ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA
JODHPUR ROMANA, MANDI DABWALI ROAD, BATHINDA,
PUNJAB – 151001
ਅਖਿਲਭਾਰਤੀਆਯੁਰਵਿਗਿਆਨਸੰਸਥਾਨ, ਬਠਿੰਡਾ
अखिलभारतीयआयुर्विज्ञानसंसथान, बठिंडा
RESEARCH ADVISORY COMMITTEE

Ref. No. AB/RAC/2024/ Date- 27/03/2025

MINUTES OF MEETING- 27/03/2025

Research Advisory Committee

1. **CALL TO ORDER**
   Dr. Lajya Devi Goyal (Dean Research) called to order the meeting for discussion at 04:00 PM on 27/03/2025

- **The following members were present in the meeting: -**
  Prof. (Dr.) Lajya Devi Goyal (Dean Research), Prof. (Dr.) Anuradha Raj (Associate Dean Research), Prof. (Dr.) Gurvinder Pal Singh, Dr. M. Altaf Mir, Dr. Sivanantham Krishnamoorthi, Dr. Ajay Kumar, Dr. Shailndra Rana,
- **The following members did not attend the meeting:-**
  Prof. (Dr) Rakesh Kakkar, Dr. Mayank Gupta

2. **AGENDA**

Following research projects were discussed by RAC and sent the subsequent comments:

Sr. No.	Principal Investigator	Title of the Project	Comments
1.	Rohit Raina (General Medicine)	Comparison of the effect of Erythromycin and Levosulpiride on gastric emptying in Diabetic Gastroparesis patients using gastrointestinal cardinal symptoms index (GCSI) score in a tertiary care hospital in North India: an open label randomised double blind study	• Justification of using an antibiotic for non-infectious etiology. Reflect upon the ethical concerns in terms of anti-antibiotic resistance. • Why is the study labeled as "open-label" and "double-blind" simultaneously? Please clarify and correct any discrepancies, as these are typically mutually exclusive terms. • Since it is double-blind, who will be blinded? How will drug concealment be maintained? • What is the scientific and clinical rationale for choosing Erythromycin and Levosulpiride for comparison?

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			• Are both drugs approved and commonly used for gastroparesis in diabetic patients? • What are the potential risks and side effects associated with Erythromycin and Levosulpiride in this patient population, need to mention? • How will adverse events be monitored, managed, and reported?
2.	Dr. Saket Sinha (Biochemistry)	Screening and evaluation of natural Cylin-dependent kinase (CDK)-5 inhibitors in chlorpyrifos-associated dementia in aging and elderly population.	• Undertaking by Site-PI • Objective 4 | Study Area Psychiatry OPD with no investigator, 100 pts • No funds for AIIMS Bathinda →Funded Project →No overhead charges calculated for Bathinda, sampling, etc. • Blood sampling in Psychiatry. • Blood collection/transportation. • Test feasibility of performing the test in AIIMS. • PIS, consent form (Site PI/CO-PI). • Reference not in Vancouver style. • Ethical Approval of CUB, Punjab (Nodal PI).
3.	Dr. Apurba Patra (Anatomy)	Influence of Demographic and Socio-Economic Factors on Academic Performance in First-Year MBBS Students : A Retrospective Cross-Sectional Study	• Student entered into INIs after clearing such competitive exam. Really the demographic factor plays role in it? Or financial factor play a role? • Various factors play in academic performance. • Single center study. If various strata of different centers then possible. • Retrospective →How data will be collected on financial status. → How the Consent will be obtained ?? (as it is retrospective study) ›Too many objectives?? • Retrospective data→Collected from registrar by dept. Anatomy_Approval from competent authority.

Sr. No.	Principal Investigator	Title of the Project	Comments
			• PICF (Role of PICF) as its is retrospective study (Also mention copy for)→ To whom & How it will be calculated? • PIS→Also provided for retrospective study??→To whom it will be communicated?
4.	Dr. Rattan (Forensic Medicine & Toxicology)	Psychological assessment of police officials who are working on Medicolegal cases- A cross-sectional study	• Checklist in Form 2- empty. • PIS format to be revised as per guidelines. • Mention the SPSS version 29. • References in Vancouver style (ex 10)
5.	Dr. Bhawna Sharma (Microbiology)	**Title:** Evaluation of in-vitro Synergy between Aztreonam and Ceftazidime-Avibactam among clinical isolates of Carbapenem Resistant Enterobacterales (CRE): A prospective observational study from North India	**Comments** • Is the drugs aztreonam plus ceftazidime-avibactam routinely tested in our lab for all patients and all samples? If yes, under which tier as per CLSI M100 – 2024, the aztreonam plus ceftazidime-avibactam is tested in our center as it is not supplemental test (required test) but supplemental test (optional test). • Context in introduction requires references (Example ….very common in isolates from tertiary care facilities, ….. CLSI 2024, etc). • Primary objective in line with the title of the study. Secondary objectives are not in line with title or lack proper methodology to access the financial aspects of the study. What other methods of synergy will be compared as it is not detailed in methodology part? How will be the role of synergy evaluated? As it is not detailed in methodology? • Methodology: the introductory lines under methodology is not clear. Need to corrected. (i.e. …….till the desired sample size will not (?) be completed…..). • Inclusion criteria: Please provide a reference for the definition of carbapenem resistant Enterobacterales. • Scheme of the study: for Ceftazidime-Avibactam and Aztreonam, AST testing mentioned as disk diffusion or VITEK N407 card and disk diffusion or N406 card mentioned respectively. Are both the tests routinely employed in all specimen and all GN isolates? What is the justification of testing disk diffusion or VITEK card in any clinical isolates? Part 3 of

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			the study is in line with title of the study. Part 1 and part 2 of the study to be specific in terms of test indication (where the disk diffusion is applied and where the VITEK is applied) in line with tier system of latest CLSI M100. • Sample size calculation: the study used for sample size calculation is missing with reference. • Data Analysis requires the details in terms of various parameters as per different objective. • PICF has been attached. To whom the participant informed consent will be obtained? How the study enrolls patients as the study setting mentioned as Department microbiology with clinical isolates? • PIS has been attached. To whom the information will be provided? If the PIS still required for this study with justification, the PIS need to be corrected as there is irrelevant study details provided under head – Do I have to take part in this research study? ..... describe the microbiological profile of BSI and ascertain the incidence of infective endocarditis among IVDUs presenting.... Not related to the submitted proposal. • After necessary changes new plagiarism report to be attached.
6.	Dr. Bhupinder Singh (Cardiology)	**Title:** Efficacy and safety of cagrilintide s.c. 2.4 mg in combination with semaglutide s.c. 2.4 mg (Cagrisema s.c. 2.4 mg/2.4 mg) once weekly on morbidity and mortality compared to placebo in people with heart failure with preserved or mildly reduced ejection fraction and obesity"	**Comments:** • Type of subjects mentioned in patients including vulnerable subjects, pregnant women & elderly. (Why not to exclude those). • Collection of samples for future research mentioned is yes (do you have a banking facility?) • How will the sample be sent abroad (transport of samples need proper strategy & proper temperature). • How was sample size calculated for global study? • Please Add-time line of study (Gantt. Chart). • Please mention the rationale for selecting Indian participants with HFpEF or HFmrEF and obesity for this global trial. Is there epidemiological evidence supporting the relevance of this population in India? • Has this combination therapy received regulatory approval from the DCGI for clinical trials in India? Please submit the clinical trial approval/NOC from CDSCO for this investigational product combination. • Considering the investigational nature of the combination

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			(CagriSema), what is the risk-benefit profile for Indian participants? • Has any prior phase 2 or early phase 3 data been evaluated in similar populations? • Please provide details of the clinical trial insurance covering Indian participants and institutions. • As the study involves the transfer of samples outside India, has appropriate Health Ministry Screening Committee (HMSC) approval been obtained? • How will participant confidentiality and data protection be ensured?
7.	Dr. Anil Kumar Goyal (Radiotion Oncology)	A phase 3, Open-label, Multicenter, Randomized Trial of Trastuzumab Deruxtecan with Bevacizumab Versus Bevacizumab Monotherapy as First-line Maintenance Therapy in HER2-Expressing Ovarian Cancer	• Private foreign funding is mentioned • Proposal need to be provide RAC clearance from Health Ministry screening committee (HMSC). This is first investigational drug needs clearance from DCGI / other regulatory authority. • What is the scientific and public health justification for including Indian patients in this international study? • What specific strategies are in place for early detection, management, and reporting of serious adverse events, particularly cardiotoxicity and pulmonary toxicity associated with Trastuzumab Deruxtecan? • Has the trial received approval from the Drug Controller General of India (DCGI)? Please provide a copy of the no-objection certificate (NOC) or clinical trial approval from CDSCO for the Indian sites. • Will participants who benefit from the combination therapy have post-trial access to the drug? What compensation mechanisms are in place in case of trial-related injury or death? • Does the sponsor provide clinical trial insurance coverage for Indian participants? If yes, please provide

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			a copy. • As the study involves exporting biological samples, has appropriate clearance from the Health Ministry's Screening Committee (HMSC) been obtained? How will participant confidentiality and data protection be ensured?
8.	Dr. Sabia Handa (Ophthalmology)	A Prospective, Multicenter, Double-Blind, Active-Controlled, Parallel-Group, Phase III Study to Compare the Efficacy, Safety and Immunogenicity of Sun's Aflibercept with Reference Biologic in Patients with Neovascular Age-Related Macular degeneration (wet AMD)	• Compensation for injury? How much?

Prof. (Dr) Lajya Devi Goyal
(Dean Research)

Prof. (Dr) Anuradha Raj
(Associate Dean Research)

Prof. (Dr) Gurvinder Pal Singh

Dr. M Altaf Mir

Dr. Ajay Kumar

Dr. Shailendra Singh Rana

Dr. Sivanantham Krishnamoorthi