Central Council for Research in Homoeopathy

(Under Deptt. of AYUSH, Ministry of Health and Family Welfare, Govt. of India)

Areas, Guidelines/Operative procedures of

Expression of Interest For Fundamental & Collaborative Research

61-65, Institutional Area, Opp. D-Block, Janakpuri, New Delhi–110058

Contents

Overview of CCRH ("The Council")

Central Council of Research in Homoeopathy (CCRH) is an autonomous Organization under the Department of AYUSH, Ministry of Health and Family Welfare, Government of India. The Council is involved in various research studies with reputed institutes. The mandate of the Council is to undertake multi-disciplinary, high quality research in the field of Homoeopathy. The Council undertakes, coordinates, develops, disseminates and promotes these researches undertaken on scientific lines.

Aims and Objectives of the Council

- Formulate the aims and patterns of research.
- Initiate, develop, undertake and coordinate scientific research in fundamental and applied aspects of Homoeopathy.
- Exchange information with other institutions, associations and societies interested in the objectives similar to those of the Council.
- Initiate collaborations of research studies with other Institutes of Excellence towards promotion of Homoeopathy.
- Propagate research findings through monographs, journals, workshops and develop audio-visual aids for dissemination of information to the profession and the public.

Fundamental Research

The practice of Homoeopathy arises strongly from a foundation of theoretical concepts, where scientists have taken up the challenge to work upon and establish these on scientific lines. The Council collaborates with various Institutes of Excellence to utilize the potential of the best of the brains, in order to yield the maximum results. The main objective of the collaborative studies is to conduct evidence-based, inter-disciplinary research studies and to validate the efficacy/concepts of Homoeopathy on scientific parameters. The current scientific advancement has made many studies possible, which has resulted in a dedicated group of scientists taking initial steps in translating the theoretical constructs to scientific principles.

There is identifiable interaction of ultra-high dilutions with living systems. However, comprehension of an explanation of mechanism of this interaction on the basis of present day understanding of science is in its nascent stages. CCRH has undertaken collaborative studies on basic research with scientific and technical institutes and organizations in the country having the required intellectual aptitude and the scientific resource.

Priority Areas for Collaborative/Fundamental Research

The Council will determine priority areas of research from time to time and encourage collaborative studies in these identified areas.

A. Evidence based clinical research in the following areas:

i. Cardio-vascular disorders
ii. Cerebro-vascular disorders
iii. Genito-urinary disorders
iv. Cancer and/or effects of chemotherapy/Radiation effects
v. Autoimmune Disorders
vi. Neurological disorders e.g. Alzheimer, Motor Neuron Disease, Dementia, Parkinsonism
vii. Metabolic disorders especially Diabetes mellitus
viii. Infectious diseases with special emphasis to Japanese Encephalitis, Dengue, Malaria, Chikungunya, HIV/AIDS, MDR Tuberculosis

B. Pre-clinical Studies on

i. System's Biology
ii. Genomic/Epigentic studies
iii. Demonstration of law of similar
iv. Cardio-vascular disorders
v. Cerebro-vascular disorders
vi. Genito-urinary disorders
vii. Cancer and/or effects of chemotherapy/Radiation effects
viii. Autoimmune Disorders
ix. Neurological disorders e.g. Alzheimer, Motor Neuron Disease, Dementia, Parkinsonism
x. Metabolic disorders especially Diabetes mellitus
xi. Infectious diseases with special emphasis to Japanese Encephalitis, Dengue, Malaria, Chikungunya, HIV/AIDS, MDR Tuberculosis

C. Scientific research on fundamental and basic principles of Homoeopathy

i. To elicit the mechanism of action of homoeopathic medicine in biological/physical models.
ii. To demonstrate the law of similar on scientific basis and to elicit their recognizable and recordable biological effects.

iii. To identify the nature of Homoeopathic medicines in ultra-dilution in potentised form, and to compare them with nature of vehicle used in preparation of medicine.
iv. To explore and establish the pathway of action of Homoeopathic medicines
v. To understand the influence of external factors on homoeopathic medicines?
vi. To ascertain the physico-chemical nature of homoeopathic medicines, and how they differ from their components.
vii. To ascertain the effect(s) of container on homoeopathic medicines.
viii. To understand Homoeopathy in Nano-domains

D. Agro-Homoeopathy studies

E. Veterinary Homoeopathy studies

i. Subclinical mastitis
ii. Diarrhoea
iii. Skin diseases
iv. Reproductive disorders (metritis, infertility etc.)
v. Wound/Injury management
vi. Disease related to decrease productivity in animals
vii. To enhance productivity of healthy animals

F. Drug development and standardization

i. Standardization and quality assurance
ii. Pharmaceutical Research and Development
iii. Pharmacological studies
iv. Technological issues of preparation of homoeopathic medicines

Eligibility of Institute/Scientist

- Reputed Institutes/Organizations (both Government and not-for-profit Private) having adequate infrastructure in terms of equipment and manpower to conduct high quality basic and fundamental research, or in the area proposed.
- Universities/Educational Institutions.
- Eminent scholars and Scientist, reputed institutions/organizations having good research background and contribution to the medical research can apply. However, preference will be given to the institutes.
- In the collaborative studies of this nature, the permanent employee(s) of the Council will be one of the Investigators and monitoring will be done through CCRH headquarters.

Mode of Application

The interested scientist/institute may submit "Expression of Interest" to CCRH, by submitting an application in the format given at **Annexure – I (A-C)** to the **Director General**, Central Council for Research in Homoeopathy, 61-65, Institutional Area, Opp. D-Block, Janakpuri, New Delhi-110058.

Steps of Collaboration

- Receiving application and concept paper(on priority areas related to Homoeopathy) from interested scientist/Institutions
- Shortlisting of scientist/Institutions for possible collaboration by the Expert Committee constituted for the same. See "Expert Committee"
- Informal meeting with identified scientists and the institute.
- Conjoint formulations of detailed protocols.
- External/Internal review of protocols by Expert Committee
- Approval of proposal by Scientific Advisory Committee/Special Committee(s) of the Council.
- Approval by the Standing Finance Committee of the Council
- Signing of MoU between institutes and scientists
- Release of funds to the Institution.
- Conduction of study for the approved duration.
- Monitoring of study.
- Reporting of results and conjoint publication of manuscript(s)

Processes

Scrutiny of Concept Proposal

After receipt of concept proposal, the Expert Committee will scrutinize the concept proposal and invite full proposal from selected institutes/scientist, whose concept note is shortlisted.

Expert Committee

The Council will constitute Expert Committee(s) for scrutiny/review of the concept paper/proposal submitted by Institute/Scientist(s). The committee shall be responsible for scrutiny of received proposals and their follow up action(s). The committee shall be comprised of:

1. Director General
2. Programme monitoring officer
3. Subject experts (02)
4. Homoeopathic experts (02)
5. Coordinator (Convener)

Development of full proposal

The proposal shall be developed conjointly by the Council and the institute/scientist and shall be submitted to the Expert Committee. During scrutiny the Expert Committee will invite two more scientist who are currently active in the relevant field. This may vary from proposal to proposal.

During scrutiny for finalization of full proposal, the Principal Investigator shall be invited for presentation before the Expert Committee.

Approval from Scientific Advisory Committee

Once approved by the Expert Committee, the proposal shall be placed before the Scientific Advisory Committee (SAC) of the Council.

Approval from Standing Finance Committee

Once approved by the SAC, the proposal shall be placed before the Standing Finance Committee (SFC) of the Council for financial approval.

Initiation of study and release of funds

Upon approval by the SFC, a Memorandum of Understanding (MoU) will be signed between the Council and collaborating institute. The funds will be released as per terms and conditions of MoU (Annexure – III).

Monitoring of Study

The Expert Committee shall monitor the study from time to time, and may invite Principal investigator for presentation of study results and/or visit the study site. If needed, Expert Committee may involve other scientist(s) for monitoring.

Expert Committee may also refer to Data Safety & Monitoring Board (DSMB) for interim review. DSMB shall be constituted for the studies wherever essentially required.

Maintenance of Accounts

The maintenance of the account for grant-in-aid sanctioned for the study shall be done as per terms of and conditions of MoU.

Annexure-I-A: Format for Concept Paper for Projects under Fundamental and Collaborative Research

Section A: General

1. Title of the Research Project:
2. Details of the Collaborating Institution
    a. Name
    b. Postal address
    c. Telephone
    d. FAX
    e. E-mail
2. Name and Designation of
    i) Principal investigator
    ii) Co- Investigator(s)
3. Details of other research project(s) taken up by the Organization/ Institute (completed and ongoing)

S. No.	Name of Client	Project Details	Duration of Project	Scheduled period of completion	Actual period of completion

4. Existing Resources and Facilities available at the Collaborating Institute related to project
5. Projects completed/ ongoing by Principal Investigator -

S. No.	Name of the Project	Date of inception of project	Date of completion of the project /expected date of completion of the project	Total Cost (in INR)	Grant received (in INR)	Status of the Project	Status of the utilization of grants as on date.

6. Declaration and Attestation: As per the Memorandum of Understanding to be signed between CCRH and Collaborating Institution
7. Details regarding Ethical Clearance Committee of the Institute
8. Brief summary of the proposed study (enclose separately as per Annexure-I-C).

Annexure-I-B: Bio-Data of the Principal Investigator & Co-Investigator(s)

1. Name :

2. Designation :

3. Complete Postal Addresses and PIN :

4. Mobile &Telephone Number(s), Fax, E-mail :

5. Date of birth :

6. Educational Qualification:

Degrees obtained with Institution

Degree	College/University	Subject	Year

6. Research Experience:

Duration	College / University	Particulars of work done

7. Other Experience (Apart from Research)

Duration (From-To) Institution Particulars of work done

8. Research specialization:

(Major scientific fields of interest)

9. Financial support received:

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

11. Other research projects, if any:

12. Recent publications (last 5 years, with titles and references), also papers in press:

Annexure-I-C: Brief Summary of the Research Project

[Adequate information must be furnished in brief but in a self-contained manner to enable assessment of the project.]

1. Project Overview and Executive Summary
   - 1.1 Non-Technical Summary (upto 200 words written for an informed, educated lay person)
   - 1.2 Technical Summary (must not exceed two pages)
     - 1.2.1 Importance/Significance/Relevance
       - 1.2.1.1 Rationale
       - 1.2.1.2 Background
   - 1.3 Approach/Methods
     - 1.3.1 Specific Aims/Objectives/Hypothesis
     - 1.3.2 Disease/Condition/Model
     - 1.3.3 Setting
     - 1.3.4 Population/Sample
     - 1.3.5 Study Design
     - 1.3.6 Inclusion/Exclusion criteria or Sample Conditions
     - 1.3.7 Intervention and Control Group(s)
     - 1.3.8 Endpoints and Measures
     - 1.3.9 Milestones of Project
     - 1.3.10 IPR values
2. Preliminary work already done by the Investigator on the subject, e.g. selection of subjects, standardization methods, earlier research work done.
3. Links with other project (s).
4. List of important publications over the last 5 years of the Investigator relevant to the project (enclose reprints).
5. Approximate Grant-in aid required:

Annexure-II: Past and Current Collaborators

Some of the Institutes with which Council has collaborated earlier are:

S. No	Collaborating Institute	Title of the study
1.	Jawahar Lal Nehru Institute of Post-Graduate Medical Education & Research (JIPMER), Puducherry	Effect of Homoeopathic drugs used in Insomnia on Serum Melatonin and Cortisol level in health volunteer.
2.	BARC, Trombay	Investigation into the action of Homoeopathic potencies on Autonomous nervous system and variability in physiological parameter using indigenous Impedance Plethosmography (IPG), Vasomon / Medical analyzer (MA) and Anu Photo-rheography on healthy human subjects.
3.	Jamia Hamdarad, New Delhi	Studies on Homoeopathic medicine for the treatment of Cerebral Ischemia.
4.	Osmania University, Hyderabad.	Effect of Homoeopathic drugs on Central nervous System and their safety evaluation,
		Efficacy & safety evaluation of Homoeopathic drugs in experimental study – Endocrinological study.
5.	Homoeopathic Research Foundation, Lucknow	To evolve a group of most efficacious Homoeopathic Medicines in Bengin Prostatic Hyperplasia with regard to improvement in the symptom complex.
6.	School of Tropical Medicine, Kolkata	Effect of Homoeopathic Medicine on Japanese Encephalitis Virus infection on chorio-allantoic membrane (CAM) & suckling mice.
7.	Central Institute of Medicinal and Aromatic Plants, Lucknow	To evaluate the biological activity of five coded Homoeopathic drugs on plants using Bacopa Test as model system
8.	Central Institute of Psychiatry, Ranchi	An open clinical trial to ascertain role of Add on Homoeopathic therapy in the management of Schizophrenia.
		An open clinical trial to ascertain role of Add on Homoeopathic therapy in the management of

		Depression.
9.	IIT, New Delhi	A structural study of homoeopathic medicine; A pilot study
10.	High Security Animal Diseases Laboratory, Bhopal, Madhya Pradesh	Anti-viral activity (therapeutic efficacy) of Homoeopathic medicine in Avian influenza in animal model.
11.	Bose Institute, Kolkata	Role of homoeopathic medicines in cancer regression and rejuvenation of depressed immune system.
12.	Society for promotion of Youth & Masses, New Delhi and Darjeeling.	A multicentric open clinical study to evaluate the efficacy of indicated Homoeopathic medicines. I) In the management of lapse of alcohol and opioid drug addictions II) in the management symptoms of withdrawal symptoms of alcohol and opioid drug addiction and III) in the prevention of relapse of alcohol and Opioid drug abuse & Masses,
13.	RMRC (ICMR), Port Blair	Anti-leptosprial activities of Homoeopathic medicines.
14.	Safdarjung Hospital, New Delhi	Comparative Study on HIV/AIDS with antiretroviral drugs and add on Homoeopathic drugs.
15.	Defence Institute of Physiology & Allied Sciences, Delhi	Exploration of the Utility of GDV Camera as a Diagnostic Instrument in the Areas of Homoeopathic Fundamental Research - A pilot study
16.	Dr. ALM Post Graduate Institute of Basic Medical, University of Madras.	Studies on anti-diabetic properties of Homoeopathic preparation of Syzigium jambolanum and Cephalandra-indica.
17.	Dr. ALM Post Graduate Institute of Basic Medical, University of Madras.	Protective role of Homoeopathic preparation of Berberis vulgaris to alleviate kidney stone disease and its influence on molecular events leading to Calcium oxalate crystal deposition.
18.	AIIMS, New Delhi.	Changes in Electro-Physiological markers in muscle fatigue with homoeopathic preparation of

		Arnica montana – A comprehensive study.
		Safety and efficacy studies of Homoeopathic drugs
		Preliminary pharmacological studies of Homoeopathic drugs
19.	Central Drug Research Institute, Lucknow	Pharmacological evaluation of homoeopathic medicines.
20.	Sri Aurbindo Institute of Integral Health and Research, Cuttack	Efficacy of Homoeopathic Therapy on duration of labour
21.	School of Biotechnology, West Bengal University of Technology, West Bengal	In vitro studies of some Homoeopathic medicines on the proliferation and differentiation of neural stem cell.
22.	Indian Veterinary Research Institute, Izatnagar, UP	To evaluate certain homoeopathic medicines for their immuno- modulatory and antioxidant potential

Annexure – III: Format for Memorandum of Understanding

Title of the study:……..

1.0 THE AGREEMENT

1.1 THIS AGREEMENT made and entered into on -- day of --, --, between Central Council for Research in Homoeopathy, a Society registered under the Societies Registration Act (XXI of 1860), having its registered office at Jawahar Lal Nehru Bhartiya Chikitsa Avum Homoeopathic Anusandhan Bhawan, 61-65 Institutional area opposite D-block, Janakapuri, New Delhi -110058 (herein after called CCRH which expression shall where the context so admits include its successors and permitted assigns) of the one part.

and

1.2 ---------- (hereinafter called the ----------which expression shall where the context so admits include its successors and permitted assigns) of the other part.

2.0 PREAMBLE

2.1 WHEREAS CCRH under its research activities collaborates various research schemes that include Clinical Verification research, Clinical research, Drug Proving, etc. **2.2.** WHEREAS the CCRH is desirous of collaborating with the ----------on the project entitled "……."(hereinafter called the PROJECT) to be carried out at----------.

The period of project shall be for ---- year w.e.f. --

It will be a collaborative study between the CCRH and the ----------. The Co-ordination team and the Investigators in the PROJECT shall be as given below:

STUDY TEAM

A. **Principal Investigators**
B. **Investigators**
C. **Coordination:**

Now, therefore, in consideration of the premises and mutual covenants hereinafter contained, the parties hereto agree as follows:

3.0 SCOPE OF THE AGREEMENT

The agreement details the terms and conditions, financial arrangements, modalities of collaboration, intellectual property right, responsibilities and obligations of the ----------.

4.0 FINANCIAL ARRANGEMENTS

4.1 CCRH and Collaborating Institution shall bear the financial inputs under its Collaborative Research Study for the Study entitled "_____" as agreed on the basis of project approved.

4.2 Financial Support: CCRH will provide financial support for staff and contingencies-recurring and non-recurring as approved for the project and duration of study according to terms of release (4.7).

4.3 Expenditure for monitoring of the project to be carried out by independent experts/ institutions selected by the CCRH would be met by the CCRH.

4.4 Contingencies

4.4.1 Non-Recurring: Essential scientific equipments may be permitted as non-recurring expenditure. However, the quantum of such expenditure will not be more the 25% of the total budget of the project. The equipment though shall be property of the CCRH, but these will be used for research for future studies too and shall be accessible to CCRH whenever required and on completion of the study, all equipment should be transferred to any nearby Institute/unit of CCRH for its use for a specific project.

4.4.2. Recurring: The expenditure of recurring nature such as financial support for staff's salary, medicine, chemicals and glassware's ,investigations, animals, printing & stationary, postage, photo copying may be allowed to be purchased as a part of the recurring contingencies.

4.5. Traveling Allowance: Traveling Allowance/Daily Allowance (TA/DA) of the Investigators will be permitted for attending the meetings for monitoring and field-work within the sanctioned fund. Foreign tour will not be allowed. TA/DA will be allowed only as per TA rules of Govt. of India.

4.6 Certificate of Non receipt of parallel grants

The grantee Institution/individual shall furnish the certificate to the effect that the said Institution/individual has not been sanctioned grant for the same purpose from any other Deptt. of Central/State Govt. or agency during the period for which the grant has been sanctioned by CCRH.

4.7 Release of Funds

The head-wise grant-in-aid will be released to the Head of the Institution in installments as yearly/half-yearly as per the study proposal. The first installment will be released along-with the sanction letter. It would include the grant for non-recurring and recurring expenditure for the period of one year/six months. The next installment would be released after receiving the following documents in the prescribed proforma.

- Technical Progress Report.
- Utilization Certificate & Expenditure Statement
- Mid-term appraisal by monitoring committee or expert(s) after presentation by the Principal Investigator/site visit report.

4.8 Maintenance of Accounts

The Institution/ Individual shall open new A/c and maintain separate account exclusively with the bank in the name of the Institution/Individual and the same should be operated jointly at least by two Office bearers. The accounts of the grant shall be maintained properly and separately from the normal activities of the institution/Individual.

The project becomes operative with effect from the date on which the Draft/Cheque is received by the implementing institution. This date should be intimated by the institution authorities/Principal Investigator to the CCRH within one month.

A set of audited statement of these accounts duly signed by responsible officers as mentioned in para 4.10 shall be furnished to CCRH after utilization of the financial support from CCRH. Further, these accounts shall be open to inspection by the sanctioning authority and internal audit by the Accounts Officer of the CCRH, whenever the grantee Institution is called upon to do so.

4.9 Re-appropriation

Expenditure incurred should not exceed the sanctioned budget against one or more sub-heads of expenditure such as staff salary, TA/DA, contingency etc. within the overall sanctioned ceiling of that study.

Re-appropriation of fund from one primary head to another primary head is permissible upto

15% to cover excess of expenditure over authorized limits provided total expenditure does not exceed the total sanctioned budget.

No expenditure shall, however, be incurred by re-appropriation of savings on items not sanctioned by the CCRH, i.e. non-consumable equipment, store etc. Savings shall also not be re-appropriated for meeting or incurring expenditure on staff that has not been sanctioned by the CCRH.

The institute should ensure that while submitting the final UC & expenditure statement, the above norms shall be strictly followed. Excess expenditure, if any, may be borne by Institute.

4.10 Utilization Certificate & Expenditure Statement

Utilization Certificate in Form GFR 19A (**Annexure - V**) & Head-wise Expenditure Statement is required to be submitted to the CCRH immediately after utilization of amount released with certified and signed by the following responsible officers:

i) UC & ES should be duly **certified** by the Head of the Finance/Accounts Deptt. i.e. Finance Officer/Account Officer, if it is a Govt. Organization/Institution whose Accounts are being audited by Comptroller & Auditor General of India (CAG) as per rule 211 (1) (2) of GFR and duly **signed** by the Principal Investigator & Head of the Institution; followed by an audit of the accounts by the Accounts Officer, CCRH, New Delhi.

ii) UC & ES should be duly **certified** by Chartered Accountants (CA) for all others organization/institution as per rule 211 (3) of GFR and duly **signed** by the Principal Investigator & Head of the Institution; followed by an audit of the accounts by the Accounts Officer, CCRH, New Delhi..

4.11 Refund of fund

Unspent Balance, if any, must be refunded to the CCRH through Demand Draft in favour of Director General, CCRH, New Delhi on completion/termination of the Study.

The grant released by the CCRH shall be refunded in full by the institution along with 18% interest per annum when the Investigator discontinues the Study midway or does not follow the detailed technical programs laid down as approved.

The interest earned on financial support from CCRH in Bank A/c should be reported to the CCRH and reflected in the Expenditure Statement. The interest earned shall be refunded to CCRH, New Delhi or will be adjusted towards further installment of grant.

4.12 General Financial Conditions

The entire grant should be exclusively utilized only for the research activities for which it has been sanctioned within the specified period. The grant will not be regarded as a subvention towards the normal work of the Institution.

Expenditure should not exceed the sanctioned financial support for the study.

All items (other than sanctioned by CCRH for the study) i.e. basic equipment and ordinary laboratory chemicals, glassware, furniture and other assistance, shall be provided by the institute for the smooth working of the research study.

Ten percent (10%) of total sanctioned budget of the study will be retained by CCRH, New Delhi till satisfactorily conclusion of the study and submission of the peer- reviewed report of study for publication in the journal(s).

The CCRH, New Delhi reserves the right to terminate the project at any stage, if it is convinced that the grant has not been properly utilized or appropriate progress is not being made.

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5.0 MODALITIES OF COLLABORATION

5.1 The responsibilities of the ----------and schedule of fulfillment thereof shall be as per the guidelines of CCRH. CCRH will provide the financial assistance based on the project proposal submitted by ----------.

5.2 The execution of the project will be monitored by a committee chaired by the Director General, CCRH or his nominee every six months. The Investigator(s) will make a presentation before the experts or a site visit may be arranged. The final outcome of the Project will be evaluated by the expert group who will give their recommendation to the CCRH.

5.3 There will be a Data Monitoring Committee (DMC) for the PROJECT. The DMC shall consist of Scientists nominated by CCRH. The DMC shall review (every six months) the progress of the PROJECT.

6.0 RESPONSIBILITIES OF THE ----------

6.1 Necessary Institutional facilities will be provided if the research project is approved for financial assistance

6.2 All records and reports related to the project shall be shown and furnished to the authorized representatives of the CCRH or Department of AYUSH.

6.3 Project shall be open for evaluation of the physical progress and utilization of funds to the discretion of the competent authority. A periodical report of the progress of the project shall be given by the Investigator every month.

6.4 The grantee organization/Individual agrees to submit within one month from the date of termination of the project, final report and a list of articles, both expendable and non-expendable left on the closure of the project.

6.5 No portion of the grant will be utilized for furtherance of a political movement, prejudicial to the security of the Nation

6.6 The grantee will not indulge in corrupt practices.

6.7 Maintenance of Stores

6.7.1 The items purchased out of the grant of the CCRH shall be entered in the separate stock register maintained for the purpose and the same shall be properly kept in the store and presented to auditors for check and endorsement, as and when desired. The usual forms prescribed for this purpose by the grantee institution should be used for these registers and all purchases made in accordance with the procedure in vogue in the institution.

Only such equipment for which provision has been made in the budget shall be purchased.

All the non-expendable articles purchased out of the funds of the CCRH will be the property of the CCRH. However, the equipment/instruments/machines, etc. purchased out of the grant can be retained, on submission on a term and condition laid down under **4.4.1** of this MoU.

General terms and conditions of appointment

Appointment will be of temporary and contractual nature for a maximum period of the duration of the period;

The staff employed for the term of the study will be subject to the rules and administrative control of the institute and will be appointed in accordance with the normal recruitment rules and procedures of the concerned institute.

The scales of pay allowances etc. applicable to the staff of the scheme shall not in any circumstance exceed the limit as mentioned in the proposal of the study.

The CCRH will not be liable to bear any expenditure on pension/ provident fund contribution and leave salary contribution incurred or committed by the grantee for persons appointed on deputation from any other organization.

Allowance (CCA), Bonus, Leave Travel Concession (LTC) and medical benefits are not admissible to any category of project staff.

If the PI to whom a grant for a project has been sanctioned wishes to leave the Institution where the project is based, the Institute/ PI will inform the same to the CCRH and in consultation with CCRH, evolve steps to ensure successful completion of the project, before relieving the PI.

7.0 COMPLETION

7. 1 The work envisaged to be done by the ----------shall be deemed to have been successfully completed by the ---------- (on submission of the Final Report/fulfillment of its/their responsibilities as detailed in their project proposal)

7.2 The PROJECT shall be deemed to have been successfully completed on satisfaction of criteria fixed by the DMC or any other criteria mutually agreed by the parties hereto.

8.0 RESULTS OF PROJECT

8.1 The intellectual property that is copyrights, generated in the collaborative PROJECT shall be jointly owned by the CCRH and the ----------. The CCRH will bear all the expenditure involved in patent procedure. However, the technology developed out of the Project is the sole property of CCRH and it has full rights to transfer the technology to any Industry of its choice.
If the results of research are to be legally protected, the results should not be published without action being taken to secure legal protection for the research results.

8.2 The procedural formalities for securing and maintaining the intellectual property rights (copyright) if any shall be the joint responsibility of the CCRH and the ----------.

8.3 Publication: The parties shall consult each other for any publication in respect of the PROJECT and it will be joint publication. These publications (papers, reports etc.) shall be in the names of Principal Investigator and research workers of both CCRH and ----------, wherein it will be duly acknowledged that the work has been carried out under the collaborative programme between the parties.

8.4 Patents

The CCRH shall have the right to file patents in respect of inventions/discoveries made under a scheme/project financed by the CCRH. The Officer-in-Charge or the staff employed in this project shall not apply or obtain patents for any invention/discovery made by them without prior approval of the CCRH.
All patents will be registered with **NRDC** in the name of the Central Council for Research in Homoeopathy, New Delhi, India.

8.5 Source Documents

8.5.1: Photocopy of completed case records should be sent to CCRH Headquarters on monthly basis.

8.5.2: At the end of the study, the original source documents should be submitted to the CCRH. However, a photocopy of these documents may be kept by the PI/----------.

9.0 CONFIDENTIALITY

9.1 During the tenure of the agreement

Thereafter both the CCRH and the ---------- undertake on their behalf and on behalf of their sub-

contractors / employees / representatives / associates to maintain strict confidentiality and prevent disclosure thereof, of all the information and data exchanged/ generated pertaining to work under this agreement for purposes other than in accordance with this agreement. Both parties, however, retain the rights to use the R &D results generated during the PROJECT for its own R &D programmes without any obligation to the other.

10.0 UTILIZATION OF INTELLECTUAL PROPERTY DEVELOPED

10.1 The CCRH shall have the full rights for commercially exploiting the intellectual property generated in the allotted PROJECT

11.0 FORCE MAJEURE

11.1 Neither party

shall be held responsible for non-fulfillment of their respective obligations under this agreement due to the exigency of one or more of the force major events such as but not limited to acts of God, war, flood, earthquakes, strike, lockouts, epidemics, riots, civil commotion, etc. provided on the occurrence and cessation of any such events, the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force-major conditions continue beyond six months, the parties shall then mutually decide about the future course of action.

12.0 EFFECTIVE DATE, DURATION & TERMINATION OF THE AGREEMENT

12.1 These terms and conditions will be valid for a period of one year and its extension/continuation or otherwise shall be jointly decided by CCRH and ---------- two months prior to the end of above period. However, the rights/obligations arising from the implementation of this agreement shall survive the termination of the agreement.

12.2 The agreement shall be effective from …….. and shall remain in force for a period of one year from the said date. The agreement shall terminate on the expiry of the period, unless extended by both the parties.

12.3 During the tenure of the agreement, parties hereto can terminate the agreement either for breach of any of the terms and conditions of this agreement or otherwise by giving three month notice in writing to the defaulting party. Failure of either party to terminate the agreement on account of breach or default by the other shall not constitute a waiver of that party's right to terminate this agreement.

12.4 In the event of termination on the agreement vide Clause 12.3, the right and obligations of the parties thereto shall be settled by mutual discussion; the financial settlement shall take into consideration not only the expenditure incurred but also the expenditure committed by the parties hereto.

12.5 The agreement arrived at between the parties for the utilization of the intellectual property shall survive the termination of the agreement.

13 NOTICES

13.1 All notices and other communications required to be served on the ----------under the terms of this agreement shall be considered to be duly served if the same shall have been delivered to, left with or posted by registered mail to the ----------. Similarly, any notice to be given to the CCRH shall be considered as duly served if the same shall have been delivered to, left with or posted by registered mail to the CCRH at its registered address in New Delhi.

14 AMENDMENTS TO THE AGREEMENT

14.1 No amendment or modification of this agreement shall be valid unless the same is made in writing by either the parties or their authorized representatives and specifically stating the same to be an amendment of this agreement. The modifications/changes shall be effective from the date on which they are made / executed, unless otherwise agreed to.

15 ASSIGNMENT OF THE AGREEMENT

15.1 The rights or/and liabilities arising to any party to this agreement shall not be assigned except with the written consent of the other party and subject to such terms and conditions as may be mutually agreed upon.

16 ARBITRATION

In the event of any dispute or differences between the parties hereto, such disputes or differences shall be resolved amicably by mutual consultations.

16.1 If such a resolution is not possible, then the unresolved disputes or differences shall be referred for attribution, as per the Indian Arbitration and Conciliation Act, 1996. In which, DG, CCRH shall be the arbitrator, whose decision shall be final & biding.

17. Jurisdiction

The courts at New Delhi shall have the exclusive jurisdiction in case of any dispute between the parties.

SEAL OF PARTIES

In the witness whereof parties hereto have signed this agreement on the day, month and year, mentioned hereinbefore.

For and on behalf of ----------	**For and on behalf of CCRH**

Signature with Seal	**Signature with Seal**
Name:	**Name:**
	Designation: Director General
Designation:	
Signature Witness	**Signature Witness**
(Name & address)	**(Name & address)**
1.	**1.**
2.	**2.**

Annexure – IV: Format for Detailed Proposal

1. **Detailed Description of the Proposed Research**
   - **1.1 Specific Aim/Objective/Hypothesis**
     - **1.1.1 Primary Objectives**
     - **1.1.2 Secondary Objectives**
   - **1.2 Background**
   - **1.3 Preliminary data**
   - **1.4 Approach/Methods**
     - **1.4.1 Disease condition/Model**
     - **1.4.2 Setting**
     - **1.4.3 Population/Sample**
     - **1.4.4 Study design**
     - **1.4.5 Inclusion/Exclusion criteria, sample conditions, sample size**
     - **1.4.6 Intervention and Control group(s) and their allocation**
     - **1.4.7 Randomization procedure and type of randomization**
     - **1.4.8 Material and Methods used and their sources or production procedures**
     - **1.4.9 Parameters to be studied including their sensitivity, reliability etc.**
     - **1.4.10 Procedure along with nature and description of reagents.**
     - **1.4.11 Outcome measures and endpoints (primary / secondary / intermediary)**
2. **Analysis and statistical approaches, stopping points and continuation criteria (with justification and rationale of choosing appropriate statistical tests).**
3. **Milestones and Timeline of the project**
4. **Expected Outcomes and anticipated results**
5. **References used in the proposal (Vancouver style)**
6. **Budget requirements (head wise and item wise) with detailed break-up year wise and with full justification regarding**
   - **6.1 Manpower requirement along with Salary (including technical and non-technical persons)**

6.2 Equipment

6.3 Books

6.4 Other Non-Recurring Expenditure

6.5 Recurring Expenditure

6.6 Travelling allowance

6.7 Institutional Support Fee (if applicable)

6.8 Appropriate fee of PI and Co – PI

6.9 Miscellaneous expenses, if any.

7. Communication

7.1 Name of journal(s) to which manuscript will be submitted (or intended to be submitted)

7.2 IPR values

Annexure – V: Form GFR 19A Format

(Name of Institution)

(Full Address)

Form GFR 19-A

[See Government of India's Rule 212 (1)]

Utilization Certificate

Sl.No	Sanction Letter No. & Date	Amount
1		
	Total	

Certified that out of **Rs** _____ of grant-in-aid sanctioned by Central Council for Research in Homoeopathy, Deptt. of AYUSH, Ministry of Health & Family Welfare, Govt of India vide letter no. given in the margin during the year _____ in favour of _____(Name of Institution) and **Rs** _____ on account of unspent balance of the previous year, a sum of **Rs.** _____ has been utilized for the Collaborative Study entitled "_____ _____ _" and that the balance amount of **Rs.** _____ remaining unutilized at the end of the financial year _____ has been surrendered to CCRH, New Delhi (vide DD No. ____ dated _____). / will be adjusted towards the grants-in-aid payable during the next financial year _____.

2. Certified that I have satisfied myself that the conditions on which the grants-in-aid was sanctioned have been duly fulfilled/are being fulfilled and that I have exercised the following checks to see that the money was actually utilized for the purpose for which it was sanctioned.

Kind s of Checks exercised.

1.
2.
3.
4.
5.

(Chartered Accountants)
(With Seal & date)

Signature

Designation Project Investigator Finance/Accounts Officer, Head of Institution,

Seal

Date