr. Sarvjit Singh Sandhu Dr. Pardeep Singh	1. Clarification of objective is required 2.Reframe Title	Approved
52	Study of Serum Vitamin D Level in Hypothyroid Patients	Biochemistry	Dr. Shubhi Mishra	Dr G P Singh Dr V K Singh Dr Anil Kumar	Modify Aim	Approved
53	Treatment satisfaction, efficacy and safety of combination of metformin with Glimepride Vs. Metformin with Sitagliptin in patients of type 2 diabetes mellitus	Pharmacology	Dr. Prithpal S Matreja	Dr. Prithpal S Matreja Dr V K Singh Dr Preeti Singh	No suggestion has been given by any member	Approved
54	Safety analysis of antidepressant prescribed and comparison of the effects on efficacy	Pharmacology	Dr. Kirti Vishwakarma	Dr. Prithpal S Matreja Dr. Prerna Gupta Dr. Seema Parmar	1. Reframe Aim 2. Modify objective 3. Side effects to be included	Approved
55	Evaluation of Iron Deficiency anemia related knowledge among medical & paramedical students	Pharmacology	Dr. Priyanka Kumawat	Dr. Prithpal S Matreja	Reframe Aim	Approved
56	Spectrum of abnormal microbial flora in patients presenting with vaginal discharge	Pharmacology	Shweta Jaiswal (MBBS)	Dr. Shweta Yadav Dr. Kirti Vishwakarma	1.Reframe Title 2.Include microbiologist as Co guide	Approved



57	"Clinico-Radiological Outcome of total Hip replacement: A prospective on retrospective study"	Orthopaedics	Dr. Pratyush Parag	Dr. Madan Singh Chaudhry Dr. Najmul Huda	1.Reframe Title 2.Definite Patient number to be specified	Approved
58	"Clinico –Radiological outcome of management of fracture neck of femur in elderly using Austin Moore's prosthesis: A Prospective retrospective study"	Orthopaedics	Dr. Pulkit Jain	Dr Ajay Pant Dr. Najmul Huda	1.Reframe Title 2. Mention number of subjects /patients	Approved
59	"Treatment of osteoarthritis (OA) knee by fibular osteotomy: A clinical study"	Orthopaedics	Dr. Shailesh Singh	Dr. Najmul Huda Dr Ajay Pant	1. Reframe Aim	Approved
60	"A prospective study of non union of long bones managed by corticotomy & distraction using limb reconstruction system"	Orthopaedics	Dr. Siddarth Sinha	Dr Ajay Pant Dr. Najmul Huda	Study Design- Longitudinal study	Approved

Action

All the protocols were approved by committee with few suggestions.
The meeting concluded with vote of Thanks to Chair.

Dr. Jayballabh Kumar
Member Secretary
Institutional Ethics Committee
TMMC&RC, Moradabad



MINUTES OF THE 19th MEETING (ONLINE) OF THE EXECUTIVE COUNCIL HELD ON SATURDAY,
JUNE 12, 2021 AT 1130 Hrs.

Following members were present during the meeting:

1. Prof Raghuvir Singh, Hon'ble Vice Chancellor	Chairperson
2. Prof Jai Pal Vyast, MLC, U.P. State Legislative Council	member
3. Prof Kuldeep Singh Bansal	Member
4. Prof R.M. Dubey	Member
5. Sri Vishal Sehgal	Member
6. Sri Akshat Jain	Member
7. Prof K.K. Pande	Member
8. Prof R.K. Dwivedi	Member
9. Dr Ankita Jain	Member
10. Prof Manjula Jain	Special Invitee
11. Dr Aditya Sharma, Registrar	Member Secretary

The meeting began with introduction of the members of the newly reconstituted Executive Council since the adoption of the new Statutes framed under the U.P. Private Universities Act 2019. The Vice Chancellor welcomed the members to the meeting and requested the Registrar to present the agenda of meeting.

Following are the discussions and decisions which took place during the meeting:

EC 19.1 Confirmation of the minutes of the last meeting.

The minutes of the last meeting of the Executive Council held on 17 August 2020 were circulated to all the members vide letter no. TMU/R.O./19-20/Executive Council/166 dated 27.08.2020. As there were no comments, the Council considered and confirmed the minutes of the last meeting. The motion was seconded by Prof K.S. Bansal.

Annexure-01

RESOLVED THAT THE MINUTES OF THE LAST MEETING AS ABOVE ARE CONFIRMED.

EC 19.2 Discussing the Action Taken Report (ATR) on the minutes of the last meeting.

The Council took note of the follow-up action taken on the decisions of the last meeting of the Executive Council, the ATR is annexed herewith.

Annexure-02

RESOLVED THAT ATR AS ABOVE IS NOTED AND RECORDED.



sanctioned positions and requirement/vacancies should also be included in the document mentioning the appointment of teaching staff so as to have the complete information about existing teaching staff.

Annexure-13

RESOLVED THAT THE ACTION TAKEN BY THE VICE CHANCELLOR IN APPROVING THE RECRUITMENTS OF OFFICERS AND OTHER NON-TEACHING STAFF WITH THE SUGGESTIONS AS ABOVE IS RATIFIED.

EC 19.14 Consideration of the IP Policy and formation of IPR Cell of the University.

The IP policy document and constitution of IPR Cell of the University was placed before the council. The members discussed and considered the action taken by the Vice Chancellor in approving the IP Policy and creation of IPR Cell in anticipation of the approval of the Council. The highlights of the policy:

1. Objectives: To encourage innovative research leading to the generation of new knowledge, ideas and inventions and to facilitate the transfer of university-developed research results and new knowledge to commerce and industry.
2. Scope: IPR cell shall facilitate and help the members of faculty, researchers and students of Teerthanker Mahaveer University in identification, protection and commercialization of various IPRs such as Invention(s), Designs, Integrated Circuit Layouts and other creative & artistic works. The faculty members desirous of filing a patent or any other IPR application would be given the necessary advice and guidance by the IPR cell.
3. Composition of IPR Cell committee:

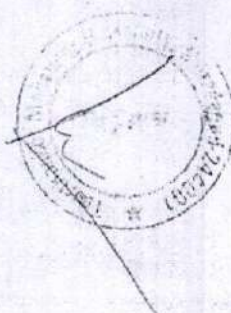
Vice Chancellor	Chairman
Associate Dean (Academic)	Member
Principal of the College concerned	Member
Joint Registrar (R&D)	Member
Registrar	Member Secretary

4. Policy on commercialization:

The net earnings from the commercialization of IP owned by Teerthanker Mahaveer University (TMU) would be shared as follows:

S.no.	Net earnings	Inventor(s)	TMU Share
1	For the first amount 'X'	60%	40%
2	For the next amount X	50%	50%
3	For amounts more than X	40%	60%

Annexure-14



EC 19.19 Ratification of the establishment of Entrepreneurship Development Cell (EDC) in the University.

The members were apprised that University with the objective to motivate students to choose the entrepreneurship as a career and to prepare them to exploit the market opportunities for own enterprise successfully, has established the Entrepreneurship Development Cell (EDC) with the approval of Vice Chancellor. The Council was requested to consider the decision taken by the Vice Chancellor as above in anticipation of the approval of the Council. Sri Akshat Jain advised that the EDC should work in coherence with the TMU-Business Incubator and not in isolation otherwise the objective of establishing it will not meet its ends. The members had the consensus over his suggestion. The Council discussed and considered the action taken by the Vice Chancellor as above.

RESOLVED THAT THE ACTION TAKEN BY THE VICE CHANCELLOR IN ESTABLISHING THE EDC ALONG-WITH THE SUGGESTIONS AS ABOVE IS RATIFIED.

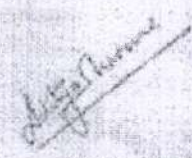
EC 19.20 Any other matter with the permission of the Chair.

With the permission of Chair, following points were discussed:

19.20 A. Prof R.M. Dubey with the permission of chair raised three concerns i.e. if the University is following the procedures for recruitment as prescribed by UGC and other statutory bodies, if the qualification norms are being followed and whether the employees are being paid the salary at par with the UGC norms. Registrar briefed that the procedures for recruitment of teaching and non-teaching staff and norms for qualification are being followed as per the UGC norms. The employees are being paid salary as per their cadre.

19.20 B. Prof R.K. Dwivedi suggested that the administrative audit should also be carried out in the way the academic audits are being conducted on regular basis so as to have the holistic growth of the University and quality in all aspects is ensured. The members had the consensus over it.

The meeting ended with the appreciating notes being given by Sri Akshat Jain and thanks to the Chair by the members.


(Aditya Sharma)
Registrar

