

Request for Proposals (RFP)

The provision of services for conducting Phase I clinical trials on human participants in South Africa for the CSIR

RFP No. 1047.3/08/05/2023

Date of Issue	24 April 2023	
Compulsory / <u>Non-Compulsory</u> Briefing MS Team / Session or Site Inspection	Date and Time	N/A
	Address/Link	N/A
Enquiries	Strategic Procurement Unit	E-mail: tender@csir.co.za
	Please use RFP No and RFP Description as subject reference	
Last date for submission of enquiries/clarifications	01 May 2023	
Electronical Submission	tender@csir.co.za (If tenders exceed 25MB multiple emails can be sent)	
CSIR business hours	08h00 – 16h30	
Category	Professional Services	
Closing Date and Time	08 May 2023	

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`SECTION A
GENERAL RFP TERMS AND CONDITIONS

1 INTRODUCTION

The Council for Scientific and Industrial Research (CSIR) is one of the leading scientific research and technology development organisations in Africa. In partnership with national and international research and technology institutions, the CSIR undertakes directed and multidisciplinary research and technology innovation that contributes to the improvement of the quality of life of South Africans. The CSIR's main site is in Pretoria while it is represented in other provinces of South Africa through regional offices.

2 SUBMISSION OF PROPOSALS

- 2.1 All proposals are to be submitted electronically to tender@csir.co.za. No late proposals will be accepted.
- 2.2 All proposals will only be considered if received by the CSIR before the closing date and time (***as indicated on the cover page***). The CSIR business hours are between **08h00** and **16h30**.
- 2.3 All emailed proposal submissions are to be clearly subject-referenced with the **RFP number and RFP Description**. Proposals must consist of two parts, each of which must be sent in two separate emails with the following subject:

PART 1: Technical Proposal (Please indicated the RFP Number on each Files/folder)

PART 2: Pricing Proposal, Specific Goals claim documentation: RFP No

:1047.3/08/05/2023 (Please indicated the RFP Number on each Files/folder)

- 2.4 Proposals submitted by companies must be signed by a person or persons duly authorised.
- 2.5 Proposals submitted at incorrect location, will not be accepted for considerations and where practicable, be returned unopened to the Bidder(s).

- 2.6 Proposals received after the closing date and time, at the address indicated in the bid documents, will not be accepted for consideration and where practicable, be returned unopened to the Bidder(s).
- 2.7 All dates and times in this bid are South African standard time.
- 2.8 Any time or date in this bid is subject to change at the CSIR's discretion. The establishment of a time or date in this bid does not create an obligation on the part of the CSIR to take any action or create any right in any way for any bidder to demand that any action be taken on the date established. The bidder accepts that, if the CSIR extends the deadline for bid submission (the Closing Date) for any reason, the requirements of this bid otherwise apply equally to the extended deadline.
- 2.9 Documents submitted via cloud solutions such as: WeTransfer, Google Drive, Dropbox, etc. will not be considered.
- 2.10 The naming / labelling syntax of files or documents must be short and simple.
- 2.11 The CSIR will award the contract to qualified tenderer(s)' whose proposal is determined to be the most advantageous to the CSIR, taking into consideration the technical (functional) solution, price and specific goals.

3 COUNTER CONDITIONS

Bidders' attention is drawn to the fact that amendments to any of the RFP Conditions or setting of counter conditions by Bidders or qualifying any RFP Conditions will result in the invalidation of such bids.

4 FRONTING

- 4.1 Government supports the spirit of broad based black economic empowerment and recognizes that real empowerment can only be achieved through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent and legally compliant manner. Against this background the Government condemn any form of fronting.

- 4.2 The Government, in ensuring that Bidders conduct themselves in an honest manner will, as part of the RFP evaluation processes, conduct or initiate the necessary enquiries/investigations to determine the accuracy of the representation made in bid documents. Should any of the fronting indicators as contained in the Guidelines on Complex Structures and Transactions and Fronting, issued by the Department of Trade and Industry, be established during such enquiry / investigation, the onus will be on the Bidder / contractor to prove that fronting does not exist. Failure to do so within a period of 14 days from date of notification may invalidate the bid / contract and may also result in the restriction of the Bidder /contractor to conduct business with the public sector for a period not exceeding ten years, in addition to any other remedies the CSIR may have against the Bidder / contractor concerned.

5 **PRICING PROPOSAL**

- 5.1 Pricing must be provided in South African Rand (including all applicable taxes less all unconditional discounts).
- 5.2 Prices that are subject to escalation and exchange rate fluctuations are to be clearly indicated, with the currency and ROE used in the quotation must be clearly indicated.
- 5.3 Price should include additional cost elements such as travel cost, freight, insurance until acceptance, duty where applicable, etc.
- 5.4 Payment will be according to the CSIR Payment Terms and Conditions ([Link](#)).
- 5.5 Please provide a detail pricing using a Pricing Schedule/Bill of Quantities outlined under **Annexure D. Pricing must strictly be in accordance with the Pricing Schedule.**

6 **APPOINTMENT OF SERVICE PROVIDER**

- 6.1 The contract will be awarded to the tenderer who scores the highest total number of points during the evaluation process, except where the law permits otherwise.
- 6.2 Appointment as a successful service provider shall be subject to the parties agreeing to mutually acceptable contractual terms and conditions. In the event of the parties failing to reach such agreement, CSIR reserves the right to appoint an alternative supplier.

- 6.3 Awarding of contracts will be published on the same platform where the bid was published, and no regret letters will be sent to unsuccessful bidders.

7 SERVICE LEVEL AGREEMENT

- 7.1 Upon award the CSIR and the successful bidder will conclude a Service Level Agreement in line with applicable form of contract (i.e. [Draft Supplier Agreement](#)) regulating the specific terms and conditions applicable to the services being procured by the CSIR, more or less in the format of the draft Service Level Indicators (**Annexure M**) included in this tender pack.
- 7.2 Bidder(s) are requested to:
- a. Comment on draft Service Level Indicators and where necessary, make proposals to the indicators;
 - b. Explain each comment and/or amendment; and
 - c. Use an easily identifiable colour font or “track changes” for all changes and/or amendments to the Service Level Indicators for ease of reference.
- 7.3 The CSIR reserves the right to accept or reject any or all amendments or additions proposed by a bidder if such amendments or additions are unacceptable to the CSIR or pose a risk to the organisation.

8 ENQUIRIES AND CONTACT WITH THE CSIR

Any enquiry regarding this RFP shall be submitted in writing to CSIR to the email and format outlined in the table on cover page of this RFP document.

Any other contact with CSIR personnel involved in this tender is not permitted during the RFP process other than as required through existing service arrangements or as requested by the CSIR as part of the RFP process.

9 MEDIUM OF COMMUNICATION

All documentation submitted in response to this RFP must be in English.

10 CORRECTNESS OF RESPONSES

- 10.1 The tenderer must confirm satisfaction regarding the correctness and validity of their proposal and that all prices and rates quoted cover all the work/items specified in the RFP. The prices and rates quoted must cover all obligations under any resulting contract.
- 10.2 The tenderer accepts that any mistakes regarding prices and calculations will be at their own risk.

11 VERIFICATION OF DOCUMENTS

- 11.1 Tenderers should check the numbers of the pages to satisfy themselves that none is missing or duplicated. No liability will be accepted by the CSIR in regard to anything arising from the fact that pages are missing or duplicated.
- 11.2 Pricing schedule and specific goals credentials should be submitted with the proposal, but as a separate document and no such information should be available in the technical proposal.

12 RESPONSIBILITY FOR SUB-CONTRACTORS AND BIDDER'S PERSONNEL

A bidder is responsible for ensuring that its personnel (including agents, officers, directors, employees, advisors and other representatives), its sub-contractors (if any) and personnel of its sub-contractors comply with all terms and conditions of this bid. In the event that the CSIR allows a bidder to make use of sub-contractors, such sub-contractors will at all times remain the responsibility of the bidder and the CSIR will not under any circumstances be liable for any losses or damages incurred by or caused by such sub-contractors.

13 ADDITIONAL TERMS AND CONDITIONS

- 13.1 A tenderer shall not assume that information and/or documents supplied to CSIR, at any time prior to this request, are still available to CSIR, and shall consequently not make any reference to such information document in its response to this request.
- 13.2 Copies of any affiliations, memberships and/or accreditations that support your submission must be included in the tender.

13.3 In case of proposal from a joint venture, the following must be submitted together with the proposal:

- Joint venture Agreement including split of work signed by both parties;
- The Tax Compliance Status (TCS) of each joint venture member;
- Proof of ownership/shareholder certificates/copies; and
- Company registration certificate.

13.4 An omission to disclose material information, a factual inaccuracy, and/or a misrepresentation of fact may result in the disqualification of a tender, or cancellation of any subsequent contract.

13.5 Failure to comply with any of the terms and conditions as set out in this document will invalidate the Proposal.

14 SPECIAL CONDITIONS

The CSIR reserves the right to:

- 14.1 Extend the closing date of this RFP;
- 14.2 Correct any mistakes at any stage of the tender that may have been in the Bid documents or occurred at any stage of the tender process;
- 14.3 Verify any information contained in the bidder's submission;
- 14.4 Request documentary proof regarding the bidder's submission;
- 14.5 Carry out site inspections, product evaluations or explanatory meetings in order to verify the nature and quality of the product/service offered by the bidder(s) or verify any information whether before or after the adjudication of this RFP;
- 14.6 Award this RFP as a whole or in part;
- 14.7 Award this RFP to multiple bidders;
- 14.8 Cancel and/or terminate the tender process at any stage, including after the Closing Date and/or after presentations have been made, and/or after tenders have been evaluated and/or after the preferred bidder(s) have been notified of their status as such.

15 CONFLICT OF INTEREST, CORRUPTION AND FRAUD

- 15.1 The CSIR reserves its right to disqualify any bidder who either itself or any of whose members (save for such members who hold a minority interest in the bidder through shares listed on any recognised stock exchange), indirect members (being any person or entity who indirectly holds at least a 15% interest in the bidder other than in the context of shares listed on a recognised stock exchange), directors or members of senior management, whether in respect of CSIR or any other government organ or entity and whether from the Republic of South Africa or otherwise ("Government Entity")
- a. engages in any collusive tendering, anti-competitive conduct, or any other similar conduct, including but not limited to any collusion with any other bidder in respect of the subject matter of this bid;
 - b. seeks any assistance, other than assistance officially provided by a Government Entity, from any employee, advisor or other representative of a Government Entity in order to obtain any unlawful advantage in relation to procurement or services provided or to be provided to a Government Entity;
 - c. makes or offers any gift, gratuity, anything of any value or other inducement, to any Government Entity's officers, directors, employees, advisors or other representatives in order to obtain any unlawful advantage in relation to procurement or services provided or to be provided to a Government Entity;
 - d. accepts anything of value or an inducement that would or may provide financial gain, advantage or benefit in relation to procurement or services provided or to be provided to a Government Entity;
 - e. pays or agrees to pay to any person any fee, commission, percentage, brokerage fee, gift or any other consideration, that is contingent upon or results from, the award of any tender, contract, right or entitlement which is in any way related to procurement or the rendering of any services to a Government Entity;
 - f. has in the past engaged in any matter referred to above; or
 - g. has been found guilty in a court of law on charges of fraud and/or forgery, regardless of whether or not a prison term was imposed and despite such bidder, member or director's name not specifically appearing on the List of Tender Defaulters kept at National Treasury.

16 MISREPRESENTATION DURING THE LIFECYCLE OF THE CONTRACT

16.1 The bidder should note that the terms of its Tender will be incorporated in the proposed contract by reference and that the CSIR relies upon the bidder's Tender as a material representation in making an award to a successful bidder and in concluding an agreement with the bidder.

16.2 It follows therefore that misrepresentations in a Tender may give rise to service termination and a claim by the CSIR against the bidder notwithstanding the conclusion of the Service Level Agreement between the CSIR and the bidder for the provision of the Service in question. In the event of a conflict between the bidder's proposal and the Service Level Agreement concluded between the parties, the Service Level Agreement will prevail.

17 PREPARATION COSTS AND LIMITATION OF LIABILITY

The Bidder will bear all its costs in preparing, submitting and presenting any response or Tender to this bid and all other costs incurred by it throughout the bid process. Furthermore, no statement in this bid will be construed as placing the CSIR, its employees or agents under any obligation whatsoever, including in respect of costs, expenses or losses incurred by the bidder(s) in the preparation of their response to this bid.

A bidder participates in this bid process entirely at its own risk and cost. The CSIR shall not be liable to compensate a bidder on any grounds whatsoever for any costs incurred or any damages suffered as a result of the Bidder's participation in this Bid process.

18 INDEMNITY

If a bidder breaches the conditions of this bid and, as a result of that breach, the CSIR incurs costs or damages (including, without limitation, the cost of any investigations, procedural impairment, repetition of all or part of the bid process and/or enforcement of intellectual property rights or confidentiality obligations), then the bidder indemnifies and holds the CSIR harmless from any and all such costs which the CSIR may incur and for any damages or losses the CSIR may suffer.

19 PRECEDENCE

This document will prevail over any information provided during any briefing session whether oral or written, unless such written information provided, expressly amends this document by reference.

20 TAX COMPLIANCE

No tender shall be awarded to a bidder who is not tax compliant. The CSIR reserves the right to withdraw an award made, or cancel a contract concluded with a successful bidder in the event that it is established that such bidder was in fact not tax compliant at the time of the award, or has submitted a fraudulent Tax Clearance Certificate to The CSIR, or whose verification against the Central Supplier Database (CSD) proves non-compliant. The CSIR further reserves the right to cancel a contract with a successful bidder in the event that such bidder does not remain tax compliant for the full term of the contract.

21 TENDER DEFAULTERS AND RESTRICTED SUPPLIERS

No tender shall be awarded to a bidder whose name (or any of its members, directors, partners or trustees) appear on the Register of Tender Defaulters kept by National Treasury, or who have been placed on National Treasury's List of Restricted Suppliers. The CSIR reserves the right to withdraw an award, or cancel a contract concluded with a Bidder should it be established, at any time, that a bidder has been blacklisted with National Treasury by another government institution.

22 GOVERNING LAW

South African law governs this bid and the bid response process. The bidder agrees to submit to the exclusive jurisdiction of the South African courts in any dispute of any kind that may arise out of or in connection with the subject matter of this bid, the bid itself and all processes associated with the bid.

23 CONFIDENTIALITY

Except as may be required by operation of law, by a court or by a regulatory authority having appropriate jurisdiction, no information contained in or relating to this bid or a

bidder's tender(s) will be disclosed by any bidder or other person not officially involved with the CSIR's examination and evaluation of a Tender.

No part of the bid may be distributed, reproduced, stored or transmitted, in any form or by any means, electronic, photocopying, recording or otherwise, in whole or in part except for the purpose of preparing a Tender. This bid and any other documents supplied by the CSIR remain proprietary to the CSIR and must be promptly returned to the CSIR upon request together with all copies, electronic versions, excerpts or summaries thereof or work derived there from.

Throughout this bid process and thereafter, bidder(s) must secure the CSIR's written approval prior to the release of any information that pertains to (i) the potential work or activities to which this bid relates; or (ii) the process which follows this bid. Failure to adhere to this requirement may result in disqualification from the bid process and civil action.

24 AVAILABILITY OF FUNDS

Should funds no longer be available to pay for the execution of the responsibilities of this bid, the CSIR may terminate the Agreement at its own discretion or temporarily suspend all or part of the services by notice to the successful bidder who shall immediately make arrangements to stop the performance of the services and minimize further expenditure: Provided that the successful bidder shall thereupon be entitled to payment in full for the services delivered, up to the date of cancellation or suspension.

25 PERSONAL INFORMATION

- 25.1 Each Party consents to the other Party holding and processing "personal information" (as defined in the POPI Act) relating to it for legal, personnel, administrative and management purposes (including, if applicable, any "special personal information" relating to him/her, as defined in the POPI Act). Notwithstanding the generality of the aforesaid, each Party hereby undertakes to comply with all relevant provisions of the POPI Act and any other applicable data protection laws. The tenderer further agrees to comply with all CSIR's reasonable internal governance requirements pertaining to data protection.

25.2 Each Party consents to the other Party making such information available to those who provide products or services to such parties (such as advisers, regulatory authorities, governmental or quasi-governmental organisations and potential purchasers of such Party or any part of their business).

25.3 While performing any activity where a Party is handling personal information as a “responsible party” (as defined in the POPI Act), each Party undertakes that it will process the personal information strictly in accordance with the terms of the POPI Act, this Contract, and the other Party’s instructions from time to time, and take appropriate operational measures to safeguard the data against any unauthorised access.

25.4 Each Party acknowledges that in the course of conducting business with each other, each Party intends to maintain and process personal information about the other Party in an internal database. By signing this Contract, each Party consents to the maintenance and processing of such personal information.

Where relevant, the tenderer shall procure that all of its personnel, agents, representatives, contractors, sub-contractors and mandataries shall comply with the provisions of this clause 30 (Personal Information). The CSIR shall be entitled on reasonable notice to conduct an inspection or audit tenderers compliance with the requisite POPI Act safeguards.

26 DISCLAIMER

This RFP is a request for proposals only and not an offer document. Answers to this RFP must not be construed as acceptance of an offer or imply the existence of a contract between the parties. By submission of its proposal, tenderers shall be deemed to have satisfied themselves with and to have accepted all Terms & Conditions of this RFP. The CSIR makes no representation, warranty, assurance, guarantee or endorsements to tenderer concerning the RFP, whether with regard to its accuracy, completeness or otherwise and the CSIR shall have no liability towards the tenderer or any other party in connection therewith.

SECTION B

EVALUATION METHODOLOGY

27 EVALUATION CRITERIA

The CSIR has set minimum standards that a bidder needs to meet in order to be evaluated and selected as a successful bidder. The minimum standards consist of the following:

Elimination Criteria (Phase 1)	Technical Evaluation Criteria (Phase 2)	Price and Preference Points Evaluation (Phase 3)
Only bidders that comply with ALL the criteria set on paragraph 31.1 on Phase 1 below will proceed to Technical/Functional Evaluation (Phase 2).	Bidder(s) are required to achieve a predetermined minimum threshold on each of the individual criteria, and a predetermined minimum threshold on 100 points overall. Only bidder (s) who met and/or exceeded the minimum threshold points on Phase 2 below will proceed to Price and Specific Goals Evaluation (Phase 3)	Bidder(s) will be evaluated out of 100 points i.e. 80 points for Price and 20 points for Specific Goals.

27.1 Elimination Criteria (Phase 1)

Proposals will be eliminated under the following conditions:

- Bidders that submit late bids will not be considered.
- Bidders that submit to the incorrect location or email address will not be considered (Only electronic submission to tender@csir.co.za would be considered).
- Bidder that are listed on the NT database of restricted suppliers will not be considered.
- Bidders that are registered on the NT Register of Tender Defaulters will not be considered.
- Bidder that did not submit mandatory returnable documents as **Annexure E: Proposal Form and List of Returnable Documents**.
- Supplier does not demonstrated experience in conducting clinical trials in South Africa for respiratory infections/diseases such as asthma
- Supplier does not demonstrate the regulatory requirements to conduct clinical trials in South Africa
- Supplier that is going to outsource the clinical trial services from the third party

27.2 Technical Evaluation Criteria (Phase 2)

The evaluation of the functional / technical detail of the proposal will be based on the following criteria:

No	ELEMENT	WEIGHT
1	Qualifications for Lead Advisor	10%
2	At least 10 years of track record, previous experience and past performance in conducting clinical trials for a wide range of respiratory diseases or infections such as asthma	40%
3	Demonstrated knowledge and understanding of the South African regulatory affairs for conducting clinical trials	30%
4	Clinical trial design, monitoring and data management technical expertise in clinical research, e.g., pharmacovigilance, biostatistics, etc	20%
TOTAL (%)		100

Proposals with functionality / technical points of less than the pre-determined minimum overall percentage of 70 % and less than 50 % on each of the individual criteria will be eliminated from further evaluation on Price and Preference Points Evaluation.

Refer to **Annexure C (Technical Evaluation Matrix/Rubrics)** for the scoring ranges/rubrics that will be used to evaluate functionality.

The Bidder shall prepare for a possible presentation should the CSIR require such and the Bidder shall be notified thereof no later than four (4) days before the actual presentation date. As part of due diligence, the CSIR may also request to visit the bidder's site/facilities to view the equipment and other resources, or conduct a site visit at a client of the bidder (reference) for validation of the services rendered. The choice of site will be at CSIR's sole discretion.

27.3 Price and Preference Points Evaluation (Phase 3)

Only Bidders that have met meet minimum thresholds on Technical/functional Evaluation will be evaluated for price and preference points. Price and Preference Points will be evaluated as per **Annexure H: Preference Points Award Form**.

28 NATIONAL TREASURY CENTRAL SUPPLIER DATABASE (CSD) REGISTRATION

Respondents are required to self-register on National Treasury's Central Supplier Database (CSD) which has been established to centrally administer supplier information for all organs of state and facilitate the verification of certain key supplier information. Business may not be awarded to a Respondent who has failed to register on the CSD. Only foreign suppliers with no local registered entity need not register on the CSD. In order to enable the CSIR to verify information on the CSD, Respondents are required to provide the unique registration reference number: _____.

Before any negotiations will start with the winning bidder it will be required from the winning bidder to:

- be registered on National Treasury's Central Supplier Database (CSD). Registrations can be completed online at: www.csd.gov.za;
- provide the CSIR of their CSD registration number.

Annexure A

Standard Bidding Document (SBD) 1

PART A: INVITATION TO BID

YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE CSIR					
BID NUMBER:	1047.3/08/05/2023	CLOSING DATE:	08 May 2023	CLOSING TIME:	16:30
DESCRIPTION	THE PROVISION OF SERVICES FOR CONDUCTING PHASE I CLINICAL TRIALS ON HUMAN PARTICIPANTS IN SOUTH AFRICA FOR THE CSIR				
BID RESPONSE DOCUMENTS MAY BE DEPOSITED IN THE BID BOX SITUATED AT (STREET ADDRESS)					
In light of the Covid-19 pandemic, the CSIR requires that all tender submissions be submitted electronically to tender@csir.co.za . Should tender file size exceed 25MB, bidders submit tender in multiple emails. Use the tender number 1047.3/08/05/2023 and description of the tender as the subject on your email.					
BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO			TECHNICAL ENQUIRIES MAY BE DIRECTED TO:		
CONTACT PERSON		CONTACT PERSON			
TELEPHONE NUMBER		TELEPHONE NUMBER			
FACSIMILE NUMBER		FACSIMILE NUMBER			
E-MAIL ADDRESS	tender@csir.co.za	E-MAIL ADDRESS	tender@csir.co.za		
SUPPLIER INFORMATION					
NAME OF BIDDER					
POSTAL ADDRESS					
STREET ADDRESS					
TELEPHONE NUMBER	CODE		NUMBER		
CELLPHONE NUMBER					
FACSIMILE NUMBER	CODE		NUMBER		
E-MAIL ADDRESS					
VAT REGISTRATION NUMBER					
SUPPLIER COMPLIANCE STATUS	TAX COMPLIANCE SYSTEM PIN:		OR	CENTRAL SUPPLIER DATABASE No:	MAAA
1 ARE YOU THE ACCREDITED REPRESENTATIVE IN SOUTH AFRICA FOR THE GOODS /SERVICES /WORKS OFFERED?	☐ Yes ☐ No [IF YES ENCLOSE PROOF]		2 ARE YOU A FOREIGN BASED SUPPLIER FOR THE GOODS /SERVICES /WORKS OFFERED?		☐ Yes ☐ No [IF YES, ANSWER THE QUESTIONNAIRE BELOW]
QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS					
IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)?					☐ YES
☐ NO					

DOES THE ENTITY HAVE A BRANCH IN THE RSA? ☐ YES ☐ NO

DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA? ☐ YES ☐ NO

DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA? ☐ YES ☐ NO

IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION? ☐ YES ☐ NO

IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO REGISTER FOR A TAX COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE (SARS) AND IF NOT REGISTER AS PER 2.3 BELOW.

PART B: TERMS AND CONDITIONS FOR BIDDING

1. BID SUBMISSION:

- 1.1. BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION.
- 1.2. **ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED-(NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.**
- 1.3. THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.
- 1.4. **THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7).**

2. TAX COMPLIANCE REQUIREMENTS

- 2.1 BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS.
- 2.2 BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS.
- 2.3 APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA.
- 2.4 BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID.
- 2.5 IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED, EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER.
- 2.6 WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED.
- 2.7 NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE."

NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.

SIGNATURE OF BIDDER:

CAPACITY UNDER WHICH THIS BID IS SIGNED:
(Proof of authority must be submitted e.g. company resolution)

DATE:

Annexure B

Technical specification/scope of services for the provision of services for conducting phase I clinical trials on human participants in south Africa for the CSIR.

RFP No. 1047.3/08/05/2023

1 INVITATION FOR PROPOSAL

Proposals are hereby invited for the supply of services to the CSIR, to undertake Phase I clinical studies based on the plant species according to the requirements of South African Health Products Regulatory Authority (SAHPRA) requirements to conduct clinical trials on human participants and according to the South African Good Clinical Practice Guidelines and the CSIR Research Ethics Policy (CSIR-MS-POL-R&D-048 2007), respectively. The service provider must be certified South African Clinical Research Organisation with vast experience in conducting clinical studies for respiratory infections or diseases such as asthma.

The CSIR, through its Advanced Agriculture and Food and Next Generation Health Clusters, is implementing a project which seeks to add value to a South African indigenous plant species known as *Siphonochilus aethiopicus* through Phase I clinical studies to investigate safety on health individuals recruited for this activity. The CSIR has investigated toxicity of the *Siphonochilus aethiopicus* in vitro and in vivo studies, respectively. In both sets of experiments, the CSIR found that the plant species demonstrated no evidence of toxicity as shown by the data generated.

The CSIR further identified major chemical markers for quality purposes and has developed and optimised the extraction process technology during the research and development phase based on the plant species for the manufacture of safe and quality capsules, which can be implemented into the controlled manufacturing facility for manufacturing purposes. However, the CSIR does not have the clinical research capabilities to fully implement the project to completion. We are therefore requiring your clinical research services in support of the CSIR project.

2 PROPOSAL REQUIREMENTS

All proposals are to be submitted in a format specified in this enquiry (if applicable). However, tenderers are welcome to submit additional / alternative proposals over and above the originally specified format.

2.1 Technical Proposal

The following must be submitted as part of the **technical** proposal:

- a. Company profile.
- b. Detailed Technical Proposal
- c. CVs of the proposed individuals on the project.

2.2 Financial Proposal:

The following must be submitted as part of the **financial** proposal:

- Cover Letter.
- Completed Pricing Schedule (**Annexure D**) on official company letterhead.
- CSD registration report (RSA suppliers only).

3 PROPOSAL SPECIFICATION

3.1 Scope of Work

The type of services required:

- Protocol Development
- Follow up -Regulatory and Ethics
- Clinical Trial Conduct
- Analytical Lab
- Safety Labs
- Independent Monitor
- Data Management and Statistics
- Clinical Study Report

Proposal format, not limited to the following

- Company background
- Company demonstrated track record in conducting clinical trials in South Africa

- Knowledge and requirements for conducting clinical trials in South Africa
- Knowledge of respiratory infections including asthma
- Designing clinical trials
- Risks and mitigating factors
- Breakdown budget
- Project plan: milestones, deliverables, outcomes
- Partners (if any)

Annexure C

Evaluation Criteria

NO	CRITERIA	SCORING	WEIGHT
1.	Qualifications for Lead Principal Investigator Highest educational qualification obtained in: • Pharmaceutical Sciences • Clinical Sciences • Medical Technology	10 = PHD or higher 5 = Masters or higher 4= Honors degree or higher (NQF8); 4 = Degree (NQF7) 3 = National diploma (NQF6)	10%
2.	Years of experience, track record, previous experience and past performance in conducting clinical trials for a wide range of respiratory diseases or infections such as asthma.	10 = 10 years and more. 7 = more than 8 and up to 9 years 5 = more than 5 and up to 8 years 0 = 0 and up to 4 years	40%
3.	Demonstrated knowledge and understanding of the South African regulatory affairs for conducting clinical trials.	10 = Excellent (demonstrated at least four components and above) 7 = Good (demonstrated at least three components) 5 = Average (demonstrated at least two components) 1 = Below Average (demonstrated at least one components)	30%
4.	Years of experience in clinical trial design, monitoring and data management, technical expertise in clinical research, e.g., pharmacovigilance, biostatistics, etc.	10 = 10 years and more. 7 = more than 7 and up to 9 years 5 = more than 5 and up to 6 years 0 = 0 and up to 4 years	20%
	Total		100

	Minimum threshold	70%
--	-------------------	-----

Annexure D

Pricing Schedule- Professional Services

Provision of services for conducting phase I clinical trials on human participants in south Africa for the CSIR.

RFP No. 1047.3/08/05/2023

ITEM NO.	QUANTITY	DESCRIPTION	BID PRICE IN RSA CURRENCY ** (ALL APPLICABLE TAXES INCLUDED)	
1.		The accompanying information must be used for the formulation of proposals.		
2.		Bidders are required to indicate a ceiling price based on the total estimated time for completion of all phases and including all expenses inclusive of all applicable taxes for the project. R.....		
3.		PERSONS WHO WILL BE INVOLVED IN THE PROJECT AND RATES APPLICABLE (CERTIFIED INVOICES MUST BE RENDERED IN TERMS HEREOF)		
4.	PERSON AND POSITION RATE		HOURLY RATE	DAILY
		-----	R-----	-----
		-----	R-----	-----
		-----	R-----	-----
		-----	R-----	-----
		-----	R-----	-----
5.		PHASES ACCORDING TO WHICH THE PROJECT WILL BE COMPLETED, COST PER PHASE AND MAN-DAYS TO BE SPENT		
		-----	R-----	-----days
		-----	R-----	-----days
		-----	R-----	-----days
		-----	R-----	-----days

- 5.1 Travel expenses (specify, for example rate/km and total km, class of air travel, etc.). Only actual costs are recoverable. Proof of the expenses incurred must accompany certified invoices.

DESCRIPTION OF EXPENSE TO BE INCURRED	RATE AMOUNT	QUANTITY
.....	R.....	
.....	R.....	
.....	R.....	
.....	R.....	
TOTAL: R.....		

** "all applicable taxes" includes value- added tax, pay as you earn, income tax, unemployment insurance fund contributions and skills development levies.

- 5.2 Other expenses, for example accommodation (specify, eg. Three star hotel, bed and breakfast, telephone cost, reproduction cost, etc.). On basis of these particulars, certified invoices will be checked for correctness. Proof of the expenses must accompany invoices.

DESCRIPTION OF EXPENSE TO BE INCURRED	RATE	QUANTITY	AMOUNT
.....			
R.....			R.....
.....			R.....
R.....			
TOTAL:			R.....

6. Period required for commencement with project after acceptance of bid.....
7. Estimated man-days for completion of project.....
8. Are the rates quoted firm for the full period of contract?
*YES/NO
9. If not firm for the full period, provide details of the basis on which

adjustments will be applied for, for example consumer price
index.....
.....
.....

Annexure E

Proposal Form and List of Returnable Documents

**provision of services for conducting phase I clinical trials on human participants in
south Africa for the CSIR.**

RFP No. 1047.3/08/05/2023

I/We _____

[name of entity, company, close corporation or partnership] of [full address]

carrying on business trading/operating as

represented by _____ in my capacity
as

being duly authorised thereto by a Resolution of the Board of Directors or Members or Certificate
of Partners, dated _____ to enter into, sign execute and complete any documents
relating to this proposal and any subsequent Agreement. The following list of persons are hereby
authorised to negotiate on behalf of the abovementioned entity, should CSIR decide to enter into
Post Tender Negotiations with shortlisted bidder(s).

FULL NAME(S) CAPACITY SIGNATURE

I/We hereby offer to supply the abovementioned Services at the prices quoted in the schedule of prices in accordance with the terms set forth in the documents listed in the accompanying schedule of RFP documents.

I/We agree to be bound by those conditions in CSIR's:

1. General RFP Terms and Conditions; and
Any other standard or special conditions mentioned and/or embodied in this Request for Proposal.

I/We accept that unless CSIR should otherwise decide and so inform me/us in the letter of award/intent, this Proposal [and, if any, its covering letter and any subsequent exchange of correspondence], together with CSIR's acceptance thereof shall constitute a binding contract between CSIR and me/us.

I/We further agree that if, after I/we have been notified of the acceptance of my/our Proposal, I/we fail to enter into a formal contract if called upon to do so, or fail to commence the supply of Services within 4 [four] weeks thereafter, CSIR may, without prejudice to any other legal remedy which it may have, recover from me/us any expense to which it may have been put in calling for Proposals afresh and/or having to accept any less favourable Proposal.

I/We accept that any contract resulting from this offer will be for a period as determined by the CSIR.

Furthermore, I/we agree to a penalty clause/s which will allow CSIR to invoke a penalty against us for non-compliance with material terms of this RFP including the delayed delivery of the Services due to non-performance by ourselves, failure to meet Subcontracting.

I/we agree that non-compliance with any of the material terms of this RFP, including those mentioned above, will constitute a material breach of contract and provide CSIR with cause for cancellation.

ADDRESS FOR NOTICES

The law of the Republic of South Africa shall govern any contract created by the acceptance of this RFP. The domicilium citandi et executandi shall be a place in the Republic of South Africa to be specified by the Respondent hereunder, at which all legal documents may be served on the Respondent who shall agree to submit to the jurisdiction of the courts of the Republic of South Africa. Foreign Respondents shall, therefore, state hereunder the name of their authorised representative in the Republic of South Africa who has the power of attorney to sign any contract which may have to be entered into in the event of their Proposal being accepted and to act on their behalf in all matters relating to such contract.

Respondent to indicate the details of its domicilium citandi et executandi hereunder:

Name of Entity:

Facsimile: _____

Address: _____

NOTIFICATION OF AWARD OF RFP

As soon as possible after approval to award the contract(s), the successful Respondent [**the Service provider**] will be informed of the acceptance of its Proposal. Unsuccessful Respondents may be advised in writing of the name of the successful Service provider and the reason as to why their Proposals have been unsuccessful, for example, in the category of price, delivery period, quality, B-BBEE or for any other reason.

VALIDITY PERIOD

CSIR requires a validity period of 90 [Ninety calendar Days from closing date] against this RFP.

Bidders are to note that they may be requested to extend the validity period of their bid, at the same terms and conditions, if the internal evaluation process has not been finalised within the validity period. However, once the adjudication body has approved the process and award of the business to the successful bidder(s), the validity of the successful bidder(s)' bid will be deemed to remain valid until a final contract has been concluded.

NAME(S) AND ADDRESS / ADDRESSES OF DIRECTOR(S) OR MEMBER(S)

The Respondent must disclose hereunder the full name(s) and address(s) of the director(s) or members of the company or close corporation [**C.C.**] on whose behalf the RFP is submitted.

1. Registration number of company / C.C.

2. Registered name of company / C.C.

3. Full name(s) of director/member(s) Address/Addresses ID Number(s)

RETURNABLE DOCUMENTS

All Sections, as indicated in the footer of each page, must be signed, stamped and dated by the Respondent. **Returnable Documents** means all the documents, Sections and Annexures, as listed in the tables below.

a) Mandatory Returnable Documents

Failure to provide all Mandatory Returnable Documents at the closing date and time of this bid will result in a Respondent's disqualification. Bidders are therefore urged to ensure that all these documents are returned with their Proposals.

Please confirm submission of the mandatory Returnable Documents detailed below by so indicating [Yes or No] in the table below:

MANDATORY RETURNABLE DOCUMENTS	SUBMITTED [Yes/No]
Completed Annexure D: Pricing Schedule on official company letterhead.	
Cover Letter	
CSD registration report (RSA suppliers only).	
Letter of Good Standing	

b) Essential Returnable Documents

In addition to the requirements of section (a) above, Respondents are further required to submit with their Proposals the following **essential Returnable Documents** as detailed below.

Essential Returnable Documents required for evaluation purposes:

Failure to provide all essential Returnable Documents used for purposes of scoring a bid, by the closing date and time of this bid will not result in a Respondent's disqualification. However, Bidders will receive an automatic score of zero for the applicable evaluation criterion. Bidders are therefore urged to ensure that all these documents are returned with their Proposals.

Please confirm submission of these essential Returnable Documents by so indicating [Yes or No] in the table below:

ESSENTIAL RETURNABLE DOCUMENTS USED FOR SCORING	SUBMITTED
Annexure G: Preference Points Award Form (Mandatory documents to claim preference points)	
Annexure A: Standard Bidding Document (SBD) 1 Form	
Annexure I: Standard Bidding Document (SBD) 4 Form	

Other Essential Returnable Documents:

Failure to provide other essential Returnable Documents may result in a Respondent's disqualification. Bidders are therefore urged to ensure that all these documents are returned with their Proposals.

Please confirm submission of these essential Returnable Documents by indicating Yes or No in the table below

<u>OTHER</u> ESSENTIAL RETURNABLE DOCUMENTS	SUBMITTED [Yes/No]
Annexure E: Proposal Form and List of Returnable documents (<i>This document</i>)	
In the case of Joint Ventures, a copy of the Joint Venture Agreement or written confirmation of the intention to enter into a Joint Venture Agreement	
Proof of subcontracting arrangements if the respondent will subcontract some of the works	
Annexure F: Certificate of Acquaintance with RFP, Terms & Conditions & Applicable Documents	
Annexure J: RFP Declaration and Breach of Law Form	

CONTINUED VALIDITY OF RETURNABLE DOCUMENTS

The successful Respondent will be required to ensure the validity of all returnable documents, including but not limited to its Tax Clearance Certificate and valid B-BBEE Verification Certificate, for the duration of any contract emanating from this RFP. Should the Respondent be awarded the contract [**the Agreement**] and fail to present CSIR with such renewals as and when they become due, CSIR shall be entitled, in addition to any other rights and remedies that it may have in terms of the eventual Agreement, to terminate such Agreement forthwith without any liability and without prejudice to any claims which CSIR may have for damages against the Respondent.

SIGNED at _____ on this _____ day of _____ 20_____

SIGNATURE OF WITNESSES ADDRESS OF WITNESSES

1 _____

Name _____

2 _____

Name _____

SIGNATURE OF RESPONDENT'S AUTHORISED REPRESENTATIVE:

Name: _____

Designation: _____

Annexure F

Certificate of Acquaintance with RFP, Terms & Conditions & Applicable Documents

provision of services for conducting phase I clinical trials on human participants in south Africa for the CSIR.

RFP No. 1047.3/08/05/2023

By signing this certificate the Respondent is deemed to acknowledge that he/she has made himself/herself thoroughly familiar with, and agrees with all the conditions governing this RFP. This includes those terms and conditions contained in any printed form stated to form part hereof, including but not limited to the documents stated below. As such, CSIR will recognise no claim for relief based on an allegation that the Respondent overlooked any such condition or failed properly to take it into account for the purpose of calculating tendered prices or any other purpose:

Should the Bidder find any terms or conditions stipulated in any of the relevant documents quoted in the RFP unacceptable, it should indicate which conditions are unacceptable and offer alternatives by written submission on its company letterhead, attached to its submitted Bid. Any such submission shall be subject to review by CSIR's Legal Counsel who shall determine whether the proposed alternative(s) are acceptable or otherwise, as the case may be. A material deviation from any term or condition may result in disqualification.

Bidders accept that an obligation rests on them to clarify any uncertainties regarding any bid which they intend to respond on, before submitting the bid. The Bidder agrees that he/she will have no claim based on an allegation that any aspect of this RFP was unclear but in respect of which he/she failed to obtain clarity.

The bidder understands that his/her Bid will be disqualified if the Certificate of Acquaintance with RFP documents included in the RFP as a returnable document, is found not to be true and complete in every respect.

SIGNED at _____ on this _____ day of _____ 20____

SIGNATURE OF WITNESSES ADDRESS OF WITNESSES

1 _____

Name _____

2 _____

Name _____

SIGNATURE OF RESPONDENT'S AUTHORISED REPRESENTATIVE:

Name: _____

Designation: _____

Annexure G

Preference Points Award Form in Terms of the Preferential Procurement Regulations 2022

provision of services for conducting phase I clinical trials on human participants in south Africa for the CSIR.

RFP No. 1047.3/08/05/2023

This preference form must form part of all bids invited. It contains general information and serves as a claim form for the preference points allocated on the basis of specific goals outlined in point 3 below.

NB: BEFORE COMPLETING THIS FORM, BIDDERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF SPECIFIC GOALS, AS PRESCRIBED IN THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022

1. GENERAL CONDITIONS

- 1.1 The following preference point systems are applicable to this bid:
- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included).
 - the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included)
- 1.2 Points for this bid shall be awarded for:
- (a) Price; and
 - (b) Preference Points based on specific goals.
- 1.3 The maximum points for this bid are allocated as follows:

	POINTS
PRICE	80
Preference Points	20
Total points for Price and Preference Points must not exceed	100

- 1.4 Failure on the part of a bidder to submit proof of preference points together with the bid, will be interpreted to mean that preference points are not claimed.
- 1.5 The CSIR reserves the right to require of a bidder, either before a bid is adjudicated or at any

time subsequently, to substantiate any claim in regard to preferences, in any manner required by the CSIR.

2. POINTS AWARDED FOR PRICE

2.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

$$P_s = 80 \left(1 - \frac{P_t - P_{\min}}{P_{\min}} \right) \quad \text{or} \quad P_s = 90 \left(1 - \frac{P_t - P_{\min}}{P_{\min}} \right)$$

Where

P_s = Points scored for price of bid under consideration

P_t = Price of bid under consideration

$P_{\min}$ = Price of lowest acceptable bid

3. PREFERENCE POINTS AWARDED

3.1 In terms of Regulation 4 (2) and 4 (2) of the Preferential Procurement Regulations, preference points may be awarded to a tenderer for the specific goal specified for the tender in accordance with the table below:

3.2 Specific goals must be determined per tender.

Specific Goals	Preference Points
Black Women Ownership	10
Black Youth Ownership	10
Total	20

3.3 Total preference points per specific goal to be determined per tender.

3.3.1. Total preference points per specific goal to be awarded as follows:

3.3.1.1. Preferential points for black ownership will be awarded as follows:

Black Women Ownership	% of Preferential points
Tenderer with 100% black women ownership	100%
Tenderer with 30% to 99% black women ownership	50%
Tenderer with less than 30% black women ownership	0%

3.3.1.2. Preferential points for black youth ownership will be awarded as follows:

Black Youth Ownership	% of Preferential points
-----------------------	--------------------------

Tenderer with 100% black youth ownership	100%
Tenderer with 30% to 99% black youth ownership	50%
Tenderer with less than 30% black youth ownership	0%

4. BID DECLARATION

4.3. Bidders who claim points in respect of specific goals **must** submit the following documents:

Mandatory documents to claim preference points	Submitted	
	Yes √	No √
CIPC Register Documents (Updated)		
Valid copy of BBBEE certificate.		
Certified copy of Directors' identity documents		
Medical reports		
Consolidated B-BBEE scorecard or each party in their individual capacity submit a BEE Certificate in case of Joint Ventures and/or subcontracting agreement		
Sworn affidavit in case of EMEs and QSEs.		

DECLARATION WITH REGARD TO COMPANY/FIRM

Name of company/firm:.....

VAT registration number:.....

Company registration number:.....

I/we, the undersigned, who is / are duly authorised to do so on behalf of the company/firm, certify that the documents submitted to claim preference points based on the specific goals are valid, and I / we acknowledge that:

- i) The information furnished is true and correct;
- ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 3 of this form;
- iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 3, the contractor may be required to furnish further documentary proof to the satisfaction of the CSIR that the awarded are correct;
- iv) If any document is obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the CSIR may, in addition to any other remedy it may have –
 - (a) disqualify the person from the bidding process;
 - (b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;
 - (c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;
- (d) recommend that the bidder or contractor, its shareholders and directors, or only the shareholders

and directors who acted on a fraudulent basis, be restricted by the National Treasury from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

- (e) forward the matter for criminal prosecution.
- v) If the CSIR is of the view that a tenderer submitted false information regarding a specific goal, it must—
 - (a) inform the tenderer accordingly; and
 - (b) give the tenderer an opportunity to make representations within 14 days as to why the tender may not be disqualified or, if the tender has already been awarded to the tenderer, the contract should not be terminated in whole or in part.
- vi) After considering the representations referred to in subregulation (v)(b), the CSIR may, if it concludes that such information is false—
 - (a) disqualify the tenderer or terminate the contract in whole or in part; and
 - (b) if applicable, claim damages from the tenderer.

WITNESSES

- 1.
- 2.

.....
SIGNATURE(S) OF BIDDERS(S)

DATE:

ADDRESS.....

RFP Clarification Request Form

RFP No. 1047.3/08/05/2023

[illegible]

Annexure I
Standard Bidding Document (SBD) 4

RFP No. 1047.3/08/05/2023

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest¹ in the enterprise, employed by the state? YES ☐ / NO ☐

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	Identity Number	Name of State institution

¹ the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

2.2 Do you, or any person connected with the bidder, have a relationship with any person who is employed by the procuring institution? YES ☐ /NO ☐

2.2.1 If so, furnish particulars:

.....
.....

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract? ☒ YES ☐ /NO

2.3.1 If so, furnish particulars:

.....
.....

3 DECLARATION

I, the undersigned, (name).....in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

- 3.1 I have read and I understand the contents of this disclosure;
- 3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;
- 3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium² will not be construed as collusive bidding.
- 3.4 In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.
- 3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.
- 3.5 There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.
- 3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat

² Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.

I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

.....
Signature

.....
Date

.....
Position

.....
Name of bidder

Annexure J

DECLARATION BY TENDERER AND BREACH OF LAW FORM

provision of services for conducting phase I clinical trials on human participants in south Africa for the CSIR.

RFP No. 1047.3/08/05/2023

Only tenderers who completed the declaration below will be considered for evaluation.

NAME OF ENTITY:

We _____ do hereby certify that:

1. CSIR has supplied and we have received appropriate responses to any/all questions [as applicable] which were submitted by ourselves for RFP Clarification purposes;
2. we have received all information we deemed necessary for the completion of this Request for Proposal [**RFP**];
3. we have been provided with sufficient access to the existing CSIR facilities/sites and any and all relevant information relevant to the Services as well as CSIR information and Employees, and has had sufficient time in which to conduct and perform a thorough due diligence of CSIR's operations and business requirements and assets used by CSIR. CSIR will therefore not consider or permit any pre- or post-contract verification or any related adjustment to pricing, service levels or any other provisions/conditions based on any incorrect assumptions made by the Respondent in arriving at his Bid Price.
4. at no stage have we received additional information relating to the subject matter of this RFP from CSIR sources, other than information formally received from the designated CSIR contact(s) as nominated in the RFP documents;
5. we are satisfied, insofar as our entity is concerned, that the processes and procedures adopted by CSIR in issuing this RFP and the requirements requested from Bidders in responding to this RFP have been conducted in a fair and transparent manner; and
6. we have complied with all Obligations of the Bidder/Supplier as indicated in paragraph 3 of the CSIR Supplier Integrity which includes but is not limited to ensuring that we take all measures necessary to prevent corrupt practices, unfairness and illegal activities in order to secure or in furtherance to secure a contract with CSIR;
7. furthermore, we declare that a family, business and/or social relationship **exists / does not exist** [delete as applicable] between an owner / member / director / partner / shareholder of our entity and an employee or board member of the CSIR Group including any person who may be involved in the evaluation and/or adjudication of this Bid.
8. In addition, we declare that an owner / member / director / partner / shareholder of our entity **is / is not** [delete as applicable] an employee or board member of the CSIR.
9. If such a relationship as indicated in paragraph 6 and/or 7 exists, the Respondent is to complete the following section:

FULL NAME OF OWNER/MEMBER/DIRECTOR/
PARTNER/SHAREHOLDER: ADDRESS:

Indicate nature of relationship with CSIR:

[Failure to furnish complete and accurate information in this regard will lead to the disqualification of a response and may preclude a Respondent from doing future business with CSIR]

10. We declare, to the extent that we are aware or become aware of any relationship between ourselves and CSIR [other than any existing and appropriate business relationship with CSIR] which could unfairly advantage our entity in the forthcoming adjudication process, we shall notify CSIR immediately in writing of such circumstances.
11. We accept that any dispute pertaining to this Bid will be resolved through the Ombudsman process and will be subject to the Terms of Reference of the Ombudsman. The Ombudsman process must first be exhausted before judicial review of a decision is sought.
12. We further accept that CSIR reserves the right to reverse an award of business or decision based on the recommendations of the Ombudsman without having to follow a formal court process to have such award or decision set aside.

BREACH OF LAW

13. We further hereby certify that I/we (the bidding entity and/or any of its directors, members or partners) have/have not been [delete as applicable] found guilty during the preceding 5 [five] years of a serious breach of law, including but not limited to a breach of the Competition Act, 89 of 1998, by a court of law, tribunal or other administrative body. The type of breach that the Respondent is required to disclose excludes relatively minor offences or misdemeanours, e.g. traffic offences. This includes the imposition of an administrative fine or penalty.

Where found guilty of such a serious breach, please disclose:
NATURE OF BREACH:

DATE OF BREACH: _____

Furthermore, I/we acknowledge that CSIR reserves the right to exclude any Respondent from the bidding process, should that person or entity have been found guilty of a serious breach of law, tribunal or regulatory obligation.

SIGNED at _____ on this _____ day of _____
20____

For and on behalf of _____ duly authorised hereto	AS WITNESS:
Name:	Name:
Position:	Position:
Signature:	Signature:
Date	Registration No of Company/CC
Place	Registration Name of Company/CC

