

Minutes of the meeting of Local Research Advisory Committee under MRU held on 27 January, 2024 at UP University of Medical Sciences, Saifai.

Following faculty member of UPUMS and other medical Colleges attended the meeting of LRAC MRU on 27 January, 2024 offline and online mode:-

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| 1) Dr. Balvir Singh, Principal, ASMC, Firozabad | Chairperson |
| 2) Dr. Prabhat Kumar Singh, VC, UPUMS | Nodal Officer/Member Secretary. |
| 3) Dr. D.S. Martolia, Professor & Head,
Department of Community Medicine,
GMC, Kannuj | Co-Chairperson |
| 4) Dr. Tej Pal Singh, Professor (Medicine)
SNMC, Agra | NCD-Expert (External) |
| 5) Dr. Ramakant Yadav, HOD Neurology & Pro-VC | NCD-Expert (Internal) |
| 6) Dr. Dhiraj Kumar Srivastava,
Prof. Community Medicine | NCD-Expert (Internal) |
| 7) Dr. Sushil Kumar Shukla, Professor
Prof. Community Medicine | Co-ordinator |
| 8) CMO, Etawah | Nominee of State Health Department |

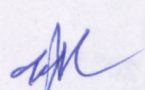
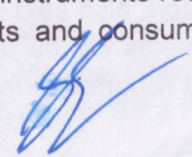
In the third meeting of LRAC, Dr. Prabhat Kumar Singh, Vice Chancellor of UPUMS and Member Secretary, MRU, UPUMS to know about the current progress of the projects approved in the second meeting which was held on 9 November, 2023. The coordinator has explained the progress of LRAC approved projects. The Coordinator MRU stated that the procurement of all necessary instruments and consumable are under process and tenders have been published on GEM portal. The member secretary has instructed the Coordinator MRU and Joint Director, Material Management to purchase all the necessary instruments/consumables at the earliest.

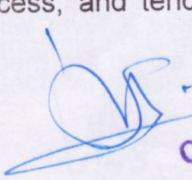
The Coordinator, MRU has briefed the call for multi-centric proposal invited by Department of Health Research, MoHFW, Gov. of India for the hosting institute of MRU.

Member Secretary of MRU Welcomed the Chairperson Dr. Balvir Singh, Principal ASMC, Firozabad, Co-chairperson Dr. D.S. Martolia, Professor and Head, Department of Community Medicine, GMC, Kannauj and NCD expert (external) Dr. Tej Pal Singh, Professor, Department of Medicine, SNMC, who attended meeting on online mode.

Dr. Ramakant Yadav, NCD expert (internal) UPUMS and CMO, Etawah (Nominee of State Health Department) also attended the meeting on online mode. Dr. Dhiraj Srivastava NCD expert (internal) UPUMS has also attended the meeting in physical mode. Dr. Neha Mishra is not available for the meeting due to prior commitments.

Very first in brief I explain all of you about the progress of MRU research Projects sanctioned in the second meeting. To begin, a total of nine research projects were sanctioned along with the list of 24 instruments required for the smooth function of the Projects. The procurement of instruments and consumables are under process, and tenders are published on the GEM-Portal.


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Agenda of today's meeting as under: -

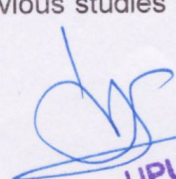
- (i) Approval of multi centric Research Projects (Enclosure No. 1) submitted under call for proposal invited by Department of Health Research, MoHFW, Govt. of India. for hosting institute of MRU for further considerations.
- (ii) Approval for the adoption of three state of art equipments (Next generation sequencer, oligonucleotide synthesizer and Flowcytometry; Enclosure No. 2) at MRU for the promotion of quality medical research at UPUMS, Saifai, Etawah, U.P.
- (iii) Recommendation and Approval for the establishment of Data management cum teaching training centre at DHR-MRU (Enclosure No. 3)

Following are the multi-centric Research Projects for approval:

- 1) **Dr. Durgesh Kumar, Professor, Department of Pediatric, UPUMS Saifai Etawah presented his Research Topic in front of committee for approval. His Topic for Research is **Clinical and laboratory profiles including potential biomarkers to predict severity and outcomes of Dengue Fever among Children: A Multicentric cross-sectional study****

Dr. Durgesh Kumar has presented the objective of the study, rationale, hypothesis, methodology, outcome, and budget requirements for research on his topic. Dr. Durgesh Kumar also stated the role of other investigators from the Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, and Government Medical College, Kannauj, for the execution of the proposed research project. He has informed the committee members that the investigators will take 1160 samples (386 samples from each site) for their research study. The Member Secretary, Prof. P.K. Singh, asked investigators what the new finding for this study is, as if the routine biomarkers had already been in use for the detection of viruses. Why are investigators measuring the routine clinical parameters in this study, among which many are not specific to dengue? How could they set up a correlation specific to the severity of dengue? He also asked how this study helped in predicting the severity of dengue. The Investigators responded that the Prediction of the severity helps to better management and escalate care. Studies to the above end have been limited in pediatric population and can provide a varied combinations of clinical and biochemical predictors of disease in pediatric. Therefore, exploration of clinical and biochemical parameters at the time of patient's presentation can be a potential predictor to access the severity of dengue disease. A system to predict those at risk of severe disease early in the infection i.e. within 2-3 days of onset of fever, could prevent unnecessary hospital admission and time intervention which may ultimately reduce the mortality risk due to dengue.

Prof. T.P. Singh (NCD expert-external) asked investigators how the sample size is calculated and how they would get samples after 2-3 days of the onset of fever. The investigators responded that they took the help of a biostatistician, and based on the prevalence rate in India, they calculated the sample size. The investigators also said that the children with OPD and IPD who have a fever will be enrolled, and samples will be taken after 2-3 days. Prof. T.P. Singh also asked are there any previous studies reported in this area? The investigators

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responded that only a few studies have been reported and only in adult patients. Prof. T.P. Singh (NCD expert-external) also asked are the investigators included biomarkers specific to the dengue? Investigators said a few biomarkers showed elevated levels in adult patients infected with dengue, and they will check the similar role in pediatric populations. The approximate budget for this research project is Rs. 49,75,900 (Projects attached, Encl. 04).

Decision: The committee approved the project proposal for further submission and consideration under the call for proposals invited by the Department of Health Research, MoHFW, Govt. of India, New Delhi.

- 2) **Dr. Dinesh Kumar, Professor, Department of Pediatric, UPUMS, Saifai** presented his Research Topic in front of committee for approval. His Topic for Research is **“Clinico-Epidemeological Profile of Rickettsial Diseases in Children of Western Uttar Pradesh”**.

Dr. Dinesh Kumar has presented the objective of the study, rationale, hypothesis, methodology, outcome, and budget requirements for research on his topic. Dr. Dinesh Kumar also stated the role of other investigators from GSVM Medical College, Kanpur, and SN Medical College, Agra, in the execution of their proposed research project. He has informed the committee members that the investigators will take 2000 samples (667 samples from each site) for their research study. The committee asked how the sample size was calculated using the incidence rate of rickettsial disease. The investigators responded that the sample size was calculated after consulting a biostatistician. The committee also asked how many patients are approaching OPD in UPUMS with rickettsial disease and how are investigators diagnosing it? What is the prevalence rate of rickettsial disease in the state of Uttar Pradesh? The investigators responded that paediatric patients with eschar and fever for more than five days are approaching the OPD with possible rickettsial infection, and currently we do not have the facility to categorize rickettsial infections. Few studies in Gorakhpur and Lucknow showed the prevalence rate was approximately 5%. Prof. (Dr.) P.K. Singh, Member Secretary, asked how investigators would calculate the complications of rickettsial disease. The investigators responded that the presenting clinical features, like lymphadenopathy and involvement of multi-organs like the lung, liver, and kidney, etc., will be accessed during infection and treatment procedures. Investigators will also evaluate the hospital discharge time.

The approximate budget for this research project is Rs. 10077429; Project attached (Encl. 05).

Decision: The committee approved the project proposal for further submission and consideration under the call for proposals invited by the Department of Health Research, MoHFW, Govt. of India, New Delhi.

- 3) **Dr. Savita Agarwal, Department of Pathology, UPUMS, Saifai.** Presented her research topic **“A Prospective study to assess correlation of immunohistochemical expression of biomarkers and response with FDG PET in oro, hypopharyngeal and laryngeal carcinoma after treatment with radical radiotherapy**

Dr. Savita Agarwal has presented the objective of the study, hypothesis, methodology, outcome, and budget requirement for research on his topic. She informed the committee member that she would take 50 patients for the proposed study. The samples will be taken from ESIC Medical College before PET-Scan analysis. The rest of the objectives will be done at UPUMS. Prof. (Dr.) P.K. Singh, Member Secretary, asked about the significance of the

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study and how the investigators would decide on PET scan analyses of patients. The investigator responded that in this study, they will perform immunohistochemical expression of certain biomarkers (CAIX, Bcl-2, Ki-67, EGFR, and HPV) and correlate them with the PET scan. If they find any correlation with biomarkers, that will assist in patient stratification and identify those patient groups that would most likely benefit from specific targeted therapies. Prof. (Dr.) T.P. Singh, NCD-Expert-external, asked where the PET-Scan analysis will be done and who will bear the cost of the scan. The investigators responded that the PET-Scan analysis is routinely done at ESIC, Faridabad. The Member Secretary also asked what the follow-up time is for patients with carcinoma and what investigators will address during follow-up. The investigators responded that every follow-up time will be 2-5 months, and they will access any new site recurrence and tumour progression. Approximate Budget for this research project is Rs. 1,590,320_/_-(Project attached Encl. 06).

Decision: The committee approved the project proposal for further submission and consideration under call for proposal invited by Department of Health Research, MoHFW, Govt. of India, New Delhi.

- 4) **Dr. Amit Singh, Professor, Department of Microbiology**, presented his research topic "Screening of biofilm inducing genes in drug resistant *M. tuberculosis* and identification of druggable molecule inhibiting the biofilm formation"

Dr. Amit Singh has presented the objective of the study, hypothesis, methodology, outcome, and budget requirement for research on his topic. **The approximate budget for this research project is 25,760,558/-.** PI Demanded Rs 2.2 crore in equipment head for the state-of-the-art equipment "Next Generation Sequencer" (Encl. 02 and 07). He also stated that a total of 10 samples of drug-resistant tuberculosis will be taken from SN Medical College, Agra, and ASMC, Firozabad. The committee asked to increase the sample size. The investigators have given consent to increase the sample size to 60 (20 from each site). Dr. P. K. Singh, Member Secretary, asked how would the project help society with better patient care, and Prof. T.P. Singh (NCD Expert—External) has also asked how the outcomes would provide a better option with standard treatment procedures? The investigator responded that the project's findings will reveal various new targets and drug repurposing potential for the development of novel or combination therapies, and help in the management of TB disease. The screened drugs (FDA-approved) from the proposed study can be a new treatment approach that would minimizing the risk of emergence of drug resistant strains of *M. tuberculosis*. The combinational therapeutics may also aid to reduce the longevity of the regimens. The outcomes of the study can also be subjected to human trials directly.

Decision: The committee approved the project proposal for further submission and consideration under call for proposal invited by Department of Health Research, MoHFW, Govt. of India, New Delhi.

- 5) **Dr. Rajesh Kumar Thakur, Associate Professor, Department of Biochemistry**, presented his research topic "Prevalence of extents of DNA damage in the Cells of oral cavity among tobacco chewers: A cross-sectional study for molecular predictors of oral cancer"

Dr. Rajesh Kumar Thakur has presented objective of study, Hypothesis, Methodology, Outcome and Budget requirement for research of his Topic. He informed the committee member that the study will take 600 patients for the proposed study. The Investigators from

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Sharda University will also be participated in this project, they will contribute to the molecular, proteomic, and genomic sequencing sections. Prof. (Dr.) P.K. Singh, Member Secretary, asked about the other similar studies conducted in India. The investigators responded that few part of projects like micro-nucleic/ comet assay in oral cancer patients have also been reported in Andhra Pradesh and Tamil Nadu, however no such studies have been done in north India. The Committee has suggested to develop own infrastructure to conduct this proposed research work within DHR-MRU premise. Investigator has included the equipment flowcytometry in the items required for project and also in budget head. Approximate Budget for this research project is Rs. 1,77,12,962 (Project attached Encl.08, including one state of art equipment flowcytometry-Encl. 02).

Decision: The committee approved the project proposal for further submission and consideration under call for proposal invited by Department of Health Research, MoHFW, Govt. of India, New Delhi.

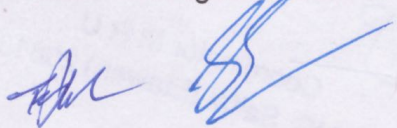
- 6) **Dr. Sanjay Kumar Kannaujia, Associate Professor, Department of Pathology, UPUMS Saifai Etawah** presented his Research Topic in front of committee for approval. His Topic for Research is Role of PCA3 in screening and diagnosing the case of prostate cancer and its correlation with DRE, PSA and Histopathological examination: A Prospective cross-sectional study in tertiary care center

Dr. Sanjay Kumar Kannaujia has presented the objective of the study, rationale, hypothesis, methodology, outcome, and budget requirements for research on his topic. Dr. Sanjay Kumar Kannaujia also stated that an investigator from SGPGIMS, Lucknow, will also do the sampling for the execution of the proposed research project. He has informed the committee members that the investigators will take 80 samples (40 from each site) for their research study. The committee asked how investigators calculated the sample size up to 80. Investigators responded that a total of 25-30 patients approach at the proposed site had prostate cancer; based on that, they calculated the samples. The committee asked how the screening of PCA3 will be better than the estimation of PSA level. The investigators responded that there is a false rate of PSA-level diagnosis of prostate carcinoma, and PCA-3 level has been found to be a more sensitive assay than PSA-level. The member secretary asked investigators to modify your project in order to develop a sensitive diagnostic assay for prostate carcinoma using PCA-3 levels. The investigators have given consent to modify the proposal according to the suggestions given by the committee. Approximate Budget for this research project is Rs. 22,75,900 a/- (Project attached- Encl. 09).

Decision: The committee approved the project proposal for further submission and consideration under call for proposal invited by Department of Health Research, MoHFW, Govt. of India, New Delhi.

- 7) **Dr. Sushil Kumar Shukla, Department of Community Medicine, UPUMS Saifai Etawah** presented his Research Topic in front of committee for approval. His Topic for Research Next generation sequencing based platforms for bacterial pathogens of Hospital settings

Dr. **Sushil Kumar Shukla** has presented objective of study, rational, Hypothesis, Methodology, Outcome and Budget requirement. Dr. Sushil Kumar Shukla also stated the role of other investigators from S.N. Medical College, Agra, and AMSC, Firozabad, for the




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execution of their proposed research project. Approximate Budget for this research project is Rs. 27,501, 824, which includes a state of art equipments NGS sequencing with approximate cost 2.2Cr. (Project attached Encl.10).

Decision: The committee approved the project proposal for further submission and consideration under call for proposal invited by Department of Health Research, MoHFW, Govt. of India, New Delhi.

- 8) **Dr. Sajag Gupta**, Department of Neurosurgery UPUMS Saifai Etawah presented his Research Topic in front of committee for approval. His topic for research is Prognostic Evaluation Brain Biomarkers (GFAP, NSE, NfL, T-tau and S100 β) In Moderate – Severe traumatic Brain Injury: Observational Study.

Dr. Sajag Gupta has presented the objective of the study, hypothesis, methodology, outcome, and budget requirement for research on his topic. He informed the committee member that the study will take 80 patients (40 TBI subjects and 40 age- and gender-matched non-TBI subjects) for the proposed study. The Member secretary asked how the biomarkers (GFAP, NSE, NfL, T-tau, and S100 β) proposed in this study would affect the outcomes. The investigators responded that an elevated level of biomarkers may correspond to worst outcomes, and combining serum biomarker will increase prognostic value for functional outcome GOS in traumatic brain injury. The NCD expert Internal, Prof. Ramakant Yadav, asked how investigators would differentiate the level of biomarkers expressed under ischemia from TBI. The investigator responded that these biomarkers may also be expressed in ischemia, but we can differentiate them by history, clinical examination, and the presentation of causalities.

Decision: The Committee stated that the proposed research project is of single centric nature. So, it should be conducted within MRU. The committee has approved the approximate Budget of Rs 4,00,000 (Encl.11).

- 9) **Dr. Amita Singh**, Department of Physiology, UPUMS Saifai Etawah presented his Research Topic in front of committee for approval. His topic for research is investigating the association of HLA- Class I and HLA-Class-II alleles with the severity of *Mycobacterium tuberculosis* infection: A prospective study

Dr. Amita Singh has presented the objective of the study, hypothesis, methodology, outcome, and budget requirement for research on his topic. She informed the committee member that the study will take 336 newly identified TB patients' samples for the proposed study. The Member secretary asked if there any correlation between malnutrition, HLA typing, and the emergence of drug-resistant tuberculosis. The PI responded that there may be a possibility with the malnutrition and change in HLA typing linked with the emergence of drug-resistant M. tuberculosis. The PI has given consent to include one more objective in this proposed research project to assess the effect of malnutrition on HAL-typing and TB infection.

Decision: The Committee stated that the proposed research project is of single centric nature. So, it should be conducted within MRU. The committee has approved the approximate Budget of Rs. 500000 (Encl.12).

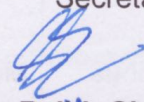
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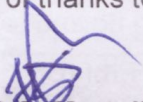
The Final Decision taken by the LRAC

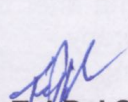
The committee has approved total Seven Multi-centric Projects for their further submission to DHR, MoHFW under the Extramural Project Grant scheme.

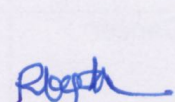
Committee has also approved two single-centric projects which are to be conducted under MRU. The committee approved the adoption of three state-of-the-art equipments (the Next Generation Sequencer, Oligonucleotide Synthesizer, and Flowcytometry; Enclosure 2) for an estimated cost of 4.8 Crore in order to promote and encourage quality medical research at UPUMS as well as the execution of approved projects under MRU. The committee also approved the establishment of a data management and teaching training centre under DHR-MRU (enclosure. 3), with an estimated cost of Rs 38 lakh.


In this meeting, the Member Secretary gave a clear message to all faculties/investigators that that medical research should be undertaken in hospitals/Medical college to strengthen the hospital's medical infrastructure in order to provide better patient care. Meeting ended by the Chairperson and Member Secretary of MRU with the vote of thanks to all.



(Dr. Balvir Singh)
Chairperson

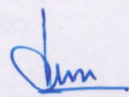

(Dr. D.S. Martolia)
Co-Chairperson

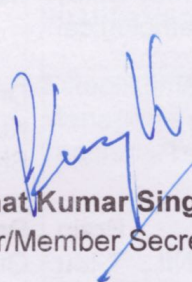

(Dr. Tej Pal Singh)
NCD-Expert (External)


(Dr. Ramakant Yadav)
NCD-Expert (Internal)


(Dr. Dhiraj Kumar Srivastava)
NCD-Expert (Internal)


(Dr. Sushil Kumar Shukla)
Co-ordinator

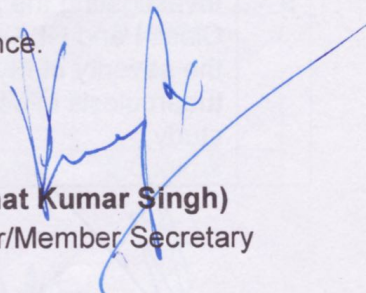

(CMO, Etawah)
Nominee of State Health Department


(Dr. Prabhat Kumar Singh)
Nodal Officer/Member Secretary

Ref No. 128/MRU/22/UPUMS/23-24

Date : 29 Jan, 2024

Copy to all above concern officer for information and necessary compliance.



(Dr. Prabhat Kumar Singh)
Nodal Officer/Member Secretary

Encl:- As Above

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Enclosure -01

Sr. No.	Title of the Project	Name of PI	Department	Domain	Type of Study
1	Clinical spectrum and laboratory profiles including potential biomarkers to predict severity, complications and outcomes of Dengue Fever among Children: A Multicentric cross-sectional study	Prof. (Dr.) Durgesh Kumar	Paediatric	Viral epidemic	Multi-centric
2	Clinico-Epidemiological Profile of Rickettsial Diseases in Children of Western Uttar Pradesh	Prof. (Dr.) Dinesh Kumar	Paediatric	Bacterial disease	Multi-Centric
3	A Prospective study to assess correlation of immunohistochemical expression of biomarkers and response with FDG PET in oro, hypopharyngeal and laryngeal carcinoma after treatment with radical radiotherapy	Prof. (Dr.) Savita Agarwal	Pathology	Cancer	Multi-centric
4	Screening of biofilm inducing genes in drug resistant <i>M. tuberculosis</i> and identification of druggable molecule inhibiting the biofilm formation.	Prof (Dr.) Amit Singh	Microbiology	Infectious disease/ tuberculosis	Muti-centric
5	Prevalence of extents of DNA damage in the Cells of Oral Cavity among tobacco chewers: A cross-sectional study for molecular predictors of oral cancer.	Dr. Rajesh Kumar	Biochemistry	Cancer	Multi-centric
6	Role of PCA3 in screening and diagnosing the case of prostate cancer and its correlation with DRE, PSA and Histopathological examination	Dr. Sanjay Kumar Kannaujia	Pathology	Cancer	Multi-centric
7	Next generation sequencing based platforms for bacterial pathogens	Dr. Sushil Kumar Shukla	Community Medicine	Bacterial Disease	Multi Centric
8	Prognostic Evaluation Brain Biomarkers (GFAP, NSE, NfL, T-tau and S100 β) In Moderate – Severe traumatic Brain Injury: Observational Study.	Dr. Sa raj Gupta	Neurosurgery	Trauma	Single Centric
9	Investigating the association of HLA-Class I and HLA-Class-II alleles with the severity of Mycobacterium tuberculosis infection: A prospective study	Dr. Am ita Singh	Physiology	Bacterial Disease	Single Centric


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Enclosure: 2

- List of instruments are required for the establishment of State-of-the-Art equipments at MRU and smooth functioning the projects approved/submitted under DHR-MRU, UPUMS, Saifai-206130.

Sr. No.	Name of Equipment	Quantity	Justifications	Approximate cost
1	Next Generation Sequencer	1	<u>State of the Art equipment</u> and required for the Project Sr. No.4 & 7	2.2 Cr
2	Oligonucleotide Synthesizer	1	<u>State of the Art equipment</u> and required for Sr. No. 2, 4, 5 & 6 and functioning of previously LRAC approved projects (P01-03, 05, 07-08)	1.5 Cr
3.	Flowcytometry	1	<u>State of the Art equipment</u> and required for the Project Sr. No. 5	1.1 Cr.
Total Approximate Cost				4.8 Cr.

Enclosure 3

- Establishment of Data Management cum Teaching/Training Centre at DHR-MRU

Sr. No.	Name of Equipment	Quantity	Justifications	Approximate cost
1	Dump Terminal Desktop/Computer with all accessories Networking, Application Server, Storage Server,	30	Establishment of Data Management cum Teaching/Training Centre	30.0 lakhs
2	(i) Multifunctional heavy-duty network-based laser printer	01	Establishment of Data Management cum Teaching/Training Centre	5.0 lakh
	(ii) Photocopy Machine	01		1.0 lakh
4	LED projector with Screen	01	Required to Conduct Seminar/workshop/training/ at DHR-MRU, UPUMS, Saifai	2.0 lakhs
Total Cost (Approximate)				38.0 lakhs

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