

**OPERATIVE PROCEDURES/ GUIDELINES
FOR
EXPRESSION OF INTEREST (EOI)
FOR
COLLABORATIVE RESEARCH
IN**



**CENTRAL COUNCIL FOR RESEARCH IN UNANI
MEDICINE**

61-65, Institutional Area, Opposite 'D' Block, Janakpuri, New Delhi-110058
(Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH),
Government of India)

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Overview of CCRUM (“The Council”)

Central Council for Research in Unani Medicine (CCRUM) is an autonomous organization under the Ministry of AYUSH, Government of India. The Council is involved in multifaceted research studies through a network of 22 institutes functioning in different parts of the country. Council’s research programmes are executed through intra mural and extra mural modes. Research programmes include pre-clinical safety and pharmacology, clinical research, cultivation of raw drugs, preparation of compound formulations and their standardization and historical and literary research. The Council undertakes, coordinates, develops, disseminates and promotes above research activities on scientific lines.

Aims and Objectives of the Council

- To undertake collaborative research programme for conducting clinical trial and other research programme in Unani medicine.
- Assistance in research, for the propagation of knowledge and experimental measures generally in connections with the causation, mode of spread and prevention of diseases.
- To initiate, aid, develop and coordinate scientific research in different aspects, fundamental and applied, of Unani Medicine, and to promote by assisting institutions of research for the study of diseases, their prevention, causation and remedy.
- To exchange information with other institutions, associations and societies interested in the objects similar to those of the Central Council and especially in observation and study of diseases.
- Print, publish and exhibit papers, posters, pamphlets, periodicals and books for furtherance of the objective of the Central Council and to contribute to such literature.
- To finance enquiries and researches for the furtherance of objective of the Central Council for Research in Unani Medicine.

Objectives of Collaborative Research programme

- The Council is established to scientifically validated the fundamental concepts of Unani medicine as well as to generate adequate statistical data to support claims of efficacy and safety through experimental and clinical research using modern tools in areas in which Council and its institution do not have sufficient facilities and expertise and vice versa.
- Under this scheme the Council is taking a new initiative to undertake collaborative programme with an aim to establish firm links with state of art, Institutions of Excellence which have expertise and facilities in order that collaboration research provides globally acceptable results.
- Through collaborative studies CCRUM desires to utilize the available infrastructure and facilities created for a period of time and provide adequate funds for fellowship and consumables so that health related benefits to be occurred can be maximised from the given resource.

Priority Areas

The priority area of research of the Council is a dynamic process and revisited from time to time. Presently Council encourage collaborative studies in these identified areas.

- A. Translating classical/clinical experience through evidence based experimental research in the following areas.
 - i. Auto immune diseases
 - ii. Lifestyle disorders like cardiovascular, obesity, diabetes mellitus and cognitive impairment.
 - iii. Viral infections
 - iv. Adjuvant therapies to counter side effects of conventional medicines like cancer chemotherapy, anti tuberculosis drugs, anti retroviral drugs, epileptic drugs etc.
 - v. Diseases originating due to radiation effects.
- B. Modulation of immune mechanism in infectious diseases.
- C. Scientific Validation of fundamentals and basic principles of Unani Medicine
- D. Safety and pharmacology of Unani drugs
- E. Pharmacokinetics and Pharmacodynamics of Unani drugs
- F. Exploring the mechanism of action and ascertain the physico-chemical nature of the drugs
- G. Molecular co-relation/genetic co-relation studies to understand temperament of drugs
- H. Redesigning of various dosage forms as per need and requirement
- I. Developing organ-specific immunomodulators
- J. Co-opting Nano techniques for Unani formulations

Eligibility conditions for Collaboration

- Reputed Institutes/Organizations (Government/non Government/registered NGOs) having adequate infrastructure in terms of equipment and manpower to conduct high quality research.
- Universities/Educational Institutions.
- Eminent scholars and scientist working in reputed institutions/organizations having good research background and who have made contribution to the bio-medical including clinical research areas.
- In the collaborative studies, the Council's scientists will be one of the Investigators and monitoring will be done through CCRUM Headquarters.

Process of scrutiny for collaborative programme

- Receiving application and concept paper (on priority areas related to Unani Medicine) from interested Scientists/Institutions
- Reviewing concept paper as given in the application form and Short listing of scientist/Institutions for possible collaboration by CCRUM in the presence of experts of concerned discipline or sub-committee members.
- Informal meeting with short listed scientists of the reputed institute.
- Conjoint formulations of detailed protocols
- External/Internal review of protocols by Scientific Advisory Committee/Special Committee(s) of the Council.
- Review of the finalized proposal by Standing Finance Committee of the Council
- Signing of MoU between CCRUM/Institutes and scientists
- Release of funds to the institution
- Review of progress and monitoring
- Reporting of results

Terms and Conditions

- (a) The grant-in-aid will be subject to the conditions and principles laid down in Rules 148 to 151 GFR and government of India's decision there under as amended from time to time as well as the other specific conditions enumerated in annexure to this letter.
- (b) The expenditure on Pay & Allowances and other recurring contingencies are covered by the specific sanction of the Council and also that the staff engaged on the project performed the functions for which the grant is given should be ensured.
- (c) The grant-in-aid will be paid by Demand Draft on receipt of the under mentioned documents and after all the requirements mentioned in this sanction have been fulfilled by the grantee.
 - a. The grantee should give an undertaking in writing that the grantee agrees to be governed by the conditions of the grant mentioned in this letter.
 - b. The grantee should furnish a certificate.
 - That the person signing the undertaking is duly authorized to operate upon and bind the funds of the units.
 - That the grantee is not involved in any proceeding relating to the accounts of conduct of any its office bearers.
 - That the grantee has not been sanctioned grant for this purpose by any other Ministry/Department/Organisation of the Central Government during the period to which this grant relates.
 - That all rules and instructions are being followed and the prescribed documents are being maintained.
- (d) The grant-in-aid should be utilised within a period of one year from the date of receipt of the money for the purpose for which it is sanctioned.
- (e) If the grant or any part there of is proposed to be utilised for a purpose other than that for which it is sanctioned prior approval of this Council should be obtained by the grantee.
- (f) The grantee will not, without the prior sanction of the Council, dispose of encumber or divert the use for any other purpose of permanent and semi-permanent assets that may be created or acquired out of the grant. If and when body is dissolved, the assets are reverted to Council.
- (g) The grantee should maintain a register in Form GFR 19 of all assets acquired out of this grant. This register is required to be maintained separately in respect of each sanction and two copies of the extract of the same duly signed by the grantee be furnished to this Council annually.
- (h) The register of the assets maintained by the grantee should be available for scrutiny and audit or any other person authorised in this behalf by this Council.
- (i) The Council reserves the right to have the accounts and other records of the grantee inspected by the Comptroller and Auditor General of India, if and when occasion demands in order to satisfy themselves regarding the manner of utilization of the grants and the way in which the affairs of the Institution are being managed.
- (j) The accounts of the grantee should be open for test check and regular audit by the Comptroller and Auditor General of India at his discretion.
- (k) The grantee should keep the Director General, Central Council for Research in Unani Medicine, New Delhi informed of the progress of the scheme by submitting quarterly progress reports for the quarter ending every year.
- (l) The grantee should forward to this Ministry a signed utilization certificate along with the Audited Statement of Accounts reflecting therein the grant and the item by item expenditure incurred therefore duly certified by a Chartered Accountant/AG and detailed statement of accounts, progress report and other requisite documents as soon as possible after the close of the financial year.
- (m) While applying for the release of further grant-in-aid in Audited Statement of Accounts for the previous year will have to be sent.
- (n) The grantee shall not indulge in corrupt practices.
- (o) No portion of the grant shall be utilized for furtherance of a political movement prejudicial to the security of the Nation.

Format for Concept Paper for Project under 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
3. Name and Designation of
 - i) Principal Investigator
 - ii) Co-Investigator(s)
4. Priority area selected for developing concept paper and the proposal
5. Duration process for collaborative Research Project:
 - a) Period required for pre trial preparations
 - b) Period needed for collecting the clinical trial data
 - c) Period for analyzing the data
 - d) Period preparing manuscript and submit to a peer review journal
6. Amount of Grant in aid asked for:

Particulars	1 st year (Rs.)	2 nd year (Rs.)	3 rd year (Rs.)	Total (Rs.)

7. Details of other research project(s) taken up by the Organization/Institute (completed and ongoing)

S.N.	Name of funding organization	Project Details	Duration of Project	Scheduled period of completion	Actual period of completion

8. Existing Resources and Facilities available at the Collaborating Institute related to project.
9. 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

10. Declaration and Attestation: As per the Memorandum of Understanding to be signed between CCRUM and Collaborating Institutions.
11. Details regarding Ethical Clearance Committee of the Institute.

Bio-Data of the Principal Investigator & Co-Investigator(s)

1. Name :
2. Designation:
3. Complete Postal Addresses and PIN code:
4. Mobile & Telephone Number(s) Fax, E-mail:
5. Date of Birth:
6. Education Qualification:
Degrees obtained with Institution

<u>Degree</u>	<u>College/University</u>	<u>Subject</u>	<u>Year</u>
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7. Research Experience:

<u>Duration</u>	<u>College/University</u>	<u>Particulars of work done</u>
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8. Other Experience (Apart from Research)
Duration (From-To) Institution Particulars of work done
9. Research Specialization:
(Major Scientific Fields of interest)
10. Financial support received:
11. Research Projects in hand under any other Grant in aid scheme of Government of India:
12. Other research Projects, if any:
13. Recent publications (last 5 years, with titles and references), also papers in press:

Brief Summary, timeline, deliverables and scope of the Research Project in the priority area

(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 (up to 200 words written for an informed, educated lay persons)
 - 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.

MoU for Collaboration

To be developed jointly

BOND

This bond made this the _____ day of _____, _____ between _____, an association registered under the Societies Registration Act, _____ and having its office at _____ in the _____ hereinafter called the 'obligor' (Which expression shall unless excluded by or repugnant to the context be deemed to include its successors-in-interest) of the First part and the President of India hereinafter called 'the Government') of the Second part; WHEREAS at the request of the obligor, the Government have sanctioned a grant-in-aid of _____ vide their letter _____ (hereinafter referred to as the said letter) which forms an integral part of these presents and a copy whereof is annexed hereto and marked with the letter 'A' for the purpose of and on condition of the obligor executing a bond in favour of the Government on the terms and conditions and the manner hereinafter contained which the obligor has agreed to do.

Now, this Bond Witnesseth and it is hereby agreed and declared as follows:

1. That the obligor shall utilise the said grant-in-aid of _____ only for the purpose of specified in the said letter and for no other purpose whatsoever.
2. That the obligor shall abide by all the terms and conditions specified in the said letter and the General Financial Rules 1963 and any orders or instructions that may be issued by Government from time to time.
3. That in the event of any failure on the part of the obligor to abide any of the terms and conditions of the grant-in-aid specified in the said letter or his committing any breach thereof, the Government will be at liberty to order the obligor to repay in full (forthwith entire grant-in-aid amounting to _____ only or any part thereof with interest thereon at the rate of six percent (6%) per annum and any order made by Government in this respect will be final and binding on the obligor and on receipt of the said order of the obligor forthwith and without any objection pay to the Government such sum not exceeding a sum of _____ only plus interest thereon as may be fixed by the Government and the decision of the Secretary to the Government of India in the Ministry of AYUSH about the amount so to be paid shall be final and conclusive.
4. The society/trust agrees and undertakes to surrender/pay to the Government the monetary value of all such pecuniary or other benefits which it may receive or derive/have received or derived through/upon unauthorised use (such as letting out the premises for adequate or less than adequate consideration or use of the premises for any purpose other than that for which the grant was sanctioned) of the property/building/created/acquired /constructed largely from out of Government grant. The decision of the Secretary, the Government of India in the Ministry of AYUSH as regards to the monetary value afore mentioned to be surrendered/ paid to the Government of India will be final and binding on the Society/Trust.
5. Upon the obligor utilising the grant-in-aid only for the purpose specified in the said letter and abiding by fulfilling and performing all the terms and conditions of the said letter the above written obligation shall be void and no effect but otherwise it shall be and remain in full force effect and virtue.

PROVIDED always and it is hereby agreed and declared that the decision of the Secretary, Ministry of AYUSH as to whether the obliger has or has not performed and observed the obligations and conditions herein before receive shall be final and binding.

6. The stamp duty on the bond shall be borne by the Government INWITNESS whereof these presents have been signed by _____ and _____ for and on behalf of the obliger and _____ for and on behalf of the President of India on the dates appearing against their respective signatures.

Signed by:

1. _____ dated _____ and

2. _____ dated _____

1. Signature _____

2. Signature _____

1. Witness

Name and Address

2. Witness

Name and Address

Signed by _____ dated _____ for and on behalf of the President of India in the presence of:

Signature _____

1. Witness

2. Witness

(Each page of the bond has to be signed by the two office bearers of the institution who are authorised to operate upon and bind its funds).

Undertaking

PROFORMA FOR UNDERTAKING / CERTIFICATE

To,

The Director General,
Central Council for Research in
Unani Medicine,
New Delhi

**Subject: Release of grant-in-aid under the Short Term Research Inquiry
furnishing of undertaking /certificate/pre-stamped receipt – regarding.**

Sir,

With reference to your letter No.
_____ dated _____ sanctioning
Rs. _____ lakhs (Rupees
_____ only) as 1st instalment of grant-in-aid under the scheme
for short term research inquiry for undertaking the research project titled
“ _____ ”, I
hereby submit the following undertaking / certificate / document:

1. The terms and conditions of the grant-in-aid are acceptable to this organisation;
2. It is certified that this organisation is not involved in any proceeding relating to the accounts or conduct of its office bearers;
3. Being Non Government Organisation, this organisation has executed necessary bond;
4. A ‘pre-stamped receipt’ is enclosed herewith.

It is requested that necessary crossed Demand Draft may be issued in favour of
_____ at the earliest.

Signature of Principal Investigator

Signature of Registrar/Finance Officer/Head of Department/Principal/Dean

Pre-Receipted Bill

PRE-STAMPED RECEIPT

Received Demand Draft No. _____ dated _____ for Rs.

(Rupees _____)
only from the Central Council for Research in Unani Medicine (CCRUM), (Ministry of AYUSH,
Government of India) towards 1st instalment of grant-in-aid under the Collaborative Research
Programme with CCRUM for undertaking the research project titled
“ _____ ”.

Affix one Rupee Revenue Stamp
--

(_____) Signature of Head of the Organisation
with Official seal

FORMAT FOR ANNUAL STATEMENT OF ACCOUNTS
(to accompany request for release of next instalment)
(Year means Financial Year, i.e., 1st April to 31st March of next year)

1. Sanction Order No.:
2. Total Project Cost: Rs.
3. Sanctioned/ Revised Project cost (if applicable): Rs.
4. Date of Commencement of Project:
5. Statement of Expenditure:

S. No.	Sanctioned/ Heads	Funds Allocated	Expenditure Incurred			Balance as on (Date)	Requirement of Funds up to 31 st March	Remarks
			1 st Year	2 nd Year	3 rd Year			
1.	Salary							
2.	Equipments							
3.	Books							
4.	Other Non-Recurring Expenditure							
5.	Recurring Expenditure							
6.	TA/DA							
7.	Institutional Support							
8.	Appropriate fee of PI and Co-I							
9.	Miscellaneous expenses							
Total								

**Signature of
Principal
Investigator with
date**

**Signature of Head of
Institution with date &
Seal**

**Signature of Registrar
with date & Seal**

GFR 19-A
FORMAT FOR UTILIZATION CERTIFICATE (ANNUAL/FINAL)
(To be submitted in original)

Name of the Institution:

Department:

Principal Investigator:

Title of the Project:

S. No.	Sanction No. & Date	Amount Sanctioned	Certificate
			<p>Certified that out of Rs. of Grant-in-aid sanctioned during the financial year in favour of for the first/ second/ third year by the CCRUM (vide Sanction Order No., Cheque/DD No. dated) and Rs. on account of unspent balance of the previous year, a sum of Rs. has been utilized for the purpose of for which it was sanctioned and that the balance amount of Rs. remaining unutilized as on 31st March, 20..... has been surrendered to CCRUM (vide letter No., Cheque/DD No. dated)/ will be adjusted towards the grant-in-aid payable during the next year, i.e.,</p>
Total			

Certified that I have satisfied myself that the conditions on which the grant-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.

Kinds of checks exercised:

1. Sanction Order copy of CCRUM.
2. Statement of Expenditure

**Signature of
Principal
Investigator with
date**

**Signature of Head of
Institution with date &
Seal**

**Signature of Registrar
with date & Seal**

**NO FINANCIAL ASSISTANCE CERTIFICATE
(To be submitted on Institution Letter Head)**

This is to certify that no financial assistance has been received from any other Department of central or state Government/ Organisation/ Institutions /DBT/DST/CSIR/ AIIMS/ICMR. etc. for the project entitled “.....”
.....”
to the Principal Investigator (Name) and
Co-Investigator (Name) of
..... (Name of the Institute).

**Signature of
Principal
Investigator with
date**

**Signature of Co-
Investigator with date**

**Signature of Head of
Institution with date &
Seal**