



**Spoorthi Ayurveda Medical College and
Dr S.V.Savadi Ayurvedic Medical college Gangavathi**

ISO 9001:2015 Recognized Institution

(Recognized By Govt. of Karnataka & N.C.I.S.M. New Delhi)

(Affiliated to Rajiv Gandhi University of Health Sciences, Bangalore)

Date: 16-09-2026

CLINICAL TRIAL UNIT

To,

✓ I & II Professional BAMS Students

Spoorthi Ayurveda Medical College &

Dr. S. V. Savadi Ayurveda Hospital

Gangavathi – 583227

Subject: Provisional Registration of Students Selected under YUKTI Research Grant 1.0 – 2026 Reg.

Dear Students,

This is to inform all concerned students and faculty members that the following students have been **provisionally selected/registered under the YUKTI Research Grant 1.0 – 2026** for undertaking their respective research projects under the guidance and supervision of the designated faculty guides.

The provisional registration is subject to fulfilment of the prescribed **YUKTI Research Grant requirements, institutional research procedures, scientific and ethical requirements, approval of the research protocol, and submission of all necessary documents within the stipulated period.**

Sl. No.	Title of Research Project	Guide(s)	Student Name	Status
1	A Comparative Phytochemical Analysis of Lakshmana (<i>Ipomoea sepiaria</i>) and Its Pratinidhi Dravya Mayurasikha (<i>Adiantum caudatum</i>)	Dr. Spoorthi C. Mathad	Kavana H. S.	Provisionally Registered
2	Effect of Bhramari Pranayama on Sleep Quality and Perceived Stress Among College Students: A Randomized Controlled Study	Dr. B. M. S. V. Maheshwari	Tejaswini Sudhir Kendre	Provisionally Registered
3	In Vitro Comparative Evaluation of ADME-Related Parameters of Trayodashanga Guggulu with Rasnasaptaka Kashaya Using UV-Vis Spectrophotometry	Dr. Vinod Kumar L. H.	Madhukar L.	Provisionally Registered



4	A Clinical study to evaluate the efficacy of badhakonasana & setubandhansana in primary Dysmenorrhea	Dr. Saraswati	Trupti M. A. Salunke	Provisionally Registered
5	Comparative Pharmaceutical and Phytochemical Evaluation of Different Kashaya of Mandukaparni with Special Reference to Medhya Rasayana	Dr. Vinod Kumar L. H. & Dr. Spoorthi C. Mathad	Swagat Galande	Provisionally Registered
6	A clinical study to evaluate the efficacy of Dushivishari Agada and Dushivishari Agada Lepa in mukhadoshita	Dr. Saraswati	Gargi Ganesh Jangam	Provisionally Registered
7	A Cross-Sectional Study on the Association Between Pre-Bed time Screen Exposure and Sleep Quality Among Young Adults	Dr. Ajay Kumar A.	Spoorti	Provisionally Registered
8	A Comparative Clinical Study to Evaluate the Efficacy of Krishnadi Churna with Madhu and Ghrita as Anupana in Tamaka Svasa W.S.R. to Bronchial Asthma	Dr. Vinod Kumar L. H.	Manavi K. Linga	Provisionally Registered
9	A Randomized Comparative Clinical Study to Evaluate the Effect of Dhanvantara Taila Janu Basti With & Without Eranda Patra Upanaha in Janu Sandhigata Vata (Osteoarthritis of the Knee)	Dr. Vinod Kumar L. H. & Dr. Manoj Kumar Patil	Ms. Swati G. Khatanvi	Provisionally Registered
10	A Comparative Clinical Study to Evaluate the Efficacy of Modified Dosage Form of Sitopaladi Churna into Capsule in Kasa	Dr. Saraswati	G. Niharika	Provisionally Registered
11	Comprehensive Chemical, Phytochemical & Physicochemical Characterization of Dhatura and In-Vitro Evaluation of Its Interaction with Tandulodaka	Dr. Saraswati	Anjali	Provisionally Registered
12	An Open-Label, Double-Arm, Randomized Control Trial To Evaluate The Efficacy Of Gandhaka Rasayana And Gairikadi Lepa In Comparison With Acyclovir And Calamine Lotion In The Management Of Pittaja Visarpa (Herpes Zoster)"	Dr Karhik N	Harshitha	Provisionally Registered
13	A Cross Sectional Study Assessment of Water Geochemistry And Dietary Risk Factors Associated With	Dr Khalid B.M	Varsha	Provisionally Registered



	Prevalence In Shwira Kustha(Vitiligo) In Gangavathi Taluk Koppal			
14	A Comparative Pharmaceutical and Analytical Study of <i>Nava Ghrita</i> and <i>Purana Ghrita</i>	Dr Shwetha	Shaziya	Provisionally Registered

Clarification

1	A Cross-Sectional Study on the Association of Satva Sara Lakshana with Screen Time and Sleep Quality Among Professional College Students	Dr. Vinod Kumar L. H.	Geetika Prashant Sutar	Provisionally not registered
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Instructions to the Selected Students

1. **All provisionally registered students shall contact their respective Research Guides** immediately and proceed with the research work only after obtaining the necessary institutional approvals.
2. Students shall prepare and submit the final research protocol, Participant Information Sheet/Informed Consent Form, Case Record Form (CRF)/data collection forms, questionnaires, laboratory formats and other required documents to the Clinical Trial Unit (CTU), wherever applicable.
3. Any research involving human participants shall commence only after obtaining Institutional Ethics Committee (IEC) approval and all other applicable institutional/regulatory permissions. No participant shall be recruited before completion of the required approvals.
4. CTRI registration is compulsory as an institutional requirement for all the above YUKTI research projects. Each student, under the supervision of the respective Research Guide and Clinical Trial Unit (CTU), shall complete the Clinical Trials Registry-India (CTRI) registration process before commencement of participant recruitment/data collection, as applicable to the study design. A project shall not be permitted to commence participant enrolment until the required CTRI registration process has been completed.
5. A copy of the CTRI registration acknowledgement/registration details and CTRI number, upon registration, shall be submitted to the Clinical Trial Unit (CTU) and maintained in the respective Research Project File.
6. Students shall maintain complete and accurate research records, laboratory records, source documents, case/data sheets, consent documents, investigation reports and supporting documents throughout the project.
7. Any modification to an approved research protocol shall be undertaken only after obtaining approval from the competent institutional committee/authority and IEC, wherever required. Corresponding CTRI information shall also be updated wherever applicable.



8. Students and Guides shall strictly comply with the YUKTI Research Grant guidelines, Clinical Trial Unit (CTU) guidelines, Institutional Ethics Committee requirements, CTRI requirements and institutional research procedures.
9. Provisional registration shall not by itself constitute final approval of the research project or guarantee release/sanction of the research grant. Final approval and grant-related decisions shall remain subject to fulfilment of applicable requirements and the decision of the competent authority.
10. The concerned Research Guides shall closely supervise the projects, periodically review their progress, verify research documentation and ensure timely submission of all required reports and documents.
11. Students shall maintain the highest standards of scientific integrity, research ethics, participant confidentiality, data accuracy and academic discipline. Fabrication, falsification, plagiarism, manipulation of research data or any other research misconduct shall not be permitted.

All the provisionally registered students are hereby instructed to treat this research opportunity with **utmost responsibility and academic seriousness** and work in close coordination with their respective Research Guides and the **Clinical Trial Unit (CTU)** for successful and timely completion of their research projects.

The Institution congratulates all the selected students and their Research Guides and wishes them success in their research endeavours.


Principal

PRINCIPAL

**Spoorthi Ayurvedic Medical College &
Dr.S.V.Savadi Ayurvedic Hospital,
Vidyanagar, GANGAVATHI-583 227.**

Copy to:

1. Dean office
2. IQAC
3. Chairman 3RD Criteria NAAC,
4. Clinical Trail Unit
5. Notice Board
6. Office File

Principal

PRINCIPAL

**Spoorthi Ayurvedic Medical College &
Dr.S.V.Savadi Ayurvedic Hospital,
Vidyanagar, GANGAVATHI-583 227.**



ATREYA AYURVEDA PRATISHTHANA®

SPOORTHY AYURVEDA MEDICAL COLLEGE & DR. S. V. SAVADI AYURVEDA HOSPITAL

Gangavathi - 583227, Karnataka

CLINICAL TRIAL UNIT (CTU)

GUIDELINES & STANDARD OPERATING FRAMEWORK



ETHICS

Rights, dignity & safety



RESEARCH

Scientific methodology



CLINICAL CARE

Participant-centred



DATA

Integrity & traceability

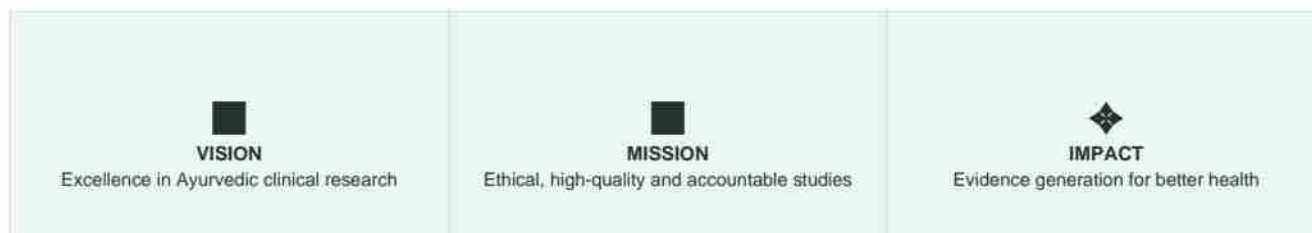
Traditional Wisdom • Scientific Validation • Better Patient Care

Institutional framework for faculty research, YUKTI/undergraduate projects, clinical trials, observational studies, Ayurveda interventions, Panchakarma, Yoga/lifestyle research and collaborative studies.

1. PURPOSE • VISION • MISSION • SCOPE

Purpose

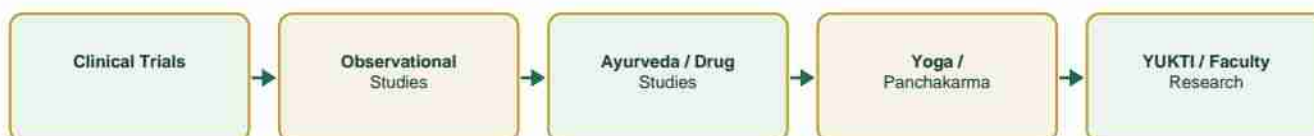
The Clinical Trial Unit provides an organized institutional system for planning, coordinating, documenting, monitoring and supporting human-participant research. It promotes scientific validity, ethical conduct, participant safety, data integrity and responsible reporting.



Core Objectives

- Promote well-designed Ayurveda and integrative-health research.
- Support investigators in protocol development, methodology, biostatistics and documentation.
- Facilitate scientific review, IEC processes and CTRI registration where applicable.
- Standardize recruitment, consent, intervention, assessment, follow-up and safety reporting.
- Promote quality assurance, research integrity, transparent publication and archival.

Scope



2. GOVERNANCE & RESEARCH APPROVAL PATHWAY

Governance Structure



The CTU may include representatives from clinical departments, Samhita & Siddhanta, Dravyaguna, Rasashastra & Bhaishajya Kalpana, Roga Nidana, laboratory, pharmacy, nursing, data/IT, administration and a biostatistician. Subject experts may be invited when required.

INDEPENDENT ETHICS OVERSIGHT

The Institutional Ethics Committee (IEC) retains independent ethical review and oversight. CTU operational support does not replace IEC approval.

Mandatory Research Pathway



Key rule: No participant shall be recruited until all approvals and registrations required for that particular study have been completed.

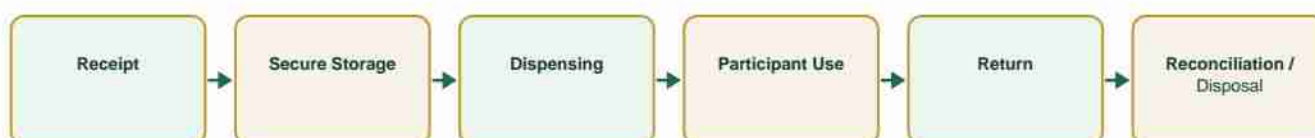
3. PROTOCOL REQUIREMENTS & AYURVEDA-SPECIFIC STANDARDS

SCIENTIFIC DESIGN	CLINICAL METHODS	ETHICS & REPORTING
• Protocol title / ID / version • Background & rationale • Research question / aim • Objectives / hypothesis • Study design & setting • Duration & sample size • Sample-size justification • Eligibility criteria	• Recruitment procedure • Randomization / blinding • Intervention & comparator • Dose / route / duration • Outcome measures • Assessment / follow-up • Safety assessment • Statistical analysis plan	• Ethical considerations • Informed consent • Confidentiality • Compensation where applicable • Publication plan • References • Annexures • Protocol amendments

Ayurveda-Specific Documentation

- Record relevant Ayurvedic diagnostic variables such as Dosha, Dushya, Agni, Ama/Nirama, Prakriti, Sara, Satmya, Satva, Ahara, Vihara, Desha, Kala, Bala, Rogabala, Rogibala and classical Lakshana where applicable.
- For formulations, record classical reference, ingredients, botanical identity/part used where relevant, manufacturer/source, batch, manufacturing/expiry details, dose, Anupana, route, Kala, duration, storage and available quality-control information.
- Use standardized, reproducible outcome measures and clearly define Ayurveda as well as modern clinical parameters.

Investigational Product Accountability



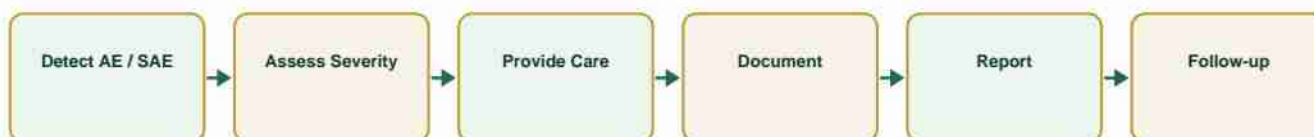
4. INFORMED CONSENT • PARTICIPANT SAFETY • RECRUITMENT



Informed Consent Essentials

- Explain purpose, procedures, duration, foreseeable benefits and risks, alternatives where relevant, confidentiality, voluntary participation, right to withdraw, study contacts and applicable injury/compensation provisions.
- Obtain written informed consent before study-specific procedures unless an IEC-approved alternative applies.
- Provide consent information in language(s) understandable to the participant, including Kannada where appropriate.
- Consent is an ongoing process; allow adequate opportunity for questions and voluntary decision-making.

Participant Safety Pathway



Participant safety always takes priority over completion of the research project.

Recruitment Standards

- Recruit only according to IEC-approved eligibility criteria and protocol.
- No coercion, misleading claims, concealment of material risks or therapeutic guarantees.
- Use approved recruitment materials where required.

5. CTRI • SOURCE DOCUMENTS • DATA INTEGRITY

Clinical Trial Registration

Applicable clinical studies should be prospectively registered with the Clinical Trials Registry-India (CTRI) before enrolment of the first participant. Trial information, IEC details and recruitment status must be accurate and updated as applicable. A submitted CTRI application/reference number alone is not treated as completed registration.



Source Documentation

Maintain appropriate original clinical records such as OPD/IPD case sheets, examination records, investigation/laboratory reports, prescriptions, procedure records, participant diaries and follow-up sheets. CRF entries should be traceable to source records wherever applicable.

ALCOA+ Data Integrity

A ATTRIBUTABLE Who recorded it?	L LEGIBLE Readable and permanent	C CONTEMPORANEOUS Recorded at the time	O ORIGINAL Original / verified source	A ACCURATE Correct and verified
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PLUS: Complete • Consistent • Enduring • Available

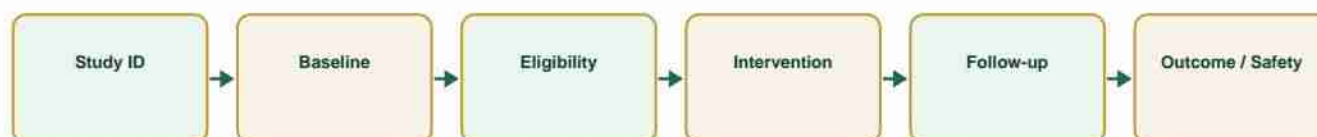
Confidentiality

- Use unique study IDs where appropriate and securely separate identifiers from analysis data.
- Use coded/de-identified datasets where practicable.
- Restrict access to authorized persons; do not share research data through unauthorized channels.

6. ESSENTIAL REGISTERS • CRF • STUDY MASTER FILE

✓ CTU Research Project Master Register	✓ Protocol Submission Register
✓ IEC Approval Register	✓ CTRI Registration Register
✓ Investigator Register	✓ Screening Register
✓ Participant Enrolment Register	✓ Participant Identification Log
✓ Informed Consent Log	✓ Randomization Register
✓ Intervention Allocation Register	✓ Investigational Product Accountability Register
✓ Laboratory Sample Register	✓ Follow-up Register
✓ Protocol Deviation//violation Register	✓ Adverse Event Register
✓ Serious Adverse Event Register	✓ Withdrawal/Dropout Register
✓ Monitoring Visit Register	✓ Research Document Archive Register

Case Report Form (CRF)



Study Master File / Trial Master File

Maintain the approved protocol and amendments, investigator documents, IEC correspondence, CTRI records, participant information/consent forms, CRFs, study tools, randomization records, investigational-product records, laboratory documents, AE/SAE reports, deviation reports, monitoring records, analysis documents, final report, publications and closure documents.

7. INVESTIGATOR RESPONSIBILITIES & YUKTI RESEARCH

 PRINCIPAL INVESTIGATOR Scientific conduct, safety, delegation, reporting	 RESEARCH GUIDE Active supervision and verification	 STUDENT INVESTIGATOR Protocol compliance and accurate records
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Principal Investigator

- Responsible for scientific conduct, protocol compliance and participant protection.
- Ensure appropriate delegation, supervision, documentation, safety reporting, data integrity and final reporting.

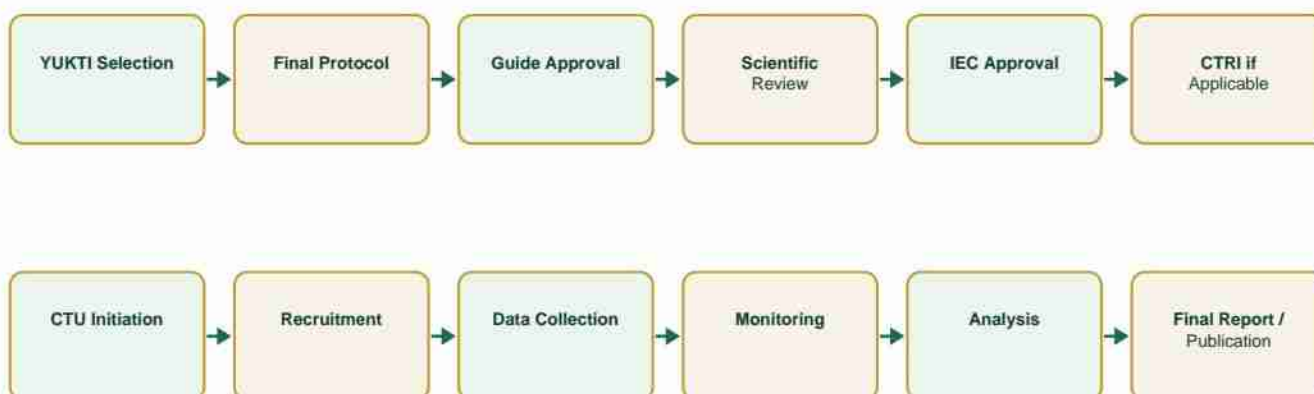
Research Guide

- Guide protocol development, scientific validity, feasibility, submissions, consent, recruitment, safety review, analysis and reporting.
- Student investigators shall not conduct unsupervised clinical experimentation.

Student Investigator

- Complete required training; understand and follow the approved protocol.
- Maintain accurate records and confidentiality; report adverse events promptly; do not make unauthorized protocol changes.

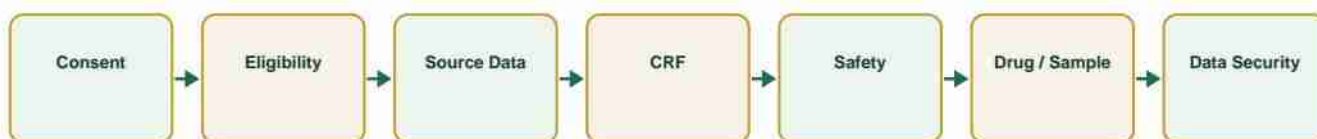
YUKTI / Undergraduate Clinical Research Pathway



Provisional YUKTI selection or grant registration alone does not constitute permission to recruit human participants.

8. QUALITY ASSURANCE • RESEARCH INTEGRITY • SOP SYSTEM

CTU Monitoring



Research Misconduct - Zero Tolerance

- Fabrication or falsification of data; forged signatures; fabricated or back-dated consent.
- Plagiarism, manipulation of results, false registration information or deliberate suppression of adverse events.
- Enrolment before required approval/registration, unauthorized alteration of records or misrepresentation of authorship/contribution.

Core Standard Operating Procedures

SOP-01 Protocol Submission & Review	SOP-02 Ethics Committee Submission
SOP-03 CTRI Registration	SOP-04 Site Initiation
SOP-05 Screening & Recruitment	SOP-06 Informed Consent
SOP-07 Randomization & Allocation	SOP-08 Investigational Product Management
SOP-09 Clinical Assessment & CRF Completion	SOP-10 Laboratory Sample Handling
SOP-11 AE/SAE Management	SOP-12 Protocol Deviations
SOP-13 Data Entry & Data Management	SOP-14 Monitoring & Quality Assurance
SOP-15 Confidentiality & Data Protection	SOP-16 Study Closure
SOP-17 Record Retention & Archiving	SOP-18 Publication & Dissemination
SOP-19 Research Misconduct Management	SOP-20 YUKTI / UG Clinical Research

9. TRAINING • PUBLICATION • STUDY CLOSURE • APPROVAL



Training

Investigators, guides, students and CTU personnel should receive periodic training in research methodology, ethics, Good Clinical Practice, informed consent, CTRI processes, Ayurveda research methodology, AE/SAE reporting, data management, biostatistics, research integrity and scientific writing. Training records shall be maintained.

Publication & Authorship

- Report findings responsibly whether positive, negative or inconclusive.
- Authorship shall reflect genuine scholarly contribution.
- Acknowledge the institution and funding source appropriately.
- Mention ethics approval and trial registration details where applicable.
- Protect participant confidentiality in presentations and publications.

Study Closure



CTU QUALITY POLICY

**NO PARTICIPANT WITHOUT APPROVAL • NO TRIAL WITHOUT DOCUMENTATION
NO DATA WITHOUT VERIFICATION • NO COMPROMISE ON PARTICIPANT SAFETY**

Prepared by: Clinical Trial Unit / Research Cell Signature: _____ Date: _____

Reviewed by: Dean / Research Coordinator Signature: _____ Date: _____

Approved by:

Dr. B. S. Savadi

Principal

Spoorthi Ayurveda Medical College & Dr. S. V. Savadi Ayurveda Hospital

Gangavathi - 583227

Institutional Seal: _____

This institutional framework should be read together with the latest applicable ethical, regulatory, CTRI, sponsor/funder and institutional requirements. Where a specific legal or regulatory requirement applies, that requirement prevails.