

## CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES

### Identification/ Selection of Ayurveda institutions for large scale observational studies/ pragmatic trials through Expression of Interest (EoI)

**Background:** The classical Ayurvedic formulations and therapies are being in clinical use since several centuries. Safety and efficacy is evident by their long history of use besides textural references. Some scientific evidence has been generated through observational studies conducted at academic and research institutes. To maximum utilization of these practices by promoting evidence based use, CCRAS, Ministry of AYUSH desires to generate strong evidences on clinical safety and efficacy through Multicentre observational studies/pragmatic trials through Expression of Interest (EoI) on large number of participants at different geographical zones across the country involving academic/research/Ayurveda healthcare setups functioning under State/Central government/recognized by CCIM.

**Modus operandi:** The Council will extend following support for this purpose.

- Clinical research protocol as required for Multicentric studies.
- Investigator training will be imparted prior to initiation of clinical trial.
- Quality assured drugs in requisite quantity.
- The financial support in terms of manpower, logistics, lab investigations etc.
- Monitoring of clinical trial from time to time.
- Release of grant to the government will be as per the norms laid under EMR scheme.

**Purpose:** To accomplish the scientific validation of Ayurveda drugs/therapies Council invites Expression of Interest (EoI) to conduct observational studies / pragmatic trials in India with following benchmark, terms and conditions.

*The interested institutes/hospitals fulfilling the same may offer their consent for this purpose.*

#### **Essential:**

1. Ayurveda Teaching Institutions recognized by respective Regulatory councils such as CCIM imparting PG education in clinical disciplines for at least 10 years/Ayurveda Hospitals functioning under the Central Government (such as CGHS, ESIC etc.) and functioning under State Government having a record of at least 200 OPD per day for past 3 years.
2. The Hospital/College should have experienced teachers/physicians Post Graduate degree in Ayurveda system and proposed PI should have at least 5 research papers to his/her credit.
3. Laboratory facility for clinical pathology, bio-chemistry, Haematology and preferably with Radiology and sonography.
4. The Ayurveda Teaching Institutions/Ayurveda Hospitals should have functional Institutional Ethics Committee (IEC).
5. The Ayurveda Teaching Institutions / Ayurveda Hospitals should be able to adopt the clinical trial protocols provided by the Council/or able to develop protocols where ever required.
6. It should comply with the requirement of sending the requisite documents to the Council as and when required.
7. It should be able to complete the studies within the timeframe.
8. The proposal should be routed through head of the institute/ concerned controlling authority whose permission is required for undertaking such study (as applicable).

**Desirable:**

1. Track record of the experiences in conducting clinical trials other than PG/Ph.D. research supported by other agencies like CCRAS, Ministry of AYUSH, DST etc.
2. Ayurveda Hospitals having facility of *Panchakarma/Ksharasutra* and allied procedures.
3. Academic / research linkage with reputed research organization / University.

**How to apply:** The details, consent along with requisite documents substantiating the terms and conditions may be furnished to the following address by **25<sup>th</sup> February, 2016** for further appraisal.

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