NATIONAL INSTITUTE OF AYURVEDA

(MINISTRY OF AYUSH, GOVT. OF INDIA)
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JAIPUR 302002 (Rajasthan)
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NOTICE INVITING LETTER OF EXPRESSION OF INTEREST

The Institute invites Letter of Expression of Interest in the prescribed Template from Registered Clinical Research Organizations (CRO) up-to 30-5-2020 5.00 p.m. to help the Institute in conducting a Community Based Research Project. More Details are given in our Website: www.nia.nic.in Interested CROs may access the Website and submit the LEI to E-Mail: nia-rj@nic.in by the prescribed Date.

PROF. SANJEEV SHARMA
DIRECTOR
22-5-2020

NATIONAL INSTITUTE OF AYURVEDA

Letter of Expression of Interest in the following Template are invited UPTO 30th May 2020 5.00 p.m. from Registered Clinical Research Organizations (CRO) to help NIA in conducting a Community based Research Project.

The Study details in brief, are as follows:

1. **Study Design**: Multi-centric, Comparative, Interventional, Randomized, Prospective, Population (Community) based Clinical Study
2. **Study Duration**: 45 Days Intervention
3. **Study Arms**: Two Arms (One Arm will be administered Guduchi Ghana Tablets and the other Arm will not be administered any Intervention)
4. **Study Locations**: 6 District Locations spread across Rajasthan (Containment Zones)
5. **Study Sample Size**: A total of 12000 subjects to be divided into two Groups of 6000 subjects each. Additional 20% subjects may be recruited.
6. Site Investigators (Nodal Officers) and Junior Research Fellows will be provided at each Center by NIA/State Government.
7. **Primary Outcome Parameters** – Incidence of Infection of COVID19 and Non-COVID Infections in the Study Population.

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Template of Expression of Interest

To

The Director

National Institute of Ayurveda, Jaipur

Subject: Conducting a Population Based Prophylactic Clinical Study on Ayurvedic Compound (Guduchi Ghana Vati).

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Sir,

Our Organisation, _____,
will be glad to be part of this Study and would provide the following Services:

Activities	CRO Role	Comments
Development of Protocol and other Study Documents for IEC Approval	Yes	With inputs from NIA
Training on Protocol and GCP of the Study Staff including Investigators and Research Fellows (CRC)	Yes	Site Selection, Investigator Selection and Research Team Selection to be done by NIA
E-CRF Preparation	Yes	-
Data Management Plan	Yes	-
Data Validation Plan	Yes	-
Database Specifications	Yes	-
Database Designing	Yes	-
Edit Check Programming	Yes	-
UAT of Screens and Edit Checks	Yes	-
Data Entry Guidelines	Yes	-
Training of EDC tool	Yes	All Investigators and Study Staff will be provided Training before initiation of the Study and also on regular basis throughout the Trial for E-CRF Filling
User Manual	Yes	-
User Management	Yes	-
Database Live	Yes	-

Data Entry	No	Site will perform the Real Time Data Entry
Query Management	Yes	In discussion with the Site and NIA
Source Data Verification	Yes	Remote SDV will be done and as required site visit to monitor the study will be done
Database Lock/Freeze	Yes	After confirmation from the Sites and NIA
Data Extraction	Yes	As per Study requirement
Reports and Access on Dash Board	Yes	-
Final Data Extraction	Yes	After Database is locked
Data in CD/Pendrive	Yes	After Database is locked
Patient Data Report (in PDF)	Yes	After Database is locked
Technical Issues/ Maintenance/ Upgradation	Yes	As and when required
Site Monitoring to check with compliance with Protocol	Yes	As per the Study Requirement (Remote Monitoring/Risk Based Monitoring will be done)
Statistical Analysis	Yes	-
CSR Preparation	Yes	-
Publication (Manuscript Preparation, Submission and Resolution of Query)	Yes	-

The Cost for the above Services will be Rs. _____

(Rupees_____)

Signature of the

Authorized Signatory