CCRUM INTRA-MURAL RESEARCH POLICY-2013

CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE

DEPARTMENT OF AYUSH, MINISTRY OF HEALTH & FAMILY WELFARE

GOVERNMENT OF INDIA

CCRUM INTRA-MURAL RESEARCH POLICY-2013

1. BACKGROUND

Health is a fundamental right of the people. This has also been accepted by the World Health Organization (WHO). In India, different systems of healthcare like Ayurveda, Yoga, Unani, Siddha and Homoeopathy (AYUSH) have had a long and cherished tradition and are still in vogue. For centuries, these systems have been serving the health needs of the people. To develop these various Indian systems of medicine on scientific parameters, the Government of India established a Central Council for Indian Medicine and Homoeopathy (CCRIMH) in 1969. In 1978, the CCRIMH was split into four independent Central Research Councils - one each for Ayurveda and Siddha, Unani, Yoga and Naturopathy, and Homoeopathy under the Ministry of Health & Family Welfare on the lines of the Indian Council of Medical Research (ICMR). The Central Council for Research in Unani Medicine (CCRUM), which started functioning in 1979, is engaged in multidisciplinary research through its centres in different parts of the country. At present, 23 centres of the Council are functioning in different States. These include two Central Research Institutes, seven Regional Research Institutes, and the rest are smaller Units. These centres were established at different point in time in the last three decades. Some of them, established in recent years, do not have the critical mass, adequate infrastructure, nor they are fully equipped. As a result, their capacity and capability are of different order for conducting clinical / fundamental / pharmacological research. Only few Institutions of the CCRUM are at preferred locations. In the Council, efforts were made to prioritize research areas and to initiate good quality research by the limited scientific staff of the Council.

As a result of sustained efforts, a good number of single and compound Unani drugs have been standardized, and have been documented as pharmacopoeial drugs published in nine volumes of *Unani Pharmacopoeia of India*. Simultaneously, Standard Operating Procedures (SOPs) were developed for manufacturing processes of compound drugs. Besides, SOPs for various Regimenal therapies of Unani system of medicine were also developed. Also, emphasis was laid on ethno-botanical survey, collection and cultivation of Unani medicinal plants and dissemination of knowledge generated through research conducted by CCRUM. Clinical trials of Unani drugs were conducted at the centres of CCRUM on self-designed clinical trial protocols. To develop required capacity and

capability for clinical research especially Pharmacology, there was always a challenge to get our products acceptable at international arena.

2. GENESIS

Government of India is committed to promote scientific research in AYUSH Systems of Medicine. This aspiration is reflected in National Health Policy documents of 1983 and of 2002 as well as in National Policy on Indian Systems of Medicine and Homoeopathy 2002. In these policy documents, emphasis has been laid on reorientation, prioritization of research in AYUSH as a whole and to validate therapy and drugs in chronic and lifestyle-related diseases. In 2007, ICMR formulated for the first time it's Health Research Policy to guide health research in this sector. An in-house SWOT evaluation exercise was undertaken in CCRUM. The analysis indicated that sincere and concerted attempts were made in the past to conduct comprehensive and meaningful multidisciplinary research in accordance with the fundamental concepts of Unani System of Medicine. Therefore, the organization can be credited for attaining few leads in the areas of clinical research and drug standardization research, but the organization lacks a definite and comprehensive formal IMR policy like ICMR and similar other organizations. Such a policy when put in place shall give research a direction, and the output would get regularly monitored, and would be open to international evaluation. Also, the implementation of such a policy is essential for optimal utilization of the system's strengths and its global acceptance. It will enable the CCRUM centres to formulate their own research programmes, and work thereon in a time bound manner. It was felt that in order to create acceptable scientific evidence on known Unani formulations a comprehensive approach through a clearly defined and efficiently functional intramural research policy needs to be formulated and documented and made available in the public domain.

In view of the above, the CCRUM officers and scientists working at the headquarters prepared an initial draft of the Council's Intramural Research Policy with an expectation that once implemented; this will give a meaningful direction to research and help utilize fully the potentials of the scientists of the Council. This initial draft document was placed before the Council's Scientific Advisory Committee (SAC). It was felt that the Council needed to have a well-documented IMR policy so that the scientists engaged in research at the Council's centres could carry out and complete their research projects in a self-

estimated time frame through assured funding. The SAC appreciated the idea of developing an IMR policy for the CCRUM and agreed in principle that such a policy should be formulated, discussed thoroughly, and once finalized it should be implemented. The SAC members went through the initial draft of the policy and made several suggestions. They observed that as the policy will have wider implication in future, the prepared draft should also be seen by others who are experts in policy making and need to be refined by the Council with their consultation. In the meantime, the Council might consider sensitizing the scientists working at its Central/Regional Institutes through Brainstorming sessions, Workshops and Interactive meetings, and accordingly taking necessary steps. The SAC felt that this step was necessary as it would be helpful in preparing them in advance towards the change that is being brought in. As per directions of the SAC, this exercise was carried out by inviting In-charges / Scientists of different CCRUM Institutions. In these meetings, it was noticed that the work and the mindsets of the scientists were changing in the right direction.

However, the work in the core area i.e. Clinical Research, is still being influenced by the Bio-molecular approach of Western Medicine rather than the Unani, Mizaj-based approach. Secondly, on the one hand the basic elements of modern research, such as a clear-cut Primary Endpoint, determination of Sample Size on the basis of the magnitude and variability of the desired Difference in Response etc., are not being fully implemented and, on the other hand, some optional elements such as Blinding etc. are being considered sacrosanct. Hence, keeping in view the above,

To give right direction and optimum speed to its IMR, the Council will adopt a two-point strategy:

(1) The IMR will adopt both the following approaches:

(i) Essentials of modern research methodology, and

(ii) Methodology based on Kulliyat-e Tib (Fundamentals of Unani Medicine).

(2) The IMR will promote dynamism among the scientists of the Council and optimal utilization of their potential in implementing the Research Projects of the Council, and in providing feedback to improve and develop next-stage Research Projects.

The present policy document henceforth will be referred to as **CCRUM IMR Policy-2013**.

3. EXPECTATION

The policy document should serve as a motivation point and push the scientists to convert their research ideas into meaningful project proposals. Enhanced capacity and capability and need-based training programmes should increase their confidence and performance. Depending upon the mandate of the Institutes, the policy should help enable them to acquire needed infrastructure and equipment in adequate quantity in identified priority areas in the coming years. Thus the Council as a whole should be able to conduct clinical studies in identified areas through well-designed and expert-generated protocols. Besides, it should validate pharmacopoeial drugs in identified diseases, and develop protocols for quick relief drugs and newly-designed Unani products.

4. AIMS AND OBJECTIVES

The corner-stone of the CCRUM IMR Policy would be the fundamental principles laid down in The National Health Policy, 1983 and reiterated by The National Policy on Indian Systems of Medicine and Homeopathy 2002 that:

"….it was necessary to initiate measures to enable each of these various systems of medicine and health care *to develop in accordance with its genius*."

Thus, the aim of research at CCRUM would be to enable optimum practice of Unani Medicine in contemporary times *according to its traditional character*.

The IMR policy will have the following aims and objectives:

(i) To validate theories and philosophies of Unani Medicine and apply them in both basic and applied research.

(ii) Identification, standardization and quality control of single and compound drugs and development of SOPs for formulations.

(iii) Survey and cultivation of medicinal plants to ensure availability of genuine raw drugs.

(iv) Documentation and validation of folk medicinal claims.

(v) To undertake preclinical and toxicological studies for development of new formulations.

(vi) To accelerate research on development of new drugs.

(vii) To conduct Clinical studies especially on new emerging diseases where conventional modern system of medicine has little to offer.

(viii) Validation of Clinical efficacy/safety of Unani classical/ pharmacopoeial formulations including adjuvant therapy and validation of Ilaj bit Tadbeer.

(ix) To conduct Literary and theoretical research in Unani Medicine including philosophy of Medicine, and critical review, editing and translation of classical texts.

(x) To undertake high quality basic research for generating translational value for Unani system of medicine.

(xi) To explore new disease indications of existing pharmacopoeial drugs.

(xii) To identify areas of promising early stage research including analytical review, pre-clinical research, pilot studies and observational research.

(xiii) To organize focussed group meetings, workshops, training programmes for enabling scientists to turn outputs into outcomes.

(xiv) To introduce systems for facilitating the replication of published results and validation of research products.

(xv) To set up think tank to accelerate research, e.g. new Unani drugs discovery.

(xvi) To organize regular IPR training so that innovation occupies centre stage.

(xvii) To preserve sand validate classical diagnostic methods such as Nabz (pulse examination).

(xviii) To develop mechanism for preservation of traditional knowledge of Unani medicine from bio-piracy.

5. BROAD AREAS OF RESEARCH

The basic purpose of Research at the Council would be to develop new drugs as well as validate traditional Unani therapies and drugs by adopting appropriate modern research methodology and technology but without losing the system's traditional character. To serve this purpose, the Council has set the following as priority areas of Research:

a. Clinical research in the priority areas including new drug development and clinical Validation of pharmacopoeial drugs,
b. Validation of various modes of Ilaj bit Tadbeer and Important Unani Treatments
c. Experimental Pharmacology of Important Unani Drugs

d. Phytochemical studies, drug standardization, and Pharmacognostic Studies of Important Unani Drugs
e. Collection, Translation, Editing, Elucidation, Compilation and Publication of Classical Information
f. Scientific validation of Basic Principles of Unani Medicine
g. Collection, Analysis, Review and Dissemination of Research Findings

6. IMPLIMENTATION : GUIDELINES

The IMR Policy has been designed to cover all centres of the CCRUM. The policy will be implemented initially at such centres as have adequate infrastructure, manpower and capacity, followed by other centres that are in developing stage. The guidelines for implementation of the policy are as follows:

1. Depending upon the core strength and the current manpower, each centre of the Council should identify areas of priority out of those mentioned in the policy document. These areas should be discussed either in the SAC or at the CCRUM headquarters for finalization.
2. Once the areas are finalized, the centres will mainly focus on research activities in the identified areas for the next three years.
3. The scientists working at the Council's centres will be exposed to need-based trainings to undertake clinical research and experimental activities in the approved areas.
4. Equipment, infrastructure and manpower shall be procured for the activities in the identified areas.
5. Researchers will be encouraged to seek funding from national scientific agencies in order to demonstrate the worth of the proposal. Acceptance of the formulated proposal will increase their confidence.
6. The CCRUM headquarters will make effort to develop a well-structured mechanism so that Quality proposals can be submitted for funding. The training and awareness programmes will cover Research Methodology (Clinical as well as Experimental), Good Clinical Practices, Ethics, etc**.** The headquarters will also organize administrative and financial trainings for its staff for the smooth functioning of the projects.

7. For validation of the fundamental concepts of Unani Medicine, such as Akhlat, Mizaj, etc., researchers should develop proposals for studies on healthy individuals, on diseased population, and in basic sciences for understanding biomolecule-temperament relationship. These proposals can be collaborative in nature where more than one centres of the CCRUM are involved.
8. Joint proposals may also be encouraged at different centres of the Council, which have specified research facilities, e.g. preclinical, clinical, etc.
9. Emphasis on drug standardization covering all its aspects should be given in the projects.
10. The funds shall be released to the centre that has submitted the proposal. However, the Principal Investigator (PI) will be given sufficient funds for contingency expenses.
11. Scientists will be encouraged to publish research findings as early as possible so as to enforce replication of results and validation of research product.
12. While formulating projects, efforts should be made to work on a new idea/ concept/ hypothesis, so that innovation becomes the 'hall mark' of the centre.

It is believed that once the IMR policy is implemented in letter and spirit, the Council would be able to realize its full potential in terms of research output and outcomes.

Annexure-1

PRIORITY AREAS:

1. **Fundamental Research**
   a. Studies on Theory of Akhlat (Humours), Mizaj (Temperament) and other Kulliyat-e Tib (fundamentals of Unani Medicine)
   b. Expression of Mizaj (temperament) and genomic correlation in different individuals
   c. Studies on Nabz (Pulse)

2. **Literary Research**
   d. Survey, Collection, Collation, Editing, Digitization and Printing of Manuscripts of Unani System of Medicine
   e. Critical review, Translation, subject-wise compilation and Publication of Classical literature of Unani System of Medicine
   f. Standardization of Unani Classical Terminology
   g. Preparation of Standard Treatment Guidelines

3. **Drug Research and Drug Development**
   a. Ethno-medicinal Research: Survey and documentation of medicinal plants / practices etc.
   b. Digitization of Herbarium
   c. Establishment of Temperament of newly identified drugs and to include them into the Pharmacopoeia after proper verification of therapeutic claims.
   d. Development of SOPs for manufacturing of compound drugs.
   e. Standardization and Quality Assurance of single and compound drugs.
   f. Pharmacology [Preclinical toxicity and efficacy].
   g. Molecular level based Mechanism of action of drugs.
   h. Development of SOPs on method of preparations of Kushtajat and their standardization
   i. Shelf-life studies of the Unani Drugs
   j. Demonstrating therapeutic efficacy of Unani Products by developing multi-targeted Bio-assays system

4. Clinical Research

Broad Areas

a. Validation of Unani classical / Pharmacopoeial drugs
b. New Drug Development
c. Development of SOPs for Ilaj bit Tadbeer (Regimenal Therapy)
d. SOPs for Munzij-Mushil (Concoctive and purgative)Therapy
e. Preventive Health
f. Adjuvant therapy
g. Unani Diagnostics

First Line Priorities:

i. Skin Diseases

- Baras (Vitiligo)
- Taqashshur al-Jild (Psoriasis)
- Nar-e Farsi (Eczema)
- Buthur Labaniyya (Acne vulgaris)
- Quba (Ringworm)

ii. Musculo-skeletal Disorders.

- Waja al-Mafasil (Arthritis of various origin)

iii. Development of SOPs for Ilaj Bit Tadbeer (Regimenal Therapy)

- Hijamat (Cupping)
- Taaliq (Leeching)
- Fasd (Venesection)

iv. Neurological /Psychosomatic Disorders.

- Nisyan (Lack of Memory/Dementia)
- Alzheimer's Syndrome
- Thulma (Depression)

v. **Gastro Intestinal Disorders**

- Waram al-Kabid (Hepatitis)
- Acid Peptic disorder
- Ishal-e-Dimaghi (Irritable Bowel Syndrome)
- Bawaseer (Haemorrhoids)
- Ulcerative Colitis

vi. Metabolic Disorders

- Ziyabitus Sukkari (Diabetes mellitus)
- Siman-e Mufrit (Obesity)
- Dislipidaemia
- Niqris (Gout)

vii. Respiratory Diseases

- Warm-e-Shoab-tur Riyah (Chronic Bronchitis)
- Rabw (Bronchial Asthma)
- Shaheeqa (whooping Cough)
- Iltehab-e-Tajaweef-e-Anf (Sinusitis)

viii. Cardiac Disorders

- Zaght al-Dam Qawi (Hypertension)
- Ifqar Marad-i-Qalb (Ischemic Heart Disease)

ix. Gynaecological Diseases

- Sayalan al-Raham (Leucorrhoea)
- Post-menopausal syndrome

x. Uro-genital Diseases

- Male Sexual disorders
- Oligospermia
- Chronic Urinary Tract Infection
- Urolithiasis
- Renal Failure

xi. Maternal Health

- Anaemia
- Galactogogue
- Problems related to Pre-natal and Post-natal Care

xii. Supportive/Adjuvant Therapy

- Supportive/adjuvant therapy in preventing the toxicity of ATT / Chemotherapy/ Anti-HIV drugs etc.
- Adjuvant therapy to improve Quality of Life in terminal HIV/AIDS and Cancer patients

xiii. Newly Emerging Disorders

- Dengue Fever

- Chikungunya

xiv. Geriatric Care

<u>Second Line Priorities</u>

i. Musculo-skeletal Disorders

Osteoporosis

ii. Skin Diseases

- Quba (Ringworm)
- Cosmeto-therapeutics

iii. Neurological Disorders

- Anxiety neurosis
- Sara (Epilepsy)
- Laqwa (Bell's palsy)
- Faalij (Paralysis)
- Parkinsonism

iv. Gynaecological and Obstetrical Diseases

- Cervicitis
- Chronic Dysfunctional Uterine Bleeding (DUB)
- Studies on Unani Galactogogue

v. Evaluation of Regimenal Therapies in Various Diseases

- Nutul (Fomentation)
- Hamam (Baths)
- Dalak (Massage)
- Aabzan (Sitz Bath)
- Riyazat (Exercise)

vi. Dental Problems

- Gingivitis
- Teeth Hypersensitivity

vii. Other Diseases

- Benign prostate hypertrophy
- Thyroid Disorder
- Infertility

APPROACH

Clinical studies may be conducted mainly in the form of:

- Preclinical/clinical studies for new Drugs
- Observational/validation studies for classical/pharmacopoeial drugs/therapies

Preclinical/clinical studies for new Drugs

Clinical trials will be conducted for the development of new drugs for the treatment of various diseases. The drugs may be:

- New combinations of a few single drugs
- Modified drug dosage forms of the existing classical drugs e.g. sugar-free capsule or granules in place of Khameeras (as a cardiac tonic for diabetic patients).

The focus of this approach has been on evaluating the potential of Unani Medicine for new indication or for the treatment of new emerging diseases of national importance, and also on increasing the system's wider acceptability. These types of studies will include animal studies (preclinical toxicity and pharmacological evaluation), and human studies (pilot studies, Phase-wise Randomized clinical trials) for therapeutic evaluation. Protocols will be developed as per standard guidelines. Parameters related to the philosophies and theories of Unani Medicine will be given due importance in formulating the protocols. Sample size in each trial will be decided taking all necessary factors into consideration, and a biostatistician will be consulted for the development of the protocols. These protocols may be discussed with the scientists of different disciplines engaged in clinical research before submitting the proposal for approval. Ethical Clearance and other regulatory requirement will be mandatory for all clinical trials.

Observational/ Validation Studies

Following two types of studies will be conducted.

- Observational/ Validation studies of classical/Pharmacopoeial drugs
- Validation/ Development of SOPs for various modes of Ilaj bit-Tadbeer (Regimenal Therapy)

The focus of this approach has been on validating the safety and efficacy of the existing classical/Pharmacopoeial drugs. These studies may be designed in two ways:

- **Clinico-Pharmacological approach**
  (Validation of a combination of formulations will be tried in the patients)

- **Drug-based approach** (Validation of a drug for its therapeutic interventions)

Protocols will be developed as per standard guidelines. Parameters related to the philosophies and theories of Unani Medicine will be given due importance in formulating protocols for the studies. Control group will not be necessary for the trials, as these drugs are already in use for centuries. These studies may have more subjective parameter as mentioned in the literature. Only such objective parameters as are absolutely required for the study will be included in the protocols.

These protocols may be discussed with the scientists of other scientific organizations such as ICMR/academic institutions etc. The scientists of these institutions may be involved in problem selection, protocol designing and monitoring.

In clinical studies on new drugs, the clinical trials will have to be undertaken as per the guidelines formulated by the Department of AYUSH, Ministry of Health and Family Welfare, Government of India.

- **Preclinical studies:** The Preclinical studies on the Unani classical formulations are not necessary as they are in practice and used since ages. However, pre-clinical studies will be conducted in case of new drug development.
- **Procurement of trial drugs:** Trial drugs for the projects will be procured from authentic resources.
- **Participating Centres:** Clinical research will be carried out at all centres of CCRUM.
- **Monitoring and evaluation:** The CCRUM on its own through its identified committees will monitor and evaluate the progress of the projects.

ELIGIBILITY:

Who are eligible?

Only Research officers and above who are permanent employees of the CCRUM are eligible to apply for IMR Projects**.** However, Council's scientists may collaborate with other institutes as per project requirement and these projects will be considered by the CCRUM as per procedure.

Infrastructure

The investigators seeking a project under IMR Scheme should have adequate infrastructure to pursue the research project and in case such facilities are not available, the same requirement must be reflected in the project proposal or may be outsourced

through accredited laboratories. The investigators may also carry out projects in collaboration with reputed academic/research institutions.

Investigators and Tenure of the Project

There will be one Principal Investigator (PI) and one or more Co-Investigators, as per the need of the project. Their roles should also be well defined in the project.

While submitting a research project, the PIs should give the details of all the research projects (completed, on-going under IMR Scheme and under any other scheme of Government of India or any other organization).

Change of Principal Investigator (PI)

- The PIs will be encouraged to have at least two Co-Investigators (Co-Is) in the project.
- If for any reason the PI leaves the project, an eligible Co-Investigator could be considered as the PI subject to recommendation of the PI, the Head of the Institution, and the approval of the Council. Such a request should be sent well in advance.
- The Principal Investigator will have to inform the Council of any changes and, in consultation with the Council, take steps to ensure successful completion of the project.

The tenure of a project will normally be for a period of three years, however, in exceptional cases, the tenure may be extended for a period of one year or more.

MODE OF APPLICATION

The details of the IMR policy will be available at the website of the CCRUM: **www.ccrum.net**

The Principal Investigators should have to apply in the prescribed format (**Annexure - 2)**, with all the required documents, to the Director General, CCRUM.

Principal Investigators have to submit their applications through Head of the Institute.

Preparation of the Project:

The project proposal should be prepared in the format for application enclosed at **Annexure - 2**.

Section A of the Application format requires General Information of the project. Also, a description of all the projects taken up by the Principal Investigator under IMR Scheme is to be given. This would include the Title of the Study, Objectives, Date of inception of

the project, Date of completion, Names and Designations of the Principal Investigators and Co-Investigators of the study and details of budget for the proposed IMR Project.

Section-B of the Application format requires Bio-Data of PI, Co-I(s) proposed in the research study.

Section-C of the Application is the 'Brief Summary of the Project'.
Section-D of the application relates to the detailed 'Protocol' of the study.

(Note –It is mandatory to submit the application in five hard copies and one soft copy in CD)

The study design and conduct may follow the prevalent guidelines.
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 **Ethics** Committee (IEC) or Institutional Animal Ethics Committee (IAEC) is essential before initiation of the study.

SUBMISSION OF PROPOSALS AND EVALUATION

Submission of IMR Proposals: Research projects will be invited from Research Officers and above who are permanent employees of the CCRUM working at the peripheral Institutes of the CCRUM.
IMR-Project Evaluation Committee (IMR-PEC): The projects will be evaluated on their merit and competitive basis. The Research proposals will be scrutinized at Headquarters and evaluated by SAC/expert committee constituted by the DG, CCRUM with the following composition:

1. Director General, CCRUM - Chairman
2. 3-4 Subject experts - Members
3. Bio-statistician - Member
4. Senior Officer from CCRUM headquarters dealing with the Programme-Member Secretary

Terms of reference of IMR-PEC: The PEC after evaluation/scrutiny of the Research Proposals may

- Recommend and approve suitable IMR projects
- Call for the Principal Investigator/Co-Investigator for presentation and discussion.
- Invite comments from the expert(s) in the concerned field.
- Inform the applicants to modify their proposals (as per their observations), if deemed fit.
- Reject the proposals, if not found suitable.

FINANCIAL SUPPORT:

The project cost shall be met from sanctioned budget of CCRUM Headquarters from Research activities head.

The Principal Investigators applying for the project should have adequate staff, equipment and laboratory/other facilities to conduct the particular research. Financial support will be given to fulfill the requirement not available in the institutes.

Operation of Accounts: The fund will be provided to the institutes as a part of Institute's budget, in the mechanism followed by the Council normally and the Head/ In-charge will provide the fund as per the requirement from the PI from time to time. In the matter of purchase of non-recurring items, codal formalities will be followed.

PERSONNEL/STAFF: No initial staff shall be provided

SUBMISSION OF REPORTS:

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

Progress Report

- Quarterly progress report on physical achievements is to be submitted to the Council regularly.
- The Progress Report for the first and second year is to be submitted within one month of completion of reporting year in the prescribed format.
- The project will not be renewed for the next financial year unless the CCRUM receives the progress report in time.
- The PI will be asked to present the progress at the meeting of the PEC.

- The suggestion and views of the PEC and mid-course rectification, if any, would be conveyed to the PI, for effective conduct of the project. This would be binding on the PI.
- Five hard copies and one soft copy (in CD) of the yearly progress report will be submitted to CCRUM.

Final Project Completion Report

At the completion of the project, the final report should be sent in the prescribed format. The report should be submitted within three months from the date of completion of the project. **2 hard copies and soft copy (in CD)** of the Final project completion report should be submitted.

MONITORING:

Local Monitoring: The Head of the Institute would ensure periodic review and day-to-day monitoring of the projects going on under the IMR Scheme at the institute level.

Central Project Monitoring Committee (CPMC): The Central Project Monitoring Committee constituted by Director General, CCRUM with the following composition will monitor the technical and financial execution of the project

1. Director General, CCRUM - Chairman
2. 1 Unani Expert in relevant field from reputed Unani institute -Member
3. Bio-statistician - Member
4. Subject experts (1-1) - Member
5. One Senior Officer from CCRUM headquarters dealing with the Programme - Member Secretary

Terms of reference of Central Project Monitoring Committee (CPMC)

- Review the progress reports received from time to time by the CCRUM from the PI.
- Invite the PI to make a presentation before the experts
- Invite the PI to bring all the relevant papers and documents related to the project.
- Make an on-site visit, where the PI would ensure their access to all the relevant documents related to the Project.

It is mandatory on the part of the PI and head of the Institution to provide all information and records to the monitoring person(s), etc.

OUTCOME OF THE PROJECT:

The final technical of each completed study will be examined by the PEC, who will convey their views to the Director General, CCRUM for consideration. The PEC will also give their comments on publication of the results of the studies and the patents claimed by the Principal Investigators.

INTELLECTUAL PROPERTY RIGHTS AND PATENTS:

The **INTELLECTUAL PROPERTY RIGHTS** (IPR) and patents will be generated exclusively by the Council. Council will make efforts to commercialize the product as applicable.

The investigator or the staff employed on the research project shall not obtain patents for any invention/discovery made by them.

PUBLICATION:

Outcome of the project shall be published in the peer reviewed indexed journals etc. It is mandatory to publish the findings after completing the project subject to IPR issues. The PI will submit the final consolidated report (as per Annexure 5) to the Council, after the completion of the project. A manuscript of the paper would also be sent to the CCRUM by the PI for publication in the Research Journals of the Councils. Publications of the study in part or full are not permissible before acceptance of the final report by the Director General, CCRUM.

ANNEXURE – 2

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

APPLICATION (FORMAT) FOR CCRUM INTRA MURAL RESEARCH PROJECTS IN UNANI MEDICINE

SECTION-A

GENERAL INFORMATION

1. Title of the Research Project:

2. Institution responsible for the research project
Name:
Postal address:
Telephone:
Telegraphic address:
Fax:
E-mail:

3. In case of Individuals applying for the Research project:
(Name of the collaborating institute may be cited at S. No. 2 above)

Name of the individual:
Postal address:
Telephone:
Telegraphic address:
Fax:
E-mail:

4. Name and Designation of

i) Principal investigator:

ii) Co-Investigator(s):

iii) Consultant (s):

5. Duration of Research Project:

i) Period required for pre-trial preparations:

ii) Period which may be needed for generating the data:

iii) Period that may be required for analyzing the data:

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

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	Names and Designation of the PI and the Co-I	Status of the Project	Status of the U.C.

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

S.No.	Title of the Project	Date of inception of project	Date of completion of the project	Names and Designation of the PI and the Co-I	Status of the Project

Name and Signature of the:

a) Principal Investigator(s) _____ _____

Name **Signature**

b) Co-Investigator(s) _____ _____

Name Signature

_____ _____

Name **Signature**

Signature of the Head - CCRUM Institute (Forwarding Authority)

Name:

Date:

Seal:

LIST OF DOCUMENTS ENCLOSED:

1. _____
2. _____
3. _____
4. _____
5. _____

SECTION–B

FORMAT FOR BIO-DATA OF *THE* INVESTIGATORS (PI, Co-I(s), Consultants)

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1. Name (Dr./Mr./Ms.): _____

   First name(s) Surname

2. Designation:

3. Complete Postal Addresses and PIN:

   Telephone Number(s), Fax, E-mail

4. Date of birth:

5. Educational Qualification: Degrees obtained (Graduation Degree Onwards)

   Degree Institution Year

6. Research Experience

   Duration (From-To) Institution Particulars of work done

7. Research specialization

   (Major scientific fields of interest)

8. Financial support received

   a) From the Ministry of Health and Family Welfare

      Past

      Present

      Pending

   b) From other organizations

      Past

      Present

      Pending

9. Research projects in hand under IMR

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

11. Other research projects, if any:

12. List of five important publications of the Investigator relevant to the project,

13. Other information, if any:

Signature:
Date:

SECTION–C

BRIEF SUMMARY OF THE RESEARCH

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

1. Title of the Research Project:

2. Objectives.

3. Summary of the proposed research (up to 150 words) indicating overall aims of the research, importance of the objectives and their application in the context of the priority areas set out in the application form.

4. Milestones with deliverables in the research project

5. IPR values

6. Present knowledge and relevant bibliography including full titles of articles relating to the subject.

7. List of important publications concerned to the project (enclose reprints).

8. Ethical and other clearances:

i. The description of ethical considerations relating to the trial is to be mentioned and Approval of the Institutional Ethical Committee/Institutional Animal Ethics Committee should be enclosed for research involving human subjects/animal experimentation. However, ethical clearance may be obtained during the process of the approval of the project.
ii. If radio tagged material is proposed to be used in the project either for clinical trials or experimental purposes, then clearance from Nuclear Medicine Committee, Bhabha Atomic Research Centre, Mumbai, should be attached.

9. Budget requirements (head wise and item wise) if any (should come through In-charge of the Institute)

SECTION-D

Detailed Research Protocol (to be enclosed)

Give here the design of the study as per guidelines for clinical trial protocol including toxicity investigations, indicating the total number of the cases/samples to be studied, as well as the mode of selection of subjects especially in experiments involving human subjects, equipment and other materials to be used, the techniques to be employed for evaluating the results including statistical methods etc. Also, detail the Standard Operational Procedures (SOPs) for preparation of trial drugs and method of selection of ingredients should also be specified. Facilities in terms of equipment, etc., available at the institution for the proposed investigation are to be specified.

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

ANNEXURE- 3

FORMAT FOR PROGRESS REPORT

1. Project title
2. PI (name and address)
3. Co-I (name and address)
4. Collaborating institutes
5. Other Scientific Staff engaged in the study
6. Non-Scientific Staff engaged in the study
7. Date of start
8. Duration
9. Objectives of the proposal
10. Methodology followed till end of period of reporting
11. Interim modification of objectives/methodology, if any (with justifications)
12. Summary on progress (during the period of report)
13. Milestones with deliverables achieved during the reporting period as proposed in the scheme
14. Applied value of the project
15. Research work which remains to be done under the project

Signature of PI: Date:

Signature of Head of the Institute: Date:

ANNEXURE-4

FORMAT FOR FINAL REPORT

1. Title of the Project:
2. PI (name and address)
3. Co-I (name and address)
4. Collaborating Institutes
5. Other Scientific Staff engaged in the study
6. Non-Scientific Staff engaged in the study
7. Implementing Institution and other collaborating Institutions
8. Date of commencement
9. Duration
10. Date of completion
11. Objectives as approved

12. Deviation made from original objectives if any, while implementing the project and reasons thereof.

13. Experimental work giving full details of experimental set-up, methods adopted, data collected supported by necessary tables, charts, diagrams and photographs.

14. Detailed analysis of results indicating contributions made towards increasing the state of knowledge in the subject.

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

16. Manuscript for publication (300 words for possible publication in Council's Bulletin).

Name and signature with date

1. _____

(Principal Investigator)

2. _____

(Co-Investigator)

Forwarded by Head of the Institute:

(Name and signature with date)

HUMAN RESOURCE DEVELOPMENT AND INCENTIVE POLICY FOR CCRUM SCIENTIFIC STAFF

1. HUMAN RESOURCE DEVELOPMENT CENTRE

The CCRUM Headquarters at New Delhi will be the nodal Human Resource Development Centre for promoting professional human resource in the Council by evolving a holistic human resource development plan.

- The centre will offer structured and customized training programmes such as:
    - Induction / Orientation training programmes for freshly recruited officers.
    - Refresher functional skills up-gradation training programmes for Officers.
    - Training in Research Methodology (Experimental and Clinical Research) including GCP, GMP, GLP, IPR, etc.
- Management skills development training programmes for leadership, team working will be developed. Senior staff with management skills will be sent to reputed institutes in India and abroad for training.
- Inculcate team spirit among CCRUM officers.
- **Develop and upgrade with modern training methodology and tools.**

The centre will organize regular, structured and customized training and skills up-gradation programmes in the broad areas of **research methodology (experimental and clinical research)** management of research, patents & IPR and supporting functional besides personal skills up-gradation programmes such as leadership, team building, computer training, communication, presentation skills etc. These modules for programmes will be designed and conducted by eminent professionals in the field.

2. INCENTIVES FOR EXCEPTIONAL PERFORMANCE *

Up to two advance increments may be granted by the Director General, CCRUM to the CCRUM officers who perform exceptionally well in any of the following areas:

1. Patents which ultimately lead to commercialization and generate revenues for the Council.
2. Cost saving and income generation for the institute
3. Exceptional contribution to the CCRUM.

3. CCRUM YOUNG AWARDS FOR SCIENTISTS

3.1 CCRUM Scientist Award:

The awards will be given to the outstanding contributions made by the young CCRUM scientists based on work done during the last three years preceding the year of the award. Five awards i.e. 3 for Unani Medicine and 2 for Allied Sciences may be given annually

Any scientist, engaged in research work in any CCRUM institutes/laboratories, who is not more than 50 years of age, is eligible for the award. Nominee should be a regular employee of CCRUM holding a post of Research Officer or above and must have at least one research paper based on Councils work as the first author published in peer reviewed journal **with** impact factor of more than 1.0. Directors should propose nominations of officers belonging to the CCRUM institutions/laboratories with which they are associated. In case of head/In-charges nomination will be done by Joint Director (Technical).Each of them can send only one nomination for a year

Each award consists of a citation, plaque and a cash prize of Rs.3,00,000/-

3.2 CCRUM Excellence Awards:

CCRUM will encourage multi-disciplinary in-house team efforts and external interaction for Unani drug development, technology transfer and successful commercialization. These include <u>one each</u> for **Avicenna Award, Rhazi Awards** and **Ajmal Khan Award** in the last three years:

a) AVICENNA AWARD - for exceptional contribution in the field of basic sciences.

**All the issues having financial implications are subjected to the approval of the Standing Finance Committee (SFC) / Governing Body (GB).*

b) RAZI AWARD - for exceptional contributions in the field of Clinical Research.

c) AJMAL KHAN AWARD - for exceptional contribution in the field of Drug Standardization.

Each Award consists of a citation, plaque and a cash prize. Each award will carry a cash prize of Rs. 3, 00,000/-

The criteria for the awards shall be based on the high scientific content, innovative character, novelty and competitiveness/commercialization of the technology in Unani drug development and National healthcare. These awards will be given for outstanding contribution to CCRUM.

Any scientist engaged in research work in any of the CCRUM institutes/laboratories is eligible for the award. Nominee should be a regular employee of the CCRUM holding a post of Research Officer or above. Directors should propose nominations of officers belonging to the CCRUM institutions/laboratories with which they are associated. In case of Head/In-charges nomination will be done by Joint Director (Technical). Each of them can send only one nomination and a nominator for the award should not himself be the member of the group nominated for the award.

4.3 CCRUM Award Selection Committee: The CCRUM Award Selection Committee will scrutinize the applications and nominate the scientists for the awards. The committee will comprise:

1. Chairman, SAC - Chairman
2. Two Technical experts (nominated by DG, CCRUM) - Member
3. DG, CCRUM - Member Secretary

4. **Expenditure:** The expenditure for these awards will be met from the grants received as part of the Incentive policy by the CCRUM.