GUIDELINES FOR CENTRAL SECTOR SCHEME FOR AYURGYAN

1. Background of the Scheme

Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and Homoeopathy (AYUSH), offer a wide range of holistic treatments covering preventive, promotive, curative, rehabilitative and rejuvenatory needs. These systems of medicine are generally cost effective and valuable and attracting increasing attention globally. AYUSH systems of medicine are being used for centuries and have continuous traditions of acceptance and practice. There is a need for spreading the knowledge; benefits of AYUSH system of medicines to the large section of the peoples across the globe. The Ministry has "**AYURGYAN Scheme**" to **support Education, Research & Innovation in AYUSH by providing academic activities., training, Capacity Building etc**. having three separate components for the promotion of AYUSH's education and Research.

Capacity Building and Continuing Medical Education (CME) in AYUSH

Capacity-building is the "process of developing and strengthening the skills, instincts, abilities, processes and resources that organizations and communities need to survive, adapt, and thrive in a fast-changing world. The essential ingredient in capacity-building is transformation that is generated and sustained over time.

The scheme of Continuing Medical Education (CME) was implemented in 11th Plan and has continued since then, the scheme covered maximum number of AYUSH teachers, doctors, paramedical and others personnel. However, in the current scenario, there is still a need for continuing the training for upgrading their professional competence & skills and their capacity building. Emerging trends of healthcare and scientific outcomes necessitate time to time enhancement of professional knowledge of teachers, practitioners, researchers and other professionals. The overall structure of the Scheme is aimed at encouraging AYUSH personnel to undergo need-based professional training and bridge the knowledge gaps.

Furthermore, it is pertinent to mention here that the Sectoral Group of Secretaries in the recommendation has suggested for Capacity building of AYUSH workforce.

Research and Innovation in AYUSH Component

Ayush represents Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa-Rigpa & 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 then 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 off take 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, neutraceuticals, 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.

Ayurveda Biology Integrated Health Research Programme

Several research studies have been conducted at different levels to demonstrate the feasibility, efficacy and safety of integrative treatment modalities involving Ayurveda and other Ayush interventions. Efforts to generate evidences are needed to standardize and validate integrative protocols through high impact coordinated research studies. The evidences generated through such larger studies may certainly provide a scope for introducing these practices into National programs.

Development of a basic understanding of the principles, procedures and products of Ayurveda in context of modern sciences such as Molecular biology, pharmacology, Immunology, Chemistry, biotechnology, bioinformatics set may be initiated, as Ayurvedic approach of treatment can be better appreciated and applied if it is understood along with its fundamental principles. Even though considerable efforts are being put in for validation of basic tenants of Ayurveda by organizations like Institute of Public health, University of Pune, CSIR-Institute of Genomics and Integrative Biology, New Delhi, Central Council for Research in Ayurvedic Sciences (CCRAS) etc., such as Development of Diagnostic Tools and Tools for assessment of Prakriti etc., *still there is a lot to be explored with the parameters and principles of contemporary sciences for its better understanding and application through translational approaches.*

Realizing the above, to promote evidence based integrative medical practices involving Ayurveda, the Ministry of Ayush introduces a special programme to tap the potential of Ayurveda through integration with basic sciences and conventional system of medicine for addressing health related challenges. The programme reflects inclusive approaches of Ayurveda Biology and trans-disciplinary research for drug development and related aspects.

2. Objective of the Scheme

2.A. **Capacity Building and Continuing Medical Education (CME) in AYUSH**

i. To create, enhance and develop constituent's capacity at country level in the AYUSH health care sector.

ii. To improve health practices through AYUSH which are sustainable.

iii. To encourage AYUSH professionals to undergo need-based professional orientation and professional skill development in an organized manner.

iv. To update the professional knowledge of teachers and doctors to adopt good teaching practices and good clinical practices respectively.

v. To encourage the use of Information technology and web-based education programmes for widespread dissemination of AYUSH developments and updates.

vi. To train doctors in emerging trends of healthcare and scientific outcomes for keeping up the standards to health care delivery.

vii. To provide information to doctors on professional journals to keep them professionally updated. AYUSH-CME Guidelines.

viii. To encourage AYUSH paramedics and health workers to undergo periodical training for improving healthcare services in hospitals and dispensaries.

ix. To arrange need-based management training programmes to administrators of AYUSH institutions and hospitals on health aspects for delivering quality services.

x. To update regarding current trends in R & D activities for development of AYUSH systems and highlight the areas of research and avenues for collaborative activates.

xi. To apprise regarding new Acts/Notifications and other information addressing regulatory issues in AYUSH systems etc.

xii. To Standardize/validate and develop scientific evidence for AYUSH' s research and Education;

xiii. To make scientific exploration of AYUSH system with interdisciplinary approaches; to achieve need based outcome in priority areas;

2.B. **Research and Innovation in AYUSH Component**

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

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

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

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

v. 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;

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

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

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

2.C **Ayurveda Biology Integrated Health Research**

1. To strengthen and advance the ongoing Ayurveda biology research by mean of following objectives:

   1.1 To develop a sustainable platform in field of Ayurveda Biology meant for the basic understanding of the principles, procedures and products of Ayurveda interms of modern sciences such as Molecular Biology, pharmacology, Immunology, biotechnology, bioinformatics, Chemistry etc.

   1.2 Trans-disciplinary approach for understanding the pharmacokinetics and pharmacodynamics of Ayurveda Drugs and validating the bimolecular pathways and effects of Ayurveda Drugs.

2. To create an ecosystem of integrative health research for the convergence of evidence-based elements within Ayush systems in sync with biomedicine, bio-technology, bio-physics, nano-technology, advances in IT and such other advanced technologies for pragmatic integrative health practice by doing the following:

   2.1. To support high end integrative research with translational value for translation of Ayush based leads into public health

2.2. Generation of molecular, clinical and real world evidences to demonstrate safety, efficacy of Ayush interventions by synthesis of observations from diverse settings and develop protocols for tangible integrative practice.

2.3. To promote competitive technology development in the field of devices and diagnostic tools with eminent institutions who have shared interest in Ayush, Bio-medical engineering, Ayur-tech and integrative biology.

3. MAIN Components of AYURGYAN Scheme

3.A. Capacity Building and Continuing Medical Education (CME) in Ayush &

3.B. Research and Innovation in Ayush

3.C. Ayurveda Biology Integrated Health Research (ABIHR)

3. C. AYURVEDA-BIOLOGY INTEGRATED HEALTH RESEARCHPROGRAMME

1. BACKGROUND:

The global indicators in the field of Medicine evolved through ages have demonstrated a gross shift from Medical Care towards Health Care, covering preventive health, promotive and rehabilitative aspects besides therapeutic management and cure. This has gained the attention of Integration of different health systems to complement and supplement the unmet need. Broadly the translation of Integrative models for public utility needs two diverse interventions viz. Integrative model for clinical research for effective integration, secondly Pragmatic Public Health Care delivery model.

Integrative medicine uses the safest and most effective combination of approaches and treatments from the world of conventional and complementary/traditional medicine. Integration of Traditional Medicine around the globe has proved to be a great step in providing comprehensive, cost-effective health care service to the society.

The 67th World Health Assembly resolution on traditional medicine has been instrumental in the development of updated WHO Traditional Medicine Strategy (2014–23) with objectives to harness its contribution and promote effective use.

Ayurveda has age-old acceptance in the communities in India and in most places it is the first line of treatment in case of common ailments. India enjoys the distinction of having the largest network of Ayurveda health care, which is fully functional with a network of registered practitioners, Govt. dispensaries and Hospitals, Research institutions and licensed pharmacies etc.

Policy Provisions and support:

The recent three major documents related to health policy, viz. National Health Policy (NHP) 2017; Situation Analyses - Backdrop to NHP 2017, Ministry of Health and Family Welfare, Government of India; and Three-Year Action Agenda 2017-2020 (draft), NITI Aayog, Government of India, highlighted on prevention through lifestyle advocacy, health care delivery through integration, collocation, and medical pluralism.

Several research studies have been conducted at different levels to demonstrate the feasibility, efficacy and safety of integrative treatment modalities involving Ayurveda and other Ayush interventions. Efforts to generate evidences are needed to standardize and validate integrative protocols through high impact coordinated research studies. The evidences generated through such larger studies may certainly provide a scope for introducing these practices into National programs.

Development of a basic understanding of the principles, procedures and products of Ayurveda in context of modern sciences such as Molecular biology, pharmacology, Immunology, Chemistry, biotechnology, bioinformatics set may be initiated, as Ayurvedic approach of treatment can be better appreciated and applied if it is understood along with its fundamental principles. Even though considerable efforts are being put in for validation of basic tenants of Ayurveda by organizations like Institute of Public health, University of Pune, CSIR-Institute of Genomics and Integrative Biology, New Delhi, Central Council for Research in Ayurvedic Sciences (CCRAS) etc., such as Development of Diagnostic Tools and Tools for assessment of Prakriti etc., *still there is a lot to be explored with the parameters and principles of contemporary sciences for its better understanding and application through translational approaches.*

Realizing the above, to promote evidence based integrative medical practices involving Ayurveda, the Ministry of Ayush introduces a special programme to tap the potential of Ayurveda through integration with basic sciences and conventional system of medicine for addressing health related challenges. The programme reflects inclusive approaches of Ayurveda Biology and trans-disciplinary research for drug development and related aspects.

The Programme is designed to encourage R&D in priority areas based on disease burden in alignment to National and global health policy documents. It also aims to utilize the vast research potential available within the country and globally for studying effective integrative models for introducing Ayurveda in integration with basic sciences and conventional system of medicine.

1.1 VISION

To demonstrate a dynamic and vibrant model of integrated health research emphasizing on translation of key outcomes of fundamental research into evidence based practices for mainstreaming through implementation research.

2. OBJECTIVES:

3. To strengthen and advance the ongoing Ayurveda biology research by mean of following objectives:

1.1 To develop a sustainable platform in field of Ayurveda Biology meant for the basic understanding of the principles, procedures and products of Ayurveda interms of modern sciences such as Molecular Biology, pharmacology, Immunology, biotechnology, bioinformatics, Chemistry etc.

1.2 Trans-disciplinary approach for understanding the pharmacokinetics and

pharmacodynamics of Ayurveda Drugs and validating the bimolecular pathways and effects of Ayurveda Drugs.

4. To create an ecosystem of integrative health research for the convergence of evidence-based elements within Ayush systems in sync with biomedicine, bio-technology, bio-physics, nano-technology, advances in IT and such other advanced technologies for pragmatic integrative health practice by doing the following:

   2.1. To support high end integrative research with translational value for translation of Ayush based leads into public health

   2.2. Generation of molecular, clinical and real world evidences to demonstrate safety, efficacy of Ayush interventions by synthesis of observations from diverse settings and develop protocols for tangible integrative practice.

   2.3. To promote competitive technology development in the field of devices and diagnostic tools with eminent institutions who have shared interest in Ayush, Bio-medical engineering, Ayur-tech and integrative biology.

3. SCOPE:

3.1 To develop a sustainable platform for strengthening and advancing the ongoing Ayurveda biology research and create an ecosystem of integrative health research for the convergence of evidence based elements within Ayush systems in sync with biomedicine for pragmatic integrative health practice in clinical setup.

3.2 To promote collaborative research in new drug discoveries using proof of concepts and creating new botanicals by taking leads from these researches.

3.3 To promote collaborative research in developing new diagnostic tools and devices based on Ayurveda principles using proof of concepts and advanced technology that would be useful in clinical practices as well as in establishing Ayurveda as scientific medicine and health care system.

3.4 To consider proposals from other Ayush streams under similar guiding principles.

The outcomes of the Programme are expected to optimize the utilization of Ayush systems for achieving P4 (Predictive, Preventive, Personalized, Participatory) Medicine and public health as part of integrative health care delivery.

4. PRIORITY AREAS*:

Fundamental, drug and clinical research shall be conducted on following priority areas:

I. To create an exhaustive open database of Ayurveda Biology and promote trans-

disciplinary research in this domain. The key areas of focus for the same are as follows:

- Translation of Research findings for the utilization in real time practice of P4 (Predictive, Preventive, Personalized, Participatory) Medicine.
- Use of advancement in sciences, Artificial Intelligence (AI), and other computing technologies for understanding of physiology and pathology with individualistic approach for the prevention and management of diseases.
- Generation of evidence on safety and efficacy of Ayurveda *interventions e.g.*
    - Validation of therapeutic procedures in Ayush
    - Studies on the efficacy of Ayush system of medicine in Non-Communicable Diseases (NCD) or lifestyle disorders e.g. diabetes, cardio-vascular diseases etc.
    - Validation of the various Panchakarma (bio-cleansing) procedures including purva and paschat karma.
    - Studies on Ayurveda Aahar
    - Any other area of National importance.
    - Database of safety and efficacy of Ayurvedic drugs including meta-analysis, data mining, mapping studies etc.
    - Public Health research with Ayush interventions.
- Whole system approach of any of the Ayushsystems in diseases of national importance

II. Ayush intervention in public health care:

- Epidemic diseases
- Geriatric Health Care
- Paediatric diseases
- Mental Health & cognitive disorders
- Immunological Disorders
- Anemia& nutritional disorders
- Maternal & Child health
- Add on treatment in prevention & control of non-communicable diseases
- Vector borne diseases
- New Rare diseases etc

III. Drug development &Standardization:

- Phase-I Human Pathogenetic Trials (As per Good Clinical Practice of Homoeopathy Guidelines)
- Pharmacological studies, safety & toxicity evaluation
- Pharmacokinetics & Pharmacodynamics Studies

- High end Clinical Trials

IV. Studies on the standardization, quality, biodynamic properties and effect of *Ayush interventions:* To develop consortium of Ayush based integrative medicine research for Validation of Safety, Efficacy of different Ayush Interventions & approaches/ Treatment modalities as standalone or as a co-management with conventional system of medicine for preventive, curative and rehabilitative aspects in the area of non-communicable disorders and other diseases of National importance.

V. To improve Ayush based products quality through latest Functional Materials Research, Development of commercially viable products, design and innovation strategies, decision analysis frameworks for R&D and sustainable use of Ayush etc.

VI. AI-driven Network pharmacology-based drug research for complex Ayush formulations to generate evidence for the safety, efficacy, drug/food interactions studies and real-world evidence for integrative practice. To develop Ayush based standardized diagnostic and therapeutic devices/equipment by utilization of cutting-edge medical instrumentation technologies and computational tools for bringing in objectivity, validity.

***Note**: Proposals in a financial year will be invited in alignment to important identified prioritized areas and other strength areas by Project Development and Screening Committee and as per the recommendations of National Ayush Research Consortium. The Central Government may also consider supporting important research proposals in other areas of National interest depending upon the credential of the institution & investigator from time to time.

While the scheme includes identified priority areas, identified research activities and further R&D, may be given preference where they are aligned with the focus areas and activities identified and/or operationalized by the National Ayush Research Consortium, to ensure alignment between Government- Academia-Industry.

5. ELIGIBILITY CRITERIA

5.1. <u>Investigator credentials</u>: (the investigators should be attached to the affiliated institutions on regular basis)

The investigators should be highly qualified in the subject having track record of innovative initiatives and leadership.

5.1.1. There will be **one Principal Investigator (PI) responsible for** applying,

reporting the progress and all financial transactions regarding the project. There may be Co-Is with expertise essential for the project. The PI shall be responsible to meet the time lines approved to complete the project.

5.1.2. There could be Co-I from foreign organization subject to complying with MEA, DPIIT and Ministry of Ayush norms.

5.1.3. Normally, at a time one PI who has been granted a project will not be considered for another project unless completion of the prior project. Fresh research proposals may be considered if Committee finds that previous project is on verge of completion.

5.1.4. Change of PI

- If for any reason the PI leaves the project, an eligible Co-investigator could be considered as the PI subject to recommendation of the PI, the Head of the Institution, and the approval of the Ministry of Ayush, as the case may be. Such request should be sent well in advance.
- In case the PI is shifting to any other Institution, the Co-investigator could be made the new PI, or the project could be transferred to the new Institution with the mutual agreement of both Institutions and the prior approval of the Ministry of Ayush.
- If for any reason the Co-I is required to be changed, prior approval of the institution and Ministry of Ayush is mandatory.
- The host Institution has an important role to play in the project. The Institution/Principal Investigator will have to inform the Ministry of Ayush as the case may be, of any change, and in consultation with the Ministry of Ayush take steps to ensure successful completion of the project before relieving of the Principal Investigator.

Note: Once accepted it is the whole responsibility of the PI has to complete the project. An undertaking in this regard may be submitted. However, in rare circumstances the above may be applied.

5.2 <u>Institutional credentials</u>:

Institute/ organization (including Govt./Private) applying under the scheme shall have track record of high-quality research with appropriate infrastructure for undertaking the research.

A foreign institute may also be a partner institute subject to valid MoU signed with Indian counterpart and the Indian organization is the primary applicant under international joint research call.

6. MODE OF APPLICATION FORGRANT-IN-AID

6.1. Invitation of proposals: The proposals may be invited in two-pronged approach viz. Proactive approach and Reactive approach

- The PDMC may also co-opt domain experts from proposed NARC as per requirement and feasibility from time to time while developing/screening the proposals under Programme on Ayurveda-Biology Integrated Health Research. Further PDMC will also inter-alia take up and coordinate under the scheme Research projects at identified institutions as recommended by NARC from time to time.
- **Proactive approach:** Ministry of Ayush will directly approach to nationally reputed academic / research organizations like ICMR, CSIR, ICAR, DST, DBT, AIIMS, IITs, PGIs, DRDO, research councils under Ayush, universities etc. and industries, and other Govt. as well as Non-Govt. organizations for participation in specific identified areas based on their previous records, publications, infrastructure and expertise etc. The PDMC shall act as high-level search committee to identify gaps, shortlist such institutes expertise in specific domain for inviting proposals in identified priority areas and finalize the proposals. Further PDMC will also inter-alia take up and coordinate under the scheme Research projects at identified institutions as recommended by NARC from time to time.

- **Reactive approach**: Ministry of Ayush shall invite proposals under Programme on Ayurveda-Biology Integrated Health Research through open advertisement placed in the National dailies. The advertisement would also be placed on the website of the Ministry of Ayush. Proposals received apart from the time frame as advertised by Ministry of Ayush for submission of proposals, will not be considered and no communication will also be made in this regard.
- Programme details, Other Formats, Checklist of mandatory requirement for projects shall be available on following sources:

  Website of the Ministry of Ayush: www.ayush.gov.in

  https://ngo.ayush.gov.in/ [after designing of application format & report for the new component of Program on "Ayurveda-Biology Integrated Health Research"]

- The Individuals/Institutions, interested for the grants-in-aid in connection with their proposed project may apply in the prescribed formats through Web-application along

with all the required documents, to Director (Programme), Ministry of Ayush, Ayush Bhawan, B Block, GPO Complex, INA, New Delhi – 110023.

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

6.2. Formulation of the Project:

6.2.1 The project proposal should be prepared in the format for application, as given on Web-application. **Section A** of the Application format requires General Information of the project. A description of all the projects taken up by the Institutions under any Grant in aid Programme of Ministry of Ayush, Govt. of India and other Grant in aid Programme of the Govt. of India under other ministries is to be given. This would include the Title of the Study, Objectives, Date of inception of the project, Date of completion, Name and Designation of the Principal Investigator and Co-Investigators of the study and grant-in- aid received for the study. **Section-B** of the Application format requires Bio-Data of PI, Co- I(s) and the Consultants proposed in the research study. **Section-C** of the Application is the "Brief Summary of the Project" **Section-D** of the application relates to the detailed Protocol of the study.

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

6.2.3 Ethical clearance from the Institutional Ethics Committee (in case of human trials) or Institutional Animal Ethics Committee (for animal studies) of the Institutions applying for the Research Proposal is mandatory. **A certificate of clearance from the Institutional Ethics Committee (IEC) or Institutional Animal Ethics Committee (IAEC) is to be enclosed along with the application form.** For Ethical Guidelines and constitution of the Ethics Committee the Institution may

refer to the ICMR Guidelines available at ICMR Website at www.icmr.nic.in(Hyperlink to "About us" and then Ethical Guidelines for Biomedical research on Human Subjects) and ASU&H Good Clinical Practice Guidelines for Clinical Trials of ASU Medicines.

6.2.4 Other Documents to be enclosed along with the Application Form-

The Institutions seeking assistance for Research projects under Grant are required to submit the following documents along with the Application:

i. A copy of the Memorandum of Association, Rules and Regulations of the Institutions under which it has been established;

ii. A copy of Bye Laws certificate issued to them under the relevant Act wherein it has been registered (self-attested);

iii. Annual Report along with the Audited Statement of Accounts for the last year;

iv. Justification and breakup of all budget heads as proposed in the proposal;

v. Undertaking from the Head of the Institute/Department regarding non-availability of equipment proposed to be procured for the project;

vi. Concept note as per format;

vii. Agency details as per format;

viii. Mandatory NGO/VO details as per format;

ix. Credentials of the Institute/Organization (Details of the infrastructure, equipment and other facilities available in the institute).

x. Forwarding of Application through Head of Institute.

7. PROJECTAPPROVAL

7.1. Development, Screening and Appraisal of the project

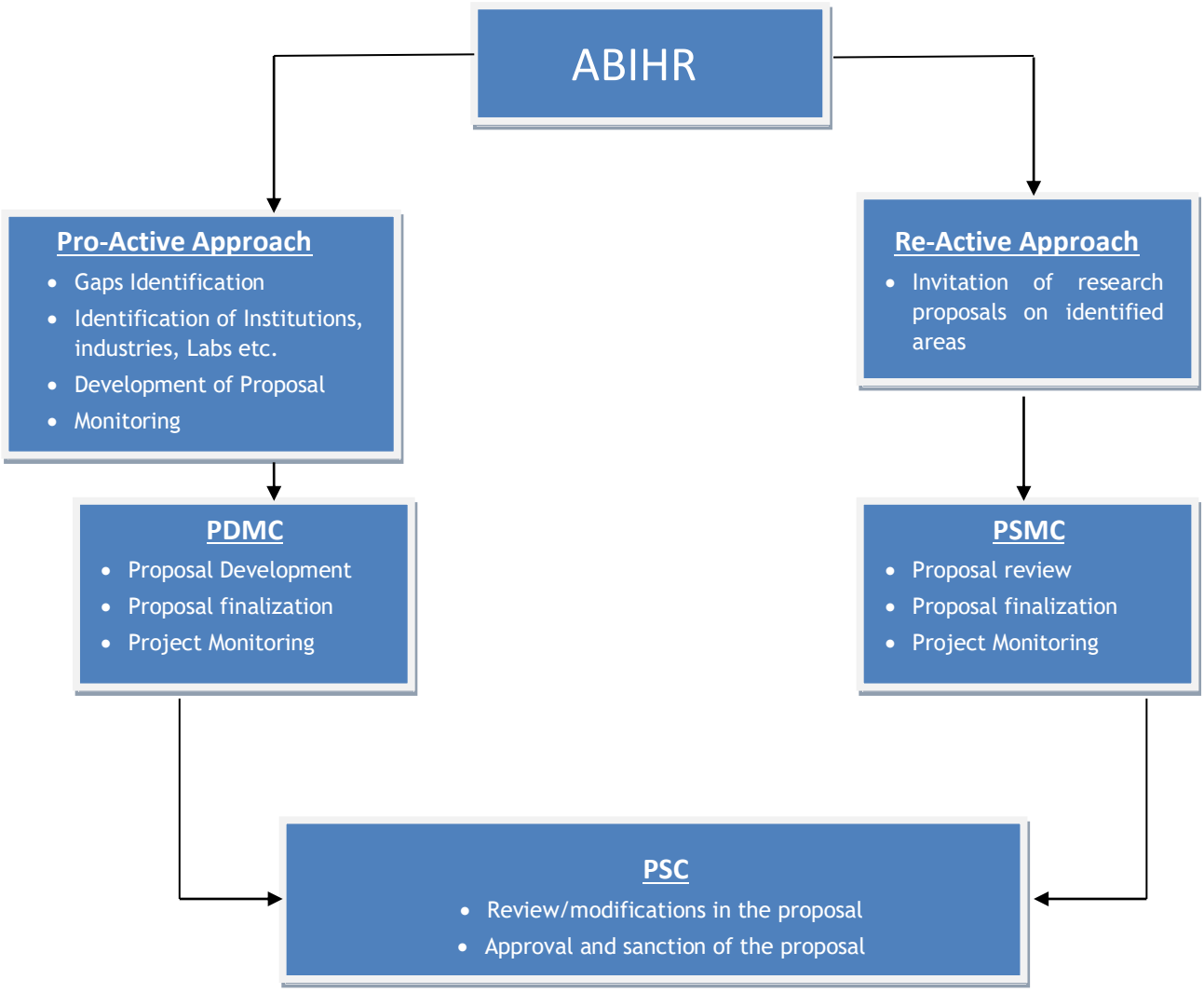
- A separate secretariat may be set up in CCRAS, Ministry of Ayush to manage the consortium in a sustainable manner. The secretariat shall have experts representing all of the Ayush systems and the experts of technology branches as necessary to examine the proposal. In case of need, the secretariat shall take the opinion of subject specific technical experts by circulation.
- The proposal received through re-active approach under Programme on Ayurveda-Biology Integrated Health Research shall be reviewed by the Project Screening and Monitoring Committee (PSMC). However, projects formulated through Pro-active approach shall be developed and monitored through Project

Development and Monitoring Committee (PDMC).

- The secretariat at CCRAS, Ministry of Ayush will examine the proposals and concept note received through re-active approach within 15 days of time after receiving the proposal and maximum up to 60 days, if any revision is required in consultation with domain expert as appropriate, in the project as per advertisement released from time to time. If the proposals or concept note not found suitable as per the Programme guidelines i.e. proposals with major deficiency in terms of objectives and eligibility criteria etc., would be rejected and applicant will be informed accordingly.
- Projects developed by adopting a Proactive approach under Programme on Ayurveda-Biology Integrated Health Research, the PDMC will directly approach the nationally reputed academic/ research organizations like ICMR, CSIR, ICAR, DST, DBT, AIIMS, IITs, PGIs, DRDO, research councils under MoA, universities, industries, GLP compliant laboratories of International repute, etc. and other Govt. as well as Non-Govt./ private organizations, industries, and laboratories for participation in specific identified areas based on their previous records, publications, infrastructure, expertise etc., through an all-inclusive approach. The PDMC shall identify/shortlist such institutes' expertise in specific domains for developing proposals in identified priority areas.
- The PDMC may also co-opt domain experts from proposed NARC as per requirement and feasibility from time to time while developing/screening the proposals under Programme on Ayurveda-Biology Integrated Health Research. Further PDMC will also inter-alia take up and coordinate under the scheme Research projects at identified institutions as recommended by NARC from time to time.
- The developed or shortlisted proposals through PDMC or PSMC will be submitted to the Project Sanctioning Committee (PSC)for final approval and sanction, (and first) installments of the sanctioned grant would be released (and further installments will) only (be released) after liquidation of the Utilization certificate of previous installment and acceptance of Annual Performance Report and approval of the PSC and the Integrated Finance Division of the Ministry.

The ceiling of the financial support for the project shall be upto**Rs.10.00 (Ten) Crores**.

Note: Any revision in the proposal shall be carried out and completed within two-months. Principal Investigator not sticking to time limits for submission of revised proposal, their proposals may be rejected.



Project Sanctioning Committee (PSC)

Project Sanctioning Committee chaired by the Secretary, (Ayush), would consider the proposals screened or developed by PSMC or PDMC for approval and sanction.

The PDMC & PSMC would comprise of: -

I. Project Development and Monitoring Committee (PDMC)

1.	Director General, CCRAS	Chairperson
2.	Two renowned scientists having track record in Integrated Research (to be nominated by Secretary Ayush).	Member
3.	One expert from reputed/renowned institution like AIIMS [to be nominated by the Secretary (Ayush]	Member
4.	Joint Adviser (Ayurveda)	Member
5.	Scientist E and above from ICMR, CSIR &DST nominated by respective organizations	Member
6.	One Ayush Scientist as nominated by DGs from each concerned Research Councils	Member
7.	Director –Program, Ministry of Ayush	Member
8.	Deputy Director General, CCRAS	Member Secretary

Project Screening and Monitoring Committee (PSMC)

1.	A senior technical expert nominated by Secretary (Ayush)	Chairperson
2.	Two experts from the concerned discipline having published research work(to be nominated by Secretary Ministry of Ayush)	Member
3.	DGs of ICMR, CSIR &DST or his/her representative (Not below the rank of DDG/Scientist-F level)	Member
4.	One Expert from reputed/renowned institution like AIIMS (to be nominated by the Secretary (Ayush)	Member
5.	Adviser (Ayurveda)	Member
6.	Director General, CCRAS/CCRUM/CCRS/CCRH/CCRYN	Member
7.	Director/ Vice Chancellor from AIIA, NIA& ITRA	Member
8.	DDG, CCRAS	Member Secretary

Note: Experts from respective technology streams may be adopted for particular meetings as necessary.

Project Sanctioning Committee

1.	Secretary (Ayush)	Chairperson
2.	Secretaries or their representatives from Research consortium	Members
3.	Financial Adviser or his/her representative (not below the rank of DS)	Member
4.	Joint Secretary, Ministry of Ayush	Member
5.	Adviser (Ayurveda)	Member
6.	DGs of ICMR, CSIR, DST&DBT or their representatives not below the rank of DDG/Scientist-F level	Member
7.	Director AIIA, NIA & ITRA	Member
8.	Representative of MEA in case of international research project	Member
9.	DG, CCRAS	Member
10.	One Vice Chancellor of State Ayush University nominated by Secretary (Ayush)	Member
11.	Three co-opted members from scientific background (to be nominated by Secretary (Ayush)	Member
12.	Director Programme , Ministry of Ayush	Member Secretary

*Note : The subject experts from the relevant field can be co-opted for the particular meeting of PSC depending upon the nature of the research proposal received.

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

An honorarium of Rs.5,000/- would be paid to co-opted and expert members in PSMC and PDMC as per rules, it can further be revised by Project Sanctioning Committee with the concurrence of IFD if required.

An honorarium of Rs.5,000/- would be paid to reviewer/external expert, it can further be revised by PSC with the concurrence of IFD if required.

7.2. Project Monitoring Unit and Secretariat

S. N.	Number of Post	Educational Qualification/Experience	Monthly remuneration
1.	02 Sr. Consultant- (technical)	**1. Educational Qualification**: Having PG degree in Ayurveda, from recognized institute under NCISM Act, 2020. **Desirable:** Having Ph.D degree in Ayush. **Experience**: The candidate shall have	In accordance with the existing Ministry's guidelines for engagement of

		minimum 05 years' experience in Research and having at least 05 no. of publications in reputed journal. 2. **Educational Qualification:** Having Master degree in bio-technology/Molecular & Cell biology/ pharmacology /microbiology/ biochemistry/or as per requirement of intended research work **Experience**: The candidate shall have post PG 05 years working experience in Research. The candidate should have excellent communication and interpersonal skills, knowledge of computer applications such as MS word, MS excel and Power Point etc. The candidate should be well conversant with office procedure like drafting, noting, budget and basic finance etc.	Consultants on contractual basis
2.	02 Consultant (Technical)	**Educational Qualification**: Having PG degree in Ayush or Ayurveda Biology or after graduation in Ayush PG in public health, pharmacology, microbiology or related disciplines as per the requirement of intended research work from a recognized institute. **Experience**: The candidate shall have minimum 03 years' experience in Research or related fields.	In accordance with the existing Ministry's guidelines for engagement of Consultants on contractual basis
3.	01 Consultant (Finance &Accounts)	**Educational Qualification**: MBA from recognized Institute/University. **Experience**: The candidate shall have 5 years' working experience in Finance and Accounts Preference will be given to candidates who have prior experience to have dealt with the schemes/programmes concerning Government/ PSU/ autonomous	In accordance with the existing Ministry's guidelines for engagement of Consultants on contractual basis

		organization.	
4.	02 Office Assistant	Graduate Degree with 03 years' experiences preferably in Govt. Sector. The candidate should have excellent communication and interpersonal skills, knowledge of computer applications such as MS word, MS excel and Power Point etc.	In accordance with the existing Ministry's guidelines for engagement of Office Assistant on contractual basis.

- The consultant explained in PMU will work for inviting proposals, preliminary evaluations, organization of meetings and coordination with the stakeholders for proper execution of the program and all other scientific and non- technical work as directed by concerned authority in the Ministry of Ayush.

7.3. Monitoring committee for the projects under the programme:-

A project specific ad-hoc monitoring committee shall be recommended by PDMC/PSMC when required, to assess the progress of the project involving official/personnel from all the stakeholders as per need.

8. OUTCOME OF THE PROJECT:

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

9. FINANCIALSUPPORT:

- ✓ The Ministry of AYUSH will provide financial support for the Research project upto Rs.10.00 (Ten) Crores**.**
- ✓ The Ministry of Ayush will provide financial support, payable on yearly installment basis, for the research including staff, equipment and contingencies (recurring and non-recurring) for the project for a duration of 02 years, which can be extended with

the approval of Chairman PSC subject to extension of the scheme beyond 15th Finance Commission period.

- ✓ The Institution both in public & private sector/individual applying for the grants-in-aid should have adequate staff, equipment and laboratory/other facilities to conduct the particular research. Financial support will be given only for the minimum required staff, equipment, books and contingent items.
- ✓ Institutional Support not exceeding 5% of the total cost (excluding the cost of equipment) of the project after successful completion of the project may be provided to the Institution.
- ✓ In case of Private Industry, the share of grant by the Ministry may not exceed 50 % of the total cost proposed. The matching share of industry should be made available with each installment of the fund released by the Ministry.

10. EXPENDITURE:

All recurring and non-recurring items required for work of the project should be purchased in accordance with the Govt. procedures and guidelines. For permanent and semi- permanent assets acquired solely or mainly out of the grant, the Institutions shall maintain a separate audited record in the form of register such as cash book, asset register, paid bills, bank statements and bank accounts, etc. The term "assets" means movable property where the value exceeds Rs.1000/-. Separate assets registers may be maintained.

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. In exceptional cases this may exceed 15% but not more than 40% with prior approval of Chairman PSC and with appropriate/strong justification for the same.

The equipment should be purchased according to GFR 2017 and the grantee institution will ensure that equipment proposed in the study will be properly maintained as per GFR. After completion of the study, the grantee institute will furnish a detailed list of equipments including cost, date of installation, present value after depreciation etc., to the Ministry for deciding further course of action i.e., disposal, maintenance, accessible/transfer to Research Council/Institutions of the Ministry etc. Books purchased out of the contingencies may be retained by the Principal Investigator after successful completion of the project.

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

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.

- **Guidelines for incurring expenditure (both recurring and non-recurring):**

The grant can be utilized for purposes like, but not limited to:

a. Acquisition of books, in case these are not available in the library.
b. Chemicals/Consumable items required solely for research project.
c. Charges for specialized investigations for which facilities do not exist in the grantee institutions.
d. Data entry charges.
e. Printing of questionnaires, case report forms, consent forms, etc. for the research project.
f. Computer utilities, charges for analysis of data.
g. Typing and printing of research reports.
h. Communication charges
i. Travelling Charges for patient/Re-imbursement for patient expenses as approved by Ethics Committee of the Institute.

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

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 programme for the following purposes:

- Attending seminars/symposia/conferences relevant to research projects within the country provided the PI himself/herself or the project staff is presenting a research paper (related to the subject of the study), which has been accepted. Copy of the acceptance letter should be sent to the Ministry of Ayush.
- Taking up field work/travel connected with the research work.

- Visiting the Ministry of Ayush/CCRAS 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/Institutions) or those of the Central Government (in case of Central Government Organizations).

11. PERSONNEL/STAFF:

11.1. Scientific Staff

The pre requisite for selection of the scientific staff in the projects and their remuneration shall be as per the guidelines issued by CCRAS from time to time. In absence of CCRAS guidelines, the guidelines issued by ICMR e.g. by ICMR (Admn. II) From time to time (e.g. Order No.16/107/2008-Admn.II dated 24.08.2016, 04.10.2016 and 07.11.2016, 11.06.2019). All subsequent orders will be automatically applicable.

Note:

- The qualifications must be recognized by the concerned regulatory Council's/Universities/ Faculties/Boards.
- Number of RA/Project Scientist -1 (Medical/Non-Medical) (erstwhile SRF/JRF)* should be claimed as per actual need of the project and the decision of the PSC is final in this respect.
- The amount of assistance for RA/ Project Scientist -1 (Medical/Non-Medical) (erstwhile SRF/JRF) may be revised by Ministry of Ayush to keep at par with the Indian Council of Medical Research (ICMR).

ICMR OM No. 16/29/2023-Admin/Eoffice No. 157401 dated 19.09.2023 & 01.08.2023

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'.

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.

General terms and conditions of man-power engagement:

- The appointment of all categories of staff would be made initially for one year and extended by specific orders for such period as may be necessary, but not exceeding one year at a time.
- Appointment will be of temporary and contractual nature for a maximum period of the duration of the study.
- The personnel will have no claim for regular/permanent appointment under the Research Councils / Ministry of Ayush or the Grantee Institution on completion of the period of appointment.
- Dearness Allowance (DA) and City Compensatory Allowance (CCA) are not admissible to any category of staff employed under Programme on Ayurveda-Biology Integrated Health Research projects.
- HRA will be allowed to all categories of Project Scientist -1 (Medical/Non-Medical) (erstwhile SRF/JRF) and Research Associates as per the rules of the Institutions where they are working. For this purpose, the fellowship amounts for Project Scientist -1 (Medical/Non-Medical) (erstwhile SRF/JRF) and Research Associates will be taken as basic pay.
- Leave, salary and other service benefits: RAs, Project Scientist -1 (Medical/Non-Medical) (erstwhile SRF/JRF) will continue to be eligible for the Casual Leave. However, Maternity Leave will be given to female staff as per rule of Govt. of India.
- Bonus, L.T.C and Retirement benefits are not admissible to any staff under this programme.

Break-up of cost norms for Research Project.

Heads	1st year	2nd Year	3rd year	Total
Salary Research Associate (RA)	The remuneration shall be as per the guidelines issued by CCRAS/ICMR from time to time.			-
Project Scientist -1 (Medical/Non-Medical) (erstwhile SRF/JRF)				-
Number of RA/ Project Scientist -1 (Medical/Non-Medical) (erstwhile SRF/JRF) **should be claimed as per actual need of the project and the decision of the PSC is final in this respect.**				
Fee for PI*	Rs. 90,000/- One-time payment to be made after successfully completion of the project			
Fee for Co-Investigator (s)*	Rs. 45,000/- One-time payment to be made after successfully completion of the project			
Other Supporting Staff	As approved by the PSC (as per the Ministry's guidelines for engagement of Contractual Staff)			
Recurring Expenditure	As approved by the PSC on the basis of the merit of the proposal			
Equipment Not more than 25% of total cost of the project	Appropriation for Budget for equipment to be sought in the 1st year			
TA/DA	As approved by the PSC on the basis of the merit of the proposal			
Institutional Support/Overhead Charges **(5 % of the total cost of the project)**				
Miscellaneous Expenses (5 % of the total cost of the project) excluding the cost of equipment)	-	-	-	

(* **Fees of PI & Co-I is not applicable to Investigator in Govt. Service**)

Re-appropriation: Re-appropriation within sanctioned item of expenditure may be done from one head to another head. The same will be done with the approval of Chairperson of Project Sanctioning Committee (PSC), based on proper justification.

12. RELEASE OF FUNDS:

The approved grant will be released in the name of the Institute/Head of the Institution as yearly installments. The first installment will be released along with the sanction letter, which would include the entire grant for purchase of equipment and books, and recurring grant for first year. The subsequent installment can be claimed on having utilization of 75% the previous installment subject to the satisfactory progress of the study and timely receipt of the following documents in the prescribed proforma:-

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

13. INCEPTION OF PROJECT:

13.1. Date of inception of the project:

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

14. MAINTENANCE OFACCOUNT:

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

Auditors:

- The Ministry may normally accept audited reports from statutory auditors. The Ministry may also accept statement of accounts duly audited by Chartered Accountants registered with Institute of Chartered Accountants of India (M/o Corporate Affairs). The necessary registration number should be provided for record.
- Expenditure should, on account, not exceed the amount sanctioned (head wise) for the research project.
- No re-appropriation of funds shall be allowed for over-expenditure in any of the heads or sub-heads. However, in exceptional cases, re-appropriation of funds, from one head/sub head to another may be permitted with the prior approval of the PSC.
- All expenditure is to be made as per the norms and guidelines of the Financial Rules as applicable to the grantee institution.

15. SUBMISSION OF REPORTS

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

Progress Report

- The Progress Report for the first and second year shall be submitted within one month of completion of reporting year as in the prescribed format at Annexure-4.
- The progress of the project shall be evaluated by the Adviser/ CCRAS of Ministry of Ayush in consultation with peer reviewer/experts if required.

- The project may not be continued in the next financial year unless the Ministry receives the progress report in time.
- The PI shall be asked to present the progress at the meeting of the PSC, if considered necessary.
- The suggestion and views of the PSC and mid-course correction, if any, conveyed to the PI, shall be binding on the PI/grantee institution.

Two hard copies and one soft copy in pdf format of the progress report shall be submitted.

Annual utilization certificate

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

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

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

The subsequent installment shall only be considered only after acceptance of progress report and UC (at least 75% utilized grants) of previous instalment.

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

Final Project Completion Report

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

16. FINAL SETTLEMENT OF ACCOUNTS

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

a. Final audited statement of expenditure **(Annexure-10)**.

b. Final utilization certificate (UC) **(Annexure -6, 7).**

c. List of equipment procured for the project along with their cost and date of purchase and suggestions for future use.

d. Final Project Completion Report

16.1. Extension of the Project*:* Extension beyond the approved duration normally may not be entertained except for specific reasons, viz. interesting/important leads emerging which need to be followed-up etc. Duration of project, however, in any case should not go beyond 2 year of extension, baring duration of logistical delay. If required can be extended by the prior permission of Project Sanctioning Committee. For extension, PI may apply in the format at **Annexure-12**.

17. PRE-MATURE TERMINATION OF PROJECT:

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

17.2 During the course of the study, the peer review experts (since there is no project screening committee)may recommend to the PSC for termination of the study on ground of Technical/Financial/Ethical irregularities or that the project is not in accordance with the approval of PSC. The final decision of the PSC shall be binding on the PI and the grantee Institution. In such case, the Ministry of Ayush with the prior approval of PSC may revoke the funds given to the Grantee Institution, partially or fully.

18. INTELLECTUAL PROPERTY RIGHTS ANDPATENTS:

- The patent will be jointly applied by the Ministry of Ayush and the Principal Investigator/Institution. The Ministry of Ayush/PI will make joint efforts to commercialize the product as applicable.
- The investigator or the staff employed on the research project shall not obtain patents for any invention/discovery made by them without prior approval of the Ministry of Ayush.
- Ministry of Ayush will convey such approvals for patent within 3 months from receipt of application.
- Ministry of Ayush reserves the right to undertake completed Projects under Programme on Ayurveda-Biology Integrated Health Research into further research either in collaboration with PI/Institute (completed the project) or other PI/Institute.

19. PUBLICATIONS:

The PI shall submit the final consolidated report (as per **Annexure-9**) to the Ministry, after the completion of the project. Outcome of the project shall be mandatorily published in a reputed peer reviewed (Preferably high impact) journal or in the form of book or in the journal of the Council etc. There is no bar on publication of the study in part or full before acceptance of the final report by the PSC.

A manuscript of the paper may also be sent by the PI to the Ministry for record. Funding by the Ministry of Ayush should be acknowledged in the publication. Any violation of this will be viewed seriously and may invite penal action. Expenditure on publication of the research findings in the journals of repute shall be met from the programme.

20. 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 Programme on Ayurveda-Biology Integrated Health Research support should declare financial conflict of interest, if any, before submitting the project for support. They should also ensure that during the conduct of the project, they would also

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

21. IN THE EVENT OF DEFAULT:

a. In the event, the grantee Institution fails to perform its activities, duties, obligations, acts and deeds as per the programme and the Annexure appended thereto, instructions, orders issued from time to time, will amount to default and in such circumstances, the Ministry of Ayush can recall the entire funds provided and stop further release of installments.

b. Head of the Institution shall be held responsible in case the project is not completed at all or partially completed or not completed in time. Penal interest -@ 10% P.A. shall be levied in the case of grantee not complying with the terms and conditions. However, in exceptional cases, where extension of project timelines becomes necessary, time period for completion of the projects may be extended without any additional financial implications. Extension up to maximum two-year period may be given after evaluating the progress of the project. If required can be extended by the prior permission of Project Sanctioning Committee. The extension may be given only with the condition that if the project is not completed within the extended period of two years, the PI and the Institution may be blacklisted. The Government will transfer the project along with the assets created under the project to other suitable institutions.

c. All the Officer Bearers, Principal Investigators, Co-Investigators, President, Chairperson, Secretary, or any other person or person(s) functioning to the grant-in-aid Institution shall be generally and severally responsible and liable to refund the amount with the interest and can also be prosecuted both under the Civil and Criminal Law for breach or default as stated above.

d. Jurisdiction: All disputes or differences between the Ministry of Ayush and the grantee Institutions shall be decided by referring to arbitration to Delhi International Arbitration Centre (DIAC), Delhi High Court, New Delhi, whose decision shall be final and binding.

e. PI/Institution not complying with provisions of programme will be debarred from further grants.

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

ANNEXURE-1

MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY

APPLICATION FOR GRANT-IN-AID OF PROGRAMME ON AYURVEDA-BIOLOGY INTEGRATED HEALTH RESEARCH

Section-A

1. Title of the Research Project:

2. Details of the Institution submitting the Research project

Name of Institute:

Postal address:

Type of Institute:

Telephone: Fax: E-mail:

3. In case of Individuals submitting the Research project:

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

Name of the individual:

Postal address:

Telephone: Fax: E-mail:

4. Name and Designation of

Principal investigator: Co-Investigator(s): Consultant(s):

5. Duration of Research Project:

i) Period required for pre-trial preparations:

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

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

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

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

7. DECLARATION AND ATTESTATION Certified that:

I/We have read the provisions, terms and conditions, mentioned in the Programme on Ayurveda-Biology Integrated Health Research along with its Annexure, Guidelines formulated by the Ministry of Ayush and I/we shall abide by the relevant provisions contained under the Programme on Ayurveda-Biology Integrated Health Research and General Financial Rules of Govt. of India.

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 TO BE ENCLOSED: (See section 6.6.4 in the programme)

1. _____

2. _____

3. _____

4. _____

5. _____

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 Ayush

      Past

      Present

      Pending

   b) From any other Ministry of Govt. of India

      Past

      Present

      Pending

   c) From other Institutions (National or International)

      Past

      Present

      Pending

10. Research projects in hand under Programme on Ayurveda-Biology Integrated Health Research of Ministry of Ayush
11. Research Projects in hand under any other Grant-in-aid programme of Govt. of India
12. Other research projects, if any:
13. Recent publications (last 5 years, with titles and references), also papers in press
14. Other information, if any:

Signature

Date

Section – C

BRIEF SUMMARY OF THE RESEARCH PROPOSAL

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

1. Title of the Research Project:

2. Objectives

3. Methodology

4. Anticipated Outcome

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

6. Relevance and usefulness of the study with particular reference to concerned Ayush system.

7. IPRvalues

8. Translational Value

9. Utilization of outcomes of project

SECTION-D

Detailed Research Protocol

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

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

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

SECTION-E

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

REQUISITION FORM FOR THE ELECTRONIC TRANSFER OF FUNDS

(To be submitted in duplicate)

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

(FOR THE USE OF PAO(S) ONLY)

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

(Sr. Accounts Officer)

Pay &Accounts Office (Sectt.)

ANNEXURE-2

GUIDELINES FOR PREPARATION OF CLINICAL TRIAL PROTOCOL

General information

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

Background information

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

- When and how to withdraw subjects from the trial/investigational product treatment;

- The type and timing of the data to be collected for withdrawn subjects;
- Whether and how subjects are to be replaced;
- 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)/intervention, the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.
2. Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
3. Procedures for monitoring subject compliance.

Assessment of efficacy

1. Specification of the efficacy parameters.
2. Methods and timing for assessing, recording, and analyzing of efficacy parameters.

Assessment of safety of trial subjects/research participants

1. Specification of safety parameters.
2. The methods and timing for assessing, recording, and analyzing safety parameters.
3. Procedures for eliciting report of and for recording and reporting adverse event and undercurrent illnesses.
4. The type and duration of the follow-up of subjects after adverse events.

Statistics

1. A description of the statistical methods to be employed, including timing of any planned interim analysis (ses).
2. The number of subjects planned to be enrolled. In multi-center 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 Ministry of Ayush providing direct access to source data/documents.

Also the privacy policy to be followed by the Institutions /PI mentioning the persons who would have an access to the source data and documents related to the research study, is to be elaborated.

Quality control and quality assurance

The medicine used in the study shall comply the pharmacopoeial and quality standards.

Ethics

Description of ethical considerations relating to the trial.

Data handling and record keeping

- The policy to be followed for handling of data, source documents and record is to be mentioned.
- If the Institutions does not have any such policy for its research projects, guidelines for data handling are to be incorporated keeping in view the Confidentiality concerns that will dictate how data is collected, retained and shared. The data handling and record keeping requirements can include:

- How the Source documents, Case Report Forms, assessment forms, etc., would be completed, checked for inaccuracies?
- How long data would be kept? With whom data can be shared? Who has rights to the data?
- Where and how the data is to be stored Where and How to Store Research Records?
- What computer practices would be followed, i.e. who will enter the data, who would have an access to the data and how data loss would be prevented?

Financing and insurance

Financing and insurance is to be detailed.

ANNEXURE–3

GUIDELINES FOR TOXICITY INVESTIGATION OF AYURVEDAMEDICINE

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

SHORT TERM TOXICITY TEST

Animal species

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

Sex

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

Number of animals

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

Route of administration

- Ordinarily, the oral route is sufficient, as this is the normal route of clinical administration.
- However, some regulatory agencies suggest in addition, 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 functional 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.

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.

5. 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 hematological and blood chemical analysis. At autopsy a macroscopic examination of organs and tissues and measurement of organ weights should be recorded. A full histopathological examination should be performed in an attempt to characterize the nature (severity of degree) of all toxic changes.

All survivors should be autopsied at the end of the administration period or of the recovery period after taking blood samples for hematological (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 reveals significant changes. On the other hand, histopathological examination of all rodents will further improve the chances of detecting toxicity.

Recovery from toxicity

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

ANNEXURE- 4

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 Initiation
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 programme
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.
16. Any Publications

Signature of PI:
Date:
Signature of Head of the Institutions:

ANNEXURE- 5

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

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

1. Sanction letter no. .....……
2. Total Project Cost Rs……
3. Sanction /Revised Project cost (if applicable) Rs…….....
4. Date of Commencement of Project …
5. Statement of Expenditure …

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

Signature of Principal Investigator with date & Seal	Signature of Head of Institution with date & Seal	Signature of Authorized Auditor with date & Seal

ANNEXURE-6

Check list for covering note to accompany Utilization Certificate of grant for the project for theperiodending_____)

1) Title of the project

2) Name of the Institutions

3) Principal Investigator

4) Ministry of Ayush letter No. and date sanctioning the project.

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

6) Amountreceivedduringthefinancialyear(PleasegiveNo.anddateofMinistry'ssanction 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 31stMarch).

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

10) Amount already committed, if any.

ANNEXURE-7

GFR 12 – A

[(See Rule 238 (1)]

FORM OF UTILIZATION CERTIFICATE

FOR AUTONOMOUS BODIES OF THE GRANTEE ORGANIZATION

UTILIZATION CERTIFICATE FOR THE YEAR…… in respect of recurring/non-recurring

GRANTS-IN-AID/SALARIES/CREATION OF CAPITAL ASSETS

1. Name of the Programme.....

2. Whether recurring or non-recurring grants.....

3. Grants position at the beginning of the Financial year

   (i) Cash in Hand/Bank

   (ii) Unadjusted advances

   (iii)Total

4. Details of grants received, expenditure incurred and closing balances :(Actuals)

Unspent Balances ofGrants Receivedyears [figure as at Sl. No. 3 (iii)]	**Interest Earned thereon**	**Interest deposited back tothe Govern-ment**	**Grant received during the year**			**Total Available funds (1+2-3+4)**	**Expenditure incurred**	**Closing Balances (5-6)**
1	2	3	4			5	6	7
			Sanction No. (i)	Date (ii)	Amount (iii)			

Component wise utilization of grants:

Grant-in-aid– General	Grant-in-aid– Salary	Grant-in-aid– creation of capital assets	Total

Details of grants position at the end of the year

(i) Cash in Hand/Bank

(ii) Unadjusted Advances

(iii) Total

Certified that I have satisfied myself that the conditions on which grants were sanctioned have been duly fulfilled/are being fulfilled and that I have exercised following checks to see that the money has been actually utilized for the purpose for which it was sanctioned:

(i) The main accounts and other subsidiary accounts and registers (including assets registers) are maintained as prescribed in the relevant Act/Rules/Standing instructions (mention the Act/Rules) and have been duly audited by designated auditors. The figures depicted above tally with the audited figures mentioned in financial statements/accounts.

(ii) There exist internal controls for safeguarding public funds/assets, watching outcomes and achievements of physical targets against the financial inputs, ensuring quality in asset creation etc. & the periodic evaluation of internal controls is exercised to ensure their effectiveness.

(iii) To the best of our knowledge and belief, no transactions have been entered that are in violation of relevant Act/Rules/standing instructions and programme guidelines.

(iv) The responsibilities among the key functionaries for execution of the programme have been assigned in clear terms and are not general in nature.

(v) The benefits were extended to the intended beneficiaries and only such areas/districts were covered where the programme was intended to operate.

(vi) The expenditure on various components of the programme was in the proportions authorized as per the programme guidelines and terms and conditions of the grants-in-aid.

(vii) It has been ensured that the physical and financial performance under……..(name of the programme has been according to the requirements, as prescribed in the guidelines issued by Govt. of India and the performance/targets achieved statement for the year to which the utilization of the fund resulted in outcomes given at Annexure – I duly enclosed.

(viii) The utilization of the fund resulted in outcomes given at Annexure – II duly enclosed (to be formulated by the Ministry/Department concerned as per their requirements/specifications.)

(ix) Details of various Programmes executed by the agency through grants-in-aid

received from the same Ministry or from other Ministries is enclosed at Annexure – II (to be formulated by the Ministry/Department concerned as per their requirements/specifications).

Date:

Place:

Signature	Signature
Name.....	Name.....
Chief Finance Officer	Head of the Organization
(Head of the Finance)	(Strike out inapplicable terms)

ANNEXURE-8

NO FINANCIAL ASSISTANCE CERTIFICATE

(To be submitted on Institution letter head)

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

Signature of Principal Investigator with date & Seal	Signature of Head of the Institution with date & Seal	Signature of Co- Investigator with date & Seal

ANNEXURE-9

FORMAT FOR FINAL REPORT

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

S. No.	Name of Equipment	Make /Model	Cost FE/Rs	Date of Installation	Utilization rate %	Remarks regarding maintenance/break down

16. Science and Technology benefits accrued:

- List of research publications with complete details: Authors, Title of paper, Name of Journal, Vol., page, year
- Manpower trained in the project:

- Research Scientists or Research Fellows
- No. of Ph.Ds. produced
- Other Technical Personnel trained

- Patents taken, if any:
- Products developed, if any.

17. A summary sheet of not more than two pages under following heads (Title, Introduction, Rationale, Objectives, Methodology, Results, and Translational Potential).
18. Manuscript/Abstract for Publication (300 words for possible publication in Council's/Ministry Bulletin).

Name and signature with date

1. _____

(Principal Investigator)

2. _____

(Co-Investigator)

ANNEXURE -10

FORMAT FOR FINAL STATEMENT OF EXPENDITURE

(To accompany the Final Report)

(To be submitted in original)

1) Sanction letter no.
2) Total project cost

   (Sanctioned/revised project cost, if applicable)
3) Date of commencement of project:
4) Date of completion of project:
5) Grant received in each year(financial):

   1st Installment : Date of release of grant…… grant received Rs…….

   2nd Installment: Date of release of grant…… grant received Rs……..

   3rd Installment : Date of release of grant…… grant received Rs…….
6) Statement of Expenditure:

S. No	Sanctioned/Heads (Mention all items under each head)	Funds Allocated	Expenditure Incurred: Financial Year wise					Balance as on (Date)	Remarks
			1st Instt.	2nd Instt.	3rd Instt.	Remaining amount (10%)	Withheld Amount (10%)		
	Salary								
	Equipment								
	Books								
	Other Non-Recurring Expenditure								
	Recurring Expenditure								
	TA/DA								
	Institutional Support Charges								
	Appropriate fee of PI and Co I								

	Miscellaneous expenses								
	Total								

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

Signature of Principal Investigator with date& Seal	Signature of Head of Institution with date& Seal	Signature of Authorized Auditor with date& Seal

ANNEXURE-11

GENERAL CONDITIONS FOR THE RELEASE OF GRANT-IN-AID TO NON-GOVERNMENTAL VOLUNTARY ORGANISATIONS

1. The Institutions should maintain separate account exclusively with a bank in the name of the 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 Institutions should be audited by a Chartered Accountant or a Government Auditor immediately after the end of financial year. The accounts of the grant shall be maintained properly and separately from its normal activities and submitted as and when required. They shall always be open to inspection by any person authorized on this behalf by this Ministry. They shall also be open to a test check by the Comptroller and Auditor General of India at his discretion.
5. (i) The grantee Institutions (in not individual) will execute a bond in the prescribed proforma on a non-judicial stamp paper only with two sureties to the effect that the 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 Institutions is a society registered under the Societies‟ Registration Act, 1860 or is a cooperative society; and

   (iii) When the bond is also signed by two sureties, both of them should be solvent and owner of such assets worth not less the amount of the bond as can be attached and sold in execution by the District magistrate or other equivalent on the body of the bond;
6. The Institutions should furnish the certificate to the effect that the grantee has not been sanctioned for the same purpose by any other Department of the Central or State

Government during the period to which the grant relates;

7. When the Central or State Government have reasons to believe that the sanctioned money is not being utilized for approved purpose, the payment of further grants may be stopped and the earlier grants recovered;
8. Any portion of the grant, which is not utilized for expenditure upon the objects for which it was sanctioned, will be refunded in case to the Government of India in this Ministry;
9. No portion of the grant will be utilized for furtherance of a political movement prejudicial to the security of the nation;
10. Essential scientific equipment including computer and software if needed may be permitted as non-recurring expenditure. However, the quantum of such expenditure will not be more than 25% of the total project cost. The equipment will become property of the host Institutions after completion of the project. The purchases are to be made as per rules and the procedures of the host Institution. Books purchased out of the contingencies may be retained by the principal Investigator.
11. The grantee will not indulge in corrupt practices;
12. The grantee Institutions should give an undertaking in writing that the grantee agrees to be governed by the conditions of the grant mentioned in this Annexure and the sanction letter;
13. The grantee should forward the following documents duly certified as correct by a Chartered Accountant/Auditor to this Ministry by the Institutions after the grant is fully utilized: -
    (i) A utilization Certificate to the effect that the grant has been utilized for the purpose for which it was sanctioned; and
    (ii) Audited Statement of Accounts reflecting there in the grant and the items of expenditure incurred there-from.

ANNEXURE-12

REQUEST FOR EXTENSION

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

1. Reference No:
2. Name of the Investigator:
3. Title of the Project:
4. Approved duration of the project from _____ to _____.
5. Requested extension from _____ to _____.
6. Original objectives (quoted from project proposal)
   a.
   b.
   c.
7. Results achieved so far (in relation to attainment of objectives)
8. Clear statement of objectives that have not been achieved so far but will be achieved during the extended period:
9. Financial implications:
   A. Total Sanctioned Amount:
   B. Total expected expenditure till the end of present sanctioned duration:
   C. Expected expenditure during extended period:
      C.1 Manpower costs (at the existing level)

Existing level means average of last 6-12 months expenditure

      C.2 Consumables (at existing level)
      C.3 Travel (if absolutely necessary)
      C.4 Contingencies
   D. Expected amount to be refunded to Ministry of Ayush

   or

Expected amount in addition to the sanctioned amount.

Name and Signature of PI

Seal

Name and Signature of the Head of the Institution

Seal