CCRS RESEARCH POLICY

Central Council for Research in Siddha
(Ministry of Ayush, Government of India)
Tambaram Sanatorium,
Chennai – 600 047.

BACKGROUND

The Siddha system of medicine is one of the traditional medical system, providing preventive, promotive, curative, rejuvenative and rehabilitative health care by adopting scientific and holistic approach. The word 'Siddha' is derived from the root word 'Citti' meaning attainment of perfection, eternal bliss and accomplishment. In Indian subcontinent, Siddha medicine has strong roots reflecting the culture, tradition and heritage of India.

The movement for revival of rich and centuries old heritage of medical sciences in India gained greater momentum. First of all, these systems were officially recognised and became part of national health care programme. The state and central governments have established hospitals, dispensaries, institutions and research organizations throughout India for mainstreaming these systems for catering to the primary health needs of our country. The clinical research is supported by literary research, drug standardization and pre-clinical research. These departments gained importance and started functioning with their exclusive mandate of supporting clinical research.

Ministry of Health and Family Welfare, Government of India in its National Health Policy 2002 on AYUSH 2002 highlights re-orientation & prioritization of research in AYUSH and to scientifically validate drugs and treatment for chronic and Non-Communicable Diseases. The National Health Policy 2017 also accentuates on R&D in AYUSH systems.

Central Council for Research in Siddha (CCRS) is an apex organization for the formulation, co-ordination, development and promotion of research on scientific lines in Siddha medicine. CCRS is dedicated to encourage research in areas of National priority and importance. Thus, the Research Policy of CCRS aims to promote 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 / units can apply through this scheme according to their research interest, prevalence of disease conditions in their constituency, research leads, etc. or CCRS headquarters office can assign projects taking into consideration the National / International need and directives from Ministry of Ayush. The Council also requires to collaborate with nationally reputed organizations like ICMR, CSIR, AIIMS, IIT, DST, DBT, ICAR, PGIs, DRDO, and Siddha institutions like NIS, Chennai and DIM&H, Chennai, etc.

The strengths of Siddha have to be harnessed at the same time the expertise and infrastructure of multiple organizations are warranted for chronic intractable diseases like cancer, HIV/AIDS, tuberculosis, etc. Industries also would approach the Council to carry out preclinical / clinical research on the research leads where the IPR benefits can be shared. In addition, Council has also developed 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. Therefore, it is necessary to conduct pre-clinical and/or clinical studies and before getting the drug patented / marketed and so the collaborative mode

of research is warranted. Thus, this research policy envisages technical, administrative and financial aspects in an inclusive manner.

The recent trend globally indicates that foreign countries are inclined towards AYUSH medicines. As a result, it is the need of the hour on the part of the Council to initiate/ execute/coordinate or monitor R & D activities. This Research Policy of CCRS covers guidelines for IMR/ in-house research and collaborative research at national and international level.

Vision

Preservation and transmission of knowledge and enhancement of the quality of research for developing Siddha drugs with quality, safety and efficacy through well-established preclinical and clinical research facilities — to prevent / manage /cure the diseases of varied aetiology.

Mission

- To undertake scientific research works in Siddha in a time-bound and cost-effective manner, to coordinate, aid, promote and collaborate research with different units of sister Councils and Research Organizations.
- To publish research articles/research journals, to exhibit achievements and to propagate research outcomes for all the stakeholders.
- To aim for AYUSHMAN Bharat by way of promoting better health through evidence based Siddha principles and practices.
- To develop CCRS into a dynamic, vibrant, and model research organization for undertaking, coordinating, aiding and promoting research in Siddha.
- To bring-up modern scientific knowledge, technology to explore Siddha scientific treasure following prevalent scientific methods.
- To attain global leadership in research for treatment and prevention of emerging important life style related disease and health requirement.

Objectives of CCRS

- To formulate the aims and patterns of research on scientific lines in Siddha.
- To undertake any research or other related programmes in Siddha.
- To undertake on principles and practices of Siddha including diet, formulation, dosage forms, drug delivery system, Thokkanam procedures, Varmam therapy.etc.
- To develop scientific assessment tools and parameters suitable to Siddha.
- To conduct research on natural resources for their sustained availability, quality etc.
- Clinical research for safety and efficacy evaluation of Siddha pharmacopoeial formulations and other drugs and approaches in identified diseases/conditions

- Medico Ethno Botanical Survey across the country
- To establish novel methods of analysis for standardization and quality control of single drugs and compound formulations.
- Experimental studies to establish safety profile of Siddha drugs / formulations
- Tribal Health Care Research Programme including documentation of Local Health Traditions / folk claims
- To initiate, aid, develop and coordinate scientific research in different aspects, fundamental and applied aspects of Siddha and to promote and assist institutions of research for the study of diseases, their prevention, causation and remedy.
- To exchange information with other institutions, associations and societies interested in the objects similar to those of the Central Council and especially in observation and study of diseases.
- To prepare, print, publish and exhibit any papers, posters, pamphlets, periodicals, Monographs and books for furtherance of the objects of the Central Council and contribute to such literature.
- To undertake R & D consultancy projects and transfer of patents on drugs and process to industry.
- To undertake international and inter-agency collaboration.
- To constitute Management Committees consisting of eminent Scientists/Physicians to monitor the R & D activities and suggest remedial measures for the improvement of activities of all Central as well as Research institutes of the Council.

To meet aforesaid objectives, the mandatory requisites which need to be addressed are:

Capacity building / Human Resource Development: It is important for the investigators/co-investigators across all peripheral Institutes/ Units of CCRS 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.

CCRS has adopted the below mentioned schemes to meet the objectives of quality research:

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

1. INTRA-MURAL RESEARCH

1.1. ELIGIBILITY

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

a) National PriorityAreas

b) Mandate of the Institute/ Unit

c) Strength areas of Siddha

d) Any other task given by CCRS / Ministry of Ayush

The Officer who desires to submit the project must make sure that his/her institute has sufficient infrastructure in the 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 sufficient 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 ccrschennai@gmail.com)**. The application will be available at the website of CCRS (www.siddhacouncil.in).

1.2. SELECTION OF PROJECT

The initial screening will be carried out by the Technical Screening Committee of CCRS Hqrs. and then the projects will be examined by the Internal Scrutiny Committee (ISC). The composition and terms of reference of ISC is enclosed as **Annexure-2.** After which the projects recommended by ISC will be submitted to concerned subject expert (through email) for comments/suggestions. The comments received from the experts will be suitably incorporated.

The projects recommended by the ISC will be placed before the Project Evaluation and Monitoring Committee (PEMC). The composition and terms of reference of PEMC is enclosed as **Annexure-3.** The PEMC will evaluate the projects based on presentation 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/unit as multi-centric trial with the officer who has submitted the project as one of the Investigators. The projects which are approved by PEMC have to be placed in Scientific Advisory Board (SAB) for further approval.

1.3. MODE OF PROJECT DEVELOPMENT / ALLOTMENT

The Intra Mural Research of CCRS 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 CCRS.

Modality-B: Intra-Mural Research project which is centrally initiated from CCRS 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. 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 fundamental parameters for assessment of Udaliyal/basic principles of Siddha, etc. related to therapeutic approach.

ii. Redefining and developing parameters for assessment of Suvai, Gunam, Viryam, Vipakam and Prabhavam of the drugs described in Siddha texts and also of non-classical drugs 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 Thathu and Gunapaadam 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 Siddha Diagnostics (Udaliyal and Nadi Iyal including Enn vagai thervu)

iv. Development of methods/ modalities/ protocols for Clinical Research of Siddha

v. R & D and standardization of external therapies (Pura Maruthuvam), Varmam, Thokkanam 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 Siddha 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 five qualities /properties of drug of extra pharmacopoeial drugs 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 Siddha drugs.

vii. Safety, toxicity and drug interaction studies.

viii. Standardization and Quality Assurance related to Siddha drugs.

ix. Pharmaceutical Research and Development related with Siddha drugs.

x. Veterinary Siddha products.

xi. Development of experimental models, Dosage forms, Cell line studies, Shelf life and Quality issues.

xii. Revalidation and critical analysis/enquiries as per the concepts of Siddha based farming.

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 Siddha 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 Siddha / related areas / specificareas.

iv. Research on Siddha drug SOPs

v. Epidemiological Research

vi. Promotive and preventive health care / Kaya karpam

vii. Any other areas found to be important from time to time, including endemics, epidemics, pandemics etc.

1.4.5. Prioritized Disease Conditions/Areas

i. Preventive Cardiology

- Atherosclerosis
- Hypertension

- Dyslipidemia

ii. Gastro intestinal disorders

- Hepatic Disorders
- Diarrhoeas 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. Anaemia

xii. Vector borne diseases

xiii. Diseases of Siruneragam (Kidney) including Renal failure, Benign prostatic hyperplasia, Urolithiasis, Chronic Nephritis, etc.

xiv. Fevers of various etiologies (Condition with hyperpyrexia)

xv. Para – surgical procedures: Karanool for Fistula –in-ano, Haemorrhoids, Pilonidal sinus, Suttigai, Attai vidal,etc.

xvi. Neurological, Neuro-muscular and Neuro- degenerative disorders

xvii. Kaya karpam therapy & Geriatrics

xviii. Reproductive & Child Health (RCH)

xix. Quality of life (QoL) in Cancer / HIV – AIDS, etc.

xx. Siddha Dietetics.

xxi. Pain dominating conditions and pain relievers (drugs / therapies).

xxii. Other priority areas of National importance (For example: Covid-19)

xxiii. Keeping in view the health care burden and strength of Siddha the following disease areas will be taken on priority viz. Osteoarthritis, Metabolic syndrome, Chronic nephritis, Acid peptic disease, Allergic rhinitis & Hepatitis.

xxiv. Any other researches related to Siddha system of Medicine and its scopes.

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 multi-centric 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 CCRS headquarters and the Principal Investigator may be the person responsible for answering the scientific / public queries.

(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 PIs of concerned institutes are

required to submit 2 hard copies and 1 soft copy of the approved project proposal including CRFs /formats from the 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 Siddha pharmacopoeial standards is to be procured from the manufacturer. In case, for any formulation, if the Siddha pharmacopoeial standards are not available, then in-house standards may be developed in consultation with Botany and Chemistry section of SCRI, Chennai and SRRI, Thiruvananthapuram. The list of minimum standards required for various common medicines may be decided from time to time in consultation with Chemistry section of SCRI, Chennai and SRRI, Thiruvananthapuram. 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 (GMP certified) or CCRS 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 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 should be ensured by the PI while submitting the project proposal.

1.5.7. Laboratory Investigations

Under the modalities A & B the institutes and centres under CCRS should have sufficient 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/Unit 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, requiring long-term studies the maximum duration may be up to 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 CCRS Hqrs.

1.5.10. Ethical Clearance

Once the project is approved by the Internal Scrutiny Committee (ISC), it is the responsibility of the Principal Investigator and the concerned Head of each institution to convene a meeting of the IHEC (Institutional Human Ethics Committee) / IAEC (Institutional Animal Ethics Committee) (as applicable) to obtain the ethical clearance. The IHEC/IAEC approval needs to be communicated for placing it in PEMC.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 communicated to DG CCRS and SAB before incorporating.

1.5.11. Funding

i. The project costing up to 200 Lakhs will be approved by DG, CCRS (Power of DG, CCRS). Approval of Standing Finance Committee (SFC) will be obtained for studies amounting more than 200 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 will be released as 1st instalment at the time of sanction of the project. Next instalment(s) will be released after receipt of interim progress report and UC/statement of expenditure of first instalment. 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 31stMarch and the proposal for re-validation of unspent balance as on 31stMarch 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/ 4thweek of March should be paid within 31stMarch.

1.6. PROJECT PERSONNEL/STAFF

1.6.1. Engagement of Project Personnel:

The Investigator may propose for engaging Research Associate if they possess M.D. (Siddha) for medical discipline and non medical if they possess Ph.D) / JRF and SRF for BSMS/ JRF / SRF (for non-medical disciplines) / Office Assistant (OA) for Literary Projects, etc. as per the need of the project with remuneration as adopted by CCRS from time to time following the pattern of CCRAS / 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. Co-Investigator (Member) 4. 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 Council 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

1.6.3.1. 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. The Interim report should be submitted by PI whenever asked for 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.

1.6.3.2. 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/annual) 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 CCRS 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, CCRS / PEMC / SAB 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 / units. In such case, the unspent balance will be refunded to the CCRS 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.

i. The protection of intellectual property rights shall be enforced in conformity with the national laws, rules and regulations.

ii. Notwithstanding anything in paragraph (i) above, the intellectual property rights in respect of any technological development, and any products and services development, carried out will be jointly owned / shared by the CCRS and collaborating MoU institutes. Any financial benefit will be decided proportionate to the financial contribution made in the project or sharing may be decided by mutual discussion.

1.11. PUBLICATION

i. Where the research outcome is not patentable, the Principal Investigator must publish the findings of research in peer reviewed journal / reputed journal with impact factor not less than 0.1 after completion of the trials. The draft article must be submitted to Hqrs. office within 3 months of the acceptance of the final report. In case of multicentric studies, the PI of the nodal Institute and the nodal officer at CCRS Hqrs. is responsible to coordinate with all who participated or contributed in the study for planning of publication. After publication, three copies of the reprints of the article are

to be submitted to Headquarters.

ii. The research work will be published jointly by the CCRS and collaborating MoU institutes. No study related research publication will be published without due permission of DG, CCRS for collaborative projects. Authorship should be based on ICMJE guidelines. However, the decision of Director General, CCRS shall be final and binding with respect to authorship based on conceptualization, study designing, coordination, implementation and other contributions made in the project.

2. COLLABORATIVE RESEARCH AT NATIONAL LEVEL

2.1. Proposed Areas of Research:

i. Development of technology based on theory of Siddha such as R & D on Siddha Diagnostics/Methods &Techniques (including Udaliyal and Nadi Parisoothanai) and R & D on therapies to pacify the vitiated humour and other therapeutic procedures, their standardization. Software development, development of disease coding for medical record maintenance; Siddha technology; Cancer- preventive, curative as well as supportive intervention / therapy; research on areas related to MCH and MDG (Millennium Development Goals), cardiac rehabilitation; Kaaya karpam 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 Siddha.

iv. Protocol development for Randomised Clinical Trial for Siddha drugs (Pharmacopoeial and newer formulations) and conduct of RCTs as Research studies

v. Development of Siddha Pharmacovigilance programme and Research studies on Pharmacovigilance

vi. Development of methods/ modalities for Clinical Research/ Instrumentation in Siddha.

vii. Mode of action of Siddha formulations (with classical parameters/modern parameters/both)

viii. Epidemiological Research

ix. Promotive and Preventive Health Care / Kaayakarpam

x. Veterinary Siddha / Siddha Farming

xi. Dietetics and nutrition

xii. Cosmetics/skin care

xiii. Integrative Medicine Research with participation of Siddha Experts in Non-Communicable Diseases and Non communicable Diseases.

xiv. Any other important areas of National importance (Example : Covid-19)

2.2. Selection of Collaborating Institutes

2.2.1. There are certain areas in which infrastructure/facilities available at CCRS 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, CCRS will approach to nationally reputed academic / research organizations like ICMR, CSIR, ICAR, DST, DBT, AIIMS, IITs, DRDO, Siddha institutions like NIS, Chennai, DIM&H, Chennai, etc. and other MoU institutes of CCRS, 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, CCRS.

2.3. Modalities of Implementation

2.3.1. The collaborating institutes should have the PIs from each of the organization

2.3.2. If the total budget of the proposal is below 200 Lakhs (i.e. Power of DG, CCRS) the approving authority will be Director General and he / she will approve subject to recommendation of Project Evaluation and Monitoring Committee (PEMC) and Scientific Advisory Board (SAB) and the details of the same has to be appraised / approved by the Standing Finance Committee of CCRS.

2.3.3. For execution of research which requires involvement of individual researchers/traditional practitioners/claimants, CCRS will decide the issue based on scientific strength of the proposed formulations / appliances / therapies, feasibility of manufacturing, marketing, etc. If found suitable, DG CCRS 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 CCRS 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 200 Lakhs will be approved by the Director General and he / she will approve subject to recommendation of Project Evaluation and Monitoring Committee (PEMC) and Scientific Advisory Board (SAB) and the details of the same has to be appraised / approved by the Standing Finance Committee of CCRS.

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 instalments, 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

i. 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.

ii. 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.

iii. 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 CCRS / Ministry of Ayush.

iv. But the travel expenses of the scientists travelling to the collaborating country from India for implementation / monitoring of the project will be borne by CCRS/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.

v. Before any funding, the Research proposal should be approved in SFC of CCRS, Ministry of Ayush.

vi. However, for international collaborative research, technical inputs and research drug can be provided by CCRS 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.

vii. With a view to propagate Siddha 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.

viii. In all such collaboration with foreign organizations, one MoU should be signed along with *Non-Disclosure Agreement* to maintain confidentiality of the data.

ix. The ownership of the assets purchased will be decided in the MoU.

x. The cost of the project will be inclusive of Institutional charges.

xi. For all such projects, there should be a joint monitoring team involving experts from participating organization and CCRS/Ministry of Ayush who will periodically oversee the research work.

xii. 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.~~ COLLABORATIVE RESEARCH IN SIDDHA WITH INDUSTRIES

4.1. In case, pharmaceutical industries approach CCRS for collaborating in research for a particular disease/area, then this will be decided by DG-CCRS subject to recommendations of Scientific Advisory Board (SAB). The proposal will be placed before Standing Finance Committee (SFC) for approval.

Essential criteria

1. GMP certified Siddha Pharmacies with Minimum 10 years experience in manufacturing and marketing of Siddha 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 of CCRS 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 lum-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 CCRS and interested party/organization

Annexure 1

Section A

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

MINISTRY OF AYUSH, GOVERNMENT OF INDIA

APPLICATION (FORMAT) FOR CCRS - INTRA MURAL RESEARCH PROJECTS IN SIDDHA

(Please furnish 2 hard copies and one soft copy)

GENERAL

1. Title of the Research Project:

2. Institution responsible for the research project

   Name:

   Postal address:

   Telephone: Fax: Mobile No:

3. E-mail:

4. Principal Investigator details:

   Name:

   Qualification:

   Area of interest/ specialization:

   Postal address:

   Telephone: Fax: Mobile No:

   E-mail:

5. Co-Investigator details:

   Name:

   Qualification:

   Area of interest/ specialization:

   Postal address:

   Details of Collaborating Institute (If applicable):

   Telephone: Fax: Mobile No:

   E-mail:

6. Duration and Time lines of Research Project:

Period required for pre-study preparations like staff recruitment, purchase of equipment, procurement of the trial drugs and necessary permission, etc.:

Period which may be needed for execution of real work like enrolment of patients, laboratory work, survey, etc:

Period that may be required for analyzing the data (usually after target is achieved):

7. 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.

8. Research Projects in hand under any other Grant-in-aid scheme of Government ofIndia

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

9. Budget requirements (head wise and item wise**)**

Details (provide the calculation for each head)	**1st year**	**2nd year**	**3rd 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**

Signature of the Head - CCRS 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
   Mobile no.
   E-mail
4. Date of birth:
5. Educational Qualification: Degrees obtained (Begin with Bachelor'sDegree)

Degree (PG / Ph.D.)	Institution	Year

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, ifany:

Signature:

Date:

Section – C

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:					

	Brief Research Plan: (For non-clinical projects, detailed methodology/mode of execution may be described) Study designs (in case of clinical research studies):			
	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	:	
	Drug / intervention references (Classical textual / SPI / SFI / Publications Detailed posology (Dose / Duration / Anupaanam / Time of administration / Dosage form)			
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 Siddha 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.	DG, CCRS	-	Chairman
2.	Nodal Officer (IMR), CCRS	-	Member
3.	Bio Statistician	-	Member
4.	In-charge of concerned Peripheral Institute/Units	-	Member*
5.	Programme Officer of CCRS Headquarters	-	Member Secretary

*Internal Scrutiny committee will have the in-charges of respective Institutes/Units as member for the project of the concerned peripheral Institute / Units to visualize and implement the suggestions of ISC.

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 subject 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, CCRS	-	Chairman
2.	DDO, CCRS	-	Member
3.	2 Subject Experts (Co-opted members (Subject wise- relevant to the project)	-	Member
4.	Epidemiologist	-	Member
5.	Bio-statistician	-	Member
6.	One representative from the Ministry of Ayush	-	Member
7.	Nodal Officer - IMR	-	Member
8.	Programme Officer	-	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)
- 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.

The role of PEMC is to evaluate the project proposal before approval and to monitor the Research work during and after completion of the project. The Co-opted members (Subject experts) as far as possible should be retained prior to evaluation till the completion of the said project.

Annexure 4

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

1. IMPCOPS, Government of Tamil Nadu
2. TAMPCOL Tamil Nadu State Pharmacy

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 fulfil other requirements as per Schedule T of D&CAct.
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 Siddha 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 labelling 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 CCRS 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 Siddha drugs for research purpose.
3. Experience of manufacturing export quality Siddha products and exporting abroad.
4. They should be able to provide lab scale samples of Siddha drugs as and when required, along with standards and COAs.
5. Inclination towards Research and active mutual interaction with CCRS 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 CCRS Hqrs. along with Total Sanctioned Amount for particular project	
7.	Details of amount released as Instalment in particular financial year (please specify the particulars of Instalment such as 1st, 2nd, 3rd, etc.)	
8.	Details of unspent balance as on 31st 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 31st 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. Principal 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. Publications, if any
14. Applied value of the project
15. Research work which remains to be done under the project

Signature of Investigator: **Date:**

Signature of Head of the Institute: **Date:**

Annexure 7

FORMAT FOR FINAL REPORT

1. Title of the Project:
2. Principal Investigator:
3. Co-Investigator:
4. Details of Collaborators:
5. CTRI application no.:
6. IEC/IAEC 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. In case of clinical trials, furnish the following

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

16. Causes of delay (if any) and partial achievement of target:

17. Conclusions summarizing the achievements and indication of scope for future work.

18. 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

19. Publication details.

20. IPR details (If any).

21. Outcomes of the project & significance for Siddha systems:

1. _____

(Principal Investigator)

2. _____

(Co-Investigator)

Forwarded by Head of the Institute: Name and signature with date

Annexure 8

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

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 Instalments received with amount and status of utilization (head wise)

10. Date of Initiation / Enrolment

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	Name of monitoring committee	Signature	Date
PI					
Co-I					
Head of the Institute					