



Z. 28015/49/2013-HPC (EMR)-AYUSH
Government of India
Ministry of Health & Family Welfare
Department of AYUSH

AYUSH Bhawan, B-Block
G.P.O. Complex, INA,
New Delhi 110023
Date: 10.11.2014

To

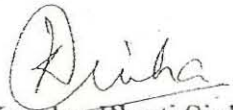
1. **Director General,**
CCRAS/CCRUM/CCRH
Opposite D-Block, Janakpuri,
New Delhi-110058
2. **Director,**
CCRYN,
Opposite D-Block, Janakpuri,
New Delhi-110058
3. **Director General**
CCRS,
SCRI Building, Arumbakkam,
Chennai- 600 106

Subject: Revised Extra Mural Research (EMR) Scheme.

Sir,

I am directed to forward herewith the revised Extra Mural Research (EMR) Scheme under Ministry of AYUSH duly approved by the Competent Authority for information and necessary action.

- 2 It is requested that the scheme may be given wide publicity.


((Kundan Bharti Sinha)
Under Secretary to the Govt. of India

Copy to:

1. Advisor (Health), Planning Commission, Yojna Bhawan, New Delhi-110001
2. Advisor (Unani)/Advisor (Hoomoepathy), Ministry of AYUSH, New Delhi-110023
3. Director (IFD), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi-110001
4. PPS to Secretary (AYUSH)
5. PS to JS (BP)
6. IEC Section-with the request to give the scheme wide publicity.
7. NIC Section-with the request to upload the information on the Ministry's website.
8. Department of AYUSH of all States (list enclosed).

Deans (CR&M)

विभाग : समन्वय विभाग
Dept.: COORD. SECTION
संदर्भ संख्या/Ref. No. 2014/ICDN/1618
दिनांक /Date : 18/12/14

Dr. Bansal pl.

18/12/14
22/12/14

AR
18/12/14

May kindly advise whether
the Scheme could be circulated
to CBME or to all Delhi pl.
Kansarp
19/12/14
AR (Box) / Deans (Ro)
To circulate to all Secretary
18/12

**SCHEME FOR
EXTRA MURAL RESEARCH
IN
AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA, SOWA
RIGPA AND HOMOEOPATHY**

**MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND
HOMOEOPATHY
GOVERNMENT OF INDIA
www.indianmedicine.nic.in**

**SCHEME FOR
EXTRA MURAL RESEARCH
IN
AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA, SOWA RIGPA AND
HOMOEOPATHY**

1. BACKGROUND:

Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy, offer a wide range of holistic treatments covering preventive, promotive, curative, rehabilitative and rejuvenatory needs. These systems of medicine are generally cost effective and valuable and attracting increasing attention globally. AYUSH systems of medicine are being used for centuries and have continuous traditions of acceptance and practice.

There is a need for spreading the knowledge & benefits of AYUSH system of medicines to the large section of the peoples across the globe. This is possible only if the drugs & practices are validated through an exhaustive research process based on standard parameters.

The AYUSH Research councils have been conducting research over last 40 years. In the country several other educational, scientific institutions and universities have also contributed significantly to clinical research, ethno-botanical surveys, pharmacognostical and pharmacological studies on plants and drugs standardization of simple and compound formulations used in Ayurveda, Siddha and Unani system of medicine. The growth is largely through multi-disciplinary approach.

In this current genome era evidence for safety and efficacy is being demanded by the users. Though various organisations are actively involved in this herculean task, yet a lot remains to be achieved. The Ministry of AYUSH has taken up a series of programs/interventions wherein to create evidence based support for the efficacy, safety, quality control and consistency of products.

In the post globalization era, India has to compete with foreign herbal products within its own territory. The need to have a greater impetus on research will not only boost trade and practice of Indian product but will also help in spreading the traditional Indian knowledge to other parts of the world by fulfilling the national as well as international regulatory requirements.

Many public and private organisations, pharmaceutical industries, educational institutions, Universities, hospitals and individuals in India have been also conducting research on their own initiatives over the years. But it has been observed that research has not been keeping pace with the times and not been re-oriented and prioritized as per the requirement of scientific standards. The Ministry of AYUSH has introduced a scheme for Extra Mural Research to tap the potential of these organisations for the research needs of AYUSH sector.

In the context described above the Extra Mural Research Scheme of Ministry of AYUSH is designed to encourage R&D in priority areas based on disease burden

in alignment to National Health programme. It also aims to utilize the vast research infrastructure available within the country for standardization and validation of classical drugs. This scheme is meant for focused outcome in tandem with the needs of AYUSH sector and also encourage young scholars of AYUSH system, to use their wisdom and energy in the research of AYUSH system on modern scientific parameters.

2. OBJECTIVE:

The objective of Extra Mural Research Scheme are as follows:

- ❖ To support Research and development in Extra Mural mode for treatment of prioritized diseases.
- ❖ To Standardize/validate and develop scientific evidence for safety, efficacy and quality of AYUSH drugs & therapies.
- ❖ To make scientific exploration of AYUSH system with interdisciplinary approaches.
- ❖ To achieve need based outcome in a priority areas.
- ❖ To develop the potential of Human Resource in AYUSH system specially to inculcate aptitude and expertise to AYUSH systems.

3. THE SCOPE OF SCHEME:

The scheme is aimed at developing the opportunity for scientific scrutiny of AYUSH systems for the benefit of users, researchers, practioners, industries & common people at large. The outcomes of the scheme are expected to harness the potential of AYUSH in the interest of public health delivery. The evidences thus generated will help in propagating rational use, clinical application & mainstreaming of AYUSH. The scheme would widen the scope for clinical, fundamental, pharmaceutical, literary and medicinal plant research in Extra Mural mode.

4. PRIORITY AREAS OF RESEARCH:

The scheme will support primarily on the following priority areas:-

- I. Fundamental Concepts, Basic Principles & Theories of AYUSH Systems
- II. Standardization / Validation of Safety, Efficacy & Quality different AYUSH classical drugs, Therapies, Intervention & approaches / Treatment modalities
- III. AYUSH Pharmaceutical Research (New Drug development)
 - Pharmacological studies, safety & toxicity evaluation of ASU&H drugs as per standard guidelines
 - Pharmacokinetics Studies
 - Pharmacodynamics Studies
 - Development of new dosage forms for classical ASU&H formulation
 - Stability & Shelf life studies of ASU&H medicines

- Clinical Trials
- IV. Scientific exploration & operational research of metallic compounds, Bhashmas, Kushtas, Chunduram & other herbomineral preparations
 - V. The study of integrated approach of treatment involving AYUSH systems
 - VI. Drug interaction, bioavailability & dose determination studies
 - VII. AYUSH intervention in public health care in following areas:-
 - Epidemics diseases & Genus Epidemicus
 - Geriatric Health Care
 - Neglected diseases
 - Mental Health & cognitive disorders
 - Immunological Disorders
 - Anemia & nutritional disorders
 - Maternal & Child health
 - Study on constitution, temperament and miasms
 - Role of AYUSH system as alone or add on treatment in prevention & control of non-communicable diseases
 - Role of AYUSH systems as standalone or adjuvant treatment in National Health Programme
 - Disease prevention / Health promotion
 - Vector borne diseases
 - VIII. Systemic review and meta-Analysis of AYUSH research studies
 - IX. Literary research & scientific documentation and development of data base
 - X. Health Economics related to AYUSH
 - XI. Role of ASU & H Intervention in Veterinary Health
 - XII. Development of software & Bio instrumentation related to AYUSH

The central government may consider supporting important research proposals in other areas of National interest depending upon the credential of the institution & investigator.

5. ELIGIBILITY CRITERIA:

5.1 Who are eligible

- Medical, scientific and Research & Development institution, university/ institutional department in Govt. & Pvt. Sector with adequate infrastructure & technical expertise
- GMP compliant Industries of ASU&H drugs both in public & private sector with R&D facilities.
- Principal Investigator (regular employees in the institution) having minimum five year research experience in the concerned field.
- Investigator who is the member of Project Screening Committee (PSC)/Project Approval Committee (PAC) would recuse themselves from the decision of those projects in which they are associated in any capacity.

5.2 Verification of credentials of the Principal Investigator /Institutions

5.2.1 Verification of credentials of the Principal Investigator /Institution ,etc. shall be made by the Ministry of AYUSH / respective Research Councils through predefined guidelines to assess whether requisite infrastructure to carry out the research project applied for is available.

5.2.2 Institutions exempted from verification of credentials

Following are the Institutions exempted from verification of their credentials:

- Statutory/Autonomous Institutions under the Ministry of Health and Family Welfare, Govt. of India
- CSIR and its Institutions,
- ICMR and its Institutions,
- Accredited Institutions of DST, DRDO
- Central and State Universities/ Institutions
- 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. For Example, In case of clinical research, clinical facilities including OPD and IPD (wherever required) and laboratory facilities for physiological, bio-chemical, pathological & radiological investigations supported with necessary equipment relevant to the project should be available. In case of studies for drugs standardization, safety & toxicity study of the drugs adequate laboratory facilities and animal house should be in place.

5.4 Investigators:

5.4.1 There will be one Principal Investigator (PI) and not more than two Co-Investigator(s) [Co-I] but in exceptional cases number of Co-Is may be increased with the approval of PSC/ PAC. The Principal Investigator should have previous experience in the field of the proposed study. Importance will be given to projects where preliminary work has already been done on the topic, substantiated by publications. A PI can apply for the project under EMR scheme at least before 3 ½

years of attaining the age of superannuation in case of project of duration of 3 years. Similar restriction may be imposed for projects of different duration and it may be ensured that PI must complete the project before superannuation.

The PI or one of the Co-Is should have experience for working in the AYUSH field along with sufficient research background. In exceptional cases, where PI & Co-Is have no experience working in AYUSH field, the PSC would decide if the study requires an AYUSH expert to be engaged as a consultant.

5.4.2 Normally, if the PI and Co-I are having two ongoing research projects from EMR scheme, further research proposal from them shall not be entertained. Fresh research proposals may be considered if Committee finds that previous project is on verge of completion.

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 but in exceptional cases number of Co-Is may be increased with the approval of PAC.
- 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 Ministry of AYUSH, as the case may be. Such 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 Ministry of AYUSH.
- If for any reason the Co-I is required to be changed, Prior approval of the institution and Ministry of AYUSH is mandatory.
- The host Institution has an important role to play in the above contract. The Institution/Principal Investigator will have to inform the Ministry of AYUSH, as the case may be, of any change, and in consultation with the Ministry of AYUSH take steps to ensure successful completion of the project before relieving of the Principal Investigator.

5.4.4 Age of PI

A PI can apply for the project under EMR scheme at least before 3 ½ years of attaining the age of superannuation for projects of 3 years duration. Similar restriction may be imposed for projects of different duration and it may be ensured that PI may complete the project before superannuation. There is no minimum age for PI however he should have experience of minimum 2 years of work in AYUSH or allied field. The PAC can waive the 2 years experience condition in case of exceptionally good project.

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

6.1 Ministry of AYUSH, shall invite proposals from the individuals, Institutions (both Government and Private), Universities/Educational Institutions, GMP compliant Industries of ASU&H drugs both in public & private sector with R&D facilities etc. for grants-in-aid, under Extra-Mural scheme and 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 Ministry of AYUSH/ websites of the Research Councils and also published in the research Journal and Newsletter of the Ministry of AYUSH and Research Councils.

6.2 Application shall be submitted both in hard and soft version (in PDF / word files). The soft copy should be emailed at the designated Email ID of EMR, Ministry of AYUSH on the following address:-

emr_ayush@yahoo.com

emr_ayush@nic.in

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

- Website of the Ministry of AYUSH: www.indianmedicine.nic.in
- Website of the Research Councils:
 - CCRAS: www.ccras.nic.in
 - CCRS: www.siddhacouncil.com, www.siddharesearchcouncil.org
 - CCRH: www.ccrhindia.org
 - CCRUM: www.ccrum.net
 - CCRYN: www.ccryn.org

The website of the AYUSH Ministry shall also provide details of the status of the applications (received, under consideration, approved and rejected).

6.4 The Individuals/ Institutions, interested for the grants-in-aid in connection with their proposed project may apply in the prescribed format (**Annexure -1**), along with all the required documents, to the Ministry of AYUSH.

The Ministry of AYUSH and Director Generals/Director of the concerned Research Councils can also approach reputed Institutions, GMP compliant Industries of ASU&H drugs both in public & private sector or eminent scientist for submitting proposals on specified areas. The Councils will identify top institutions (academic, research, universities etc.) /GMP compliant Industries of ASU&H drugs both in public & private sector in the country for inviting good quality proposals. Ministry of AYUSH and Councils may also guide and help them in formulating the proposals.

6.5 Time line for Receipt of Application

The applications would be received and processed in four quarters:

Quarter	Processing by the PSC	Processing by PAC
I	March. First week	March. last week
II	June first week	June last week
III	Sep. first week	Sep. last week
IV	Dec. First week	Dec. last week

6.6 In case of Institutions/GMP compliant Industries of ASU&H drugs both in public & private sector the PIs have to submit their applications through their Controlling authorities/Head of the Institutions who will be designated authority responsible

for quality work and utilization of the grant and are accountable in the event of any default. In case of individuals, the PIs should apply through the Heads of the Institutions with which they want to collaborate.

6.7 Formulation of the Project:

6.7.1 The project proposal should be prepared in the format for application, as given at **Annexure-1**. Section A of the Application format requires General Information of the project. A description of all the projects taken up by the Institutions 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, Name and Designation of the Principal Investigator 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, Co-I(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.

4 Hard copies and two soft copies (Pdf / word files) may be provided by the PIs to the Ministry of AYUSH.

6.7.2 Preparation of the Protocol and the Research Plan shall be in accordance with the Guidelines for Methodology and Research and Evaluation of Traditional Medicine (WHO 2001). **Annexure-2** and **Annexure-3** indicate broad guidelines on preparation of protocol and research plan. GCP guidelines for ASU drugs published by Ministry of AYUSH and the 'Good Clinical Practices for Clinical Research in India' provided by Central Drug Standard Control Organisation, Directorate General of Health Services, Ministry of Health and Family Welfare, GOI may also be referred to.

6.7.3 Ethical clearance from the Institutional Ethics Committee (in case of human trials) or Institutional Animal Ethics Committee (for animal studies) of the Institutions applying for the Research Proposal is mandatory. **A certificate of clearance from the Institutional Ethics Committee (IEC) or Institutional Animal ethics Committee (IAEC) is to be enclosed along with the application form.** For Ethical Guidelines and constitution of the Ethics Committee the Institution 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 Institutions (other than those mentioned under 5.2.2) seeking assistance for 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 Institutions 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 Institutions 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 Institutions mentioned under 5.2.2)

7. PROJECT APPROVAL

7.1 Screening and Appraisal of the project

- Once the proposal is received the proposal shall be reviewed by concerned Adviser of the Ministry and Director General/ Director of the respective Research councils. They shall submit their opinion/ comments to EMR Cell Ministry of AYUSH within 30 days of time after receiving of soft copy of proposal. The proposal may also be send for the comments/ opinion of the eminent subject experts if required by the concerned Adviser of Ministry of AYUSH.
- EMR cell of the Ministry will facilitate communication with the PI, concerned Adviser of the Ministry, Research Councils & subject experts.
- The credential of the institutions/Pis will be verified by the respective Councils as indicated below:-

Name of Research Council for credential verification	AYUSH discipline
<ul style="list-style-type: none"> • Central Council for Research in Ayurvedic Science, (C.C.R.A.S.) 61-65, Institutional Area, Opposite 'D' Block, JanakPuri New Delhi-110058 Email: ccras_dir1@nic.in Fax: 011-28520748, 011-28525959 	Ayurveda
<ul style="list-style-type: none"> • Central Council for Research in Yoga and Naturopathy (C.C.R.Y.N.) 61-65, Institutional Area, Opposite 'D' Block, JanakPuri New Delhi-110058 Email: ccryn@vsnl.net Fax: 011-28520435, Phone:28520430, 31,32 	Yoga & Naturopathy
<ul style="list-style-type: none"> • Central Council for Research in Unani Medicine, (C.C.R.U.M.) 61-65, Institutional Area, Opposite 'D' Block, JanakPuri New Delhi-110058 Email: ccrum@rediffmail.com, unanimedicine@gmail.com Fax:011-28522965 	Unani
<ul style="list-style-type: none"> • Central Council for Research in Siddha, (C.C.R.S.) (SCRI) Building, Arumbakkam, Chennai-600 106 Email-dgccrs@hotmail.com 	Siddha

<ul style="list-style-type: none"> • Central Council for Research in Homoeopathy, (C.C.R.H.) 61-65, Institutional Area, Opposite 'D' Block, JanakPuri New Delhi-110058 Email:ccrh@del3.vsnl.net.in Fax: 011-28521060 	Homoeopathy
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On the basis of the comments received from the concerned Adviser and Director General of the respective Research councils, the proposal if found suitable shall be placed before the PSC for further evaluation. PI shall be asked to make a presentation before the Committee.

7.1.1 Project Screening Committee (PSC)

The Research proposals of Extra Mural Research (EMR) shall be screened by the PSC which shall be common for all AYUSH systems constituted by the Ministry of AYUSH and would comprise of following:

1.	JS (AYUSH)	Chairperson
2.	Two experts from the concerned discipline having published research work(to be nominated by Concerned Adviser of Ministry of AYUSH)	Member
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 DD)	Member
6.	Director(IFD) or his nominee (not below the rank of US)	Member
7.	Adv./Jt. Adv./Dy. Adv. of all disciplines of AYUSH	Member
8.	Two co-opted member from scientific background (to be co-opted by Chairperson)	Member
9.	Representative of Ministry of AYUSH dealing with the EMR Scheme	Member Secretary

7.1.2 The function of Project Screening Committee (PSC)

- Shall call for the Principal Investigator/Co-Investigator to explain their proposals in person.
- May invite comments from the expert(s) in the concerned field.
- May ask the applicants to modify their proposals (as per observations of the Committee)
- Return back the proposal to the PI/ Institution highlighting their deficiencies, with instructions to re-submit the proposals after fulfilling the shortcoming.

- Reject the proposal
- Recommend the proposal to PAC for consideration and approval.
- Give extension of ongoing project for one year without any financial assistance.

7.1.3 The PSC, after thorough evaluation of the technical as well as financial aspects of the Research Proposals will forward the recommended proposals to the PAC for consideration, approval and sanction of funds.

7.1.4 The work done by the Investigators will also be periodically reviewed by PSC. The PSC will also approve the subsequent installments.

7.2 Project Approval Committee (PAC)

Project Approval Committee chaired by the Secretary, Ministry of AYUSH, would consider the proposals recommended by the PSC 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 (not below the rank of DS)	Member
4 Adviser/Joint Adviser/Deputy Adviser of all disciplines of AYUSH	Member
5 Representative of DG, ICMR/DGs, CSIR/DST/DBT Not below DDG/Scientist-F level	Member
6 All D.G's /Director of the Research Councils	Member
7 Two co-opted member from scientific background (to be nominated by Secretary (AYUSH))	Member
8 Representative of Ministry of AYUSH dealing with the EMR Scheme	Member Secretary

7.2.1 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.

7.2.2 An honorarium of Rs. 3,000/- would be paid to co-opted and expert member in PSC and PAC, it can further be revised by Project Approval Committee with the concurrence of IFD if required.

7.2.3 An honorarium of Rs. 2,000/- would be paid to reviewer/external expert, it can further be revised by PAC with the concurrence of IFD if required.

8. OUTCOME OF THE PROJECT:

The final technical and financial reports of each completed study will be examined and reviewed by the PSC, who will convey their views to the PAC for consideration. PSC will also give their comments on publication of the results of the studies and the patents claimed by the Ministry of AYUSH and PI/Grantee institutions jointly. 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 Ministry of AYUSH will provide financial support for staff, equipment and contingencies (recurring and non-recurring) for the project up to an amount not exceeding Rs. 70.00 Lakh.

9.2 The Institution/ GMP compliant Industry of ASU&H drugs both in public & private sector/individual applying for the grants-in -aid 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 not exceeding 5% of the total cost (excluding the cost of equipment) of the project after successful completion of the project may be provided to the Institution.

9.4 In case of Private Industry the share of grant by the Ministry may not exceed 50 % of the total cost proposed. The matching share of industry should be made available with each installment of the fund released by the Ministry.

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 Institutions) or those of the Central Government (in case of Central Government Institutions). For permanent and semi-permanent assets acquired solely or mainly out of the grant, the Institutions 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 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.

It shall be ensured that the estimate of expenditure under equipment, books, software, etc of the required project is sought in the first year itself.

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 (both recurring and non-recurring):

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 institutions.
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 equipment's 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 Ministry of AYUSH.
- Taking up field work/travel connected with the research work.
- Visiting the Ministry of AYUSH 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 Organisations/ Institutions) or those of the Central Government (in case of Central Government Organisations).

11. PERSONNEL/STAFF:

11.1 Scientific Staff

The pre requisite for selection of the scientific staff and their remuneration shall be as per following table:

S. No	Staff	Qualifications and Experience	Amount of assistance as per revised rates of ICMR*
1.	Research Associate (RA): (One or Two)	Ph.D. in the concerned subject OR Post-Graduation in Ayurveda/ Siddha/ Unani/ Homoeopathy/ Yoga/Yoga and Naturopathy/Sanskrit/Arabic/Persian/Philosophy; OR Degree qualification in the respective AYUSH System/ Allopathy; M.Pharm/ M.E./M.Tech./ MVSc. with minimum 3 years research experience i.e. having worked for any research project funded by the Ministry of AYUSH, ICMR, CSIR, DST or equivalent organisation.	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. 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 Ministry of AYUSH, ICMR, CSIR, DST or equivalent organisation.	MEDICAL 1 st , 2 nd and 3 rd Year - Rs.20,000/- per month + HRA NON-MEDICAL 1 st and 2 nd Year - Rs.18,000/- per month + HRA. 3 rd year - Rs.20,000/- per month + HRA
3.	Junior Research Fellow (JRF): (One or Two)	<ul style="list-style-type: none"> Bachelor Degree in the required discipline 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) 	1 st and 2 nd Year - Rs.16,000/- per month + HRA 3 rd 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 PSC is final in this respect.

3. The amount of assistance for RA/SRF/JRF may be revised by Ministry of AYUSH to keep at par with the Indian Council of Medical Research (ICMR).

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 Fee to the PIs and Co-Is: as per the details given in the table below may be admissible. In case of 2 Co-Is or more, this amount shall be shared between them. This fee would be released only after successful completion of the project and acceptance of the final report of the study by the PSC /PAC.

	Projects having a period of one year	Projects having a period of two years	Projects having a period of three years or more
Fee of PI	Rs. 30,000/-	Rs. 60,000/-	Rs. 90,000/-
Fee of Co-Is	Rs. 15,000/-	Rs. 30,000/-	Rs. 45,000/-

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 / Ministry of AYUSH or the Grantee Institution 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 as per rule of Govt.of India.

- 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:

The approved grant will be released in the name of the Head of the Institution as yearly installments. The first installment will be 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 subsequent installment can be claimed on having utilization of 75% the previous installment subject to special permission of Ministry of Finance. The 2nd/3rd installment(s) would be released subject to the satisfactory progress of the study, report of monitoring committee and timely receipt of the following documents in the prescribed proforma:-

- Annual Progress Report (as per Annexure 4)
- No Financial Assistance Certificate (as per Annexure-8)
- Statement of expenditure and Utilization Certificate (Annexure 5,6,7) in original, duly signed by the PI, Head of the Institution and the Auditor; and
- Mid-term appraisal by monitoring committee or expert(s) after presentation by the Principal Investigator/Co-I.
- 20% of the approved project cost of the study will be held back till the receipt and acceptance of final Report & the manuscript.
- This 20% will be released in 2 parts i.e. 10% after acceptance of final report & remaining 10% after publication of the article and receipt of the UC along with audited statement of accounts.

13. INCEPTION OF PROJECT:

13.1. Date of inception of the project:

The sanction letter shall specify a prospective date from which the project is to be commenced. If, however, no date is mentioned in the sanction letter, the project shall be deemed to have become operative from the day the grant is received by the Investigator. This date shall be communicated by the host Institution to the Ministry within one month from the receipt of the grant. The date of inception of a project can be changed on the request of the PI, duly forwarded by the sponsoring institution, provided no expenditure has been incurred by the PI/ Institution at the time of making such request.

14. MAINTENANCE OF ACCOUNT:

The Grantee institution shall maintain a separate account for the grant received and expenditure incurred. Statement of bank transaction should be submitted at the time of submission of Utilization Certificate. The account shall 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 Ministry of AYUSH. Any unspent balance must be refunded to the Ministry. 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 organisations/NGOs will follow other additional instructions given at **Annexure 11**.

14.1 Auditors:

The Ministry may normally accept audited reports from statutory auditors. The Ministry 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 shall be 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 PAC.

14.4 All expenditure is to be made as per the norms and guidelines of the Financial Rules as applicable to the grantee institution.

15. SUBMISSION OF REPORTS:

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

15.1. Progress Report

- The Progress Report for the first and second year shall be submitted within one month of completion of reporting year as in the prescribed format at **Annexure-4**.
- The progress of the project shall be evaluated by the Concerned Adviser Ministry of AYUSH in consultation with peer reviewer/experts if required.
- The project may not be continued in the next financial year unless the Ministry receives the progress report in time.
- The PI shall be asked to present the progress at the meeting of the PSC / PAC, if considered necessary.
- The suggestion and views of the PSC / PAC and mid-course correction, if any, conveyed to the PI, shall be binding on the PI/grantee institution.

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

15.2. Annual utilization certificate

A statement of accounts indicating the funds received and expenditure incurred thereof by 31st March, needs to be submitted along with utilization certificate, duly signed, dated and stamped by the authorized Auditor, the Principal Investigator and the Head of the Institution (**Annexure 5,6,7**).

The PI shall also provide a certificate indicating that the grant has not been accepted from any other institution against expenditure on project concerned.

Unspent balance must be refunded to the Ministry. An audited statement shall be mandatorily submitted to enable release of the second installment of the annual grant from second year onwards.

15.3 Only on receipt of the Annual progress Report and Annual Utilization Certificate (at least 75% if approved by Finance Ministry) previous sanction installment, the release of subsequent installment (s) of the grant shall be considered subject to special permission of Ministry of Finance.

15.4 The study is liable to be discontinued without any notice to the PI/institution, if a report is not submitted within the prescribed time.

15.5 Final Project Completion Report

The final report should be sent by the PI/ Institution in the prescribed format (**Annexure-9**) within three months from the date of completion. Two hard copies and one soft copy (in CD) of the Final project Completion report shall be submitted. 10% of the amount of the total cost of the project shall be released after successful completion of the project, duly approved by PAC and remaining 10% released after publication of the report. The PIs shall ensure that all financial documents related to earlier grants have been submitted to the Ministry of AYUSH.

16. 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 -6, 7**).
- c. List of equipment procured for 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).

17. MONITORING:

Local institutes of concerned councils will monitor the project. If required as special case Director/ In charge of the institute will co-opted the subject expert for monitoring the project. PI/Institution shall provide all information and records to the members of the monitoring committee.

18. AWARD:

PIs and Co-Is who have Completed their projects under EMR during the financial year, may be considered for AYUSH Award for excellence in Research as per table given below:

Award	PIs	Co-Is
AYUSH award for excellence in Research under EMR scheme	Rs. 50,000/-	Rs.25,000/-

18.1. Extension of the Project: Extension beyond the approved duration normally may not be entertained except for specific reasons, viz. interesting/important leads emerging which need to be followed-up etc. Duration of project, however, in any case should not go beyond maximum 5 years. One year extension given by Project Screening Committee and if required another year can be extended by the prior permission of Project Approval Committee. For extension, PI may apply in the format at **Annexure-12**.

19. PRE-MATURE TERMINATION OF PROJECT:

19.1. Prior permission of the Ministry 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 premature termination of the Project may not be allowed without the refund of entire funds with interest. However, in exceptional circumstances, the PAC may waive off the return of funds or return of interest or both, decided on case to case basis. In all such cases, the matter shall be referred to the Ministry of Finance for final decision.

19.2 During the course of the study, the PSC may recommend to the PAC for termination of the study on ground of Technical/Financial/Ethical irregularities or that the project is not in accordance with the approval of PAC. The final decision of the PAC shall be binding on the PI and the grantee Institution. In such case, the Ministry of AYUSH with the prior approval of PAC may revoke the funds given to the Grantee Institution, partially or fully.

20. INTELLECTUAL PROPERTY RIGHTS AND PATENTS:

20.1 The patent will be jointly applied by the Ministry of AYUSH and the Principal Investigator. The Ministry of AYUSH/PI will make joint efforts to commercialize the product as applicable.

20.2 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 Ministry of AYUSH.

20.3 Ministry of AYUSH will convey such approvals for patent within 3 months from receipt of application.

21. PUBLICATIONS:

The PI shall submit the final consolidated report (as per **Annexure-9**) to the Ministry, after the completion of the project. Outcome of the project shall be mandatorily published in a reputed peer reviewed (preferably high impact) journal or in the form of book or in the journal of the Council etc once the project is approved as completed.

A manuscript of the paper may also be sent by the PI to the Ministry for record. Funding by the Ministry 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 PAC. Expenditure on publication of the research findings in the journals of repute shall be met from the Scheme.

22. 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 Ministry of AYUSH /Research Council come to know of any unethical conduct on the part of Investigator(s) including improper/incomplete declaration, the project shall be liable to be terminated, immediately along with action taken for recovery of funds.

23. 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 Ministry of AYUSH can recall the entire funds provided and stop further release of installments.

2. **Designated authority** of the Institution 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 shall be levied in the case of grantee not complying with the terms and conditions. However, in exceptional cases, where extension of project timelines becomes necessary, time period for completion of the projects may be extended without any additional financial implications. Extension up to maximum of two year period may be given after evaluating the progress of the project. One year extension given by Project Screening Committee and if required another year can be extended by the prior permission of Project Approval Committee. The extension may be given only with the condition that if the project is not completed within the extended period of two year, the PI and the Institution may be blacklisted. The Government will transfer the project along with the assets created under the project to other suitable institutions.

3. All the Officer 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 Ministry of AYUSH and the grantee Institutions shall be decided by referring to arbitration in which the

Secretary, Ministry of AYUSH shall be the arbitrator, whose decision shall be final and binding.

5. PI/Institution not complying with provisions of scheme will be debarred from further grants.

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

MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDHA AND HOMOEOPATHY
APPLICATION FOR GRANT-IN-AID OF EXTRA MURAL RESEARCH PROJECTS IN AYUSH

Section-A

1. Title of the Research Project:

2. Details of the Institution submitting the research project

Name: Postal address:

Telephone: Fax: E-mail:

3. In case of Individuals submitting the Research project:

(Name of the collaborating institute may be cited in S. No. 2 above)

Name of the individual: Postal address:

Telephone: Fax: E-mail:

4. Name and Designation of

Principal investigator: Co-Investigator(s): 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 analyzing the data:

6. Amount of Grant-in-aid asked for:

	Total	1st Installment	2nd Installment	3rd Installment	Remaining Amount (10%)	Withheld amount (10%)
Salary						
Equipment						
Books						
Other Non-Recurring Expenditure						
Recurring Expenditure						
TA/DA						
Institutional Support						
Fee of PI and Col						
Miscellaneous expenses						
Total						

7. DECLARATION AND ATTESTATION**Certified that:**

I/We have read the provisions, terms and conditions, mentioned in the Extra-mural Scheme along with its Annexure, Guidelines formulated by the Ministry of AYUSH and I/we shall abide by the relevant provisions contained under EMR Scheme and General Financial Rules of Govt. of India.

Name and Signature of the:

a) Principal Investigator

b) Co-Investigator(s)

c) Head of the Department

Signature of the Head of the Institution

Place:

Date:

LIST OF DOCUMENTS TO BE ENCLOSED :(As per para 6.7.4 of the scheme and as uploaded on the website)

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
 - a) From the Ministry of AYUSH
Past
Present
Pending
 - b) From other Institutions
Past
Present
Pending
10. Research projects in hand under EMR Scheme of Ministry 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 PROPOSAL

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

1. Title of the Research Project:
2. Objectives
3. Methodology
4. Anticipated Outcome
5. 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.
6. Relevance and usefulness of the study with particular reference to concerned AYUSH system.
7. IPR values
8. Translational Value
9. Utilization of outcomes of project

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 GCP guidelines for ASU drugs published by Ministry of AYUSH, Good Clinical Practices (GCP) for Clinical Research in India provided by Central Drug Standard Control Organisation (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of India.)

See Annexure - 2 and 3 for preparation of detailed research protocol.

SECTION-E

Agency Details	
Type of Registration	
Agency Name	
Act/Registration No.	
Date of Registration (DD/MM/YYYYYY)	
Registering Authority	
State of Registration	
TIN/TAN No.	
Address Line 1	
Address Line 2	
Address Line 3	
City	
State	
District	
Pin Code	
Contract Person	
Phone	
Email	
Unique Agency Code	
Unique Agency code is like short code of agency, it will accept only alphanumeric value no special character or space (e.g. if agency name is ABC limited than unique code will be ABCL or ABCLTD)	
Scheme/Bank Details	
Scheme	
Bank	
Address	
Branch	
Account No.	
Agency Name as per bank	

REQUISITION FORM FOR THE ELECTRONIC TRANSFER OF FUNDS

(To be submitted in duplicate)

Name of Grantee Institute/ other organisation	
Name of the Bank	
Address of the Bank	
Account No.	
RTGS Code of the Bank (Real Time Gross Settlement Code)	(IFSC Code)
MICR Code No.	
Amount to be transferred	
() Under Secretary to the Govt.of India	

(FOR THE USE OF PAO(S) ONLY)

Name of the D.D.O	
Bill No.	
D.V. No.	
Cheque No. and Cheque date	
Cheque amount	

(Sr. Accounts Officer)
Pay & Accounts Office (Sectt.)

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.
8. Name of the chairman & member Secretary of Institutional Ethics committee.

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 analyzing 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 analyzing 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(es).
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/Ministry of AYUSH providing direct access to source data/documents.

Also the privacy policy to be followed by the Institutions /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 Institutions 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.

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.

SHORT TERM 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 or 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.

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 Institutions:

ANNEXURE- 5

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 31 st March	Remarks
			1 st year	2 nd Year	3 rd Year			
1	Salary							
2	Equipments							
3	Books							
4	Other Non-Recurring Expenditure							
5	Recurring Expenditure							
6	TA/DA							
7	Institutional Support							
8	Appropriate fee of PI and Col							
9	Miscellaneous expenses							
10	Total							

Signature of Principal Investigator with date & Seal	Signature of Head of Institution with date& Seal	Signature of Authorized Auditor with date& Seal
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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) Ministry 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 Ministry'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.

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

S.No.	Sanction No. & date	Amount Sanctioned	Certificate
			Certified that out of Rs..... of grants-in-aid sanctioned during the year in favour of under Ministry 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 Rsremaining unutilized at the end of the year has been surrendered to Ministry of AYUSH letter No. Dated..... /will be adjusted towards the grants-in-aid payable during the next year i.e.....
		Total:-	

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

Kinds of checks exercised:-

1. Sanction order copy of Government of India.
2. Statement of Expenditure.
- 3.
- 4.

Signature of Principal Investigator with date& Seal	Signature of Head of the Institution with date& Seal	Signature of Authorized Auditor of the Institute with date& Seal
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**NO FINANCIAL ASSISTANCE CERTIFICATE
(To be submitted on Institution letter head)**

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

Signature of Principal Investigator with date & Seal	Signature of Head of the Institution with date& Seal	Signature of Co- Investigator with date & Seal
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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	Utilization rate %	Remarks regarding maintenance/break down

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

Name and signature with date

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

**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 Installment : Date of release of grant..... grant received
Rs.....
 - 2nd Installment: Date of release of grant..... grant received
Rs.....
 - 3rd Installment : 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
			1 st Instt.	2 nd Instt.	3 rd Instt.	Remaining amount (10%)	Withheld Amount (10%)		
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 with date& Seal	Signature of Head of Institution with date& Seal	Signature of Authorized Auditor with date& Seal
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GENERAL CONDITIONS FOR THE RELEASE OF GRANT-IN-AID TO NON-GOVERNMENTAL VOLUNTARY ORGANISATIONS.

1. The Institutions should maintain separate account exclusively with a bank in the name of the organisation 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 thereof 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 Institutions 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 Institutions (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 organisation 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 Institutions 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 Institutions 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 Institutions 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 Institutions 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.

REQUEST FOR EXTENSION

(4 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 Ministry of AYUSH
or
Expected amount in addition to the sanctioned amount.

Name and Signature of PI

Name and Signature of the Head of the Institution

Seal

Seal