

CCRAS RESEARCH POLICY



CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES

Ministry of AYUSH, Government of India

New Delhi

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BACKGROUND

Ayurveda is a comprehensive scientific system of medicine developed through ancient wisdom, clinical experiences and experimentation. Evidences of clinical experiences for centuries exist in various classical texts and compendia of Ayurveda. However, one of the key challenges facing by the AYUSH systems including Ayurveda is generating scientific evidence on quality-based data, safety and efficacy of formulations/therapies and other interventions including basic principles.

The National Population Policy 2000 and National Health Policy 2002 of Ministry of Health and Family Welfare, Government of India, National Health Policy on AYUSH 2002 emphasizes on re-orientation & prioritization of research in AYUSH and to validate therapy and drugs in chronic and life style related diseases. Draft National Health Policy 2015 also emphasizes on R&D in AYUSH systems.

Being an apex organization for the formulation, co-ordination, development and promotion of research on scientific lines in Ayurveda and Sowa-rigpa systems of medicine, the Central Council for Research in Ayurvedic Sciences (CCRAS) is committed to promote research in important disease areas of national priority. Therefore, the Research Policy of CCRAS is aimed at encouraging its scientists for the formulation, submission and execution of research projects aimed at generating quality data for scientific validation of safety and efficacy of formulations/ therapies and other interventions including basic principles. The scientific staff from peripheral institutes applies in this scheme as per their area of interest, prevalence of disease conditions in their region, leads etc. or CCRAS Hqrs. allots different projects considering the national/international need and directives form Ministry of AYUSH. In domestic sector also, the Council requires to collaborate with nationally reputed non Ayurveda organizations like ICMR, CSIR, AIIMS, IIT, DST, DBT ICAR, PGIs, DRDO, and Ayurvedic institutes like IPGT&RA Jamnagar, NIA Jaipur, IMS BHU, AIIA New Delhi etc. especially in the areas where Ayurveda/Sowa-rigpa who have strengths but expertise and infrastructure of multiple organizations are required in the areas like cancer, HIV/AIDS, malaria, tuberculosis, genomics, biomedical instrumentation etc. Often some industries also approach the Council to conduct preclinical/clinical research on the leads obtained by them where the IPR benefits can be shared. Apart from this, Council has also developed some new combinations/proprietary drugs from the claims/consultation with experts and there is a potency to develop some more such drugs from suitable leads obtained through documentation of local health traditions/folklore claims/practices of traditional practitioners. In such cases, it may be necessary to conduct pre-clinical and/or clinical studies and before getting the drug patented/marketed, the collaborative mode of research is essential. As such, this research policy envisages all these aspects from technical, administrative and financial aspects in comprehensive manner.

Due to increasing global interest in Ayurveda, very often foreign countries have shown interest to collaborate in the field of research in Ayurveda and it has become imperative on the part of the Council to initiate/ execute/coordinate or monitor such activities. This Research Policy of CCRAS encompasses separate guidelines for IMR/ in-house research and collaborative research at national and international level.



Vision

To develop scientific evidence in Ayurvedic Principles, drug therapies by way of integrating ancient wisdom with modern technology and to bring Ayurveda to the people through innovations related diagnostics, preventive, promotive as well as treatment methods and also introduce scientific research for sustained availability of quality natural resources, to translate them into products and processes and in synergy with concerned organizations to introduce these innovations into public health systems.

Mission

1. To aim for AYUSHMAN Bharat by way of promoting better health through evidence based Ayurvedic principles and practices.
2. To develop CCRAS into a dynamic, vibrant, and model research organization for undertaking, coordinating, aiding and promoting research in Ayurveda.
3. To bring-up modern scientific knowledge, technology to explore Ayurveda scientific treasure following prevalent scientific methods.
4. To attain global leadership in research for treatment and prevention of emerging important life style related disease and health requirement.

Objectives of CCRAS

1. To undertake research on principles and practices of Ayurveda including diet, formulation, dosage forms, drug delivery system, panchakarma procedures, marma therapy, Shalya-Shalaky procedures etc.
2. To undertake epidemiological surveys for various purposes like Prakriti, Sarata other health indicators, dietary habits, changing disease patterns etc.
3. To develop scientific assessment tools and parameters suitable to Ayurveda.
4. To conduct research on natural resources for their sustained availability, quality etc.
5. Identifying newer natural resources for purpose of prevention and treatment of various diseases.
6. Clinical Research for safety and efficacy evaluation of Ayurvedic Pharmacopoeial formulations and other Drugs and Approaches in identified diseases/conditions
7. Medico Ethno Botanical Survey across the country
8. To Establish novel methods of analysis for standardization and quality control of single drugs and compound formulations
9. Experimental studies to establish safety profile of Ayurvedic drugs/ formulations
10. Tribal Health Care Research Programme including documentation of Local Health Traditions/ folk claims
11. Retrieval and revival of Ayurvedic texts from ancient manuscripts and publication of journals, monographs, books, technical reports, Information, Education and Communication material (IEC) etc.



To meet these objectives, following 3 (three) pre-requisites need to be addressed urgently:

- ❖ **Capacity building / Human Resource Development:** It is important for the investigators/co-investigators across all Peripheral Institutes of CCRAS so as to strengthen the quantitative and qualitative research method skills. Capacity building through trainings on personality development and reorientation on research is useful for development of knowledge, skills and attitude of Scientists.
- ❖ **Infrastructure:** Efficient and specific basic infrastructure such as modernization of laboratories, hospitals, up-gradation of existing facilities, equipments and instruments need to be proper for taking up the Research projects.
- ❖ **Linkages:** To achieve universally acceptable outcomes, networking among researchers, national and international research bodies, academia, industry, policy makers are essential.

To meet the objectives of quality research, CCRAS has adopted following schemes:

1. Intra Mural Research Scheme
2. Collaborative Research Scheme at National level
3. Collaborative Research Scheme at International level
4. Collaborative research in Ayurveda with industries

INTRA-MURAL RESEARCH

1 ELIGIBILITY

The regular scientific staff of CCRAS (Assistant Research Officer and above) are at liberty to develop the project keeping in view the following areas:

- a) National Priority Areas
- b) Mandate of the Institute
- c) Strength areas of Ayurveda
- d) Any other assignment by CCRAS / Ministry of AYUSH

The officer who submits the project must ensure that his/her institute has adequate infrastructure in that area of research and prevalence of the disease condition identified for research (in case of clinical research studies). In case of non-clinical research, it must be ensured that adequate infrastructure and manpower are available to conduct the study. It may be noted that no major equipments/instruments will be permissible under this project as the ceiling of the budget in project (for uni-centric or multi-centric) is Rupees one crore only. The Officer who has less than 2 years of service and who has not completed 2 years of service can be the Co-Investigator but not the Principal Investigator. The application for the proposed IMR project needs to be submitted as per the format mentioned in **Annexure-1 (Section A, B, C & D) through E-mail to ccras_tec@nic.in**). The application is available at the website of CCRAS (www.ccras.nic.in).



1.2 SELECTION OF PROJECT

Initially the preliminary screening work will be done by respective sections (Clinical, Botany/ Pharmacognosy/Chemistry/Pharmacology and Literary) of CCRAS Hqrs. and thereafter the same will be examined by one Internal Scrutiny Committee (ISC). The composition and terms of reference of ISC is placed at **Annexure-2**. Thereafter the projects recommended by ISC will be submitted to concerned subject expert (through E-mail to ccras_tec@nic.in) for comments/suggestions. The comments received from the experts will be suitably incorporated.

The projects recommended in ISC will be put before the Project Evaluation and Monitoring Committee (PEMC). The composition and terms of reference of PEMC is placed at **Annexure-3**. The PEMC will evaluate the projects based on presentations made by PI / Co-I. The PEMC has the discretion to accept, reject or modify the project or extend the project to any other identified institute as multi-centric trial with the officer who has submitted the project as one of the Investigators.

1.3 MODE OF PROJECT DEVELOPMENT/ALLOTMENT

The Intra Mural Research of CCRAS will be operative as per following modalities:

Modality-A: Intra-Mural Research project submitted by the scientists of the Institutes/Centers for conducting the study either as uni-centric or involving multiple Institutes/Centers of CCRAS.

Modality-B: Intra-Mural Research project which is centrally initiated from CCRAS Hqrs.

In case of Modality-A, the protocol of study will be submitted by the Principal Investigator. However, for both the modalities, the design/protocol of the study will be finalized at Hqrs. level in consultation with inter-disciplinary experts, Principal Investigators and Co-Investigators.

1.4 PRIORITY AREAS

1.4.1 Fundamental Research

- i. Development of parameters to assess/quantify *Panchmahabhoota, Tridosha, Agni, Dhatu, Ojas, Concept of Srotas, Ama* and *Guruvadi gunas* Parameters for assessment of various stages of *Shatkriyakala*/assessment of *Samprapti*/standard parameters for assessment of *Prakriti*/basic principles of Sowa-rigpa etc. related to therapeutic approach.
- ii. Redefining and developing parameters for assessment of *Rasa, Guna, Virya, Vipaka* and *Prabhava* of the drugs described in Ayurvedic texts and also of non-classical drugs (*Anukta*) usually prevalent in traditional practices with the help of modern technology. Validation of other principles related to collection of drugs season/time/habitat wise, acceleration/ declination of potency/shelf life etc. and also *Rasashastra* and *Bhaishajya Kalpana* related principles like different dosage forms, efficacy of fresh/old formulations, proportion/ ingredient wise / substitutes as well as shelf life study using ancient parameters.



- iii. R & D on Ayurvedic Diagnostics (Including *Prakriti* and *Nadi Pariksha*)
- iv. Development of methods/ modalities/ protocols for Clinical Research of Ayurveda
- v. R & D and standardization of *Panchakarma / Ksharasutra / Kriyakalpa / Agnikarma / bloodletting* and other therapeutic procedures along with technological inputs therein.

1.4.2 Literature research

Survey and Collection of Manuscripts and rare books, their transcription, translation and publication, revival and retrieval of Ancient Classics and Manuscripts, Medico-historical investigations of Ayurveda/ Sowa-rigpa in medical and non-medical literature. In the coming five years, efforts should be made to make available the books scheduled under Drug & Cosmetic Act in the market

1.4.3 Drug Research

- i. Ethno- medicine survey and documentation of medicinal plants/cultivation and collection practices etc including in-vitro propagation techniques and plant biotechnology.
- ii. Assessment of *Rasadipanchaka of Anukta Dravya* through experimental and pilot clinical studies.
- iii. Market surveys of source materials including substitutes, adulterants and alternative sources/species.
- iv. Pharmacognosy studies.
- v. Pharmacodynamics and Pharmacokinetics including reverse Pharmacology.
- vi. Biomarker based Mechanism of action related with Ayurvedic/ Sowa-rigpa drugs.
- vii. Safety, toxicity and drug interaction studies.
- viii. Standardization and Quality Assurance related to Ayurvedic/ Sowa-rigpa drugs.
- ix. Pharmaceutical Research and Development related with Ayurvedic/ Sowa-rigpa drugs.
- x. Veterinary Ayurveda products.
- xi. Development of experimental models, Dosage forms, Cell line studies, Shelf life, *Grahya lakshanas*, quality issues
- xii. Revalidation and critical analysis/enquiries as per the concepts of *Vriksha* Ayurveda.



1.4.4 Clinical research

- i. Validation studies on classical formulations / therapies (As existing in classics).
- ii. New indications of classical formulations (Formulation existing in classics, but indication is changed with some clinical experience).
- iii. Research on newer medicinal plants of Indian origin for various disease conditions. Clinical studies with new drug combination derived from Ayurvedic texts other than referral under D&C Act; from claims of physicians including traditional healing practices/folk claims or new dosage form from pre existing classical drugs/new drugs of Ayurveda- Sowa-rigpa / related areas / specific areas.
- iv. Research on Ayurvedic and Sowa Rigpa drug SOPs
- v. Epidemiological Research
- vi. Promotive and preventive health care / *Rasayana Chikitsa*
- vii. Any other areas found to be important from time to time, including endemics, epidemics etc.

1.4.5.1 Prioritized Disease Conditions/Areas

- i. Preventive Cardiology
 - Atherosclerosis
 - Hypertension
 - Dyslipidemia
- ii. Gastro intestinal disorders
 - Hepatic Disorders
 - Diarrheas and chronic Enteropathies
 - Irritable bowel syndrome
- iii. Musculo –skeletal disorders
 - Osteoporosis
 - Osteoarthritis
 - Rheumatoid Arthritis
- iv. Eye diseases
 - Diabetic Retinopathy
 - Computer Vision Syndrome
 - ARMD
 - Dry Eye
 - Allergic & Autoimmune eye disorders



- Glaucoma /Neuro-retinal degeneration
- v. Metabolic Syndrome
- vi. Obesity
- vii. Diabetes Mellitus and its complications e.g. neuropathy, nephropathy and ulcers.
- viii. Skin diseases.
- ix. Respiratory Diseases including Allergic Rhinosinusitis
- x. Generalized Anxiety Disorder, Cognitive Deficit, ADHD, Mental Retardation
- xi. Iron deficiency Anaemia
- xii. Vector borne diseases
- xiii. Diseases of Mutravaha srotas including Renal failure, Benign prostatic hyperplasia, Urolithiasis, Chronic Nephritis etc.
- xiv. Fevers of various etiologies (Condition with hyper pyrexia)
 - xv. Para – surgical procedures: *Kshara Sutra* for Fistula –in-ano, Haemorrhoids, Pilonidal sinus, *Agni karma*, *Kshara karma* and Blood-letting etc.
- xvi. Neurological, Neuro-muscular and Neuro- degenerative disorders
- xvii. Rasayana therapy & Geriatrics
- xviii. Reproductive & Child Health (RCH)
- xix. Quality of life (QOL) in Cancer/HIV – AIDS etc.
- xx. Ayurveda Dietetics.
- xxi. Pain dominating conditions and pain relievers (drugs/therapies).
- xxii. Other priority areas of national importance.
- xxiii. Keeping in view the health care burden and strength of Ayurveda the following disease areas will be taken on priority viz. Osteoarthritis, Metabolic syndrome, Chronic nephritis, Acid peptic disease, Allergic rhinitis & Hepatitis.

1.5 METHODOLOGY AND APPROACH

1.5.1 (i) Statutory, Ethical and Research guidelines:

- The research in any area mentioned may be undertaken in accordance with the existing regulatory guidelines and other guidelines in vogue. The clinical trials should follow the statutory, ethical and research guidelines prevalent in India.
- Pilot studies may be conducted in initial phase to establish the baseline data and to ascertain the feasibility of the protocol.
- In case of single centre studies the Principal Investigator needs to ensure the registration of the trial with the CTRI.



- The multicentric trials will be coordinated by nodal institute, identified by the council's Hqrs.
- It needs to be ensured that the clinical trial is registered with Clinical Trial Registry of India (CTRI) prospectively i.e. before the recruitment of the first patient in the trial. In case of multicentre studies, the Principal Investigator of the nodal / coordinating centre is responsible to register the trial with CTRI for the study.
- The headquarters will facilitate all the prerequisites and requisites before and during execution of the trial.
- As per the requirement of the CTRI format, the sponsor may be mentioned as CCRAS headquarters and the Principal Investigator may be the person responsible for answering the scientific/public queries.

1.5.1 (ii) Role of PI & Co-I

- The co-investigator should bear the responsibility to contribute in any manner as required by the PI. As per the need of the project, co-investigator may also be incorporated from outside the Council

1.5.2 Investigators of the Project

There will be one Principal Investigator and at least one Co-Investigator from the participating institute. There will be maximum three Co-Investigators per project per centre. A group of Investigators from Council's institutes (maximum three centers) can also submit the proposal together or any one of these centers can submit the proposal in consultation with each other. The nodal centre will be decided by the Hqrs. in such multicentric studies.

After the project is duly approved by the PEMC, the PI(s) of concerned institutes are required Hard copy of the approved project proposal including CRFs /formats should be obtained from concerned institutes.

1.5.3 The Budget

The budget should be proposed strictly on the basis of actual requirement. If manpower and instruments/ equipments are required, proper justification should be given in terms of their existing availability. Generally, staff, equipment etc. will be sanctioned on sharing basis for different projects and not exclusively for a single project. The equipment to be asked in a project should be relevant to that particular project. The furniture, laptop, data card and mobile phone etc. are not permissible in the project. Expenditure Head-wise bifurcation for budget should be given with justification as given in the application format.

1.5.4 Standardization, Safety/Toxicity of the Trial Drug

If it is a classical formulation for validation studies, analysis report as per Ayurvedic pharmacopoeial standards is to be procured from the manufacturer. In case, for any formulation if the Ayurvedic pharmacopoeial standards are not available, then in-



house standards may be developed in consultation with Botany and Chemistry Section at CCRAS Hqrs. The list of minimum standards required for various common medicines may be decided from time to time in consultation with Chemistry Section of Hqrs. This may be subject to change in accordance with national/international guidelines.

If it is a new drug combination or new dosage form or new route of administration, safety/toxicity studies should also be done preferably at GLP certified & NABL accredited laboratories. The quality analysis report of the trial drugs should be cross checked by Council's laboratory or any other GLP / Government certified laboratory.

1.5.5 Procurement of trial drug

The trial drugs may be manufactured at pharmacies of CCRAS institutes as per feasibility, but for bulk requirement, the same will be procured following codal formalities as per GFR from the listed pharmacies communicated by the Ministry of AYUSH and/or also other Government/Cooperative/Private pharmacies complying benchmarks as suggested by PEMC/Sub-Committee (**Annexure-4**). In all these cases the analysis certificate is mandatory to be provided by the supplier.

1.5.6 When to procure the drug

On receiving sanction order of particular project, the PI or Nodal Officer (in case of multi-centric study) through Head of the Institute should place the order for procurement of drugs according to classical reference, dosage, packing specification and total quantity required under intimation to the Council Hqrs.

In case the duration of the project is more than 2 years, PI will specify the batch size of the trial drug along with the date of supply in view of the shelf life of the trial drugs. However, all the batches should comply the quality standards.

Note: SOPs including identification and availability of ingredients will be ensured by PI while submitting the project proposal.

1.5.7 Laboratory Investigations

Under the modalities A & B the institutes and centres under CCRAS should have adequate facility for laboratory investigation to execute the research project(s) and in case such facilities are not available, the same may be reflected in the project proposal. Overall attempt should be made to develop the required facilities by upgrading the laboratories of the Institute or otherwise may be outsourced. In such cases, codal formalities must be observed by inviting quotations from NABL accredited laboratories (minimum 3) or in a normal competition in case 3 NABL accredited laboratories are not available.

In case of multi-centric studies, the PI of the nodal institute will take step for selection of a laboratory taking into consideration that the branches of such laboratories exist at the vicinity of all participating centres and selected laboratory will not further outsource any of the investigations. Methodology, chemicals/kits, equipments and/ or the reference value of the investigations should be uniform at all centres.



1.5.8 Duration of the Project

All the projects submitted under the IMR policy should be of minimum one year and maximum of 3 years duration. However, in exceptional cases, especially requiring long-term studies the maximum duration may be upto five years subject to recommendation of PEMC.

1.5.9 Change of the Principal Investigator

Principal Investigators are encouraged to have at least one Co-Investigator (Co-I) in the project from Institute/Center. So that, the Co-I can handle the responsibilities during leave/absence of the Principal Investigator. In case, change is needed among PI/Co-I due to transfer, retirement etc. the same should be done with the approval of CCRAS Hqrs.

1.5.10 Ethical Clearance:

Once the project is approved by the PEMC, it is the responsibility of the Principal Investigator and the concerned Head of the each institution to convene a meeting of the IEC (Institutional Ethics Committee) / IAEC (Institutional Animal Ethics Committee) (as applicable) to obtain the ethical clearance. The IEC/IAEC approval needs to be communicated to the Council headquarters before initiation of the project. Subsequently if any modification is needed in any component / modality of the project, the same will be duly informed to IEC / IAEC. If Ethical Committee suggests some modifications, these are to be discussed with DG CCRAS before incorporating.

1.5.11 FUNDING

- i. The project costing up to 100 Lakhs will be approved by PEMC. Approval of Standing Finance Committee (SFC) will be obtained for studies amounting more than 100 Lakhs.
- ii. The project cost will be met from the Hqrs. budget earmarked for research activities.
- iii. Funds will be provided to the in-charge of the participating Institutes/Centers and separate account will be maintained for each project. 60% of the total sanctioned amount or amount earmarked for first year (whichever is more) will be released as 1st installment at the time of sanction of the project. Next installment(s) will be released after receipt of interim progress report and UC/statement of expenditure of first installment. The statement of expenditure should correspond with head-wise bifurcation of budget mentioned in the sanction order. The head of the institute should also certify that the expenditure has been incurred for the purpose for which it was sanctioned. After completion of the project, the concerned PI should submit the audited UC and statement of expenditure along with final report of the project.
- iv. Change of budget head, if needed, should be done with the prior approval of the headquarters.



- v. All the expenditure should be made as per GFR, Government of India. The operation and utilization of accounts of the projects will be subject to internal audit.
- vi. Utmost attempt should be made to make payment of the liabilities of a particular financial year within 31st March and the proposal for re-validation of unspent balance as on 31st March should be submitted to Hqrs. within one month in prescribed format (**Annexure-5**). If fund is available, then the expenses for laboratory investigations/contingencies etc. upto 3rd / 4th week of March should be paid within 31st March.

1.6 PROJECT PERSONNEL/STAFF

1.6.1 Engagement of Project Personnel:

The Investigator may propose for engaging SRF / Consultant (for medical discipline) / JRF / SRF (for non-medical disciplines) / DEO etc. as per the need of the project with remuneration as adopted by CCRAS from time to time following the pattern of ICMR. The remuneration for each project staff will be uniform for particular category among all the institutes. The engagement of manpower will be made only after completion of 1.5.6, 1.5.7, 1.5.10. However, the selection procedure should be completed well in advance.

1.6.2 General terms and conditions for engaging temporary project manpower

- i. A Selection Committee will be constituted at the institute level consisting of 1. Head of the institute (Chairman) 2. Principal Investigator (Member) 3. Subject Expert from outside.
- ii. The appointment of all categories of project personnel would be made initially for twelve months and extended for another term of twelve months at a time and total duration will not exceed the project period i.e. three years. Extension of tenure of these temporary project personnel may be done at the Institute level based on the performance of the incumbent and recommendation of PI.
- iii. In the recommendation of Selection Committee, there will be panel of candidates, one selected and at least three on wait list (subject to availability). The panel will be valid for one year from the date of approval of the minutes of Selection Committee.
- iv. The personnel will have no claim for regular/permanent appointment under the Council. **Their engagement will be co-terminus with the project**, which should be clearly mentioned in appointment letter of the selected candidate under the project.
- v. The project personnel will be trained by PI before initiation of the trial as required.



1.6.3 SUBMISSION OF REPORTS

1.6.4 Progress Report

- The progress of the project in accordance with approved timeline and deliverable should be submitted to the nodal officer of Council Hqrs. on monthly basis in the prescribed format (**Annexure-6**).
- The Principal Investigator may be asked to present the progress before the IMR-PEMC, if the nodal officer recommends that the progress report submitted by PI is not satisfactory.

1.6.5 Final Project Completion Report

The final report should be sent in the prescribed format (**Annexure-7**). The report should be submitted within two months from the date of completion of the project.

1.7 DISPOSAL OF UNUSED TRIAL DRUG

- 1.7.1** In case of classical medicines, the remaining/unused trial drugs within expiry date may be consumed by general OPD/IPD patients. The expired medicines should be destroyed.
- 1.7.2** In case of coded/placebo controlled study; the remaining/unused trial drug should be destroyed following prevalent statutory provisions /GFR.
- 1.7.3** In all the cases, the destruction of medicines should be as per GFR of Government of India keeping all the relevant records.

1.8 MONITORING

1.8.1 Local Monitoring

The Head of the Institute/Center would ensure periodic review and monitoring of the projects ongoing under the IMR scheme at Institute/Center level and the same needs to be reflected in the periodic (monthly/quarterly/annually) report of the institute that is being communicated to the Council headquarters.

1.8.2 Central Monitoring

A monitoring team for every project would be set up at CCRAS Headquarters. The team will comprise of Programme officer, Nodal officer and/or any other officer including Biostatistician as deemed fit by the competent authority. They will monitor the activities online and may make field visit as and when required (**Annexure-8**).

1.8.3 Underperformance

If the Investigator does not perform satisfactorily, he/she needs to give justification for not performing up to the mark.

1.8.4 Outcome of the Project

The final outcome of the project will be evaluated through oral presentation by the P.I. / Co-P.I. before the PEMC (Project Evaluation and Monitoring Committee).



1.9 PRE-MATURE TERMINATION OF PROJECT

If Director General, CCRAS / PEMC feel that a project should be prematurely terminated due to technical/financial/ethical reasons then the same will be communicated to concerned PI, Co-I and Head of the institutes. In such case, the unspent balance will be refunded to the CCRAS Hqrs. If the premature termination is due to deliberate negligence/misconduct by any concerned officer(s), he/they may also be liable for disciplinary proceedings as per rules.

1.10 INTELLECTUAL PROPERTY RIGHTS AND PATENTS

The Council, will have the rights to take decision on IPR issue on case-to-case basis. The Council will make efforts to commercialize the product as and when applicable.

1.11 PUBLICATION

Where the research outcome is not patentable, the Principal Investigator must publish the findings of research in peer review journal / reputed journal with impact factor after completion of the trial. If the article is to be submitted to a journal other than CCRAS, prior approval of the manuscript by Hqrs. is mandatory. The draft article must be submitted to Hqrs office within 3 months of the acceptance of the final report. In case of multicentre studies, the PI of the Nodal Institute or the Nodal Officer at CCRAS Hqrs. is responsible to coordinate with all who participated or contributed in the study for planning of publication. In case of coded formulations, the CCRAS Hqrs. will regulate all patent and publication issues. In case of non-clinical projects, the issue of the publication will be decided by the headquarters on case to case basis. After publication, three copies of the reprints of the article are to be submitted to Hqrs.

2. COLLABORATIVE RESEARCH AT NATIONAL LEVEL

2.1 Proposed Areas of Research:

- i. Development of technology based on theory of Ayurveda such as R & D on Ayurvedic Diagnostics/Methods & Techniques (including *Prakriti* and *Nadi Pariksha*) and R & D on *Panchakarma*, *Kriyakalpa* & other therapeutic procedures, their Standardization. Soft ware development, development of disease coding for medical record maintenance; Ayurtechnology; Cancer- preventive, curative as well as supportive intervention / therapy; research on areas related to MCH and MDG (Millennium Development Goals), cardiac rehabilitation; *Vajikarana* in reproductive technologies etc.
- ii. **Pre-clinical Studies:** Pharmacognosy, standardization, isolation of markers, biological activity and safety-toxicity studies etc.
- iii. **Clinical Research:** Clinical studies with classical drugs and therapies, new drug combination and/or new dosage form or new indication from existing classical formulations/single drugs of Ayurveda/ Sowa-rigpa.



- iv. Development of methods/ modalities for Clinical Research/ Instrumentation in Ayurveda / Sowa-rigpa.
- v. Mode of action of Ayurveda/ Sowa-rigpa formulations (with classical parameters/modern parameters/both)
- vi. Epidemiological Research
- vii. Promotive and Preventive Health Care / *Rasayana Chikitsa*
- viii. Veterinary Ayurveda / *Vrikshaayurveda*
- ix. Dietetics and nutrition
- x. Cosmetics/skin care
- xi. Any other important areas of National importance.

2.2 Selection of Collaborating Institutes

2.2.1 There are certain areas in which infrastructure/facilities available at CCRAS peripheral institutes are not adequate. There is a need of support from other reputed institutes where such facilities along with expertise are available e.g. areas of cancer, HIV/AIDS, tuberculosis, malaria, leprosy etc. Further, there are some other areas like filariasis, bronchial asthma, metabolic syndrome, hypertension, diabetes mellitus including complication, rheumatoid arthritis etc. in which the association of other specialized institutes will boost the quality of research.

2.2.2 To identify such institutes, CCRAS will directly approach to nationally reputed academic / research organizations like ICMR, CSIR, ICAR, DST, DBT, AIIMS, IITs, PGIs, DRDO, IPGT&RA Jamnagar, NIA Jaipur, IMS BHU, AIIA New Delhi etc. and other Govt. as well as Non Govt. organizations, Universities, R& D labs etc. The institutes so selected will be specific to the project proposal and will be decided on case to case basis by a committee as approved by DG, CCRAS.

2.3 Modalities of Implementation

2.3.1 If the total budget of the proposal is below 100 Lakhs (i.e. Power of DG, CCRAS) the approving authority will be Director General and he will approve subject to recommendation of PEMC. If the budget is above 100 Lakhs, then the proposal will be placed before Standing Finance Committee (SFC) for approval. All such approved projects will be appraised to Scientific Advisory Board (SAB) from time to time.

2.3.2 In case, pharmaceutical industries approach CCRAS for collaborating in research for a particular disease/area, then this will be decided by DG-CCRAS subject to recommendations of Scientific Advisory Board (SAB). The proposal will be placed before Standing Finance Committee (SFC) for approval, if the budget is above 100 Lakhs.

2.3.3 For execution of research which requires involvement of individual researchers/traditional practitioners/claimants, CCRAS will decide the issue based on scientific strength of the proposed formulations/ appliances / therapies, feasibility of



manufacturing, marketing etc. If found suitable, DG CCRAS may get such proposals evaluated by expert group after which such proposal will be placed before SAB for recommendations. The budget part will be dealt with as per delegated powers of DG.

- 2.3.4** In all collaborative projects, the sharing of work component, engagement of manpower, financial liability and IPR issues including publication, marketing etc. will be clearly demarcated and decided before execution of the project. All the participating institutes should strictly adhere to timelines and deliverables as approved in the project.
- 2.3.5** In all such cases, the MoU has to be signed among collaborating institutes to maintain non-disclosure of data and commitment to own liabilities. Always the Head of collaborating organization should be approached along with individual researcher (if applicable) for smooth execution of project and for proper flow and utilization of fund.
- 2.3.6** In all collaborative projects, there will be joint monitoring; involving official/personnel from all the stakeholders as per need. For project above 50 lakhs there will be a committee with experts from relevant fields to evaluate the project. Routine monitoring report should be obtained by CCRAS Hqrs.
- 2.3.7** A provision of DSMB (Data and Safety Monitoring Board) will be there as per requirements of the project.
- 2.3.8** The ethical clearance of the research projects will be obtained by the institutes (IEC / IAEC) conducting the research work.

2.4 Funding

- 2.4.1** The budget along with sharing will be decided while finalizing the proposal. In case of project of more than one year duration, the 2nd/3rd installments will be released based on the progress made two months before completion of each year so that the continuity of the project is maintained.
- 2.4.2** The project costing up to 100 Lakhs will be approved by PEMC. Approval of Standing Finance Committee (SFC) will be obtained for projects amounting more than 100 Lakhs.
- 2.4.3** The project cost will be met from the Hqrs. budget earmarked for Research activities.
- 2.4.4** The fund released and spent will be subject to audit by sponsoring authority and Government audit system. Before release of subsequent installments, a technical progress report and statement of expenditure should be submitted by the executing institute/organization. On completion of the project, the executing institute/organization should submit the audited utilization certificate (UC) along with audited statement of expenditure to the funding authority.
- 2.4.5** For such funds, a separate account has to be maintained by the executing institute.



3. COLLABORATIVE RESEARCH AT INTERNATIONAL LEVEL

- 3.1 Any international collaboration will be taken up only after approval of Ministry of AYUSH as per the norms and procedures prevalent at the particular time.
- 3.2 Before undertaking any collaborative research with foreign academic/research organization, the *Memorandum of Understanding* should be signed through the Embassy/High Commission of the collaborating country with prior approval of Ministry of AYUSH.
- 3.3 The expenditure for collaborative research work in foreign country should be borne by that country; whereas the expenditure incurred in India should be borne by CCRAS / Ministry of AYUSH.
- 3.4 But the travel expenses of the scientists travelling to the collaborating country from India for implementation/monitoring of the project will be borne by CCRAS/Ministry of AYUSH whereas the travel expenses of the scientists of the collaborating country coming to India will be borne by the collaborating country. Local hospitality and transportation should be borne by the respective countries/organizations where visited.
- 3.5 Before any funding, the Research proposal should be approved in SFC of CCRAS or competent authority of Ministry of AYUSH.
- 3.6 However, for international collaborative research, technical inputs and research drug can be provided by CCRAS on recommendation of the Ministry of AYUSH. In case of material transfer the National Biodiversity Act and other prevalent rules should be taken into account.
- 3.7 With a view to propagate Ayurveda in other countries, if it is desired to fund other than equal sharing basis then each component of the project work along with funding pattern should be spelt out very clearly before approval of the project.
- 3.8 In all such collaboration with foreign organizations, one *MoU* should be signed alongwith *Non-Disclosure Agreement* to maintain confidentiality of the data.
- 3.9 The ownership of the assets purchased will be decided in the *MoU*.
- 3.10 The cost of the project will be inclusive of Institutional charges.
- 3.11 For all such projects, there should be a joint monitoring team involving experts from participating organization and CCRAS/Ministry of AYUSH who will periodically oversee the research work.
- 3.12 In these collaborative researches, all the IPR issues including publication will be jointly shared between organizations of involved countries on case-to-case basis.

4. BENCHMARKS FOR UNDERTAKING RESEARCH / RESEARCH CONSULTATION FOR ALREADY COMMERCIALIZED / MARKETED AYURVEDA PRODUCTS

Essential criteria

1. GMP certified Ayurvedic Pharmacies with Minimum 10 years experience in manufacturing and marketing of Ayurveda Products.



2. Minimum 10 years record of use/commercialization of the formulation.
3. Published research papers on safety and efficacy of the proposed formulation.
4. Physical verification for assessment of credential as per requirement.

Desirable criteria

1. Standardization, quality assurance including safety and stability data.
2. Experimental safety studies.

Administrative & IPR issues

1. Willing to share complete information on ingredients, SOPs etc.
2. Share of IPR as co-applicant if the products are already patented.
3. Willing to sign agreement/memorandum of Agreement for sharing of benefits with mutual consensus/one time lump-sum royalty.
4. Sharing of financial requirement for conducting further studies as per requirement.
5. Satisfactory recommendation by SAB/SAG of CCRAS as appropriate for scientific merit.
6. Benefit sharing (in terms of lump-sum payment)/Annual royalty payment.

Other conditions

The Benefit sharing (in terms of lump-sum payment)/Annual royalty payment shall be decided on case to case basis considering the following issues viz.

1. Scientific merit and translational value/market potential of the product /technology.
2. Based on the amount of expenditure sharing between the CCRAS and interested party/organization.



ANNEXURE – 1

Section A

**CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
MINISTRY OF AYUSH, GOVERNMENT OF INDIA**

**APPLICATION (FORMAT) FOR CCRAS- INTRA MURAL RESEARCH PROJECTS
IN AYURVEDIC SCIENCES
(Please furnish 1 hard copy and one soft copy)**

GENERAL

1. Title of the Research Project:
2. Institution responsible for the research project
Name:
Postal address:
Telephone:
Telegraphic address:
Fax:
E-mail:
3. Principal Investigator details:
Name:
Qualification:
Area of interest/ specialization:
Postal address:
Telephone/ Mob.:
Fax:
E-mail:
4. Co-Investigator details:
Name:
Qualification:
Area of interest/ specialization:
Postal address:
Details of Collaborating Institute (If applicable):
Telephone/ Mob.:
Fax:
E-mail:



5. Duration and Time lines of Research Project:

- i) Period required for pre-study preparations like staff recruitment, purchase of equipment, procurement of the trial drugs and necessary permission etc.:
- ii) Period which may be needed for execution of real work like enrollment of patients, laboratory work, survey etc:
- iii) Period that may be required for analyzing the data (usually after target is achieved):

6. Details of research project(s) taken up by the institute in the last three years (completed and ongoing) :

S. No.	Details of the Sponsoring Agency	Name of the Project	Investigator and Co-I	Date/expected date of completion of the project	Budget	Grant received	Date of inception of project	Status of the Project	Status of the U.C.

7. Research Projects in hand under any other Grant-in-aid scheme of Government of India

Sl. No.	Name of the Project and the granting Ministry / Organization	Date of inception of project	Date of Completion /expected date of completion of the project	Total Cost	Grant received (till the date of applying)	Names and Designation of the PI and Co-I	Status of the Project	Status of the U.C.

8. Budget requirements (head wise and item wise)

Details (provide the calculation for each head)	1 st year	2 nd year	3 rd year	Total	Justification
Salary					
Non-Recurring Expenditure (Equipments & other non consumables if any)					
Recurring Expenditure (Trial drug & other consumable items)					
Travel expenses (TA/DA)					
Contingency					
Grand Total					



Name, Designation and Signature of the:

a) Principal Investigator(s) _____
Name with designation Signature

b) Co-Investigator(s) _____
Name with designation Signature

Name with designation Signature

Name with designation Signature

Signature of the Head - CCRAS Institute (with seal)

Signature of the Head of other participating institute, where ever applicable (with seal)



Section – B

FORMAT FOR BIO-DATA OF THE INVESTIGATORS [PI, CO-I (S)]

1. Name (Dr. / Mr./Ms.): _____
First Name (s) Surname
 2. Designation:
 3. Complete Postal Addresses and PIN:
Telephone Number (s), Fax, E-mail
 4. Date of birth:
 5. Educational Qualification: Degrees obtained (Begin with Bachelor's Degree)
Degree Institution Year
(PG / Ph.D.)
 6. Research Experience
Duration (From – To) Institution Particulars of work done
 7. Research specialization
(Major scientific fields of interest)
 8. Financial support received
 - a. From the Ministry of AYUSH
Past
Present
Pending
 - b. From other organizations
Past
Present
Pending
 9. Research projects in hand under IMR
 10. Research Projects in hand under any other Grant-in-aid scheme of Government of India
 11. Other research projects, if any:
 12. List of five important publications of the Investigator relevant to the project, also accepted papers
 13. Other information, if any:
- Signature:
- Date:

**SUMMARY OF THE PROPOSED PROJECT**

(To be submitted by PI / Co-I)

Title of the Project:					
1.	Type/Category of the project (Clinical Research, Pharmacology, Chemistry, Botany, Literary, any other)	:			
2.	Mandate of Institute	:			
3.	Name & qualification of the Investigator (With complete Address, Ph. No./Mobile No. & E-mail etc.)	:			
4.	Name & Qualification of the Co-Investigator (s) (With complete Address, Ph. No./Mobile No. & E-mail etc.)	:			
5.	Complete Postal address of the Institute/Organization responsible for the project	:			
6.	Complete postal address of other participating institutes, if any	:			
7.	Project cost	:			
8.	Duration of the project	:			
9.	Budgetary breakup (year wise):				
	Details	1st year	2nd year	3rd year	Total
	Salary				
	Non-Recurring Expenditure (Equipments & other non consumables if any)				
	Recurring Expenditure (Trial drug & other consumable items)				
	Travel expenses (TA/DA)				
	Contingency				
	Grand Total				



10.	Technical Part: Literary review about the work (updated and latest publications on drug & Disease for clinical research): (Enlist at least five important publications concerned to the project)																																																																
	<u>Objectives:</u> a. Primary: b. Secondary:																																																																
	<u>Brief Research Plan:</u> (for non-clinical projects, detailed methodology/mode of execution may be described)																																																																
	<u>Study designs (in case of clinical research studies):</u>																																																																
	<table border="1"><tr><td>i.</td><td>Study Type</td><td>:</td><td></td></tr><tr><td>ii.</td><td>Purpose</td><td>:</td><td></td></tr><tr><td>iii.</td><td>Masking</td><td>:</td><td></td></tr><tr><td>iv.</td><td>Control</td><td>:</td><td></td></tr><tr><td>v.</td><td>Timing</td><td>:</td><td></td></tr><tr><td>vi.</td><td>End Point</td><td>:</td><td></td></tr><tr><td>vii.</td><td>No. of Groups</td><td>:</td><td></td></tr><tr><td>viii.</td><td>Sample Size</td><td>:</td><td></td></tr><tr><td>ix.</td><td>Inclusion criteria</td><td>:</td><td></td></tr><tr><td>x.</td><td>Exclusion criteria</td><td>:</td><td></td></tr><tr><td>xi.</td><td>Diagnostic criteria</td><td>:</td><td></td></tr><tr><td>xii.</td><td>Withdrawal criteria</td><td>:</td><td></td></tr><tr><td>xiii.</td><td>Outcomes measures</td><td>:</td><td></td></tr><tr><td></td><td>a) Primary</td><td>:</td><td></td></tr><tr><td></td><td>b) Secondary</td><td>:</td><td></td></tr><tr><td>xiv.</td><td>Assessment Criteria</td><td>:</td><td></td></tr></table>	i.	Study Type	:		ii.	Purpose	:		iii.	Masking	:		iv.	Control	:		v.	Timing	:		vi.	End Point	:		vii.	No. of Groups	:		viii.	Sample Size	:		ix.	Inclusion criteria	:		x.	Exclusion criteria	:		xi.	Diagnostic criteria	:		xii.	Withdrawal criteria	:		xiii.	Outcomes measures	:			a) Primary	:			b) Secondary	:		xiv.	Assessment Criteria	:	
	i.	Study Type	:																																																														
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xii.	Withdrawal criteria	:																																																															
xiii.	Outcomes measures	:																																																															
	a) Primary	:																																																															
	b) Secondary	:																																																															
xiv.	Assessment Criteria	:																																																															
	<u>Drug/Intervention references (Classical textual/API/AFI/Publications, if available):</u>																																																																
	<u>Detailed posology (Dose/Duration/<i>Anupana</i>/Time of administration/Dosages form etc.):</u>																																																																
11.	Other drug related information, if applicable:																																																																
	i. Whether selected intervention is from Scheduled books:																																																																
	ii. Whether the intervention proposed is indicated for the same disease condition as per Ayurvedic literature:																																																																



	iii. Whether quality standards are available for the selected formulation(s):
	iv. Availability of the trial drugs:
12.	Ethical issues / Lab investigation details
13.	Milestone with deliverables:
14.	Expected outcomes:
15.	Applicability/Translational value / relevance in the light of AYUSH:



Section – D

DETAILED RESEARCH PROPOSAL **(To be enclosed)**

Give here the design of study as per guidelines for clinical trial/methodology to be adopted for the project. Furnish the details of standard operating procedures (SOP) for preparation of trial drugs along with specification of ingredients. Specify Facilities in terms of equipment etc. available at the institution for carrying out the project.

Furnish Re-prints of at least five important publications concerned to the project.

(Note: The Investigators are required to go through prevalent guidelines as applicable)



ANNEXURE-2

COMPOSITION OF IMR – INTERNAL SCRUTINY COMMITTEE

- | | | |
|---|---|-----------------|
| 1. Deputy Director (Tech.), CCRAS | - | Chairman |
| 2. Deputy Director (Admn.), CCRAS | - | Member |
| 3. Programme Officers of CCRAS Headquarters | - | Members |
| 4. Accountant/Accounts Officer | - | Member |
| 5. Expert Bio Statistician | - | Member |

Term of reference of IMR - ISC

- Recommend suitable IMR projects to PEMC.
- Call the Principal Investigator/Co-Investigator for discussion (if necessary).
- Invite comments from the expert(s) in the concerned field (if necessary).
- Inform the applicants to modify their proposals , if needed.
- Review the progress report received from time to time from the Investigator.
- Ask for the relevant papers and documents related to the projects (if necessary) from PI.
- Make site visit, where in the Principal Investigator would ensure access to all the relevant research facilities and documents related to the project (if necessary).



ANNEXURE-3

INTRA MURAL RESEARCH - PROJECT EVALUATION & MONITORING COMMITTEE (IMR-PEMC)

1.	Director General, CCRAS	-	Chairman
2.	2 Subject Experts (Co-opted members (Subject wise) as per necessity)	-	Member
3.	Epidemiologist	-	Member
4.	Bio-statistician	-	Member
5.	Two representatives from the Ministry of AYUSH (Including one from Finance Division)	-	Member
6.	Deputy Director (Technical), CCRAS	-	Member Secretary

Terms of reference of IMR-PEMC: The IMR- Project Evaluation Monitoring Committee (IMR- PEMC) after the evaluation/ scrutiny of the Research Proposals may-

- Recommend and approve suitable IMR projects
- Call the Investigator/Co-Investigator for discussion (If required)
- Invite comments from the expert(s) in the concerned field (If required)
- Inform/Ask the PI/Co-I to modify their proposals if needed.
- Reject the proposals, if not found suitable with reasoning.
- Review the progress from time to time as appraised by the council .



List of Central Government / State Government Pharmacies/Cooperatives manufacturing ASU &H medicines

1. Indian Medicines Pharmaceuticals Corporation Ltd.(IMPCL), Govt. of India Enterprise
2. OUSHADHI The Pharmaceutical Corporation (IM.) Kerala Ltd, State Pharmacy
3. IMPCOPS, Government of Tamilnadu
4. TAMPCOL Tamilnadu State Pharmacy
5. M.P. Minor Forest Products Cooperative Federation- Madhya Pradesh-State Pharmacy
6. Cooperative Drug Factory, Chilyanaula Ranikhet Uttarakhand

Benchmark for Drug Procurement from Government/ Cooperative/Private Pharmacies Essential:

1. The Pharmaceutical Company should be having a valid GMP certificate for maximum varieties of dosage forms and fulfill other requirements as per Schedule T of D&C Act.
2. It should have an in house Quality Control Section and R&D facility and requisite expertise.
3. It should be having at least 10 years of experience in manufacturing and marketing of Ayurvedic drugs.
4. It should be able to prepare drugs as per SOP for manufacturing of classical formulations and Coded /Proprietary drugs developed by the Council.
5. The pharmaceutical company must sign a Non Disclosure Agreement to maintain the confidentiality of New/coded drugs developed by the council through R&D and shall not claim any Intellectual Property Rights at any stage.
6. The company should comply with quality standards of raw materials, intermediate and finished products (viz. Pharmacognostic, Physico-chemical and Safety parameters) as per format provided by the Council/or able to develop in-house standard where ever required.
7. It should also comply with the requirement of packing and labeling specifications provided by the Council.
8. It should have in house capability to produce different types of plant extracts as required for the manufacturing of Coded/Proprietary drugs developed by the Council or should be able to procure them from reputed Companies having capacity to produce export quality plant extracts along with Standard Operative Procedures (SOPs) of manufacture and Certificate of Analysis (COA).
9. It should be able to supply the drugs in a time bound manner within a maximum period of three months/or as specified from time to time in the supply order.
10. It should be able to supply the drugs directly to specified destinations through transportation.
11. The company should allow CCRAS team to oversee the manufacturing procedure as and when required.



Desirable:

1. WHO GMP compliance of the manufacturing unit.
2. Prior experience in manufacturing of Ayurvedic drugs for research purpose.
3. Experience of manufacturing export quality Ayurvedic products and exporting abroad.
4. They should be able to provide lab scale samples of Ayurvedic drugs as and when required, along with standards and COAs.
5. Inclination towards Research and active mutual interaction with CCRAS as and when required in the process of preparation and supply.



ANNEXURE- 5

Format for submission of request for Revalidation of unspent balance as on 31st March of particular financial year sanctioned for Intra Mural Research Projects

SL. No.	Particulars	Details
1.	Title of the project	
2.	Name of the Principal Investigator and Co-Investigator(s)	
3.	Name of the Institute	
4.	Nodal Officer	
5.	Particulars of approval/allocation of the project (please specify the particulars of approval either in IMR-PEMC meetings or under Annual Action Plan with year)	
6.	Details of sanction (please specify the office order with date issued from CCRAS Hqrs. along with Total Sanctioned Amount for particular project)	
7.	Details of amount released as Installment in particular financial year (please specify the particulars of Installment such as 1 st , 2 nd , 3 rd etc.)	
8.	Details of unspent balance as on 31 st March of particular financial year for which revalidation is required to carry forward the work.	
9.	Statement of Expenditure (SoE) head-wise and item wise as on 31 st March of particular financial year (please annex duly signed copy separately)	
10.	Remarks if any	

Signature of Principal Investigator with date

Signature of the In-charge with date



ANNEXURE- 6

**FORMAT FOR THE INTERIM PROGRESS REPORTS TO BE SUBMITTED BY
PI/Co-I**

1. Project title
2. Investigator (name)
3. Co-I (name)
4. Date of sanction/release of money of the project
5. CTRI reference / registration no.
6. IEC approval no. (Copy to be enclosed)
7. Date of initiation of the project (Recruitment of first patient in clinical trial or survey, standardization etc.)
8. Objectives/ deliverables with time line fixed for the project
9. Deliverables achieved during the reporting period as proposed in the scheme
10. Interim modification of objectives/methodology, if any (with justifications)
11. If deliverables are not met with timeline specified in the proposal then give reasons
12. Summary on progress (during the period of report)
13. Applied value of the project
14. Research work which remains to be done under the project

Signature of Investigator:

Date:

Signature of Head of the Institute:

Date:



FORMAT FOR FINAL REPORT

1. Title of the Project:
2. Investigator:
3. Co-Investigator:
4. Details of Collaborators:
5. CTRI application no.:
6. IEC approval no.:
7. Date of sanction/release of money
8. Date of commencement:
9. Duration:
10. Date of completion:
11. Objectives as approved:
12. Objectives achieved:
13. Deviation made from original objectives (if any) & administrative / ethical approval taken for the same:
14. Details of the work done, methodology adopted and results obtained with tables, charts, diagrams and photographs. (As available):
15. Causes of delay (if any) and partial achievement of target
16. Conclusions summarizing the achievements and indication of scope for future work.
17. Usage of Equipment purchased under the project:

S. No.	Name of Equipment	Make/ Model	Cost FE/Rs	Date of Installation	Utilization rate %	Remarks regarding maintenance/breakdown

18. Publication details.
19. IPR details (If any).



20. Outcomes of the project & significance for Ayurveda / Sowa - Rigpa systems:

No. of cases screened	No. of cases enrolled	No. of cases continued	No. of cases completed	Drop outs	Screening failure	No. of completed CRFs submitted to Hqrs	Remarks

1. _____
(Principal Investigator)

2. _____
(Co-Investigator)

**Forwarded by Head of the Institute:
with date**

Name and signature



ANNEXURE-8

**CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
EVALUATION FORM
DURING VISIT OF MONITORING TEAM**

- 1. Name of the Institute**
- 2. Date of Visit of Monitoring Team**
- 3. Category of the project (IMR/ Collaborative)**
- 4. Title of the Project**
- 5. Name of the Principal Investigator**
- 6. Name of the Co –investigator(s)**
- 7. Collaborator (If applicable)**
- 8. Budget sanctioned and date of sanction**
- 9. No. of Installment received with amount and status of utilization (head wise)**
- 10. Date of Initiation/Enrollment**
- 11. Status of IEC / IAEC clearance**
- 12. Status of CTRI Registration /CTRI Registration No:**
- 13. OPD Register (Random checking of entries enrolled participants)**
- 14. Status of Execution**
- 15. CRFs in Original(random checking)**
Randomly selected clinical/ demographical information/ investigations to be cross verified in CRFs & E- format / Original reports
- 16. Current stock /Whether trial drug is present in sufficient quantity**
- 17. Storage conditions of trial drugs**
- 18. Registers / files / receipts (technical / drug / accounts, etc) related to clinical / Pharmacological trial**
- 19. Any other information**



20. **Expected period of completion of targets**

21. **At the time of monitoring the targets achieved as per deliverables**

Investigators/ Head of institute	Signature	Date
PI		
Co-I		
Head of the Institute		

**Name of
monitoring
committee**

Signature

Date

VISION DOCUMENT 2030

- 15 years vision document
- 7 years strategy from 2017-18 to 2023-24
- 3 years Action document for 2017-18 to 2019-20



**CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
MINISTRY OF AYUSH, GOVERNMENT OF INDIA
JANAKPURI, NEW DELHI**



Background

The Sustainable Development Goals (SDGs), officially known as **Transforming our world: the 2030 Agenda for Sustainable Development** are an intergovernmental set of aspiration Goals with 169 targets. The Goals are contained in paragraph 54 United Nations Resolution A/RES/70/1 of 25 September 2015.

Considering the strength of Ayurveda, current unmet medical needs, the council has proposed the following strategy of R&D with focussed research outcomes in next 15 years focussing on development of investigational new drugs based on leads from classical Ayurvedic for diseases of national importance besides Systematic validation of classical formulations and therapies.

I. Vision 2030

Vision Statement of CCRAS: To develop scientific evidence in Ayurvedic Principles, drug therapies by way of integrating ancient wisdom with modern technology and to bring Ayurveda to the people through innovations related diagnostics, preventive, promotive as well as treatment methods and also introduce scientific research for sustained availability of quality natural resources, to translate them into products and processes and in synergy with concerned organizations to introduce these innovations into public health systems.

Sustainable Development Goals (SDGs) of CCRAS for vision 2030 (15 years)

- ❖ Translation of research outcome into clinical practice through commercialization of new drugs developed by CCRAS through translational research for making them accessible to the public.
- ❖ Main streaming of Ayurveda therapies through integration and including them in a National Health Programme.
- ❖ Development of new drugs/combinations based on the leads from classical literature and also from local health traditions on different conditions to meet the demand of unmet medical needs.
- ❖ Development of safe /effective products for diseases of national and global importance as add-on/ adjuvant therapies and also for standalone management for improvement of quality of life.
- ❖ Generation of scientific evidence on safety of Ayurvedic formulations and therapies.
- ❖ Revalidation of certain Classical formulations for evidence on safety and efficacy.
- ❖ Dissemination of research outcome through appropriate media for sustainable utilization by medical practitioners and public
- ❖ R&D infrastructure development to improve the quality of research.

IX. 7 years strategy from 2017-18 to 2023-24 (long term vision) (A 7 years strategy from 2017-18 to 2023-24 to convert the long term vision into implementable policy and action as a part of the National Development Agenda with a midterm review after 3 years i.e. the year ending March 2020.)

Development and validation of Ayurvedic drugs and regimen for inclusion in the important National programme viz.



- Development of add-on/ adjunct therapies for Multi Drugs Resistant (MDR), Tuberculosis for improvement of quality of life and introducing in National Tuberculosis Control Programme.
- Evidence based Ayurvedic intervention for improvement of vision and prevention of blindness for inclusion in the *National Programme for Prevention and Control of Blindness* for disease such as Glaucoma, Retinal disorders, Neuro ophthalmic conditions.
- Integration of Ayurveda in *National Reproductive and Child Health Programme* by developing evidence based Ayurvedic interventions for Amni Natal, Post Natal and Child Health Care.
- Development of Ayurvedic interventions for improvement in quality of life in different types of cancers.
- General of evidence on Ayurvedic interventions and drugs as add-on/ adjunct therapies in HIV/ AIDS for inclusion in National AIDS control programme.
- Evidence based Ayurvedic drugs for National Control Programme for Vector borne /Infection diseases like Filariasis, Dengue and Malaria etc. which are challenging needs of the country.
- Development of products for chronic refractory Non communicable diseases and life style disorders where conventional system of medicine has limited role in management.viz. Diabetes mellitus , Hypertension, Osteoarthritis, Rheumatoid Arthritis, preventive cardiology, Skin diseases, allergic disorder, Hepato Biliary disorders, Mental health and Metabolic disorders.
- Development of drugs and products for improvement of memory and cognitive function and other psychiatric diseases such as Anxiety neurosis, dementia etc.
- Development of drugs and products for improvement of nutritional disorder like Anaemia
- Generation of scientific evidence on safety and toxicity of selected Ayurveda herbal and herbo- mineral drugs.

III. **3 years Action document for 2017-18 to 2019-20** (*A 3 years Action document for 2017-18 to 2019-20 aligned to the predictability of financial resources during the 14th Finance commission Award period. This is also to help translate into action the goals of the government to be achieved by 2019.*)

Research plan (for 3 years)

1. **Development of the Directives** addressing different research needs viz. i. Drug development (addressing issues of quality, shelf life, safety issues and other requirements), ii. Safety evaluation (pre-clinical) and iii. Clinical research for AYUSH interventions
2. **Validation of Fundamental principles of Ayurveda** including **Ayurveda biology** such as
 - Standardization and validation of Panchakarma procedures including physiological/metabolic changes due to Panchakarma
 - Panchakarma and microbiome
 - Biology of gunas in health and disease
 - Understanding of shat-kriyakala
 - Scientific rationale of swasthavrita



- Understanding Rasa, Guna, Virya and Vipaka with reference to action of Ayurvedic drugs
 - Development of wellness index and quality of life instruments based on Ayurveda
 - Ayurvedic intervention for medicine and public health etc in a phased manner.
3. Development of **Standard Ayurvedic terminologies** and its publication in different volume in a phased manner.
 4. Short term Projects on **Occupational Health** such as respiratory disorders, Computer vision syndrome, Generalized Anxiety Disorder/Stress etc.
 5. Development of Modules on **Behavioural Change Communication** focusing on Ayurveda based life style interventions for prevention, health promotion and disease management and mechanism for effective implementation of Ayurveda based behavioral interventions in association with clinical psychologists in CCRAS institutes.
 6. Development of comprehensive, pragmatic, adaptable an Ayurvedic user's friendly format for **clinical diagnosis and clinical examination** for utilization among health care professionals and its validation.
 7. **ICMR collaboration:** Collaborative research with ICMR based on available leads with council viz. AYUSH 82 for diabetes, Sunthi Guggulu for Rheumatoid Arthritis identifying the gaps besides validation of Ayurvedic Coded drug in the management of Dengue, fatty liver degeneration and hepato protection as add on to Anti tubercular Therapy (ATT).
 8. Development and validation of Clinical Decision Support Systems and HIMS and e-management.
 9. Development and commercialization of coded Ayurvedic drug AYUSH-QOL-2C for improvement of quality of life of cancer patients.
 10. Validation and value addition to standalone Ayurveda interventions (Carctol-S) for management of certain cancer such as cervical and ovarian cancer through collaborative research.
 11. Validation, product development and commercialization of Ayurvedic coded drug of C1 oil for wound healing and eczema.
 12. Product development and commercialization of coded Ayurvedic drug AYUSH PJ-7 for management of Dengue.
 13. Development of dosage form for Hepato-protective agents (with focus on add-on/adjuvant therapy to anti tubercular drugs) from Ayurvedic leads- *Phalirikadi Kwatha*
 14. Clinical validation and product standardization of *Gomutra Haritaki* for the management of fatty liver degeneration.
 15. Development and commercialization of coded Ayurvedic drug AYUSH-D for Diabetes mellitus.
 16. Clinical safety and efficacy studies of classical Ayurveda drugs for chronic and refractory diseases Rheumatoid Arthritis, Osteoarthritis, Hypertension, Gout, Kidney stone, Urolithiasis, PCOS, Bronchial asthma, Chronic bronchitis
 17. Generation of scientific evidence on safety of 10 Metal/mineral based Ayurvedic formulations at GLP laboratories.



18. **Dissemination of Research Outcomes** of the council through press release, audio visual documentary, AYUSH research journal etc. in a phased manner.
19. **Establishing linkages with CSIR** and identification of areas for Collaborative Research.
20. **Outreach programmes for extending health care and documentation**
 - Tribal Health Care Research Programme (under Tribal Sub Plan) in 14 states.
 - Swasthya Rakshan Programme linked with Swachha Bharat in 19 states.
 - Ayurveda Mobile Health Care Programme under Scheduled Castes Sub Plan in 18 states.
 - NPCDCS Programme.



CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES

Ministry of AYUSH (Government of India)

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