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/2025/11/19 **Date- 06/11/2025**

MINUTES OF MEETING- 06/11/2025

Research Advisory Committee

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1. **CALL TO ORDER**
   Prof. (Dr) Lajya Devi Goyal (Dean Research) called to order the meeting for discussion at 03:30 PM on 06/11/2025

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

Dr. Sivanantham Krishnamoorthi, Dr Gurvinder Pal Singh,, Dr. Shailendra Rana

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

Prof. Dr. Lajya Devi Goyal, Prof. (Dr) Anuradha Raj, Dr. Rakesh Kakkar, Dr. M. Altaf Mir, Dr. Ajay Kumar, Dr. Mayank Gupta,

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2. **AGENDA**

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

Sr.No.	PI	Title of the Project	Comments
1	Dr. Manjit Kaur (Pathology)	DHR-ICMR Advanced Medical Oncology Diagnostic Services (DIAMONDS) Under HTA In, Pilot Research Project: Unpinning the Genomic profilling of breast Carcinomas.	• In form 2 some of the boxes remain unchecked. • 7(iv)-Use of pre-existing/stored/left over samples? • 7(v)-Collection for banking- storage facility? Future research-how long? • 7(viii)-Proper disposal of materials? • 10(ii)- risk/discomfort? • 5(iv)-Mentioned as inclusion/exclusion criteria-No but in description inclusion/exclusion provided-to change appropriately. • Mention sample size calculation in details.

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			• Details on bioinformatics analysis in methodology. • Details on Next Generation Sequencing(NGS)/WES in methodlogy.
2	Dr. Manjit Kaur (Pathology)	Enhancing cervical cancer Screening: A Deep learning approach with a Comprehensive Cytology image dateset.	• Multi center – other centers? Provide details/IEC clearance of nodal center? • 11(i) Details of DSMB as mentioned yes, please provide details of this Committee/Board. • 11(ii) What is adverse events?? Ref. 10(i) in form 2 mentioned as no risk. • Aim: to be redefined
3.	Dr. Klein Dantis	To assess and study the outcomes in patients with tuberculous bronchopleural fistula.	• The title is currently written as a purpose statement ("To assess and study the outcomes in patients with tuberculous bronchopleural fistula"). Could you revise this to a more concise and specific title that directly reflects the content and methodology of your study? For example, consider something like "Outcomes of Surgical and Medical Management in Tuberculous Bronchopleural Fistula: A Prospective Single-Institution Study." Or any other. • The ideal academic flow for any research study is outlined below. Please reorganize the proposal to follow this sequence: ▪ Title and Abstract ▪ Introduction

Sr.No.	PI	Title of the Project	Comments
			▪ Rationale, Aim, and Objectives ▪ Review of Literature ▪ Materials and Methods ▪ Statistical Analysis Plan ▪ Expected Outcomes / Results (prospective if proposal) ▪ Discussion (if completed study) ▪ Conclusion and Implications ▪ References ▪ Annexures (proforma, consent forms, etc.) • Explain the novelty of study through FINER Criteria. • **Objectives**: It is better make the primary/secondary objective split clearer. • **Selection Criteria:** rewrite as- "Refusal to participate or provide inform consent" → "Refusal to participate or provide informed consent." • Define research questions, null hypothesis and alternative hypothesis • There's a lack of **clear outcomes definition**: e.g., how is "successful lung re-expansion" defined? Radiographically? Functionally? • Please remove repeated sections, particularly the **inclusion and exclusion criteria**, which currently appear multiple times across the proposal. These should be stated

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			once, clearly, under the appropriate heading to improve readability and avoid redundancy. • Sample Size Justification: You use both "29" and "30" as the final number. Pick one. • **Expected Outcomes:** Separate "primary" and "secondary" outcomes into a table or bullet list. • In Gantt chart, add clear start and end dates on the chart or use milestones (e.g., "Month 0," "Month 6," "Month 12"). This will make the timeline easier to interpret at a glance. Using different colors or patterns for each phase (submission, clearance, intervention, follow-up, analysis) will make the sequence clearer. • Include how **missing data** will be handled (e.g., complete case analysis, imputation). --- • Revise the Title – It is broad, so make it concise and outcome-focused, aligning with the objectives. • Refine Objectives – Expand measurable, specific objectives, such as comparisons of surgical techniques, predictors of outcomes, and improvements in lung function. • Sample Size: Please justify 'acceptable precision of ±17 %' and '30 % attrition' • Study Design – Can modify as 'a single-centre, prospective and observational study using consecutive sampling'. • Enhance Statistical Plan – Add

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			regression or multivariate analysis to identify predictors of successful outcomes and complications. • Modify SPSS v29.0 (AIIMS Bathinda Institutional version)
4	Dr. Gargi Kapatia (Assistant Professor)	Spectrum Of Anti- nuclear antibody patterns among paients with Hepatitis C virus infection on indirect immunofluroscence (IIF) in a tertiary care institute of North India.	• Include the type of study in tittle. • Rewrie review of literature in detail with citation of reference. • Rewrite the novelty of rationale to the level of satisfaction of justification. • Sample size to be calculated using formula or software and mention the formula of add screenshot if software is used. • Inclusion & Exclusion criteria should be mutually exclusive (e.g. If in inclusion age is >18 years then there is no need to write in exclusion criteria the age <18 years. • Write statistical test to be used in this prospective study. • Write references in Vancouver study. • Attach PIS&PICF in new format. • Rewrite objectives as primary & secondary. --- • Inclusion criteria's needs to be more refined • Page 21 Last line Hindi should be Punjabi • How will you address interplay of different diseases with HCV in ANA positive patients?

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5	Dr. Jawahar Singh (Psychiatry)	Development and validation of an artificial intelligence Avatar (AI - Avatar) as co-therapist in managing patients with Depressive disorder- A Multicentric Randomised Controlled Trail."	• Recommendation from HoD is missing • Please mention sample size of AIIMS Bathinda. • Attach study tool (performa) • Attach PIS/PICF in new format. --- • Add background of study or introductions heading before the problem statement. • **Sampling and Group Selection:** You've listed six stakeholder groups, but it's not clear how many FGDs will be drawn from each. Will each group have separate FGDs, or are you mixing groups in sessions? If mixing, justify why. If separate, clarify the plan and rationale. • **Recruitment Strategy:** Purposive sampling makes sense, but how will you identify and recruit participants? Are there inclusion/exclusion criteria? Any considerations for diversity (age, gender, severity of illness, professional experience) to avoid bias? • **Inclusion Criteria – Clarity and Justification:** The age range (18–60) is standard, but why exclude those above 60? Depression in older adults is important and they often have different perspectives on technology and care. If you have a reason, explain to avoid confounding by cognitive decline. • "DSM-5 criteria for MDD: Who will perform the diagnostic assessment, and what tool or structured interview will they use?

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			• Uncontrolled severe medical illness" is also appropriate, but the examples given (hypertension, diabetes) could be clarified. Would controlled diabetes be included? What defines "uncontrolled"—recent hospitalization, abnormal lab results, or clinical judgment? • For both inclusion and exclusion, specify who's making the clinical judgments—a psychiatrist, psychologist, or another clinician? • Exclusion Criteria: Care-Providers: The "uncontrolled severe medical illness" line is vague. Spell out what "uncontrolled" means—hospitalized in the past 6 months? Not on medication? Clinical judgment? • Inclusion/Exclusion Criteria: Experts-specify minimum years of experience or clarify what counts as "formal training." For example, does a master's degree in computer science qualify, or only those working in AI/ethics? • Target sample size: 900 video interviews per site is a lot. Please explain exactly how you'll recruit participants, record, and process all these interviews. If you're doing this at more than one center, make that clear. Also, outline your timelines, staffing plans, and what resources you'll need to handle this workload. If each session is an hour, that's 900 hours of video. What's your plan for data storage, transcription, and annotation?

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			• You mention "standard medical format" for histories and "item wise response transcript" for rating scales. Attach an appendix or link to your format. • **Missing Data/Attrition:** With a study this size, not every patient will complete all steps. What's your plan for missing or incomplete data? Will you have a minimum data threshold for inclusion in the final analysis?
6	Dr. Rakesh Kakkar (Professor and head)	Facility evaluation of an outpatient opioid-assisted treatment (OOAT) clinic in rural Punjab.	• OOAT Clinic comes under Deaddiction Programme of the Ministry of Health and Family Welfare, Punjab • Permission to be taken from Director Health Services Punjab and Director Social Justice and Empowerment • In author some faculty of Psychiatry may be considered. • Rule out psychiatric morbidity and history taking and mental status examination is not mentioned • Open endded questions details are not mentioned • Deaddiction assessment proforma is not mentioned --- • Kindly cite all references present in the Background section in Vancouver style. • Kindly cite references in review of literature • Define how sample size is calculated. • Kindly add bibliography.

Sr.No.	PI	Title of the Project	Comments
7	Dr. Madhur Verma (Associate professor)	Weight trajectory before and after childbirth in women residing in rural area of punjab, India : A community based observational study.	• No of objectives in iThenticate are two but in five in brief description of proposal. --- • Weight trajectory cannot be derived by only one measurement, but has to be multiple readings at different points of time for participants. • How will you rule out subsequent pregnancy/ tumor/ ascites/ hypothyroidism/ endocrinal disorders etc etc which can cause weight gain?
8	Dr. Rakesh Kakkar (Professor and head)	Assessment of accessibility, service availability and patient experience at a rural OOAT clinic in Punjab: a cross-sectional Evaluation.	• OOAT Clinic comes under Deaddiction Programme of the Ministry of Health and Family Welfare, Punjab • Permission to be taken from Director Health Services Punjab and Director Social Justice and Empowerment • In author some faculty of Psychiatry may be considered. • Rule out psychiatric morbidity and history taking and mental status examination is not mentioned • Open endded questions details are not mentioned • Deaddiction assessment proforma is not mentioned. --- • Please mention the full form of OOAT clinic in title. • Cite the index study for sample size calculation if any. • Rewrite references in Vancouver style. • Attach PIC/PICF in new format.

Sr.No.	PI	Title of the Project	Comments
9	Dr Bhawna Sharma	Genomics and Klebsiella pneumoniae and Escherichia coli from young infants in India: A multicentric observational study	• Reference should be in Vancouver style. • Checklist for PI: to be filled, and as per the checklist, add all required forms • Refine the title for clarity and impact. • Modify objectives • Strengthen justification and novelty - may include a rationale/gap paragraph highlighting the lack of Indian neonatal genomic datasets, the importance for global surveillance, and the relevance to One Health and AMR policy frameworks. • Methodology Enhancements - Add clarity on study design, duration, Sample transport, biosafety, and cold chain maintenance, including its cost implications. • Clarify the Data management and sharing policy in line with ICMR-GENESIS or DBT norms. Since samples are sent to PGIMER, it is essential to clearly mention the Material Transfer Agreement (MTA). • Sample Size Justification - The sample size (n = 32) appears underpowered for a multicenter genomic study. Please justify or expand with a minimum of 100–150 isolates to ensure diversity and statistical significance for genomic correlations. • Clarify on ethical aspect and consent

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10	Dr. Bhupinder Singh
	
	(Cardiology)
		COLchinine in Heart Failure(COLHEF): A Randomized Controlled Study	• Title Refinement
			  • In addition to the current title (short title), it may be modified to: COLHEF Trial: Efficacy and Safety of Low-Dose Colchicine in Heart Failure with Reduced Ejection Fraction – A Multicentric Randomised Controlled Study.
			  • Incorporate the trial phase (e.g., "Phase II") if applicable,
			• Primary Objective Simplification
			  • The primary objective currently combines efficacy and safety.
			  • It can be split it into two:
			  • To evaluate the efficacy of colchicine in reducing the composite endpoint of all-cause mortality and heart failure hospitalisation.
			  • To assess the safety and tolerability of colchicine versus placebo.
			• May add exploratory objectives also on cost-effectiveness and ethnic/geographic subgroup analysis (North vs South India) for national relevance.
			• Ethical and Regulatory Considerations
			  • Clarify the data safety and monitoring plan, adverse event escalation workflow, and specify the DSMB composition (independent cardiologist, biostatistician, and pharmacologist).
			  • Add interim analysis or DSMB review criteria for adaptive decision-making.
			  • Add a dedicated section on potential adverse events and risk mitigation strategies,

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			referencing guidelines such as those from the ICMR, to enhance ethical oversight and participant safety.
11	Dr.Shivani Bansal	Uneviling the inflammatory hematological markers in vitiligo: A cross sectional retrospective study.	• Title of the study as per PICOT needs to be framed. • Fill the checklist completely – Pg 11 • Refine title for precision- may change it to 'Evaluation of Inflammatory Haematological Markers in Vitiligo: A Retrospective Cross-Sectional Study. • What are the implications and novelty of the study • Enhance objectives with subgroups- Modify secondary objective to "Correlate haematological markers with vitiligo activity (VIDA), severity (VASI/VES), type (generalised vs. localised), and duration"; add exploratory objective on MHR if HDL data available. • Clarify sample size estimation • Strengthen Control selection- may exclude those with any systemic illness to minimise confounding. • Expand exclusion criteria- Include recent infections (<3 months), medications affecting haematology (e.g., steroids, immunosuppressants), and add a BMI cutoff for obesity (e.g., >30 kg/m²). • Refine Statistical Analysis - Specify tests explicitly (e.g., independent t-test/Mann-Whitney for comparisons, Spearman/Pearson for correlations, multivariate regression for confounders like age/sex); add subgroup analysis and ROC for biomarker cutoffs; correct "p-

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			value<0.05" to include multiplicity adjustment. • What type of Bias is expected and measures to minimise it.
12	Dr. Sunanda Sethi	Evaluatiion of Oral Morphine Prescription Practices in Cancer pain patients at pain and palliative Care Out Patient Department of a Tertiary Care Centre in North India.	• PI should be faculty. • Proposal should be in AIIMS Bathinda format. • SR can be CO-PI.

Minutes of Meeting held on 06/11/2025 regarding the evaluation of Faculty projects

Not Present

Dean Research

Not Present

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

Prof. (Dr) Gurvinder Pal
Singh

Dr. M Altaf Mir
(Alt. Member Secretary)

Prof. (Dr.) Ajay Kumar

Prof. (Dr) Rakesh kakkar

Dr. Sivanantham
Krishnamoorthi

Dr. Shailendra Singh Rana