



**INSTITUTE RESEARCH COMMITTEE  
ALL INDIA INSTITUTE MEDICAL SCIENCES, PATNA.**

Ref No. AIIMS/Pat/IRC/2020/PGTh/Jan21/22

Date: 29-12-2021.

**Research Cell Approval Letter**

To,

**Dr. Rahul Arya**

Senior Resident (Academic)

Department of Gastroenterology

Dear Resident (PG),

The Institute Research Committee, All India Institute of Medical Sciences, Patna reviewed & discussed your study titled as **"Prevalence and risk factors of Lymphatic dysfunctions in cirrhosis patients with refractory ascites."** to be conducted under the Guidance of **Dr. Ramesh Kumar** and the proposal stands approved. This Approval letter is valid only after obtaining approval from Institutional Ethics Committee.

The following members of Research Committee were present in the meeting to review the synopsis.

Sl. No.	Name and address of the IRC members	Designation
1.	<b>Dr. Prem Kumar</b> , Dean (Research), AIIMS Patna.	<b>Vice Chairman</b>
2.	<b>Dr. Punam Prasad Bhadani</b> , Professor, Department of Pathology.	Member
3.	<b>Dr. Rajeev Nayan Priyadarshi</b> , Additional Professor, Department of Radio Diagnosis.	Member
4.	<b>Dr. Amit Patil</b> , Additional Professor, Department of FMT.	Member
5.	<b>Dr. Pragya Kumar</b> , Additional Professor, Department of C&FM.	Member
6.	<b>Dr. Prashant Kumar Singh</b> , Additional Professor, Department of General Surgery.	Member
7.	<b>Dr. Pankaj Kumar</b> , Additional Professor, Department of Psychiatry.	Member
8.	<b>Dr. Bhaskar Thakuria</b> , Additional Professor, Department of Microbiology.	Member
9.	<b>Dr. Ramesh Kumar</b> , Associate Professor, Department of Gastroenterology.	Member
10.	<b>Dr. Alok Ranjan</b> , Assistant Professor, Department of C&FM, AIIMS Patna.	Member
11.	<b>Dr. Pramod Kumar Manjhi</b> , Assistant Professor, Department of Pharmacology, AIIMS Patna.	Member
12.	<b>Dr. Sanjay Pandey</b> , Additional Professor, Department of C&FM, AIIMS Patna.	<b>Member Secretary</b>

**The Institute Research Committee approves the study to be conducted in its presented form.**

Principal Investigator is responsible for fulfilling the following requirements:

- The investigator must obtain necessary regulatory approvals e.g. from DCGI and the IEC before starting the study.
- All Co-investigator must be kept informed of the status of the project.
- Any, amendment(s) to the protocol or the consent form(s), must be informed and submitted to the Research Cell for review and approval prior to the activation of the same.
- Serious Adverse Events (SAE), if any, should be reported to the Research Cell immediately (within 24 hours). New information that becomes available which could change the risk-benefit ratio must be submitted promptly for review.
- Records of documents related to signed consent (by subjects/witnesses) should be maintained properly for the audit by Research Cell.
- Approved study needs to be reviewed by Research Cell, AIIMS Patna periodically at least once in a year as appropriate.
- After completion of the permitted tenure of the study, submission of the study report to the Research Cell, AIIMS Patna is mandatory.
- A continuing review application must be submitted to the Research Cell in order to continue the study beyond the approved period. Failure to submit the same will result in the termination of the study.
- The investigator must make adequate arrangements for compensation of the subjects either through the sponsor or insurance. If the trial is investigator initiated, then the investigator should make arrangement for providing compensation. As of today, no mechanism exists to pay compensation by AIIMS if the trial is not sponsored by a company/industry. It is proposed that the trials, which are funded by any government agency e.g. ICMR/DST/DBT, should either be insured or contribute a significant amount of funds for this purpose. The problem will arise if the trial is not funded by any organization. In that case, the Institute will not be hard pressed to pay any compensation.
- The investigators must start audio-visual recording of the consent from the participants. The recordings must be preserved and confidentiality of the subject must be maintained.

With Best Regards,



**Member Secretary**  
Institute Research Committee,  
AIIMS, Patna.