



INSTITUTIONAL HUMAN ETHICS COMMITTEE

Meeting on Monday, 9th July 2022, 2pm to 3:30pm

Minutes of the meeting:

- Committee members were welcomed.
- The agenda of the meeting was read. The agenda for the meeting was circulated earlier through email.

Following members were present for the meeting:

Sr. No.	Members of Ethics Committee	Name and designation of a member
1)	Co-Chairperson	Dr. Dasmit Singh
2)	Member Secretary	Dr. Kedar Limbkar
3)	Lawyer	Adv. Madhav Godse
4)	Social Scientist	Mrs. Vaishali Deshpande
5)	Layperson	Mrs. Nanda Kathale
6)	Staff	Dr. Chandrakant Tagad
7)	Member	Dr. Madhura Chandrashekar
8)	Member	Dr. Aruna Sivaram
9)	Member	Dr. Nayna Patil
10)	Invited Member	Dr. Rupali Mahajan
11)	Invited Member	Prof, Madhavi Bhongale

- Dr. (Mrs.) Lalita Limaye could not attend the meeting due to personal reasons. She had authorized Dr. Dasmit Singh, Senior pediatrician, Sassoon General Hospital, Pune.
- The hard copies of the progress reports of the ongoing projects were circulated to the committee members and were approved. The softcopies of the same were circulated earlier through email.
- The final project completion report of the project entitled '*Development of rowing simulator to enhance the performance of young Indian rowers*' by Dr. Anant Chakradeo was approved by committee members.
- The following new proposals were presented before the committee
 - ***Developing an integrated system for strategic brand style assessment of consumer products.***
The consent forms and the proposals were evaluated and approved by the committee.
 - ***Android-based assistive therapy for ADHD kids***
The child psychotherapist was also present for the proposal presentation who will use the therapy for ADHD kids. The questionnaire and games which will be used for therapy application were presented in front of committee. After asking few



questions the committee was satisfied with the justifications and project was sanctioned.

➤ ***Construction and validation of unfolded protein response gene signature for detection and prognosis of gynaecological cancers***

The samples will be procured by the experienced hospital staff and the institute is having MoU with hospital, hence the project proposal was approved.

➤ ***To study the effect of n-3 PUFAs as an adjunct to chemotherapy in the prevention of side effects of chemotherapy especially myeloablation and osteonecrosis***

The investigator was asked to include the detailed methodology for the evaluation of samples on cell lines as well as validation on normal cells. The proposal will be accepted with these modifications.

➤ ***Investigation of the cytokine profile of blood sample induced by metal micro/nanoparticles***

The project was approved by the committee.

➤ ***Development of septum cartilage using tissue engineering for potential application in rhinoplasty***

The first phase i.e. *In vitro studies* and biocompatibility studies was approved by the committee. The second phase of the project i.e. studies on humans should be sent for DCGI approval.

➤ ***Preparation of snake venom detection kit***

The researcher was asked to add more biomarkers to the proposed kit to increase its validity of the kit.

- There were minor suggestions for each project, and suggestions were noted by respective investigators.
- The proposals will be approved after the incorporation of suggestions. The modified proposals will be shared online for approval.
- Dr. Dasmit Singh was proposed as a chairperson of the committee which was approved by all committee members.
- The meeting was concluded with a vote of thanks.

KRN

(Dr. Kedar R. N.)

Signature of Member Secretary

Date : 9th July 2022

To,
The Chairman, Board of Research
MIT ADT University, Pune

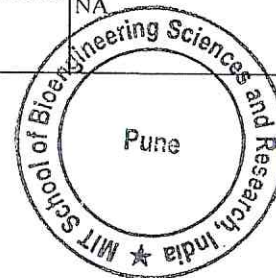
Subject: Constitution of Research Advisory Committee (RAC) for the Research Scholars of Ph.D. Batch...9 - Institute/ Dept. of BIOENGINEERING
SCIENCES & RESEARCH

Dear Sir,

As per the clause 8.0 of Ph.D. Ordinance, MIT ADT University the recommendation of Proposed Research Advisory Committee (RAC) for the Research Scholars of Ph.D. Batch 9 (2022-23) Institute/ Dept. of School of Bioengineering Sciences & Research is forwarded to you for its constitution. The details of RAC are as follows:

Proposed Research Advisory Committee (RAC) for Ph.D. Batch 9 Institute/ Dept. of School of Bioengineering Sciences and Research						
Sr. No	Name of Research Scholar	Chairman	Name of Research Supervisor/ Convener (with Designation and Affiliation)	Name of Research Co-Supervisor (if any) (with Designation and Affiliation)	RAC Experts with Name, Designation and Affiliation	
					Internal Member (Domain expert within the department/institute)	External Member (Domain expert outside MIT ADTU)
1	Ms. Vandana Yadav <i>Vandana</i>	Dr. Renu Vyas	Dr. Aruna Sivram, Associate Professor, MIT SBSR. <i>Aruna</i>	Dr. Renu Vyas, Professor and Head of School, MIT SBSR.	Dr. Kedar Nirmla, Assistant Professor, MIT SBSR.	Dr. Laila Garda, Director, KEM Hospital Research Centre, Pune
2	Ms. Deepali Ghorpade <i>Deepali</i>		Dr. Renu Vyas, Professor and Head of School, MIT SBSR. <i>Renu</i>	NA	Dr. Shama Mujawar, Assistant Professor, MIT SBSR.	Dr. Anamika Krishnakumar, Senior Domain Specialist and Multi-omics group leader, Persistent systems, Pune. <i>Pooja</i>
3	Ms. Sunita Dominic <i>Sunita</i>		Dr. Madhura Chandrashekar, Assistant Professor, MIT SBSR. <i>Madhura</i>	Dr. Priyanka Sharma, Assistant Professor, MIT SBSR.	Dr. Pranav Pathak, Associate Professor, MIT SBSR.	Dr. Sujoy Saha, Principal Scientist (Plant Pathology), ICAR, NRCC, Pune. <i>Sujoy</i>
4	Mr. Amol Kahandal <i>Amol</i>		Dr. Chandrakant Tagad, Assistant Professor, MIT SBSR. <i>Chandrakant</i>	Dr. Preetam Bala, Assistant Professor, MIT SBSR.	Dr. Aruna Sivram, Associate Professor, MIT SBSR.	Dr. Jalindar Ambekar, ST-V Center for Materials for Electronics Technology, Pune. <i>Jalindar</i>
5	Ms. Sonali Gaikwad <i>Sonali</i>		Dr. Renu Vyas, Professor and Head of School, MIT SBSR. <i>Renu</i>	Dr. Narendra Kadoo, Professor and Head, Biochemical Division, MIT SBSR.	Dr. Priyanka Sharma, Assistant Professor, MIT SBSR.	Dr. Sunil Dalvi, Scientist, Vasantdada Sugar Institute, Pune. <i>Sunil</i>
6	Ms. Sagarika Saha <i>Sagarika</i>		Dr. Renu Vyas, Professor and Head of School, MIT SBSR. <i>Renu</i>	NA	Dr. Aruna Sivram, Associate Professor, MIT SBSR.	Dr. Vrushali Korde, Professor Obstetrics & Gynecology, MIMER Medical College, Thalegoan. <i>Vrushali</i>

Dr. Madhura Chandrashekar
Institute Ph.D. Coordinator,



Prof. Dr. RENU VYAS
HOI/HoD, Institute/Dept.




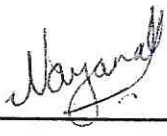
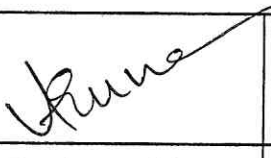
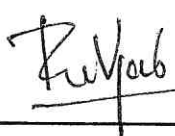
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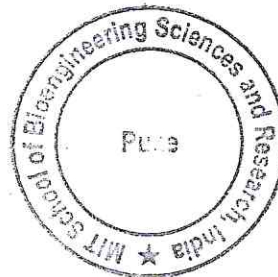
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Details of discussion:

The members of the committee discussed and recommended the following members for the research committee of Manoj Sabnani.

RAC designation	Name	Designation	Affiliation
Chairman	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Convener/Research Supervisor	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Co-supervisor	Dr. Neeraj Maheshwari	Assistant Professor	SBSR, MIT ADT University, Pune
Member (External)	Dr. Rajesh Singh	Deputy General Manager	Gennova Biopharmaceuticals, Pune
Member (Internal)	Dr. Sanket Bapat	Assistant Professor	SBSR, MIT ADT University, Pune

			
Dr. K.V. Swamy Member RC (Internal)	Dr. Nayana Patil Member RC (Internal)	Dr. Aruna Sivram Member RC (Internal)	Dr. Renu Vyas Chairman RC





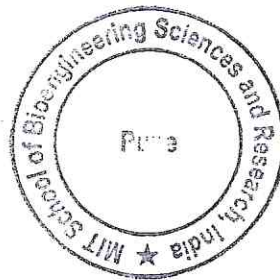
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**Minutes of the Research committee meeting held on 4th October, 2021 at MIT School
of Bioengineering Sciences & Research**

The following members attended the meeting

Sr. No	Committee composition	Name and designation
1	Chairman	Dr. Renu Vyas Head of the School, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
2	Member (Internal)	Dr. K. V. Swamy Associate Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
3	Member	Dr. Nayana Patil Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
4	Member (Internal)	Dr. Aruna Sivaram Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra



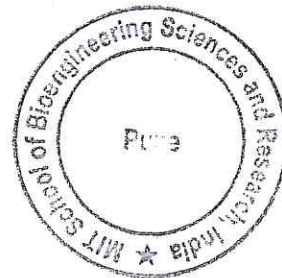


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**Minutes of the Research committee meeting held on 4th October, 2021 at MIT School
of Bioengineering Sciences & Research**

The following members attended the meeting

Sr. No.	Committee composition	Name and designation
1	Chairman	Dr. Renu Vyas Head of the School, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
2	Member	Dr. K. V. Swamy Associate Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
3	Member	Dr. Nayana Patil Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
4	Member	Dr. Aruna Sivaram Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra





**Government of India
Ministry of Health & Family Welfare
Department of Health Research**

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 20-Dec-2021

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter-IV of the New Drugs and Clinical Trials Rules, 2019.

Name : Ethics Committe for Biomedical and Health Research involving Human Participants, School of Bio-engineering Sciences and Research, MIT-ADTU Pune
Address : School of Bioengineering, Sciences and Research, School of Bioengineering, Sciences and Research, MIT-ADT University Pune, Pune, Maharashtra - 412201
Contact No: 020-30693600
Fax : -NA-

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.



ANU Digitally signed
by ANU NAGAR
Date: 2021.12.20
16:26:56 +05'30'

NAGAR

(Anu Nagar)

Joint Secretary

Department of Health Research
Designated Authority

Ref. No: MIT-ADTU/Dean/Ph.D. admin/2021-22/122

Date: 23/10/2021

OFFICE ORDER

Subject: Ph.D. Batch 8 (Aug. 2021) MIT School of Bioengineering Sciences & Research – Allocation of Research Supervisor

On the recommendation of Institute Research Committee (IRC) of MIT School of Bioengineering Sciences & Research, and sanction accorded by the 8th Board of Research Meeting for allotment of Research Supervisor and Research Co-Supervisor are as per the details given below:

Sr. No.	Name of the Candidate	Name of	
		Research Supervisor	Research Co-Supervisor
1	Ms. Sneha Shivaji Bhosale	Dr. Nayana Patil, Asst. Professor, MIT SBSR	Dr. Sujoy Saha, Principal Scientist, ICAR- National Research centre for Grapes (NRCC), Pune
2	Ms. Madhavi Bhongale	Dr. Renu Vyas, HOI, MIT SBSR	—
3	Mr. Manoj Sabnani	Dr. Renu Vyas, HOI, MIT SBSR	Dr. Neeraj Maheshwari, Assistant Professor, School of Bioengineering Sciences and Research, Pune

The Research Scholar concerned are advised to report to Head of Institute and the Research Supervisor immediately to initiate the Research activity.

J.K. Bhojwani

Prof. Dr. Virendra Bhojwani,
Associate Dean, (R & C)



CC to,

1. The HoI, MIT SBSR,
2. Concerned Research Supervisors
3. Institute Ph.D. Coordinator - MIT SBSR
4. Concerned Research Scholars



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**Minutes of the Research committee meeting held on 24th October, 2020 at MIT School
of Bioengineering Sciences & Research**


The following members attended the meeting

Sr. No	Committee composition	Name and designation
1	Chairman	Dr. Renu Vyas Head of the School, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
2	Member	Dr. Nayana Patil Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
3	Member	Dr. Chandrakant Tagad Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra


Details of discussion:

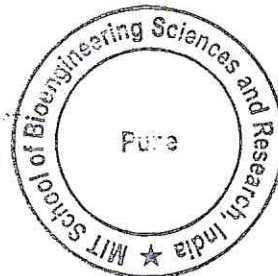
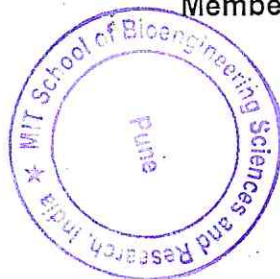
The members of the committee discussed and recommended the following members for the research committee of Neeta Dabke.

RAC designation	Name	Designation	Affiliation
Chairman	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Convener/Research Supervisor	Dr. Madhura Chandrashekar	Assistant professor	SBSR, MIT ADT University, Pune
Co-supervisor 1	Dr. Pranav Pathak	Assistant professor	SBSR, MIT ADT University, Pune
Member (External)	Dr. Milind Chawak	General Manager	Poultry Diagnostic and research center, Venkys India Ltd. Pune
Member (Internal)	Dr. Preetam Bala	Assistant professor	SBSR, MIT ADT University, Pune


Dr. Nayana Patil
Member RC


Dr. Chandrakant Tagad
Member RC


Dr. Renu Vyas
Chairman RC





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Minutes of the Research committee meeting held on 24th October, 2020 at MIT School
of Bioengineering Sciences & Research

The following members attended the meeting

Sr. No	Committee composition	Name and designation
1	Chairman	Dr. Renu Vyas Head of the School, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
2	Member	Dr. Nayana Patil Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
3	Member	Dr. Chandrakant Tagad Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra

Details of discussion:

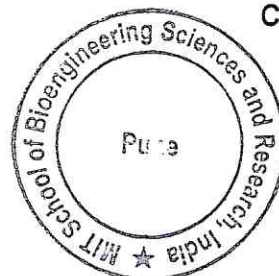
The members of the committee discussed and recommended the following members for the research committee of Surojit Sadhu.

RAC designation	Name	Designation	Affiliation
Chairman	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Convener/Research Supervisor	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Co-supervisor	-	-	-
Member (External)	Dr. Krishnakumar	Manager	Gennova Biopharmaceuticals, Pune
Member (Internal)	Dr. K.V. Swamy	Associate professor	SBSR, MIT ADT University, Pune

Dr. Nayana Patil
Member RC

Dr. Chandrakant Tagad
Member RC

Dr. Renu Vyas
Chairman RC






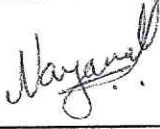
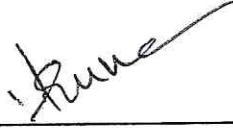
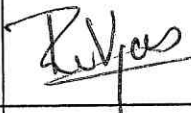
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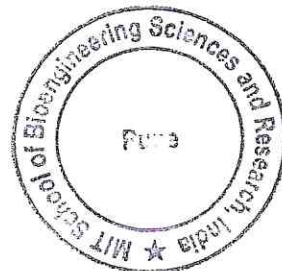
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Details of discussion:

The members of the committee discussed and recommended the following members for the research committee of Sneha Bhosale.

RAC designation	Name	Designation	Affiliation
Chairman	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Convener/Research Supervisor	Dr. Nayana Patil	Assistant Professor	SBSR, MIT ADT University, Pune
Co-supervisor	Dr. Sujoy Saha	Principal Scientist	National center for Grapes, ICAR, Pune
Member (External)	Dr. N. Kadoo	Professor and Head	Biochemical Division, National Chemical Laboratory, CSIR Pur
Member (Internal)	Dr. Sanket Bapat	Assistant Professor	SBSR, MIT ADT University, Pune

			
Dr. K.V. Swamy Member RC (Internal)	Dr. Nayana Patil Member RC (Internal)	Dr. Aruna Sivram Member RC (Internal)	Dr. Renu Vyas Chairman RC





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Minutes of the Research committee meeting held on 24th October, 2020 at MIT School
of Bioengineering Sciences & Research


The following members attended the meeting

Sr. No	Committee composition	Name and designation
1	Chairman	Dr. Renu Vyas Head of the School, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
2	Member	Dr. Nayana Patil Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
3	Member	Dr. Chandrakant Tagad Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra

Details of discussion:

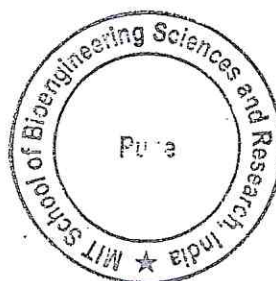
The members of the committee discussed and recommended the following members for the research committee of Pradnya Gurav.

RAC designation	Name	Designation	Affiliation
Chairman	Dr. Kedar Nirmala	Head of the School	SBSR, MIT ADT University, Pune
Co-supervisor	Dr. Mohan R. Vani,	Scientist G,	NCCS, Pune
Member (External)	Dr Anup Kulkarni,	Director,	iBIO Solutions, Pune
Member (Internal)	Dr. Dr Neeraj Maheshwari	Assistant professor	SBSR, MIT ADT University, Pune


Dr. Nayana Patil
Member RC


Dr. Chandrakant Tagad
Member RC


Dr. Renu Vyas
Chairman RC





Ref. No: MIT-ADTU/Dean/Ph.D. admin/2020-21/83

Date:23/11/2020

OFFICE ORDER

Subject: Constitution of Institute Research Committee (IRC) - MIT School of Bioengineering Sciences & Research – Reg.


Ref.: Approval Note No. MIT- ADTU/Dean/Ph.D. admin/2020-21/72, Dated 4th November 2020.

Sanction is accorded by Hon. Executive President and Vice Chancellor (I/C) for constitution of Institute Research Committee (IRC) for MIT School of Bioengineering Sciences & Research, MIT ADT University, as details^{ed} below.

Sr. No.	Name & Designation of Member	Remark
1	Prof. Dr. Renu Vyas, HOI, MIT - SBSR, MIT ADT University	Chairperson
2	Prof. Dr. K. V. Swamy, Associate. Professor MIT- SBSR	Member
3	Prof. Dr. Nayana Patil, Senior Asst. Professor MIT- SBSR	Member
4	Prof. Dr. Aruna Shivaram, Senior Asst. Professor MIT- SBSR	Member
5	Prof. Dr. Vasant Pawar, Dean, Faculty of Technology and Principal MIT- SFT, MIT ADT University.	Member

The tenure of the Institute Research Committee is for a period of three years from the date of its order.

The function and responsibilities of the Institute Research Committee (IRC) is given in Annexure enclosed herewith.


Prof. Dr. Kishore Ravande,
Dean, (R & C)



CC to:

1. Hon. Executive President & Vice Chancellor (I/C)
2. The Registrar, MIT-ADT University, Pune
3. The Dean, Faculty of Technology, MIT ADT University.
4. The Head of the Institute, MIT - SBSR.
5. All members of IRC

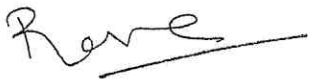


ANNEXURE

The Functions & Responsibilities of IRC/ DRC

The functions of Institute Research Committee (IRC) /Department Research Committee (DRC) are as follows:

1. The Institute/Department Research Committee (IRC/DRC) is to scrutinize the applications of Faculty Members for recognition as Research Supervisor/ Co-Supervisor and make appropriate recommendations to Dean (R & C).
2. The IRC/DRC to scrutinize the research proposal and topic of research submitted by Research Scholars and accordingly allot the Research Supervisor and Co-Supervisor (if required).
3. The IRC / DRC to monitor the progress of all Research Scholar of the Institute/ Department from time to time preferably every 3 months.
4. The IRC / DRC consider and scrutinize all the Research Proposals prepared by Faculty Members for seeking research funding's from various funding agencies and forward the same through proper channel as per norms of the University.
5. The IRC / DRC ensure that Research Scholars and Supervisor(s) follow the best practices of research documentation/publishing/communication and avoid plagiarism or any unethical publishing practices.
6. Any matter relevant to Research activities carried out by the Institute/Department as deemed appropriate for consideration of IRC/DRC.


Prof. Dr. Kishore Ravande
Dean, (R & C)





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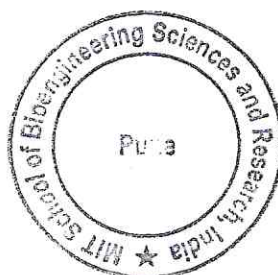
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Details of discussion:

The members of the committee discussed and recommended the following members for the research committee of Madhavi Bhongale.

RAC designation	Name	Designation	Affiliation
Chairman	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Research Supervisor	Dr. Renu Vyas	Head of the School	SBSR, MIT ADT University, Pune
Co-supervisor	Dr. Pauroosh Kaushal	Assistant Professor	SBSR, MIT ADT University, Pune
Member (External)	Dr. Krishnakumar	Manager	Gennova Biopharmaceuticals, Pune
Member (Internal)	Dr. Rupali Mahajan	Associate Professor	SBSR, MIT ADT University, Pune

Dr. K.V. Swamy Member IRC (Internal)	Dr. Nayana Patil Member IRC (Internal)	Dr. Aruna Sivram Member IRC (Internal)	Dr. Renu Vyas Chairman IRC



MOM
RAC



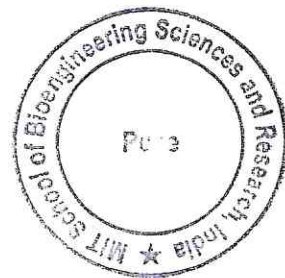
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Minutes of the Research committee meeting held on 4th October, 2021 at MIT School
of Bioengineering Sciences & Research

The following members attended the meeting

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1	Chairman	Dr. Renu Vyas Head of the School, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
2	Member (Internal)	Dr. K. V. Swamy Associate Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
3	Member (Internal)	Dr. Nayana Patil Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra
4	Member (Internal)	Dr. Aruna Sivaram Assistant Professor, MIT-School of Bioengineering Sciences & Research, Pune, Maharashtra





File No. EC/19/000361
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 25-Nov-2019

To

The Chairman
MIT School of Bioengineering Sciences and Research
MIT School of Bioengineering Sciences and Research
Rajbaug Loni Kalbhor Loni Kalbhor Pune Maharashtra
- 412201 India

Subject: Ethics Committee Registration No. ECR/1308/Inst/MH/2019 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2019/3833 dated 16-Jul-2019 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1308/Inst/MH/2019. The said registration is subject to the conditions as mentioned below:

Yours faithfully

V G
SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.
2. This certificate is issued to you on the basis of declaration/submission made by you.
3. Composition of the said Ethics Committee is as per the Annexure.
4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
 - (i) medical scientist (preferably a pharmacologist);
 - (ii) clinician;
 - (iii) legal expert;
 - (iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
 - (v) lay person.



19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8: Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre: Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940 and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.





सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 25-Nov-2019

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Ms. VAISHALI DESHPANDE	BSc (MA - Anthropology)	Social Scientist
2	Dr. DASMIT SINGH	MBBS (MD - Paediatrics)	Clinician
3	Dr. ABHIJEET TILAK	MBBS (MD-Pharmacology)	Basic Medical Scientist
4	Dr. KETAN SARODE	BSc (MSc)	Member
5	Dr. MADHURA Chandrashekar	BSc (MSc)	Member
6	Dr. NAYANA PATIL	BSc (MSc)	Member
7	Mr. KEDAR RAMAKANT LIMBKAR	BSc (Biotechnology)	Member Secretary
8	Dr. LALITA SHRIKANT LIMAYE	BSc (Microbiology)	Chair Person
9	Mr. MADHAV GODSE	LLB (Drafting)	Legal Expert
10	Mr. NANDA KATHALE	BA (Masters in drawing and painting)	Lay Person
11	Dr. REEMA SHUKLA	BSc (BE Biomedical engineering)	Member
12	Dr. SUBHASH T ROMAN	BAMS (Not Applicable)	Member

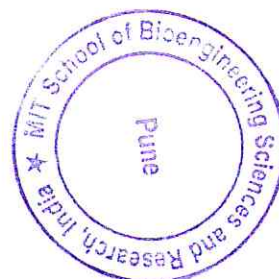
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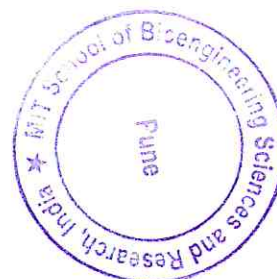
(Dr. V.G. Somani)

Drugs Controller General (I) &
Central Licensing Authority

Digitally signed by V G SOMANI
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5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
- (i) one lay person;
 - (ii) one woman member;
 - (iii) one legal expert;
 - (iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.
6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.
7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.
8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.
9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.
12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any
14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.
15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.
16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.
17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.
18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.



UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairperson Lalita Limaye, National Centre For Cell Science, Pune, Pune, Pune, Maharashtra, India - 411007
2. Name and address of the office : of the Ethics Committee* Ethics Committe for Biomedical and Health Research involving Human Participants, School of Bio-engineering Sciences and Research, MIT-ADTU Pune, School of Bioengineering, Sciences and Research, School of Bioengineering, Sciences and Research, MIT-ADT University, Pune, Pune, Maharashtra - 412201
Contact No. : 020-30693600 Fax No. :

3. Names, address, qualifications & designation of all the members of the Ethics Committee*

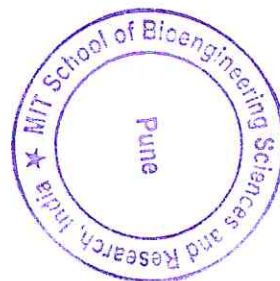
S.No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail and mailing address	Designation/ role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Lalita Limaye	BSc (Others)	National Centre For Cell Science, Pune	Mobile: 9272545654, email: lslimaye@gmail.com Add: Flat No 7, Lot No 35, Saroj Apt., Pune, Pune, Maharashtra-411052	Chair Person	No
2	Dr. Kedar Ramakant Nirmala	BSc (Biotechnology)	School Of Bioengineerin g, Sciences & Research	Mobile: 8806983088, email: kedar.nirmala@mituniversity.edu.in Add: 6, Ketty Mansion, Solapur Bazar, Pune, Pune, Maharashtra-411001	Member Secretary	Yes
3	Dr. Abhijeet Tilak	MBBS (MD-Pharmacology)	Dr. DY Patil Medical College, Pimpri, Pune - 411018	Mobile: 9226145484, email: abhijeet.tilak@yahoo.com Add: Flat 302, Viola Building, Nyati Windchimes, Undri, Pune, Maharashtra-444307	Basic Medical Scientist	No
4	Dr. Dasmit Singh	MBBS (M.Ch - Pediatric Cardio-Thoracic Vascular Surgery)	B. J. Govt Medical College And Sassoon General Hospital	Mobile: 9822393660, email: dasmitsingh@gmail.com Add: E-201, Maestros, Wanawadi, Pune, Maharashtra-411040	Clinician	No



10	Dr. Nayana Patil	BSc (MSc)	School Of Bioengineering, Sciences & Research	Mobile: 9922946188, email: nayana.patil@mituniversity.edu.in Add: C105 East Heaven, Opp MIT-ADT University, Loni Kalbhor, Pune, Maharashtra-412201	Member	Yes
11	Mr. Chetan Potdar	Other (Biomedical Engineering)	School Of Bioengineering, Sciences & Research	Mobile: 9372525811, email: chetan.potdar@mituniversity.edu.in Add: A-501, Mithras Park, Pimple Saudagar, Pune, Maharashtra-411002	Member	Yes
12	Dr. Madhura Chandrashekar	BSc (MSc)	School Of Bioengineering, Sciences & Research	Mobile: 9503096907, email: madhura.chandrashekar@mituniversity.edu.in Add: W/o Dr. Subashchandrabose Chinnathambi, Pune, Pune, Maharashtra-411008	Member	Yes

4. Commitments:

- (1) The Committee shall review and accord its approval to a biomedical research and also carry ongoing review of the study at appropriate intervals, as specified in latest edition of National ethical guidelines for biomedical and health research involving human participants - ICMR for safeguarding the rights, safety and well-being of the research participants.
- (2) In case of any serious adverse event occurring to research participants during the research study, the Committee shall analyze and forward its opinion as per procedures specified under National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.
- (3) The Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of biomedical and health research.
- (4) We agree to maintain adequate and accurate records after the completion or termination of biomedical & health research study for not less than 3 years from the date of completion or termination of the study (both in hard and soft copies).



(Signature of the Chairperson)

Date :

(Signature of the Member secretary)

Date :



5	Ms. Vaishali Deshpande	BSc (MA - Anthropology)	Consultant, Clinical Research	Mobile: 9326022386, email: vaishalideshpande@hotmail.com Add: 109/14, Mithila Apt., Thorat Col., Erandwane, Pune, Maharashtra-411004	Social Scientist	No
6	Mr. Madhav Godse	LLB (M.Sc.)	Sinhgad Dental College And Hospital	Mobile: 9423588277, email: mvgodse72@gmail.com Add: B- 304, Akashdeep, Paranjape Schemes, Dhayari, Pune, Maharashtra-411041	Legal Expert	No
7	Ms. Nanda Kathale	BA (Not Applicable)	MIT Gurukul, IB School, Loni Kalbhor 412 201	Mobile: 9823541141, email: nanda.kathale@mitgurukul.com Add: A-4, MIT Gurukul Staff Quarters, Rajbaugh, Loni Kalbhor, Pune, Maharashtra-412201	Lay Person	No
8	Dr. Chandrakant Tagad	BSc (MSc)	School Of Bioengineering, Sciences & Research	Mobile: 9096381286, email: chandrakant.tagad@mituniversity.edu.in Add: B 302, Sai Shrushti Apt., Pashankar Baug, Loni Kalbhhor, Pune, Maharashtra-412201	Other Supporting Staff	Yes
9	Dr. Pranav Pathak	BSc (MSc)	School Of Bioengineering, Sciences & Research	Mobile: 9923957222, email: Pranav.pathak@mituniversity.edu.in Add: C/o Nandkishor Raut, Flat Number 1803, Pancham B, Nanded City, Pune, Maharashtra-411041	Member	Yes



FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALENCE STUDY

Registration No. ECR/1308/Inst/MH/2019

The Central Licencing Authority hereby registers and permits MIT School of Bioengineering Sciences and Research , MIT School of Bioengineering Sciences and Research Rajbaug Loni Kalbhor Loni Kalbhor Pune Maharashtra - 412201 Contact No.: 020 3069 3600-3411 Fax No.: 020 3069 3600-3412 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place : New Delhi

Date : 25-NOV-2019

V G
SOMANI
Central Licencing Authority
Stamp

Digitally signed by V G SOMANI
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CONTROLS, ou=INDIA, email=V.G.
SOMANI@cdco.gov.in, c=IN,
serialNumber=12002, #>=0, cr=C,
date=2019.11.25 16:54:25 +05'30'



INSTITUTIONAL HUMAN ETHICS COMMITTEE (IEC)
Meeting held on Tuesday, 14th December, 2019, 2: 00 pm to 4:30 pm at MITBIO
Conference room

Following members were present at the meeting

Sr. No.	Name	Position on IEC	Designation and affiliations	Qualification
1)	Dr. Dasmit Singh	Chairperson (Outside institution)	Paediatric Surgeon, Sassoon General Hospital, Pune	M.Ch. (Paediatric Surgery)
2)	Dr. Kedar Limbkar	Member Secretary	Asst. Professor, SBSR, MIT-ADT University, Pune-412201	Ph.D. (Biotechnology)
3)	Dr. Reema Shukla	Co-Member Secretary: Biomedical Expert	Asst. Professor, SBSR, MIT-ADT University, Pune-412201	Ph.D. (Bioengineering)
4)	Dr. Abhijeet Tilak	Clinician (Outside institution)	Professor & Head, Dept. of Pharmacology, at Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune-18.	M.D. (Pharmacology)
5)	Dr. Chandrakant Tagad	Staff	Asst. Professor, SBSR, MIT-ADT University, Pune-412201	Ph.D. (Biochemistry)
6)	Adv. Madhav Godse	Legal expert (Outside institution)		LL. B. (Special: Labour Laws & Co-operative Law)
7)	Vaishali Deshpande	Social scientist (Outside institution)		M.Sc. (Anthropology)



8)	Dr. Nayana Patil	Member – Research Faculty	Asst. Professor, School of Bioengineering Sciences and Research, MIT- ADT University, Loni Kalbhor, Pune-412201	Ph.D. (Biotechnology)
9)	Nanda Kathale	Lay Person (Outside institution)	Visual Art teacher IB and IGCSE MIT Pune’s Vishwashanti Gurukul, Pune- 412201	M.A. (Drawing and painting)
10)	Dr. Madhura Chandrashekar	Member- Basic Sciences	Asst. Professor, School of Bioengineering Sciences and Research, MIT- ADT University, Loni Kalbhor, Pune-412201	Ph.D. (Genetics and Plant Breeding)
11)	Dr. Aruna Sivaram	Member – Research Faculty	Asst. Professor, School of Bioengineering Sciences and Research, MIT- ADT University, Loni Kalbhor, Pune-412201	Ph.D. (Biotechnology)
12)	Dr. Neeraj Maheshwari	Member	Asst. Professor, School of Bioengineering Sciences and Research, MIT- ADT University, Loni Kalbhor, Pune-412201	Ph.D. (Biomaterials and Bioengineering)
13)	Dr. Preetam Bala	Member	Asst. Professor, School of Bioengineering Sciences and Research, MIT- ADT University, Loni Kalbhor,	Nanotechnology



			Pune-412201	
14)	Dr. Pranav Pathak	Invited Member	Asst. Professor, School of Bioengineering Sciences and Research, MIT- ADT University, Loni Kalbhor, Pune-412201	Chemical Engineering
15)	Mr. Chetan Potdar	Invited Member	Asst. Professor, School of Bioengineering Sciences and Research, MIT- ADT University, Loni Kalbhor, Pune-412201	Biomedical Engineering

Dr. (Mrs.) L.S. Limaye, chairperson of IEC, could not attend the meeting. She had appointed Dr. Dasmit Singh to chair the meeting on her behalf.

Agenda for the meeting:

- Approving the project proposals discussed in the previous meeting
- To discuss new proposals
 - Development of a Rowing Simulator Model to Enhance performance for Young Indian Rowers
 - Development of paper-based analytical devices for point-of-care diagnostics
 - Validation of *in silico* mutations in ovarian cancer samples
 - Automatic assistive device for abnormal gait pattern
- To add new members to the existing ethical committee
- To constitute the Ethics Committee for Biomedical and Health Research involving Human Participants

Minutes of the meeting:

- Dr. Dasmit Singh chaired the session on behalf of Dr. L.S. Limaye as she was out of station on that day.
- Project proposal discussed in the previous meeting **‘Identification and validation of biomarkers for oral sub mucous fibrosis (OSF)’** was approved by the committee.
 - The project was approved earlier by IEC of MIMER medical college (IEC/652). MIMER medical college is a collaborating institute that will provide the samples from patients. MoU has been signed with MIMER medical college by the host institute.
 - This project was approved.
- The research proposal **‘Development of a Rowing Simulator Model to Enhance Performance for Young Indian Rowers’** from MIT institute of design, MIT ADT University was presented by Dr. Wricha Mishra.
 - Researchers were asked to include Anthropometric profiles of test individuals by Mrs. Vaishali Deshpande.
 - The proposal was approved with minor corrections by the committee.
 - The corrected copy is enclosed (Annexure 1).
- Project proposal **‘Development of point of care analytical devices for clinical diagnosis’** was presented by Dr. Chandrakant Tagad.
 - Dr. Dasmit Singh suggested to use punched filter papers to get uniform size of test area and to avoid pipetting. He also suggested performing standardisation of pictures taken from mobile for collecting data for the project.
 - The proposal was accepted by the committee after asking some questions related to project.
- Project proposal **‘Validation of *in silico* mutations in ovarian cancer samples’** was presented by Dr. Aruna Sivaram.
 - The committee appreciated the need of development of early stage biomarkers for ovarian cancer.
 - They also pointed out that late diagnosis of ovarian cancer leads to lower survival rate among the patients, thus reiterating the development of a technology for detection of ovarian cancer in early stage.
 - Dr. Dasmit Singh and Dr. Abhijeet Tilak approved this project since the collaborating institute will collect biopsy samples and host institute will analyse them.
- Dr. Reema Shukla presented a proposal entitled **‘Automatic assistive device for abnormal gait pattern’**
 - The committee advised to complete the prototype for developed device and resubmit the proposal in the next IEC meeting.
 - Some suggestions were given by committee member for the improvements of the project.
 - Dr. Abhijeet Tilak suggested taking help of Artificial Limb Centre (AFMC) for the development of product.
 - Dr. Dasmit Singh asked to make the sole of the shoe as soon as possible.

- He also suggested replace scissor arrangement with another more sturdy arrangement that would also generate electricity.
- Dr. Abhijeet suggested this technology is more suitable for paediatric patients first because it requires less weight to be balanced.
- Dr. Kedar R.N. proposed addition of three new members to the committee; Dr. Aruna Sivaram, Dr. Neeraj Maheshwari, and Dr. Preetam Bala. This was approved by the committee.
- Ethics Committee for Biomedical and Health Research involving Human Participants was constituted as per gazette issued by Department of Health and Research (DHR) Govt. of India 'New Drugs and Clinical Trial Rules, 2019' dated 19/03/2019.
The following documents were duly signed by each member of the committee (Annexure II):
 - Confidentiality Agreement
 - Declaration of Conflict of Interest
 - Consent Letter
- In conclusion, the chairperson appreciated the nature of interdisciplinary and complementary expertise of the institute.
- The meeting was concluded with the vote of thanks by the Member Secretary.

Enclosures:

- Annexure I: Modified proposal for 'Development of a Rowing Simulator Model to Enhance Performance for Young Indian Rowers'
- Annexure II: Documents pertaining to Ethics Committee for Biomedical and Health Research involving Human Participants
- Annexure III: Project approval letters of human IEC, MIT – School of Bioengineering Sciences and Research.

Member Secretary


Dr. Kedar R.N.




MIT School of
**Bioengineering Sciences
& Research**
Breathe Life into Engineering Career!

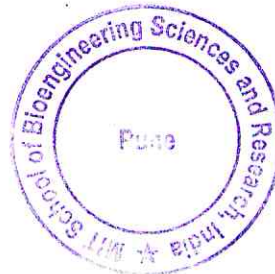



**MIT-ADT
UNIVERSITY**
PUNE, INDIA
Always Research. Always Learn. Always Educate.

Allocation of Research Supervisor/ RAC for Ph.D Batch 7 (Sep 2020) -Bio Engineering

Sr. No	Name of Scholar	Name of Research Supervisor - Allotted (with designation and affiliation)	Name of Co-Supervisor/ Co-guide (if any) (with designation and affiliation)	RAC Experts with name, designation &	
				Internal Member	External Member
1	Ms. Pradnya Pravin Gurav	Dr. Kedar Nirmala, Assistant Professor, MIT SBSR, Pune	Dr. Mohan R. Vani, Scientist G, NCCS, Pune	Dr Neeraj Maheshwari	Dr Anup Kulkarni
2	Mr. Ramakant Bhikoba Bhosale	Dr. Aruna Sivram, Assistant Professor, MIT SBSR, Pune	Dr. Renu Vyas, Head of the School, MIT SBSR, Pune	Dr Nayana Patil	Dr Sujoy Saha, Senior scientist, ICAR NRCG, Pune
3	Mrs. Neeta Ashok Chaughule	Dr. Madhura Chndrashekar, Assistant Professor, MIT SBSR, Pune	Dr. Pranav Pathak, Assistant Professor, MIT SBSR, Pune	Dr Preetam Bala	Dr Chawak ,General Manager, PDRC, Pune
4	Ms. Vaishnavi Suresh Chepe	Dr. Madhumita Tarai, Assistant Professor, MIT SBSR, Pune	Dr. Preetam Bala, Assistant Professor, MIT SBSR, Pune Dr. Kedar Nirmala, Assistant Professor, MIT SBSR, Pune	Dr Chandrakant Tagad	Dr Vivek Vaidya, Director Serum Institute OF India, Pune
5	Mr. Surojit Sadhu	Dr. Renu Vyas, Head of the School, MIT SBSR, Pune	-	Dr KV. Swamy	Dr Krishnakumar, Manager, Genova Biopharmaceuticals, Pune


Dr. Madhura Chandrashekar
PhD coordinator
MITSBSR




Dr.-Renu Vyas
Head of the School
MITSBSR