Maharashtra Arogya Mandal's
Sumatibhai Shah Ayurved Mahavidyalaya
* An ISO 9001:2015 Certified Mahavidyalaya
* NABH Accredited & ISO 9001:2015 Certified Hospital
Malwadi, Hadapsar, Pune - 411028

Recognized by : Government of India, Ministry of Health & Family Welfare, (Department of AYUSH) N.C.I.S.M, Ministry of AYUSH, Government of India New Delhi & Government of Maharashtra. Affiliated to Maharashtra University of Health Sciences, Nashik.

||अभ्यासात् प्राप्यते दृष्टिः कर्मसिद्धिप्रकाशिनी||

Code of Ethics for Research

Validity Year - 2016-2021 Version : 01 Revision :00

Draft Prepared By: Criteria 03
Reviewed By: NAAC coordinator
Approved By : Principal

1. About the Institute:

Maharashtra Arogya Mandal (MAM) is a registered Charitable Trust (NGO) estab- lished by 5 young doctors Dr. Dada Gujar, Dr Baba Adhav, Dr Martand Patil, Dr Gopal Shah and Dr Sindhu Ketkar who nurtured a dream of Rural Medicare. Initially focused on preventive healthcare which eventually widened the scope of work in support areas like sanitation, school health monitoring, education, water conservation rural and tribal development. MAM's current work is focused on Health, Education & Tribal Development with many prestigious appreciations from Government of India and International Agencies.

1.2 PARAS: Programme for Advanced Research in Ayurveda Sciences (MAM's Autonomous R & D Institute) (established in Feb 2015):

Research can provide wings to the traditional assets of Ayurveda Knowledge. Continuous data monitoring, clinical trials and development is necessary to keep any academic and clinical institute up to date with present social requirements. MAM has established an autonomous division to establish culture of systematic research activities amongst practitioners, academician and postgraduate students across all units of MAM. PARAS take initiative in proposals for various grants and institutional development as a whole.

2.0 PRP Preamble:

Maharashtra Arogya Mandal established Sane Guruji Arogya Kendra in 1960 and as a result of huge clinical and social service; founders felt the need of more same minded doctors. Education is the key to transformation of society. On this firm social welfare foundation of 30 years MAM started SSAM in 1990, keeping in view need of well trained, research oriented social service minded doctors. From the very first batch students had opportunities in basic, clinical and research work. Clinical service project in tribal area

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M. A. M's, Sumatibhai Shah Ayurved Mahavidyalaya PUNE-28. Hadapsar

helped them to provide innovative solutions to tribal healthcare along with Ayurveda care for sickle cell anemia patients not only in tribal area but economically under privileged patient base in Sane Guruji Arogya Kendra gave them research orientation to develop sustainable and easy to adopthealth solutions. 'Single herb' preparations and development of new in-house formulations, gave them practical raining in research practices.

Research in Ayurveda has been dominated by studies on medicinal plants and the development of herbal drugs. However, basic research which employs modern physiology, immunology, and biochemistry to investigate the concepts, procedures, and products has received littleattention.

Research in Ayurvedic academic institutions are limited to MD/MS, PhD thesis writing and some clinical trials only. That is not sufficient to sustain current trends in Ayurveda research.

With new institute PARAS founded on 28 February 2015, MAM is proposing an "active autonomous R&D body under MAM" to facilitate, provide, encourage and appreciate research ideas and projects to gather funds from various academic/research/industry/social organizations' to develop in house research meshwork and platform according to global needs for promoting MAM activities on national and international research ground. Currently PARAS is headed by Research Coordinator Dr Pranita Joshi-Deshmukh Associate Professor and HODRMMS SSAM.

3.0 Vision

To develop synergic research promoting culture in AYUSH research practices by multidisciplinary integrated systematic methods to establish traditional principals using contemporary tools to address the needs of society pertaining to ethos of MAM's work dimensions in health, education and rural development by nurturing new Ayurveda formulations, clinical trials and extension activities across the globe.

4.0 Mission:

To nucleate and nurture technology and knowledge-based support system at MAM to facilitate advanced evidence based Ayurveda research activities at PARAS.

Priority Research Thrust Areas:

- **Project proposals relating to the R and D infrastructure development using new AYUSH related national and international funding opportunities.**
- **In house pharmacy drug standardization along with clinical trials**
- **Herbal products standardization or Ayurvedic procedures for safety and efficacy will be**
- **given priority by R &D unit.**
- **Medical Educational research**
- **School and social welfare projects**

- **Tribal development and healthcare Initiatives in remote areas**
- **Water conservation and Waste management**
- **Quality Assurance Cell: ISO/NAAC/NABH**
- **International collaborations for faculty/student exchange, academic and clinical research as well as academic collaborations for short term AYUSH courses.**
- **Incubation center for new ideas and start ups by students/faculties and associated staff of MAM.**

Research Facilities at MAM:

1. Sumatibhai Shah Ayurved Mahavidyalaya with 60 UG, 72 PG, 12 Diploma, 10 fellowship and PhD seats with good infrastructure of laboratories and museums.
2. Sane Guruji Arogya Kendra 250 bedded NABH and ISO accredited hospital.
3. SSAM's Dr Dada Gujar Institute of Post Graduate Research in Ayurveda established in 2006 facilitates PG educational activities for MD, MS and PhD courses in Ayurveda

2. PG Library and E library with good collection of traditional books.
3. SSAM's separate PG Research Department to provide guidance and training in Research Methodology and Medical Statistics with research laboratory.
4. MAM's Autonomous R and D institute PARAS (Programme for Advanced Research in Ayurveda Sciences) for all R and D related needs under one umbrella.
5. RASAMRUT Ayurveda Pharmacy for development of herbal, herbomineral compounds for pharmaco-clinical research activities.
6. Associated tribal healthcare centre for Sickle Cell research and other rural healthcare projects.
7. Primary, Secondary Schools for educational research and awareness activities.

6.0 Objectives of PARAS Research Policy

To undertake research on principles and practices of Ayurveda including diet, formulation, dosage forms, drug delivery system, panchakarma procedures, marma therapy, Shalya,Shalakya procedures with Ashtang Ayurveda multidisciplinary and transdisciplinary approach.

To undertake epidemiological surveys for various purposes like Prakriti, Sarata other health indicators, dietary habits, changing disease patterns etc.

To develop scientific assessment tools and parameters suitable to Ayurveda.

To conduct research on natural resources for their sustained availability, quality etc.

Identifying newer natural resources for purpose of prevention and treatment of various diseases.

Clinical Research for safety and efficacy evaluation of Ayurvedic Pharmacopeial formulations and other Drugs and Approaches in identified diseases/conditions

Medico Ethno Botanical Survey across the country

To Establish novel methods of analysis for standardization and quality control of single drugs and compound formulations.

Experimental studies to establish safety profile of Ayurvedic drugs/ formulations

Tribal Health Care Research Programme including documentation of Local Health Traditions/ folk claims as well as providing affordable health solutions.

Retrieval and revival of Ayurvedic texts from ancient manuscripts and publication of journals, monographs, books, technical reports, Information, Education and Communication material (IEC) etc.

Establishing quality culture in publication and IPR by facilitating publications and patents by PARAS IPR Cell.

Capacity building and training in research for students and faculties by regular work- shops, symposiums and workshops to strengthen the quantitative and qualitative research method skills.

Continuous improvement and upliftment in R and D Infrastructure: Efficient and specific basic infrastructure such as modernization of laboratories, hospitals, upgradation of existing facilities, equipments and instruments need to be proper for taking up the Research projects.

Collaborations / MOUs/ Linkages: To achieve universally acceptable outcomes, networking among researchers, national and international research bodies, academia, industry, policy makers.

7.0 Implementation :

To meet the objectives of quality research, PARAS has adopted following practices at MAM units

1. Faculty and Student Research Scheme
2. Collaborative Research Scheme at National level
3. Collaborative Research Scheme at International level
4. Collaborative research in Ayurveda with industries

(Details of above mentioned practices are available at PARAS office)

Statutory, Ethical and Research guidelines:

The research in any area mentioned may be undertaken in accordance with the existing regulatory guidelines and other guidelines in vogue. The clinical trials should follow the statutory, ethical and research guidelines prevalent in India.

Pilot studies may be conducted in initial phase to establish the baseline data and to ascertain the feasibility of the protocol.

In case of single centre studies the Principal Investigator needs to ensure the registration of the trial with the CTRI.

The multicentric trials will be coordinated by PARAS institute, identified by the MAM.

It needs to be ensured that the clinical trial is registered with Clinical Trial Registry of India (CTRI) prospectively i.e. before the recruitment of the first patient in the trial. In case of

multicentre studies, the Principal Investigator of the nodal/coordinating centre is responsible to register the trial with CTRI for the study.

PARAS will facilitate all the prerequisites and requisites before and during execution of the trial.

Role of PI & Co-I : The co-investigator should bear the responsibility to contribute in any manner as required by the PI. As per the need of the project, co-investigator could be from any associated instituted linked with PARAS by MOU or collaborations

PRP Rules and Regulations to Prevent Plagiarism :

Definitions :

"Plagiarism is copying another person's text or ideas and passing the copied material asyour own work researcher must both delineate (i.e., separate and identify) the copied text from own text and give credit to (i.e., cite the source) the source of the copied text to avoid accusations of plagiarism. Plagiarism is considered fraud and has potentially harsh consequences including loss of job, loss of reputation, rejection of synopsis / dissertation and the assignation of reduced or failing grade in a course."

Accidental or Unintentional Plagiarism : You may not even know you are plagiarizing. It is your responsibility to make certain that you understand the difference between quoting and paraphrasing, as well as the proper way to cite and delineate quoted material.

Blatant Plagiarism : Students/Researchers are well aware that they are plagiarizing. Purposefully using someone else's ideas or work without proper acknowledgment is plagiarism. This includes turning in borrowed or bought research papers as one's own.

Self Plagiarism: Turning in the same term paper (or substantially the same paper) for two courses/projects/publications without getting permission from one's instructor is plagiarism.

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Extensive use of Plagiarism Software : PARAS has set up plagiarism assessment cell tocheck plagiarism status of new write ups time to time before publications/submissions of project documents.

Plagarism Report must be collected by student/researcher from PARAS plagiarism assessment cell prior to publications and submissions of research work.

Research Approvals and Monitoring System:

Approval of Institutional Ethics Committee (IEC)

IEC approvals and timely reporting to IEC will be mandatory for every research project un-der this policy for any work related to academic, clinical, pre clinical and social areas.

(Refer to IEC SOP for more details)

Submission of Progress Report

The progress of the project in accordance with approved timeline and deliverable should be submitted to the PARAS office on monthly basis in the prescribed format of MUHS or other agencies.

The Principal Investigator may be asked to present the progress before the IEC, if the PARAS office recommends that the progress report submitted by PI is not satisfactory.

Final Project Completion Report: The final report should be sent in the prescribed format The report should be submitted within two months from the date of completion of the project with all the details of unused drug, allocation and expenditure of funds with audited utilisation certificates.

Monitoring of Research

:Local Monitoring

The concerned unit Head of the Institute/Center would ensure periodic review and monitoring of the projects ongoing under the particular scheme at Institute/Center level and thesame needs to be reflected in the periodic (monthly/quarterly/annually) report of the institute that is being communicated to the PARAS.

: Central Monitoring

A monitoring team for every project would be set up at PARAS. The team will comprise funding sponsors, Programme officer, PARAS officer and/or any other officer including

Biostatistician as deemed fit by the competent authority. They will monitor the activities on-site or online and may make field visit as and when required.

: Underperformance

If the Investigator does not perform satisfactorily, he/she needs to give justification for notperforming up to the mark.

: Outcome of the Project

The final outcome of the project will be evaluated through oral presentation by the P.I. / Co-I. before the PEMC (Project Evaluation and Monitoring Committee) set up at PARAS.

11.0 PRE-MATURE TERMINATION OF PROJECT:

If Secretary MAM feel that a project should be prematurely terminated due to technical/financial/ethical reasons then the same will be communicated to concerned PI, Co-I and Head of the institutes. In such case, the unspent balance will be refunded to the concerned funding agency. If the premature termination is due to deliberate negligence/misconduct by any concerned officer(s), he/they may also be liable for disciplinary proceedings as per rules.

INTELLECTUAL PROPERTY RIGHTS AND PATENTS:

The MAM and PARAS IPR Cell, will have the rights to take decision on IPR issue on case- to-case basis. MAM will make efforts to commercialize the product as and when applicable.

Publications:

Where the research outcome is not patentable, the Principal Investigator must publish the findings of research in peer review journal / reputed journal with impact factor after completion of the trial. If the article is to be submitted to a journal other than Satyanveshanam Today, prior approval of the manuscript by PARAS is mandatory. The draft article must be submitted to PARAS office within 3 months of the acceptance of the final report. In case of multi-centre studies, the PI of the MAM/PARAS Institute or the funding / collaborating institute is responsible to coordinate with all who participated or contributed in the study for planning of publication. In case of coded formulations, the PARAS will regulate all patent and publication issues. In case of non-clinical projects, the issue of the publication will be decided by PARAS on case to case basis. After publication, three copies of the reprints of the article are to be submitted to concerned units.

IPR : All the IPR generated by researches undertaken, facilitated and sponsored by MAM will be sole property of MAM.

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Draft Prepared By: Criteria 03
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