



### भारतीय आयुर्विज्ञान अनुसंधान परिषद INDIANCOUNCILOFMEDICALRESEARCH

स्वास्थ्य अनुसंधान विभाग (स्वास्थ्य एवं परिवार कल्याण मंत्रालय) वी. रामलिंगस्वामी भवन, अन्सारी नगर, नई दिल्ली - 110 029

DEPARTMENT OF HEALTH RESEARCH (MINISTRY OF HEALTH & FAMILY WELFARE) V. RAMALINGASWAMI BHAWAN, ANSARI NAGAR, NEW DELHI - 110 029

Date: Sept 8, 2020

#### Tender ID / EOI No. ICMR / MPD / NTF/PRE-DIAB/EOI/2

**Subject**: Extension of date for Expression of Interest (EOI) on Designing, Conducting, Analyzing and Reporting of Phase I trial on a Phytopharmaceutical Drug in Healthy Volunteers for Pre-diabetes.

#### **CORRIGENDUM**

Please refer to our EOI no. ICMR / MPD / NTF/PRE-DIAB/EOI/2, dated 28<sup>th</sup> July 2020 for Designing, Conducting, Analyzing and Reporting of Phase I trial on Phytopharmaceutical Drug in Healthy Volunteers with due date, 4<sup>th</sup> Sept 2020. Due to administrative reasons, the date for submission of application for above tender is extended to 28<sup>th</sup> Sept, 2020, 5.30 PM.

Accordingly, any query/clarification related to this EOI can be sought telephonically on 24<sup>th</sup> Sept. 2020 from 11.00 AM to 5.00 PM. The tender application should reach latest by 5.30 PM on 28<sup>th</sup> Sept, 2020 and the same would now be opened on 30<sup>th</sup> Sept. at 11.30 AM in the virtual presence of the tenderers and Technical Selection Committee members.

Those who have already applied need not apply again.

Sd-Head MPD

# Indian Council of Medical Research, New Delhi Invites

**Expression of Interest (EOI)** 

For

Designing, Conducting, Analyzing and Reporting of Phase I trial on a Phytopharmaceutical Drug in Healthy Volunteers

Funded and Monitored by

**Indian Council of Medical Research** 

July, 2020

#### **Indian Council of Medical Research**

V. Ramalingaswami Bhawan P.O. Box No. 4911, Ansari Nagar East New Delhi -110029, India

Telephones: 91 (011) 26589556 Fax: 91 (011) 26588662

Confidential

No part of this document can be reproduced in any form or by any means, disclosed or distributed to any person without the prior consent of ICMR except to the extent required for

submitting bid and no more.

**Disclaimer** 

1. Though adequate care has been taken while preparing the Expression of Interest (EOI)

Document, the Bidders shall satisfy themselves that the document is complete in all respects. Intimation of any discrepancy shall be given to this office immediately. If no intimation is received from any Bidder within seven (07) days from the date of notification of

EOI Documents/ Issue of the EOI Document, it shall be considered that the EOI Document

is complete in all respects.

2. ICMR reserves the right to modify, amend or supplement this EOI Document.

3. While this EOI Document has been prepared in good faith, neither ICMR nor their employees or advisors make any representation or warranty, express or implied, or accept

any responsibility or liability, whatsoever, in respect of any statements or omissions herein, or the accuracy, completeness or reliability of information, and shall incur no liability under any law, statute, rules and regulations as to the accuracy, reliability or completeness of this

EOI Document, even if any loss or damage is caused by any act or omission on their part.

Place: New Delhi

Date: 28/07/2020

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### 1. Bid Information Sheet

The time schedules for various EOI related events are follows:

**Document Description** Designing, Conducting, Analysing and Reporting of a

Phase I trial on a Phytopharmaceutical Drug in Healthy

Volunteers

EOI Documents No. & Date Ref.No.MPD/NTF/Pre-Diab /EOI/2, dated 28/07/2020 21/08/2020

Last Date for submission of written

queries for clarifications

Last date & Time of Submission of

Response to EOI Document

Pre-Bid clarification meeting

24/08/2020 at 11:00hrs (Video/Audio conference)

04/09/2020 till 17:00hrs

Technical Bid (opening) of all the bidders 11/09/2020 at 10:30 hrs.

(Note: Interested bidders can also join the

meeting through videoconference)

Presentation/demonstration capabilities

(To be presented by the bidders/ representatives through virtual meeting)

Technical Inspection and performance

Evaluation

11/09/2020 at 12:00 hrs.

ICMR may carry out a visit of expert committee constituted by the competent authority to the Bidders premises to assess the level of services and facilities

etc. available & performance evaluation.

Declaration of bidder qualified for opening ICMR on the recommendation of expert committee shall

of Financial bid

inform to technically qualified Shortlisted Bidders only.

Validity of EOI 180 days (one hundred eighty days) from the date of

opening of EOI.

DD/Pay order Rs. 1000/- towards the cost of the EOI document (Non-refundable) EMD of Rs. 200,000/- (DD/Pay order)

Name, Designation, Address and other details (For submission of queries and

Response to EOI document)

Dr. Neerai Tandon Scientist-G and Head

Room No 415, Divisions of Publications & Information and Medicinal Plants Indian Council of Medical

Research, V. Ramalingaswamy Bhawan,

(Ministry of Health & Family Welfare, Govt. of India),

Ansari Nagar, New Delhi - 110029 Email: tanneeraj@gmail.com; Ph: 011-26589599, 9811462137

Important Note: Prospective Bidders are requested to remain updated for any notices/amendments/ clarifications etc. to the EOI Document through the websites www.icmr.nic.in. No separate notification will be issued for such notices/amendments/clarifications etc. in the print media or individually.

### 2. Introduction

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research. ICMR's mandate cover capacity building in research in the country; providing fellowships and funding to foster research in medical colleges and research/academic institutions; initiate nationwide task force projects oriented to new knowledge generation, technology development, evaluation of products or interventions and generating evidence for programmatic improvement and policy. ICMR's research priorities are aligned to the nation's health priorities and focus on maternal and child health, nutrition, communicable diseases and non-communicable diseases through intramural and extramural research undertaken by a network of affiliated 26 National institutions/Research Institute/ Regional Medical Research Centre.

#### Scope of work

# Conducting Clinical trial on a Phytopharmaceutical drug through DCGI/CDSCO route:

- Medical Writing Task (designing, developing, preparing, and submission) for Phase I clinical trial protocol, drafting of Investigator's Brochure (based on CMC and available preclinical data); Patient Informed Consent Form, CRF design in accordance with appendix- X, schedule Y, Drugs and cosmetics act 1940.
- 2. Preparation and submission of ethics protocol and other documents and follow up till study approval.
- 3. Conducting phase I trial, obtaining subject insurance, recruitment, monitoring, preparation and maintenance of file, data collection, data management, data analysis, pharmacovigilance in case of any serious adverse effect (SAE) or adverse effect (AE), management of trial activities at sites & archival of data as per the regulatory norms, and preparation of final Phase I study report ready for submission.

# (Prospective Bidder is expected to attend ICMR pre-bid meet (virtual) to present their capabilities and also to collect information about the project)

- 2.1 Parameters, Processes and Methodology to be prepared in consultation with ICMR and get the same approved by ICMR
- 2.2 The agency selected for the work will have the responsibility to initiate, conduct, monitor, and submit report in mutually agreed time period of ICMR.
- 2.3 The agency will have to develop appropriate Dashboard for project monitoring, if not developed already.
- 2.4 Computer and other hardware/Software requirements will not be provided by ICMR.
- 2.5 Lead Team manager/ Team Manager will have to submit various progress and status reports to ICMR authorities at mutually agreed intervals as well as whenever required by ICMR;
- 2.6 The work would be required to be completed in 6 months time (except in condition with justifiable cause) and no further extension will be given (if the performance of the bidder were found unsatisfactory. Competent authority of ICMR has discriminatory power to terminate the contract without assigning any reason).

## 3. Definitions

- "Expression of Interest (EOI)" means all Volumes and its Annexure and any other documents provided along with this EOI or issued during the course of the selection of bidder, seeking a set of solution(s), service(s), materials and/or any combination of them.
- "Contract/Agreement/Contract Agreement/Master Service Agreement" means
   The agreement to be signed between the successful bidding firm/agency and ICMR, including all attachments, appendices, all documents incorporated by reference there to together with any subsequent modifications, the EOI, the bid offer, the acceptance and all related correspondences, clarifications, presentations.
- "Bidder" means any agency/firm/Institute registered in India or having registered office in India offering the solution(s), service(s) and/or materials as required in the EOI.
- The word Bidder when used in the pre-award period shall be synonymous with parties bidding against this EOI, and when used after award of the Contract shall mean the successful party with whom the agreement is signed for rendering of services for implementation of this project.
- "Proposal/Bid" means the Technical and Commercial bid submitted for this project against this EOI.
- "Authorized Signatory" shall indicate the authorized person/signatory who can discuss and correspond with ICMR, with regard to the obligations under the contract.
- "Bid" shall mean the Technical/Commercial and the Price Bid submitted by the Bidding Company/Bidding Institute/Bidder Organization/Bidder/Bidder along with all documents/credentials/ attachments, formats, etc., in response to this EOI Document, in accordance with the terms and conditions here of;
- "Bidding Company" shall refer to such single Company/Institute/Organization that has submitted the response in accordance with the provisions of this EOI Document;
- "Bid Deadline" shall mean the last date and time for submission of Bid in response to this EOI document as specified in information Sheet of this document including all amendments there to:
- "Chartered Accountant" shall mean a person practicing in India or a firm where of all the partners practicing in India as a Chartered Accountant(s) within the meaning of the Chartered Accountants Act, 1949;
- "Company" shall mean a body corporate incorporated in India under the Companies Act, 1956 or the Companies Act, 2013, as applicable;
- "Contract" shall mean the Contract signed by the Parties and all the attached documents listed in the EOI document, also including all amendments/clarifications thereof;
- "ICMR" shall mean Indian Council of Medical Research (ICMR Hqrs and ICMR Institutes) (An Autonomous Body under MOHFW);
- "Selected Bidder or Successful Bidder" shall mean the eligible Bidder company/institute/Organization who has been Selected based on this EOI Document issued by ICMR;
- "Services" shall mean requirements defined in this EOI Document including all necessary and additional services associated there to be delivered by the bidder;

- "EOI Document" shall mean the bidding document issued by ICMR including all Flowcharts, Drawings, Photographs, Formats & Annexures etc. vide this EOI Document also including all amendments/clarifications thereof;
- "The Goods" means all the material/services, which the Vendor is required to Supply to the Organizational Authority under the Contract;
- "The Government" means the Government of India.
- "Day" means calendar day;
- "Week" means calendar week;
- "Month" means calendar month:
- "TEC" means Technical Evaluation Committee:
- "SP" means Service Provider
- "Corrupt practice" means (i) the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence the action of any person connected with the Selection Process (for avoidance of doubt, offering of employment to or employing o reengaging in any manner whatsoever, directly or indirectly, any official of the ICMR who is or has been associated in any manner, directly or indirectly with the Selection Process or the EOI or has dealt with matters concerning the Agreement or arising there from, before or after the execution thereof, at any time prior to the expiry of one year from the date such official resigns or retires from or otherwise ceases to be in the service of the ICMR, shall be deemed to constitute influencing the actions of a person connected with the Selection Process);or (ii)save as provided here in, engaging in any manner whatsoever, whether during the Selection Process or after the issue of the LOA or after the execution of the Agreement, as the case may be, any person in respect of any matter relating to the Project or the LOA or the Agreement, who at any time has been or is a legal, financial or technical consultant/adviser of the ICMR in relation to any matter concerning the Project;
- "Fraudulent practice" means a misrepresentation or omission off acts or disclosure of incomplete facts, in order to influence the Selection Process;
- "Coercive or property to influence any person's participation or action in the Selection Process practice" means impairing or harming or threatening to impair or harm, directly or indirectly, any persons;
- "Undesirable practice" means (i) establishing contact with any person connected with o
  reemployed or engaged by ICMR with the objective of canvassing, lobbying or in any
  manner influencing or attempting to influence the Selection Process; or (ii) having a
  conflict of Interest; and
- "Restrictive practice" means forming a cartel or arriving at any understanding or arrangement among Bidders with the objective of restricting or manipulating a full and fair competition in the Selection Process.

# 4. Bid Information and Instructions to Bidders

#### 4.1 Technical and Commercial Eligibility Of Bidder

#### A. Mandatory Eligibility:-

- i. The bidding firm should be an Indian firm and have a registered office in India.
- ii. The bidding firm should be a reputed agency having 2 years experienced in conducting, monitoring and managing Phase I trial preferably on Botanical medicine in India and should have past experience of undertaking at least 3 such studies abiding necessary national/international regulatory norms, with necessary documentations.
- iii. The bidding firm should have completed, in last three financial year (i.e. current year and two previous financial years) at least one similar assignment of amount not less than Rs 30 Lakhs.
- iv. The bidding firm should have electronic Regulatory Data Management Software (eDMS / rDMS) and data management experience for at least 3 clinical trials.
- v. The Project Lead Manager must be of age less than 65 years and have 10 years of experience of working within such institution at senior executive level.
- vi. The Project Manager should not be more than 45 years of age and shall have a minimum professional experience of 5 years.
- vii. The firm should have at least one medical personnel with post-graduate degree in their team.
- viii. The Project Manager should have minimum post graduate qualification in medical /health sciences.
  - ix. The Aggregate Annual Turnover for last three financial years of the bidding firm should not be less than 1.0 Crore.
  - x. The firm should have PF and ESI registration (for private firm only)

#### B. Desirable Eligibility:-

i. The Lead Manager/Project Manager should be a post-graduate from reputed Medical Institutes preferably from Central/State Medical Colleges. Such qualification will be assigned additional weightage while putting marks for evaluation

#### (Documentary proof for the eligibility criteria must be submitted along with the technical bid)

### **4.2 Instructions to Bidders**

- i. The cost of bidding and submission of EOI documents is entirely the responsibility of bidders, regardless of the conduct or outcome of the process.
- ii. Language of Bids: The bid and supporting documents shall be submitted in English.
- iii. **Period of Bid validity:** The bids shall be valid for a period of 180 days from the closing date of the bid.

- iv. **Format and Signing of bid:** Each page of the bid document should be numbered and must be signed and duly stamped by an authorized person of the bidding firm. Each bid will be submitted in the legal name of the Bidder.
- v. Last Date and Time for acceptance of Bids: Duly completed Bids along with all supporting documents should reach the address given latest by the date given in the section on Bid-Information. Incomplete or late bids shall be summarily rejected.
- vi. **Signing of Contract:** The successful bidder shall be required to enter into a Service Level Agreement with ICMR.
  - Point wise compliance of the each clause enumerated in the EOI document.
  - Technical Bid.
  - Financial Bid.
  - Signed Copy of the EOI document.
  - E.M.D. amount of Rs. Two lakhs in the form of Demand Draft/Pay order in favour of "Director General, ICMR" payable at New Delhi valid for at least 45 days beyond the final bid validity period. (As per provision of GFR 170).
  - Bids without supporting documents and EMD will not be considered.

#### **4.3 Mode of Bids Submission:**

The applications to be addressed to:

The Director General, Indian Council of Medical Research, V. Ramalingaswami Bhawan, Ansari Nagar East, New Delhi-110029

And should be dropped in the sealed Tender Box kept at ICMR HQ, Ansari Nagar, New Delhi as per Bid- information sheet. The subject line as 'EOI-MPD' should be clearly mentioned on the envelope.

- Incomplete bids shall be summarily rejected.
- Any bid received after due date & time will not be entertained and considered.

#### Method of submission

- The bidders should submit their proposal in the sealed tender box at ICMR HQ, Ansari Nagar, New Delhi.
- The submission of bid should be in Two- bid systems as per details given below.

**Covering Envelope -** Super scribed as "Covering Envelope containing bid document for **EOI-MPD**" at the top of the Envelope; and "Name and Address of the Bidder" on the left hand side bottom. It should be addressed to ICMR and shall contain three sealed envelopes inside it as per the following arrangement.

#### 1st Sealed Envelope:- (Super scribed as "EMD for Bid")

It should contain-

- i. Covering Letter as per Format 1.
- ii. DD/Pay order Rs. 1000/- towards the cost of the EOI document (Non-refundable)
- iii. EMD of Rs. 200,000/- (DD/Pay order)

#### 2nd Sealed Envelope:- (Super scribed as "Technical Bid")

It should contain the Technical Bid Proposal having the following-

- i. All the documents submitted in support of the fulfillment of bidder's eligibility.
- ii. Details of the Lead Manager, Project Manager along with their qualification documentation.
- iii. Details with necessary documentations of registered office, organogram, infrastructure, study team members list, their qualification and past experiences, number and list of important clients/projects handled in this field.
- iv. The details of post-graduate medical personnel.
- v. Documents supporting the firm turnover of last three years.
- vi. Supporting documents/ copy of challans for last month and registration fees for PF and ESI registration (For private firm only).
- vii. Copy of the bid document duly signed on each page as a mark of unconditional acceptance of terms and conditions

#### 3rd Sealed Envelope:- (Super scribed as "Financial Bid")

It should contain the "Financial Bid" and should be clearly marked and sealed. It should contain the commercial Bid submission in the Performa attached with the bid document for Financial Bid at Format 5. The envelope should have clear mention as "**Financial Bid**"

All these three sealed envelopes should be kept inside the main envelope having proper marking on the face of it.

(Bid not submitted in the desired manner will be summarily rejected)

## 5. Bid Evaluation

#### 5.1 Criteria for Evaluation

- The Overall objective of this evaluation process is to select the capable and qualified firm/agency who can undertake the desired functions at most competitive rates on turn-key basis.
- II. The competitive bids shall be evaluated in the following 3 successive stages:
  - Stages 1 Technical Qualification Criteria (Technical Bid);
  - Stages 2 Call for "Work Execution Presentation" by technically qualified Agencies; and
  - Stages 3 Financial Bid evaluation
- III. The first stage would evaluate the bidders' credentials as per the Qualification Criteria mentioned in Section 4 of EOI. The bidders having successfully cleared all the qualification criteria and the technical requirements of conducting Phase I human trial job/functions as asked by ICMR and accepting the terms and conditions of these documents will only be called for work execution presentation.
- IV. There will be marking of bidders and scores will be given to their proposals at Stage 1 as well as Stage 2 as mentioned above. The technical score of all the bidders would be calculated by Technical Expert Committee and competent authority decision will be bounding and final. The qualified bidders would be eligible for the next stage, i.e. financial bid opening.
- V. Financial bid will be evaluated on the basis of <u>the total costs quoted by the technically</u> <u>successful bidders.</u>
- VI. ICMR reserves the right to allot the work to one or more than one bidder. DGs decision in this regard would be final.

# 6. Special Conditions of Contract (SCC)

#### 6.1 Terms of Reference

Through this document, ICMR is looking for an outsourced partner to conduct, monitor, management, analysis and reporting of Phase I human trial on a Phytopharmaceutical Drug through approval of DCGI/CDSCO for the work as mentioned under Scope of work.

#### 6.2 Instruction to Bidders

- I. Bidder shall create a process document for carrying out the Phase I human trial activities and submit the same to ICMR within 15 days of the award of the contract. This document shall clearly define all the processes to be undertaken by the bidder and standard operating procedures (SOP), the processes involved to meet all the requirements in the scope of work.
- II. Bidder will provide the sufficient resources to fulfill service level requirements and availability as defined in this document.
- III. ICMR will process the bid as per procedures mentioned in EOI. It however, reserves the right to reject any bid without assigning any reason. ICMR would not be under obligation to give any clarifications to those agencies whose bid have been rejected.
- IV. ICMR reserves the right to modify and amend any of the tender condition/criterion depending upon Project priorities vis-à-vis urgent commitments. ICMR also reserves the right to cancel this bid without assigning any reason therefore.

#### 6.3 Fraud and Corrupt Practices

The Bidders and their respective officers, employees, agents and advisers shall observe the highest standard of ethics during the Selection Process. Notwithstanding anything to the contrary contained in this EOI, ICMR shall reject the Proposal without being liable in any manner whatsoever to the Bidder, if it determines that he Bidder has, directly or indirectly or through an agent, engaged in corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practice (collectively the "Prohibited Practices") in the Selection Process. In such an event, the ICMR shall, without prejudice to its any other rights or remedies, as the case may be, as mutually agreed genuine pre-estimated compensation and damages payable to the Authority for, inter alia, time ,cost and effort of the Authority, in regard to the EOI, including consideration and evaluation of such Bidder's Proposal.

#### **Conflict of Interest**

The Vendor shall disclose to ICMR in writing, all actual and potential conflicts of interest that exist, arise or may arise (either for the Vendor for the Bidder's team) in the course of performing the Service(s) as soon as practical after it becomes aware of that conflict.

#### 6.4 Consequences of Termination

- I. In the event of termination of the Contract due to any cause whatsoever, [whether consequent to the stipulated term of the Contract or otherwise], ICMR shall be entitled to impose any such obligations and conditions and issue any clarifications as may be necessary to ensure an efficient transition and effective business continuity of the Service(s) which the vendor shall be obliged to comply with and take all available steps to minimize loss resulting from that termination/breach, and further allow the next successor Vendor to take over the obligations of the erstwhile Vendor in relation to the execution/continued execution of the scope of the Contract.
- II. Nothing herein shall restrict the right of ICMR to invoke/ enforce the Deed of indemnity and pursue such other rights and /or remedies that may be available ICMR under law or otherwise.
- III. The termination hereof shall not affect any accrued right or liability, if either Party nor affect the operation of the provisions of the Contract that are expressly or by implication intended to come into or continue in force on or after such termination.

#### **6.5 PENALTY**

- I. The Bidder shall perform its obligations under the agreement entered into with the ICMR, in a professional manner.
- II. In the event of failure of executing the tasks to the satisfaction of ICMR, penalty would be levied per payment subject to a minimum of 10% of the payment for that period or as decided by the Competent Authority.
- III. If any act or failure by the bidder under the agreement results in failure or inoperability of systems and if the ICMR has to take corrective actions to ensure functionality of its property, the ICMR reserves the right to impose penalty, which may be equal to the cost it incurs or the loss it suffers for such failures.
- IV. ICMR may impose penalty to the extent of delay caused due to non-performance and loss of time, if the delay was due to the actions directly attributable to the bidding firm.
- V. ICMR shall implement all penalty clauses after giving due notice to the bidding firm.
- VI. If the bidding firm fails to complete the due performance of the contract in accordance with the specification and conditions of the offer document, the ICMR reserves the right either to cancel the order or to recover a suitable amount as deemed reasonable as Penalty/ Liquidated Damage for non performance. ICMR also reserves the right to get the work done through alternate agency and recover the cost of such work from the bidding firm.

#### 6.6 INDEMINIFICATION & LIMITATION OF LIABILITY

- 6.6.1 Subject to Clause 6.6.4 below, Implementation Agency/Service Provider (the "Indemnifying Party") undertakes to indemnify, hold harmless the purchaser/ ICMR (the "Indemnified Party") from and against all claims, liabilities, losses, expenses (including reasonable attorneys' fees), fines, penalties, taxes or damages (Collectively "Lose") on account of bodily injury, death or damage to tangible personal property arising in favour of any person, corporation or other entity (including the Indemnified Party) attributable to the Indemnifying Party's negligence or willful default in performance or non-performance under this Agreement.
- 6.6.2 If the indemnified Party promptly notifies Indemnifying Party in writing of a third party claim against indemnified Party that any Service provided by the Indemnifying Party infringes a copyright, trade secret or patents incorporated in India of any third party, Indemnifying Party will defend such claim at its expense and will pay any costs or damages, that may be finally awarded against Indemnified Party.
- 6.6.3 Indemnifying Party will not indemnify the Indemnified Party, however, if the claim of infringement is caused by
  - I. Indemnified Party's misuse or modification of the service;
  - II. Indemnified Party's failure to use corrections or enhancements made available by the Indemnifying Party;
  - III. Indemnified Party's use of the Service in combination with any product or information not owned or developed by Indemnifying Party; however, if any service, information, direction, specification on materials provided by Indemnified Party or any third party contracted to it, is on likely to be held to infringing, Indemnifying Party shall at its expense and option either
    - Procure the right for Indemnified party to continue using it
    - Replace it with a no infringing equivalent
    - Modify it to make it no infringing.

The foregoing remedies constitute Indemnified Party's sole and exclusive remedies and Indemnifying Party's entire liability with respect to infringement.

- 6.6.4 The indemnities set out in Clause 6.6 shall be subject to the following conditions:
  - I. The Indemnified Party as promptly as practicable informs the Indemnifying Party in writing of the claim or proceedings and provides all relevant evidence, documentary or otherwise;
  - II. If the Indemnifying Party does not assume full control over the Defense of a Claim as provided in this Article, the Indemnified Party may participate in such Defense at its sole cost and expense, and the Indemnified Party may participate in such Defend the claim in such

- manner as it may deem appropriate, and the cost and expense of the Indemnified Party will be included in Losses:
- III. The Indemnified Party shall not prejudice, pay or accept any proceedings or claim, or compromise any proceedings or claim, without the written consent of the Indemnifying party;
- IV. All settlements of claims subject to indemnification under this clause with:
  - Be entered into only with the consent of the indemnified Party, which consent will not be unreasonable withheld and include an unconditional release to the Indemnified Parry from the claimant or plaintiff for all liability in respect of such claim; and
  - Include any appropriate confidentiality agreement prohibiting disclosure of the terms of such settlement;
  - I. The Indemnified Party shall account to the indemnifying party for all awards, settlements, damages and costs (if any) finally awarded in favour of the Indemnified Party which are to be paid to it in connection with any such claim or proceedings;
- II. The Indemnified Party shall take steps that the Indemnifying Party may reasonably require to mitigate or reduce its loss as a result of such a claim or proceedings;
- III. In the event that the Indemnifying Party is obligated to indemnify an Indemnified Party pursuant to this Article, the Indemnifying Party will upon payment of such indemnity in full, be subrogated to all rights and defenses of the indemnified Party with respect to the claims to which such indemnification relates; and
- IV. If a Party makes a claim under the indemnity set out under Clause 6.6.1 above in respect of any particular Loss or Losses, then that Party shall not be entitled to make any further claim in respect of that loss or losses (including any claim for damages).
- 6.6.5 The liability of either Party (whether in contract, tort, negligence, strict liability in tort, by statute or otherwise) for any claim in any manner related to this Agreement, including the work, deliverables or Services covered by this Agreement, shall be the payment of direct damages only which shall in no event exceed one time the total contract value payable under this Agreement. The liability cap given under this Clause shall not be applicable to the indemnification obligations set out in Clause 6.6 and breach of Clause 6.7 and 6.8.
- 6.6.6 In no event shall either party be liable for any consequential, incidental, indirect, special or punitive damage, loss or expenses (including but not limited to business interruption, lost business, list profits, or lost savings) nor for any third party claim (other than those set-forth in Clause 6.6.1) even if it has been advised of their possible existence.
- 6.6.7 The allocations of liability in this Section of 6.6 represent the agreed and bargained-for understanding of the parties and compensation for the Services reflects such allocations. Each Party has a duty to mitigate the damages and any amounts payable under an indemnity that would

otherwise be recoverable from the other party pursuant to this Agreement by taking appropriate and commercially reasonable actions to reduce or limit the amount of such damages or amounts.

#### 6.7 Security and Safety

- I. The Implementation Agency shall comply with the requirements of the confidentiality, relevant security, safety and other requirements of the information as specifically stated in the EOI and follow the industry standards related to confidentiality, safety and security (including those as stated in the EOI), in so far as it applies to the provision of the Services and information generated thereafter.
- II. Each Party to the Agreement shall also comply with Purchaser or the Government of India, and the respective State's security standards and policies in force from time to time at each location of which Purchaser or its nominated agencies make the Implementation Agency aware in writing in so far as the same apply to the provision of the Services.
- III. The parties to the /Agreement shall use reasonable endeavors to report forthwith in writing to each other all identified attempts (whether successful or not) by unauthorized person (including unauthorized persons who are employees of any Party) wither to gain access to on interfere with the Purchaser as the case may be or any of their nominees data, facilities or Confidential information.
- IV. The implementation Agency shall upon reasonable request by the Purchaser as the case may be or their nominee(s) participate in regular meetings when management report and security matters are reviewed.
- V. As per the provisions of this Agreement, the Implementation Agency shall promptly report in writing to the Purchaser or its nominated agencies, any act or omission which they are aware that could have an adverse effect on the proper conduct of safety and information technology security at the facilities of Purchaser as the Case may be.

#### 6.8. CONFIDENTIALITY

- 6.8.1 The Purchaser or its nominated agencies shall allow the Implementation Agency to review highly confidential public records at sites and the Implementation Agency shall maintain the highest level of secrecy, confidentiality and privacy with regard thereto.
- 6.8.2 Additionally, the Implementation Agency shall keep confidential all the details and information with regard to the Project, including systems, services, facilities, operations, management and maintenance of the systems/facilities.
- 6.8.3 The Purchaser or its nominated agencies shall retain all rights to prevent, stop and if required take the necessary punitive action against the Implementation Agency regarding any forbidden disclosure.
- 6.8.4 The Implementation Agency shall ensure that all its employees, agents and sub-contractors involved in the project, execute individual non disclosure agreements, which have been duly approved by the Purchaser with respect to this Project. (Optional) for the avoidance of doubt, it is expressly clarified that the aforesaid provisions shall not apply to the following information:

- Information already available in the public domain:
- Information which has been disclosed to the public pursuant to a court order.
- 6.8.5 To the extent the Implementation Agency shares its confidential or proprietary information with the Purchaser for effective performance of the Services; the provisions of the Clause 6.8.1 to 6.8.3 shall apply mutandis on the Purchaser or its nominated agencies.
- 6.8.6 Any handover of the confidential needs to be maintained in a list, both by ICMR & SP, containing at the very minimum, the name of provider, recipient, date of generation of the data, date of handing over of data, mode of information, purpose and signatures of both parties.
- 6.8.7 Notwithstanding anything to the contrary mentioned hereinabove, the Implementation Agency shall have the right to share the Letter of Intent/ work order provided to it by the ICMR in relation to this Agreement, with its prospective ICMRs solely for the purpose of and with the intent to evidence and support its work experience under this Agreement.

# 7. General Conditions of Contract (GCC)

#### 7.1 Terms and Conditions

- Rates: The charges quoted should include the entire facilities required to render the services without any hidden charges. All costs in the bid should be expressed in India Rupees without any dependence on exchange rate, duty or tax structure.
- No payment over and above the quoted charges will be made by ICMR.
- Indemnity: bidder shall indemnify, protect and save ICMR against all claims, losses, costs, damages, expenses, legal suits and other proceedings, resulting from failure or malfunctioning of the equipment or facilities provided as above or resulting from infringement of any patent, trademarks, copyrights etc. or such other statutory infringements in respect of all the hardware, software and network equipment etc. it shall be at ICMR's discretion to enforce a penalty to make up for the losses incurred due to any of the above reasons.
- Technical Inspection and performance Evaluation: ICMR may carry out a visit to the Bidders premises to assess the level of services and facilities etc. & performance evaluation.
- Payments: Payments for Services will be made by ICMR on yearly basis after assessment
  of the completed work. (In case of reduction in cost or in ward credit of GST, benefit shall
  accrue to ICMR).
- Publicity: Any publicity by the vendor in which the name of ICMR is to be used should be
  done only with the explicit written permission of ICMR. If vendor fails to do so, it shall be
  considered a breach of contract.
- **Performance Security:** The successful bidder shall furnish, for the due and faithful fulfillment of the contract by him/her, an interest free security deposit in the form of Demand Draft/Pay order/ or Bank Guarantee of the commercial banks in favour of "Director General, ICMR", payable at New Delhi (As per provision of GFR 171). Bank Guarantee Performa is given in format 10.
- Security deposit will be forfeited in case of non-compliance of any terms and conditions of contract and government rules, regulations, instructions etc.
- The work would be for a period of Three years only, and in no case extension would be given.
- The contract can be terminated by either party by giving Three (3) months notice.

#### 7.2 Force Majeure:

- Notwithstanding the provisions of the EOI, the Bidder shall not be liable for forfeiture of its performance security, liquidated damages or termination for default, if and to the extent that its failure to perform its obligations under the contract is the result of an event of Force Majeure.
- For purposes of this Clause, "Force Majeure" means an event beyond the control of the Bidder and not involving the Bidder and not involving the Bidder's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the client, either

- in its sovereign or contractual capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.
- If a Force Majeure situation arises, the Bidder shall promptly notify the client in writing of such conditions and the cause thereof. Unless otherwise directed by the ICMR in writing, the Bidder shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event, the client may terminate this contract by giving a written notice of minimum 30 days to the Bidder, if as a result of Force Majeure, the Bidder being unable to perform a material portion of the services for a period of more than 60 days.
- In case of any damage/ theft of ICMR resources sole responsibility lies on the bidder.
- In case of urgent situations failure bidders shall provide corrective support on Holidays/ out
  of working hours.

#### 7.3 Governing Law and Disputes

- All disputes, differences, claims and demands arising under or pursuant to or touching upon this contract shall be referred to the sole arbitrator constituted by the competent authority of ICMR. The award of the sole arbitrator shall be final and binding on both the parties under the provisions of the Arbitration and conciliation Act, 1996 or any statutory modification / reenactment thereof for the time being in force. Such arbitration shall be held at New Delhi.
- The vendor shall continue work under the Contract during the arbitration proceedings unless
  otherwise directed in writing by ICMR or unless the matter is such that the work cannot
  possibly be continued until the decision of the Arbitrator or the umpire, as the case may be,
  is obtained.
- The venue of the Arbitration shall be in Delhi. Any disputes would be subject to jurisdiction of Delhi courts only.

#### FORMAT-1

### **Covering Letter**

# (The covering letter should be on the Letter Head of the Bidding Company/Institute/Organization)

Date:
Reference No:
From:(Insert name and address of Bidding Company/ Institute/Organization)
Tel.:
Fax:
E-mail address :
To,
Director General
Indian Council of Medical
Research V. Ramalingaswami
Bhawan,
Ansari Nagar East, NewDelhi-
110029
<b>Sub:</b> Response to RFP Document Nodatedfor RFP document for conducting Phase I human trial on Phytopharmaceutical drug through DCGI approval.
Dear Sir,
We, the undersigned*insert name of the 'Bidder'+ having read, examined and understood in detail the RFP Document hereby submit our response to RFP Document. We confirm that in response to the aforesaid RFP Document, we including have not submitted more than one response to RFP Document including this response to RFP Document.
1. We give our unconditional acceptance to the RFP Document, dated*Insert date in dd/mm/yyyy], issued by ICMR. In token of our acceptance to the RFP Document, the same have been initialed by us and enclosed with the response to RFP Document.
2. We have enclosed EMD of Rs(Insert Amount), in the form of DD/Pay Order no*Insert DD/Pay Order number & dated*Insert date of DD/Pay Order.

- 3. We have submitted our response to RFP Document strictly as per Formats for Bid submission of this RFP Document, without any deviations, conditions and without mentioning any assumptions or notes in the said Formats. We are hereby submitting our Proposal, which includes Pre-Qualification, Technical bid and the Financial Bid sealed in a separate envelope.
- 4. We here by unconditionally and irrevocably agree and accept that the decision made by ICMR in respect of any matter regarding or arising out of the RFP Document shall be binding on us. We hereby expressly waive and withdraw any deviations and all claims in respect of this process.
- 5. Familiarity with Relevant Indian Laws & Regulations:
  We confirm that we have studied the provisions of the relevant Indian laws and regulations as required to enable us to submit this response to RFP Document, in the event of our selection as Successful Bidder.
- 6. We are enclosing here with our response to the EOI Document with formats duly signed as desired by you in the RFP Document for your consideration.
- 7. It is confirmed that our response to the EOI Document is consistent with all the requirements of submission as stated in the RFP Document and subsequent communications from ICMR.
- 8. The information submitted in our response to the EOI Document is correct to the best of our knowledge and understanding. We would be solely responsible for any errors or omissions in our response to the RFP Document.
- 9. We hereby declare that our company has not been debarred/ blacklisted by any Central/State Govt. Ministry or Department/Public Sector company/Government autonomous body.
- 10. We confirm that all the terms and conditions of our Bid are valid upto\_\_\_\_\_\_(Insert date in dd/mm/yyyy) for acceptance (i.e. a period of hundred eighty (180days from the date of opening of RFP).
- 11. Contact Person Details of the representative to be contacted by ICMR are furnished as under:

Name:	
Designation:	
Company/Agency:	
Address:	
Phone Nos.:	
Mobile Nos.:	

Fax Nos.	:		 				 		
E-mail ad	dress	:	 			 		 	

12. We have neither made any statement nor provided any information in this Bid, which, to the best of our knowledge, is materially inaccurate or misleading. Further, all the confirmations, declarations and representations made in our Bid are true and accurate. In case this is found to be incorrect after our selection as successful bidder, we agree that the same would be treated as a Seller's event of default.

Dated the day of , 20...

Thanking you,

Yours faithfully,

(Name, Designation and Signature of Authorized Person)

#### **FORMAT-2**

# FORMAT FOR PERFORMANCE BANK GUARANTEE (To be on Rs100/-non-judicial stamp paper)

In consideration of the[Insert name of the Bidder] (herein after referred to as selected Bidder') submitting the response to Bid inter alia for "Conducting a Phase I human Trial on a Phytopharmaceutical Drug through DCGI approval" by Indian Council of Medical Research (ICMR) and at study site/subsites in response to the Bid datedissued by Indian Council of Medical Research (herein after referred to as ICMR) and ICMR considering such response to the Bid of*insert the name of the selected Successful Bidder] (which expression shall unless repugnant to the context or meaning thereof include its executers, administrators, successors and assignees) and selecting Successful Bidder/Trader and issuing Letter of award Noto(Insert Name of selected Successful Bidder) as per terms of Bid and the same having been accepted by the selected Successful Bidder, M/s, if applicable]. As per the terms of the RFP, the
[insert name, branch code & address of bank] hereby agrees
unequivocally, irrevocably and unconditionally to pay to ICMR at [Insert Name of the Place from the address of ICMR] forth with on demand in writing from ICMR or any Officer authorized by it in this behalf, any amount up to and not exceeding Rupees[Total Value] only, on behalf of M/s
[Insert name of the selected Successful Bidder]
This guarantee shall be valid and binding on this Bank upto and includingand shall not be terminable by notice or any change in the constitution of the Bank or the term of contract or by any other reasons what so ever and our liability here under shall not be impaired or discharged by any extension of time or variations or alternations made, given, or agreed with or without our knowledge or consent, by or between parties to the respective agreement.
Our liability under this Guarantee is restricted to Rsonly).
Our Guarantee shall remain in force untilICMR shall be entitled to invoke this Guarantee till
The Guarantor Bank hereby agrees and acknowledges that ICMR shall have a right to invoke this BANK GUARANTEE in part or in full, as it may deem fit.
The Guarantor Bank hereby expressly agrees that it shall not require any proof in addition to the written demand by ICMB, made in any format, raised at the above

addition to the written demand by ICMR, made in any format, raised at the above mentioned address of the Guarantor Bank, in order to make the said payment to ICMR.

The Guarantor Bank shall make payment here under on first demand without restriction or conditions and not withstanding any objection by-----[Insert name of the selected Successful Bidder] and/or any other person. The Guarantor Bank shall not require ICMR to justify the invocation of this BANKGUARANTEE, nor shall the Guarantor Bank have any recourse against ICMR in respect to any payment made hereunder

This BANK GUARANTEE shall be interpreted in accordance with the laws of India and the courts at Delhi shall have exclusive jurisdiction.

The Guarantor Bank represents that this BANK GUARANTEE has been established in such form and with such content that it is fully enforceable in accordance with its terms as against the Guarantor Bank in the manner provided herein.

This BANK GUARANTEE shall not be affected in any manner by reason of merger, amalgamation, restructuring or any other change in the constitution of the Guarantor Bank.

This BANK GUARANTEE shall be a primary obligation of the Guarantor Bank and accordingly ICMR shall not be obliged before enforcing this BANK GUARANTEE to take any action in any court or arbitral proceedings against the selected Successful Bidder, to make any claim against or any demand on the selected Successful Bidder or to give any notice to the selected Successful Bidder or to enforce any security held by ICMR or to exercise, levy or enforce any distress, diligence or other process against the selected Successful Bidder

	I herein above, our liability under this Guarantee is only) and it shall remain in force
	y the guaranteed amount or any part thereof under
this Bank Guarantee only if ICMR serv	ves upon us a written claim or demand.
Signature	
Name Power of Attorney No	
Power of Attorney No	
Ган	
For[Insert Name of the Bank]	
IIISER Name of the bankj	
Banker's Stamp and Full Address. Dated	thisday of,20
Witness:	
1	2
Signature	Signature
Name and Address	Name and Address

Note: The Performance Bank Guarantee shall be executed by any of the Nationalized Bank.

# Format-3 Compliance Sheet and Check List for Pre-Qualification

S.No	Basic Requirement	Required	Provided	Reference & Page Number
1	Document Fee		Yes/No	
2	Power of Attorney		Yes/No	
3	Particulars of the Bidders		Yes/No	
4	Earnest Money Deposit		Yes/No	
5	The Agency should be an entity registered in India under the Company Act, 1956/2013 or have a registered office in India		Yes/No	
6	Turnover Aggregate Turnover of the Agency for the last three Financial years 2016-17, 2017-18, 2018-19		Yes/No	
7	The Organization should have a valid GST Registration and Income Tax returns and PAN card.		Yes/No	
8	Organogram/Organization chart and infrastructure		Yes/No	
9	List of study team members their qualification and past		Yes/No	
10	List giving important clients/ number and list of projects handled in this field		Yes/No	

### FORMAT- 4

### **FINANCIAL PROPOSAL**

### **Covering Letter**

(On Bidder's letter head)

[Date and Reference]	
To,	
The Director General Indian Council of Medical Research V. Ramalingaswamy Bhawan, Ansari Nagar East, New Delhi-110029	
Tel./Fax No.:	
Phytopharmaceutical Drug through	ument for "Conducting a Phase I human Trial on a gh DCGI/CDSCO approval" by Indian Council of Medical sites by ICMR vide RFP Document No
Dear Sir,	
I/We,	(Applicant's name) enclose here with the Financial Proposal
	ny/agency for "Conducting a Phase I human Trial on a DCGI/CDSCO approval", as a Bidder.
	main valid for a period of 180 (One Hundred eighty) days from h further period as may be mutually agreed upon.
Yours faithfully,	
(Signature, name and designation	of the Authorized Signatory)
(Signature, name and designation	of the Authorized Signatory) submitted strictly as performs given in the RFP Document.

# FORMAT-5 FINANCIAL COST SHEET

**Subject:-** Response to RFP Document No--------Dated------for "Conducting a Phase I human Trial on a Phytopharmaceutical Drug through DCGI/CDSCO approval".

Table-A: Cost Break-up

SI. No.	Key Technical service personnel	Total Cost (In Rs.) In Figures	Total Cost (In Rs.) In Words
1	Medical Writing Task for developing a phase I human trial protocol, drafting of Investigator's Brochure (based on CMC and available preclinical and clinical data); Patient Informed Consent Form, CRF/eCRF design in accordance with appendix- X, schedule Y, Drugs and cosmetics act 1940. (Excluding Taxes)		
2	Preparation, submission and obtaining ethics approval of Phase I trial protocol and other documents, obtaining trial/volunteers insurance and follow up till study approval, enrollment of participants, sample collection & processing, monitoring of trial, preparation and maintenance of Trial master file/site files, DSMB and pharmacovigilance in case of any serious adverse effect (SAE) or adverse effect (AE), management of trial at sites till study completion & archival of data as per the regulatory norms. (Excluding Taxes)		
3	DM functions (Clinical Data management and data archival for 15 years). (Excluding Taxes)		
4	Data analysis and preparation of clinical trial report ready for submission. (Excluding Taxes)		
5	Taxes and statutory Levies GST Others, please specify.		
6	Total Cost Inclusive of Taxes and Levies.		

#### Note:

- 1. Total cost shall be quoted as a fixed amount in Indian Rupees only. Conditional proposal shall be summarily rejected.
- 2. In the event of any discrepancy between the values entered in figures and in words, the values entered in words shall be considered.
- 3. The values (both in figures and words) should be clear and there should be no over writing. In case of the overwriting, ICMR reserves the right to take decision accordingly.
- 4. In the event of arithmetic calculation mistake, the price in words shall be considered for calculation.
- 5. All figures are to be rounded off to the nearest Rupee only. Any figures given in paisa will be not considered.

Authorized Signatory Name Designation Name of the Company Address

#### **FORMAT-6**

#### **Draft Contract Agreement**

#### (To be executed on Rs.100/-Stamp Paper/s)

This Agreement is made at New Delhi on the	day of	2018
	Between India	an Council of Medical
Research, Ansari Nagar, New Delhi 110029 here	ein after called	
"the Purchaser" of the one part and (Name of	Successful Bidder)(A	ddress of Successful
Bidder)herein after called "the Supplie	r" of the other part. of	_

Whereas the Purchaser is desirous that certain Works should be executed, viz Whereas the Purchaser is desirous that certain Works should be executed, viz "CRO services for ICMR's on Conducting a Phase I human Trial on a Phytopharmaceutical Drug through DCGI approval" by Indian Council of Medical Research (ICMR)"(as described on these bidding documents) herein after called "the Works" and has accepted a bid by the Supplier for the execution and completion of such works and the remedying of defects therein. NOW THIS AGREEMENT WITNESSET Has follows:

(as described on these bidding documents) herein after called" the Works" and has accepted a bid by the Supplier for the execution and completion of such works and the remedying of defects therein. NOW THIS AGREEMENT WITNESSET Has follows:

- 1. In this Agreement words and expression shall have the same meanings as a respectively assigned to them in the Conditions of Contract herein after referred to.
- 2. The following documents shall be deemed to form and be read/construed as part of this Agreement, viz:
  - Letter of Award and Acceptance
  - Bid Information Sheet
  - Bid information and Instructions to Bidders
  - Bid Evaluation
  - Special Conditions of Contract (SCC)
  - General Conditions of Contract (GCC)
  - Formats for submission of Bid
- 3. In consideration of the payments to be made by the Purchaser to the Supplier as herein after mentioned, the Supplier hereby covenants with the Purchaser to execute and complete the works by\*\*\_and remedy any defects therein in conformity in all respects with the provisions of the Contract.
- 4. The Purchaser hereby covenants to pay the Supplier in consideration of the execution

**Rsbeing the sum state	edying of defects therein, the Contract Price of ed in the letter of award subject to such additions by be made under the provisions of the Contract at y the Contract.						
Jurisdiction of Court: The Courts at Delhi/New Delhi shall have the exclusive jurisdiction to try all disputes arising out this agreement between the parties with cause of action arising at New Delhi. Other disputes with cause of action arising at the respective Institutes of ICMR shall be within the concerned Courts/Tribunals of respective city where the Institutes is situated.							
	re to have caused their respective Common Seals nto set their respective hands and seals) the day						
For and on behalf of the Supplier of the authorized official the official Stamp/Seal of the Supplier	For and on behalf of the Purchaser Signature Signature o the authorized official Name of Name of the official Stamp/Seal of the Purchaser						
SIGNED, SEALED AND DELIVERED  By the saidon behalf of	By the said Name						
The Supplier in the presence	on behalf of						
of: Witness	the Purchaser in the presence of:						
	Witness						
Name	Name						
Address	Address						
	finalization of the Form of Agreement.						
Note:  **Blanks to be filled by the Purchaser at the time of							

#### **FORMAT-7**

# Support Personnel Details

Sr.No.	Name and designation	Qualification /Certifications possessed	Years of Experience in bidder's Organization	Total years of experience	Mobile No.
	Lead Manager/ Director				
2	Project Manager				

#### Note:

1. The updated CV of the above Support Personnel has to be submitted as part of EOI submission. Each CV must be signed and stamped by the authorized person on behalf of the Bidder.

(Signature, name and designation of the Authorized Signatory)

#### Format- 8

#### **Agency Aggregate Turnover Information Sheet**

We hereby certify that the aggregate turnover of M/s(name of the bidder) for the last three years is as given below:							
Annual turnover for the last 3 Financial Years in Indian Rupees (in Crores)							
Year(2017-2018)	Year(2018-2019)	Year(2019-2020)	Aggregate				
We also certify that the average annual turnover of M/s(name of the bidder) or the last three years are as given below:							
Annual turnover from for the last 3 Financial Years in Indian Rupees(in Crores)							

Year(2019-2020)

Average

Year(2018-2019)

(Signature of Statutory Auditor/CA) Name of Statutory Auditor/CA:

Year(2017-2018)

Name of Statutory Auditor/CA Firm: Seal

#### Format-9

### Declaration that the agency has not been blacklisted in last three years

(To be submitted on the Letterhead of the responding SI) {Place} {Date}
To,
Ref: RFP Notification no./ Ref No:dateddated
Subject: Self Declaration of not been blacklisted in response to the RFP for Conducting a Phase I human Trial on a Phytopharmaceutical Drug through DCGI approval' by ICMR
Dear Sir,
We confirm that our company/agency,, is not black listed in any manner what so ever by any of the State/UT and/or central government in India in last three years on any ground including but not limited to indulgence in corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practice.
Place: Date: Bidder's Company/Agency/Institute Seal: Authorized Signatory's Signature: Authorized Signatory's Name and Designation:

Note: The Bidder shall necessarily provide a copy of 'Power of Attorney' authorizing the Signatory for signing the Bid on behalf of the Bidder in its Pre-Qualification Bid.

#### **FORMAT-10**

#### FORMAT FOR BID SECURITY BANK GUARANTEE

(OnRs100/- stamp paper from any Nationalized Bank or Scheduled Bank)

To, The Director General Indian Council of Medical Research, V. Ramalingaswami Bhawan, Ansari Nagar East, New Delhi-29

Dear Sir,

	consideration		•	•					
				) in	ı lie	eu of	payme	ent from	M/s
				(herein	after	called	the Bide	der) towards	s Bid
secu	urity in respect	of yo	our RI	FP no					
					ie fulf	illment o	of the teri	ms and cond	ditions
of t	he said RFP, mnified to the e	we he	ere by						
			(Rup	ees					)
suffe of a argu you liabi	he event of an ered by you by ny terms and co ument, and with in full satisfaction lity under t	reasor endition out reconnofy his	n of any ns of the eference our de guaran	breach or e said RFP to the bic mand the a tee shall (Rupees	non-o , we s lder, i moun not	bservan hall on d rrevocal ts claime at	ce on the demand a oly and u ed by you	part of the E and without can inconditionall in provided th	Bidder avil or y pay at our
						) .			

This guarantee here in contained shall remain in full force and till you finalise the bid and select the bidder as per your choice and it shall in the event of the said bidder beings elected and entrusted with the said work, continue to been forcible till the said bidder executes the Agreement with you and commences the work as stipulated under the terms and conditions of the said RFP have been fully and properly carried out the said bidder and accordingly discharges the guarantee.

We also agree that your decision as to whether the bidder has committed any breach or non-observance of the terms and conditions of the said RFP shall be final and binding on us.

We undertake to pay you any money so demanded by you not withstanding any dispute or disputes raised by the Contractor(s) in any suit or proceedings pending before any Court or Tribunal relating there to, our liability under this present being absolute and equivocal.

The payment so made by us under this bond shall be valid discharge of our liability for payment there under and the contractor(s) shall have no claim against us for making such a payment.

This guarantee shall continue to be in full force and effect for a period of......days from the date of issue. Notwithstanding the above limitations, we shall honour and discharge the claims preferred by you within thirty days of expiry of this guarantee.

We shall not revoke this guarantee during its currency except with your previous consent in writing. This guarantee shall not be affected by any change in Constitution of our bank or of the bidder firm. Your neglect or forbearance in the enforcement of the payment of any money, the payment where of is intended to be hereby secured or the giving of time for the payment hereto shall in no way relieve us from our liability under this guarantee.

Yours faithfully,
Signature &seal of the

Bank (Authorised

Signatory)

Dated.....