# Clinical Research Submission

## 1. Administration

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|---|---|
| **Name:** | shanmuka sagar |
| **Department:** | Clinical Research |
| **Submission Date:** | 30/6/2025 |
| **Review Type:** | Full Committee Review |
| **Study Title:** | medical research |
| **Short Title:** | MR |
| **Protocol:** | 1254ABC |
| **Version:** | 8798879 |
| **Date:** | 2025-06-24 |

## 2. Investigators

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|---|---|
| **Type:** | principal |
| **Name:** | shanmuka sagar |
| **Designation:** | Co-Investigator |
| **Qualification:** | MD, PhD |
| **Department:** | Clinical Research |
| **Email:** | shanmukasagar2019@gmail.com |
| **Contact:** | 9876543210 |

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| **Type:** | hod |
| **Name:** | Shanmuka Sagar Tullimilli |
| **Designation:** | software developer |
| **Qualification:** | B.Tech |
| **Department:** | computer science |
| **Email:** | shanmukasagar2019@gmail.com |

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| **Contact:** | 9876543210 |

## 3. Investigators Count

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| **PI Count:** | 12 |
| **Co-PI Count:** | 21 |
| **Duration:** | 20 |

## 4. Funding Details

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| **Estimated Budget:** | 50000 |
| **Funding Source:** | Self-funding |
| **Other Details:** | |

## 5. Overview Research

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| **Summary:** | fhskfhkf k |
| **Study Type:** | Academic clinical trials |
| **Other Type:** | |

## 6. Methodology

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| **Sample Size:** | 250 |
| **Participants per Site:** | 12 |
| **Lab Outsourcing:** | No |
| **Lab Details:** | |

## 7. Participants

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| **Type:** | Patient |
| **Vulnerable Groups:** | |
| **Other Participant:** | |
| **Reimbursement:** | No |
| **Details:** | |
| **Additional Safeguards:** | |
| **Justification:** | |

## 8. Benefits

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| **Any Risk:** | No |
| **Risk Details:** | |
| **Risk Strategy:** | |
| **Participant Benefits:** | Indirect |
| **Social Benefits:** | Direct |
| **Scientific Benefits:** | Indirect |

## 9. Consent

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| **Waiver Consent:** | No |
| **Translated Languages:** | |
| **Other Reason:** | |

## 10. Payment

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| **Injury Treatment:** | NA |
| **SAE Compensation:** | No |

## 11. Storage

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| **Docs Control:** | No |
| **Drugs Control:** | No |

## 12. Additional Info

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| **Any Additional:** | No |
| **Details:** | |

## 13. Declaration

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| **PI Name:** | shanmuka sagar |
| **Guide Name:** | |
| **HOD Name:** | |

## 14. Checklist

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| **Cover letter** | View File |
| **Brief CV of all Investigators- Updated, signed and dated** | View File |
| **Good Clinical Practice (GCP) training of investigators in last 3 years** | View File |
| **EC clearance of other centers** | File: null |
| **Agreement between collaborating partners** | File: null |
| **MTA between collaborating partners** | File: null |
| **Insurance policy / certificate** | View File |
| **Copy of CTA signed with the sponsor** | View File |
| **Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs / Regulatory authorities** | File: null |

| | |
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| **for proposed study (whether in same location or elsewhere) and modification(s) to protocol** | |
| **Copy of the detailed protocol (clearly identified numbered and dated) and synopsis (summary as far as possible in non-technical language, flowchart, diagrammatic representation of the protocol)** | View File |
| **Investigators Brochure (If applicable for drug / biologicals / device trials)** | View File |
| **Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated) with version number and dated** | View File |
| **Assent form for minors (12-18 years) (English and Translated)** | File: null |
| **Proforma / Questionnaire / Case Report Forms (CRF) / Interview guides / Guides for Focused Group Discussions (FGDs) (English and translated)** | View File |
| **Advertisement / material to recruit participants (fliers, posters, etc.)** | File: null |
| **DCGI Approval letter** | View File |
| **Others specify** | File: null |