# SCHEME FOR EXTRA AND INTRA MURAL RESEARCH (EMR)(IMR) IN AYURVEDA, YOGA and NATUROPATHY, UNANI, SIDDHA, SOWA RIGPA AND HOMOEOPATHY

**GOVERNMENT OF INDIA**
**MINISTRY OF HEALTH and FAMILY WELFARE**
**DEPARTMENT OF AYURVEDA, YOGA and NATUROPATHY, UNANI, SIDDHA, SOWA RIGPA AND HOMOEOPATHY (AYUSH)**

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## 1. BACKGROUND:

AYUSH is the acronym for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy and includes therapies documented and used in these Systems for the prevention and cure of various disorders and diseases. India has a large infrastructure for teaching and clinical care under these Systems. The scientific validation of these therapies, however, remains to be done on a wider scale.

The Department of AYUSH has introduced a Scheme for Extra-Mural Research in addition to the intra-mural research undertaken by the Research set up by the Ministry of Health and Family Welfare three decades ago. The off-take and output from this scheme has improved in last few years. The Department has taken up a series of programs/interventions wherein evidence based support for the efficacy claims is needed. Safety, quality control and consistency of products are also very much required.

In the present era of globalization and development of a world market for traditional and herbal medicine, research and development is needed to promote the production and export of quality products in the form of drugs, nutraceuticals, toiletries and cosmetics. There is an intense competition from other countries in the trade of herbal products. India's share in the world market is negligible. The revised extra-mural research project has, therefore, been designed to encourage R and D in priority areas so that the research findings lead to validation of claims and acceptability of the AYUSH approach and drugs. The features of the Scheme are given below:-

## 2. AIMS AND OBJECTS:

2.1 Development of Research and Development (R & D) based AYUSH Drugs for prioritized diseases;

2.2 To generate data on safety, standardization and quality control for AYUSH products and practices;

2.3 To develop evidence based support on the efficacy of AYUSH drugs and therapies;

2.4 To encourage research on classical texts and investigate fundamental principles of AYUSH Systems;

2.5 To generate data on heavy metals, pesticide residues, microbial load, safety/toxicity etc. in the raw drugs and finished Ayurveda, Siddha, Unani and Homoeopathy drugs;

2.6 To develop AYUSH products having Intellectual Property Rights (IPR) potential for increasing AYUSH exports

2.7 To develop the potential Human Resource in AYUSH systems, especially to inculcate scientific aptitude and expertise relating to AYUSH systems;

2.8 To develop joint research venture among the AYUSH Department and other Organizations/Institutes.

**3. THE SCOPE OF APPLICATION:**

The AYUSH therapies can be utilized as:

| | | |
|---|---|---|
| 3.1 | First line therapy | To meet unmet medical needs of current relevance. |
| 3.2 | Adjuvant therapy | To improve the response of Primary therapy. |
| 3.3 | Rational poly-therapy | For individualized management. |
| 3.4 | Protective therapy | To prevent/treat adverse effects and reactions to Primary therapy. |
| 3.5 | Economic therapy | To reduce the dose/cost of therapy. |

**4. PRIORITY AREAS OF RESEARCH:**

The Department will determine priority areas of research from time to time and encourage submission of proposals in these identified areas. For the present these are determined individually for each of the AYUSH systems and are placed at **Annexure-1**

## 5. ELIGIBILITY FOR GRANT-IN-AID:

### *5.1 Who are eligible*

- Reputed Institutes/Organizations (both Government and Private) Laboratories, Drug Manufacturers, etc. having adequate infrastructure in terms of equipment and manpower to conduct high quality research.

- Universities/Educational Institutions
- Eminent scholars and Scientist, (who are full time regular employees of the institute), reputed institution /organization having good research background and contribution to the medical research can apply, as stated above. However, preference will be given to institutes directly as they have better infrastructure. The grants will be released to the concerned organization, who would be responsible for expenditure and utilization of funds.
- **The institute/units of the Research Councils & the National Institutes of Department of AYUSH may apply for Intra Mural Research.**

### *5.2 Verification of credentials of the individuals/organizations/laboratories*

***5.2.1*** Verification of credentials of the individuals/organizations/laboratories, etc. will be made by the respective Research Councils to assess whether they have the requisite infrastructure to carry out the research project, for which they have applied.

### *5.2.2 Organizations/Institutes exempted from verification of credentials*

The organizations/institutes which will be exempted from verification of their credentials are:

- Statutory/autonomous organizations/Institutes/Laboratories under the Ministry of Health and Family Welfare, Govt. of India
- CSIR and its Institutes,
- ICMR and its Institutes,
- Institutes/Accredited organizations of DST, DRDO
- Central and State Universities
- Deemed Universities declared by the Ministry of HRD, Govt. of India, under the UGC Act 1956.

### *5.3 Infrastructure required*

The institutions/investigators seeking a project under EMR Scheme should have adequate infrastructure to pursue the research project. In case of clinical research, clinical facilities including OPD and IPD (wherever required) and laboratory facilities for bio-chemical, pathological, radiological and electro-physiological investigations supported with necessary equipment relevant to the project should be available. In case of studies for safety and standardization, adequate laboratory facilities and animal house should be in place. In case of Intra Mural Research (IMR) projects, the concerned institutions/ units of Ayush Research Councils & National Institutes should have adequate infrastructure. In case such facilities are not available, the same may be reflected in the project proposal and same may be developed from the funds sanctioned for the project.

### *5.4 Investigators:*

***5.4.1*** There will be ***one Principal Investigator (PI)*** and ***one or maximum two Co-Investigator(s) [Co-I]*** for each project. The Principal Investigator should have previous experience in the field of the proposed study. Importance will be given to projects where preliminary work has been done on the topic, substantiated by publications. Principal Investigator should not be superannuating during the period of the proposed study.

The PI or one of the Co-I should be from the concerned field along with sufficient research background. In exceptional cases, where there is no subject (AYUSH System) expert in the proposal submitted, the PEC would decide if the study requires a subject expert to be engaged as a consultant.

***5.4.2*** Under normal conditions, at a given point in time, a PI or the Co-I should not be implementing more than TWO research projects funded by the Department of AYUSH. While submitting an application for a research project, the PI should give in detail all the research projects (completed, on-going under EMR Scheme and under any other scheme of Government of India or any other organization). Fresh research proposals can be considered only when the on-going research proposal are about to conclude.

#### *5.4.3 Change of PI*

- PIs are encouraged to have a Co-Investigator (Co-I) in the project. However, in one study there should not be more than two Co-Is.
- 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 Research Council(s), as the case may be. Such a request should be sent well in advance.

- In case the PI is shifting to any other Institution, the Co-investigator could be made the new PI, or the project could be transferred to the new Institution with the mutual agreement of both Institutions and the approval of the Research Council(s).
- The host Institution has an important role to play in the above contract. The Institute/Principal Investigator will have to inform the Research Council(s), as the case may be, of any changes, and in consultation with the Council take steps to ensure successful completion of the project before relieving the Principal Investigator.

## 6. MODE OF APPLICATION FOR GRANT-IN-AID:

**6.1** The Research Councils, as stated below, on behalf of the Department of AYUSH, will invite proposals from the individuals, organizations (both Government and Private), Universities/Educational Institutions, industries etc. for grant-in-aid, under Extra-Mural scheme as well as Intra Mural Research, as also through open advertisement placed in the National dailies, twice a year (First in the month of January and Second in the month of July). The advertisement would also be placed on the website of the Department of AYUSH and the websites of the Research Councils (para 6.2) as also in the research Journal and Newsletter of the Department of AYUSH and Research Councils

| **Name of Research Council to whom proposal is to be submitted** | **AYUSH discipline** |
|---|---|
| • **Central Council for Research in Ayurvedic Science, (C.C.R.A.S.)**<br>61-65, Institutional Area,<br>Opposite 'D' Block,<br>Janak Puri<br>New Delhi-110058<br>Email: ccras_dir1@nic.in<br>Fax: 011-28520748, 011-28525959 | Ayurveda |
| • **Central Council for Research in Siddha, (C.C.R.S.)**<br>No. 61-65, Institutional Area, Opp. D-Block, Janak Puri New Delhi-58<br>Email-ccrsdelhi@gmail.com<br>Fax-011-28524163,<br>Tel. 011-28524163 | Siddha |
| • **Central Council for Research in Homoeopathy, (C.C.R.H.)**<br>61-65, Institutional Area<br>Opposite 'D' Block,<br>Janak Puri<br>New Delhi-110058<br>Email:ccrh@del3.vsnl.net.in | Homoeopathy |

| | |
|---|---|
| Fax: 011-28521060 | |
| • **Central Council for Research in Unani Medicine, (C.C.R.U.M.)**<br>61-65, Institutional Area<br>Opposite 'D' Block,<br>Janak Puri<br>New Delhi-110058<br>Email: ccrum@rediffmail.com, unanimedicine@gmail.com<br>Fax:011-28522965 | Unani |
| • **Central Council for Research in Yoga and Naturopathy (C.C.R.Y.N.)**<br>61-65, Institutional Area<br>Opposite 'D' Block,<br>Janak Puri<br>New Delhi-110058<br>Email: ccryn@vsnl.net<br>Fax: 011-28520435<br>• Phone:28520430, 31,32 | Yoga and Naturopathy |

**6.2** Scheme details and Application Format shall be available on following sources:

- Website of the Department of AYUSH: www.indianmedicine.nic.in
- Website of the Research Councils:
    - CCRAS: www.ccras.nic.in
    - CCRS: www.crisiddha.tn.nic.in
    - CCRH: www.ccrhindia.org
    - CCRUM: www.unanimedicine.com and www.ccrum.org
    - CCRYN: www.ccryn.org
- Research Councils as mentioned at 6.1
- State Health Departments/State Health Directorates

The website of the Councils would also detail the status of the applications (received, under consideration, rejected, approved).

**6.3** The Individuals/Organizations interested for the grant in aid have to apply in the prescribed format (**Annexure -2)**, including all the required documents, to the Heads of Research Councils, as stated at 6.1.

**6.4** The Director Generals/Director of the concerned Research Councils can also approach reputed Institutes/Organizations or eminent scientist or submitting proposals on specified areas. The Councils will identify top institutions (academic, research, universities etc.) in the country for inviting good quality proposals. Councils will also guide and help them in formulating the proposals

**6.5** Time line for Receipt of Application by the Research Councils
The applications would be received and processed in four quarters:

| Quarter | Processing by the PEC | Processing by PAC |
|---|---|---|
| I | Feb. First week | Feb. last week |
| II | May first week | May last week |
| III | Aug. first week | Aug. last week |
| IV | Nov. First week | Nov. last week |

**6.6** In case of Institutions/Organizations, the PIs have to submit their applications through their Controlling authorities/Head of the Institute/Organization who will be designated authority responsible for quality work and utilization of the grant and be accountable in the event of any default. In case of individuals, the PIs should apply through the Heads of the Organization/Institutions with which they want to collaborate.

**6.7** ***Preparation of the Project:***
**6.7.1** 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 Organization/Institute under EMR Scheme and other Grant in aid scheme of the Govt. of India 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 grant-in-aid received for the study. Section-B of the Application format requires Bio-Data of PI, CoI(s) and the Consultants 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 10 hard copies and one soft copy in CD)***

**6.7.2** The Protocol and the Research Plan are to be prepared as per the 'Guidelines for Methodology and Research and Evaluation of Traditional Medicine' (WHO 2001). Broad Guidelines on preparation of protocol and Research plan are enclosed at Annexure-3 and 4.
*Also the Investigator is required to go through the 'Good Clinical Practices for Clinical Research in India' provided by Central Drug Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, GOI.*

**6.7.3** Ethical clearance from the Institutional Ethical Committee (in case of human trials) or Institutional Animal Ethics Committee (for animal studies) of the Institute/Organization applying for the Research Proposal is mandatory. **A certificate**

**of clearance from the Institutional Ethical Committee (IEC) or Institutional Animal ethics Committee (IAEC) is to be enclosed along with the application form.** For Ethical Guidelines and constitution of the Ethical Committee the Institute/Organization may refer to the ICMR Guidelines available at ICMR Website at www.icmr.nic.in (Hyperlink to 'About us' and then 'Ethical Guidelines for Biomedical research on Human Subjects')

**6.7.4** Other Documents to be enclosed along with the Application Form
The Institutes/Organization (other than those mentioned under 5.2.2) seeking Research projects under EMR Grant are required to submit the following documents along with the Application:

1. A copy of the Memorandum of Association, Rules and Regulations of the organization under which it has been established.
2. A copy of certificate issued to them under the relevant Act wherein it has been registered (duly attested by a gazetted officer of the Central or State Government)
3. Annual Report along with the Audited Statement of Accounts for the last year.
4. In case, Annual Report of the organization is not published, a note on activities during last year in brief may be enclosed.
5. Ethical clearance certificate from IEC/IAEC (Also to be submitted by institutes/organizations mentioned under 5.2.2)

## 7. EVALUATION AND SCREENING OF THE PROPOSALS

### 7.1 *Internal Scrutiny Committee (ISC)*

- An Internal Scrutiny Committee would be constituted by the concerned Research Council to scrutinize/screen the proposals received from the individuals/organizations. Two outside experts will also be included in the committee. Internal Scrutiny Committee will examine the proposal within a month after receiving the proposals. After thorough scrutiny, the Committee may:
-
- Get additional information, if required, **from concerned Institutes /investigators** whose applications are otherwise meritorious but lack detail on some key issues.
- Identify applications that lack sufficient scientific merit in advance of the PEC meeting.
- Return back the proposal to the Institutes/Organizations highlighting their deficiencies, with instructions to re-submit the proposals after fulfilling the shortcoming.
- May invite comments from the expert(s) in the concerned field, prior to its recommendation to PEC.
- Recommend 'as it is' to the PEC for consideration.
- Call for the PI/Co-I to the concerned Research Council for compliance/ clarification/ presentation of the proposal, if required.

- Upon receipt of the required information Internal Scrutiny Committee/reviewer would provide their final assessment of the application. Proposals complete in all respect will only be placed before the PEC.

### 7.2 *Project Evaluation Committee (PEC)*

The Research proposals both of Extra Mural Research (EMR) & Intra Mural Research (IMR) will be scrutinized/evaluated by the Project Evaluation Committee which is common for all AYUSH systems constituted by the Department of AYUSH would comprise of:

1. JS (AYUSH) — Chairperson
2. Two subject experts having published research work (to be nominated by Director of Research Council) — Members
3. One modern medicine expert from AIIMS/ICMR like institution (to be nominated by the secretary (AYUSH)) — Member
4. One modern science expert from CSIR/DST/DBT (to be nominated by the Secretary (AYUSH) — Member
5. Director Generals /Directors of the Concerned Council or his nominee (not below the rank of JD/DD) — Member
6. Director/US(IFD) — Member
7. Adv./Dy. Adv. of all disciplines of AYUSH. — Member
8. Representative of Department of AYUSH dealing with the subject — Member Secretary

**7.2.1** The PEC after the evaluation/scrutiny of the Research Proposals may:

- Call for the Principal Investigator/Co-Investigator to explain their proposals in person
- May invite comments from the expert(s) in the concerned field
- Reject the proposals, if not found suitable
- Inform the applicants to modify their proposals (as per their observations)
- Recommend the proposal to Project Approval Committee for consideration and approval.

**7.2.2** The PEC, after thorough evaluation/scrutiny of the technical as well as financial aspects of the Research Proposals will forward the recommended proposals to the Project Approval Committee (PAC) for consideration, approval and sanction of funds.

**7.2.3** The Internal Scrutiny Committee (ISC) will also evaluate the ongoing research projects and send recommendations to the Project Evaluation Committee (PEC) for release of subsequent installments of the grants. The work done by the Investigators will also be periodically reviewed by PEC. Project Evaluation Committee (PEC) will finally approve the subsequent installments.

### *7.3 Project Approval Committee (PAC)*

Project Approval Committee chaired by the Secretary, Department of AYUSH, would consider the proposals recommended by the PEC for acceptance. The PAC would comprise of:-

| | | |
|---|---|---|
| 1 | Secretary (AYUSH) | Chairperson |
| 2 | Joint Secretary (AYUSH) concerned with EMR | Member |
| 3 | Financial Adviser or his/her representative | Member |
| 4 | Chairperson of PEC | Member |
| 5 | Adviser/Deputy Adviser of all disciplines of AYUSH | Member |
| 6 | Representative of DG, ICMR/DGs, CSIR/DST/DBT Not below DDG/Scientist-F level | Member |
| 7 | All D.G's /Director of the Research Councils | Member |
| 8 | Director(AYUSH) concerned with EMR | Member Secretary |

7.3.1 The Project Evaluation Committee (PEC) and Project Approval Committee (PAC) are in common for all the proposals of Ayush disciplines to avoid duplication of work.

The Chairperson of the PAC may invite other specialist(s) to attend the meeting of the PAC to give their expert views on the project proposals. The decision of the PAC in respect of approval of the research project (s) and sanction/release of funds shall be final.

## 8. OUTCOME OF THE PROJECT:

The final technical and financial reports of each completed study will be examined and reviewed by the PEC, who will convey their views to the PAC for consideration. PEC will also give their comments on publication of the results of the studies and the patents claimed by the PI/Grantee institutions. The decision of the PAC in this respect will be final and binding. Deliverables will be assessed through various outcomes of the project like publication in reputed journals, product development, patents, technology developed, SOPs, presentations on International platform etc.

## 9. FINANCIAL SUPPORT:

**9.1** The Department of AYUSH will provide financial support for staff, equipment and contingencies (recurring and non-recurring) for the project over a period of 1-3 years up to a maximum **of Rs. 30.00 Lakh.**

**9.2** The institutions /individual applying for the grant should have adequate staff, equipment and laboratory/other facilities to conduct the particular research. Financial support will be given only for the minimum required staff, equipment, books and contingent items.

**9.3** ***Institutional support:*** 5% of the total cost of the project *(excluding the cost of equipment)* would be provided to the educational institutions and 3% of the cost of the project *(excluding cost of equipment)* would be provided to the organizations, other than educational institutions, engaging in research under EMR scheme, as Institutional Support after the successful completion of the project to the satisfaction of the PEC/ PAC.

## 10. EXPENDITURE:

All recurring and non-recurring items required for work of the project should be purchased in accordance with the procedures and guidelines of the State Government (for State Government, Private and Non-Governmental Organizations/Institutes) or those of the Central Government (in case of Central Government Organizations). For permanent and semi-permanent assets acquired solely or mainly out of the grant, the Institute shall maintain a separate audited record in the form of register such as cash book, asset register, paid bills, bank statements and bank accounts, etc. The term "assets" means moveable property where the value exceeds Rs.1000/-. Separate assets registers for items costing more than Rs. 1000/- and less than Rs.20,000/- and more than Rs.20,000/- may be maintained.

***10.1 Non-Recurring Expenditure:*** Essential scientific equipment including computer and software, if needed, may be permitted as non-recurring expenditure. However, the quantum of such expenditure will not be more than 25% of the total project cost. The equipment will become the property of the host institution(s) after successful completion of the project. Books purchased out of the contingencies may be retained by the Principal Investigator after successful completion of the project.

***10.2 Recurring Expenditure:*** The expenditure of recurring nature such as medicines, chemicals, glassware, cost of investigations, animals, stationeries, postage, printing, photocopying, etc. may be allowed to be purchased as a part of the recurring contingencies.

### *10.3 Guidelines for incurring expenditure:*

This is meant for recurring as well as non-recurring expenditure. The grant can be utilized for purposes like, but not limited to:

1. Acquisition of books, in case these are not available in the library
2. Chemicals/Consumable items required solely for research project
3. Charges for specialized investigations for which facilities do not exist in the grantee institute
4. Data entry charges
5. Printing of questionnaires, case report forms, consent forms, etc. for the research project
6. Computer utilities, charges for analysis of data
7. Typing and printing of research reports
8. Communication charges

The grant cannot be used for purchase of furniture items, office equipments such as telephone, fax machine, photocopiers, etc.

***10.4 Utilization of Travel grant:*** The funds earmarked under TA/DA can be utilized, for travel within the country, by the PI, Co-Investigator or Research staff working on the scheme for the following purposes:

- Attending seminars/symposia/conferences within the country provided the PI himself/herself or the project staff is presenting a research paper (Related to the subject of the study), which has been accepted. Copy of the acceptance letter should be sent to the Research Council(s).
- Taking up field work/travel connected with the research work
- Visiting the Research Council(s) for meetings related to the project
- Attending a training course/seminar/conference/workshop related to the project

The travel grant cannot be used for foreign travel.

In utilization of Travel Grant, TA/DA should be as per the rules and guidelines for entitlement as prescribed by the State Government (for State Government, Private and Non-Governmental Organizations/Institutes) or those of the Central Government (in case of Central Government Organizations).

## 11. PERSONNEL/STAFF:

### 11.1 *Scientific Staff*

| S. No | Staff | Qualifications and Experience | Amount of assistance as per revised rates of ICMR* |
|---|---|---|---|
| 1. | Research Associate (RA): (One or | Ph.D. in the concerned subject<br>OR<br>Post-Graduation in Ayurveda/ | |

| | | | |
|---|---|---|---|
| | Two) | Siddha/ Unani/ Homoeopathy/ Yoga/Yoga and Naturopathy/Sanskrit/Philosophy;<br>OR<br>Degree qualification in the respective AYUSH System/ Allopathy; M.Pharma/ M.E./ M.Tech./ MVSc. with minimum 3 years research experience i.e. having worked for any research project funded by the Department of AYUSH, ICMR, CSIR, DST or equivalent organization. | 23000 per month + HRA |
| 2. | Senior Research Fellow (SRF): (One or Two) | Degree qualification in the related AYUSH system/ Allopathy/ Pharmacy/ Pharmacology/ Engineering/ Biotechnology/ Agriculture/ Veterinary Science/Bio-Statistics/Physiotherapy/ Occupational therapy, etc.<br><br>Preference will be given to those who possess higher qualification or who have previous research experience i.e. having worked for any research project funded by the Department of AYUSH, ICMR, CSIR, DST or equivalent organization. | MEDICAL<br><br>1st, 2nd and 3rd Year – Rs.20,000/- per month + HRA<br><br>NON-MEDICAL<br><br>1st and2nd Year – Rs.18,000/- per month + HRA.<br><br>3rd year – Rs.20,000/- per month + HRA |
| 3. | Junior Research Fellow (JRF): (One or Two) | • Bachelor Degree in the required discipline<br><br>• Graduate degree in Yoga/Yoga and Naturopathy/Graduate Degree with one year full time regular PG Diploma/Diploma in Yoga from a recognized University/Institute with one year experience (For yoga therapist/yoga instructor) | 1st and 2nd Year – Rs.16,000/- per month + HRA<br>3rd year – Rs.18,000/- per month + HRA |

**Revised rates are as per ICMR office order 16/35/2010-ADMN II dt.11-6-2010*

***Note: 1. The qualifications must be recognized by the concerned regulatory Council's /Universities/Faculties/Boards.***

***2. Number of RA/SRF/JRF should be claimed as per actual need of the project and the decision of the SC is final in this respect.***

***3. <u>The amount of assistance may be revised by the Department of AYUSH to keep at par with those at Indian Council of Medical Research (ICMR).</u>***

**11.2** ***Supporting Scientific Staff (Consultants):*** Engagement of minimum number of supporting staff (Consultants), having expertise in the concerned research study and clearly identified role in the proposed study, may be proposed with fixed monthly remuneration which, if approved, may be paid from the head 'Salary'. In such cases less number of RA/SRF/JRF may be proposed.

**11.3** ***Non-Scientific Staff:*** The other supporting staff will be considered on the basis of the requirement relevant to the study and would be time bound on consolidated emoluments. Permissible manpower will depend upon the proposal.

**11.4** ***Appropriate fee*** of Rs.20,000/- to Rs.60,000/- (for the total duration of project) to the Principal Investigator may be provided depending on the nature/duration of the project. Appropriate fee of Rs. 10,000/- to 30,000/- (for the total duration of project) may be provided to the Co-I(s) depending on the nature/duration of the project. In case of 2 Co-Is, this amount would be shared by them. This fee would be released only after successful completion of the project and acceptance of the final report of the study by the PEC/SC.

**11.5** ***General terms and conditions of man-power engagement:***

- The appointment of all categories of staff would be made initially for one year and extended by specific orders for such period as may be necessary, but not exceeding one year at a time.
- Appointment will be of temporary and contractual nature for a maximum period of the duration of the study.
- The personnel will have no claim for regular/permanent appointment under the Research Councils / Department of AYUSH or the Grantee Institute on completion of the period of appointment.
- Dearness Allowance (DA) and City Compensatory Allowance (CCA) are not admissible to any category of staff employed under EMR projects.
- HRA will be allowed to all categories of JRFs/SRFs and Research Associates as per the rules of the Institutions where they are working. For this purpose, the fellowship amounts for JRFs/SRFs and Research Associates will be taken as basic pay.
- Leave, salary and other service benefits: RAs, JRFs, SRFs will continue to be eligible for the Casual Leave. However, Maternity Leave will be given to female staff.
- Bonus, L.T.C and Retirement benefits are not admissible to RA/SRF/JRF/non-scientific staff employed for the study.

## 12. RELEASE OF FUNDS:

Agreement for all EMR proposals have to be henceforth signed only with reputed institutes, NOT with individuals. However, great care should be taken in identifying the PI. The grants will be released in the name of the Head of the Institution as yearly installments. The first installment is released along with the sanction letter, which would include the entire grant for purchase of equipment and books, and recurring grant for first year. The $2^{nd}/3^{rd}$ installment(s) would be released subject to the satisfactory progress of the study and timely receipt of the following documents in the prescribed proforma:-

- Annual Progress Report **(as per Annexure 5)**
- Statement of expenditure and Utilization Certificate **(Annexure 6,7,8)** in original, duly signed by the PI, Head of the Institute and the Auditor; and
- Mid-term appraisal by monitoring committee or expert(s) after presentation by the Principal Investigator/Co-I.
- 20% of the proposed expenditure of the study will be held back till the receipt and acceptance of Concluding Report & the manuscript.
- This 20% will be released in 2 parts i.e. 10% after acceptance of Concluding report & remaining 10% after publication of the article and receipt of the UC along with audited statement of accounts.

## 13. INCEPTION AND DURATION OF PROJECT:

**13.1**. ***Date of inception of the project:*** The sanction letter would specify the date from which the project is to start, which will be a prospective date. If, however, no date is mentioned in the sanction letter, the project would deemed to have become operative on the day the grant is received by the Investigator. This date would have to be communicated by the host Institute to the Concerned Research Council. It should be within one month after the receipt of the draft by the Institute and will in no case be later than 03 months. The date of inception of a project can be changed on the request of the PI, made through the sponsoring institution, provided no expenditure has been incurred from the grant released by the concerned Research Council.

**13.2**. ***Duration of the project:*** Extension beyond the approved duration normally would not be entertained. If interesting/important leads emerge that need to be followed-up, a separate proposal may be submitted. Only in exceptional cases, where a valid justification exists, an extension can be considered to complete the project. Duration of project, however, in any case should not go beyond maximum 4 years.

## 14. MAINTENANCE OF ACCOUNTS:

The Grantee institution shall maintain a separate account for the grant received and expenditure incurred. The account will be subject to audit by the authorized auditors. An audit certificate from the auditors to the effect that the account has been audited and the money was actually spent on the objects for which it was sanctioned shall be submitted to the concerned Research Council(s), as the case may be. Any unspent balance must be refunded to the concerned Research Council on termination of the scheme. Further grants will be released on receipt of audited statement of accounts and utilization certificates along with detailed expenditure statement (head wise and item wise) in original, duly signed by the PI, Head of the Institution and the Auditor, within a period of one month after the end of the financial year for which grant was sanctioned.
Voluntary organizations/NGOs will follow other additional instructions given at **Annexure 11**.

**14.1** ***Auditors:***
The Council would normally accept audited reports from statutory auditors. The Council may also accept statement of accounts audited by Chartered Accountants approved by or registered with CAG and/or Ministry of Health and Family Welfare. The necessary registration number should be provided for record.

**14.2** Expenditure should, on no account, exceed the amount sanctioned (head wise) for the research project.

**14.3** No re-appropriation of funds is allowed for over-expenditure in any of the heads or sub-heads. However, in exceptional cases, re-appropriation of funds, from one head/sub head to another may be permitted with the prior approval of the Department of AYUSH, through the concerned Research Council.

**14.4** All expenditure is to be made as per the norms and guidelines of the State Government (for State Government, Private and Non-Governmental Organizations/Institutes) or those of the Central Government (in case of Central Government Organizations).

## 15. FINAL SETTLEMENT OF ACCOUNTS

The final settlement of the accounts will be done only after the receipt of the following:

a. Final audited statement of expenditure **(Annexure-10)**.
b. Final utilization certificate (UC) **(Annexure -7,8)**.
c. List of equipment procured from the project along with their cost and date of purchase and suggestions for future use.
d. Final Project Completion Report (See Sr. no. 15.5)

## 16. SUBMISSION OF REPORTS:

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

**16.1.** ***Progress Report***

- 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, at **Annexure-5**.
- The progress of the project would be evaluated by the Respective Councils through peer review/experts.
- The project will not be renewed for the next financial year unless the respective Councils receives the progress report in time.
- The PI may be asked to present the progress at the meeting of the PEC/SC, if considered necessary.
- The suggestion and views of the PEC/SC and mid-course correction, if any, would be conveyed to the PI, for effective conduct of the project. This would be binding on the PI/grantee institution.

Five hard copies and one soft copy (in CD) of the progress report would be submitted.

***16.2. Annual utilization certificate***

Each year, a statement of accounts giving the funds received and expenditure incurred by
31$^{st}$ March, needs to be submitted, duly signed by the authorized Auditor, the Principal Investigator and the Head of the Institution **(Annexure 6,7,8).**
Unspent balance would be adjusted in the installment for the next year
An audited statement would be essential for release of the second installment of the annual grant from second year onwards.

***16.3*** On receipt of the Annual progress Report and Annual Utilization Certificate, the release of 2$^{nd}$/3$^{rd}$ installment(s) of the grant will be considered.

***16.4 If a report is not submitted within the prescribed time, the study is liable to be discontinued immediately without giving any notice.***

***16.5 Final Project Completion Report***

At the completion of the project, the final report should be sent in the prescribed format, **(Annexure-9)**. The report should be submitted within three months from the date of completion of the project. Five hard copies and one soft copy (in CD) of the Final project Completion report would be submitted.10% of the amount of the total cost of the project will be released only after successful completion of the project and acceptance of the publication of the research findings and receipt of the UC along with audited statement of accounts.

## 17. MONITORING:

The Director General/Director of the Research Council would ensure periodic review and monitoring of the projects on going under the EMR Scheme. The experts, selected by the Director General/ Director of the concerned Research Council, will monitor the technical and financial execution of the project. For the purpose of monitoring the Director General/ Director of the respective concerned Research Council and/or the experts selected by the Director General Director may:

- Review the progress reports received from time to time by the Council from the PI
- Invite the PI to make a presentation before the experts
- Invite the PI to bring 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
- To involve experts of the concerned fields to streamline the monitoring process by the Councils; onsite visits will also be arranged to cross check the quality of the work.

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

The expenditure for monitoring of the project would be provided by the respective Research Councils from their budget.

## 18. PRE-MATURE TERMINATION OF PROJECT:

**18.1**. Prior permission of the Department of AYUSH shall have to be obtained if the Principal Investigator desires to discontinue the projects before the expiry of the approved duration. A final report of the work done is required to be submitted within one month from the date of termination of the projects. Normally pre-mature termination of the Project would not be allowed without the refund of entire funds with interest. However, in exceptional circumstances, the SC may waive off the return of funds or return of interest or both, decided on case to case basis. In such cases, the matter would be referred to the Ministry of Finance for final decision.

**18.2** During the course of the study, the PEC may recommend to the SC for termination of the study, if it is convinced that the study is not being done in accordance with the research proposal approved by the PEC/SC, or in view of any other Technical/Financial/Ethical irregularities. The final decision of such pre-term termination would be that of SC and the decision of the SC would be final and binding to the PI and the grantee Institution. In such case, the Department of AYUSH, through the respective Research Councils would have the authority to revoke the funds given to the Grantee Institution, partially or fully, as recommended by the PEC and approved by the SC.

## 19. INTELLECTUAL PROPERTY RIGHTS AND PATENTS:

**19.1** The patent will be jointly applied by the Concerned Research Council, and the Principal Investigator. The Concerned Council will make joint efforts to commercialize the product as applicable.

**19.2** The investigator or the staff employed on the research project shall not obtain patents for any invention/discovery made by them without prior approval of the Department of AYUSH (on the basis of the recommendation of the PEC / SC).

**19.3** Department of AYUSH will convey such approvals, through the concerned Research Council, as the case may be, within 3 months after receipt of application (for patent).

## 20. PUBLICATIONS:

It is mandatory to publish the findings after completing the project. Outcome of the project shall be published in a reputed peer reviewed (preferably high impact) journal or in the form of book or in the journal of the Council etc. The PI will submit the final consolidated report (as per **Annexure 9**) to the concerned Council, after the completion of the project. A manuscript of the paper would also be sent by the PI to the respective Councils for record. Funding by the Department of AYUSH should be acknowledged in the publication. Any violation of this will be viewed seriously and may invite penal action. Publications of the study in part or full are not permissible before acceptance of the final report by the Screening Committee on the recommendation of the PEC. Expenditure on publication of the research findings in the journals of repute shall be met from the Scheme.

## 21. CONFLICT OF INTEREST

In order to maintain the objectivity in the conduct and reporting of research, it is imperative that the investigators should not have any interests that undermine scientific integrity while recording and reporting their data. Any research or other links of the investigators with industry are discouraged as such a link would compromise or likely to compromise unbiased reporting of research data. In addition, such a financial conflict of interest could lead to loss of public faith on the credibility of data being reported. All investigators, desirous of the EMR Scheme support should declare financial conflict of interest, if any, before submitting the project for support. They should also ensure that during the conduct of the project, they would also observe the same code of conduct. If the Research Council/Department of AYUSH comes to know of any unethical conduct on the part of Investigator(s) including

improper/incomplete declaration, the project is liable to be terminated, immediately along with action taken for recovery of funds.

## 22. IN THE EVENT OF DEFAULT:

1. In the event, the grantee Institution fails to perform its activities, duties, obligations, acts and deeds as per the scheme and the Annexures appended thereto, the terms of this agreement, instructions, orders issued from time to time, will amount to default and in such circumstances, the Department of AYUSH through Research Councils can recall the entire funds provided and stop further release of installments
2. **Designated authority** of the Institutions shall be held responsible in case the project is not completed at all or partially completed or not completed in time as agreed. Penal interest -@ 18% p.a will be levied in the case of grantee not complying with the terms and conditions. However, in exceptional cases, where extension of project time lines becomes necessary, time period for completion of the projects may be extended without any additional financial implications. Extension upto maximum of one year period may be given by PEC after evaluating the progress of the project. The extension may be given only with the condition that if the project is not completed within the extended period of one year, the PI and the institute may be blacklisted. The Government will transfer the project along with the assets created under the project to other suitable institutions. Head of Institution or Controlling Officer of PI will be requested to record adverse entry in ACR of P.I.
3. All the Officers bearers, Principal Investigators, Co-Investigators, President, Chairperson, Secretary, or any other person or person(s) functioning to the grant-in-aid Institution shall be generally and severally responsible and liable to refund the amount with the interest and can also be prosecuted both under the Civil and Criminal Law for breach or default as stated above.
4. Jurisdiction: All disputes or differences between the Department of AYUSH / Research Council's and the grantee Institution shall be decided by referring to arbitration in which the Secretary, Department of AYUSH shall be the arbitrator, whose decision shall be final and binding.
5. PIs/Institutions not complying with provisions of scheme will be debarred from further grants.

The Courts at Delhi shall have the only and exclusive jurisdiction for all matters connected to such disputes / differences.

**ANNEXURE – I**

**Priority Areas**

**HOMOEOPATHY**

**FIRST PRIORITY**

- **Clinical trials on**

  - Depression and anxiety HIV infection
  - 
  - Thyroid disorders
  - Allergic asthma Attention deficit hyperactive disorders
  - Autism
  - Childhood diarrhea
  - Conjunctivitis
  - Chronic suppurative otitis media
  - Dengue
  - Dysmenorrhoea
  - Gastroenteritis
  - Herpes zoster
  - Influenza like illnesses
  - Irritable bowel syndrome
  - Migraine
  - Premenstrual syndrome
  - Sinusitis
  - Trophic ulcer
  - Vitiligo
  - Warts
  - Acid peptic disorders
  - Cervicitis and Cervical erosion
  - Chikungunya
  - Herpes simplex
  - Children Diseases
  - Skin Disease
  - Allergic disorder
  - Bronchial Asthama
  - Neonatal Jaundice
  - Colitis
  - Adenoiditis
  - Tonsillitis
  - Tinnitus

**BASIC RESEARCH**

1. To elicit the mechanism of action of small dose of Homoeopathic medicine
2. To identify the nature of Homoeopathic medicines in ultra dilution in potentised form
3. To explore and establish the pathway of action of Homoeopathic medicine

- To understand the science behind action of Homoeopathic medicine

**SECOND PRIORITY**

- **Clinical trials on**
  - Low back pain
  - Urolithiasis
  - Bronchitis
  - Insomnia
  - Osteoarthritis
  - Acute otitis media
  - Psoriasis
  - Benign hyperplasia of prostate

**AYURVEDA and SIDDHA**

**A. Broad Areas**

1. Development of Methods and modalities for Ayurvedic Clinical research
2. Development of protocols for Clinical Trials
3. Epidemiological Research
4. Preventive Health
5. R & D on Ayurvedic Diagnostics (including Nadi Pariksha)
6. R & D on Panchakarma

**B. Diseases /Areas based on strength of Ayurveda, National priorities**

- Reproductive Child Health (RCH)
- Preventive cardiology-
  - hypertension,
  - atherosclerosis,
  - Dyslipidemia
- Liver Disorders (Hepatitis B)
- Rheumatoid arthritis

- Gastrointestinal disorders
    - Hepatic disorders
    - Diarrhoea
- GI tract disorders - Gastritis, Peptric Ulcer, Non Ulcer Dyspepsia,
    - Ulcerative Colitis, Sprue Syndrome
- Musculoskeletal disorders
    - Osteoporosis
    - Osteoarthritis
    - Rheumatoid arthritis
    - Fibromyalgia
- Eye diseases
    - Diabetic retinopathy
    - Computer vision syndrome
- Metabolic syndromes
- Diabetes mellitus and its complications
- Renal Stone
- Early Stages of Nephritis
- Erectile disorder
- Skin diseases, Urticaria
- Respiratory diseases
- Generalized anxiety disorder
    - Depression
    - Insomnia
- Anaemia
- Malaria
- Benign prostatic hyperplasia, Urolithiasis,
- Ano-rectal conditions – Piles, Fistula-in-ano and Fissure, para-surgical procedures
- Benign Prostatic Hypertrophy
- Wound healing
- Neurodegenerative conditions – Parkinsonism, Senile Dementia, Neurological disorders
- Migraine
- Hemicrania
- Rasayana therapy and geriatrics
- Reproductive and child health
- Quality of life (QOL) in cancer patients.
- Male infertility - oligospermia
- Dysllipidaemia
- Leucorrhea

**Drug Research and Development**

1. Standardization and quality assurance
2. Pharmaceutical Research and Development
3. Pharmacognosy (in-vitro and in-vivo methods)
4. Biomarker based mechanism of action
5. Ethno-medicinal Research: survey and documentation of medicinal plants/practices etc.
6. Veterinary ayurveda products.

**FUNDAMENTAL RESEARCH**

- Tridosa Prakriti, Agni, Srotas, Ojas, Ama, Dhatu, Samprapti and Shad kriya-kala etc.
- Rasa, Guna, Virya, Vipaka and Prabhava
- Literature research; Survey, collection, transcription/translation and preparation of classical literature and text books, medico-historical investigations of Ayurveda.

**SIDDHA**

1. Research on fundamentals of Siddha and its principles and practice including the Literature Research

2. Clinical research: Validation of clinical efficacy of Classical Siddha Formulations on priority basis including Siddha diagnostics and preventive health care.
3. Drug Research and Development based on Siddha principles and Experimental leads.

**DISEASE / AREAS BASED ON STRENGTH OF SIDDHA**

- Psdoriasis
- Renal Stone
- Dysmenorrhea
- Polyarthritis

**YOGA AND NATUROPATHY**

- Diabetic mellitus with its complications
- Metabolic disorders: obesity/Hypo/Hyperthyroidism, Metabolic syndrome
- Cardiac disorders: Hypertension/CAD/Dyslipidemia

- Respiratory Disorders: Sinusitis, Bronchial Asthma, Bronchitis, COPD, Allergic rhinitis etc
- Musculo-skeletal disorders, Backache, Cervical and lumbar spondylosis, Fibromyalgia, Fatigue syndrome, Sports injury.
- GIT Disorders: Constipation, Piles, Peptic Ulcer, Indigestion, Anorexia, Hyperacidity, Ulcerative colitis, IBS
- Psychiatry and Neurological Disorders: Anxiety Neurosis, Mental Disorders, Depression, Schizophrenia, Epilepsy, Headache, Drug dependence, Parkinsonism, Delirium, Dementia, Cognitive impairment disorders, Alzheimer's disease etc.
- Rheumatology (immunology): Rheumatoid arthritis, Osteoarthritis, Ankylosing spondylitis, Systemic lupus erythematosus, Interstitial lung disease, Sclerosis
- Women & Child Health disorders: Menopausal syndrome, Menstrual disorders, Uterine fibroids, Pregnancy, Child development, Infertility, Polycystic Ovarian Syndrome;
- Basic physiological Research in Yoga & Naturopathy
- Geriatric problems;
- Skin diseases: Psoriasis;
- Malnutrition, Anemia;
- Cancer;
- HIV/AIDS;

- Refractive disorders
- Research on Preventive and promotive aspects of Yoga and Naturopathy practices and therapies;
- Literary Research: survey, collection, transcription/translation, editing and publication of classical literature and text books on Yoga and Naturopathy

**UNANI MEDICINE**

**Clinical Research**

**Priority -I**

- Life style disorders – Diabetes, obesity, hypertension, hyperlipidemia
- Metabolic disorders, Digestive problems
- Acid Peptic diseases
- Cardio vascular diseases – Stable Angina, Arteriosclerosis, Mycardial Infarction
- Skin Diseases- Vitiligo, Eczema, Psoriasis, Leucoderma
- Pharmacology and safety evaluation of Unani drugs
- Clinical and therapeutic studies of Unani drugs
- Communicable diseases – Malaria, Filariasis, Kala Azar
- Adjuvant therapy to improve QoL in terminal HIV/AIDS and Cancer patients
- New emerging viral diseases – Birdflu, Dengue, Chikunguniya, SARS
- Reproductive Child Health and Family Welfare – Anaemia

- Benign and malignant tumours – BPH, Cancers of different tissues
- Musculoskeletal disorders- Osteoarthritis, Rheumatoid arthritis, Osteoporosis, joint pain, polyarthritis
- Diseases of Urinary system – Renal and Vesical calculus, diabetic nephropathy, chronic UTI, chronic nephritis
- Respiratory diseases – bronchial asthma, TPA, allergic bronchitis, Sinusitis, common coldLiver Disorder
- Hepatobilliary diseases – Infective hepatitis, Chronic hepatitis, Cholecystolithiasis
- Infantile diarrhoea/chronic diarrhea, Dysentery
- Geriatric care and geriatric diseases
- Clinical validation of cosmeto-therapeutics
- Oral health
- Sport Medicines
- Emergency Medicines
- Hemipleagia
- Dementia
- Epilepsy

**Priority –II**

- Eye Diseases- conjunctivitis, cataract, trachoma, refractive errors
- Ear diseases- Otitis Media, Otorrhoea
- Amoebic dysentery
- Nutritional disorders – Kwarshiorkor, Marasmas, Beriberi, Rickets
- Common cold
- Menstrual disorders

Fundamentals Principles of Unani Medicine

- Scientific validation of concept of temperament
- Scientific validation of theory of humours
- Scientific validation of Pulse examination
- Scientific validation of Munzij Mushil Therapy
- Scientific validation of traditional concept of incompatibility of diet

- Research on Prevention of diseases and promotion of health
- Regimental Therapies – Cupping, Venesection, leaching etc.
- Dietotherapy

- Acquisition and preservation of rare books and manuscripts and editing and translation of manuscripts and rare books
- Compilation and publication on different systemic diseases.
- Standardization and Development of SOPs of Unani drugs
- Determination of heavy metals and their toxicity
- Shelf life studies of single/compound Unani drugs

- Photo effect and preservative studies
- Documentation, publication and validation of folklore
- Experimental/Field scale cultivation of rare medicinal plants.
- Development of agro techniques for medicinal plants among farmers
- Development of health based films
- Development of audio-video cassettes/CDs/DVDs/literatures

**DRUG RESEARCH**

- **Standardization and quality assurance**
- **Pharmaceutical Research and Development**
- **Pharmacognosy**

**ANNEXURE – 2**

## FORMAT FOR APPLICATION OF PROJECT UNDER EMR SCHEME

**GOVERNMENT OF INDIA**
**MINISTRY OF HEALTH and FAMILY WELFARE**
**(DEPARTMENT OF AYURVEDA, YOGA and NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY [AYUSH])**

APPLICATION FOR GRANT-IN-AID OF EXTRA MURAL RESEARCH PROJECTS IN AYUSH
**(Please furnish 10 hard copies and one soft copy in CD)**

### Section A
### GENERAL

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 in 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 collecting the data:

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

6. Amount of Grant-in-aid asked for (details are to be furnished in Section B):

| | Total | 1st year | 2nd year | 3rd year | Balance10% Of the total |
|---|---|---|---|---|---|
| Salary | | | | | |
| Equipment | | | | | |
| Books | | | | | |
| Other Non-Recurring Expenditure | | | | | |
| Recurring Expenditure | | | | | |
| TA/DA | | | | | |
| Institutional Support | | | | | |
| Appropriate fee of PI and CoI | | | | | |
| Miscellaneous expenses | | | | | |
| Total | | | | | |

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

7.1 Under EMR Scheme

| 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 | Grant received (till the date of applying) | Names and Designation of the PI and the Co-I | Status of the Project | Status of the U.C. |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

7.2 Under other schemes of the Government / other Institutions/Organizations

| S. No. | Name of the Project And the granting Ministry/Organization | Date of inception of project | Date of completion of the project/expected date of completion of the project | Total Cost | Grant received (till the date of applying) | Names and Designation of the PI and the Co-I | Status of the Project | Status of the U.C. |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

## 8. DECLARATION AND ATTESTATION

**Certified that:**

i) I/We have read the provisions, terms and conditions, mentioned in the Extra-mural Scheme along with its Annexure, Guidelines formulated by the Department of AYUSH (Ministry of Health and Family Welfare) and I/we shall abide by all the provisions contained therein.

ii) Necessary Institutional facilities will be provided if the research project is approved for financial assistance.

iii) All records and reports related to the Project shall be shown and furnished to the authorized representatives of the concerned Research Council/Dept. of AYUSH

iv) Project shall be open for evaluation of the physical progress and utilization of funds at the discretion of the concerned Research Council/Dept. of AYUSH.

v) I/We agree to submit within one month from the date of termination of the project the final report and a list of articles, both expendable and non-expendable, left on the closure of the project.

vi) I/We agree to submit audited statement of accounts duly audited by the auditors of the Institute.

vii) All information furnished is true, I/We shall be responsible for the authenticity of the information and documents furnished in the application, proposal, and all reports, and documents sent in relation to the study project, thereafter.

viii) The Department of AYUSH, through the concerned Research Council, shall have the right to recover the grant or take legal action against the Individual/Organization, for any default or deviation from the provisions/terms and conditions of the EMR Scheme.

ix) It is certified that the equipment (needed for the project and provisioned for in the budget) is/are not available in the Institute/Organization or these are available but cannot be spared for the project. (Note: If any equipment already exists with the Institute/Organization, the Investigator should justify purchase of another equipment.)

x) I/we undertake that:

a) In the event, the grantee Institution fails to perform its activities, duties, obligations, acts and deeds as per the scheme and the Annexures appended thereto, the terms of this agreement, instructions, orders issued from time to time, will amount to default and in such circumstances, the Department of AYUSH through Research Council's can recall the entire funds provided and stop further release of installments
b) In such case of default, Grantee Institutions shall refund the amount disbursed to them within 15 days of receipt of such intimation from the Department of AYUSH / Research Councils. Interest @ 12% shall be charged if the amount is not returned within this stipulated time.
c) All the Officers bearers, Principal Investigators, Co-Investigators, President, Chairperson, Secretary, or any other person or person(s) functioning to the grant-in-aid Institution shall be generally and severally responsible and liable to refund the amount with the interest and can also be prosecuted both under the Civil and Criminal Law for breach or default as stated above.
d) Jurisdiction: All disputes or differences between the Department of AYUSH / Research Councils and the grantee Institution shall be decided by referring to arbitration in which Secretary, AYUSH shall be the arbitrator, whose decision shall be final and binding.

The Courts at Delhi shall have the only and exclusive jurisdiction for all matters connected to such disputes / differences.

**Name and Signature of the:**

**a) Principal Investigator** _____

_____

**Name** **Signature**

**b) Co-Investigator(s)** _____

_____

**Name** **Signature**

_____ _____

**Name** **Signature**

**c) Head of the Department** _____ _____

**Name** **Signature**

**Signature of the Head of the Institution**
**Name in full:**
**Seal:**

**Place:**
**Date:**

LIST OF DOCUMENTS ENCLOSED (SEE SECTION 6.7.4):

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

**Section –B**

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

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 (Begin with Bachelor's Degree)
   Degree Institution Field(s) Year

6. Research Experience
   Duration (From-To) Institution 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
   a) From the Ministry of Health and Family Welfare
      Past
      Present
      Pending

   b) From other organizations
      Past
      Present
      Pending

10. Research projects in hand under EMR Scheme of Department of AYUSH

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

14. 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 Department 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. Relevance and usefulness of the study with particular reference to concerned AYUSH system.

6.IPR values

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

8. Preliminary work already done by the Investigator on the subject, e.g. selection of subjects, standardization methods earlier research work done.

9. Links with other project (s) administered by Ministry of Health and Family Welfare i.e Department of Health, Department of Family Welfare and Research bodies under the Ministry.

10. List of important publications over the last 5 years of the Investigator relevant to the project (enclose reprints).

11. Ethical and other clearances: (See section 6.7.3 in Scheme)

i. The description of ethical considerations relating to the trial is to mentioned and Approval of the Institutional Ethical Committee/Institutional Animal Ethics Committee should be enclosed for research involving human subjects/animal experimentation.

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.

iii. Projects involving recombinant DNA/Genetic engineering work should be examined and certificate by the Institutional Bisafety Committee (IBSC) to be enclosed. Guidelines for constitution of IBSC can be obtained from Secretary, Department of Bioechnology, CGO Complex, Lodhi Road, New Delhi-110003.

12. Budget requirements (head wise and item wise) with ***detailed break-up year wise*** and with full justification (Refer section 9 of Scheme)

1. Salary (See section 10.1)
2. Equipments (see section 8,9)
3. Books
4. Other Non-Recurring Expenditure (mention details item wise)
5. Recurring Expenditure (mention details item wise)
6. TA/DA
7. Institutional Support (see section 8.3)
8. Appropriate fee of PI and CoI (see section 10.4)
9. Miscellaneous expenses

Total Grant-in aid required for the period of three years: _____

## SECTION-D
## Detailed Research Protocol

Give here the design of study as per guidelines for clinical trial protocol including toxicity investigators, indicating the total number of the cases/samples to be studied, as well as the mode of selection of subjects specially 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.

*(Also, the Investigator is required to go through the Good Clinical Practices (GCP) for Clinical Research in India provided by Central Drug Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of India.)*

**See Annexure – 3 and 4 for preparation of detailed research protocol.**

**ANNEXURE-3**

## GUIDELINES FOR PREPARATION OF CLINICAL TRIAL PROTOCOL

### General information

1. Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).
2. Name and address of the institute where the study would be conducted
3. Name and Address of the head of the Institute, where the study would be conducted
4. Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s).
5. Name and title of the investigator(s) who is (are) responsible for conducting the trials, and the address and telephone numbers(s) of the trial site(s).
6. Name title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).
7. Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and /or other institutions involved in the trial.

### Background information

1. Previous knowledge of about the subject
2. Name and description of the investigational product(s).
3. A summary of findings from non-clinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.
4. References to literature and data that are relevant to the trial, and that provide background for the trial.
5. Description of the population to be studied
6. Summary of the known and potential risks and benefits, if any, to human subjects.
7. Description of, and justification for, the route of administration, dosage, dosage regimen, and treatment period(s).
8. A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).

### Trial objectives and purpose

A detailed description of the objectives and the purpose of the trial.

### Trial design*:*

1. The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design, should include a specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.

2. A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.
3. A description of the measures taken to minimize/avoid bias, including:
   (a) randomization
   (b) blinding
4. A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging and labeling of the investigational product(s).
5. The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.
6. A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.
7. Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
8. Maintenance of trial treatment randomization codes and procedures for breaking codes.
9. The identification of any data to be recorded directly on the case report forms (i.e. no prior written or electronic record of data), and to be considered to be source data.

**Selection and withdrawal of subjects**

1. Subject inclusion criteria
2. Subject exclusion criteria
3. Subject withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying:

(a) when and how to withdraw subjects from the trial/investigational product treatment;
(b) the type and timing of the data to be collected for withdrawn subjects;
(c) whether and how subjects are to be replaced;
(d) the follow-up for subjects withdrawn from investigational product treatment/trial treatment.

**Treatment of subjects**

1. The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.
2. Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
3. Procedures for monitoring subject compliance.

**Assessment of efficacy**

1. Specification of the efficacy parameters.

2. Methods and timing for assessing, recording, and analysing of efficacy parameters.

**Assessment of safety of trial subjects/research participants**
1. Specification of safety parameters.
2. The methods and timing for assessing, recording, and analysing safety parameters.
3. Procedures for eliciting report of and for recording and reporting adverse event and intercurrent illnesses.
4. The type and duration of the follow-up of subjects after adverse events.

**Statistics**
1. A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).
2. The number of subjects planned to be enrolled. In multi-centre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
3. The level of significance to be used.
4. Criteria for the termination of the trial.
5. Procedure for accounting for missing, unused, and spurious data.
6. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).
7. The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

**Direct access to source data/documents**
It should be specified in the protocol that the investigator(s)/institution(s) will permit trial-related monitoring, audits, institutional review board/independent ethics committee review, and regulatory inspection(s), by the Research Council/Department of AYUSH providing direct access to source data/documents.
Also the privacy policy to be followed by the Institute/PI mentioning the persons who would have an access to the source data and documents related to the research study, is to be elaborated.

**Quality control and quality assurance**
The medicine used in the study shall comply the pharmacopoeial and quality standards.

**Ethics**
Description of ethical considerations relating to the trial.

**Data handling and record keeping**
The policy to be followed for handling of data, source documents and record is to be mentioned.
If the Institute/Organization does not have any such policy for its research projects, guidelines for data handling are to be incorporated keeping in view the

Confidentiality concerns that will dictate how data is collected, retained and shared. The data handling and record keeping requirements can include:
How the Source documents, Case Report Forms, assessment forms, etc would be completed, checked for inaccuracies?
How long data would be kept?
With whom data can be shared?
Who has rights to the data?
Where and how the data is to be stored
Where and How to Store Research Records?
What computer practices would be followed, i.e. who will enter the data, who would have an access to the data and how data loss would be prevented?

**Financing and insurance**
Financing and insurance is to be detailed.

**ANNEXURE-4**

## GUIDELINES FOR TOXICITY INVESTIGATION OF HERBAL MEDICINE

These guidelines are intended to indicate the standard methods of non-clinical toxicological studies related to assessing the safety of herbal medicines. Not all tests are necessarily required for each herbal medicine intended for human study.

## ACUTE TOXICITY TEST

**Animal species**

Some regulatory agencies require that at least two species be used, one of them to be selected from rodents and the other from non-rodents.

**Sex**

In at least one of the species, males and females should be used.

**Number of animals**

In the case of rodents, each group should consist of at least five animals per sex. In the case of non-rodents, each group should consist of at least two animals per sex.

**Route of administration**

Ordinarily, the oral route is sufficient, as this is the normal route of clinical administration.

However, some regulatory agencies suggest in addition a parenteral route of administration.

In case where it is proposed to administer the herbal preparation to a human subject by the parenteral route, it may be sufficient to use this route alone for animal testing.

**Dose levels**

A sufficient number of dose levels should be used in rodents to determine the approximate lethal dose. In non-rodents, sufficient dose levels should be used for the observation of overt toxic signs.

**Frequency of administration**

The test substance should be administered in one or more doses during a 24 hours period.

**Observation**

Toxic signs and the severity, onset, progression and reversibility of the signs should be observed and recorded in relation to dose and time. As a general rule, the animals should be observed for at least seven to fourteen days.

Animals dying during the observation period, as well as rodents surviving to the end of the observation period should be autopsied.

If necessary, a histopathological examination should be conducted on any organ or tissue showing macroscopic changes at autopsy.

## LONG-TERM TOXICITY TEST

**Animal species**

Many regulatory agencies require that at least two species be used, one a rodent and the other a non-rodent.

**Sex**

Normally, the same number of male and female animals should be used.

**Number of animals**

In cases of rodents, each group should consist of at least ten males and ten females. In the case of non-rodents, each group should consist of at least three males and three females.

When interim examinations are scheduled, the number of animals should be increased accordingly.

**Route of administration**

Normally, the expected clinical route of administration should be used.

**Administration period**

The period of administration of the test substance to animals will depend on the expected period of clinical use. The period of administration of the toxicity study may vary from country to country, according to its individual regulations.

The following table reflects commonly used ranges of administration periods:

| Expected period of clinical use | Administration period for the toxicity study |
|---|---|
| Single administration or repeated administration for less than one week | 2 weeks to 1 month |
| Repeated administration, between one week to four weeks | 4 weeks to 3 months |
| Repeated administration, between one to six months | 3 to 6 months |
| Long-term repeated administration for more than six months | 9 to 12 months |

As a rule, the test substance should be administered seven days a week. Administration periods for the toxicity study must be recorded in each result.

**Dose levels**

Groups receiving at least three different dose levels should be used.

One dose level should not cause toxic changes (no-effect dose) and one dose level that produces overt toxic effects should be included. Within this range the addition of at least one more dose may enhance the possibility of observing a dose-response relationship for toxic manifestations. All studies should include a vehicle control group of test animals.

**Observations and examinations**

Observations and examinations should be performed on the following items (from 1 to 6):

*1. General signs, body weight and food and water intake*

For all experimental animals, the general signs should be observed daily and body weight and food intake should be measured periodically. If useful, water intake should also be determined.

The frequency of measurements should normally be as follows:

Body weight: before the start of drug administration, at least once a week for the first three months of administration and at least once every four weeks thereafter.

Food intake: before the start of drug administration, at least once a week for the first three months of administration and at least once every four weeks thereafter. If the test substance is administered mixed in the food, the intake should be measured once a week.

*2. Haematological examination*

For rodents, blood samples should be taken before autopsy. For non-rodents, blood samples should be taken before the start of drug administration, at least once during the administration period (for studies of longer than one month), and before autopsy.

For both haematological and blood chemistry examination, it is desirable to include as many parameters as possible.

*3. Renal and hepatic function tests*

Since the liver and kidneys are the usual organs of metabolism and excretion, potentially toxic agents easily affect them; their functions should be monitored in long-term toxicity studies. For rodents, a fixed number of animals from each group should be selected and urinalysis should be performed before the start of drug administration, and at least once during the administration period.

*4. Other function tests*

If appropriate, ECG and visual, auditory tests should be performed. For rodents, ophthalmological examination should be performed on a fixed number of animals from each group at least once during the administration period; for non-rodents, examination should be performed on all animals before the start of drug administration and at least once during the period of administration.

5. Animals found dead during the examination should be autopsied as soon as possible. A macroscopic examination should be made of organs and tissues. In addition, where possible, organ weight measurements and histopathological examinations should be performed in an attempt to identify the cause of death and the nature (severity or degree) of the toxic changes present.

6. In order to maximize the amount of useful information that can be obtained during the administration period, all moribund animals should be sacrificed rather than allowed to die. Prior to sacrifice, clinical observations should be recorded and blood samples collected for haematological and blood chemical analysis. At autopsy a macroscopic examination of organs and tissues and measurement of organ weights should be recorded. A full histopathological examination should be performed in an attempt to characterize the nature (severity of degree) of all toxic changes.

All survivors should be autopsied at the end of the administration period or of the recovery period after taking blood samples for haematological (including blood chemistry) examinations; organs and tissues should be examined macroscopically and organ weights measured. Histopathological examinations of the organs and tissues of animals receiving lower dosage should also be performed, if changes are found on gross or macroscopic examination of their organs and tissues of these animals, or if the highest dose group reveal significant changes. On the other hand, histopathological examination of all rodents will further improve the chances of detecting toxicity.

**Recovery from toxicity**

In order to investigate the recovery from toxic changes, animals that are allowed to live for varying lengths of time after cessation of the period of administration of the test substance, should be examined.

**ANNEXURE- 5**

## FORMAT FOR PROGRESS REPORT

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

Signature of PI: Date:

Signature of Head of the Institute/Organization: Date:

**ANNEXURE- 6**

**Format for Annual Statement of Accounts to accompany request for release of next installment**

(Year means Financial Year i.e. 1st April to 31st March of next year)

1. Sanction letter No. : ..... ……

2. Total Project Cost : Rs……

3. Sanction /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 31st March | Remarks |
|---|---|---|---|---|---|---|---|---|
| | | | 1st year | 2nd Year | 3rd 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 CoI | | | | | | | |
| 9 | Miscellaneous expenses | | | | | | | |
| 10 | Total | | | | | | | |

| | | |
|---|---|---|
| Signature of Principal Investigator<br>with date | Signature of Head of Institution<br>with date | Signature of Authorized Auditor<br>with date |

**ANNEXURE-7**

**Check list for covering note to accompany Utilization Certificate of grant for the project for the period ending 31st March, 20 __)**

1) Title of the project

2) Name of the Institutions

3) Principal Investigator

4) Department of AYUSH letter No. and date sanctioning the project.

5) Head of account as given in the original sanction letter

6) Amount received during the financial year (Please give No. and date of Department's sanction letter for the amount)

7) Total amount that was available for expenditure (excluding commitments) during the financial year (including amount remaining from earlier installment)

8) Actual expenditure (excluding commitments) incurred during the financial year (upto 31st March).

9) Balance amount available at the end of the financial year.

10) Amount already committed, if any.

11) Amount to be carried forward to the next financial year (if applicable). Indicate the amount already committed with supporting documents.

**ANNEXURE -8**

**FORMAT FOR UTILIZATION CERTIFICATE**

(ANNUAL/FINAL)

(to be submitted in original)

Certified that out of Rs..... of grants-in-aid sanctioned during the year ……..... in favour of ……..…… under Dept. of AYUSH Letter No……..... 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 of Rs . .....remaining unutilized at the end of the year has been surrendered to Dept. of AYUSH letter No. ..... Dated…..... /will be adjusted towards the grants-in-aid payable during the next year i.e. .....

| | | |
|---|---|---|
| Signature of Principal Investigator with date | Signature of Head of the Institution with date | Signature of Authorized Auditor of the Institute with date |

**ANNEXURE-9**

## FORMAT FOR FINAL REPORT

1. Title of the Project:
2. PI (name and address)
3. Co-I (name and address)
4. Other Scientific Staff engaged in the study
5. Non-Scientific Staff engaged in the study
6. Implementing Institution and other collaborating Institutions
7. Date of commencement
8. Duration
9. Date of completion
10. Objectives as approved
11. Deviation made from original objectives if any, while implementing the project and reasons thereof.
12. Experimental work giving full details of experimental set up, methods adopted, data collected supported by necessary tables, charts, diagrams and photographs.
13. Detailed analysis of results indicating contributions made towards increasing the state of knowledge in the subject.
14. Conclusions summarizing the achievements and indication of scope for future work.
15. Procurement/usage of Equipment

| S. No. | Name of Equipment | Make/ Model | Cost FE/Rs | Date of Installation | Utilisation rate % | Remarks regarding maintenance/breakdown |
|---|---|---|---|---|---|---|
| | | | | | | |

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

Name and signature with date

1. _____
(Principal Investigator)
2. _____
(Co-Investigator)

**ANNEXURE 10**

**FORMAT FOR FINAL STATEMENT OF EXPENDITURE**
***(to accompany the Final Report)***
(to be submitted in original)

1) Sanction letter No.
2) Total project cost
   (Sanctioned/revised project cost, if applicable)
3) Date of commencement of project:
4) Date of completion of project:
5) Grant received in each year (financial):
   1st Year : Date of release of grant…… grant received Rs……
   2nd year: Date of release of grant…… grant received Rs……..
   3rd year : Date of release of grant…… grant received Rs……

6) Statement of Expenditure:

| S.No. | Sanctioned/Heads (Mention all items under each head) | Funds Allocated | Expenditure Incurred: Financial Year wise | | | Balance as on (Date) | Remarks |
|---|---|---|---|---|---|---|---|
| | | | 1st year | 2nd Year | 3rd Year | | |
| 1 | Salary | | | | | | |
| 2 | Equipment | | | | | | |
| 3 | Books | | | | | | |
| 4 | Other Non-Recurring Expenditure | | | | | | |
| 5 | Recurring Expenditure | | | | | | |
| 6 | TA/DA | | | | | | |
| 7 | Institutional Support Charges | | | | | | |
| 8 | Appropriate fee of PI and Co I | | | | | | |
| 9 | Miscellaneous expenses | | | | | | |
| 10 | Total | | | | | | |

Amount to be refunded/reimbursed (whichever is appropriate): Rs.

| | | |
|---|---|---|
| Signature of Principal Investigator<br>with date | Signature of Head of Institution<br>with date | Signature of Authorized Auditor<br>with date |

**ANNEXURE-11**

## GENERAL CONDITIONS FOR THE RELEASE OF GRANT-IN-AID TO NON-GOVERNMENTAL VOLUNTARY ORGANIZATIONS.

1. The organization should maintain separate account exclusively with a bank in the name of the organization and not of an individual whether by name or by designation. The accounts should be operated jointly by two office bearers;
2. The entire amount of the grant should be utilized within the period specified in the sanction letter and only for the purpose for which it is sanctioned;
3. If the grant or any part there of is proposed to be utilized for a purpose other than that for which it is sanctioned, prior approval of the Government of India should be obtained;
4. The accounts of the organization should be audited by a Chartered Accountant or a Government Auditor immediately after the end of financial year. The accounts of the grant shall be maintained properly and separately from its normal activities and submitted as and when required. They shall always be open to inspection by any person authorized on this behalf by this Ministry. They shall also be open to a test check by the Comptroller and Auditor General of India at his discretion.

5.(i) The grantee organization(in not individual) will execute a bond in the prescribed proforma on a non-judicial stamp paper only with two sureties to the effect that the organization will abide by all the conditions of the grants. In the event of any failure to comply with these conditions or committing any breach of bond the grantee with sureties individually and jointly will be liable to refund to the Government of India the entire amount of the grant together with interest thereon;

(ii) The requirement of furnishing two sureties will not be necessary if the grantee organization is a society registered under the Societies' Registration Act, 1860 or is a cooperative society; and

(iii) When the bond is also signed by two sureties, both of them should be solvent and owner of such assets worth not less the amount of the bond as can be attached and sold in execution by the District magistrate or other equivalent on the body of the bond;

6. The organization should furnish the certificate to the effect that the grantee has not been sanctioned for the same purpose by any other Department of the Central or State Government during the period to which the grant relates;
7. When the Central or State Government have reasons to believe that the sanctioned money is not being utilized for approved purpose, the payment of further grants may be stopped and the earlier grants recovered;
8. Any portion of the grant, which is not utilized for expenditure upon the objects for which it was sanctioned, will be refunded in case to the Government of India in this Ministry;
9. No portion of the grant will be utilized for furtherance of a political movement prejudicial to the security of the nation;

10. Essential scientific equipment including computer and software if needed may be permitted as non-recurring expenditure. However, the quantum of such expenditure will not be more than 25% of the total project cost. The equipment will become property of the host Institutions after completion of the project. The purchases are to be made as per rules and the procedures of the host Institution. Books purchased out of the contingencies may be retained by the principal Investigator.
11. The grantee will not indulge in corrupt practices;
12. The grantee organization should give an undertaking in writing that the grantee agrees to be governed by the conditions of the grant mentioned in this Annexure and the sanction letter;
13. The grantee should forward the following documents duly certified as correct by a Chartered Accountant/Auditor to this Ministry by the organization after the grant is fully utilized: -

(i) A utilization Certificate to the effect that the grant has been utilized for the purpose for which it was sanctioned; and

(ii) Audited Statement of Accounts reflecting there in the grant and the items of expenditure incurred there-from.

**Annexure-12**

## REQUEST FOR EXTENSION

**(10 Copies to be sent six months prior to the Date of Expiry of the Project)**

1. Reference No:

2. Name of the Investigator:

3. Title of the Project:

4. Approved duration of the project from _____ to _____.

5. Requested extension from _____ to _____.

6. Original objectives (quoted from project proposal)

   a.
   b.
   c.

7. Results achieved so far (in relation to attainment of objectives)

8. Clear statement of objectives that have not been achieved so far but will be achieved during the extended period:

9. Financial implications:

   A. Total Sanctioned Amount:
   B. Total expected expenditure till the end of present sanctioned duration:
   C. Expected expenditure during extended period:

      C.1 Manpower costs (at the existing level)
      Existing level means average of last 6-12 months expenditure
      C.2 Consumables (at existing level)
      C.3 Travel (if absolutely necessary)
      C.4 Contingencies

   D. Expected amount to be refunded to Dept. of AYUSH
      ***or***
      Expected amount in addition to the sanctioned amount.

Name and Signature of PI
Seal

Name and Signature of the Head of the Institution
Seal