



ATREYA AYURVEDA PRATISHTHANA®

SPOORTHI 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

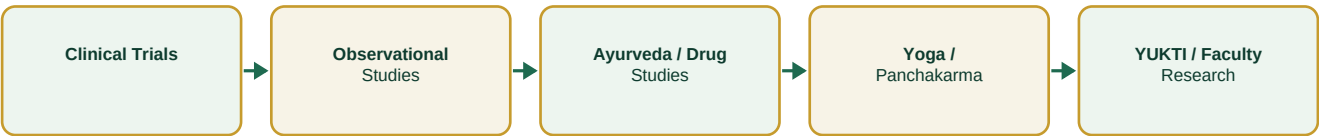
The Clinical Trial Unit provides an organized institutional system for planning, coordinating, documenting, monitoring and supporting human-participant research. It promotes scientific validity, ethical conduct, participant safety, data integrity and responsible reporting.

 VISION Excellence in Ayurvedic clinical research	 MISSION Ethical, high-quality and accountable studies	 IMPACT Evidence generation for better health
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Core Objectives

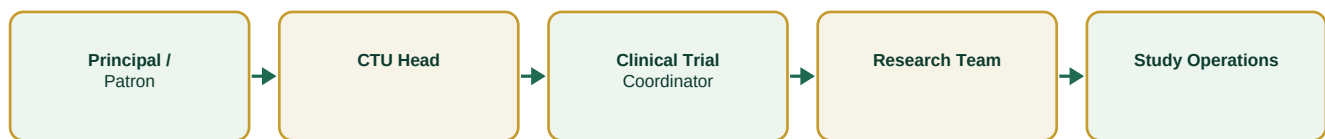
- Promote well-designed Ayurveda and integrative-health research.
- Support investigators in protocol development, methodology, biostatistics and documentation.
- Facilitate scientific review, IEC processes and CTRI registration where applicable.
- Standardize recruitment, consent, intervention, assessment,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

Scope



2. GOVERNANCE & RESEARCH APPROVAL PATHWAY

Governance Structure

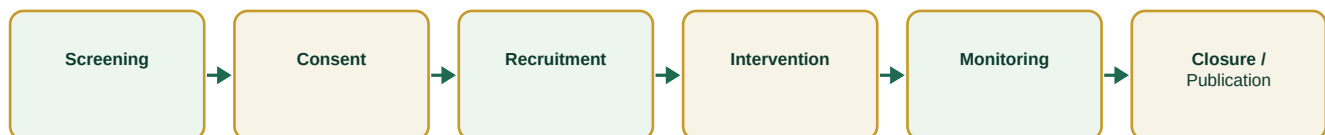


The CTU may include representatives from clinical departments, Samhita & Siddhanta, Dravyaguna, Rasashastra & Bhaishajya Kalpana, Roga Nidana, laboratory, pharmacy, nursing, data/IT, administration and a biostatistician. Subject experts may be invited when required.

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.

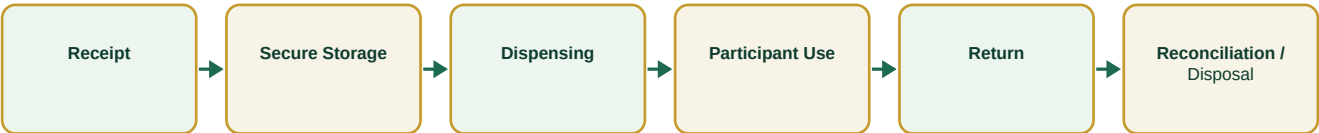
3. PROTOCOL REQUIREMENTS & AYURVEDA-SPECIFIC STANDARDS

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

 INFORM Clear, understandable study information	 CONSENT Voluntary documented consent	 RESPECT Right to refuse or withdraw	 CONFIDENTIALITY Protect participant information
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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.

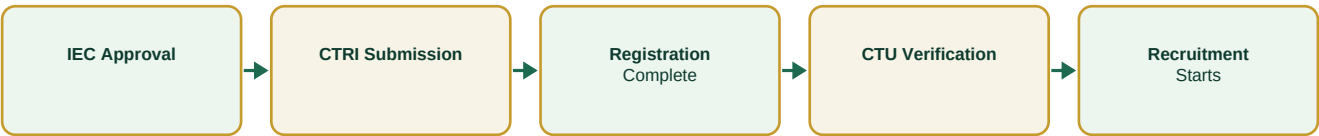
Recruitment Standards

- 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.

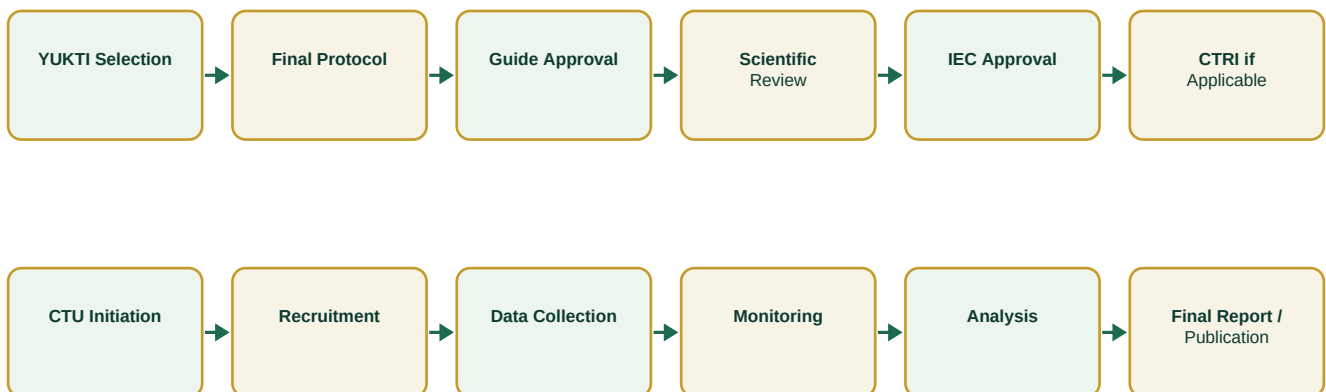
Research Guide

- 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



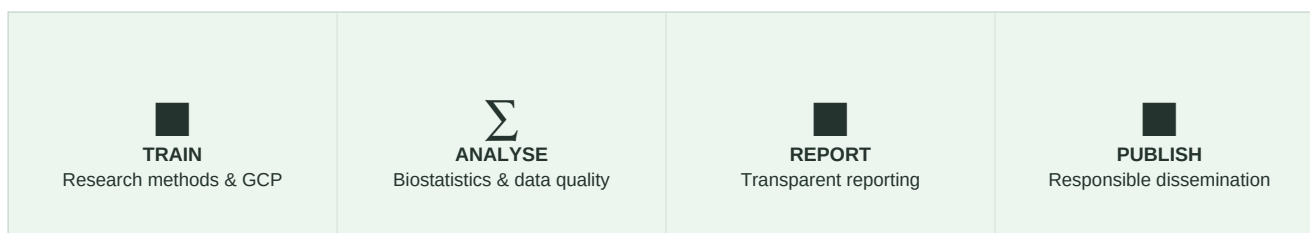
Research Misconduct - Zero Tolerance

- 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.