INTRA-MURAL RESEARCH POLICY

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Department of AYUSH, Ministry of Health & Family Welfare
Government of India
New Delhi

INTRA-MURAL RESEARCH POLICY

1. BACKGROUND

The National Population Policy 2000 and National Health Policy 2002, Ministry of Health and Family Welfare, Govt. of India, National Health Policy on AYUSH 2002 emphasizes on re-orientation, prioritization of research in AYUSH and to validate therapy and drugs in chronic and life style related diseases. According to National Commission on Macro-economics and Health, Ministry of Health and Family Welfare, Govt. of India (September 2005), the health conditions and disability - adjusted life years (DALYs) lost in India results from communicable diseases, reproductive and child health conditions and life style related disorders.

One of the key challenges facing the AYUSH systems is generating data on scientific validation on the safety and efficacy of classical formulations. On this task rests the credibility and quality of practice of the profession and scope for functional mainstreaming with National Healthcare system. Even though this goal of clinical validation has been identified by the Department as early as 2002, we could achieve very little progress in this direction.

In order to create acceptable scientific evidence on Ayurvedic formulations, a mission approach involving academic institutions (Ayurvedic and modern medical institutions), research organizations (ICMR, DST, DBT, and CSIR etc.), industry and CCRAS Institutes through a clearly defined Research Policy in a functionally efficient manner needs to be adopted. In the light of the disease burden and the strength of Ayurveda in some of these areas, it would be relevant to prioritize research areas and to initiate good quality research studies by the Council. The Council will also encourage Research proposals aiming at development of appropriate Research Methodology for Ayurveda and for identifying suitable indicators and biomarkers for Ayurvedic concepts.

2. OBJECTIVES

1. Research on Fundamentals of Ayurveda, its principles and practices including Literature Research
2. Clinical research: Validation of clinical efficacy of Classical Ayurvedic Formulations on priority basis including Ayurvedic Diagnostics and Preventive Health Care.
3. Drug Research and Development based on Ayurvedic principles and Experimental leads.

3. PRIORITY AREAS:

3.1 Fundamental Research

i. Tridosha, Prakriti, Agni, Dhatu, Ojas, Srotas, Ama, Samprapti & Khad Kriya-Kala etc.
ii. Rasa, Guna, Virya, Vipaka and Prabhava
iii. Literature Research; Survey, collection, transcription / translation and preparation of classical literature and text books, Medico-historical investigations of Ayurveda

3.2 Drug Research and Development

i. Standardization and Quality Assurance
ii. Pharmaceutical Research and Development
iii. Pharmacology [In-vitro & in-vivo methods]
iv. Biomarker based Mechanism of action
v. Ethno-medicinal Research: survey and documentation of medicinal plants/practices etc.
vi. Veterinary Ayurveda products

3.3 Clinical Research

3.3.1 Broad Areas

i. Development of Methods and modalities for Ayurvedic Clinical research
ii. Development of protocols for Clinical Trials
iii. Epidemiological Research
iv. Promotive and Preventive Health Care
v. R & D on Ayurvedic Diagnostics(including Prakriti and Nadi Pariksha)
vi. R & D on Panchakarma and standardization of its procedures.

3.3.2 Diseases /Areas based on strength of Ayurveda, National priorities:

i. Preventive Cardiology
   - Atherosclerosis
   - Hypertension
   - Dyslipidemia
ii. Gastro intestinal disorders
   - Hepatic Disorders
   - Diarrhoeas and Chronic Enteropathies
iii. Musculo-skeletal disorders
   - Osteoporosis
   - Osteoarthritis
   - Rheumatoid Arthritis
iv. Eye diseases
   - Diabetic Retinopathy
   - Computer Vision syndrome
v. Metabolic Syndrome and obesity
vi. Diabetes Mellitus and its complications
vii. Skin diseases
viii. Respiratory diseases

ix. Generalized Anxiety Disorder
x. Anaemia
xi. Malaria
xii. Benign prostatic hyperplasia, Urolithiasis
xiii. Fistula-in-ano, Para-surgical procedures
xiv. Neurological disorders and Neuro-degeneration
xv. Rasayana therapy& Geriatrics
xvi. Reproductive & Child Health (RCH)
xvii. Quality of life (QOL) in cancer patients

3.4 Any other Areas and Recommendations of IMR project evaluation committee/Scientific Advisory Committee of CCRAS.

4. METHODOLOGY AND APPROACH

For Clinical validation of classical formulations described in "Drug and Cosmetic Act" referral texts. Randomized Controlled Clinical Trials (RCT) will be designed adhering to standard procedures. The control arm could be a known modern medical therapy/drug or other AYUSH systems of medicine. In certain conditions, in which RCTs are not possible, other appropriate research trial designs will be considered.

- **Systems Validation:** Designing and developing rigorous integrated protocols (incorporating holistic approach of intervention (lifestyle, diet etc.) and holistic assessment parameters incorporating Ayurvedic Principles and approaches with adequate sample size and statistical power) for clinical trials in consultation with Ayurvedic physicians, modern medical experts, epidemiologists, clinical pharmacologists and Bio-statisticians. This design aims at assessing the efficacy of Ayurvedic system of medicine in comparison to conventional medicine/other AYUSH systems.

  - ✓ Phase- I: Healthy volunteers or subjects (20-100). Not required for classical Ayurvedic formulations. This phase may be conducted on case to case basis, wherever required.
  - ✓ Phase- II & III: Subjects (several hundred), direct phase II &III studies will be conducted.
  - ✓ Phase- IV: Subjects in select disease conditions (Several hundred to several thousand for assessing quality of life). This phase may be conducted on case to case basis, wherever required.

- **Statutory, Ethical and Research guidelines:** Clinical trials should follow the prevalent statutory, ethical and research guidelines like GCP guidelines prevalent in India and the collaborating centres and these trials will be registered with Clinical Trial Registry of India (CTRI).

- **Preclinical studies:** Though the Preclinical studies on the Ayurvedic classical formulations is not necessary since they are in use for many years. However, pre-clinical studies will be conducted on these formulations on case to case basis. Quality control studies and pre clinical Safety/toxicity studies will be conducted at CCRAS & PLIM and outsourced through NABL/GLP compliant laboratories.

- **Procurement of trial drugs:** Trial drugs for the projects will be procured from CCARS peripheral institutes and reputed GMP compliant industries. IMPCL/PLIM/ any state government undertaking will also be one of the sources for trial drugs.

- **Participating Centers:** Clinical research will be carried out at reputed Ayurvedic and modern medical institutions, governmental & non-governmental research organizations and industrial collaboration and CCRAS Institutes.

- **Monitoring and evaluation:** CCRAS and other reputed govt. organizations (e.g. National Institute of Epidemiology, Chennai; Indian Statistical Institute, Kolkata; CCRAS Hqrs. etc.) will evaluate and monitor the progress of the projects.

5. ELIGIBILITY:

5.1 Who are eligible?

- Research officers and above who are permanent employees of CCRAS peripheral Institutes are eligible to apply IMR Projects**.**

5.2 Infrastructure

- The investigators (Research officers and above who are permanent employees of CCRAS peripheral Institutes) seeking a project under IMR Scheme should have adequate experience, expertise and infrastructure to pursue the research project and in case, such facilities are not available the same requirement must be reflected in the project proposal or may be outsourced through accredited laboratories. The investigators may also carry out projects in collaboration with reputed academic/research institutions.

5.3 Investigators & Tenure of the Project

5.3.1 There will be one Principal Investigator (PI) and maximum three Co-Investigator(s) [Co-I] for each project.

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

5.3.3 Change of PI

- PIs are encouraged to have a Co-Investigator (Co-I) in the project. However, in one study there should not be more than three Co-Is.
- If for any reason the PI leaves the project, an eligible Co-investigator could be considered as the PI subject to recommendation of the PI, the Head of the Institution, and the approval of the Council. Such a request should be sent well in advance.
- The Principal Investigator will have to inform the Council, of any changes, and in consultation with the Council take steps to ensure successful completion of the project.

5.3.4 Except in exceptional cases the tenure of a project will be normally for a period of three years.

6. MODE OF APPLICATION

6.1 The details of the IMR policy shall be available from Website of the CCRAS: **www.ccras.nic.in**

6.2 The Principal Investigators should have to apply in the prescribed format (**Annexure-1)**, including all the required documents, to the Director General, CCRAS.

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

6.4 Preparation of the Project:

6.4.1 The project proposal should be prepared in the format for application enclosed at **Annexure - 1**.

Section A of the Application format requires General Information of the project. Also a description of all the projects taken up by the Principal Investigator under IMR Scheme and other Grant in aid schemes of the Govt. of India/ State Government etc. is to be given. This would include the Title of the Study, Objectives, Date of inception of the project, Date of completion, Names and Designations of the Principal Investigators and Co-Investigators of the study and details of budget for the proposed IMR Project.

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

Section-C of the Application is the 'Brief Summary of the Project'.

Section-D of the application relates to the detailed 'Protocol' of the study.

(Note – It is mandatory to submit the application in 5 hard copies and one soft copy in CD)

6.4.2 The study design and conduct may follow the prevalent guidelines as appropriate.

6.4.3 Clearance from the Institutional Ethics Committee (in case of human trials) or Institutional Animal Ethics Committee (for animal studies) of the Institute applying for the Research Proposal is mandatory. A certificate of clearance from the Institutional Ethical Committee (IEC) or Institutional Animal ethics Committee (IAEC) is essential before initiation of the study and for release of budget.

7. INVITATION OF PROPOSALS AND EVALUATION

7.1 **Invitation of IMR Proposals:** Research projects will be invited from Research Officers and above who are permanent employees of CCRAS peripheral Institutes. Collaborative projects with other Medical institutes/Research Organizations will be given preference.

7.2 **IMR-Project Evaluation Monitoring Committee (IMR-PEMC**): The projects will be evaluated on their merit and competitive basis. The Research proposals will be scrutinized and evaluated and monitored by the Committee comprising of the following members:

1. Director General, CCRAS - **Chairman**
2. Two Subject experts - **Member**
   (Co-opted members (Subject wise) as per necessity)
3. Epidemiologist - **Member**
4. Bio-statistician - **Member**
5. Two representatives from the Deptt. of AYUSH (Including one from Finance Division)
6. Deputy Director (Technical), CCRAS - **Member secretary**

7.2.1 Terms of reference of IMR-PEMC: The IMR-Project Evaluation Monitoring Committee (IMR-PEMC) after the evaluation/scrutiny of the Research Proposals may

- Recommend and approve suitable IMR projects
- Call for the Principal Investigator/Co-Investigator for discussion
- Invite comments from the expert(s) in the concerned field.
- Inform the applicants to modify their proposals (as per their observations)
- Reject the proposals, if not found suitable
- Review the progress reports received from time to time by the Council from the PI
- Invite the PI to make a presentation before the experts
- Invite the PI to bring the relevant papers and documents related to the project
- Make an on-site visit, where the PI would ensure their access to all the relevant research facilities and documents related to the Project

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

- The finally selected projects will be intimated to SAC of CCRAS for information and inputs if any.

8. FINANCIAL SUPPORT:

8.1 The project cost shall be met from sanctioned budget of CCRAS Hqrs. from Research activities head. **Maximum permissible assistance per project will be Rs.100.00 lakhs spread over a period of 3 years.** The salary component of the temporary manpower engaged under these projects should not exceed 30% of the total budget.

8.2 The Principle Investigators applying for the grant should have adequate staff, equipment and laboratory/other facilities to conduct the particular research. Financial support will be given only for the minimum required staff, equipment, books and contingent items. The Laboratory investigation for the project will be carried out at the institutes itself. In case some investigations not possible to carry out at the institute may be outsourced as per CGHS rates or through accredited laboratories.

8.3 **Assets:** All the assets created under the IMR projects shall devolve to the concerned CCRAS institute.

8.4 **Release of funds and Operation of Accounts**: The funds will be released to the Principal Investigators in such staggered manner as the PEMC may decide subject to the following ceilings:

i. 60% of the of the sanctioned amount will be released as 1st installment at the time of sanction of the project.

ii. 35% of the of the sanctioned amount will be released as 2st installment after submission of interim progress report , statement of expenditure of Ist installment and utilization certificate duly audited by Chartered Accountant.

iii. Remaining 5%of the sanction will be released after submission of final progress report, statement of expenditure of 2ndinstallment and utilization certificate duly audited.

iv. **Operation of Accounts**: The fund will be provided to the institutes as a part of Institute's budget, in the mechanism followed by the Council normally and the Head/ In-charge will provide the fund as per the requirement from the PI from

time to time. In all matter of purchase of codal formalities as per GFR will be observed.

v. The operation and utilization of accounts of the projects will be subject to internal audit.

9. PERSONNEL/STAFF:

9.1 Engagement of Consultants/ Project Personnel: Appropriate manpower/experts in concerned disciplines will be engaged as per need and nature of the project. The renumeration of all consultants/project personnel shall be within ceilings notified by Department of Research, Ministry of Health and family Welfare, Govt. of India.

9.2 Supporting Scientific Staff (Consultants): Engagement of minimum number of supporting manpower (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' of the project proposal.

9.3 Para-Medical and Non-Scientific Manpower: The Para- Medical, Non-Scientific manpower and other supporting manpower 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.

9.4 General terms and conditions for engaging temporary project manpower (above mentioned scientific, paramedical and non scientific staff):

- **Selection Committee**: A selection committee should be constituted at the CCRAS institute level consisting of the members comprising of 1. Principal Investigator 2.Head of the institute 3. Expert from concerned subject and 4. Nominee(s) of Director General CCRAS.
- The letter of engagement may be issued under the name and signature of Principle investigator of the project.
- The appointment of all categories of project personnels would be made initially for 6 months and extended by specific orders for such period as may be necessary, but not exceeding 6 months at a time and three years in all.
- Appointment will be of temporary and contractual nature for a maximum period of the duration of the study but not exceeding 6 months at a time and three years in all.
- The personnel will have no claim for regular/permanent appointment under the Council. **Their engagement will be co-terminus with the project.**

10. SUBMISSION OF REPORTS:

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

10.1. Progress Report

- Quarterly progress report on physical achievements is to be submitted to the council regularly. This will also be sent to the Dept. by Council's Hqrs Office.
- The Progress Report for the first and second year is to be submitted within one month of completion of reporting year in the prescribed format, as in **Annexure-2**

- The project will not be renewed for the next financial year unless the Council receives the progress report in time.
- The PI may be asked to present the progress at the meeting of the IMR-Project Evaluation Monitoring Committee (IMR-PEMC), if considered necessary.
- The suggestion and views of the IMR-Project Evaluation Monitoring Committee (IMR-PEMC) and mid-course correction, if any, would be conveyed to the PI, for effective conduct of the project. This would be binding on the PI/grantee institution.
- Five hard copies and one soft copy (in CD) of the yearly progress report would be submitted.

10.2 **Final Project Completion Report:** At the completion of the project, the final report should be sent in the prescribed format, **(Annexure-3)**. The report should be submitted within two months from the date of completion of the project. **2 hard copies and soft copy (in CD)** of the Final project Completion report would be submitted.

11. MONITORING:

11.1 **Local Monitoring:** The Head of the Institute would ensure periodic review and monitoring of the projects on going under the IMR Scheme at institute level. The PEMC will monitor the project at regular intervals.

11.2. **Hand Holding/ Mentoring by an Outsider:** If PI does not perform satisfatorly or inappropriately, then he/she will be ineligible to apply for grants in future for 3years.The fact of under performance

12. OUTCOME OF THE PROJECT:

The final technical and financial reports of each completed study will be examined by the IMR-Project Evaluation Monitoring Committee (IMR-PEMC), who will convey their views to the Director General, CCRAS for consideration. IMR-Project Evaluation Monitoring Committee (IMR-PEMC) will also give their comments on publication of the results of the studies and the patents claimed by the Principal Investigators. The final outcome will be presented to SAC and G.B. of CCRAS by the Director General, CCRAS time to time.

13. PRE-MATURE TERMINATION OF PROJECT:

During the course of the study, the IMR-Project Evaluation Monitoring Committee (IMR-PEMC) may recommend to the Director General, CCRAS for termination of the study, if it is convinced that the study is not being done in accordance with the research proposal approved by the IMR-Project Evaluation Monitoring Committee (IMR-PEMC)/Director General, CCRAS, or in view of any other Technical/Financial/Ethical irregularities. In such case, the Director General, CCRAS would have the authority to revoke the funds given to Principal Investigators, partially or fully, as recommended by the IMR-Project Evaluation Monitoring Committee (IMR-PEMC).

14. INTELLECTUAL PROPERTY RIGHTS AND PATENTS:

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

14.2 The investigator or the staff employed on the research project shall not obtain patents for any invention/discovery made by them without prior approval of the Director General, CCRAS (on the basis of the recommendation of the IMR-Project Evaluation Monitoring Committee (IMR-PEMC)/Director General).

14.3 Only permanent employees (scientists) of the council will be the part of Intellectual Property Rights (IPR) related issues.

14.4. **Benefit sharing:** Sharing of (a) monies realised from licensing of Intellectual Property and (b) the intellectual fees from contract Research and Development (R&D) and (c) Science and Technology (S&T) Services, with the staff as per Guidelines/procedures for sharing or monies realised from licensing of Intellectual Property, and fees from contract Research and Development (R&D) and Science and Technology (S & T) Services adopted by CSIR (**Annexure – 4)**.

15. PUBLICATION:

Outcome of the project shall be published in a **peer reviewed indexed journals** etc. It is mandatory to publish the findings after completing the project subject to IPR issues. The PI will submit the final consolidated report (as per **Annexure-3**) to the Council, after the completion of the project. A manuscript of the paper would also be sent to the Council by the PI for publication in the Research Journals of the Councils or any other good Journal. The Council will quickly dispose off. This submission and will authorize the PI to go ahead with this publication within a month time. Publications of the study in part or full are not permissible before acceptance of the final report by the Director General, CCRAS on the recommendation of the IMR-Project Evaluation Monitoring Committee (IMR-PEMC).

ANNEXURE – 1

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES

Department of AYUSH, Ministry of Health & Family Welfare

Government of India

APPLICATION (FORMAT) FOR CCRAS- INTRA MURAL RESEARCH PROJECTS IN AYURVEDIC SCIENCES
(Please furnish 5 hard copies and one soft copy in CD)

Section A

GENERAL

1. Title of the Research Project:

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

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

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

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

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

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

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

8. Budget requirements (head wise and item wise**) (to be met from already sanctioned budget of the institute / or through additional sanction from the Hqrs. on request)**

Details	**1st year**	**2nd year**	**3rd year**	**Total**
Salary				
Equipment				
Books and Journals				
Other Non-Recurring Expenditure				
Recurring Expenditure				
TA/DA				
Institutional Support				
Miscellaneous expenses				
Grand Total				

Name and Signature of the:

a) Principal Investigator(s) _____ _____

Name **Signature**

b) Co-Investigator(s) _____ _____

Name **Signature**

_____ _____

Name **Signature**

Signature of the Head - CCRAS Institute
Name:
Date:
Seal:

Signature of the Head -Collaborating Institution
Name:
Date:
Seal:

LIST OF DOCUMENTS ENCLOSED:

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

Section –B

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

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 Year

6. Research Experience

Duration (From-To) Institution Particulars of work done

7. Research specialization

(Major scientific fields of interest)

8. Financial support received

a) From the Ministry of Health and Family Welfare

Past

Present

Pending

b) From other organizations

Past

Present

Pending

9. Research projects in hand under IMR

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

11. Other research projects, if any:

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

13. Other information, if any:

Signature:

Date:

Section – C

BRIEF SUMMARY OF THE RESEARCH

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

1. Title of the Research Project:

2. Objectives.

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

4. Milestones with deliverables in the research project

5. IPR values

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

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

8. Ethical and other clearances:

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

   ii. If radio tagged material is proposed to be used in the project either for clinical trials or experimental purposes, then clearance from Nuclear Medicine Committee, Bhabha Atomic Research Centre, Mumbai, should be attached.

9. Budget requirements (head wise and item wise)(to be met from already sanctioned budget of the institute / or through additional sanction from the Hqrs. on request)

Details	**1st year**	**2nd year**	**3rd year**	**Total**
Salary				
Equipment				
Books and Journals				
Other Non-Recurring Expenditure				
Recurring Expenditure				
TA/DA				
Institutional Support				
Miscellaneous expenses				
Grand Total				

(**Note: Detailed justification for the proposed budget need to be submitted)**

SECTION-D
Detailed Research Protocol (to be enclosed)

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.

Add one page consolidated summary of the project (its aims-object, methodology, expected outcomes).

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

ANNEXURE- 2

FORMAT FOR PROGRESS REPORT

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

Signature of PI: Date:

Signature of Head of the Institute: Date:

ANNEXURE-3

FORMAT FOR FINAL REPORT

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

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

17. Manuscript for Publication (300 words for possible publication in Council's Bulletin).
18. Research paper(s) if any under preparation to be submitted to a peer reviews journal in near future.

Name and signature with date

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

Forwarded by Head of the Institute:

(Name and signature with date)

ANNEXURE – 4

(29.1.5) Sub: Guidelines/procedures for sharing or monies realised from licensing of Intellectual Property, and fees from contract R&D and S& T Services with CSIR Staff. (CSIR Letter No: 9/203/94-TU, dated, June 15, 1994.Ammend. – 4)

1. BACKGROUND

In accordance with the provisions of the Resolution of the Govt. of India setting up the CSIR, a portion of monies realised from licensing of Intellectual Property and the fees from sponsored research projects/schemes was being shared with the staff. However in 1977 on the recommendations of a Group of Ministers constituted by the president CSIR, the Governing Body decided that the distribution of monies realised from licensing of Intellectual Property and fees from sponsored projects contracted after 30th September 1977 be discontinued.

A Committee constituted in 1993 by DG, CSIR on "Marketing of Knowledge base : Set up, Staffing pattern and Incentives" with Dr.R.A.Mashelkar as Chairman inter-alia recommended revival of sharing with the CSIR staff, of monies realised from licensing of Intellectual Property and fees from contract R&D and S&T Services. This recommendation of the Committee was approved by the Governing Body in its 131st meeting held on 29th July, 1993 with minor modification in pattern of distribution of the monies/fees among the staff. The CSIR Society in its meeting held on 22nd March, 1994 concurred with the decision of the GB.

2. GUIDELINES

The consolidated guidelines for sharing of monies from licensing of Intellectual Property and Intellectual fees from Contract R&D and S&T Services with the CS1R staff are as under:

2.1. The monies/fees realised from: (a) Intellectual Property referred to NRDC (b) Intellectual Property licensed directly by lab. & (c) Sponsored Projects for which agreements were contracted upto 30th September, 1977 are to be shared as follows:

Monies realised from Intellectual Property Licensing Through NRDC	**Fees from Sponsored R&D Projects**	**Direct by Lab.**
NRDC Share 30%		
CSIR Share 30%	60%	60%
Investigators' (employees') Share 40%	40%	40%

The pattern of distribution of the portion designated as Investigators' share amongst the staff is to be as follows:

	Staff	**Share**
i.	Innovators	35%
ii.	Other members of the team	35%
iii.	Those who have provided physical and mechanical inputs *directly* associated with the project work (ex-gratia)	*15%*
iv.	Common Poll	10%
v.	Welfare/Benevolent Fund	*5%*

2.2. The Investigators' (employees') share of the monies realised from the Intellectual Property referred to NRDC/released direct by the lab. between 1. 10. 1977 and 31.3.1994 and of the fees from sponsored research projects for which agreements were executed between these dates is not distributable amongst the staff.

2.3 The Governing Body and CSIR Society have now decided to revive the sharing of (a) monies realised from licensing of Intellectual Property and (b) the intellectual fees from contract R&D and S&T Services, with the staff as follows:

a) ***Intellectual Property***

Forty percent of the monies realised from licensing of the Intellectual Property developed and referred to NRDC or approved for direct licensing by competent authority (MC/DG, CSIR) on or after 1.4.1994 is to be shared with the staff.

b) ***Contract R&D***

Forty percent of the intellectual fee or net surplus (remaining after accounting for all direct and indirect project expenditure as prescribed in the CSIR Guidelines) whichever is lower, as rising from R&D contracted on or after 1.4.1994, is to be shared with the staff.

c) ***S&T Services***

Twenty percent of the intellectual fee or net surplus (remaining after accounting for all direct and indirect expenditure for the service as prescribed in the CSIR Guidelines) whichever is lower, arising from S&T Services contracted on or after 1.4.1994, is to be shared with the staff.

2.4 The Pattern of sharing of the amount earmarked for staff at (a), (b), & (c) above is to be as follows:

	Staff	**Share**
i.	Innovators & Principal Contributors	40%
ii.	S&T and Other Staff who contribute direct Inputs to the specific development/activity	35%
iii.	Remaining staff of the laboratory	20%
iv.	CSIRWelfareFund(MaintainedatHQs)	*5%*

2.5 The sharing of portion of monies/fees as specified above in para 2.3 is subject to the following:

a) A system of cost accounting has been put in place by the laboratory.

b) A legally valid agreement has been executed for Intellectual property licensing/contract R&D;

c) The technology transfer/project has been completed in accordance with the terms of the agreement;

d) The monies/fees due have been received in full;

e) The client has not contested CSIR's fulfilment of its obligations as defined in the contract/agreement;

f) In the event of any legal action/dispute necessitating refund/payment of monies/fees by CSIR to the client, the amount paid to the staff is recoverable;

g) The maximum amount of money receivable by an employee from licensing of Intellectual Property and intellectual fee from contract R&D

and S&T Services will not exceed Rs.1 lakh per financial year or his/her salary for the particular financial year whichever is less;

h) The scheme to be reviewed by GB after two years of its operation (i.e. after July, 1995).

3. PROCEDURES

3.1 *Categorisation of Staff*

a) Innovators & Principal Contributors may comprise scientists and other S&T staff who have provided innovative, developmental, design engineering, experimental, data/information, testing/analytical, repair/fabrication, training and business development/marketing inputs for the project/activity;

b) S&T and other staff may comprise staff who have provided direct supporting inputs for the specific project/activity; and

c) Remaining staff may comprise rest of the staff of the laboratory who have not been included in the category of staff at (a) and (b) above for the specific project/activity.

3.2 *Maintenance of Project Records*

The Head of the laboratory shall ensure that the following records are maintained and retained in the laboratory:

a) By Project Leader

i. *Project File*

Document containing information on a systematic basis on initiation of the idea; date of starting of the project; list of Innovators and Principal Contributors (as defined earlier); responsibilities of the individuals and extent of their participation (whether whole time or part time); significant contributions made by the individuals alongwith the supporting inputs/contributions of the S&T and other staff.

ii. ***Completion Report***

A document listing the outcome of the Project/activity including the contributions made' by each of the Innovators & Principal Contributors, S&T and Other staff. The final record shall be signed by each of the Innovators & Principal contributors and the project Leader.

iii. Project Cost

Expenditure for each project/activity in accordance with Integrated Management & Project Accounting (IMPACT) System.

b) By Innovators & Principal Contributors and S&T and Other Staff

Record Book

A document maintained individually by the Innovators & Principal Contributors, S&T and other staff listing date of his/her joining the project; extent of participation (whether whole time or part time); work allotted and/or undertaken from time to time; contributions or achievement made, verified and countersigned by the Project Leader/Director.

3.3. ***Distribution of Monies/Fees***

a) A Standing Committee shall be set up by the Director to consider and decide on the share of the Innovators & Principal Contributors, S&T and other staff from the monies realised from licensing of Intellectual Property, the intellectual fees of Contract R&D projects and S&T Services.

b) The Project Leader shall recommend to the Standing Committee the share of the individual Innovators, Principal Contributors and S&T and other staff for a specific project/activity commensurate with the individual's contributors to the project/activity as reflected in the Project Records.

c) The Standing Committee shall decide the share of each individual [as at (b) above] in the light of the recommendations of the Project Leader and taking into consideration the Project Records, wherever necessary.

d) The recommendations of the Standing Committee shall be intimated to each of the Innovators and Principal contributors and S&T and other staff and also displayed on the Laboratory and other appropriate notice boards. In case no objections/representations are received within fifteen days on the date of notification, then the same can be submitted for consideration and approval of the Management Council.

e) Representations, if any, against the recommendations of the Standing Committee, within the stipulated time limit, shall be reconsidered by the standing committee. The Fresh Recommendations of the Standing Committee, along with the details of representations shall be put up to the Management Council for Consideration.

f) The decision of the Management Council shall be intimated to each of the Innovators & Principal Contributors and S&T and other staff and displayed on appropriate notice boards. Distribution of the monies/fees will then be done if no representations are received against the decision of the Management Council within thirty days of the date of notification.

g) Appeals against the decision of the Management Council, within thirty days of the date of notification, can be made to DG, CSIR through the Director of the Lab. Decision of DG, CSIR shall be final and binding on all concerned.

h) The portion of the monies/fees earmarked for the 'Remaining Staff of the Laboratory' is to be uniform for a salary scale and is to be distributed once a year.

i) A person is entitled for a share from the monies/fees even in the event of his transfer/retirement/resignation from CSIR. In the event of death of a person, his/her legal heir shall be entitled for his/her share of monies/fees.

(CSIR Letter No:9/203/94-TU, dated, June 15, 1994.Ammend. - 4)