

Swami Rama Himalayan University

Swami Ram Nagar,
P.O. Jolly Grant, Dehra dun 248016 (INDIA)
Phone: 91-135-2471111, Extn. 328, Fax 910135-24711122

Dated: 08.07.2024

SRHU/HIMS/ETHICS/2024/132

"Ethics Committee"

A meeting of Ethics Committee is convened on 13.07.2024 at 11.00 AM in the Deptt. of Pharmacology,
HIMS

Agenda

1. Extramural project "Real-World Indian Registry Study of Atezolizumab in Lung Cancer Tecentriq® Lung Registry". Documents Submitted by Dr Ankit Batra, Asstt. Prof, Deptt of Medical Oncology CRI, HIMS.
2. "Quantitative effect of antiplatelet therapy and second stroke in patients of ischemic stroke - An observational follow up study". By Dr. Yogesh Saxena Professor, Deptt of Physiology, HIMS
3. PhD research Synopsis entitled "Effect of family Integrated Care Model on outcomes of Preterm Neonates, Stress and Self-Efficacy of parents in the Neonatal Intensive Care Unit of a Tertiary Care Hospital in Dehradun, Uttarakhand." Submitted by Neeta Rawat, under the guidance of Dr Vandana Chauhan, Assoc Prof Himalayan College of Nursing.
4. Extramural Project entitled "Investigating Microglia Activity and Lipid Droplets in Glioblastoma Niche" By Dr Kanchan Bisht, Scientist D, Research and Development Cell, Swami Rama Himalayan University, Jolly Grant, Dehradun.
5. Extramural Project entitled "Impact of a Therapeutic Diet to prevent disease development & progression on undernourished household contacts of confirmed pulmonary tuberculosis patients." Submitted by Dr. Rakhee Khanduri, Professor & Head Respiratory Medicine, HIMS
6. Extramural Project entitled "Assessment of clinical outcome of sepsis patients in ICU on early diagnosis of causative pathogens and antimicrobial resistance using Indigenous gene-based panel." Submitted by Dr. Sonika Aggarwal, Professor and Head, Critical Care Medicine, HIMS.
7. Extramural Project untitled "Enhancing patient out comes through preoperative nutrient supplementation in breast cancer patients - A pilot study" By Dr. S.K. Verma professor Medicine HIMS.
8. STS projects (Two) : 1. from Mr Dristideum Malik Under Dr Nikita Agrawal (Paediatric) and 2. from Ms Tripti Kunwar under Dr Pragya Tripathi (Forensic Medicine)
9. PhD Synopsis "A study on the effect of yoga on drug addicts, by Navneet under supervision of Dr Samrata Zha, HSYs,

Any Other Matter:

1. Request for Upgradation of Co-PI to PI on already approved project of Dr Basanta Khatiwada entitled "Cardio-pulmonary adverse transfusion reactions (CPATR): A 4-Year experience from a hospital-based blood centre in North India" of Deptt of Immunohematology and Blood transfusion as PI to Dr Manish Raturi.
2. STS Project of Dr N. Wadhwa under guidance of Dr N. Wadhwa Biochemistry dept



Dr. D.C. Dhasmana
Member Secretary, Ethics Committee
Swami Rama Himalayan University

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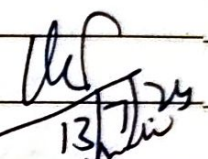
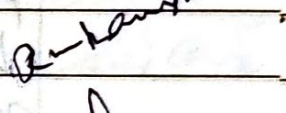
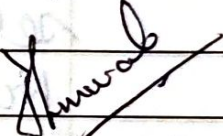
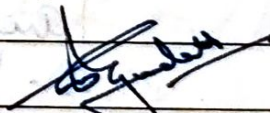
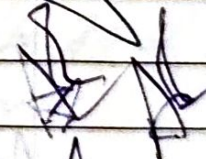
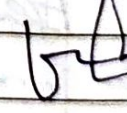
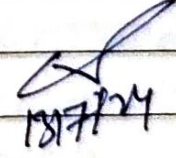
1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. All Members of Ethics Committee, HIMS, SRHU

Ethics Committee Meeting

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A meeting of Ethics Committee was held on 13.07.2024 at 11.0 AM in the dept of Pharmacology to consider the research projects as per the agenda circulated dated 09.07.2024.

The following members were present in the meeting:

1. Dr. Vinod Bihari Mahesh - Chairperson. 
2. Dr. Rajeev Mohan Koushik - Member 
2. Dr. Jayanti Senwal - Member 
4. Dr. Abha Srivastava - member 
5. Mr. GNS Gurudutt - Member 
6. Mr. Anur Kandra - member 
7. Mr. Sagar Mahwal - Member 
8. Dr. S.C. Shesmani. Member Secretary. 

At the outset the Chairperson welcomed the committee members.

The member secretary submitted the minutes of previous subcommittee held on 27/06/2024 for ratification by the full committee, and were passed

of therapeutic diet patients, submitted by Dr Rakhee Khanduri, Resp medicine was discussed and approved as such.

Agenda no 6: Extra mural project "Assessment of clinical outcome gene based panel" submitted by Dr Sanika Agrawal was approved in the present form.

Agenda no 7: Extra mural project "Enhancing patient out comes A pilot study" by Dr SK Varma, Med. dept was discussed and approved in the present form.

Agenda no 8: STS projects submitted were approved as such.

Agenda no 9: PhD Synopsis: A study on the effect of yoga addicts: by Mr Naveet under guidance of Dr. Nishita Chhabra was approved in the present form.

- Any other matter: : 2: Request of COINV to become PL for already approved project was approved.
2. STS project of Mrs. Srijan Chhabra under guidance of Dr Nishita Chhabra was approved.

The meeting ended with vote of thanks to chair.

for Journal
13/7/24

(Dr Vinod B. Mathur)
Chairman

13/7/24
(Dr SC. Shesma)
Mark Secretary

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SRHU/HIMS/ETHICS/2024/209

Dated: 20.08.2024

"Ethics Committee"

A meeting of the Sub Committee on Ethics Expedited review is convened on 24/08/2024 (Saturday) at 11:00 AM in the Deptt. of Pharmacology, HIMS.

Agenda:

1. **RESEARCH PROTOCOL (INTRAMURAL):** "Systemic immune-inflammation index (SII) as a predictor of systemic inflammation and anaesthesia risk tool in the preoperative setting- A prospective observational study. " Submitted by Principal investigator, Dr. Nirupa Ramakumar, Asstt. Professor, Deptt. of Anaesthesiology, HIMS, Swami Rama Himalayan University.
2. **RESEARCH PROTOCOL (INTRAMURAL):** "The assessment of micronutrients levels in adults experiencing depression and their correlation with severity of depressive symptoms. " Submitted by Principal investigator, Dr. Anita Sharma, Professor, Deptt. of Biochemistry, HIMS, Swami Rama Himalayan University.
3. **RESEARCH PROTOCOL (INTRAMURAL):** "Endovascular salvage of thrombosed arteriovenous fistula/ arteriovenous graft by an interventional nephrologist: An Indian experience. " Submitted by Principal investigator, Dr. Shahbaj Ahmad, Assoc. Professor, Deptt. of General Medicine, HIMS, Swami Rama Himalayan University.
4. **RESEARCH PROTOCOL (INTRAMURAL):** "The repertoire of dialysis access interventions through the radial artery." Submitted by Principal investigator, Dr. Shahbaj Ahmad, Assoc.Professor, Deptt. of General Medicine, HIMS Swami Rama Himalayan University.
5. **RESEARCH PROTOCOL (INTRAMURAL):** "Immunophenotypic aberrancies in T cell acute lymphoblastic leukemia – a tertiary health care centre experience at Uttarakhand. " Submitted by Principal investigator, Dr. Smit Garg Asstt. Professor, Deptt. of Pathology, HIMS, Swami Rama Himalayan University.
6. **RESEARCH PROTOCOL (INTRAMURAL):** "Evaluation of clinic-radiological outcome of tubercular spine patient undergoing surgical intervention at a tertiary care center." Submitted by Principal investigator, Dr. Alok Kumar Jaiswal Senior Resident (M.ch) , Deptt. of Neurosurgery, HIMS, Swami Rama Himalayan University.
7. **RESEARCH PROTOCOL (INTRAMURAL):** "Functional outcome prediction of traumatic spinal cord injury after surgical fixation." Submitted by Principal investigator, Dr. Anikt Bhatia, Senior Resident, Deptt. of Neurosurgery HIMS, Swami Rama Himalayan University.
8. **RESEARCH PROTOCOL (INTRAMURAL):** "Effect of Yoga on gestational diabetes mellitus – A randomized control trial." Submitted by Ms. Ritu, Under the guidance of Dr. Somlata Jha, Asstt Professor, Himalayan School of Yoga Sciences, Swami Rama Himalayan University.
9. **RESEARCH PROTOCOL (INTRAMURAL):** "Evaluation of trends in the risk alalysis data of clinical biochemistry laboratory: Six sigma methodology." Submitted by Principal investigator, Dr. Kiran Bhat, Professor & Head, Deptt. of Biochemistry, HIMS, Swami Rama Himalayan University.
10. **MHA Student (Batch 2023-25)** Projects for Ethics clearance (9 in Number)
11. **RESEARCH PROTOCOL (INTRAMURAL):** "Impact of Yoga Practices on Physiological, Biochemical and Psychological Parameters in young adults - A pilot Study." Submitted by Principal investigator, Dr. Ankit Sharma, Asstt Professor, Himalayan School of Yoga Sciences Swami Rama Himalayan University.



CONF... (2)

12. **RESEARCH PROTOCOL (INTRAMURAL):** "Evaluation of clinical profile, functional outcome and neurophysiological changes following carpal tunnel release a prospective study." Submitted by Principal investigator, Dr. Kunwar Raj Gandhi, Senior Resident, Deptt. of Neurosurgery, HIMS, Swami Rama Himalayan University.
13. **RESEARCH PROTOCOL (INTRAMURAL):** "Role of beta blockers in moderate and severe traumatic brain injury outcome- A randomized controlled trail." Submitted by Principal investigator, Dr. Naman Kuriyal, Senior Resident, Deptt. of Neurosurgery, HIMS, Swami Rama Himalayan University.
14. **RESEARCH PROTOCOL (INTRAMURAL):** "Predicting the malignancy in contralateral thyroid lobe in patients undergoing completion thyroidectomy- a retrospective, cross sectional study." Submitted by Principal investigator, Dr. S.S. Bist, Professor & Head, Deptt. of ENT, HIMS, Swami Rama Himalayan University.
15. **RESEARCH PROTOCOL (INTRAMURAL):** "Quantifying prevalence of pediatric preoperative device distraction (PPDD) and corresponding changes in preoperative anxiety per modified yale preoperative anxiety scale-short form (mTPAS-SE)- A cross sectional study." Submitted by Principal investigator, Dr. Divya Gupta, Professor, Deptt. of Anaesthesiology, HIMS, Swami Rama Himalayan University.
16. **RESEARCH PROTOCOL (INTRAMURAL):** "A retrospective study of limb ischemia surgery in a tertiary health center insights & comparisons with western Standards." Submitted by Principal investigator, Dr. Bhawna Singh, Assoc. Professor, Deptt. of CTVS (Surgery), HIMS, Swami Rama Himalayan University.
17. **RESEARCH PROTOCOL (INTRAMURAL):** "Preoperative nutritional assessment of children and its impact on postoperative outcome after elective major operations." Submitted by Principal investigator, Dr. Santosh Kumar Singh, Professor, Deptt. of Paediatric Surgery, HIMS, Swami Rama Himalayan University.
18. **RESEARCH PROTOCOL (INTRAMURAL):** "Pattern of intestinal obstruction in pediatrics population in Uttarakhand: A Single-centre Experience." Submitted by Principal investigator, Dr. Santosh Kumar Singh, Professor, Deptt. of Paediatric Surgery, HIMS, Swami Rama Himalayan University.
19. **RESEARCH PROTOCOL (INTRAMURAL):** "Evaluation of human umbilical cord blood derived platelets rich plasma (CB-PRP) and peripheral blood isolated PRP (PB-PRP) for antimicrobial activity." Submitted by Principal investigator, Dr. Purandhi Roopmani, Asstt. Professor, Himalayan School of Biosciences, Swami Rama Himalayan University.
20. **RESEARCH PROTOCOL (INTRAMURAL):** "A cross sectional study on knowledge and attitude regarding screen of cervical cancer among adult women in selected community area of Doiwala Dehradun, Uttarakhand." Submitted by Principal Investigator, Ashish Kukreti, Prerna daksh, Pragati gusian, Priya Rajput & Anju Negi Under the guidance of Dr. Kanchan Bala, Assoc. Professor, Himalayan College of Nursing, Swami Rama Himalayan University.
21. **P.h.d synopsis:** Investigating the impact of heavy metals and their target genes in polycystic ovary syndrome (PCOS) patients of Mr. Himanshu Under the guidance of Dr. Sajnay Gupta Professor & Principal Himalayan School of Biosciences. Swami Rama Himalayan University.
22. **Intramural Project** untitled "Enhancing patient out comes through preoperative nutrient supplementation in breast cancer patients - A pilot study, already approved change in title of the study "By Dr. S.K. Verma professor Medicin HIMS.
23. **RESEARCH PROTOCOL (INTRAMURAL):** "To study accuracy of FNAC ovarian masses with histopathologic and serological correlation for assessment of risk of malignancy. A retrospective study." Submitted by Principal investigator, Dr. Monika Singh Asstt. Professor, HIMS, Swami Rama Himalayan University.

Any Other Matter:

24. Submission of VIP Post Randomization lipid panel blinding. Dear Dr. letter template: (PI) Approval of Protocol No. CKJX839D12302 VICTORION-1 PREVENT) by Dr. Kunal Gururani
25. ~~Study Guide~~: Patient accrual method for IEC Submission of CAMBRIA 2 study D8535C00001, study already approved submitted by Dr. Ankit Batra

Copy to:-

1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. All Members of Ethics Committee, HIMS, SRHU

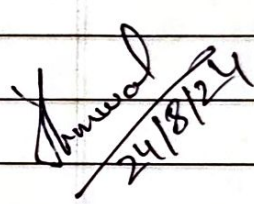
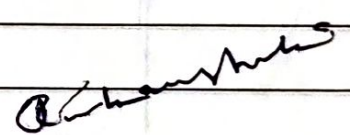
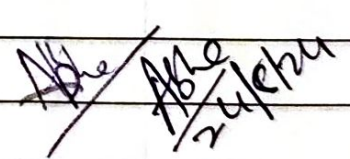
Dr. D.C. Dhasmana
Member Secretary, Ethics Committee
Swami Rama Himalayan University

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Ethics Committee Meeting
Minutes of the sub-committee meeting

A meeting of sub-committee on Ethics expedited review was held on 24.08.2024 at 11.0 AM in the Dept of Pharmacology, HIMS to consider the following projects as per the agenda circulated in advance dt 20.08.2024 vide letter no. 524/HIMS/ETHICS/2024/

The following members were present:

1. Dr Jayant Semwal
Acting chair person  24/8/24
2. Dr. Rajeev Mohan Kaushik
Member 
3. Dr Abhe Sonvadave
member  24/8/24
4. Dr D.C. Desmana.
Member Secretary 

As per the permission obtained from the Chairperson Ethics Committee, a sub-committee comprising of 4 members was constituted to evaluate the human trial projects for review as per the agenda circulated in advance.

Appropriate decisions were taken for each protocol as follows:

Agenda No 1: Systemic ... (512) - ... A prop
Obs. study by Dr Nirupa Ramakrishna kuma
dept of androscology was discussed and
approved subject to changes in method
by incorporating written informed consent and
attachment of appropriate consent form.

Agenda No 2: Assessment of micronutrients
... depressive symptoms submitted
by Dr Anita Sharma, Bf Biochemistry,
was discussed, and was approved subject to
the well defined case & controls as per case control
study and attachment of consent document.

Agenda No 3: Endovascular Salvage ...
Ar India Experience, submitted by Dr
Shahid Ahmed, Gen Med was approved as
retrospective study subject to addition
of all personal data of pt shall be anonymous
most and confidentiality of data shall
be maintained.

Agenda No 4: The repertoire of chaperon
... radiolabelled submitter by Dr Shahid
Ahmed, as part of retrospective study
was approved subject to submission
of anonymity & confidentiality state-
ment & methods.

Agenda no 5: Morphotypic abnorm
cell ... operation is Udasachand,
 submitted by Dr. Sumit Gang, dept of
Pathology was approved as such
 as retrospective study, subject to
 addition of randomization, personal
data of patients and confidentiality.

Agenda no 6: Evaluation of clinico-
radiological outcome ... tertiary
care centre by Dr. Alok K. Jaiswal, SK
Neurosurgery has approved subject to
 submission of Informed Consent
document.

Agenda no 7: Functional outcome -
surgical fixation submitted
 by Dr. Ankit Bhatia SK Neurosurgery was
 approved subject to addition of written
informed consent & methods.

Agenda no 8: Effect of Yoga on skeletal
dist ... a PhD R. Anupam was by
M. Ritu was considered and suggest
approved after rectification of
objective, method of randomization
consent form & a written informed
consent, Once revision is done shall
 then only be approved.

Agenda no 9: Evaluation of Hand ...

... methodology, submitted by Dr. Kanan Bhatt, Prof. Head biochemistry was approved as such as there was no involvement of persons directly or indirectly with the study.

Agenda NO 10: MHA Studies (2022)
Total 9 projects were screened by a subcommittee and as such approved in the meeting of Ethics Committee

Agenda NO 11: Impact of Yoga practices
... a pilot study, submitted by Dr. Ankit Sharma (HIS) was approved as such in the present form

Agenda NO 12: Evaluation of Clinical
... Prospective study by Dr. Kanan Raj Gandhi - Neurosurgery was approved as such in the present form after discussion

Agenda NO 13: Role of Betablocker
... a randomized controlled trial, submitted by Dr. Naman Kuriyal SR M.S. was discussed and after deliberations it was conveyed to us that it is better to change it to an observational study since random trial, or if trial then all the formalities need to be fulfilled. Once changes are made, it is taken to be

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approved in the meeting.

Agenda No 14: Predicting its malignancy
Thyroid. Cross sectional study
submitted by Dr SS. Bist. HOD ENT.
was considered and approved subject-
to addition of statement on
anonymisation of data and confidentiality
of patients in methods.

Agenda No 15: Quantifying prevalence
..... A cross sectional study
submitted by Dr Divya Gupta, Anesth
dept was approved subject to sub-
mitter informed consent be mentioned
in methods and appropriate consent
form to complete in all aspects be
attached with the protocol.

Agenda No 16: A retrospective study
..... western standard by
Dr Bhawna Singh. for Surgery
dept was considered and
approved as such in the meeting.

Agenda No 17: Preoperative
..... nutritional assessment
..... elective major operations. by Dr
Suresh K Singh, for Surgery was
considered and approved subject to
certification of measurements of

nutritional status of patient by anthropometric, clinical & lab investigations and adding written informed consent in methods and appropriate consent form attached.

Agenda no 18: Pattern of Intestinal Obstr. ulnar Khan, submitted by Dr. Sanjay K. Singh as part of retrospective study was approved subject to deletion of "any" name of personal data of patients as confidentiality in method.

Agenda no 19: Evaluation of Anticancer Activity submitted by Dr. Purnima Pappani Att by HRS was considered and approved subject to rectification of Cognate's name, consent form attachment, and grammatical & correction of protocol writing.

Agenda no 20: Research study A case control study ulnar Khan submitted by post basic B.S. (N) students Dr. Anshu guidance of Dr. Kamla Bala was considered and approved as such in the present form.

Agenda no 21: PhD synopsis

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entitled Investigating the impact
of Heavy metals ... patients
submitted by Dr. Sangeeta Gupta Mrs
Himanshu Kulkarni and no. guidance
of Dr. Sangeeta Gupta was considered
and approved subject to addition
of cognate from OHS/Genec
department and attachment of
appropriate consent forms.

Agenda No. 22: Enhancing patient
... A pilot study
submitted by PI Dr. SK Verma
Prof of Medicine was approved as such
as the same protocol with a slightly
different title was approved in
the previous meeting for LICOST
submission.

Agenda No. 23: To study accuracy
of A PNA - ... malignancy
submitted by PI Dr. Monika
Singh. Pathology was as a
retrospective study was approved
as such subject to addition
of Anonymisation of personal data
of patient and confidentiality
of data to be maintained by the
PI in methods.

Any other matters:-

24. Submission of a letter for
referral letter was approved
by the committee for approval letter

25. Patient access method for
DEC submission of Cambodia 2
study by Dr Anil Bhatta was
approved as submitted to the
Ethics committee. for earlier
approval letter.

The member secretary apprised
the committee members of the
latest development in the request
the update of Ethics Committee
SRHO at DHR (ICMR) site.

The meeting ended with vote
of thanks to the chair.

~~Approval~~
24/8/24

(Dr Jagant. Senarath)
Act. Chairperson

~~24/08/24~~
(Dr. N. C. Sharma)
Member
Secretary

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SRHU/HIMS/ETHICS/2024/342

Dated: 14.10.2024

"Ethics Committee"

A meeting of the Ethics Committee is convened on 19/10/2024 (Saturday) at 11:00 AM in the Deptt. of Pharmacology, HIMS.

Agenda:

1. **RESEARCH PROTOCOL (INTRAMURAL):** "Risk factors of coronary artery disease (CAD) among patients attending the coronary care unit of Himalayan Hospital: A record-based study." Submitted by Principal investigator, Dr. Ruchi Juyal, Professor, Deptt. of Community Medicine, HIMS, Swami Rama Himalayan University.
2. **RESEARCH PROTOCOL (Multicentric):** "Investigating children's experiences of preoperative fasting: Multi-centric mixed-modal cross sectional study." Submitted by Principal investigator, Dr. Divya Gupta, Professor, Deptt. of Anaesthesiology, HIMS, Swami Rama Himalayan University.
3. **PROTOCOL (STS):** "Pattern of antimicrobial use in ICU of a tertiary care teaching hospital." Submitted by Keertika Gangwar, under the guidance of Dr. Taruna Sharma, Professor & Head, Deptt. of Pharmacology, HIMS, Swami Rama Himalayan University.
4. **RESEARCH PROTOCOL (INTRAMURAL):** "Evaluation & validation of mastishq." Submitted by Principal investigator, Dr. Priyaranjan Avinash, Professor & Head, Deptt. of Psychiatry, HIMS, Swami Rama Himalayan University.
5. **RESEARCH PROTOCOL (INTRAMURAL):** "Study on the effect of transcutaneous electrical nerve stimulation (TENS) on pain, function, and quality of life in fibromyalgia (FM) patients- 2 -arm parallel-group pragmatic, randomized clinical superiority trial." Submitted by Principal investigator, Dr. Rambeer Ghuleliya, Asstt. Professor & In-charge, Deptt. of Physical Medicine and Rehabilitation, HIMS, Swami Rama Himalayan University.
6. **RESEARCH PROTOCOL (INTRAMURAL):** "Determinants of bottle feeding in the sub Himalayan region." Submitted by Principal investigator, Dr. Rakesh Kumar, Assoc. Professor, Deptt. of Pediatrics, HIMS, Swami Rama Himalayan University.
7. **RESEARCH PROTOCOL (INTRAMURAL):** "Evaluation of anthropometric parameters for prediction of cardiovascular disease risk in non-alcoholic fatty liver disease in resource-limited setting." Submitted by Principal investigator, Dr. Nishtha Wadhwa, Asstt. Professor, Deptt. of Biochemistry, HIMS, Swami Rama Himalayan University.
8. **RESEARCH PROTOCOL (INTRAMURAL):** "Ensuring integrity in healthcare: Good Clinical Practice and Medical Ethics Training." Submitted by Principal investigator, Dr. Nikku Yadav, Assoc. Professor, Deptt. of Clinical Research, HIMS, Swami Rama Himalayan University.
9. **RESEARCH PROPOSAL (Ph.D. Cell):** "Investigating metabolic biomarkers for early detection and intervention in Alzheimer's disease: A Comprehensive study." Submitted by Principal investigator, Dr. Kaushik P Sharma, Scientist D. Deptt. of Research & Development Cell, Swami Rama Himalayan University.
10. **RESEARCH PROPOSAL (Ph.D. Cell):** "Metabolic disorders in newborns: Linking laboratory testing to improved patient management and clinical outcomes in a tertiary hospital in Uttarakhand." Submitted by Principal investigator, Dr. Kiran Bhat, Professor, Deptt. of Biochemistry, Swami Rama Himalayan University.
11. **RESEARCH PROPOSAL (Ph.D. Cell):** "implementing remote ischemic conditioning (RIC) as an adjunctive therapy in acute ischemic stroke: A comprehensive study in the Uttarakhand region." Submitted by Principal investigator, Dr. Kaushik P Sharma, Scientist D. Deptt. of Research & Development Cell, Swami Rama Himalayan University.
12. **RESEARCH PROPOSAL (Ph.D. Cell):** "Investigating the role of lipid droplets in microglia within the glioblastoma microenvironment unveiling mechanisms of tumor progression and therapeutic targets." Submitted by Principal investigator, Dr. Kanchan Bisht, Scientist D. Deptt. of Research & Development Cell, Swami Rama Himalayan University.
13. **RESEARCH PROPOSAL (Ph.D. Cell):** "Investigating early microglial-lipid interactions in glioma-to-glioblastoma transition: Pathways of tumor advancement." Submitted by Principal investigator, Dr. Kanchan Bisht, Scientist D. Deptt. of Research & Development Cell, Swami Rama Himalayan University.
14. **RESEARCH PROTOCOL (INTRAMURAL):** "Retrospective analysis of lymph node metastasis in patients undergoing surgery for adnexal mass at a tertiary care centre." Submitted by Principal investigator, Dr. Jacob Sheeja, MCh Trainee, Deptt. of Surgical Oncology, CRI, HIMS, Swami Rama Himalayan University.
15. **RESEARCH PROTOCOL (INTRAMURAL):** "A retrospective study on clinicopathologic characteristics of phyllodes tumor of breast." Submitted by Principal investigator, Dr. Vinay G, MCh Trainee, Deptt. of Surgical Oncology, CRI, HIMS, Swami Rama Himalayan University.
16. **RESEARCH PROTOCOL (INTRAMURAL):** "A cross sectional Survey to evaluate the attitudes of MBBS students towards teaching and learning communication skills at tertiary care teaching medical institute in Uttarakhand. Submitted by Principal investigator, Dr. Ruchi Garg, Asstt. Professor, Deptt. of Pharmacology, HIMS, Swami Rama Himalayan University

17. **RESEARCH PROTOCOL (INTRAMURAL):** "To explore challenges and strengths in simulation-based teaching through questionnaire-based survey. Submitted by Principal investigator, Dr. Juhi Kalra, Professor, Deptt. of Pharmacology, HIMS, Swami Rama Himalayan University.
18. **RESEARCH PROTOCOL (INTRAMURAL):** "Comparison of various eGFR equations and the impact of race free CKE-EPI equation on CKD Classification. Submitted by Principal investigator, Dr. Nistha Wadhwa, Asstt. Professor, Deptt. of Biochemistry, HIMS, Swami Rama Himalayan University.
19. **RESEARCH PROTOCOL (INTRAMURAL):** "To compare the efficacy of topical administration of magnesium sulphate, dexmedetomidine and dexamethasone in post operative sore throat in patients undergoing general anaesthesia. Submitted by Principal investigator, Dr. Nidhi Kumar, Professor, Deptt. of Anaesthesiology, HIMS, Swami Rama Himalayan University.
20. **RESEARCH PROTOCOL (INTRAMURAL):** "To estimate and compare the sensitivity of Xpert ultra test with other existing molecular test for detection of tuberculosis DNA and rifampicin resistance in pulmonary and extrapulmonary tuberculosis. Submitted by Principal investigator, Dr. Rahul Gupta, Asstt. Professor, Deptt. of Respiratory Medicine, HIMS, Swami Rama Himalayan University.
21. **RESEARCH PROTOCOL (MULTICENTRIC):** "A multicentric prospective cohort study to develop artificial intelligence-assisted risk stratification tool for prediction of preterm birth. Submitted by Principal investigator, Dr. Anchal Agarwal, Asstt. Professor, Deptt. of Obst. & Gynaecology, HIMS, Swami Rama Himalayan University.
22. **RESEARCH PROTOCOL (INTRAMURAL):** "Navigating sensorium: Lemborexant vs. melatonin vs. placebo for management of delirium – a hospital-based, single-centre, parallel, double blinded, randomized controlled trial. Submitted by Principal investigator, Dr. Praveen Rikhari, Asstt. Professor, Deptt. of Psychiatry, HIMS, Swami Rama Himalayan University.
23. **RESEARCH PROTOCOL (INTRAMURAL):** "Investigating the therapeutic effect of Yoga on menstrual cramps in women. Submitted by Principal investigator, Dr. Somlata Jha, Asstt. Professor, Himalayan School of Yoga sciences, Swami Rama Himalayan University.
24. **RESEARCH PROTOCOL (INTRAMURAL):** "Development and assessment of tele-yoga protocol for thyroid disorders: A randomized controlled trail at Himalayan Hospital, Dehradun. Submitted by Principal investigator, Dr. Somlata Jha, Asstt. Professor, Himalayan School of Yoga sciences, Swami Rama Himalayan University.
25. **RESEARCH PROTOCOL (INTRAMURAL):** "Hydroponic technology to enhance commercial-scale productivity of organum vulgare from Uttarakhand, West Himalaya". Submitted by Principal investigator, Dr. Sanjay Gupta, Principal Himalayan School Biosciences, Swami Rama Himalayan University.
26. **Ph. D synopsis:** Effect of yoga on gestational diabetes mellitus: a randomized control study" submitted by Ritu under the guidance of Dr. Somlata Jha, Asstt. Professor, Himalayan School of Yoga Sciences, Swami Rama Himalayan University.
27. **Thesis Protocol for:** MD/ MS Protocol (102 in number) of Batch 2023; DM/ M.Ch (11 in Number) for ethical evaluation.
28. **MSc Epidemiology Students Project:** (3 in numbers) Ms. Shivani Dahiwalakar under the guidance of Dr. Naha Sharma 2. Mr. Siddharth Kolambkar under the guidance of Dr. Naha Verma. 3. Ms. Niharika Gaur under the guidance of Dr. Abha Srivastava, Department of community medicine.

Any Other Matter:

1. Already approved Protocol No C1071007: Protocol amendment 5 dated 10 Jun. 2024; Main ICD English; Main ICD hindi along with translation certificate and back translation of main ICD on 25th July 2024 under PI Dr. S.K. Verma on ELRANATAMAB.
2. Notification of temporary pause on EC activity and patient enrollment dated 6 Sept. 2024 of already approved Protocol No 45036: on real world Indian registry study of Atezolizumab in lung cancer, PI Dr. Ankit Batra.
3. Notification of updated study period insurance certificate of already approved protocol No. D8535C00001 under PI Dr. Ankit Batra.
4. Notification of 6 monthly study progress report of already approved Protocol No C1071007: under PI Dr. S.K. Verma on ELRANATAMAB. Dated 8 Oct 2024
5. Notification of 6 monthly study progress report of already approved Protocol No. CKJX839D12302 of VICTRION-1 PREVENT by PI Dr. Kunal Gururani, dated 23 July 2024.
6. Notification of 6 monthly study progress report of already approved Protocol No C1071007: under PI Dr. S.K. Verma on ELRANATAMAB. Dated 22 Jan. 2024.
7. Notification of protocol deviation of Protocol No C1071007; by Dr. S.K. Verma, dated 16 August 2024.
8. Notification of protocol deviation of Protocol No C1071007; by Dr. S.K. Verma, dated 16 May 2024.

9. MSc. Nursing students research study projects: MSc NURS (seven) and MSc(N) clinical care (02) for Batch 2023.

10. Mod. biology, advance molecular for the semester, a comprehensive for module Copy to:- by Dr. Gita Bhanderi (HSBS)

Dr. D.C. Dhasmana 16/11/24
Member Secretary, Ethics Committee
Swami Rama Himalayan University

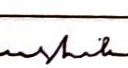
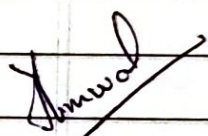
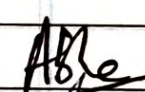
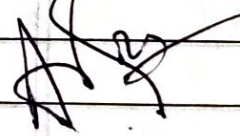
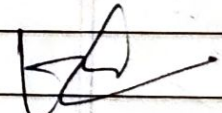
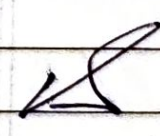
1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. The Chairperson, Ethics Committee, Professor Manisha Bisht, Deptt. of Pharmacology, AIIMS, Rishikesh
4. All Members of Ethics Committee, HIMS, SRHU

Ethics Committee Meeting

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A meeting of Ethics Committee was held on 19/10/2024 at 11:00 AM in the dept. of Pharmacology to consider the following research projects. MD/MS thesis etc. as per agenda. Circulated on 16/10/2024.

The following members were present:-

1. Dr. Manisha Bisht - Chairperson. 
2. Dr. Rajeev Mohan Kaulish - Member 
3. Dr. Jayanti Sengupta - Member 
4. Dr. Abha Srivastava - Member 
5. Mr. Arun. Kundra - Member 
6. Mr. Sagar Manwal - Member 
7. Dr. D.C. Sharma - Member Secretary 
8. Mr. G.N.S. Gundatti Member 

The new chairperson was introduced to the committee by member secretary at the onset to all members. The chairperson welcomed all the members in the meeting. The committee approved the minutes of previous sub-committee meeting.

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dated 24/08/2024. and member
Secretary was requested to take
appropriate action for regulatory trial
document approval in the meeting.
As per the agenda of today's meeting
dated 19/10/2024, the committee
discussed each protocol and app took
appropriate decisions on it as
follows:

Agenda no 1: Resubmission of CAA.....

by Dr Ruchi Jyoti, Professor Community
medicine was discussed and approved
as such.

Agenda no 2: Multicentric Investigating
Children's experiences of preop fasting by
Dr Divya Gupta - was approved as such
one appropriate consent form is attached

Agenda no 3: Pattern of ^{antimicrobial use in} ICU
hospital by Keerthi Gayanuruba guidance
of Dr Tanu Sharma was approved as such
a STROBE paper.

Agenda no 4: Evaluation and validation
of Marking. by Dr. Divya Rangan Arunachal
was discussed and it was suggested for
a statistical person may be included.
As such the protocol was approved.

Agenda no 5: Study on effect of TENS
..... Superiority trial. was by Dr
Rameer Ghulliga - was discussed
and it was decided to have an undertaking
from the PI on the trial - the trial was

be replaced into the word study, and clarity on cost of TLT and its adverse effects shall be written clearly in the protocol. Informed consent form appropriate to the study needs to be attached. Once corrected, the protocol may be taken as approved.

Agenda no 6: Determinants of ...
- Sublingual region, by Dr Rakesh Kumar, Pediatrics was discussed and approved subject to removal of sublingual region for title and inclusion of written informed consent from parents.

Agenda no 7: Evaluation of antihypertensive parameters ... Setting submitted by Dr Nisha Wadhwa. Biochemistry dept was discussed and approved subject to appropriate ICA and if possible to include subcutaneous fat in method.

Agenda no 8: Enhancing integrity ...
- Ethics training, submitted by H Dr Nikhil Kumar, was considered for as training proper and hence was exempted from Ethics review for onward submission to ICMR.

Agenda no 9: Investigating metabolic biomarkers ...
- A comprehensive study submitted by Dr Kishore P Sharma,

was considered and found approved
subject to attachment of proper ICD
and written informed consent be mentioned
in methods

Agenda no 10. Metabolic disorders in
new born. Uttaranchal, sub-
mitted by Dr Kanan Bhatt was approved
subject to proper ICD and disclosure of
cost of investigations in the protocol.
that shall not be borne by the patients.

Agenda no 11. Complement - RIC.
Uttaranchal region, submitted by Dr. Kishor
Sharma. (PhD cell) for phorbol funding was
approved subject to submission of under-
lying by PI for interventional study as
monitoring cost of investigations that shall
be borne by patients

Agenda no 12 : Investigating role of lipid
droplets therapeutic targets
submitted by Dr Kanchan Bishr (PhD cell)
was approved as such at the meeting.

Agenda no 13 : Investigating early metabolic
lipid intermedia lipid storage
met. submitted by Dr Kanchan Bishr
(PhD cell) was approved as such at the
meeting.

Agenda no 14: Receptor analysis
Lipid and Carbohydrate submitted by
Dr. Jyoti Sheela, was considered
and approved as such at the meeting

Agenda no 15: A therapeutic study

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Final of breast, submitted by Dr Vinay G. to surgical oncology was approved subject to monitoring & anonymization of personal data & confidentiality in methods.

Agenda no 17. To explore challenges & thoughts Survey, submitted by Dr Jyoti Kelkar, Pharmacology dept. was approved as such as it was an educational project not involving any personal details of individuals and hence exempted for review.

Agenda no 18: A cross sectional survey undertaken by Dr Rishi Chavhan, Pharmacology dept. was approved as such in its present form.

Agenda no 18: Comparison of Varicella & Zoster Equivocal cases classification, submitted by Dr Nishtha Wadhwa. was approved subject to monitoring & anonymization of patient data & method.

Agenda no 19 - To compare efficacy of topical General anesthesia submitted by Dr Nidhi Kumar Anesthology was a trial based study that was considered as approved subject to submission of undertaking for study by D2 and proper SOP not attached. Review may be written appropriately.

Agenda No 20: - To estimate and compare sensitivity of Xpert - - - Tuberculosis; submitted, by Dr Rahul Gupta. Respectively MOD. was approved subject to mentioning of appropriateness of data & method.

Agenda No 21: Multicentric & CMR project "Multicentric prospective study to develop artificial intelligence preterm birth, by Dr Achal Agrawal sept 2019/2020. Was approved subject to submission of ICA.

Agenda No 22: Navigating Sensorium Embryonic & neonatal - - -

RET... submitted by Dr Praveen Rikhi, 2000 & Reheating as a trial was approved subject to submission of the undertaking by PR, to modify the ^{ICA} content as per study, and clarify on the status of delirium in patients in ICU.

Agenda No 23: Investigating Herp effect of yoga in menstrual cramps. - - - women, submitted by Dr Sonali Jha. Yoga science was approved as such.

Agenda No 24: Development and assessment of tele yoga for thyroid disease. RET. For trial by Dr Sonali Jha. Was a trial based study requiring.

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underlying or clarified on to hypo
and hyperthyroidism patients and
adverse effect of any of Yoga practice
proper informed consent documents
be submitted. Once done the
project will be considered as approved.

Agenda no: 25. Hydroponic kitchen
... whether to Himalayas by Dr Arati
Rishi from Himalaya School of Yoga
Once was approved as such as
there was no human involvement.
in the study

Agenda no 26: Effect of Yoga on Gestat
Diabetes in a randomized controlled study,
submitted by a ~~PhD student~~ ^{PhD student} Dr Soumitra Jha a PhD.
Research Symposium was considered
and approved. Subject to clarification
on calculation of sample size in
method.

Agenda no 27. These protocols for MD
MS thesis (2023) a total of 102 and
SM/Mch. thesis (11) protocols were
approved after clarification and
further rectification done by the
Candidate after a subcommittee evalu-
ate of the projects on 27.09.2024
All these projects (2023) submitted
were approved after rectification.
Agenda no. 28: MSc Epidemiology and

Total (3 in number) was for 2024
were approved as such in the meeting

Any other matters:

Agenda no 1-6 was put before the committee for discussion and approval. All the documents were shared and as such approved after deliberations on the issues. As per agenda of Amendment I. Amendment of protocol no (107/1007) was approved as such.

As per agenda no. 9. of any other matters the MC Nursing students research study protocols for 2023 (Total 9 protocols: Seven MC Nurs. & 2 Undercare nursing) were approved as such submitted by Nursing College. Agenda no 10: Transparency & Accountability. The meeting ended with vote of appreciation. Thanks to Chair.

Sign

(Dr Manish Bishr)

Signature

(Dr A.C. Sharma)

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SRHU/HIMS/ETHICS/2024/

Dated: 11.12.2024

"Ethics Committee"

A meeting of the Ethics Committee is convened on 14/12/2024 (Saturday) at 11:00 AM in the Deptt. of Pharmacology, HIMS.

Agenda:

1. **RESEARCH PROTOCOL (INTRAMURAL):** "Development of millet-based functional food for pregnant and lactating women in Uttarakhand-Phase I." Submitted by Principal investigator, Dr. Ruchira Nautiyal, Professor & Head, Deptt. of Obst. & Gynaecology, HIMS, Swami Rama Himalayan University.
2. **RESEARCH PROTOCOL (INTRAMURAL):** "Predicting the concurrent chemoradiation therapy (CTRT) outcomes in localized muscle invasive bladder cancer (MIBC) patients by exploring novel biomarker in tumor samples of radioresistant patients." Submitted by Principal investigator, Dr. Amjad Hussain, Professor, Deptt. of Translational Biosciences, CRI, HIMS, Swami Rama Himalayan University.
3. **RESEARCH PROTOCOL (INTRAMURAL):** "Investigating microglial lipid droplet involvement in Glioblastoma." Submitted by Principal investigator, Dr. Kanchan Bisht, Scientist D, Deptt. of Research and Development Cell, Swami Rama Himalayan University
4. **RESEARCH PROTOCOL (INTRAMURAL):** "Enhancing patient outcomes through preoperative nutrient supplementation in breast cancer patients – A pilot study, already approved change in title of the study "By Dr. S.K. Verma professor, Medicine HIMS, Swami Rama Himalayan University, already approved.
5. **RESEARCH PROTOCOL (INTRAMURAL):** "Optimizing drug information and prescription patterns for type-2 diabetes with hypertension: advancing rational use and pharmacy education. "By Dr. Arvind Singh Farswan, Asstt. professor Pharmacology, Himalayan School of Pharmaceutical Sciences. Swami Rama Himalayan University.
6. **RESEARCH PROTOCOL (INTRAMURAL):** "Exploring the influence of maternal obesity on the health status of newborns and mothers in Hospital. "By Dr. Ujjwal Nautiyal, Asstt. professor Pharmacology, Himalayan School of Pharmaceutical Sciences. Swami Rama Himalayan University
7. **RESEARCH PROTOCOL (INTRAMURAL):** "Development of a composite biopolymer based edible coat formulation for enhancing self-life quality of fresh farm produce in Uttarakhand." Submitted by Principal investigator, Dr. Kumar Sachin, Assoc. Professor, Deptt. of Himalayan School of Biosciences, Swami Rama Himalayan University.
8. **PhD. Synopsis):** "Effect of yoga (Diaphragmatic breathing and kunjla kriya) on Asthma patients in terms of physiological and psychological parameters over a duration of 12 weeks: a randomized controlled trial." Submitted by, Dr. Mr. Amit Under guidance of Dr. Ajay Dubey, Principal & Assoc Professor, Himalayan School of Yoga Sciences, Swami Rama Himalayan University.
9. **RESEARCH PROTOCOL (INTRAMURAL):** "Role of dual cysticidal therapy in cases of multiple or diffuse cerebral neurocysticercosis (NCC) an Operable study." Submitted by Principal investigator, Dr. Deepak Goel, Professor, Deptt. of Neurology, HIMS, Swami Rama Himalayan University.
10. **RESEARCH PROTOCOL (Educational):** "Introduction of scenario based multiple choice questions as an assessment tool in competency based medical education_ A faculty perspective." Submitted by Principal investigator, Dr. Anuradha Kusum, Professor, Deptt. of Pathology, HIMS, Swami Rama Himalayan University.
11. **RESEARCH PROTOCOL (INTRAMURAL):** "Evaluation of awareness of laboratory professionals about preanalytical errors and their impact." Submitted by Principal investigator, Dr. Nishtha Wadhwa, Asstt. Professor, Deptt. of Biochemistry, HIMS, Swami Rama Himalayan University.
12. **RESEARCH PROTOCOL (Educational):** "Exploring visual arts and literature as a means to improve soft skills in undergraduate medical students." Submitted by Principal investigator, Dr. Vidisha Vallabh, Assoc. Professor, Deptt. of Community Medicine, HIMS, Swami Rama Himalayan University.


 11/12/24

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13. **RESEARCH PROTOCOL (Educational):** "Development and implementation of a teaching and training module on lumbar puncture for medical interns and first year anaesthesia postgraduates." Submitted by Principal investigator, Dr. Amit Kumar Chauhan, Assoc. Professor, Deptt. of Anaesthesiology, HIMS, Swami Rama Himalayan University.
 14. **RESEARCH PROTOCOL (INTRAMURAL):** "Analysis of factors influencing various stages of presentation of cancer of oral cavity and oropharynx." Submitted by Principal investigator, Dr. Mahima Luthra, Asstt. Professor, Deptt. of ENT, HIMS, Swami Rama Himalayan University.
 15. **RESEARCH PROTOCOL (INTRAMURAL):** "Questionnaire based assessment of sleep quality of children undergoing cleft lip and palate surgeries." Submitted by Principal investigator, Dr. Amborish Nath, Assoc. Professor, Deptt. of Plastic Surgery, HIMS, Swami Rama Himalayan University.
 16. **RESEARCH PROTOCOL (INTRAMURAL):** "Short term outcomes of perioperative pain management utilizing enhanced recovery versus standard protocol following paediatric urological surgery: A pilot randomised controlled trial." Submitted by Principal investigator, Dr. Parul Jindal, Professor, Deptt. of Anaesthesiology, HIMS, Swami Rama Himalayan University.
 17. **RESEARCH PROTOCOL (INTRAMURAL):** "Comparison of nutritional and radiological profile of hypercapnic respiratory failure with non-hypercapnic respiratory failure- A prospective observational study." Submitted by Principal investigator, Dr. Manoj Kumar, Asstt. Professor, Deptt. of Respiratory Medicine, HIMS, Swami Rama Himalayan University.
 18. **RESEARCH PROTOCOL (INTRAMURAL):** "Shorter MDR regimen outcome in association with clinical, Hematological and smoking status _ a cross sectional retrospective study in North Indian DR TB Centre." Submitted by Principal investigator, Dr. Manoj Kumar, Asstt. Professor, Deptt. of Respiratory Medicine, HIMS, Swami Rama Himalayan University.
 19. **RESEARCH PROTOCOL (INTRAMURAL):** "Comparison of imprint cytology of pleural biopsy versus cytology of parietal pleura in undiagnosed exudative pleural effusion via medical thoracoscopy." Submitted by Principal investigator, Dr. Varuna Jethani, Asstt. Professor, Deptt. of Respiratory Medicine, HIMS, Swami Rama Himalayan University.
 20. **RESEARCH PROTOCOL (INTRAMURAL):** "Prevalence and determinants of stress and anxiety among primary caregivers of substance use disorder patients in a view to develop a nurse led intervention on anxiety and stress management in selected hospital of Dehradun, Uttarakhand." Submitted by Principal investigator, Dr. Grace Madonna Singh, Professor, Deptt. of Mental Health Nursing, Himalayan College of Nursing Swami Rama Himalayan University.
 21. **RESEARCH PROTOCOL (INTRAMURAL):** "Knowledge attitude and belief of nurses regarding antimicrobials use and prevention of antimicrobials resistance." Submitted by Principal investigator, Dr. Kamli Prakash, Professor, Deptt. of Adult Health Nursing, Himalayan College of Nursing Swami Rama Himalayan University.
 22. **MS/MS Thesis Protocol:** Late submitted. 12 in Number: Paediatrics (3), General Surgery (6), Radiology (2), Pathology (1).

Any Other Matter:

- Notification of study document CKJX839D12302VICTORION-1 PREVENT dated 19/11/2024. Dr. Kunal Gururani.
- Notification of study document C1071007 ELRANATAMAB (PF- 06863135) Dr. S.K. Verma.
- Notification of protocol administrative changes letter (PACL) for study C1071007 Dr. S.K. Verma.
- Suspected unexpected serious adverse reaction (SUSAR) CKJX839D12302VICTORION-1 PREVENT dated 29/10/2024. Dr. Kunal Gururani
- Request letter from Rashmi Bhardwaj (PhD Scholar) for change in guide HCN against 150 letter approval dated 18.02.2024.

11/11/24.
Dr. D.C. Dhasmana
Member Secretary, Ethics Committee
Swami Rama Himalayan University

1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. The Chairperson, Ethics Committee, Professor Manisha Bisht, Deptt. of Pharmacology, AIIMS, Rishikesh
4. All Members of Ethics Committee, HIMS, SRHU

Ethics Committee Meeting

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A meeting of Ethics Committee was held on 14/12/2024, at 11:00 AM in the deptt. of Pharmacology to consider the following research Project & MD/MS thesis etc as per agenda circulated on 11.12.2024

The Following members were Present:-

1. Dr. Manisha Bisht - Chairperson. Manisha
2. Dr. Rajeev Mohan Kaushik - Member Rajeev
3. Dr. Jayanti Sonwal - Member Jayanti
4. Dr. Abha Srivastava - Member Abha
5. Mr. G.N.S. Gurudutt - Member G.N.S.
6. Mr. Arjun Kundra - Member Arjun
7. Mr. Sagar Manwal - Member Sagar
8. Dr. Z.C. Sharma - Member Secretary Z.C.

The meeting started at 11 am, and the chairperson welcomed all the members. The minutes of the previous meeting were approved. As per the agenda, the projects & received were considered one by one and appropriate actions were

taken unanimously in each research protocol.

Agenda No 1: Development of millet-based ...
... submitted by Dr. Ruchika Nautiyal, POF
& head, Obstetrics was discussed. As it was
a phase I study of the project detailing
production & formulation of millet based
product and procurement of materials
and equipment, the study was approved
as such and exempted from ethical
review.

Agenda No 2: Predicting concurrent chemo-
radiation therapy ... exploring novel
biomarkers ... Assistant Professor,
submitted by Dr. Anand Thakur was approved
as such subject to submission of appropriate
Informed consent in the study.

Agenda No 3: Pattern of antimicrobial use
Investigating microglial lipid droplets
... Glioblastoma. submitted by P¹
Dr. Kanchan Bisht, Scientist D, DCC, SRHU
was approved as such subject to submission
of ICD document for the same.

Agenda No 4: Enhancing patient outcome
... Breast cancer patients - A pilot
study, submitted by Dr. S. K. Verma, CCR
was approved as such, as it was already
approved in the previous EC meeting.

Agenda no 5 : Optimizing drug information education, by Dr Anand Singh Pathan, HSB, was approved subject to clarification on OPD/IPD patient population or and a co-guide from medicine dept.

Agenda NO 6: Exploring the influence of maternal obesity .. in hospital, sub. by PI Dr Ujjwal Nathwani HSB was approved subject to mentioning of study setting and study population from community med. run hospital

Agenda NO 7: Development of composite biopolymer in Uttarakhand, submitted by PI Dr Kumar Sachin of HSB was approved as such and, exempted from ethical review.

Agenda NO 8 : PhD synopsis "Effect of yoga Submitted by Mr Anil Kumar the guidance of Dr Ajay Dubey was approved subject to submission of DCD and the validated and copyright issue of PhD 9 and GAD 7 scales

Agenda no. 9: Role of dual cysteine therapy NCE, an open label study. Submitted by Dr Deepak

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Coel. Prof & Head Neurology KIMS, has discussed in detail. The project's methodology needs rectification on control point issue, ICA was also not attached. It was decided to have an explanation from PI on methodological issues raised by members, and if clarified in writing by addressing the concern in methods, the project may be approved.

Agenda NO 10: Introd. of AI generated based multiple choice questions A faculty perspective. Submitted by Dr Anurag Kumar, Prof of pathology was approved as such as it was an educational project and exempted from ethical review.

Agenda NO 11: Evaluation of awareness of laboratory impact. Submitted by PI Dr Nishtha Wadhwa Dept of biochemistry. has discussed and approved in such a form / present form.

Agenda NO 12: Exploring visual intake in undergraduate medical students submitted by Dr Vidisha Vallabh Dept of community medicine was

approved in such to present form.

Agenda no. 13: "Development and implementation of a curriculum for postgraduates" submitted by Dr. Anil K. Chandra, Dept of Anaesthesiology was approved in such and as example for ethical review.

Agenda no 14: "Analysis of factors oral cavity and oropharynx" submitted by PL Dr Mahesh Kumar, Dept of ENT. was approved. Subject to submission of DCD appropriate to the project.

Agenda no 15: "Short-term outcome of perioperative pain trial, submitted by Dr. Paul Jindal Dept of anaesthesiology was considered and discussed at length. It was decided that the methodology should have a statement that auxiliary care of patient shall be provided free of cost in case of any adverse event as written informed consent is appropriate to a trial be written in the methods. Once done the study is taken as approved.

Agenda no 15: "Questionnaire based study on assessment of sleep quality in supine" submitted by Dr Anirborish Nath, Dept of Plastic surgery was approved subject to submission of ICD appropriate to protocol and statement on validation & previous use of Questionnaire used in the study.

Agenda no 17: Comparison of nutritional prospective study, submitted by PL Dr Manoj Kumar, Dept of Resp. Medicine was approved subject to submission of appropriate ICD.

Agenda no 18. Shorter MDR regimen PRFB centre: submitted by Dr Manoj Kumar, Reg med. Dept was approved, subject to correction in the title of the project, and statement on confidentiality and anonymity of subject in analysis. Further the title be added with "Retrospective study"

Agenda no 19. "Comparison of imprint- biopsy thoracoscopy" submitted by Dr Vaibhav Jethani, Dept of Resp Medicine was approved subject to submission of appropriate ICD.

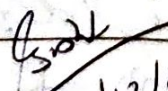
Agenda no 20: Relevance and -

determinants of stress and anxiety.
 hospital of Shwadevi, Mahakha
 submitted by Dr. Grace Madonna Singh
 was considered and approved as such
 for nursing college.

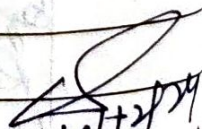
Agenda no 21: "Knowledge .. attitude ..
 selected tertiary care
 hospital" submitted by Dr. Kamali
 Baskah, from HCN, SRHU was
 considered and approved as such.

Agenda no 22, MD/ML thesis protocol
 late submitted protocols of 2023 batch
 and one from 2024. No batch were
 considered and necessary correction
 were suggested. Once corrected
 for wa submitted, they all were
 taken as approved.

Any other matters: All the documents were
 appraised to the committee and were approved
 for respective regulatory body & change in guide.
 The meeting ended with vote of thanks to chair.


 14/12/24

(Dr. Manisha Bishu)
 Chairperson


 14/12/24
 (Dr. Se Shwadevi)
 Member Secretary

Swami Rama Himalayan University
Swami Ram Nagar,

P.O. Jolly Grant, Dehra dun 248016 (INDIA)

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SRHU/HIMS/ETHICS/2025/

Dated: 27.01.2025

"Ethics Committee"

A meeting of the Ethics Committee is convened on 01/02/2025 (Saturday) at 11:00 AM in the Deptt. of Pharmacology, HIMS.

Agenda:

1. **Multicentric Regulatory Trial:** Project: (ML45036, Version 2.0 112024) REAL-WORLD INDIAN STUDY OF ATEZOLIZUMAB IN LUNG CANCER, Submission of the Study Documents to the Institutional Ethics Committee for the Review & Approval for the above-mentioned study: Submitted by Principal Investigator, Dr. Ankit Batra, Assoc. Professor, Deptt. of Medical Oncology, CRI, HIMS.
2. **Multicentric Regulatory Trial:** (GVL 1204/2024/1, Version no 2.0 Dated 18.09.2024) A Phase III Prospective, Randomized, Open-labelled, Blinded endpoint (PROBE), Multi-centric, Parallel Group, Non-inferiority Study to compare the Efficacy and Safety of GBL1204 with Ranibizumab in Patients with Wet Age-Related Macular Degeneration (PROMISES Study) by Dr. Renu Dhasmana, Professor & Head, Deptt. of Ophthalmology, HIMS.
3. **Multicentric Regulatory Trial:** (CT/2024/32, Version no 00 Dated 1.6.2024) Protocol Title: A Multicenter, Randomized, Comparative, Active-Controlled, Open label, Phase 3 Study to Evaluate the Efficacy and Safety of Semaglutide Injection in Comparison with Reference Biologic in Obesity Management. Submitted by Principal Investigator, Dr. Reshma Kaushik, Professor, Deptt. of Gen. Medicine, HIMS.
4. **Concept Note: Extramural:** - Project: Integrative Approaches for early detection and targeted therapy development in triple-negative breast cancer among clinical and biological researchers" by Dr. Gaurav Kumar. Assoc. Professor, Himalayan School of Biosciences
5. **RESEARCH PROTOCOL (INTRAMURAL):** "Quality indicators in transfusion medicine: Key element in a quality management system. A six-year experience from a nationally accredited tertiary care health center in India." Submitted by Principal investigator, Dr. Yashaswi Dhiman, Asstt. Professor, Deptt. of Immunohematology & Blood Transfusion, HIMS, Swami Rama Himalayan University.
6. **RESEARCH PROTOCOL (INTRAMURAL):** "Prediction of Diabetes-induced complications in patients of Himalayan Hospital Dehradun, Uttarakhand: An artificial Intelligence Approach." Submitted by Principal investigator, Dr. Nikku Yadav, Asstt. Professor, Deptt. of Clinical Research, HIMS, Swami Rama Himalayan University.
7. **RESEARCH PROTOCOL (INTRAMURAL):** "A protocol for evaluation and management in patients with acute undifferentiated fever in the emergency department of a tertiary care center: A Prospective study." Submitted by Principal investigator, Dr. Komal Thakur, Asstt. Professor, Deptt. of Emergency Medicine, HIMS, Swami Rama Himalayan University.
8. **RESEARCH PROTOCOL (INTRAMURAL):** "Comparison of 12-area vs. 6-area lung ultrasound scoring for predicting short term outcomes in neonates with respiratory distress: A prospective observational study." Submitted by Principal investigator, Dr. Chinmay Chetan, Assoc. Professor, Deptt. of Neonatology, HIMS, Swami Rama Himalayan University.
9. **RESEARCH PROTOCOL (INTRAMURAL):** "Impact of student-created educational podcasts as learning tool." Submitted by Principal investigator, Dr. Harvinder Singh Chhabra, Asstt. Professor, Deptt. of Forensic Medicine & Toxicology, HIMS, Swami Rama Himalayan University.
10. **RESEARCH PROTOCOL (INTRAMURAL):** "Antibiotic resistance pattern and outcome of patients with methicillin resistance staphylococcus aureus (MRSA) infection in critical care unit- longitudinal observational single center study." Submitted by Principal investigator, Dr. Sonu Sama, Assoc. Professor, Deptt. of Critical Care Medicine, HIMS, Swami Rama Himalayan University.
11. **RESEARCH PROTOCOL (INTRAMURAL):** "Development and validation of an audio-visual module to enhance parental knowledge, attitude and self-reported practices on essential newborn care in neonatal intensive care units: A pre-post intervention study." Submitted by Principal investigator, Dr. Chinmay Chetan, Assoc. Professor, Deptt. of Neonatology, HIMS, Swami Rama Himalayan University.
12. **RESEARCH PROTOCOL (INTRAMURAL):** "Pattern of recurrence and survival analysis in Ca endometrium treated with curative intent at CRI, HIMS, Dehradun" A Retrospective study, Submitted by Principal investigator, Dr. Rajeev Ranjan, MCh Trainee, Deptt. of Surgical Oncology, CRI, HIMS, Swami Rama Himalayan University.
13. **RESEARCH PROTOCOL (INTRAMURAL):** "A study on the awareness, attitude, and practice of junk food consumption among young adults in Uttarakhand, India" Submitted by Principal investigator, Dr. Mrs. Priya JP Narayan, Asstt. Prof., Himalayan College of Nursing, Swami Rama Himalayan University.
14. **RESEARCH PROTOCOL (INTRAMURAL):** "Effectiveness of continuing nursing education programme on application of safe delivery app (SDA) among nursing professionals at selected college and hospital Dehradun, Uttarakhand" Submitted by Principal investigator, Dr. Anupama Sharma, Asstt. Prof., Himalayan College of Nursing, Swami Rama Himalayan University.

15. **RESEARCH PROTOCOL (INTRAMURAL):** "A study to assess the prevalence, risk factors and awareness regarding pregnancy induced hypertension (PIH) with a view to develop nurse led intervention among antenatal women visiting gynae OPD in a selected hospital, Dehradun, Uttarakhand" Submitted by Principal investigator, Dr. Kanchan Bala, Assoc. Prof., Himalayan College of Nursing, Swami Rama Himalayan University.
16. **RESEARCH PROTOCOL (INTRAMURAL):** "A study to assess the effectiveness of awareness programme on self-collection sampling for HPV-DNA testing in terms of knowledge, attitude and practice among adult women in Himalayan Hospital, Dehradun: A mixed method" Submitted by Principal investigator, Dr. Kanchan Bala, Assoc. Prof., Himalayan College of Nursing, Swami Rama Himalayan University.
17. **RESEARCH PROTOCOL (INTRAMURAL):** "A study on health risks and self-esteem of obese adolescents in selected schools of Dehradun, Uttarakhand." Submitted by Principal investigator, Dr. Vandana Chauhan, Assoc. Prof., Himalayan College of Nursing, Swami Rama Himalayan University.
18. **RESEARCH PROTOCOL (INTRAMURAL):** "Effectiveness of family centered care approach on quality of life & generalized self-efficacy in caregivers of autistic child in selected areas of Uttarakhand." Submitted by Principal investigator, Dr. Ms. Nikita Bhatt, Asstt. Prof., Himalayan College of Nursing, Swami Rama Himalayan University.
19. **RESEARCH PROTOCOL (INTRAMURAL):** "A study to assess the effect of teaching program regarding cyberbullying on awareness of adolescent and their coping skills in selected schools of Dehradun, Uttarakhand." Submitted by Principal investigator, Ms. Shivangi Hemdan, Nursing Tutor, Himalayan College of Nursing, Swami Rama Himalayan University.
20. **RESEARCH PROTOCOL (INTRAMURAL):** "A study to assess the effect of an awareness program on knowledge and practice regarding menstrual hygiene among adolescent girls in selected Government school of Dehradun, Uttarakhand." Submitted by Principal investigator, Ms. Varsha Rawat, Nursing Tutor, Himalayan College of Nursing, Swami Rama Himalayan University.
21. **RESEARCH PROTOCOL (INTRAMURAL):** "A study to assess physical activity, psychological well-being and sleep quality of elderly people in Dehradun" Submitted by Principal investigator, Ms. Heena Negi, Nursing Tutor, Himalayan College of Nursing, Swami Rama Himalayan University.
22. **RESEARCH PROTOCOL (INTRAMURAL):** "Beyond the curriculum- assessing knowledge, attitudes and competence of medical professionals in LGBT+ healthcare," Submitted by Principal investigator Dr. Preveen Rikhari, Asstt. Professor, Deptt. of Psychiatry, HIMS, Swami Rama Himalayan University.
23. **RESEARCH PROTOCOL (INTRAMURAL):** "The impact of social media on the mental health of students." Submitted by Principal investigator Dr. Ujjwal Nautiyal, Assoc. Professor, HSPS, Swami Rama Himalayan University.
24. **RESEARCH PROTOCOL (INTRAMURAL):** "The effect on mental health of students after joining a new course post-12th exams." Submitted by Principal investigator Dr. Ujjwal Nautiyal, Assoc. Professor, HSPS, Swami Rama Himalayan University.
25. **RESEARCH PROTOCOL (INTRAMURAL):** "Assessing the efficacy of combined anterior femoral cutaneous blocks (AFCN and LFCN) on postoperative pain relief at the anterolateral thigh donor site in superficial skin graft surgeries." Submitted by Principal investigator Dr. Priyanka Mishra, Asstt. Professor, Deptt. of Anaesthesiology, HIMS, Swami Rama Himalayan University.
26. **RESEARCH PROTOCOL (INTRAMURAL):** "Use of complementary and alternative medicine by patients with ophthalmological condition: A Cross sectional study." Submitted by Principal investigator Dr. Sukhdeep Bains, Asstt. Professor, Deptt. of Ophthalmology, HIMS, Swami Rama Himalayan University.
27. **RESEARCH PROTOCOL (INTRAMURAL):** "To study the effect of topiramate on anterior chamber angle and intra ocular chamber angle and intra ocular pressure in patients with migraine." Submitted by Principal investigator Dr. Sukhdeep Bains, Asstt. Professor, Deptt. of Ophthalmology, HIMS, Swami Rama Himalayan University.
28. **RESEARCH PROTOCOL (INTRAMURAL):** "Clinical profile and risk factors of stroke in young adults." Submitted by Principal investigator Dr. Gaurav Kaushik, DM Resident, Deptt. of Neurology, HIMS, Swami Rama Himalayan University.
29. **RESEARCH PROTOCOL (INTRAMURAL):** "A systematic study of the vertical distribution of radionuclides in soil profiles of neutral and vegetation lands in doon Valley of Garhwal Himalaya, India." Submitted by Principal investigator Dr. Mukesh Prasad, Asstt. Professor, Deptt. of Medical Physics, HIMS, Swami Rama Himalayan University.

Any Other Matter:

1. - Protocol Amendment V3.0 and study documents of already approved - CAMBRIA-2 study (D1835C00001) of Camizestrant (AZD9833) study, dated 21.01.2025. Submitted by Dr. Ankit Batra.
- Additional documents (Screening visit information, Cessation of PK sample collection, Updated study insurance, modified CRTI notification, Dated 14.01.2025 of CAMRIA-2 study submitted by Dr. Ankit Batra.
2. - Notification of 5th DMC Recommendation letter dated 31.12.2024
- Notification of Six monthly study progress report dated 09.12.2024,
- Notification of Annotated CRF, Version 10.0-03/Oct/2024
of VICTORIAN -2 PREVENT (CKJX839B1302) by Dr. Kunal Gururani.
3. - Additional documents of Protocol no. CKJX839D12302 VICTORIAN -1 PREVENT submitted by Dr. Kunal Gururani as :
- Collection of patient follow-up Data version 1.0 dated Nov.2024
- Notification of investigation brochure KJX839 edition 18, Dated 11 Dec. 2024 by Dr. Kunal Gururani
4. Review of Ethics Committee SOPs, Swami Rama Himalayan University.


 Dr. D.C. Dhasmana
 Member Secretary, Ethics Committee
 Swami Rama Himalayan University

1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. The Chairperson, Ethics Committee, Professor Manisha Bisht, Deptt. of Pharmacology, AIIMS, Rishikesh
4. All Members of Ethics Committee, HIMS, SRHU

Ethics Committee Meeting

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A meeting of Ethics Committee was held on 01/02/2024 at 11:0 AM in the dept of Pharmacology to consider the following research Projects as per agenda circulated on 27/01/2025.

The following members were Present:—

1. Dr. Manisha Bisht - Chairperson *[Signature]*
2. Dr. Rajeev Mohan Kaulok - Member *[Signature]*
3. Dr. Jayanti Sennwal - Member *[Signature]*
4. Dr. Abha Srivastava - Member. *[Signature]*
5. Mr. Arun Kundra - Member *[Signature]*
6. Mr. G. N. S. Gurudatt. - Member *[Signature]*
7. Mr. Sagar Manwal - Member *[Signature]*
8. Dr. D. C. Shasana - Member Secretary *[Signature]*

The meeting started at 11:00 am, and the chairperson welcomed all the committee members at the onset. The committee approved the previous committee meeting held on 14/11/2024.

As per the agenda of the meeting, the projects were considered and discussed and appropriate decisions were taken.

unanimously for each individual
Research project, as follows

Agenda NO 1. Project NL4506 Real Indian
study of Atezolizumab in lung cancer, submitted
by Dr. Anil Kumar (PI) for the site,
was discussed thoroughly, few pertinent
issues and concerns were raised regarding
the eligibility and concomitant use of
the drug, but needs further clarification
on the part of the PI, Till then the study
was kept pending for the next meeting to
be discussed again.

Agenda NO 2. Multicentric trial GUL. Day 200
oil phase II prospective randomized open
labelled, GBL + 200 with
eye related ocular degeneration (Pompe
study) submitted by Dr. Renu Sharma
Prof Head, Ophthalmology was considered
and approved subject to the approval of ethics.
a regulatory trial

Agenda NO 3: (7/2024/32). A multicentric random-
ized comparative Age controlled open label -
senaglutide Obesity management.
Submitted by Dr. Rishu Kaurshier, Prof
Medicine was postponed for consideration
is some more information is being updated
on the trial.

Agenda NO 4. Site oral concept note on
"Integrative approaches clinical &

640

budget research, submitted by Dr
Gaurav Kumar, Asst Prof HSBs, was approved
as such, in the meeting.

Agenda no 5: Quality indication in transport
in India, submitted by Dr Yashwanti
Sharma, Dept of Transport medicine, HIMS
was approved as such as it has a service
indicated assessment project, hence
accepted for review.

Agenda no 6: Prediction of diarrhoeal incidence
an artificial intelligence approach,
submitted by Dr Arun Kumar Yadav, was
approved as such in the meeting.

Agenda no 7: A protocol for evaluation
and management of A prospective study
by Dr Karan Thakur, Emergency medicine
HIMS was approved subject to submission
of appropriate consent document.

Agenda no 8: Comparison of 12 and 18
vs 6 and Prospective study submitted
by Dr Chintan Chohan, Dept of Neurology
HIMS was approved as such with provision for

Agenda no 9: Impact of student oriented
created educational a learning tool
submitted by Dr Harinder Singh, Dept of
Preventive Medicine, HIMS was approved as
such a educational research project.

Agenda No 10: "Antibiotic resistance pattern and outcome single center study, submitted by Dr. Sonu Same, dept of critical care medicine HIMS. was approved as such in the meeting.

Agenda No 11: Development & validation of a questionnaire be part of a study by Dr. Chhanya Chetan, dept of neonatology was considered as approved. in such in the present form.

Agenda No 12: Pattern of sepsis as surveillance CRP, HIMS, de novo study; A prospective study submitted by Dr. Ranjeet Ranjan Singh and Dr. Mch. Dhanoo was considered as approved as such.

Agenda No 13: A study on awareness attitude & practice ... is attached was submitted by Mrs. Pooja JP Narayan was for HCN was approved in the present form subject to validate & copyright issues of book attached.

Agenda No 14: Effectiveness of continuing nursing is attached" submitted by Dr. Arunima Sharma, Asst Prof, HCN was approved as such in the present form.

Agenda No 15: A study to assess the prevalence The study, undertaken submitted by Dr Kanika Bala HCN, has approved subject to change in prevalence with oral occurrence in 10 methods.

Agenda No 16: A study to assess effectiveness of awareness programme The study, submitted by Dr Kanika Bala HCN, was approved in such in the present form.

Agenda No 17: A study on Health risk and self-esteem The study, submitted by Dr Vandana Chandra Bora HCN was approved subject to submission of content for parent and adolescent from adolescents.

Agenda No 18: Effectiveness of Family Centred Care The study, submitted by Mr. Nikita Bhatt HCN has found appropriate and approved as such.

Agenda No 19: A study to assess the effect of E-learning programme The study, submitted by Ms. Shrivangsi Hemda Kensing Bhatt, HCN, was approved in such in the present form.

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Subject to monitoring & answer for
no address. one done it will
be taken as approval

Agenda no 20: A study to assess...
Menstrual Hygiene among adolescent girls
... submitted by Dr. Ms.
Vansha Rawat, nursing tutor, HCN.
has approved subject to the monitoring &
write up and consent for parents. instructed
head and answer for adolescents.

Agenda no 21: A study to assess physical
health... submitted
by Ms. Heene Hegi, Uda HCN was
approved subject to rectification of elderly
population & to report notes & signs &
to be taken.

Agenda no 22: "Beyond Curricula...
... LGBT + Healthcare," submitted
by Dr. Pooja Dixhai, Dept of Psychiatry
HIMS has approved as such in the meeting.

Agenda no 23: "The Impact of social media
on mental health of students"
Submitted by Dr. Vijay Nautiyal.
Assoc Prof. HSPS, we approved as such
after necessary corrections were done.

Agenda no 24: The effect on mental health

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... Joint & new course; Pore nri Std.
Boron, submitted by Dr. Ujjwal Nathyal
Boron, H.S.P.S. was approved
as such in its present form.

Agenda No 25. "Assessing the efficacy of
combined anterior & posterior
surgery" submitted by Dr. Priyanka
Mishra, Anaesthesiology Dept HIMS.
It is considered and since it was
a trial based study, all necessary
prerequisites, including undertaking
for PI, Informed consent document
as appropriate as other requirements
have been fulfilled and rectified.
Once done the paper may be
approved.

Agenda No 26. "Use of Complimentary
A cross sectional study
submitted by Dr. Sankhdeep Bains
Dept of Ophthalmology HIMS was
approved as such in its present
form.

Agenda No 27. "To study the effect
of Topiramate on Anti Cholinergic
migraine" submitted by
Dr. Sankhdeep Bains, Dept of
Ophthalmology HIMS was approved
as such in its present form.

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Agenda no 28: "Clinical profile -
..... 'Stress' - .. adults" submitted
by Dr. Geeta Kausik, Dept of
Neurology & Resident was approved
as such.

Agenda no 29: "A systematic study
..... 'Cardiac Hemeo Index'"
submitted by Dr. Mukesh Prasad,
dept of Medical Physics HIMY was
exempted for ethical review as
no human participants are involved
directly or indirectly.

Prof. Dr. Mello: All additional documents
pertaining to previous approved
studies were tabled before the committee
and were all approved for same
studies as no 1- to 3.

Item no 4: Review of Ethics Committee
SOP (addendum) that explicitly says that
the present version of SOP shall continue
till revision is necessary has unanimously
approval by all committee members.

The meeting ended with vote of thanks to chair.

Prof.
11/2/25
(Dr. Manish Bhatt)
Chair person.

Prof.
01/02/2025
(Dr. Dushmanth)
Male Secretary

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Swami Ram Nagar,
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Phone: 91-135-2471111, Extn. 328, Fax 910135-24711122

SRHU/HIMS/ETHICS/2025/ 48

Dated: 03.03.2025

"Ethics Committee"

A meeting of the Ethics Committee is convened on 07/03/2025 (Friday) at 11:30 AM in the Deptt. of Pharmacology, HIMS.

Agenda:

1. **RESEARCH PROTOCOL (EXTRAMURAL):** "Development of minimally-invasive multi-analyte diagnostic platform for the early detection of mycobacterium leprae (MMDx-ML platform)." Submitted by Co- investigator, Dr. Divya Anthwal, Research Associate-II Deptt. of Microbiology, HIMS, Swami Rama Himalayan University.
2. **RESEARCH PROTOCOL (INTRAMURAL):** "Clinicopathological profile of breast cancer in young women and outcomes of therapeutic modalities: A Retrospective analysis." Submitted by Principal investigator, Dr. Rajanala Madhu, MCH Trainee, Deptt. of Surgical Oncology, HIMS, Swami Rama Himalayan University.
3. **RESEARCH PROTOCOL (INTRAMURAL):** "Effect of short duration "Trataka" practice on the reaction times and task-switching cognitive flexibility of young adults." Submitted by Principal investigator, Dr. Dipak Kumar Dhar, Assoc. Professor, Deptt. of Physiology HIMS, Swami Rama Himalayan University.
4. **RESEARCH PROTOCOL (INTRAMURAL):** "Role of the film array respiratory panel in pediatric pneumonia diagnostic utility and clinical management in a tertiary case setting." Submitted by Principal investigator, Dr. Ashish Simalti, Professor, Deptt. of Pediatrics HIMS, Swami Rama Himalayan University.
5. **RESEARCH PROTOCOL (EXTRAMURAL):** "Identification of resistance associated markers of newer anti-TB drugs (NPAL regimen and the correlation of genotypic mutations with phenotypic resistance in mycobacterium tuberculosis." Submitted by Principal investigator Dr. Divya Anthwal, Research Associate-III, Deptt. of Microbiology, HIMS, Swami Rama Himalayan University.
6. **RESEARCH PROTOCOL (INTRAMURAL):** "To study prognostic value of the residual cancer burden index in post NACT breast cancer cases: A tertiary care centre experience." Submitted by Principal investigator, Dr. Monika Singh, Asstt. Professor, Deptt. of Pathology, HIMS, Swami Rama Himalayan University.
7. **RESEARCH PROTOCOL (INTRAMURAL):** "Forensic application of finger print ridge density in sex determination." Submitted by Principal investigator, Dr. Harvinder Singh Chhabra, Asstt. Professor, Deptt. of Forensic Medicine & Toxicology, HIMS, Swami Rama Himalayan University.
8. **RESEARCH PROTOCOL (INTRAMURAL):** "Feasibility and accuracy of simulation free (SF-RT) versus CT simulation based (CT-RT) radiation therapy in routine practice for palliative course of radiation." Submitted by Principal investigator, Dr. Mansi Barthwal, Asstt Professor, Deptt. of Radiation Oncology, HIMS, Swami Rama Himalayan University.
9. **RESEARCH PROTOCOL (INTRAMURAL):** "Cardiovascular dynamics in preterm infants undergoing kangaroo mother care: a prospective study." Submitted by Principal investigator, Dr. Chinmay Chetan, Assoc. Professor, Deptt. of Neonatology, HIMS, Swami Rama Himalayan University.
10. **RESEARCH PROTOCOL (INTRAMURAL):** "Application of WHO reporting system for pancreaticobiliary Cytopathology with associated risk of malignancy." Submitted by Principal investigator, Dr. Smita Chandra, Professor & Head, Deptt. of Pathology, HIMS Swami Rama Himalayan University.
11. **Submission of Project entitled:** "Mutational study of lung adenocarcinoma for glycolysis metabolism by EGFR dependent RSK4" Submitted by Principal investigator, Dr. Gourav Kumar, Assoc. Professor, Deptt. of Biosciences, Himalayan School of Biosciences, Swami Rama Himalayan University.
12. **Submission of Project entitled:** "Regulation of lung adenocarcinoma glycolysis by EGFR dependent RSK4" Submitted by Principal investigator, Dr. Gourav Kumar, Assoc. Professor, Deptt. of Biosciences, Himalayan School of Biosciences, Swami Rama Himalayan University.
13. **Seeking approval** for dissertation work of MHA Batch 2023-25 students at Himalayan Hospital. 9 in number Projects.

Any Other Matter:

1. **Serious Adverse Event Report (128410020) of multicenter trial "A Randomized, 2-ARM, phase 3 study of elrantomab (PF-06863133) versus Lenalidomide in patients with newly- Diagnosed multiple myeloma after undergoing autologous stem- cell transplantation (Protocol C107107) by Dr. SK Verma, dated 24/02/2025.**
2. **Notification of Insurance certificate of VOCROTIAN-1 PREVENT (CKJX839D12302) Trial on dated 20/02/2025 by Dr. Kunal Gururan**
3. **Notification of Insurance certificate of VOCROTIAN-2 PREVENT (CKJX839B12302) Trial on dated 20/02/2025 by Dr. Kunal Gururan**
4. **Notification of Insurance certificate of Final executed CTA of Camizestrant (Protocol no. D853C00001) Trial on dated 20/02/2025 by Dr. Ankit Batra.**
5. **Reply submitted to Dr. Bamali Kakati professor & Head Deptt. of microbiology for transfer of some bacterial isolates samples to IIT Roorkee on 28.02.2025.**


Dr. D.C. Dhasmana
Member Secretary, Ethics Committee
Swami Rama Himalayan University

1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. The Chairperson, Ethics Committee, Professor Manisha Bisht, Deptt. of Pharmacology, AIIMS, Rishikesh
4. All Members of Ethics Committee, HIMS, SRHU

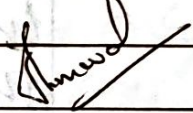
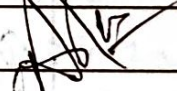
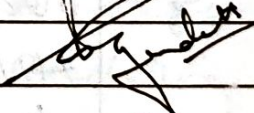
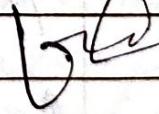
Ethics Committee Meeting

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A meeting of Ethics Committee was held on 7/3/2025 at 11:30 AM in the dept of Pharmacology. to consider the following research Projects, as per agenda circulated on 03/03/2025.

The following members were Present: -

SA

1. Dr. Manisha Bisht - Chairperson 
2. Dr. Rameev Mohan Kaulik - Member 
3. Dr. Jayanti Semwal - Member 
4. Dr. Abha Srivastava - Member 
5. Mr. Arun Kundra - Member 
6. Mr G.N.S. Gurudatt. - Member 
7. Mr. Sagar Manwal - Member. 
8. Dr. D. C. Dhasmana - Member Secretary 

The chairperson welcomed all 140 members of the committee at the outset. The minutes of the previous meeting dated 01/03/2025 were approved.

As per the agenda, the following research projects have been considered and

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appropriate decisions were taken
unanimously by the committee
members as follows in order.
Agenda no 1: "Development of
~~mycobacterium~~ *Mycobacterium* *leprae* (MMD, m m)
Platform submitted by Dr Divya
Ankhal Research Associate, Microbiology
HIMS, for ethics committee permission
to be a co-investigator in a ICMR
approved research project being
conducted at DGT Chordigard,
under Dr Sagarika Halder for which
the permission was granted as such

Agenda no 2: Clinico-pathological
..... modalities (A retrospective
analysis) submitted by Dr Rajrala
Modhu, MCh Trainee, Surgical Oncology,
HIMS, was approved as such in the
present form.

Agenda no 3: Effect of short duration
Trazate young adults, submitted
by Dr Dipak K. Dhar, Physiology HIMS,
was discussed and approved as
such in the present form.

Agenda no 4: "Role of film array
respiratory panel tertiary
care center, submitted by Dr Ashish
Saxena, Dept of Paediatrics, HIMS, was

approved as such subject to addition of written informed consent and annex in methods and attachment of appropriate consent form.

Agenda no 5: Identification of resistance in *Mycobacterium tuberculosis*, submitted by Dr Divya Anil Kiral Research Associate, Microbiology HIMS, was considered in detail and was approved subject to ^{ethical} approval from NITRD, N. Delhi for the protocol, as only killed bacteria being processed at HIMS lab, as proposed.

Agenda no 6: To study prognostic NAAC breast cancer cases. experience submitted by Dr Monika Singh, Pathology HIMS was approved subject to addition of statement in methods for anonymisation of personal data of patients and privacy and confidentially be maintained with the

Agenda no 7: "Forensic Application - density in sex determination", submitted by Dr Harvender Singh Chhabra, dept of Forensic Medicine, AIMS, was discussed and approved subject to mention of written informed consent in methods and appropriate consent form with the protocol.

Agenda no 6: "Feasibility cause of radiation" submitted by Dr. Manish Bhatnagar, Radiation Oncology, HIMS, was approved subject to addition in its title "A Retrospective study" and a statement of anonymization of personal data of patients and privacy and confidentiality of data to be maintained in its methods."

Agenda no 9: "Cardiovascular dysfunction in preterm infants. ... A prospective study" submitted by Dr. Chinmay Chote Neonatology, HIMS was approved as such, on confirming the details that the ultrasound investigation for research shall be done free of cost, as assured in its protocol.

Agenda no 10: "Application of WHO reporting system with increase of malignancy. Submitted by Dr. Sonita Chandra, HOD Pathology, HIMS was considered and as it was just a data record based study, the protocol was approved subject to addition of a statement on anonymization of personal data of patients and confidentiality & privacy of patients shall be maintained" in its methods."

Agenda No 11: "Molecular study of lung adenocarcinoma"

Submitted by Dr Gaurav Kumar, Assoc Prof, HSB, was considered and approved subject to administrative approval of transfer of sample from HIMS if any required for the project.

Agenda No 12: "Regulation of lung adenocarcinoma glycolysis" Molecular mechanism: Submitted by Dr Gaurav Kumar, Associate Professor, HSB, was approved as such as the study was based on tissue culture cell lines.

Agenda No 13: Dissertation work of MHA Batch 2023-25 for (Drumbe name - total as per the list enclosed) submitted by Incharge MHA Dr R-S Saini Prof & Head, after screening by thesis committee. All nine projects for student dissertation of MHA were considered individually and approved as such in the meeting.

Any other matter:

1. Serious Adverse Event report no. 1284/0020 as follow up report submitted by PI dated 24/2/2025, whereby patient was recruited for trial no. C1071007 developed thrombocytopenia, that was treated free

80

of Col in the hospital and was recovering.
The causality analysis was related to
drug, or the document of Follow-up
Report along to initial report of the
patient was tabled before the
Committee and all the members
unanimously agreed to the
causality analysis, to be forwarded
to CSCE, DCA for further necessary
action.

222 Document of notification of Dheeraj
Certificate for Veterans D & B line,
submitted by Dr. Kund Churnani were
tabled before the Committee.

4. Certificate for final executed CTA of
~~Dr. Kund Churnani~~ was also tabled in the
meeting.

5. Reply to Dr. Bander Kerkar on transfer
of Bacterio samples for research was
also tabled before the Committee and
the members were apprised of the same.

The meeting ended with five minutes to chair.

Guest

(x Manish)

@ Sushant

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SRHU/HIMS/ETHICS/2025/118

Dated: 25.04.2025

"Ethics Committee"

A meeting of the Sub Committee on Ethics Expedited review is convened on 26/04/2025 (Saturday) at 11:00 AM in the Dept. of Pharmacology, HIMS.

Agenda:

1. **RESEARCH PROTOCOL (EXTRAMURAL)** A multicentric research protocol entitled: "Building Inclusive Mental Health Ecosystems: Role of Panchayats and Local Governance in Uttarakhand." Submitted by Principal investigator, Dr. Malini Srivastava, Assoc. Professor & Head, Deptt. of Clinical Psychology, HIMS, Swami Rama Himalayan University.

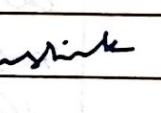
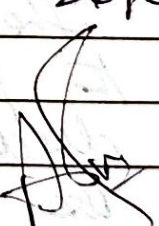

Dr. D.C. Dhasmana
Member Secretary, Ethics Committee
Swami Rama Himalayan University

Copy to:-

1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. All Members of Ethics Committee, HIMS, SRHU : Dr. Akhendra Prasad, Dr. Dinesh Kumar, Mr. Anand Kumar.

⁴ Ethics Subcommittee Meeting ⁹³

A meeting of Ethics subcommittee on expedited review of projects as per the agenda was convened on 26.04.2025 at 11:00 AM. The depy of Pharmacology as per the directives from the chairperson, Ethics Committee, consisting of following members:

- | | name. | sign |
|---|--------------------------------------|---|
| 1 | Dr D.C. Sharma
(Member Secy) |  |
| 2 | Dr. Rajeev Moha Kaurshik
(member) |  |
| 3 | Dr. Abhe Srivastava
(member) | Abhe
26/4/25 |
| 4 | Dr Arun Kundra
(member) |  |

As per the directives from the chairperson to a subcommittee comprising of Dr D.C. Sharma, Dr Abhe Srivastava, Dr Rajeev Moha Kaurshik and Dr Arun Kundra was constituted to expedite review the research projects (Multicentric, observational) entitled: Building inclusive mental

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health ecosystem: Role of
Panchayats & local governments in
"utarakhand" submitted by Dr
Dr Mehini Sonawale, Associate prof
dept of clinical psychology was
considered in the present form.
This project is to be submitted to
Indian Council of Social Science
Research, as longitudinal
research project of 5 yrs. having
multicentric approach from
H.N.S., Kumaon University and
Garhwal Kashi University, to integrate
mental health into local development
planning area so as to improve
mental health services in rural
Uttarakhand.

The subcommittee got going thing
to protocol and other documents,
discussed them, and approved
the protocol in the present form.

Abha Shrivastava
(Dr Abha Sonawale)
member


(Dr SC Shrivastava)
Member Secretary

Swami Rama Himalayan University
Swami Ram Nagar,
P.O. Jolly Grant, Dehra dun 248016 (INDIA)
Phone: 91-135-2471111, Extn. 328, Fax 910135-24711122

SRHU/HIMS/ETHICS/2025/125

"Ethics Committee"

Dated: 04.05.2025

A meeting of the Ethics Committee is convened on 10/05/2025 (Saturday) at 11:00 AM in the Deptt. of Pharmacology, HIMS.

Agenda:

1. **RESEARCH PROTOCOL (Multicentric):** Study Code- M016455/LPS17348 -"A Phase IV, open label, clinical trial to assess safety and efficacy of fexofenadine HCl +pseudoephedrine HCl fixed dose combination in Indian participants with allergic rhinitis (AR) who are 12 years and above (FAST trial)." Submitted Principal investigator, Dr. Reshma Kaushik, Professor, Deptt. of General Medicine, HIMS, Swami Rama Himalayan University.
2. **RESEARCH PROTOCOL (EXTRAMURAL):** "Unraveling the molecular generics of hemophilia A and B Identifying carrier females in the Himalayan region of Uttarakhand, India." Submitted Principal investigator, Dr. Mansi Kala, Professor, Deptt. of Pathology, HIMS, Swami Rama Himalayan University.
3. **RESEARCH PROTOCOL (INTRAMURAL):** "Comparative study of MRSA screening among healthcare workers and sepsis profile in a paediatric intensive care unit (PICU)." Submitted Principal investigator, Dr. Barnali Kakati, Professor & Head, Deptt. of Microbiology, HIMS, Swami Rama Himalayan University.
4. **RESEARCH PROTOCOL (INTRAMURAL):** "Medical negligence: Insight into the awareness and attitudes of future doctors in Uttarakhand." Submitted Principal investigator, Dr. Sanjoy Das, Professor & Head, Deptt. of Forensic Medicine & Toxicology, HIMS, Swami Rama Himalayan University.
5. **RESEARCH PROTOCOL (INTRAMURAL):** "Antimicrobial audit and stewardship practices among hospitalized patients at a tertiary care center in Uttarakhand." Submitted Principal investigator, Dr. Piyush Kumar Rai, Asstt. Professor, Deptt. of Microbiology, HIMS, Swami Rama Himalayan University.
6. **RESEARCH PROTOCOL (INTRAMURAL):** "Correlation of bronchoalveolar lavage fungal culture with clinical spectrum and radiological features: A retrospective study." Submitted Principal investigator, Dr. Varuna Jethani, Assoc. Professor, Deptt. of Respiratory Medicine HIMS, Swami Rama Himalayan University.
7. **RESEARCH PROTOCOL (INTRAMURAL):** "Anthropometric correlation between hand dimensions and stature of an individual." Submitted Principal investigator, Dr. Pragya Tripathi, Professor & Head, Deptt. of Forensic Medicine & Toxicology, HIMS, Swami Rama Himalayan University.
8. **RESEARCH PROTOCOL (INTRAMURAL):** "Respiratory rate oxygenation (ROX) and paediatric respiratory rate oxygenation (PROX) index as a predictor of outcome in children with respiratory distress on HFNC." Submitted Principal investigator, Dr. Nitika Agarwal, Assoc. Professor, Deptt. of Pediatrics, HIMS, Swami Rama Himalayan University.
9. **RESEARCH PROTOCOL (INTRAMURAL):** "Bacterial contamination of mobile phones used by healthcare workers and guardians of patients in pediatric critical care unit study from tertiary hospital in Uttarakhand." Submitted Principal investigator, Dr. Nitika Agarwal, Assoc. Professor, Deptt. of Pediatrics, HIMS, Swami Rama Himalayan University.
10. **RESEARCH PROTOCOL (Multicentric):** Study Code- 781PC00001-"DESTINY- Biliary tract cancer-01: A phase 3 study of transtuzumab deruxtecan (T-DXD) and rilvegostomig versus standard of- care gemcitabine, cisplatin, and durvalumab for first line locally advanced or metastatic HER2- expressing biliary tract cancer ." Submitted Principal investigator, Dr. Ankit Batra, Asstt. Professor, Deptt. of Medical Oncology, CRI, HIMS, Swami Rama Himalayan University.
11. **RESEARCH PROTOCOL (INTRAMURAL):** "Assessment of knowledge, attitude and practices regarding organ donation among medical students at a tertiary care teaching hospital in northern India." Submitted Principal investigator, Dr. Harvinder Singh Chhabra, Asstt. Professor, Deptt. of Forensic Medicine & Toxicology, HIMS, Swami Rama Himalayan University.
12. **RESEARCH PROTOCOL (EXTRAMURAL):** "Development of a novel CRISPR-CAS12a-based diagnostic platform for ESKAPE pathogens and associated antimicrobial resistance in sepsis patients CASPR." Submitted Principal investigator, Dr. Barnali Kakati, Professor & Head, Deptt. of Microbiology, HIMS, Swami Rama Himalayan University.
13. **RESEARCH PROTOCOL (EXTRAMURAL):** "Artificial intelligence (AI) based predicting model for long-term stroke-related motor and cognitive outcome in patients for minor stroke: a hospital study based from Uttarakhand." Submitted Principal investigator, Dr. Deepak Goel, Professor & Head, Deptt. of Neurology, HIMS, Swami Rama Himalayan University.

14. **RESEARCH PROTOCOL (EXTRAMURAL):** "An interdisciplinary study of temple architecture and yogic principles in Uttarakhand." Submitted Principal investigator, Dr. Ankit Sharma, Asstt. Professor, Himalayan School of yoga Sciences, Swami Rama Himalayan University.
15. **RESEARCH PROTOCOL (EXTRAMURAL):** "A phased approach to strengthening influenza surveillance among tourism workers: Identifying Gaps. Enhancing operational capacity and implementing a sustainable monitoring system." Submitted Principal investigator, Dr. Rajender Singh, Assoc. Professor, Deptt. of Microbiology, HIMS, Swami Rama Himalayan University
16. **Ph.D. Synopsis:** Examining the effect of the Himalayan yoga meditation technique introduced by Swami Rama on adult brain health by Swami under the guidance of Dr. Somlata Jha Asstt. Professor, Himalayan School of Yoga Sciences, Swami Rama Himalayan University.
17. **MSc. Clinical Thesis Protocol:** MSc. Clinical Research Protocols (10) in numbers of Batch 2023-25 for Ethical clearance.
18. **MSc. Epidemiology Thesis Protocol:** MSc. Epidemiology Thesis Protocols 4th Semester, 2025 (3 in numbers) for Ethical clearance.
19. **MPT Students Synopsis:** MPT Students Synopsis (45 in numbers) ³⁵ protocols ~~are not~~ received as per list received, for Ethical clearance.
20. **MSc. Clinical Research Protocol:** MSc. Clinical Research Protocols (11) in numbers) of Batch 2024-26 for Ethical clearance.
21. **MSc. Nursing:** (Batch-2024) research proposals (Total 07 in number)

Any Other Matter:

1. **Notification: Additional document of Multicentric Study: Protocol No. GBL 1204/2024/01, Version No. 2.0 Dated 18-Sep-2024: already approved study 1.** CTRI Site addition 12 Mar 2025, 2. DCGI acknowledgment for side addition 17 Feb 2025, 3. Source documents & ICD narration version 01., 4. Updated Investigator Undertaking dt. 22 Mar 2025, 5. Fully executed CTA by PI Dr. Renu Dhasmana, Professor, Department of Ophthalmology, HIMS. Swami Rama Himalayan University.
2. **Notification: Additional document of Multicentric Study: Protocol No. GBL 1204/2024/01, Version No. 2.0 Dated 18-Sep-2024: already approved study BCVA E-tumbling Chart,** by PI Dr. Renu Dhasmana, Professor, Department of Ophthalmology, HIMS. Swami Rama Himalayan University
3. **Notification: Additional document of Multicentric Study: Protocol No. GBL 1204/2024/01, Version No. 2.0 Dated 18-Sep-2024: already approved study Insurance III 2025-26 (from 01 April 2025 to 31 March 2026),** by PI Dr. Renu Dhasmana, Professor, Department of Ophthalmology, HIMS. Swami Rama Himalayan University.
4. **Notification: Additional document of Multicentric Study: Code- M016455/LPS17348 Accrual method,** dt. 25.04.2025 & ICD 21.04.2025 by Principal investigator, Dr. Reshma Kaushik, Professor, Deptt. of General Medicine, HIMS, Swami Rama Himalayan University
5. **Notification: Study No. D8535C00001, Additional document, Updated Investigator Undertaking Dated 20 Feb 2025** by Dr. Ankit Batra.
6. **Notification: Study No. D8535C00001, Additional document, CTRI Registration, DCGI Approval Amendment version 3.0 Dated 20 Feb 2024 & Risk disease recurrence evaluation pocket card version 2.0** by Dr. Ankit Batra.
7. **Notification of multicenter trial (PF-06863135) "A Randomized, 2-ARM, phase 3 study of elrantomab (PF-06863135) Six monthly progression report (Protocol C1071007)** by Dr. S.K. Verma, dated 10 April 2025
8. **Notification: Serious Adverse Event Report (12841002) of multicenter trial, follow up report II dated 11.03.2025 (PF-06863135) version 1.0** Lenalidomide in patients with newly- Diagnosed multiple myeloma after undergoing autologous stem- cell transplantation (Protocol C1071007) by Dr. S.K. Verma.
9. **Notification: Serious Adverse Event Report (12841002) of multicenter trial "A Randomized, 2-ARM, phase 3 study of elrantomab (PF-06863135) Closure Report (Protocol C1071007)** by Dr. S.K. Verma, dated 08 April 2025.
10. **Serious Adverse Event Report (12841002) of multicenter trial of Protocol C1071007 study as initial report with unknown causality** 10.04.2025, by Dr. S.K. Verma.
11. **RESEARCH PROTOCOL (EXTRAMURAL):** "Investigating the effects of yoga on neuroplasticity in adolescents and young adults: a comparative study." Submitted by Principal investigator, Dr. Somlata Jha, Asstt. Professor, Himalayan School of yoga Sciences, Swami Rama Himalayan University.


 Dr. D.C. Dhasmana
 Member Secretary, Ethics Committee
 Swami Rama Himalayan University

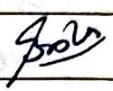
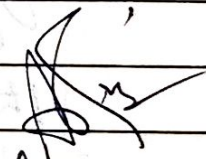
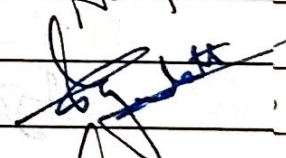
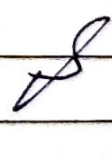
1. The Hon'ble Vice Chancellor
2. The Registrar, SRHU
3. The Chairperson, Ethics Committee, Professor Manisha Bisht, Deptt. of Pharmacology, AIIMS, Rishikesh
4. All Members of Ethics Committee HIMS, SRHU

Ethics Committee Meeting

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A meeting of Ethics Committee was held on 10/05/2025 at 11:00 AM in the dept. of Pharmacology to consider the following research projects etc. as per agenda circulated on 4.5.2025.

The following Members were Present:-

1. Dr Manisha Bisht - Chairperson 
2. Dr Rajeev Modan Kaurik - Member On leave
3. Dr Jayanti Semwal - Member 
4. Dr Abha Srivastava - Member 
5. Mr Arun Kundra - Member 
6. Mr. G. N. S. Gurudutt - Member 
7. Mr Sagar Manucl - Manucl 
8. Dr D. C. Dhasanana. Member Secretary 

The chairperson welcomed all the members of the committee for the meeting at the outset.

The minutes of the previous committee meeting dated 07.03.2025 were approved as such as no comments received. After the

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divulge if no chairperson, a sub-committee meeting was called to expedite approval of a submission project dated 28.04.2025 for submission to EMA, the minutes of which were approved by the full committee and the decision taken by sub-committee were ratified by the full committee meeting at the onset.

As per the agenda of the meeting, the following decisions were taken against each agenda item as per the minutes of the project as below after thorough discussion on the subject cited there in the agenda.

Agenda no 1. - Research Protocol (multicenter) study code: MO18455/US 3403 - a phase IV study open label clinical trial to assess safety and efficacy of Proferadimot + Mardrepredin allergic rhinitis (FAST trial) submitted by Dr. Dr. Kanishk, Prof. med. was discussed; and as per the view of many members the appropriateness of the PI from medical dept was questioned, subject to the availability of ENT dept clinicians. The issue was finally sorted out after the due clarifications from

the sponsor on this issue, so as to approve the trial, if the reasonable answer is obtained then it may be taken up as approved in the next meeting. Even a co-ll from ENT dept is admissible.

Agenda no 2: "Unravelling the molecular genetics of hemophilia A"

Extramural project. Submitted by Dr. Naveen Kaly, Pathology was discussed and it was approved subject to mentioning of genetic testing exclusively for the purpose of research only and the patient and her relatives will be counselled appropriately once the results are known for their hemophilia status as carriers.

Agenda no 3: "Comparative study of MLPA screening". P.I.C.C. submitted by Dr. Bannali Karati. Prof. Microbiology HIMS has approved as such as it was already approved as STS project in 2024, that is resubmitted to accommodate the investigative aspects through the intramural research project.

Agenda no 4. Medical negligence
.. Ubarokhand, submitted by Dr. Sanjay Sen, Inferior F.M. HIMS has approved as such in the present form.

Agenda no 5. Antimicrobial audit and steward

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ship practices undertaken
submitted by Dr Pujash K Rai
Mind history a retrospective obs.
study has approved as such subject
to permission for the appropriate
anonymity and maintenance of
anonymization of personal data of
subject to maintain privacy and
confidentiality in methods.

Agenda no 6: Correlation of Biochemical
chordan range - A retros-
pective study, submitted by Dr
Vamshi Jekani, Res. M.S. HIMS has
approved subject to maintenance of
anonymization of personal data of
patient and privacy and confidentiality
of patient be maintained in the
methods.

Agenda no 7: "Anthropometric - -
an individual" - submitted by Dr
Pragya Thapali 'FM, HIMS has
approved as such as to present form
as meant for all students to
enhance their research skills.

Agenda no 8: Respiratory rate oxygenation
(ROX). HFNC.
Submitted by Dr. Nitika Agarwal
Dept of Pediatrics, HIMS has approved

subject to obtaining of written informed consent from parents and in case of retrospective study anonymized, data & privacy & confidentiality of patients along & appropriate consent form be needed.

Agenda no 9: Biobank organization of mobile phones Uttarakhand submitted by Dr Nikita Agarwal; Prediction HIRIS was approved as such as it was previously approved as ITS project in 2024.

Agenda no 10: Multicentre Registry research project code: 781PC 00001 A study of Bilary Tract Cancers; A phase II study of transylzema dexteron (T-DKS) Bilary ^{Tract} Cancer submitted by Dr Nikita Bhatia Asst Prof, Dept of medical oncology. Was discussed and all documents were screened and approved by the committee.

Agenda no 11: Assessment of knowledge . . . medical student . . . of an workshop idea, submitted by Dr Harinder Gyl Chaudhary FM / HIRIS was approved as such in its present form, with the intention of undergraduate developing research skills.

Agenda no 12: Development of novel CRISPR

case2 based BJK, APB
penguins (CAIPR). Submitted
by Dr Barnali Kakati as co-PI in
project being conducted at PGIMER
Chandigarh was discussed and approved
subject to submission of appropriate
consent form and transmission of
biological material.

Agenda no 13: Artificial Intelligence
(AI) based predicting model
..... Uttarakhand. submitted
by Dr Deepak Goel, neurology dept
HIMS, was approved as such as he
is part of the strike registry, as
KMR Breed project.

Agenda no 14: An interdisciplinary
study of temple architecture ...
in Uttarakhand, submitted by Dr
Ankit Sharma, from HSYS was
exempted from ethical review except
for necessary permission from
the local authorities for research.

Agenda no 15: A phased approach to
strengthening influenza surveillance
among tourism workers
sustainable monitoring
system, submitted by Dr Rajendra
Singh, microbiology dept HIMS, was

approved as such as longitudinal study for 4 years during Char-dharm Yatra season.

Agende NO. 17: MSc. Clinical Research protocols (as per list attached: NO.) were screened by the committee and approved for batch 2023-25.

Agende NO 18: MSc (Epidemiology) Thesis protocols (total NO 3) for the year 2025 were screened by the committee and approved as such.

Agende NO 16: Ph.D synopsis of Ms. Shwati Sharma under the guidance of Dr. Soumitra Jha entitled "Examining the effect of brain health") was considered and approved as such.

Agende NO 19. MPT student's synopsis (Total) for batch 2024, in different specialities, were screened by the committee and approved as such in the present form.

Agende NO 20. MSc. Clinical Research protocols (total NO: 11) for batch 2024-26, as received, were screened by the committee and as such were approved.

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Agenda no 21: MSc - Nursing
(Batch 2024) Research proposals as
part of the curriculum (total 7 in number)
being forwarded by Bmynal Nursing
were screened by the committee
and were found appropriate for
approval as such.

Any Other Matter:

1. Notification requiring approval of
already approved protocol GBL/204/204
01/Version no 2.0 (Provision study) on
on wet age related macula degeneration
was approved as such

2. Additional documents notification of
already approved protocol GBL/204/204
01/Version no 2.0. (Provision study) on
wet age related macula degeneration
were approved as such in the meeting

3. Additional documents on informed consent
of GBL/204/204/01 submitted dated 12
April 2024 was also approved as such.

4. Additional documents of a phase IV feasibility
+ Redoxphedrine trial by Dr Redhwa
Kashik, as a clinical method and
ICD documents dated 21-04-2025 were

5. Additional documents, updated investigation undertaken dated 25/2/25 of DAS3500001 corrigendum filed by Dr Ankit Bhatia. was placed before the Committee.
6. Additional documents of NUS / anatomical CT scan app. as DCE approval of Dr Anant Bhatia was also placed before the committee.
7. Summary progress report of PR06863135 was also placed before the committee for Dr. S. Verma.
- 8 & 9. SAE follow up report - dated 11.03.2025 and closure report - dated and closure report dated 8/4/25 of subject 12041002 was placed and approved by the committee of C1071007 study
10. SAE initial of 12041002 of C1071007 study by Dr. SK. Ram as unknown causality of the following same AE dated 10.4.2025 was placed before the Committee and approved as such.

!! Research Protocol (Experimental) entitled "Investigating the effects of yoga on neuroplasticity in adolescents and young adults: a comparative study, submitted by Dr. Soumitra Jha, School of Yoga Sciences for ICSSR call for longitudinal studies in social & human sciences was discussed and approved subject to submission of appropriate consent form and other ^{minor} changes in the protocol.

The meeting ended with vote of thanks & chair.

(Dr. Manish Bhat)

(Dr. Anant Bhat)

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SRHU/HIMS/ETHICS/2025/195

Dated: 17.06.2025

"Ethics Committee"

A meeting of the Ethics Committee is convened on 21/06/2025 (Saturday) at 11:00 AM in the Deptt. of Pharmacology, HIMS.

Agenda:

1. **RESEARCH PROTOCOL (INTRAMURAL):** "Mindful transitions: A quasi-experimental crossover study to assess the impact of a short-term mindfulness and breathing intervention on stress, emotional health, and sleep quality among first-year medicine student." Submitted Principal investigator, Dr. Ruchi Jyval, Professor, Deptt. of Community Medicine, HIMS, Swami Rama Himalayan University.
2. **RESEARCH PROTOCOL (INTRAMURAL):** "Efficacy and safety of intra-vesicla gemcitabine+docetaxel in non-muscle invasive high and intermediate risk TCC bladder: A pilot study." Submitted Principal investigator, Dr. Rajeev Sarpal, Assoc. Professor, Deptt. of Urology, HIMS, Swami Rama Himalayan University.
3. **RESEARCH PROTOCOL (EXTRAMURAL):** "Study of VCS (Volume, Conductivity, Light Scatter) parameters in distinguishing latent tuberculosis and active tuberculosis by using machine learning algorithm." Submitted Principal investigator, Dr. Smita Chandra, Professor & Head, Deptt. of Pathology, HIMS, Swami Rama Himalayan University.
4. **RESEARCH PROTOCOL (INTRAMURAL):** "Effect of validated rehabilitation module (RehabMo) on cognitive impairment, functional disability and hospital stay in post-stroke patients: A Study from a tertiary care hospital in Dehradun." Submitted Principal investigator, Dr. Manisha Sharma, Asstt. Professor, Deptt. of Clinical Research, HIMS, Swami Rama Himalayan University.
5. **RESEARCH PROTOCOL (INTRAMURAL):** "Comparison of normal tissue low-dose volume between flattening filter (FF) and flattening filter free (FFF) linear accelerator in head and neck radiotherapy." Submitted Principal investigator, Dr. Mansi Birthwal, Asstt. Professor, Deptt. of Radiation Oncology, CRI, HIMS, Swami Rama Himalayan University.
6. **RESEARCH PROTOCOL (INTRAMURAL):** "Clinical radiological and electrophysiological features of viral encephalitis_ A clue towards an etiological agent." Submitted Principal investigator, Dr. Gaurav Kaushik, DM Resident, Deptt. of Neurology, HIMS, Swami Rama Himalayan University.
7. **RESEARCH PROTOCOL (INTRAMURAL):** "Improvising neonatal thrombocytopenia management: Insights from split volume depleted single donor apheresis platelets (SDAP)- An experience from tertiary health care centre in India." Submitted Principal investigator, Dr. Yashaswi Dhiman, Asstt. Professor, Deptt. of Immunohematology * Blood transfusion, HIMS, Swami Rama Himalayan University.
8. **Submission of Thesis Proposal** of Dr. Ipsitaa Mahendra Bhyshan, PG 1st year for Undertaking certificate from Ethics Committee
9. **Submission of Thesis Proposal** of Dr. Miteesha Rustagi, PG 1st year for Undertaking certificate from Ethics Committee
10. **Submission of Research Proposal** entitled "A study to assess the effectiveness of awareness program on knowledge, attitude and practice of adult tobacco chewers regarding oral cancer in selected community area of Dehradun Uttarakhand, by Post Basic B.Sc. Nursing 10 students. Under the guidance of Dr. Kanchan Bala from Nursing faculty.
11. **Ph.D Research Synopsis:** Effect of multigrain diet on the management of hypertensive individuals residing in rural area of district Dehradun, by Aksh Krishali, PhD Scholar Epidemiology under the guidance of Dr. Shaili Vyas, Professor, Deptt of Pathology, HIMS, Swami Rama Himalayan University.
12. **M.Sc. in Medical Microbiology:** A cross-sectional study on diagnostic yield of true NAT for detection of mycobacterium tuberculosis, by Aditi Chauhan, M.Sc. in Medical Microbiology under the guidance of Dr. Aarti Kotwal, Professor, Deptt of Community Medicine, HIMS, Swami Rama Himalayan University.

13. **M.Sc. in Medical Anatomy:** Histological study of skin thickness in fetuses of different gestational ages, by Dr. Prema Godiyal, M.Sc. Medical Anatomy, under the guidance of Dr. Deepa Singh, Professor & Head, Deptt of Anatomy, HIMs, Swami Rama Himalayan University.
14. **M.Sc. in Medical Microbiology:** Surgical site infections (SSI) in elective and emergency surgeries at a tertiary care centre in North India, by Dr. Anshul Anand, M.Sc. Medical Microbiology, under the guidance of Dr. Garima Mittal, Professor, Deptt of Microbiology, HIMs, Swami Rama Himalayan University.
15. **M.Sc. in Medical Microbiology:** Microbiological profile and antimicrobial susceptibility patterns of isolates causing bloodstream infections among cancer patients: A cross sectional study, by Dr. Kshitiz Purohit, M.Sc. Medical Microbiology, under the guidance of Dr. Barnali Kakati, Professor & Head, Deptt of Microbiology, HIMs, Swami Rama Himalayan University.
16. **RESEARCH PROTOCOL (EXTRAMURAL):** "Novel bio-sage filter-based kits for sample transport: a cost-effective approach toward increasing access to testing and improving TB and drug resistance detection in paucibacillary pulmonary tuberculosis in adults and children." Submitted Principal investigator, Dr. Divya Anthwal, Research Associate-II, Deptt. of Microbiology, HIMs, Swami Rama Himalayan University.

Any Other Matter:

1. **RESEARCH PROTOCOL (INTRAMURAL):** "Effect of short duration "Trataka" practice on the reaction times and task-switching cognitive flexibility of young adults." Submitted by Principal investigator, Dr. Dipak Kumar Dhar, Assoc. Professor, Deptt. of Physiology, HIMs, Swami Rama Himalayan University. for change of Principal Investigator, Dr. Abha Srivastava, Professor & Head, Deptt. of Physiology, HIMs.
2. **Letter from Dr. Kamli Prakash:** for change request for ethics letter of Ms. Sanjienbam Emr Charnu. Ph.D Scholar, in Nursing Sciences.
3. **Notification of Protocol deviation:** for Patient No 12841001, Site No. Dated 27/May/2025 by Dr. Sanjeev Kumar Verma.
4. **Additional Documents:** for VICTORION-1 PREVENT trial, dated 05/Jun/2025 by Dr. Kunal Gururani.
5. **Notification of Safety Event:** for Participant IDs 4189-16, 4189-17, 4189-24, & 4189-191, dated 27/May/2025 by Dr. Hemant Kumar Nautiyal.
6. **Notification of Safety Event:** for Participant IDs 4189-141, dated 27/May/2025 by Dr. Hemant Kumar Nautiyal.
7. **Notification of suspected unexpected Serious Adverse reaction:** for VICTORION-2 PREVENT trial, dated 19/04/2025 by Dr. Kunal Gururani.
8. **Notification of suspected unexpected Serious Adverse reaction:** for VICTORION-1 PREVENT trial, dated 19/04/2025 by Dr. Kunal Gururani.
9. Request for updation of Dr. Abhay Kumar's Assoc. Prof. CM. & P.D. for taking up his project "Water quality assessment in selected urban slum of Shimla" in Dist. Shimla, approved by EC under P.D. Dr. Hemant Kumar Nautiyal as per approval letter no SRHU/EC/MS/2024/81 dated 05.04.2024. in the meeting held on 03.04.2024.


Dr. D.C. Dhasmana
Member Secretary, Ethics Committee
Swami Rama Himalayan University

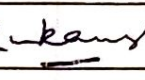
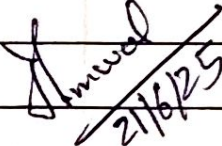
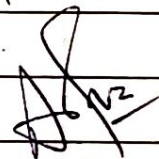
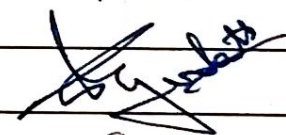
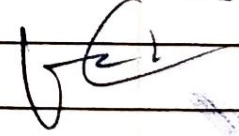
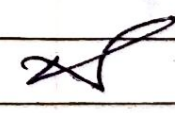
1. The Hon'ble Vice Chancellor
5. The Registrar, SRHU
6. The Chairperson, Ethics Committee, Professor Manisha Bisht, Deptt. of Pharmacology, AIIMS, Rishikesh
7. All Members of Ethics Committee, HIMs, SRHU

Ethics Committee Meeting

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A meeting of Ethics Committee was held on 21/06/2025 at 11:00 AM in the dept. of Pharmacology to consider the following research projects etc as per agenda circulated on 17/06/2025.

The following members were Present: -

1. Dr. Manisha Bisht - Chairperson. 
2. Dr. Rajeer Mohan Kaulik - Member 
3. Dr. Jayanti Semwal - Member 
21/6/25
4. Dr. Abha Srivastava - Member on leave.
5. Mr. Arun Kundra - Member 
6. Mr. GNS Gurudatt - Member 
7. Mr. Sagar Manwal - Member 
8. Dr. D.C. Shasmana - Member Secretary 

The chairman welcomed all committee members at the outset. The minutes of the previous committee meeting held on 10.05.2025 were approved as such at the outset, and action taken report was briefed by the member secretary.

As per the agenda of the meeting, the

99

Following research projects were considered and appropriate decisions were taken after thorough discussion as follows:

Agenda NO 1: Mindful Transition.....
..... 2 yr Med students submitted by Dr Ruchi Jugal. Coaxing medicine was approved subject to submission of appropriate consent form and change in the wordings of methods where crossover & washout period are mentioned as they do not fit into the protocol for reasons discussed in detail.

Agenda NO 2: Efficacy Concomitant + doxetrol Tce Bladder, submitted by P2 Dr Rajeev Jugal, Dept of Urology was considered as pilot study in 20 patients, with an intervention KAP is still not approved but having good past track & its effect available in the literature. The protocol was approved as academic study being interventional. As appropriate informed consent document should be attached with the provision of all ancillary support care to patient for even ADRs and an undertaking to this effect is to be taken from P.I. If done Once done, the study protocol is taken as approved.

Agenda no 3. Study of ves
machine learning algorithm, submitted
by P. Dr Smith Chondra, Dept of
Pathology. has an external
project has approved as such
once appropriate consent form is
attached with it.

Agenda no 4: Effect of validated
rehabilitation module - - - - - A study
for tertiary care hospital in Dehradun.
submitted by Dr. Manisha Sharma,
Dept of clinical research was considered
and was approved subject to the
details of module development
and validation of intervention to be
mentioned in the protocol in methods
more elaborately.

Agenda no 5. Comparison of - - -
- - - - - head & neck radiotherapy,
submitted by Dr. Manasi Bhatnagar
from radiation oncology was considered
and, it was taken as approved
one. There is mention of retrospective
study in title, and incorporation
of anonymization of personal data
of patients and statement on
privacy & confidentiality be added
to methods.

Agenda No 6. Clinical viral
encephalitis etiological agent,
submitted by Dr. Gaurav Kaushik
DM Resident, Neon Neurology
dept. has considered and approved
as such provided that written words
is mentioned in ^{addition to} place of consent in
method.

Agenda No 7. Improving neonatal
thrombocytopenia in India,
submitted by Dr. Yashraj Shiman,
from Immunology & Blood Transfusion
dept has approved as such as it
has an retrospective study provided
that a statement is added in method
on anonymity & personal data of
patients and privacy & confidentiality
shall be maintained. in the

Agenda No 8. Thesis project for ICMR
grant "entitled" Lifestyle
- A cross sectional study by Dr. Ishita
Mishra, under the guidance of Dr. Jayant
Jennal. Prof & Head Dept of Community
Medicine has approved subject to minor
changes in method on consent. to be
corrected. & permission from the
principal. be corrected. in method

Agenda No 9. Thesis project for ICMR

grant to be entitled: Mapping
and Understanding...

... one health framework, by Dr
Milesha Rustagi Iyr PG resident
under the guidance of Dr Abhay
Srinastora, dept of Community
medicine, was considered and
approved subject to submission
of appropriate consent form.

Agenda No 10: "A study to assess
... . Uttaranchal, a
project submitted by BSc Post basic
Nursing student under the guidance of
Dr Kamlesh Bala was approved as such
to the present forms

Agenda No 11: "Effect of multigrain
diet ... a quasi expt. study
submitted by Dr PhD scholar Akash
Kochali under the guidance of Dr.
Shaik Ugas, Prof. Community medicine
in Epidemiology, has approved
as such one written word added
to informed consent a method.

Agenda No 12: ^{Microbiology} ~~PhD~~ synopsis A
non second study ... NAT

... Mycobacterium tuberculosis
submitted by Microbiology scholar
Mr. Aditi Chakraborty under the

guidance of Dr. Arun Kumar, dept of microbiology was approved as such.

Agenda no 13: M.Sc synopsis in ~~Med~~ ^{Med} "Anatomy." Histological study of skin thickness gestational ages by Dr. Bernadine MSc & Anatomy under the guidance of Dr. Deepa Singh Prof & HOD in Anatomy was approved as such in its present form.

Agenda no 14: M.Sc ^{Med} (Microbiology) synopsis entitled "Surgical site infections wound dress," submitted by Anshul Anand Iyr MSc Med. Microbiology under the guidance of Dr. Ganesh Mehta was approved as such in its present form.

Agenda no 15: M.Sc. ~~Med~~ (Microbiology) synopsis: "Microbiological profile and A cross sectional study," submitted by Mr. Kshitiz Purshit under the guidance of Dr. Barnali Khatu Prof of Microbiology was approved subject to submission of written informed consent sentence as the methods.

Agenda no 16: "Novel bio-sensor film by Dr. Divya Any other matter which was approved as such is considered in Echo mail paper.

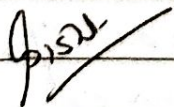
Any other matter:-

I Research poster application for change in supervisor from Dr Deepak K. Shau to Dr. Abhe Srivastava is hereby put to proper ahead. Approval has been permitted in Dr. Deepak K. Shau has left the Institution.

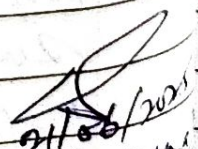
(11) Letter for Dr. Kamli Baked for change in the title retrospectively for thesis of M. S. E - Chem. was approved & there was exactly no change in the proposal except for minor change in the title, and granted change retrospectively, approved by the committee.

Notificational No. 3 to 6 of all the regulatory links was put before the committee members and were granted approval by all the members.

No 9: Request for updation by EC was approved. The meeting ended with vote of thanks to the chair.



(Dr. Manisha Bishnoi)


(Dr. Dr. Shashank)