

MINUTES OF MEETING- 25/09/2025

Research Advisory Committee

1. CALL TO ORDER

Prof. (Dr) Lajya Devi Goyal (Dean Research) called to order the meeting for discussion at 03:30 PM on 25/09/2025

- **The following members were present in the meeting: -**

Prof. Dr. Lajya Devi Goyal, Dr. Rakesh Kakkar, Dr. M. Altaf Mir, Dr. Ajay Kumar, Dr. Sivanantham Krishnamoorthi.

- **The following members did not attend the meeting:-**

Prof. (Dr) Anuradha Raj, Dr. Gurvinder Pal Singh, Dr. Mayank Gupta, Dr. Shailendra Rana.

2. AGENDA

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

S. No.	PI	Title of the Project	Comments
1.	Dr. Bhupinder Singh (Cardiology)	Selatogrel Outcome Study in suspected Acute Myocardial infraction (SOS-AMI) Multi-center, Double-blind, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of self-administered subcutaneous selatogrel for prevention of all-cause death and treatment of acute myocardial infraction in subjects with a recent history of acute myocardial infraction	<ul style="list-style-type: none"> • Attach ethical approval of nodal center. • In how many centers this study happened in India. • Attach plagiarism check report with the PI ID • Brief Summary on how many patients in AIIMS Bathinda and overall in India. <hr/> <ul style="list-style-type: none"> • Proposal/detailed protocol has not been attached, according to AIIMS Bathinda format.

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2.	Dr Sonia Kochhar (Physiology)	Normative Reference values of Cervical and Ocular VEMPs Across Age and Gender in Healthy Indian Adults: A cross-sectional Study	<ul style="list-style-type: none"> • In title please write the full form of VEMPs. • Add list of Abbreviations or write full forms in first instance. • Keep first primary objective as primary objective and others can be kept on secondary objectives. • Timeline/Gantt chart needs to be added. • Attach study performa and plagiarism check. <hr/> <ul style="list-style-type: none"> • Rationale of the study needs clarity. • Primary objective needs to be reframed. • Tools for assessment need more specification..
3.	Dr. Vandana Tiwari (Anatomy)	Exploring variational Anatomy in morphological and morphometric Analysis on Donated Cadaveric Specimens and their dried bones with clinical significance	<ul style="list-style-type: none"> • Objective “ To investigate “ can be replaced with “ To find out” • Both objectives are not clear for the study esp no. 2 • Specify the minimum no. of cadavers to be studied • Inclusion criteria not given. • Will a cadaver already dissected out will be included in the study?? • Expected duration of the study to be mentioned. • End point of the study to be mentioned. • Title needs more clarification as regards PICOT. • How will you establish the clinical significance in a already deceased individual? <hr/> <ul style="list-style-type: none"> • Please provide a more comprehensive introduction, supported with relevant citations

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			<p>to justify the significance and context of the study.</p> <ul style="list-style-type: none"> • Include a detailed review of the existing literature to position your research within the broader academic discourse. • Submit a plagiarism report to ensure originality and academic integrity. • Clearly state both the primary and secondary objectives of the study. • Explain the rationale and statistical method used for sample size calculation. • Specify the inclusion criteria for the selection of cadaveric specimens. • Attach the Participant Information Sheet (PIS) in a translated format, where applicable. • Include a copy of the consent form that will be used with participants or their representatives. • Elaborate on the methodology, providing sufficient detail for reproducibility. • Clearly articulate the central research question guiding this study. • Add a list of references supporting statements and claims made throughout the study proposal. <hr/> <ul style="list-style-type: none"> • Project is not approved since there is no novelty in this project.
4.	Dr. Rajani (Biochemistry)	Utility of Fecal Calprotectin in Assessing	<ul style="list-style-type: none"> • Remove cross sectional study from the study design.

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		Disease Severity in Ulcerative Colitis: A Prospective Cohort Study	<ul style="list-style-type: none"> • Sign on checklist. • Checklist: Not signed by investigator. • Form 2: No. of subject should be 60. • Check list for attached document – PIS, ICF is missing in Punjabi. • Sample size: Refer to point no. 2 • Is the investigator want to enroll more than 60, than what is the maximum limit??
5.	Dr. Shivani (Endocrinology)	A Multicentric, Randomized, Double-Blind, Double-Dummy, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Oral Semaglutide Tablets of Sun Pharma Laboratories Limited in Comparison to Rybelsus (Semaglutide) Tablets in Type 2 Diabetes Mellitus)	<ul style="list-style-type: none"> • The study is a good and comprehensive study. • Please mention details about the recruitment strategy and confounders (e.g., diet standardization). • Possibilities of potential bias in hospital-based enrollment; no pilot phase mentioned. • Missing comprehensive bibliography; Update references –Lacks recent data (last 5-7 years data is advisable). • No mention of confidence intervals or effect size, which are essential for interpretation. <hr/> <ul style="list-style-type: none"> • Check list 2.--EC clearance of other center in multicentric = NA but it is a multicentric study. • Form 2: Multicentric study- Nodal center IEC? • Form 2 : (3) System of medicine to be checked appropriately • Form 2: 3(iii) Investigational new drug – yes in bold and ticked as no to be corrected

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			appropriately.
			<ul style="list-style-type: none"> How the 2 tablets of same kind by different companies can be compared.
6.	Dr. Sonia Kochar (Physiology)	Potential use of Heart Rate Variability (HRV) To Predict the Level of Insulin Resistance in Patients with Metabolic Syndrome	<ul style="list-style-type: none"> Aim of the study needs to be modified as per PICOT. Patients of Type 1 or type 2 diabetes will be taken is not clear Who is going to pay for the fasting blood sugar/HOMA-IR etc tests? Rationale for leaving age of 18 -19 yrs? Why all adults were not taken needs to be explained Exclusion criteria needs to be elaborate like whether persons on treatment will be included or not. How will you take care of the confounding factors affecting insulin resistance. <hr/> <ul style="list-style-type: none"> Please include a detailed review of the literature to provide context and demonstrate how your study fits within existing research. Clearly specify the research questions, as well as the null and alternative hypotheses for your study. Clarify the blinding process: indicate whether the operator, patient, and/or assessor were blinded, and describe the method used. List the specific statistical tests that will be used for group comparisons. State who will bear the cost of the insulin resistance test. While the devices for HRV and insulin/glucose measurement are named, please describe their calibration

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			procedures, operator training, and the measurement protocols you will follow.
7.	Dr. Abhay Singh (Urology)	Efficacy of Percutaneous Nephrolithotomy (PCNL) to resolve symptoms in patients with Nephrolithiasis: A Prospective Observational Study	<ul style="list-style-type: none"> • Please submit numbers of subjects and duration of study in form II. • Consent should be written. • Rewrite the full title in form III. • Sample size calculations to be added including formula and reference of index study. • Attach consent form and patient information sheet (new format). • Re-write whole project proposal and then resubmit. • Preferably attach Turnitin plagiarism check. • What is new in this study.
8.	Dr. Bhupinder Singh (Cardiology)	Adapting Regional Indian Cuisines Using Mediterranean principles To Improve Their Anti-Inflammatory Potential- A Multicentric Study (AROMA Study) India Council of Medical Research, New Delhi protocol Version 1.0 Dated 06 Aug 2025.	<ul style="list-style-type: none"> • Ok and Approved
9.	Dr. Shivani (Endocrinology)	Reversing Type-2 Diabetes: A Study on the Efficacy of Pharmacotherapy Versus Lifestyle interventions for achieving Remission.	<ul style="list-style-type: none"> • Form for expedited review to be submitted again • Define the reasonable risk as mentioned in point no 10 form no 2 • Title needs more clarification as regards PICOT • Inconsistency in evaluation of the patient at sequential intervals at multiple points. • Who will pay for the tests to be

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			<p>done on the patient during the course of 2 years?</p> <ul style="list-style-type: none"> What do you mean by patients will be distributed across centres? <hr/> <ul style="list-style-type: none"> Please incorporate appropriate reference citations in the introduction to support the context and rationale of the study. Add a comprehensive review of the literature to highlight existing knowledge and identify research gaps. Clearly state the research questions, as well as the null and alternative hypotheses guiding your investigation.
10.	Dr. Saurabh Nayak (Nephrology)	Refining Kidney function assessment in Indian: Towards accurate estimation of glomerular filtration rate in clinical practice.	<ul style="list-style-type: none"> Study is good few suggestion- may put hypothesis on expected accuracy improvement (e.g., >10% over CKD-EPI); May take subgroup analyses for comorbidities like diabetes, which are prevalent in India. May also explore socioeconomic factors. Recruitment bias is possible in hospital-based settings. Limited innovation in the given study. Update references – preferably the last five years is advisable. Pg. 30 – site PI name to be mentioned in all language forms. <hr/> <ul style="list-style-type: none"> Check list point 2-EC from other center if multicentric.- NA but it is a multicentric study.

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			<ul style="list-style-type: none"> Funding details break up- AIIMS BTI funding - staff facility for the samples. Investigator-Biochemistry - GFR related parameter. Bio impedance analysis— Body composition – Is it available in our institute/who will do after procurement of analysis? Study setting need clarity regarding analysis. POINT 21- Reference should be in vancouver style Part B—Pilot study of which center (Prelim work). PIS of PGI—PI details –Dr. Ashok Kumar complete details of the site PI to be provided as per AIIMS Bathinda investigator. PIS point-5 to be clarified as per AIIMS Bathinda norms. PIS to be modified as per AIIMS Bathinda. Case record form to be checked for typing.
11.	Dr. Vishal Thakur Assistant Professor	Impact of insulin resistance on response to treatment with conventional non-biologic drugs in moderate to severe psoriasis: An Ambispective study.	<ul style="list-style-type: none"> Although BMI, diabetes, and lipids are recognised as confounders, no clear statistical plan is mentioned. Use of multivariate regression analysis or stratification is essential. Incorporating Indian epidemiological data on the psoriasis–metabolic syndrome link would strengthen contextual applicability. For robust inference, include effect sizes (ARR, RRR, NNT) with confidence intervals, subgroup analysis, and adjusted models. Attrition Bias Risk - Monthly follow-up over 3 months may

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			<p>face dropouts. No clear retention strategy (e.g., reminders, flexible scheduling) has been mentioned.</p> <ul style="list-style-type: none"> The study is single-centre (AIIMS Bathinda), limiting generalizability. A multicentric study would improve representativeness and applicability. Checklist for PI- to be signed. <hr/> <ul style="list-style-type: none"> 7(b) to be checked appropriately. 8. Comment box checked appropriately. Flow chart – word insulin should be insulin resistance. Vancouver style reference. Statistical analysis, methods to be in details on which tests to be applied to check the objectives.
12.	Dr Ramniwas (Pulmonary Medicine)	A Phase IV, Open Label, Multicentre, Interventional Study to Assess the Safety and Efficacy of Oral Miquaf® (Nafithromycin) as Monotherapy in the Treatment of adult patients with Community-Acquired Bacterial Pneumonia (CABP) .	<ul style="list-style-type: none"> Prepare a work up of all. View any study did in India or not. Summary/brief of project not more than 1 or 2 pages If any trial on Nafithromycin happened or not. Also show multicentric proof. Brief from project point of view. <hr/> <ul style="list-style-type: none"> PI to thoroughly read and prepare regarding the project. <hr/> <ul style="list-style-type: none"> EC clearance of other centers in multicentric project—NA but it is multicentric study. Form 2—Nodal center IEC(Form 2, Point 1, Point 5) Point 5(ii)—Duration of study-how long (not participants' timeline)(1month,1year,2year) —For the specified period, will

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			<p>SRs be in the departmental tenure?</p> <ul style="list-style-type: none"> • Point 5(iv)—Radiological investigation- Is there radiologist required in study? • Point 5(iv)5—Lab results- in Appendix III—Is laboratory personnel as Investigator to be added. • Funding source---Indian or Foreign—Indian trial if any? • Reference: Vancouver style.
13.	Dr. Apurba Patra (Anatomy)	Influence of Demographic and Socio-Economic Factors on Academic Performance in First-Year MBBS Students: A Retrospective Cross-Sectional Study.	<ul style="list-style-type: none"> • It is a captivative population hence permission from Dean/Director/Registrar is required.

Minutes of Meeting held on 25/09/2025 regarding the evaluation of Faculty projects

Not Present

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

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

Prof. (Dr) Gurvinder
Pal Singh
4/10/2025

Dr. M Altaf Mir
(Alt. Member Secretary)
04/10/2025

Prof. (Dr.) Ajay Kumar
4/10/25

Prof. (Dr) Rakesh
kakkar

Dr. Sivanantham
Krishnamoorthi

Dr. Shailendra Singh Rana