

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

**SCHEME FOR EXTRA MURAL RESEARCH (EMR) IN
AYURVEDA, YOGA and NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY**

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, still 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 Councils for Ayurveda and Siddha, Unani, Homoeopathy and Yoga and Naturopathy set up by the Ministry of Health and Family Welfare three decades ago. The offtake and output from this scheme has so far been limited and has yet to meet the standards for scientific enquiry and outcome effectively. 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:

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 practitioners having good research background and contribution to the medical research can also apply through a reputed institution/organization as stated above, as 'Emeritus Scientists' or other mechanisms applicable at host institution. *(In such cases, the grants will be released to the concerned organization, who would be responsible for expenditure and utilization of funds)*

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.

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 proposals 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 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
<ul style="list-style-type: none"> • Central Council for Research in Ayurveda and Siddha, (C.C.R.A.S.) 61-65, Institutional Area, Opposite 'D' Block, Janak Puri New Delhi-110058 Email: ccras_dir1@nic.in Fax: 011-28520748, 011-28525959 	Ayurveda and Siddha
<ul style="list-style-type: none"> • Central Council for Research in Homoeopathy, (C.C.R.H.) 61-65, Institutional Area Opposite 'D' Block, Janak Puri New Delhi-110058 Email:ccrh@del3.vsnl.net.in Fax: 011-28521060 	Homoeopathy
<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, Janak Puri 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 Yoga and Naturopathy (C.C.R.Y.N.) 61-65, Institutional Area Opposite 'D' Block, Janak Puri New Delhi-110058 Email: ccryn@vsnl.net Fax: 011-28520435 Phone:28520430, 31,32 	Yoga and Naturopathy

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

- Website of the Department of AYUSH: www.indianmedicine.nic.in
- Website of the Research Councils:
 - CCRAS: www.ccras.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 Directors of the concerned Research Councils can also approach reputed Institutes/Organizations or eminent scientists for submitting proposals on specified areas.

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 SC
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. 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, Col(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, Gol.*

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 Director of the concerned Research Council to scrutinize/screen the proposals received from the individuals/organizations. After thorough scrutiny, the Committee may:

- Reject the proposal, if found totally unacceptable. However these proposals will be placed before the PEC and the decision of the PEC would be final and binding in this regard.
- Return back the proposal to the PIs highlighting their deficiencies, with instructions to re-submit the proposals after fulfilling the shortcomings.
- 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.

7.2 *Project Evaluation Committee (PEC)*

The Research proposals will be scrutinized/evaluated by the Project Evaluation Committees of AYUSH Systems, constituted by the Department of AYUSH, for the respective disciplines. PEC would comprise of:

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| 1. A scientist of national repute (to be nominated by Secretary (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 of the Concerned Council or his nominee
(not below the rank of JD/DD) | Member |

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 Screening 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 Screening Committee (SC) for consideration, approval and sanction of funds.

7.2.3 The PEC will also evaluate the ongoing research projects and send recommendations to the Screening Committee (SC) for release of subsequent installments of the grants. The work done by the Investigators will also be periodically reviewed by PEC.

7.3 *Screening Committee (SC)*

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

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| 1 Secretary (AYUSH) | Chairperson |
| 2 Joint Secretary (AYUSH) <i>concerned with EMR</i> | Member |
| 3 Financial Adviser or his/her representative | Member |
| 4 Chairperson of PEC of the system | Member |
| 5 Adviser/Deputy Adviser of the concerned System from the
Department | Member |
| 6 Representative of DG, ICMR/DG, CSIR/DST/DBT
Not below DDG/Scientist-F level | Member |
| 7 Director (AYUSH) <i>concerned with EMR</i> | Member |
| 8 Director of the concerned Research Council | Member-Secretary |

The Chairperson of the SC may invite other specialist(s) to attend the meeting of the SC to give their expert views on the project proposals.

The decision of the SC in respect of approval of the research project (s) and sanction/release of funds shall be final.

8. FINANCIAL SUPPORT:

8.1 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 upto a maximum of Rs. 30.00 lakhs.

8.2 The institutions/ individuals 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.

8.3 *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/SC.

9. 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.

9.1 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.

9.2 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.

9.3 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.

9.4 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).

10. PERSONNEL/STAFF:

10.1 Scientific Staff

S. No	Staff	Qualifications and Experience	Amount of assistance
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/Philosophy; OR 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.	<ul style="list-style-type: none"> • 1st Year - Rs.11,000/- per month + HRA • 2nd year - Rs.11,500/- per month + HRA • 3rd year - Rs.12,000/- 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	<p>MEDICAL</p> <ul style="list-style-type: none"> • 1st, 2nd and 3rd Year - Rs.10,000/- per month + HRA <p>NON-MEDICAL</p> <ul style="list-style-type: none"> • 1st and 2nd Year - Rs.9,500/- per month + HRA

		previous research experience i.e. having worked for any research project funded by the Department of AYUSH, ICMR, CSIR, DST or equivalent organization.	<ul style="list-style-type: none"> • 3rd year - Rs.10,000/- 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) 	<ul style="list-style-type: none"> • 1st and 2nd Year - Rs.8,000/- per month + HRA • 3rd year - Rs.9,000/- per month + HRA

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. The amount of assistance may be revised by the Department of AYUSH to keep at par with those at ICMR.

10.2 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.

10.3 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.

10.4 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.

10.5 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.

11. RELEASE OF FUNDS:

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 2nd/3rd 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.

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 research findings and receipt of the UC along with audited statement of accounts.

12. INCEPTION AND DURATION OF PROJECT:

12.1. *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 be 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 provided no expenditure has been incurred from the grant released by the concerned Research Council.

12.2. *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.

13. 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**.

13.1 *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.

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

13.3 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.

13.4 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).

14. 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)

15. SUBMISSION OF REPORTS:

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

15.1. *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.

15.2. Annual utilization certificate

Each year, a statement of accounts giving the funds received and expenditure incurred by 31st 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.

15.3 On receipt of the Annual progress Report and Annual Utilization Certificate, the release of 2nd/3rd installment(s) of the grant will be considered.

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

15.5 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.

16. MONITORING:

The 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 of the concerned Research Council, will monitor the technical and financial execution of the project. For the purpose of monitoring the Director of the respective concerned Research Council and/or the experts selected by the 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

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.

17. OUTCOME OF THE PROJECT:

The final technical and financial reports of each completed study will be examined by the PEC, who will convey their views to the SC 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 SC in this respect will be final and binding.

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:

Outcome of the project shall be published in the reputed journal or in the form of book etc. It is mandatory to publish the findings after completing the project. 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 for publication in the Research Journals of the respective Councils. Funding by the Department of AYUSH should be

acknowledged in the publication. 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. Any violation of this will be viewed seriously and may invite penal action.

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. 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.
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. Pls/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.

Priority Areas

HOMOEOPATHY

FIRST PRIORITY

- **Clinical trials on**
 - Depressive neurosis
 - Tuberculosis
 - Multi Drug Resistant Tuberculosis
 - Chronic Obstructive Pulmonary Disease including Chronic Bronchitis and Emphysema
 - Psoriasis
 - Poly-cystic Ovarian disease
 - Menopause
 - HIV infection
 - Malignant and pre-malignant conditions
 - Diabetes mellitus
 - Hypothyroidism
 - Hyperthyroidism
 - Systemic Hypertension
 - Allergic disorders
 - Viral infections
 - Reproductive and Child Health
- **Research on fundamental principles of Homoeopathy**
 - Potentization
 - Miasms
 - Hering's law of cure
 - Kent's observations
 - Homoeopathic aggravation, etc.
- **Basic Research in Homoeopathy** including shelf life studies of Homoeopathic medicines and studies on mechanism of action of ultra-molecular dilutions of Homoeopathic medicines, identification of mode and pathway of action of Homoeopathic medicines.
- **In vitro studies and laboratory studies** on action of Homoeopathic medicines

SECOND PRIORITY

- **Toxicological studies, standardization studies** and study of pharmacology kinetics with respect to raw drugs and potentized drugs
- **Clinical trials on**
 - Alzheimer's disease
 - Rheumatoid arthritis
 - Cervical and Lumbar Spondylosis
 - RTI and PID
 - Filariasis
 - Kala azar
 - Parkinson's Disease
 - Gastro-esophageal reflux (GERD)
 - Irritable Bowel Syndrome
 - Hepatitis B and C
 - Chronic Renal Disorders
 - Oro-Dental Diseases
 - Alcohol and Drug Abuse and De-addiction studies and as protective therapy
 - Iatrogenic diseases
- **Research on Homoeopathy as adjuvant therapy or second line therapy**
- **Agro-Homoeopathic studies**
- **Veterinary Homoeopathic studies**
- **Preventive and health promotive aspects of homoeopathic therapy**

OTHER AREAS

- Clinical trials not stated in 1st and 2nd priority and clinical trials on drug combinations
- Proving of new drugs, not found in Homoeopathic literature
- Studies related to revival of Classical literature-Survey, collection, transcription/translation, editing and publication of classical literature and text books
- Medico-historical investigations of Homoeopathy
- Socio-Demographic/Sample survey of contemporary practices and requirements of Homoeopathy
- Use of advance technology for drug development and use of technology to establish safety, standardization and efficacy parameters of Homoeopathic drugs.

AYURVEDA and SIDDHA

Standardization of Ayurveda and Siddha Drugs, safety/toxicity studies, pharmacological studies, clinical trials, etc. under following priority areas/diseases:

Clinical Research

First priority

- Life style related disorders
- Metabolic disorders
- Peptic ulcer
- Psoriasis
- Malnutrition
- Reproductive Child Health (RCH) including infertility and contraceptives
- Benign prostate enlargement
- Preventive cardiology-hypertension, obesity
- Urolithiasis
- General Health Promotion Rasayana/Medhya Rasayana
- Mental Health/memory relating disorders
- Sports Medicine
- Liver Disorders (Hepatitis B)
- Primary health care relating issues
- Malaria
- Filaria
- Rheumatoid arthritis
- Menstrual disorder
- Reproductive tract infection
- Cancer
- Bronchial asthma, Upper respiratory tract infection
- Neurological disorders

Second priority:

- Musculoskeletal disorders
- Fever
- Diarrhoea (including dysentery)
- Indigestion and anorexia
- Skin Diseases
- Eye and ENT Diseases
- Secondary/tertiary health care relating issues

Research on fundamental principles of AYUSH:

- Pancha Mahabhutas - Tridosha
- Prakriti, Agni, Srotas, Saptadhatu, Ojas, Ama etc.
- Studies related to Pharmaco-dynamics kinetics e.g. Rasa, Guna, Virya, Vipaka and Prabhava
- Surgical and para-surgical procedures

- Similar areas of Siddha
- Molecular Pharmacology
- Genetics

Identification and evaluation of promising and widely accepted practices and skills of traditional healers in rural and tribal areas

Research on the preventive and promotive aspects AYUSH practices and therapies

Revival of ancient literature-Survey, collection, transcription / translation, editing and publication of classical literature and text books, Medico-historical investigations of AYUSH

Sample survey of contemporary requirements of AYUSH

Issues relating to the use of Modern Technology to develop the Drugs of AYUSH and Efficacy, Safety, Standards etc.

YOGA AND NATUROPATHY

First priority

- Diabetic mellitus with its complications
- Metabolic disorders: obesity/Hypo/Hyperthyroidism
- Malnutrition
- Cardiac disorders: Hypertension/CAD
- Respiratory Disorders: Sinusitis, Bronchial Asthma, Bronchitis, etc
- Musculo-skeletal disorders, Spondylitis, Backache
- Menstrual Disorders
- GIT Disorders: Constipation, Piles, Peptic Ulcer, Indigestion, Anorexia, Hyperacidity
- Ophthalmic Disorders
- Psychiatry and Neurological Disorders: Anxiety Neurosis, Mental Disorders, Depression, Schizophrenia, Epilepsy, etc.

Second Priority

- Skin diseases
 - Cancer
 - HIV/AIDS
 - Geriatric problems
- Research on Preventive and promotive aspects of Yoga and Naturopathy practices and therapies
 - Revival of ancient literature-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
- ◆ Acid Peptic diseases
- ◆ Cardio vascular diseases - Stable Angina, Arteriosclerosis, Mycardial Infarction
- ◆ Skin Diseases- Vitiligo, Eczema, Psoriasis
- ◆ 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
- ◆ Diseases of Urinary system - Renal and Vesical calculus, diabetic nephropathy, chronic UTI, chronic nephritis
- ◆ Respiratory diseases - bronchial asthma, TPA, allergic bronchitis, Sinusitis
- ◆ Hepatobilliary diseases - Infective hepatitis, Chronic hepatitis, Cholecystolithiasis
- ◆ Infantile diarrhoea/chronic diarrhoea
- ◆ Geriatric care and geriatric diseases
- ◆ Clinical validation of cosmeto -therapeutics
- ◆ Oral health
- ◆ Sport Medicines
- ◆ Emergency Medicines

Priority -II

- ◆ Eye Diseases- conjunctivitis, cataract, trachoma, refractive errors
- ◆ Ear diseases- Otitis Media, Otorrhoea
- ◆ Amoebic dysentery
- ◆ Nutritional disorders - Kwashiorkor, 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

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	Balance 10% Of the total
Salary					
Equipment					
Books					
Other Non-Recurring Expenditure					
Recurring Expenditure					
TA/DA					
Institutional Support					
Appropriate fee of PI and Col					
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 Col (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.

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(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/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.

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 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 Institute/Organization:

Date:

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	Signature of Head of Institution with date	Signature of Authorized Auditor with date
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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) 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.

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
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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	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)

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
			1 st year	2 nd Year	3 rd 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 with date	Signature of Head of Institution with date	Signature of Authorized Auditor with date
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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 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 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 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.

**“GOLDEN TRIANGLE” PARTNERSHIP (GTP) SCHEME
FOR VALIDATION OF TRADITIONAL
ASHU (AYURVEDA, SIDDHA, HOMOEOPATHY & UNANI) DRUGS
AND DEVELOPMENT OF NEW DRUGS**

The Golden Triangle Partnership concept emerged in a National Workshop on Ayurveda Research organized at Chitrakoot from 24th to 26th May, 2003 where it was decided to set up an integrated technology mission for the development of Ayurveda and traditional medical knowledge based on synchronized working of modern medicine, traditional medicine and modern science with special budgetary support. Subsequently, in a meeting on 8th July, 2004, Secretary, Department of AYUSH, Director General, CSIR and Director General, ICMR decided to work together to achieve safe, effective and standardized classical Ayurvedic products for the identified disease conditions and to develop new Ayurvedic and herbal products effective in disease conditions of national/global importance. It was also decided to utilize appropriate technologies to develop single, poly-herbal and herbo-mineral products and to develop products which have IPR potentials.

Apex Committee of GTP Scheme in its meeting Dtd. 18.10.05 decided to include Siddha, Unani and Homeopathy in Drug development under GTP Scheme. Siddha drugs have already been identified in HIV-AIDS brainstorming sessions in this regard. As per the suggestions of the Apex committee the respective task forces should be disease specific and system neutral.

Under, the GTP Scheme, Department of AYUSH, through its research Councils – Central Council for Research in Ayurveda and Siddha (CCRAS), Central Council for Research in Unani Medicines (CCRUM), Central Council for Research in Homeopathy (CCRH), – will work together with two other major partners i.e. CSIR and ICMR- to achieve the following objectives:

Objectives:

1. To bring safe, effective and standardized ASHU (Ayurveda, Siddha, Homoeopathy & Unani) products for the identified disease conditions;
2. To develop new Ayurvedic / Siddha / Unani / Homeopathic products effective in the disease conditions of national/global importance. Products should be better than the available products in the market for such disease conditions;
3. The criteria will be to have best quality, safe and effective products. Mechanism will be evolved to make products affordable for the domestic market;
4. To utilize appropriate technologies for development of single and poly-herbal products to make it globally acceptable;
5. To promote collaborative research on AYUSH with modern medicine/modern science institutions.

Time line:

All the objectives will be achieved in a mission mode in a period of five years.

Note:

At the time of inception of GTP Scheme, numbers of identified disease conditions were 12 which have now been increased to 25 in the revised scheme. In addition to this, standardization, safety toxicity studies of eight commonly used Rasayogas (Herbo-mineral/metallic preparations) are being identified for standardization and also more Rasa Yogas are to be incorporated. Since the quantum of work is now almost double hence the total time period for implementation of all these projects would be increased in proportionate. By adding Siddha, Unani and Homoeopathy, the expenditure and duration required for the project shall be extended as per the need.

Proposed Diseases/Areas of Priority

1. RASAYANA (Rejuvenators / Immunomodulators) for healthy ageing
 - i. *Manovikara – Ekagrata Hani* / Attention Deficit Hyperactive Disorders (ADHD) in Children
 - ii. *Manodvega* / Anxiety Neurosis & *Alpa Sukrata* / Oligospermia
 - iii. *Asthi Saushirya* / Osteoporosis
2. Joint disorders: *Amavata* / Rheumatoid Arthritis & *Sandhi gata vata* / Osteo arthritis
3. AIDS / HIV – OJOKSAYA: *Ojovruddhikara* / Immuno – modulatory leads from *Ayurveda* / *Siddha*.
4. *Rajonivruti Kala janya Lakshana sammuchaya* / Menopausal syndrome
5. *Tamak swasa* / Bronchial allergy
6. *Klaivya & Vandhyatva* / Infertility – Male & Female
7. Hridaya Vikara / Cardiac disorders (cardio-protective & anti-atherosclerosis)
 - i. *Vyanabala Utkshepa* / Hypertension
 - ii. *Raktagata Medo Vriddhi* / Dyslipidaemia
8. *Srama-Klama janya Anidra* Sleep disorders / Stress induced chronic Insomnia
9. *Tvak Vikara* / Skin disease: *Kittibha Kustha* / Psoriasis
10. *Jirna Kaphaja Atisara* / Irritable Bowel Syndrome (IBS)
11. Drishti Vikara / Vision disorders
 - i. *Jara Janya Drshti Bindu kshaya* / Senile macular degeneration (SMD)
 - ii. *Dristi vitana roga* / Retinopathy

12. *Visama Jvara* / Malaria
13. Mutra vikara / Urinary Tract Diseases
 - i. *Mutrashmari* / Urolithiasis & *Ashthila* / Benign Prostrate Hypertrophy
 - ii. *Prarambhika Jirna Vrka Pratighata* / Early Chronic Renal Failure
14. *Slipada* / Filariasis
15. Leshmaniasis
16. *Prameha* / Diabetes mellitus
17. *Medovridhi* / Obesity
18. *Arbuda - Karkatarbuda* / Identified Cancer conditions
19. Standardization, Safety/ Toxicity, etc. studies of *Bhasmas & Rasa Kalpas etc.* (Metalic & Herbo-mineral Preparations)
20. Any other disease condition
21. Development of Pharmacopoeial software
22. Development of Research Council Labs as per NABL / GLP.
23. Fundamental and Basic Research in ASHU disciplines

Three partner Departments will perform the following responsibilities:

Department of AYUSH - CCRAS- CCRUM- CCRH

1. To provide traditional knowledge based matrix on Ayurveda, Siddha, Unani & Homeopathy.
2. To provide leads for focusing on potential areas of research, based on the classical and contemporary texts and literatures as well as on experience based knowledge;
3. Specific lead will include the chronological development of a particular formulation which will also provide a comprehensive background and conceptual framework about the application of a particular formulation in a disease syndrome/condition;
4. To provide concept of the pathogenesis about a disease syndrome/condition as well as approach of application of old/new formulation to achieve treatment in a particular disease condition with respect to respective AYUSH discipline;
5. Department of AYUSH - CCRAS- CCRUM- CCRH will also compile and provide scientific data already created through research conducted in the past by various Institutions;
6. To coordinate preparation as well as supply of standardized ASHU drugs.

7. Provide policy support as well as regulatory system, approvals etc. to meet the legal requirements;
8. To take the products to the people for mass utilization;
9. To coordinate with the Department of Health to take up the products to the masses
10. To introduce Ayurvedic, Siddha, Unani & Homeopathy treatments in the health care system.

Council of Scientific and Industrial Research (CSIR)

1. Standardization of single and poly-herbal formulations;
2. Chemical and biological characterization of the drugs;
3. To identify chemical and biological markers as well as biological markers in animal models;
4. Animal studies;
5. Development of new drug combinations/new molecules;
6. Generate safety/toxicological data;
7. By reverse pharmacological approach, develop new drug molecules as well as explain Scientific basis of drug action of certain Ayurvedic / Siddha / Homeopathic / Unani (ASHU) formulations which could be modified and marketed;
8. Mode of action;
9. Joint IPR;
10. Industry interaction.

Indian Council of Medical Research (ICMR)

1. To provide information based on epidemiology and management of disease;
2. To develop clinical trial protocols for evaluating ASHU formulations with the concerned experts from related research councils & others ;
3. To conduct joint clinical trials of different phases to validate safety and efficacy;
4. To provide consultation relating to ethical issues for both basic and clinical studies;
5. To conduct operational research for implementation of the programme;
6. To set up Research Advisory Committees;
7. To set up Data Management & clinical trial monitoring;
8. To evaluate safety and efficacy data.
9. To provide common platform for modern medicine and traditional and Homeopathic systems

Steps for Implementation of the Project:

Each category of drug development programme will have the following steps:

1. Identify gaps in diseases and drugs
2. Brainstorming session on each disease condition – to identify formulations, strengths & weaknesses and corrective measures

3. R&D in identified formulations/drugs
 - (a) Standardization, quality control, patenting & IPR issues
 - (b) Limited safety and toxicity evaluation – identify centres and investigators
 - (c) Limited clinical evaluation – identify centres and investigators
4. Evaluation of safety and efficacy data
5. Preparation of dossiers of effective formulations
6. Interaction with the Industry for manufacturing of selected formulations
7. Operational research of the selected products for implementation into health system
8. Publicity & awareness strategies to take the product to masses

Steps for Implementation of the Project

Step 1: Identify gaps in diseases and drugs:

India's century old heritage of traditional medical systems using natural products have been utilized for addressing preventive as well as curative aspects of health care in the country. Though India's pharma sector is well known in the production of synthetic as well as herbal products it has been realized that there are a large number of chronic diseases for which the modern system of medicine has no definite answer while the traditional medicine formulations and Homeopathic formulations have been effectively used for many centuries and it was felt that the strengths of these systems should be exploited to address the problems of health care to be beneficial not only to the diseases of developing countries but also to those of developed western world. A literature review of epidemiology would be taken (from the already available data with WHO / Public Health organizations) for various diseases prevalent around the globe and available treatment modalities to assess the adequacy of such therapeutic measures to solve the problem of illness and promotion of health in different countries. These may be either communicable or non-communicable diseases, modifiable identified risk factors for diseases or may also be related to reproductive health of the population. This exercise will identify the gaps in the knowledge system of health and diseases as well as the available therapeutic products in different systems of medical and health care so that corrective steps can be initiated by identifying the most effective therapeutic regimen.

Step 2: Brainstorming session on each disease condition – to identify formulations, Strengths & weaknesses and corrective measures:

Having identified diseases for which therapeutic products are inadequate, an exercise will be undertaken to have brainstorming session for each of these conditions which will not only identify the specific formulations used in various disease conditions but also will examine the strengths and weaknesses of such formulations by way of availability of the source material, method of preparation of the formulations, mechanism of action and the side effects, reported toxicity etc., once these are identified, it will be easier to identify appropriate measures which can be adopted in the preparation of the

specific formulations as per set norms in the classical texts or pharmacopoeia. A Task Force approach will be adopted involving the expertise available in both Ayurvedic as well as modern systems of medicine so that the synergy of different systems can be best adopted to come out with the best possible therapeutic product.

Step 3: R&D in identified formulations / drugs:

(a) Standardization, quality control, patenting & IPR issues:

For implementing a successful R&D programme for any product, it is essential to go through the process of standardization and quality control so that the product used for animal as well as clinical studies, have uniform standards and do not suffer from batch to batch variation. Further, finger printing of the ingredients will be made as per the latest technology available to ensure uniform standards in all the batches that are used for pre-clinical and clinical studies. Any formulation which has been subjected to standardization and quality control procedures can be patented and the intellectual property rights of the product will be preserved so as to give benefits to the system to which it belongs. This will help to protect the country from the bio-piracy and give an edge over the other products which have not gone through such standardization procedures. This will also give confidence to the pharma industry to procure the know-how from the various laboratories to bring out quality products which will have national as well as international market. Adopting GMP is the need of the hour for all manufacturing industries and the first step towards this is to prescribe standardization procedures and quality control methods.

(b) Limited safety and toxicity evaluation – identify centres and investigators

There are beliefs existing that Ayurvedic / herbal products are totally safe and without any side effects. It is also known that such beliefs are not always true and there are well known instances of toxicity due to Ayurvedic / herbal products. Hence it is essential that limited toxicity or total toxicological evaluation of the natural products needs to be done depending upon the type of formulation to ensure safety of the users in the long run. The type of the pre-clinical toxicology in relevant animal species will depend on the nature of the formulation. For example, whether these traditional formulations have been in long term use or new herbal formulations, each product will be examined by a team of experts who will decide on case to case basis the extent of toxicology evaluation which is required for each product. Specific centres which have the capability to carry out such studies will be identified along with Investigators who can be entrusted with this responsibility. Pre-clinical studies not only give information on the toxicity profile but will also give us information on the pharmacological activity to various products as well as mechanism of action in different animal models wherever possible if well planned studies can be designed for the same.

Some of the Centres which can be entrusted with this responsibility are as follows:

1. CDRI, Lucknow
2. ITRC, Lucknow

3. RRL, Jammu
4. IICT, Hyderabad
5. Dabur Research Laboratory
6. Zandu Pharmaceuticals
7. Banaras Hindu University, Varanasi
8. PLIM
9. HPL

(c) Limited clinical evaluation – identify centres and investigators:

Any drug development after pre-clinical evaluation leads to clinical evaluation to assess the efficacy of the formulation in the specific disease conditions for which it is to be prescribed. Although some of the formulations may be in use for different disease conditions, as per the traditional knowledge, a modern method of evaluation by joint efforts between the traditional practitioners and the modern physicians will give confidence to the consumers as well as prescribers about the efficacy as well as safety of the said product. This will also ensure global acceptance of our products as these have gone through the well established path of drug development. It is also possible during these studies to pick up side effects or adverse reactions that may occur during the administration of these preparations. It is necessary that such trials are conducted after a well designed clinical trial which is planned with the help of physicians and statisticians and following good ethical practices for clinical trials. Approval of institutional ethics committees and close monitoring by the monitoring team are the essential requirements for carrying out such trials in good centres by well established researchers who have commitment and expertise to conduct clinical trials. Evaluation of such trials will be done by both modern parameters as well as traditional methods of evaluating the outcome or their effectiveness of the administered drugs. The quality of life parameters which are the hallmark of traditional drugs can also be studied during these trials. The choice of centres and Investigators will depend on disease to be studied, availability of sufficient patients for trials and committed clinicians of both systems who are willing to abide by the clinical trial protocols and conduct the trial as per GCP requirements. Ethical guidelines for biomedical research on human subjects, released by the Indian Council of Medical Research in 2000 will be followed during the trial. Periodic monitoring of the trial will be made to assess the progress by a team of experts and necessary corrective measures will be taken as deemed necessary.

Step 4: Evaluation of safety and efficacy data:

Data generated by the pre-clinical and clinical evaluation has to be examined by a team of experts to validate the safety and efficacy of formulation. It will also ensure whether a standardized formulation has been used during the study. Recommendation of the expert group to take the product forward to attract the pharmaceutical companies is essential from the regulatory point of view. Once the phase III data is evaluated and the product is found to be suitable for commercial exploitation, marketing permission can be granted with adequate post marketing surveillance to pick up any adverse effects.

Step 5: Preparation of dossiers of effective formulations:

Products which have been found to be effective and safe by the above mechanism will now be ready for presenting to various national and international pharma companies for which suitable drug dossiers incorporating various parameters prescribed for natural products will be taken into consideration. The essential requirements to be incorporated in these dossiers are method of preparation, good agricultural & collection practices, full description of the plant material as per modern scientific parameters preferably by a taxonomist, pharamcognosy, chemical finger printing, standardization and quality control of the raw material, determination of microbial pesticides, heavy metals, production source of the finished product, batch to batch variation, stability study and shelf life. The dossier will also contain the total pre-clinical pharmacological and toxicological data, clinical data of various phases and the adverse effects detected, if any. At this stage dossier will be ready for transfer to the pharma industry for taking up further large scale manufacture of the drug.

Step 6: Interaction with the Industry for manufacturing of selected formulations:

Interested pharma companies will be invited to look at the dossier and data generated. After signing proper Memorandum of Understanding and Secrecy Agreement, the selected pharma companies will be encouraged to go ahead with large scale manufacture of the drug. In the Agreement, specific clause regarding marketing rights and profit sharing between the government and the industry will be specified to protect the interest of the product developers and the industry partners. It will also be beneficial to plan strategies to identify the industry partner from the beginning so that the products can be developed as joint ventures between the government departments and the pharma industry.

Step 7: Operational research of the selected products for implementation into health system:

Safe and effective products, once approved for marketing will also be subjected to operational research to study the acceptability by the population and ease of introduction into the health care system. The results of such research will give confidence to the public regarding use of the product as well as safety of the product. This will also help to understand the extent of use and decide the acceptability and affordability of the product. Integration into the national health care system of such affordable products will help in easy availability of safe and affordable drugs to the masses in the country.

Step 8: Publicity & awareness strategies to take the product to masses:

It is essential to create a public awareness system and strategies so that the successful products can be provided enough publicity and visibility for large scale use as well as export potential to benefit the population of other countries. As the global demand for alternate/traditional system of medicine instead of the modern medicine is well evident through out the world, it will be possible to satisfy the needs of the people of the world. Thus the century old traditional knowledge of India can be harnessed to benefit the health and well being of the entire population of the world to bring back the glory to our traditional wealth of knowledge in the area of health & disease.

Milestones for Implementation of the Project (Time Schedule)

1. Identify gaps in diseases and drugs

- Identifying – 2 month
- Database, Epidemiologists, Public Health Specialists, AYUSH and Allopathic (Disease Specialists) Physicians.

2. Brainstorming session on each disease condition – to identify formulations, strengths & weaknesses and corrective measures

- Brainstorming on selected diseases / conditions / issues (3 months for each one)
- Task Force on specific diseases – 3-6 months
- Constitution of Working Groups, documentation, meeting
- Experts: Ayurvedic / Siddha / allopathic / Homeopathic / Unani physicians, pharmaceutical scientists, Dravyaguna experts, Ras Shastra experts, Pharmacologists.

3. R&D in identified formulations/drugs

(a) Standardization, quality control, patenting & IPR issues

- Identifying - 2 month
- Task force on specific issues - 3-6 months
- Constitution of working group, documentation, meeting

Standardization and Quality Control could be carried out in the following institutions:

1. RRL, Jammu
2. NIPER, Mohali
3. CDRI, Lucknow
4. NBRI, Lucknow
5. IICB, Kolkata
6. IICT, Hyderabad
7. PERD, Ahmedabad
8. CCRAS, Chennai, Kolkatta
9. IMPCL Pharmacy, Mohan
10. GAU Pharmacy, Jamnagar
11. NIA Pharmacy, Jaipur
12. CCRAS Pharmacy, Kolkata
13. CCRUM Pharmacy
14. BHU/ Ayurvedic Pharmacy, Varanasi
15. BARC, Hyderabad
16. PLIM, Ghaziabad
17. HPL
18. IMPCOPS, Chennai
19. SM Siddha pharmacy, Erode

(b) Limited safety and toxicity evaluation – identify centres and investigators

1. Standardization and quality control: 6 – 13 months.
2. Safety evaluation - 12-24 months
3. Toxicology/Pharmacology : As per list 20 or more institutions

(c) Limited clinical evaluation – identify centres, Hospitals and investigators

Clinical evaluation - 12-36 months

1. AIIMS, New Delhi
 2. PGI, Chandigarh
 3. KEM, Mumbai
 4. State Selected medical colleges
 5. BHU, Varanasi
 6. CCRAS Selected institutes
 7. CCRUM Selected institutes
 8. CCRH Selected institutes
 9. NIA, Jaipur
 10. GAU, Jamnagar
 11. Poddar, Mumbai
 12. SPARC, Mumbai
 13. Ayurvedic College, Thiruvananthapuram
 14. Arya Vaidya Sala, Kottkkal
 15. Nizam's Institute, Hyderabad
 16. Osmania, Hyderabad
 17. SGPGI, Lucknow
 18. KGMC, Lucknow
 19. Nair Hospital
 20. UCMS, Delhi
 21. MAMC, Delhi
 22. Jamia Hamdard Delhi
 23. Aligadh University
 24. JIPMER, Pondicherry
 25. CMC, Vellore
 26. MMC, Chennai
 27. Medical & Ayurvedic College – Bharati Vidyapeeth, Pune
 28. Ayurvedic College, Hasan, Udipi,
 29. Tilak Ayurvedic College, Pune.
 30. Leading AYUSH Colleges identified by Department of AYUSH.
- many more institutions

4. Evaluation of safety and efficacy data (third party evaluation)

- Evaluation of safety/efficacy data – 3-9 months
- ICMR, DCG (I), AYUSH - CCRAS- CCRUM- CCRH, Department of Health,
- Department of Family Welfare

5. Preparation of dossiers of effective formulations

- Preparation of dossier - 3 months
- Consultants to be engaged for preparing dossiers

6. Interaction with the Industry for manufacturing of selected formulations

Industry interaction – partnership from step 1, 2-3 months, continuing exercise

Industries to be partners:

- Leading AYUSH Pharmaceutical Companies.

7. Operational research of the selected products for implementation into health system

- Operation research - 1-2 years
- ICMR, Ministry of Health & F.W., AIHPH, Kolkata, State Health Departments, University Medical, AYUSH Colleges.

8. Publicity & awareness strategies to take the product to masses

- Continuing process
- Print media, advertising, TV, Radio, posters, skits, street plays

Costing per formulation (product) for one disease condition – one or two products

could be researched upon as per the expenses of AYUSH Department, ICMR, CSIR on various activities the tentative cost will be as follows:

S. No.	Activity Approximate	(Cost in lakh of Rs.)
1.	Identify gaps in diseases and drugs	10.00
2.	Brainstorming session on each (disease condition – to identify formulations, strengths & weaknesses and corrective measures)	10.00
3.	R&D in identified formulations/drugs	
	(a) Standardization, quality control, - patenting & IPR issues	100.00
	(b) Limited safety and toxicity - evaluation – identify centres and investigators	200.00
	(c) Limited clinical evaluation – -identify centres and investigators	250.00
4.	Evaluation of safety and efficacy data	100.00

5.	Preparation of dossiers of - effective formulations	25.00
6.	Interaction with the Industry -for manufacturing of selected formulations	25.00
7.	Operational research - of the selected products for implementation into health system	50.00
8.	Publicity & awareness - strategies to take the product to masses (Subject to actual)	200.00
	Total	Rs. 970 lakh say Rs.10.00 crore

For one product cost is = Rs.10 crore

Total cost for 12 products (12 x 10) = Rs.120 crore

Modus Operandi

The “Golden Triangle Partnership” (GTP) Scheme will have three major partners – Department of AYUSH (CCRAS- CCRUM- CCRH), CSIR and ICMR.

“Golden Triangle Partnership” project will be managed through the following committees:

Apex Committee: A policy making body for giving directions to the programme, chaired by Secretary, Department of AYUSH & will have DG, CSIR and DG, ICMR as other members. This committee will periodically take stock of the progress made and will suggest mid-course corrections. The Committee shall meet at least once in four months.

Steering Committee / Core Committee: will suggest the steps to be initiated at different stages and will closely monitor the Technical Advisory Committees. This committee will include three expert advisers/ representatives from each partner department. The meeting of this committee will be attended by members of all the three partners. The Committee shall meet at least once in three / four months.

Technical Advisory Committees (disease specific) for each of the discipline identified under the programme shall meet at monthly/ 2 monthly basis.

Task Force (Three Committee for Ayurveda / Unani / Homeopathy) for each Drug Development Programme, comprising of Investigators from different disciplines. Task force shall meet at 2 monthly basis.

1. All major policy decisions, however, would be taken on the overall direction and guidance of the Apex Committee i.e., Secretary (AYUSH), DG (CSIR) and DG (ICMR).
2. The GTP would work on the existing classical Ayurvedic formulations as well as new herbomineral combinations on the holistic approach to bring out validated products.
3. Department of AYUSH will take action on legal and regulatory issues.
4. Private drug manufacturing companies could also be associated in the project from the very beginning as partners for research and investment.

5. The Department of AYUSH (CCRAS- CCRUM- CCRH) will share resources for various R&D activities to be carried out through various ICMR, CSIR and other institutions.
6. The GTP will function in the Mission Mode, keeping the five year target in view for development of drugs of national importance.

Steering Committee:

The Steering Committee will comprise of the following members and the committee will meet every two months to approve the projects, release of funds and assess the progress of work.

1. Concerned Technical Advisor
2. Director of the concerned Council
3. Director of National Institute of the concerned ASHU system
4. Head, R&D Planning Division, CSIR
5. Head, Technology networking & Business Development, CSIR
6. Director, Indian Institute of Integrative Medicine, Jammu
7. Director, Indian Institute of Chemical Technology, Hyderabad
8. Senior DDG, ICMR
9. D.D.G., ICMR
10. Chair in Clinical Pharmacology, ICMR/ HOD, Pharmacology, AIIMS
11. One renowned scientist nominated by Secretary (AYUSH)

Note: Any other subject experts may be called as special invitee as per requirement from time to time

Secretarial Assistance: Work on the project will be done in a Mission Mode manner and each Council will have one Consultant in each system i.e. Ayurveda, Homeopathy, Unani with consolidated salary @ Rs.25,000/- p.m. and one Computer Data Operator with salary @ Rs.6,000/-. They will assist the technical advisers for the implementation of this project.

Funding:

- ⇒ Three partners will provide funds from their department's existing schemes/existing heads of research/drug/standardization/clinical trials/toxicological studies etc.
- ⇒ The estimated cost for developing drugs for one identified area is Rs.10 crore. Therefore, the total budgetary requirement over a period of 5 years will be in excess of Rs. 120 crores.
- ⇒ For GTP, Department of AYUSH will route the funding through involved Councils as per the approval of Steering Committee. For this purpose, CSIR, ICMR and Research Councils of AYUSH will submit the actual expenditure required for the activities carried out by them.

During the 11th plan, all the partners will contribute in GTP. Money could be routed through the Research councils/Institutes. Ayush share will be Rs. 75 crore. CSIR and ICMR will also contribute some amount. CSIR and ICMR will spell out their share soon after discussing with competent authorities.

Note: No additional funds for Development of Pharmacopoeial Software, Development of Research Council Labs as per NABL/GLP and Fundamental and Basic Research in ASHU disciplines can be taken from GTP component. However, project related infrastructure/equipment etc. could be supported.

Release of funds: Financial allocations for GTP project activities will be done through the Research Councils/Institutions of the three partner departments or directly to the project implementing institutions on annual basis. Tentative cost of various activities is indicated under the table of costing. This will be as per the norms of DST/CSIR/ICMR etc.

Funds allocations for GTP for 10th Plan:

2005-06 - Rs.15.00 crore, 2006-07 - Rs.20.00 crore

Rasa kalpas (Herbo-mineral preparations) Projects under Golden Triangle Partnership (GTP)

Scheme:

- Safety Evaluation of following 8 (eight) most widely used Bhasmas / Rasakalpas (Herbo-mineral & metallic preparations) and more are to be identified.
 1. *Kajjali*
 2. *Rasa manikya*
 3. *Rasa sindoor*
 4. *Basant kusumaksr Rasa*
 5. *Arogyavardhini Vati*
 6. *Mahayogaraja Guggulu*
 7. *Mahalaxmivilas Rasa*
 8. *Makardhwaja*
- Standardization / Drug development of prioritized disease conditions is under progress at CSIR.

Participation of AYUSH Industry in Drug Development under GTP Scheme:

Areas of interest as one disease – one industry and one Council to develop/standardize the drug and taking Drug Development under GTP Scheme.

In the Project Screening Committee meeting for Golden Triangle Partnership (GTP) scheme held on 06-03-07 at Dept. of AYUSH and ICMR is advised for taking up the Drug development project for HIV / AIDS with the involvement of CCRAS, CCRUM, AIIMS and AYUSH Industry.
