CCRS RESEARCH POLICY

PART-A: INTRA-MURAL RESEARCH POLICY

1. BACKGROUND

Siddha is a comprehensive scientific system of medicine developed through Ancient wisdom, clinical experiences and experimentation. Abundant clinical experiences exist in various classical texts and compendia of Siddha. However, one of the key challenges facing the AYUSH systems is generating data for scientific validation of the safety and efficacy of Siddha formulations.

The National Population Policy 2000 and National Health Policy 2002, Ministry of Health and Family Welfare, Govt. 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.

Being an apex organization for formulation, co-ordination, development and promotion of research on scientific lines in Siddha system of medicine, the Council is committed to promote research in the disease areas of National priority in particular. The present policy is aimed at encouraging its officers for the formulation, submission and execution of research projects aimed at generating quality data for scientific validation of fundamental research and the safety and efficacy of Siddha drugs / interventions.

2. Development of IMR Project

2.1. Basis of project selection:

The permanent officers of CCRS (R.O. and above, who have at least 3 years service period before their superannuation) are eligible to develop the project keeping in view of every aspect mentioned below:

a) The Project should focus on National Priority Diseases.
b) It should match the Mandate and infrastructure of the Institute.
c) It should match the Strength areas of Siddha.

The officer who submits the project must ensure that his / her institute has adequate infrastructure and prevalence of enough number of patients of the disease condition identified for research (in case of clinical research studies). The application for the proposed IMR project needs to be submitted vide **Annexure-1 (section A & B)** as mentioned in this document.

The council headquarters / PEMC has the discretion to modify the project or extend the project to any other identified institute as multicentric trial, if needed.

2.2. The mode of project development / allotment:

The research policy of CCRS will be operative under the following schemes i.e. A,B,C as below:

SCHEME – A: Intra-Mural Research which is centrally initiated from headquarters, the design / protocol of the study will be formulated at central level in consultation with interdisciplinary experts, Principle Investigator, Co-investigator at the periphery (study sites). These may be unicentric /multi-center trials and monitoring will be done through CCRAS headquarters. Protocols will be approved by the PEMC and Institutional Ethics Committee.

SCHEME – B: Intra-Mural research project drafted by the scientists of the institute/Unit and approved by the Institutional Ethical Committee for conducting the study either unicentric / multicentric. Protocols will be approved by the PEMC.

SCHEME – C: (Collaborative Research) Council will call for expression of interes for research in the identified areas as detailed in part B of this Research Policy.

3. PRIORITY AREAS :

3.1 Fundamental Research

- Development of parameters to assess eight diagnostic tools and their clinical applications/Manikadai nool diagnosis/ Yakkai illakanam and their clinical applications /Effect of purgation-vomiting and nasiyam in elimination of diseases - maintenance of Mukutram, and Neerkuri-neikuri analysis.
- Redefining Six taste theory and its relationship with modern pharmacology and drug development. Validation of other principles related to collection of drugs and season / time wise/area/ acceleration / declination of potency / shelf life etc.

3.2 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 and its literature. Publication of Newer findings in Research. Redefining basic concepts with contemporary science.

3.3 Drug Research and Development

i. Ethno- medicinal Research: survey and documentation of medicinal plants/ practices etc.
ii. Pharmacognosy (related with Siddha drugs)
iii. Standardization and Quality Assurance related with Siddha drugs
iv. Pharmaceutical Research and Development related with Siddha drugs
v. Pharmacology related with Siddha drugs

vi. Biomarker based Mechanism of action related with Siddha drugs
vii. Veterinary/Marine products used in Siddha.

3.4 Clinical Research

3.4.1 Broad Areas

1. Validation studies with classical Siddha formulations (As existing in classics)
2. New indications of classical formulations (Formulation existing in classics, but indication is changed with some clinical experience)
3. Clinical studies with new drug combination derived from Siddha texts other than referral under D&C Act, from claim of physicians including traditional / folk claims or new dosage form from pre existing classical drugs/raw drugs of Siddha / Related areas / Specific areas.
4. Development of methods/ modalities/ protocols for Clinical Research of Siddha.
5. Epidemiological Research
6. Promotive and preventive health care / Kaya Kalpam.
7. R & D on Siddha Diagnostics (Inclusive of topics mentioned in fundamental research)
8. R & D on Varmam and Thokkanam interventions / Kara nool and Standardization of External therapeutic procedures / automation of instrumentation etc.

3.4.2 Diseases/ Areas based on Strength of Siddha/ National priorities :

i. Preventive Cardiology
   - Atherosclerosis
   - Hypertension
   - Dyslipidemia

ii. Gastro intestinal disorders
   - Hepatic Disorders
   - Diarrheas and chronic Enteropathies

iii. Musculo –skeletal disorders
   - Osteoporosis
   - Osteoarthritis
   - Rheumatoid Arthritis

iv. Eye diseases
   - Diabetic Retinopathy
   - Computer Vision Syndrome

v. Metabolic Syndrome
vi. Obesity
vii. Diabetes Mellitus and its complications
viii. Skin diseases.
ix. Respiratory Diseases.
x. Generalized Anxiety Disorder, Cognitive Deficit, ADHD,Autism, Mental Retardation

xi. Iron deficiency Anaemia
xii. Vector borne diseases
xiii. Benign prostatic hyperplasia, Urolithiasis
xiv. Para – surgical procedures : Kara nool for Fistula –in-ano, haemorrhoids, and, leech therapy for skin diseases &others
xv. Neurological, Neuro-muscular and Neuro- degenerative disorders
xvi. Kayakalpam & Geriatrics
xvii. Reproductive & Child Health (RCH)
xviii. Quality of life (QOL) in Cancer / HIV – AIDS patients.
xix. Siddha Dietetics

4. METHODOLOGY AND APPROACH

4.1 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 and these trials will be registered with Clinical Trial Registry of India (CTRI). 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 one centre, as assigned by the council's Hqrs. In case of multicentre studies the Principal investigator of coordinating centre is expected to register the trial with the CTRI for all the centers. It needs to be ensured that the clinical trial is registered with CTRI prospectively i.e. **before the recruitment of the first patient in the trial.**

As per the requirement of the CTRI format, the sponsor may be mentioned as CCRS. PI may be the person responsible for answering the scientific / public queries of Active mode projects and Head of the Institute may be the person responsible for answering the scientific / public queries.

4.2 Standardization, Safety / Toxicity, of the Trial Drug

If it is a classical formulation for validation studies, analysis report as per pharmacopoeial standards is to be procured from the manufacturer to match the pharmacopoeial standards laid in SPI. In case the pharmacopoeial standards are not available in SPI, the in-house standards may be developed under consultation of Botany and Chemistry section at SCRI, Chennai and SRRI, Thiruvananthapuram. The list of minimum standards required for various common dosages forms needed for IMR studies is annexed **(Annexure -4).** This may be subject to change if changed in National / International scenario.

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 laboratories. The quality analysis report of the trial drugs should be cross checked by Council's laboratory or any other GLP certified laboratory.**

4.3. Procurement of trial drug

The trial drugs should be preferably procured from -

i) SCRI, Chennai.

In case if it is not possible to procure from these pharmacies, the classical trial drug can be procured from IMPCOPS/TAMPCOL or any GMP certified govt. pharmacy or any other reputed WHO certified pharmacies (as per SOP). Before purchasing the trial drug, the Principal Investigator in Single centric trial or the Principal Investigator of the coordinating centre in multicentric studies must ensure the procurement of the quality assured trial drugs from the supplier following codal formalities.

4.4. When to procure the drug

After the project is duly approved by the Project screening Committee / PEMC, the Investigator must place the order for procurement of drugs, text reference, doses and total quantity required within one month of the approval under intimation to the Council Headquarters. **SOPs will be decided after discussion of Principal Investigator, Nodal officer, Gunapadam expert, Chemistry expert and drug manufacturer.**

5. Evaluation of Project feasibility

An Internal Screening Committee will be formed at CCRS Headquarters comprising of all Programme Officers under the Chairmanship of Director General, CCRS. This committee may meet twice a year or more and discuss all the Projects / Research ideas developed and submitted by the Council officers. The project proposals may be accepted / rejected or accepted with revision by this committee. If found suitable Director General, CCRS, may put forth the project in PEMC. Extension of the project may be given to other centres, as recommended by DG, CCRS and appraised to Project Evaluation and Monitoring Committee (PEMC).

Nodal officers and Programme officers at CCRS Headquarters will be deputed to coordinate all sorts of IMR projects / studies. They will be given due recognition during publication of concerned research papers / monographs.

Studies up to 100 Lakhs will be approved by DG, CCRS under scheme A & B. Approval of Standing Finance Committee will be obtained for studies amounting more than 100 Lakhs.

Funds will be provided to the in-charge of the Institute / Unit to which the Principle/ Lead investigator to the PI which can be recouped after submission of bills to the in-charge. Monitoring will be done through CCRS headquarters.

6. Laboratory investigations

6.1. For unicentric clinical studies

The institute and units under CCRS to be considered for projects under scheme A & B should have adequate infrastructure to pursue the research project(s) and in case, such facilities are not available, the same must be reflected in the project proposal to

develop the required facilities for upgrading the laboratories of the Institute or otherwise may be outsourced through accredited laboratories with justification.

6.2. For Multicentric clinical studies

The investigations may be outsourced to NABL/GLP accredited labs. If a particular NABL/GLP accredited lab is available near selected study centers in all the two / three states, it should be preferred so that the methods / chemicals / kits and reference values of lab investigations may be uniform and the study can generate data which is scientifically more significant.

7. Investigators of the Project

There will be one Principal Investigator and at least one Co-Investigator from the participating Institute [maximum two Co-Investigator(s) admissible]. 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.

7.1. Duration of the Project

All the projects submitted under the IMR policy are expected to be of minimum one year duration. However, the maximum duration should not exceed three years.

Change of the Principal Investigator

- Principal Investigators are encouraged to have at least one Co-Investigator (Co-I) in the project. So that, the Co-I can handle the responsibilities during leave / absence of the Principal Investigator.
- If for any reason the Principal Investigator leaves the project / is transferred / retires, an eligible Co-investigator may be considered as the Principal Investigator.
- In case of two Co-Investigators, the Principal Investigator will have to inform the Council, the Co-I responsible for the project during his / her absence.

8. MODE OF APPLICATION

8.1 The details of the IMR policy shall be available at Website of the CCRS: **www.siddhacoucil.com , www.siddharesearch.org**

8.2 The Principal Investigators have to submit their applications through proper channel to CCRS Hqrs. office.

8.3 Preparation of the Project:

The project proposal should be prepared in the format for application enclosed at **Annexure - 1a**

(Note - It is mandatory to submit the application in 1 hard copy and one soft copy in CD)

8.3.1. Clearance from the Institutional Ethics Committee (in case of human trials) or Institutional Animal Ethics Committee (for animal studies) of the Institute applying for the Research Proposal is mandatory. A certificate of clearance from the Institutional Ethical Committee (IEC) or Institutional Animal ethics Committee (IAEC) is essential before initiation of the study and for release of budget.

8.3.2. **Mode of application :** The Principal Investigator should submit a brief proposal through Director / In-charge of the Institute informing title of the study, objectives, names, qualifications and designations of himself (PI) and Co-Is, study plan , approximate budget, duration of the study and expected outcome(s) **(Annexure-1a)**.

9. Evaluation of Project Proposals

IMR - ISC (Intra Mural Research - Internal Screening Committee) comprising of the following members at CCRS Headquarters will evaluate the proposals for single centre pilot studies as well as for the Multicentre studies.

1.	Director General, CCRS	-	**Chairman**
2.	Research Officer, Scientist-II, (Tech.), CCRS Secretary	-	**Member**
3.	Programme Officers of CCRS Headquarters	-	**Member**
4.	Subject experts (As per requirement)	-	**Member**
5.	Admin.officer	-	**Member**

9.1 Term of reference of IMR - ISC

- Recommend suitable IMR projects.
- Call for 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 (as per their observations, if needed).
- Reject the proposals, if not found suitable.
- Review the progress report received from time to time by the council from the Investigator.
- Invite the Principal Investigator to bring the relevant papers and documents related to the projects (if necessary).
- Make on site visit, where the Principal Investigator would ensure their access to all the relevant research facilities and documents related to the project (if necessary).

The projects if found suitable will be forwarded to the IMR-PEMC to take a final decision.

9.2 IMR-Project Evaluation & Monitoring Committee (IMR-PEMC): The Research proposals will be evaluated by the Committee comprising of the following members:

1. Director General, CCRS - **Chairman**
2. 2 Subject Experts - **Member**

   (Co-opted members (Subject wise) as per necessity)
3. Epidemiologist - **Member**
4. Bio-Statistician - **Member**
5. Two representatives from the Department of AYUSH (Including one from Finance Division)
6. Research Officer Scientist -II,CCRS - **Member secretary**

9.3 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 for the Investigator/Co-Investigator for discussion (If required
- Invite comments from the expert(s) in the concerned field. (If required)
- Inform the applicants to modify their proposals (as per their observations)
- Reject the proposals, if not found suitable
- Review the progress report received from time to time by the council from the Principal Investigator.
- Invite the Principal Investigator to bring the relevant papers and documents related to the projects.
- The finally selected projects will be intimated to SAB of CCRS for information and inputs if any.

9.4 Ethical Clearance from Institutional Ethics Committee (IEC) / Institutional Animal Ethics Committee (IAEC) :

Once the project is approved by the IMR-ISC (as applicable) or the IMR-PEMC, it is the responsibility of the Principal-investigator and the concerned Head of the each Institution to convene a meeting of the IEC / IAEC (as applicable) to obtain the Ethical clearance. The IEC / IAEC approval needs to be communicated to the Council headquarters before initiation of the project.

9.5 Consultancy from outside experts: The protocols / research methodology can be developed through consultative process calling experts from relevant fields. TA/ Sitting fees may be admissible as per entitlement.

10. FINANCIAL SUPPORT:

10.1. The project cost shall be met from sanctioned budget of CCRS Headquarters from Research activities head. The sub-heads of the budget will be proposed by the Principal Investigator and finalized by the IMR–ISC / IMR–PEMC (as applicable). Multicentre projects beyond 1 Crore would be placed before SFC for approval.

10.2. The Laboratory investigation for the project will be carried out at the institute itself. In case some investigations are not possible to carry out at the institute, may be outsourced from NABL accredited laboratories following codal formalities. If NABL laboratories are not available in accessible areas, the investigations can be outsourced to reputed laboratories identified by internal committee at Institute level following codal formalities.

10.3. Release of funds and Operation of Accounts: The funds will be released to the concerned CCRS Institute in the following manner:

(i) 70% of the sanctioned amount will be released as 1st installment at the time of sanction of the project so as to facilitate the purchase of necessary equipment if any.

(ii) Remaining 30% of the sanctioned amount will be released as 2nd installment after submission of interim progress report and liquidation of UC of first installment subject to approval of the PEMC/ DG, CCRS in the capacity of chairman- PEMC.

(iii) Operation of Accounts: The project-funds will be provided to the institutes independent of the budget sanctioned to the Institute, and the funds will be provided and utilized for the said purpose as per the breakup approved by the Council. For all purchases pertaining to the project, codal formalities as per GFR will be observed.

(iv) The operation and utilization of accounts of the projects will be subject to internal audit.

11. PERSONNEL/STAFF:

11.1. Engagement of Project Personnel:

The Investigator may be given liberty to engage **JRF/ SRF/ Research associate/ DEO** as per the feasibility and need of the project with salary as per ICMR norms as adopted by CCRS **(Annexure-1b)**.

11.2. General terms and conditions for engaging temporary project manpower

- **Selection Committee**: A selection committee should be constituted at the CCRS institute level consisting of the members comprising of 1. Head of the institute (Chairman) 2. Principal Investigator (member)3. Subject-Expert /any other officer from the institute.

  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 not exceeding three years. Extension of tenure of this temporary

project-manpower may be done at the Institute's level based on the performance and recommendation of PI.

- The personnel will have no claim for regular/permanent appointment under the Council. **Their engagement will be co-terminus with the project.**

12. SUBMISSION OF REPORTS:

The following reports on the progress of work done under the research scheme will be submitted to the Council:

12.1. Progress Report

- Interim report on physical achievements is to be submitted to the council every six months till the completion of the project (**Annexure-2)**
- The Principal Investigator may be asked to present the progress before the IMR-Project Evaluation Monitoring Committee (IMR- PEMC), if considered necessary.
- At the end of each year, statement of expenditure should be submitted by the PI through proper channel. At the completion of the project audited Utilization Certificate should be submitted along with final report.

12.2. Final Project Completion Report

The final report should be sent in the prescribed format, **(Annexure-3)**. The report should be submitted within two months from the date of completion of the project.

13. MONITORING:

13.1. Local Monitoring:

The Head of the Institute would ensure periodic review and monitoring of the projects on going under the IMR Scheme at institute level and the same needs to be reflected in the monthly report of the institute that is communicated to the Council headquarters.

13.2. Central Monitoring:

A monitoring team for every project would be created at CCRS Headquarters The team will comprise of Programme officer, Nodal officer and any other officer deemed fit by the competent authority.

13.3. Under performance:

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

14. OUTCOME OF THE PROJECT:

The final outcome of the project will be evaluated by the PEMC (Project Evaluation and Monitoring Committee).

15. PRE-MATURE TERMINATION OF PROJECT:

During the course of the study, the IMR- Project Evaluation Monitoring Committee (IMR- PEMC) may recommend to the Director General, CCRS for termination of the study, if it is convinced that the study is not being done in accordance with the research proposal approved by the IMR- Project Evaluation Monitoring Committee (IMR- PEMC)/Director General, CCRS, or in view of any other Technical/Financial/Ethical irregularities. In such case, the Director General, CCRS would have the authority to revoke the funds given to the Principal Investigator, partially or fully, as recommended by the IMR- Project Evaluation Monitoring Committee (IMR- PEMC)

16. INTELLECTUAL PROPERTY RIGHTS AND PATENTS:

The patent will be jointly applied by the Council, and the Principal Investigator (s) of the project. The Council will make efforts to commercialize the product as applicable.

17. PUBLICATION:

The Principal Investigator must publish the research in peer reviewed journal after completion of the trial for getting a good project in the future. In case of multicentric studies the PI of the coordinating Institute or the nodal officer at headquarters will coordinate including names of all principal Investigators and Co-investigators who participated in the study.

ANNEXURE – 1a

Section A

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA
DEPARTMENT OF AYUSH, MINISTRY OF HEALTH& FAMILY WELFARE
GOVERNMENT OF INDIA

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

(Please furnish 1 hard copy and one soft copy in CD)

GENERAL

1. Title of the Research Project:

2. Institution responsible for the research project

Name:

Postal address:

Telephone:

Telegraphic address:

Fax:

E-mail:

3. 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:

   Telephone/ Mob:

   Fax:

   E-mail:

5. Time lines of Research Project:
   i) Period required for pre-study preparations like staff recruitment, purchase of equipment necessary permission:
   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.	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. Budget requirements (head wise and item 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				

Name, Designation and Signature of the:

a) Investigator(s) _____ _____

Name with designation **Signature**

b) Co-Investigator(s) _____ _____

Name with designation **Signature**

_____ _____

Name with designation **Signature**

Signature of the Head - CCRS Institute

Section – B

SUMMARY OF THE PROPOSED IMR PROJECT

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.	**Project cost**	**:**	

7. 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				

8.	**Duration of the project**	**:**	
9.	**Sample size with justification**	**:**	

10. Technical Part:

<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>** **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. Assessment parameters:** **xiv. Outcomes measures :** **a. Primary:** **b. Secondary:** **<u>Drug / Intervention references (Classical textual / SPI / SFI / Publications, if available)</u>:** **<u>Detailed posology (Dose/Duration/Anupana / Time of administration / Dosages form etc.)</u>:**
11.	**Milestone with deliverables:**
12.	**Expected outcomes:**
13.	**Applicability/Translational value / relevance in the light of AYUSH:**

Annexure – 1 b

The Para Medical/ Research Staff may be engaged according to the IMR project (with justification) Remuneration will be given on Contractual basis as per CCRS norms:

(i) Research Associate (RA)
(ii) Senior Research Fellow (SRF)
(iii)Junior Research Fellow (JRF)
(iv)Data Entry Operator (DEO)
(v) Lab. Technician / Lab. Attendant
(vi)Therapist

ANNEXURE- 2

FORMAT FOR THE INTERIM PROGRESS REPORTS
(every six months)

1. Project title

2. Investigator (name)

3. Co-I (name)

4. Date of sanction / release of money of the project

5. Date of initiation of the project (Recruitment of first patient in clinical trial or survey, standardization etc.)

6. Objectives/ deliverables with time line fixed for the project

7. Deliverables achieved during the reporting period as proposed in the scheme

8. Interim modification of objectives/methodology, if any (with justifications)

9. If deliverables are not met with timeline specified in the proposal then give reasons

10. Summary on progress (during the period of report)

11. Applied value of the project

12. Research work which remains to be done under the project

Signature of Investigator: **Date:**

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

ANNEXURE-3

FORMAT FOR FINAL REPORT

1. Title of the Project:
2. Investigator:
3. Co-Investigator:
4. Date of sanction / release of money
5. Date of commencement:
6. Duration:
7. Date of completion:
8. Objectives as approved:
9. Objectives achieved:
10. Deviation made from original objectives (if any):
11. Details of the work done, methodology adopted and results obtained with tables, charts, diagrams and photographs. (As available)
12. Causes of delay (if any) and partial achievement of target
13. Conclusions summarizing the achievements and indication of scope for future work.
14. 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/breakd own

15. Publication details.
16. IPR details (If any).

1. _____
(Investigator)

2. _____
(Co-Investigator)

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

ANNEXURE - 4

Parameters for testing Siddha drugs

1. **Raw drugs of plant origin(Latin name of the plant and part of the plant)** identification
   a. Macroscopic characterization
   b. Microscopic characterization
2. Physico-chemical constants
   a. Foreign matter
   b. Total ash
   c. Acid- insoluble ash
   d. Alcohol soluble extractive
   e. Water soluble extractive
   f. Loss on drying (110^{0} c)
3. Thin Layer Chromatography (TLC)(with photograph)
4. Assay for marker(if possible)

A. Siddha Dosage Forms

Sl. No.	Name of the Dosage form	Parameters
1.	**Churanam**	**Identification(mesh size of the curna)** Microscopy **TLC** **Identification test if any** **Physico-chemical parameters** 1. Loss on Drying 2. Total Ash 3. Acid-insoluble ash 4. Alcohol-soluble extractive 5. Water –soluble extractive 6. pH (10% aqueous solution) **Assay if any** 7.

		Other Requirements 8. Microbial Load 9. Aflatoxins 10. Heavy Metals & As 11. Pesticides
2.	**Tablet***	**Identification** Microscopy **TLC** **Physico-chemical Parameters** 1. Loss of Drying at 105^{o}C 2. Total Ash 3. Acid Insoluble Ash 4. Alcohol Soluble extractive 5. Water Soluble extractive 6. Disintegration time 7. Uniformity of weight 8. Friability 9. Hardness **Assay if any** **Other Requirements** 10. Microbial Load 11. Aflatoxins 12. Heavy Metals & As 13. Pesticides
3.	**Kulikai**	**Identification** **Microscopy** **TLC** **Physico-chemical Parameters** 1. Loss on Drying 2. Total Ash 3. Acid-insoluble ash 4. Alcohol-soluble extractive 5. Water –soluble extractive 6. pH (10% aqueous solution) 7. Disintegration time 8. Uniformity of weight 9. Friability 10. Hardness **Assay:** **Other Requirements**

		1. Microbial Load 2. Aflatoxins 3. Heavy Metals & As 4. Pesticides
4.	**Ilaham (Semi solid preparation)**	**Identification** **TLC** **Physico-chemical Parameters** 1. Loss on Drying 2. Total Ash 3. Acid-insoluble ash 4. Alcohol-soluble extractive 5. Water –soluble extractive 6. Reducing sugars 7. Non reducing sugars 8. Total tannins (if any) 9. pH (1% aqueous solution) 10. Assay if any **Other Requirements** 11. Microbial Load 12. Aflatoxins 13. Heavy Metals & As 14. Pesticides
5.	**Asava & Arista**	**Identification** **TLC** **Physico-chemical Parameters** 1. Total solids 2. Total Phenolic content 3. Specific gravity at 25^0C 4. pH 5. Reducing Sugar, 6. Non -Reducing Sugar 7. Alcohol Content 8. Presence of Methanol **Other Requirements** 9. Microbial Load 10. Aflatoxins 11. Heavy Metals & As 12. Pesticides
6.	**Nei (Semi-Liquid Preparation)**	**Identification** **TLC** **Physico-chemical Parameters** 1. Refractive index at 40^0 2. Specific gravity at 40^0

		3. Acid value 4. Saponification value 5. Iodine value 6. Peroxide value 7. Congealing point **Other Requirements** 8. Presence of Mineral oil 9. Microbial Load 10. Aflatoxins 11. Heavy Metals & As 12. Pesticides
7.	**Thailam**	**Identification** **TLC** **Physico-chemical Parameters** 1. Refractive index at 40^0 2. Specific gravity at 40^0 3. Saponification value 4. Iodine value 5. Acid value 6. Peroxide value **Other Requirements** 7. Presence of mineral oil 8. Microbial Load 9. Aflatoxins 10. Heavy Metals & As 11. Pesticides
8.	**Kashaya Churanam**	**Identification** Microscopy **TLC** **Mesh size:** All particles pass through 710 μm IS Sieve (old sieve number 22) and not more than 10 percent passes through 355 μm IS Sieve (old sieve number 44). **Physico-chemical Parameters** 1. Loss on Drying 2. Total Ash 3. Acid Insoluble Ash 4. Alcohol Soluble extractive 5. Water Soluble extractive 6. pH **Other Requirements** 7. Microbial Load

		8. Aflatoxins 9. Heavy Metals & As 10. Pesticides
9.	**Parpam**	**Physical Parameters** 1. Nature 2. Colour 3. tou 4. Lusture 5. Transparency 6. Magnetism (Loh based bhasma) *Density:* *Loss on Ignition* *Loss on drying at 130^0:* *Water Solubles:* *Acid Insolubles:* *Acid Insoluble Ash:* **Assay**- For particular element(s) of the Parpams
10.	**Herbo mineral drugs**	**Microscopy(for plant drug ingredients)** **TLC** **Chemical tests (Qualitative)** **Test for Dosage form (Kulikai/Tablet etc.)** **Physico-chemical Parameters** 1. Loss of Drying at 105^{o}C 2. Total Ash 3. Acid Insoluble Ash 4. Alcohol Soluble extractive 5. Water Soluble extractive 6. pH (in 5% aqueous clear solution) 7. Estimation of inorganic ingredients **Assay:** (Appropriate Phytoconstituents) **Other Requirements** 8. Microbial Load 9. Aflatoxins 10. Heavy Metals & As (if not inbuild) 11. Pesticides

Note:

1. The Standardization Parameters of dosages forms not covered above may be obtained from the Chemistry Section of the SCRI, if required.
2. Tablet dosages forms may clearly indicate the percentage of the excipient in the formulation
3. Subject to change in National / International guidelines in vogue.

PART – B: COLLABORATIVE RESEARCH POLICY

The Central Council for Research in Siddha Sciences (CCRS) is an autonomous organization under the Department of AYUSH (Siddha, Yoga & Naturopathy, Unani, Siddha and Homeopathy), Ministry of Health & Family Welfare, Government of India. It is an apex organization in India for the formulation, co-ordination, development and promotion of research on scientific lines in Siddha system of medicine. Collaboration is desired in the area where other organizations have more infrastructure facilities, expertise and technical inputs, funding participation etc. by CCRS will provide excellent scope for research which is not feasible only by one organization.

Proposed Areas of Research:

- Clinical Research: Clinical studies with new drug combination and/or new dosage form or new indication from existing classical formulations/single drugs of Siddha.
- Development of methods/ modalities for Clinical Research/ Instrumentation in Siddha.
- Mode of action of Siddha formulations (With Siddha parameters/modern parameters/both)
- Epidemiological Research
- Promotive and preventive health care / Kayakalpam procedures
- R & D on Siddha Diagnostics (Including Yakkaiyin ilakkanam and Pulse reading)
- R & D on Varmam and Thokkanam and Standardization of Varmam procedures.

Basis of Selection of Disease Condition / Area of Research:

- National Priority Diseases
- Strength areas of Siddha
- Mandate of the CCRS Institutes keeping in view the Infrastructure and expertise at the collaborative centers.

Selection of Collaborating Institutes:

1. The collaborating institute may be selected through specific call for Expression of Interest (EOI). The institutes will be selected as per rules. The number of institutes selected will be specific to the project proposal and will be decided case to case by DG, CCRS.

2. The “Institutes of National Importance” as intimated by Dept. of AYUSH (vide F. No. Z.15015/11/2010-COE (Pt.1) from time to time could also be invited by the council for participation in the study on the basis of lowest rates quoted by EOI (following point no.1). **(Annexure – I :** List of Institutes as per the report of Task Force Committee for identification of potential Collaborative Institutes with Research Councils under Dept. of AYUSH). It is obvious that such organizations have strength in a particular field or in several fields of research. Other similar organizations of ICMR, CSIR and autonomous organizations like PGI, Chandigarh, JIPMER, Puduchery etc. have also such repute. If council wants to conduct research in a particular disease / area then the execution modalities, funding pattern may be decided by mutual discussion on case to case basis.
3. Initiation of Collaboration with pharmaceutical industry to carry out research projects at CCRS Institutes may be decided by DG-CCRS with due approval of SAB and SFC. However, the expenditure incurred in the project and IPR will be shared equally by the council and the collaborator in such case. In such case, either the industry may come up with some leads or council may negotiate with industries to take up products developed by CCRS.

Steps of Initiation, Implementation and Monitoring of Collaborative Projects:

1. Selection of diseases condition and trial drug / conceptualization of hypothesis / research ideas / Investigational New Drug coming from claim / Clinical experience or coded drug with prior approval of Scientific Advisory Board (SAB)
2. Preparation of background papers/ dossier for proposed study.
3. Floating of EOI (**Annexure-II**, model EOI).
4. Selection of collaborating institutes on the basis EOI as per rules / direct discussion with reputed institutes.
5. Seeking of approval of SFC for projects budget exceeding 100 lakhs.
    a. Projects less than 100 lakhs will be approved by DG, CCRS
    b. In case of Multi centric trials, the total project cost would be cumulative of cost incurred in all participating centers
6. Signing of MOU with collaborating institutes (**Annexure-III**, model MOU)
7. Finalization of research protocol in consultation with subject experts and collaborating institutes.
8. Procurement and preparation of Trial Drugs.
9. Approval of IEC of the collaborating Institutes
10. Sanction and release of project funds
11. Registration in CTRI will be done by nodal officer approved by DG, CCRS for the collaborating Institute with CCRS as sponsor.
12. Initiation of project at collaborating institutes.

13. Time to time monitoring of the research projects by nodal officer / programme officer from CCRS.
14. The data generated by the collaborating institutes will be periodically submitted and analyzed at the Biostatistics Section, CCRS Hqrs.
15. The results/ outcomes of the study will be shared by CCRS as well as collaborating institute. Joint publication as scientific articles or monograph will be done with involved institutes of CCRS as corporate author.

Criteria and Responsibilities of Collaborating Institutes:

- **For Institution:**
  - (i) Government or Govt. autonomous Universities /Academic / Research Institutions having experience / expertise in R&D / Clinical Research in relevant areas.
  - (ii) Availability of infrastructures and experts to conduct research studies.
  - (iii) Availability of investigation facilities. The laboratory investigation will be centrally decided to maintain uniformity.
  - (iv) Availability of NABL accredited laboratories preferably in the institute or in the locality.
  - (v) IPR sharing will be done according to the proportion of research funding shared by the collaborating institute.
  - (vi) Seeking the Institutional Human / Animal Ethics Committee approval.
  - (vii) Compliance of requirements specified by Institutional Ethics Committee, Research Protocol, MoU, Ethics guidelines, Good clinical practices and other national norms.
  - (viii) Willingness to meet other requirements specific to the project.
  - (ix) Funding or exemption of intuitional changes.
- **For Investigators (from Collaborating Institutes):**
  - (i) Investigators must be well qualified post graduate and expert in concerned field with at least 5 years of experience in conducting clinical research.
  - (ii) In the proposed research / disease area with at least 2 peer reviewed indexed publications, preferably with impact factor.

Responsibilities of CCRS:

1. Finalization of research protocol in consultation with subject experts and collaborating institutes
2. Provision of trial drug
3. Implementation of the project.

4. Co-ordination and Monitoring of Research Activities -

   - The officer-in-charge/ Programme officer of project at CCRS Hqrs. and one officer from other CCRS peripheral institutes, if necessary would be deputed for visiting the collaborating institution and submit a report regarding progress of the project from time to time.

   - **Time points of monitoring visit:**

     - Within initial one month, before real execution of study / work i.e. enrolment of patients in the project (i.e. within one month of release of first instalment) – Investigators would be briefed about various issues such as adherence to protocol, filling of CRFs/e-CRFs, basic principles of ethics and good clinical practices and other relevant guidelines.

     - Within one month of submission of yearly reports.

     - Within one month of submission of study completion report.

     - A Project specific monitoring team would be constituted by the approval of DG CCRS. The members of this team would be empowered to verify copies of CRFs / laboratory reports / other source documents from the Investigators, if necessary.

Research Publication and Intellectual Property Rights:

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

b) Notwithstanding anything in paragraph (a) 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 institutes. Any financial benefit will be decided proportionate to the financial contribution made in the project or sharing may be decided by mutual discussion.

c) The research work will be published jointly by the CCRS and collaborating institutes. No study related research publication will be published without due permission of DG, CCRS. 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.

ANNEXURE – I

The "Institutes of National Importance" as intimated by Dept. of AYUSH
(Vide F. No. Z.15015/11/2010-COE (Pt.1)

List of Institutes as per the report of Task Force Committee for identification of potential Collaborative Institutes with Research Councils under Dept. of AYUSH –

(i) All India Institute of Medical Sciences, New Delhi

(ii) Defence Institute of Physiology & Allied Science (DIPAS), New Delhi

(iii) National Institute of Nutrition, Hyderabad

(iv) KEM Hospital, Mumbai

(v) National Institute of Mental Health and Neuro Sciences NIMHANS, Bangalore

(vi) Indian Institute of Integrative Medicine, Jammu

(vii) Central Institute of Medicinal and Aromatic Plants (CIMPAP), Lucknow

(viii) Central Drug Research Institute (CDRI), Lucknow

(ix) Central Institute of Psychiatry, Ranchi

(x) School of Tropical Medicine, Kolkata

(xi) Bose Institute, Kolkata

(xii) Sri Ramachandra Medical College, Chennai

(xiii) Bharat Hospital and Institute of Oncology, Bangalore

ANNEXURE-II

MODEL EXPRESSION OF INTEREST (EOI)

Sub: Expressions of interest for funding to support Siddha medicine research

1.0 The Central Council for Research in Siddha Sciences (CCRS) is an autonomous organization under the Department of AYUSH (Siddha, Yoga & Naturopathy, Unani, Siddha and Homeopathy), Ministry of Health & Family Welfare, Government of India. CCRS is an apex organization in India for the formulation, co-ordination, development and promotion of research on scientific lines in Siddha system of medicine.

2.0 Study : Multicentric Double Blind Randomized Controlled Clinical Study of Siddha Coded Drug 'Ayush–A' In the management of mild to moderate Persistent Bronchial Asthma)

Background

Swasakasam is a major cause of chronic morbidity and mortality globally and there is evidence that the prevalence has increased over the past few decades. As per the National Commission on Macroeconomics and Health report of 2005, it is estimated that there were roughly 2.5 crore cases of asthma in 2001 which may increase by nearly 50% by 2016. The primary goal of asthma care is to achieve and maintain control of the clinical manifestations of the disease for prolonged periods. When asthma is controlled, patients

can prevent most attacks, avoid troublesome symptoms and keep physically active with better quality of life.

Purpose

Siddha has documented effective treatment modalities in asthma care. However, the approaches have been insufficiently researched and have not been validated by conventional standards. For this purpose, coded drug combinations have been developed with pre-clinical studies and a protocol has been drafted in consultation with experts from Siddha and Medicine discipline. Hence, this multicenter, controlled randomized study is planned to evaluate efficacy and safety of the Siddha formulation.

OBJECTIVES

Primary Objectives

- To evaluate the efficacy of Ayush-A in the patients of mild to moderate persistent asthma.

Secondary Objectives

- To evaluate the safety of Ayush-A in the patients of mild to moderate persistent asthma.

STUDY DESIGN

- Study Design : Multicentric, double blind, randomized, controlled study.
- Study Centres : 3 Centres
- Sample size : 120 patients per centre
- Study Period per patient : 24 Weeks (12 weeks drug treatment and 12weeks of follow-up)

TIMELINES

- Total Study Period : 2 years
- Recruitment : 18 months
- Treatment & Follow-up Period : 6 months

STUDY GROUPS:

- Group-1 :
- Group-2 :
- Group-3 :

INCLUSION CRITERIA

1. Age between 18 to 60 years
2. Either sex with or without rhinitis

3. Mild to Moderate persistent cases of Asthma(as per WHO GINA Guideline) of duration more than 6 months
4. Asthmatics who meet reversibility criteria

   [12% and 200 ml improvement in FEV1 after two puffs of beta-2 agonist inhalation]
5. FEV1 > 60% of the predicted value
6. Non smoker
7. Written consent

EXCLUSION CRITERIA

1. Intermittent asthma, severe persistent asthma, status asthmaticus.

2. FEV1<60%.

3. Age below 18 years and more than 60 years

4. Associated diseases like left ventricular failure, COPD (Chronic Bronchitis, Emphysema), Upper respiratory tract obstruction, Bronchiectasis, cases of Tuberculosis, Interstitial lung disease/occupational Lung disease, Tropical Pulmonary Eosinophilia, Loffler's disease & Allergic Bronchopulmonary Aspergillosis etc.

5. Diabetes Mellitus

6. Hypertension.

7. Severe renal disease

8. Severe hepatic disease

9. Patient who needs rescue medication daily (salbutamol inhaler).

10. Known case of skin allergy

11. Pregnant/lactating mother

LABORATORY PARAMETERS

- **At Baseline:**

1. HbA1c
2. Fasting blood sugar
3. Sputum for AFB
4. Chest X-ray
5. ECG

- At **baseline, 4 weeks, 8 weeks, 12weeks, 16 weeks and 24 weeks:**

1. Hematology: Hb, TLC, DLC, Absolute Eosinophil count, ESR
2. Kidney function test: Blood Urea and serum creatinine

3. Liver function test: Total Bilirubin, Direct/indirect bilirubin, AST, ALT, Total protein, serum albumin/globulin, SAP, serum uric acid.
4. Serum IgE
5. Spirometry

3.0 CCRS will be the sponsoring authority responsible for providing trial drug, provision of study protocol and required funding for implementation of the study.

4.0 Eligibility Criteria for the interested applicants:

- **For Institution:**

(x) Government or Govt. autonomous/ Universities and Academic / Research Institutions having experience / expertise in R&D / Clinical Trials in relevant areas.

(xi) Availability of infrastructures and experts to conduct research studies.

(xii) Availability of investigation facilities. The laboratory investigation will be centrally decided to maintain uniformity.

(xiii) Willingness to meet other requirements of the project.

- **For Investigators:**

(iii) Investigators must be well qualified post graduate and expert in concerned field with at least 10 years of experience.

(iv) Past experience in conducting clinical research in relevant areas of at least 5 years with evidence of research publications.

(v) In the proposed research / disease area with at least2 peer reviewed indexed publications preferably with impact factor.

5.0 Information to be furnished by interested applicants:

(i) The application should be submitted by Principal Investigator through Head of the Institution. The application should include following aspects:

a. Background of the organization, availability of infrastructure and experts to conduct such studies.

b. Willingness of the Head of the Institution to provide required Administrative support and infrastructure facilities to conduct research.

c. CV of Principal Investigator and 1 or 2 Co-investigators with details of past experience in conducting clinical research, evidenced by publications.

d. Copies of 2 best relevant publications of PI should be attached.

e. Statement about infrastructure, human resource available in the department to conduct the proposed research study.

f. Availability of NABL accredited laboratories in the locality.

g. Participating centre will state whether they will share any proportion of funding or IPR.

7.0 Staffs admissible in this project would be one SRF (Siddha.) (Rs. 20,000/- + HR) & one DEO. The heads of budget are Salary to staff, cost of investigations, contingency, TA/DA. The interested Institutions may submit the estimated budget.

7.1 Officer from nearby CCRS Institute if exists will be participating in the project.

8. Interested organization should submit their Expression of Interest (EoI) in sealed envelope within 21 days from the date of advertisement, clearly marked "Expression of Interest for Research Projects" to the following address:

Director General,
Central Council for Research in Siddha
SCRI Building,Anna Hospital Campus,Arumbakkam,Chennai-106.

9. CCRS may seek additional information from the interested party (ies) following submission of EoI. However, Director General, CCRS reserves all the rights of rejections / acceptance of the EoI or inviting fresh EoI, if required so.

10 A pre-selection meeting (if necessary), may be organized for effective interaction with qualified, experienced and interested organizations for clarification of doubts, details of scope of work, etc. The date and venue for the same will be intimated after the EoI are assessed by CCRS. However, no TA/DA will be provided for this purpose.

11. Following such discussions, short listing of agencies may be done and detailed proposals, including fund requirement, will be invited for further consideration.

12. Applications received after due date will not be entertained. Director General, CCRS reserves the right to cancel this notice / process without assigning any reason thereof.

ANNEXURE – III

MEMORANDUM OF UNDERSTANDING

BETWEEN

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

(CCRS)

AND

XXX

This memorandum of understanding (MoU) entered into and executed on _____ day of _____, 2013 at _____, India, between **CENTRAL COUNCIL FOR RESEARCH IN SIDDHA,** a society registered under the Societies Registration Act 1860, having its office at SCRI Building,Anna Hospital Campus,Arumbakkam,Chennai-106. India acting through its Director General on the one hand of the first Part;

AND

XXX

_____, India on the other part.

Whereas, The Central Council for Research in Siddha (CCRS), an autonomous organization under Department of AYUSH, Ministry of Health and Family Welfare, is an apex body in India for undertaking, coordinating, formulating, developing and promoting research in Siddha sciences on scientific lines. The activities are carried out through 5 Institutes located all over India and also through collaborative studies with various Universities, hospitals and institutes. The research activities of the Council include Medicinal Plant Research, Drug Standardization, Pharmacological Research, Literary research & Documentation, and Clinical Research.

Whereas, **XXX**

AND WHEREAS CCRS had decided to undertake _____ study and had invited EOI by releasing an advertisement on (date) in (name of the newspaper).

AND WHEREAS, the EOI submitted by _____(XXX Institute) was considered and accepted by CCRS.

AND WHEREAS CCRS and _____(XXX Institute) have agreed to enter into and execute this Memorandum of Understanding agreeing on the terms and conditions set forth hereinafter:

HAVE AGREED TO as follows:

ARTICLE I

COMMENCEMENT & DURATION

1.1. This MoU will be effective from the date of signing of this MoU between CCRS and **(details to be added).**

1.2. This MoU will be valid for a period of (**number of years)** from the date when this MoU becomes effective.

ARTICLE II

OBJECTIVE

The Parties, subject to the terms of this Memorandum of Understanding and the laws, rules, regulations and national policies in force and as amended from time to time, agree to cooperate with each other in order to develop, strengthen and promote the study in the field of Siddha and to study _____. **(Details of any other objective may be added)**

ARTICLE III

AREAS OF COOPERATION

Each Party will, subject to the laws, rules and regulations, take necessary steps to cooperate with each other in order to develop, strengthen and promote the following and shall be governed by the laws of India.

In conducting clinical research study in Siddha entitled _____

ARTICLE IV

FINANCIAL ARRANGEMENTS AND OTHER CONDITIONS

The financial arrangements to cover expenses for the proposed clinical research study within the framework of this MoU shall be mutually agreed upon by both the Parties;

The terms and conditions in the execution of the research project shall be –

CCRS will be the sponsoring authority responsible for providing trial drug, provision of study protocol and required funding for implementation of the study.

XXX will be responsible for

1. Providing Administrative support and infrastructure facilities to conduct research.
2. Seeking the Institutional Ethics Committee (IEC) approval and Compliance of requirements specified by local IEC, Research Protocol, ICMR Ethics guidelines and Good clinical practices.
3. Utilization of the grant-in-aid funds for the purpose as specified in the sanction letter and the fund shall not be utilized for any other purpose whatsoever; and shall abide by all the General Financial Rules 2005 and any orders or instructions issued by CCRS from time to time.
4. In the event of any failure on the part of the executing Institution to abide any of the terms and conditions of the grant-in-aid specified in the sanction letter or committing any breach thereof, the CCRS will be at liberty to order to repay in full forthwith entire grant-in-aid fund or any part thereof with interest thereon at the rate of six percent (6%) per annum and any order made by CCRS in this respect will be final and binding on the executing institution and on receipt of such said order by the executing institution forthwith and without any objection shall pay to the Council such sum and the decision of the Director General, CCRS about the amount to be paid shall be final and conclusive.
5. Submission of monthly and annual progress report of the ongoing study to the CCRS.
6. The manpower sanctioned for assistance under this project will be employed on contract basis and the service of manpower will be terminated immediately after completion of the project.
7. After completion of the study, the executing institution shall furnish detailed study completion report, utilization certificate, and expenditure statement duly audited by the authorized Auditor / Charted Accountant along with unspent balance.

(Any other details, if any, in addition to the ones already stated in the draft MoU, may be added)

ARTICLE V

PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

d) The intellectual property rights of the parties shall be protected and enforced in conformity with the national laws, rules and regulations.

e) Notwithstanding anything in paragraph (a) above, the intellectual property rights in respect of any technological development, and any products and services development, carried out: jointly by the parties or research results obtained through the joint activity effort by the Parties, shall be jointly owned by the Parties; and in case of multicentric study, it would be jointly shared by all other parties involved in the study. Any financial benefit will be divided in the ratio of contribution. However, the decision of Director General, CCRS shall be final and binding with respect to percentage of sharing in this regard.

f) The research work carried out jointly by the parties will be jointly published by the parties, it would be jointly owned by the Parties; and in case of multicentric study, it would be jointly shared by all other parties involved in the study. However, the decision of Director General, CCRS shall be final and binding with respect to authorship and other issues in this regard.

ARTICLE VI

CONFIDENTIALITY

(a) Each Party undertakes to observe the confidentiality and secrecy of documents, information and other data received from, or supplied to, the other Party during the period of the implementation of this Memorandum of Understanding or any other agreements made pursuant to this Memorandum of Understanding;

(b) Both Parties agree that the provisions of this Article shall continue to be binding between the Parties notwithstanding the termination of this Memorandum of Understanding.

ARTICLE VII

REVISION, MODIFICATION AND AMENDMENT

(a) Either Party may request in writing a revision, modification or amendment of all or any part of this Memorandum of Understanding;

(b) Any revision, modification or amendment agreed to by the Parties shall be reduced into writing and shall form part of this Memorandum of Understanding.

(c) Such revision, modification or amendment shall come into force on such date as may be determined by the Parties; and

(d) Any revision, modification or amendment shall not prejudice the rights and obligations arising from or based on this Memorandum of Understanding prior or up to the date of such revision, modification or amendment.

ARTICLE VIII

SETTLEMENT OF DISPUTES

Any difference or dispute between the Parties concerning the interpretation and/or implementation and/or application of any of the provisions of this Memorandum of Understanding shall be settled amicably through mutual consultation and/or negotiation between the Parties. In case a difference or dispute arises between the parties and the same is not resolved through negotiation or by adopting amicable measures, the said difference or dispute will be settled through arbitration and the arbitrator shall be appointed with the mutual consent of the parties in terms of the Arbitration and Conciliation Act, 1996. The expenses of arbitration shall be borne equally by both parties.

ARTICLE IX

ENTRY INTO FORCE, DURATION AND TERMINATION

(a) This MoU shall come into force on the date of signing of this MoU and shall remain in force for a period of five years. The MoU may be extended for a further specific period on the expression of willingness to do so by both the parties. In this regard, the willingness to extend the Memorandum of Understanding must be expressed by both the parties, atleast six month prior to the date of expiry of the MoU.

(b) Notwithstanding anything contained in this Article, either party may terminate the Memorandum of understanding by notifying the other party of its intention to terminate the MoU by giving a three months notice in writing to the other party conveying its intention.

(c) The termination of this Memorandum of Understanding shall not affect the completion

and implementation of the on-going activities and programmes which have been agreed to be undertaken before the date of termination of the MoU.

In witness whereof the undersigned details to be added of details to be added and details to be added, being duly authorised to sign and execute this Memorandum of Understanding have affixed their signatures to this Memorandum of Understanding in the presence of the following witness.

A. For and on behalf of, CCRS
Director General,

CCRS

Date:

B. For and on behalf of,
Head of the XXX Institution

Date: Principal Investigator,

XXX Institution

Date: