

**HLL LIFECARE LIMITED**  
**(A Government of India Enterprise)**  
**CORPORATE R & D CENTRE,**  
**AKKULAM, SREEKARIYAM P.O,**  
**THIRUVANANTHAPURAM-695017**

**Email: [crdc@lifecarehll.com](mailto:crdc@lifecarehll.com)**

**Website: [www.lifecarehll.com](http://www.lifecarehll.com)**

**PH: +91 471 277 4700**

**FAX: +91 471 277 4707**

# **TECHNICAL BID DOCUMENT FOR APPOINTMENT OF**

## **CLINICAL RESEARCH ORGANIZATION (CRO)**

**(FOR THE STUDY OF NOVEL INTRAUTERINE DEVICE (IUD))**



**HLL LIFECARE LIMITED**  
**Corporate R & D Centre,**  
**Akkulam, Thiruvananthapuram - 695017**

**CONTENTS OF BIDDING DOCUMENTS**

SN	Schedule	Description	Page No
<b>Part – I (Technical Bid)</b>			
1.	----	Disclaimer	03
2.	Section I	Notice Inviting Tender (NIT)	04 - 06
3.	Section II	Instruction To Tenderers (ITT)	07 - 13
4.	Section III	Terms And Conditions	14 - 18
5.	Form A	Form of Bid	19 - 20
6.	Form B	Format for Bank Gurantee Advance Payment	21 - 24
7.	Form C	Pre – Contract Intergrity Pact	25 - 33
8.	Form T-I	General Information	34
9.	Form T-II	Number of Clinical Trials Conducted in the last five years in contraceptatives for female.	35
10.	Form T-III	Key Personnel Details	36 - 37
11.	Form T-IV	CV's of te Key Staff	38
12.	Annexure I	Annexure I : Confidentiality Disclosure Agreement	39 - 44
<b>Part – Ii (Financial Bid)</b>			
13.	----	Form D (Financial Bid)	47

**HLL LIFECARE LIMITED**  
**Corporate R & D Centre,**  
**Akkulam, Thiruvananthapuram - 695017**

**DISCLAIMER**

HLL Lifecare Limited, (HLL) India has prepared this document for appointing of Clinical Research Organization (CRO) for conducting a clinical trial for a novel IUD. The information is provided to bidders on the terms and conditions set out in this document and any other terms and conditions subject to which such information is provided. This document is not an agreement, is not an offer or invitation to any other party.

The information is provided on the basis that it is non – binding on HLL, any of its authorities or agencies or any of their respective officers, employees, agents or advisors.

HLL reserves the right not to proceed with the project or to change the configuration of the project, to alter the timetable reflected in this document or to change the process or procedure to be applied. It also reserves the right to decline to discuss the project further with any party submitting the tender.

While HLL have taken due care in the preparation of the information contained herein and believe it to be accurate neither HLL nor any of its authorities or agencies nor any of their respective officers, employees, agents or advisors gives any warranty or make any representations, express or implied as to the completeness or accuracy of the information contained in this document or any information which may be provided in association with it.

No reimbursement of cost of any type will be paid to persons or entities submitting their Tender.

**HLL LIFECARE LIMITED**  
Corporate R & D Centre,  
Akkulam, Thiruvananthapuram - 695017

**NOTICE INVITING TENDER (NIT)**

**1.1 Brief Description of the Project**

This is an interventional, parallel-arm, single blind study of an Intrauterine device developed by HLL. The study is to be initiated after obtaining regulatory clearance and the duration of study is expected to be 1 year, excluding the recruitment period and study report preparation. It is to be conducted in multiple sites across India and aims to enroll 200 subjects (100 subjects in each arm).

HLL wishes to appoint a CRO for this project. The nature of services to be provided by the CRO will include, but will not be limited to study document development, selection of investigators, site identification and screening, ethics committee submission, study initiation, medical writing, data management and analysis, project management and vendor management. The scope of services would also include, dossier preparation, getting all requisite regulatory approvals from the regulatory authorities and timely reporting of all safety data to EC and HLL. The CRO will be required to provide sufficient technically qualified and experienced staff for providing the required level of service. The CRO should be a preferred partner from Bill & Melinda Gates Foundation for conduct of clinical trials in the Asia pacific region.

**1.2 TENDER DETAILS**

<b>Earnest Money Deposit</b>	Rs. 10,00,000.00(Rupees Ten lakh only) (DD Only – in favour of ‘HLL LIFECARE LIMITED’ payable at ‘THIRUVANANTHAPURAM’)
<b>Cost of Tender form (Non-refundable)</b>	Tenders can be downloaded from HLL website <a href="http://www.lifecarehll.com">www.lifecarehll.com</a> free of cost. The cost of the Tender Documents of Rs.300.00 (DD Only – in favour of ‘HLL LIFECARE LIMITED’ payable at ‘THIRUVANANTHAPURAM’) should be furnished along with Technical Bid.
<b>Expected Duration of activities</b>	a. Regulatory submission & Identification of sites 3- 4 months from the date of award of work b. Recruitment period 4-5 months after approval. c. Study period 1 year (Including Interim data analysis on 6 <sup>th</sup> month) d. Data analysis and final Clinical study report 2 months.
<b>Availability of Tender documents at HLL website.</b>	15 <sup>th</sup> March 2014.
<b>Last date &amp; time of submission of Tender</b>	16.00 hours, 04 <sup>th</sup> April 2014.
<b>Date &amp; Time of opening of technical Bid</b>	17.00 hours, 04 <sup>th</sup> April 2014.

### 1.3 POINTS TO BE NOTED

Tenderers shall submit a written Power of Attorney authorizing the signatory (ies) of the tender to commit the tender.

The authorized signatory of the Tenderer shall sign each page of tender.

Cancellation or creation of a document such as Power of Attorney, Partnership deed, Constitution of firm etc., which may have bearing on the Tender/Contract shall be communicated forthwith in writing by the Tenderer to HLL.

### 1.4 TENDER DOCUMENTS

The offers will be received in TWO PARTS – a) Technical Bid and b) Financial Bid in two separate sealed envelopes. The two envelopes shall be wrapped in an outer envelope addressed to **HEAD (R&D), CORPORATE R&D CENTRE, HLL LIFECARE LTD, AKKULAM, SREEKARYAM (P.O), THIRUVANANTHAPURAM, KERALA - 695 017**, duly superscribing on top ‘Offer for conducting clinical trial for the study of Intrauterine Device’, on or before the last date and time for submission. The envelope should also bear the name and address of the Tenderer.

The firm(s) must include in their Technical Bid the following information in the format given in the Terms of Reference:

1. The general and overall experience of the firm including the number of years of operations, indicating the number of years in conducting the clinical trials especially in the area of contraception. The minimum period required is three years.
2. Annual turnover of the firm(s) by way of Professional Fees for Consultancy for the last three years duly audited by a Chartered Accountant.

### 1.5 TENDER EVALUATION

The Technical Bids will be evaluated based on the eligibility criteria and responsiveness to the tender requirements. The Financial Bids of firm(s) who fulfill the tender requirements alone will be opened for further evaluation. HLL reserves the right to reject any or all of the offers without assigning any reason.

The successful bidder shall be required to execute a Contract Agreement within fifteen days of issue of Letter of Acceptance/ Work orders, failing which the Earnest Money shall be forfeited and the offer cancelled.

The Terms of Reference and Conditions of Contract (Bid Document) can be downloaded from HLL website [www.lifecarehll.com](http://www.lifecarehll.com).

The offers must be delivered to the address below on or before 16.00 hrs. of 04<sup>th</sup> April 2014. The envelope should be duly super scribed clearly “Offer for conducting clinical trial for the study of Intrauterine Device’ along with EMD in the form of a Bank Draft for Rs.10,00,000.00 in favour of ‘*HLL Lifecare Limited*’ payable at *Thiruvananthapuram*. The Earnest Money Deposit of Rs. 10,00,000.00 shall be refunded in case of firm(s) whose offers are not accepted.

Further information if any, may be obtained from the address and telephone no. given below:

**Head (R&D)**  
Corporate R & D Centre  
HLL Lifecare Limited,  
AKKULAM, SREEKARIYAM  
Thiruvananthapuram – 695 017  
Ph: 0471 – 277 4700 /  
Fax: 0471 – 277 4707  
e mail: [materialscrdc@lifecarehll.com](mailto:materialscrdc@lifecarehll.com)  
[crdc@lifecarehll.com](mailto:crdc@lifecarehll.com)

**HLL LIFECARE LIMITED**  
**Corporate R & D Centre,**  
**Akkulam, Thiruvananthapuram - 695017**

**INSTRUCTION TO TENDERERS (ITT)**

**1. Brief Description of Project**

This is an interventional, parallel-arm, single blind study of an Intrauterine device developed by HLL. The study is to be initiated after obtaining regulatory clearance and the duration of study is expected to be 1 year. It is to be conducted in multiple sites across India and aims to enroll 200 subjects (100 subjects in each arm).

**Overview of study design**

<b>Study Type</b>	Interventional
<b>Study Design</b>	Allocation: Randomized Endpoint Classification: Safety Study ( specifically reduced bleeding side effect) Intervention Model: Parallel Assignment Masking: Single Blind (Subject) Primary Purpose: Treatment
<b>Condition:</b>	Comparing in terms of initial bleeding and pain post insertion of IUD and clinical performance of Novel IUD versus conventional copper T in women desiring contraception
<b>Interventions</b>	Device: Novel IUD Device: <b>Copper T - 380A</b> IUD
<b>Study Duration</b>	One year
<b>Study size</b>	<b>200 women.</b> A total of 100 subjects are planned to be enrolled in each arm.
<b>Study Details/Protocol</b>	Can be shred after signing a NDA (Format Enclosed), with the Tenderer.

## 2. SCOPE OF WORK

Clinical Research Tasks expected to be performed by the CRO/vendor Study Requirements:

### 2.1 Study Documents development

- a) Protocol (Final & Amendment if any)
  - ✓ Protocol Review
  - ✓ Protocol Formatting
- b) Investigator Brochure
  - ✓ IB Review
  - ✓ IB Formatting
- c) Patient Informed Consent (Translated in to local languages and back translated)
  - ✓ Design
  - ✓ Review and discussion with PI
  - ✓ Review and approval
- d) Case Report Form
  - ✓ Design CRF
  - ✓ CRF review
  - ✓ Prepare CRF completion guideline
- e) Subject Assessment Diary
- f) Insurance statement (HLL/CRO/Investigator/Subject), subject insurance to be according to the current DCGI norms.
- g) Confidentiality Disclosure Agreement with Investigator
- h) Investigator Undertaking and statement

### 2.2 Selection of Experienced and Qualified Investigators in contraceptives.

### 2.3 Site identification and screening

- ✓ Site Selection visits
- ✓ Generate site selection report
- ✓ Review and approval

### 2.4 Preparation of Dossier and submission to DCGI for regulatory clearance.

- ✓ Dossier Preparation
- ✓ Submission in corporation with HLL
- ✓ Queries Raised from the regulatory agencies should be handled accordingly.

### 2.5 Ethics committee submission, notification and investigators meeting

- ✓ EC/IRB Submission

### 2.6 Investigator Activities

- ✓ Investigator meeting
- ✓ Organization and preparation
- ✓ Attendance
- ✓ Meeting minutes



### **2.7 Study initiation**

- ✓ Preparation
- ✓ Set-up study master file
- ✓ Collect and compliance pre-study documents
- ✓ Site Initiation visits and reports
- ✓ Site Initiation meeting
- ✓ SIV report
- ✓ Review and approval

### **2.8 Clinical Monitoring (Including Audit)**

- ✓ Routine & non-routine on site monitoring
- ✓ Source document verification
- ✓ Verify site compliance to protocol and GCP requirements
- ✓ Review of CRFs
- ✓ Review drug records
- ✓ Monitoring reports
- ✓ Review and approval

### **2.9 Safety Recording, Reporting (to EC & HLL) and Analysis.**

#### **2.10 Data Management**

- ✓ Data Management using Oracle clinical EDC
- ✓ Data base designing
- ✓ Data management plan(DMP)/ Data Validation Plan(DVP)
- ✓ Database Validation
- ✓ CRF & Data Clarification Form (DCF)Tracking
- ✓ DCF Resolution
- ✓ Database lock

#### **2.11 Statistical Analysis [Using SAS (Latest Version)]**

- ✓ Statistical Analysis Plan (SAP)
- ✓ Programming
- ✓ Primary/Secondary End point assessment
- ✓ Safety assessment & Final Data Analysis
- ✓ Interim analysis.
- ✓ Statistical Analysis report
- ✓ Generation of tables, listings and figures

#### **2.12 Medical writing**

- ✓ Develop Clinical study report
- ✓ Review & approval
- ✓ Study report finalization

### 2.13 Project Management

- ✓ Set up of project management plan
- ✓ Generate study progress reports
- ✓ Develop study monitoring and report system
- ✓ Negotiate contract with investigators
- ✓ Communication with HLL (monthly conference call, emails etc.)

### 2.14 Site Management

- ✓ Investigators payments/grants administration
- ✓ Study file update & management
- ✓ IP shipping, accountability, archival and temperature monitoring log
- ✓ Subject Enrollment log

### 2.15 Vendor Management (Third Party)

- ✓ Central Lab Identification
- ✓ Selection of LAB (Accredited lab)
- ✓ Negotiations.
- ✓ Testing laboratory should have GLP accreditation
- ✓ Data management
- ✓ Insurance

### 2.16 Others

- ✓ Translations
- ✓ Reporting of study progress on timely manner to HLL and sites
- ✓ Interim and Final Report preparation and submission to HLL and Investigator

## 3. Information to be provided in the technical bid:

- 3.1 List the clinical trials carried out by your organization during the last 3 years (with: study phase, therapeutic area and services you executed)
- 3.2 Number of studies with special focus on contraceptive/ women health clinical trials
- 3.3 List the key persons assigned to the trials with their qualifications and experience.
- 3.4 List of SOPs to be shared.

## 4. Essential Criteria to be met by the CRO/Vendor

- 4.1 The CRO should be a preferred partner from Bill & Melinda gates Foundation for conduct of clinical trials in the Asia pacific region.
- 4.2 The CRO should be authorized and registered in India as per DCGI norms.
- 4.3 Experience in Clinical trials for contraceptives and women healthcare necessary.
- 4.4 The company should have an annual turnover of Rs. 200.00 crores or above for the last 3 years.
- 4.5 Details of the inspection activities by Health Authorities/ competent Authorities for GCP activities. Past audit reports on the GCP compliance by the CRO.

4.6 The CRO should have experience in Data management using ORACLE software system, Electronic Data Capture system (EDC) / Remote Data Capture (RDC) and Statistical analysis using SAS.

4.7 The technical team should include;

4.7.1 Clinical Trial/ Study Project Manager

4.7.2 Clinical Research Associate (CRA) for site monitoring

4.7.3 Medical scientist / medical monitor

4.7.4 Clinical Data Manager

4.7.5 Biostatisticians and statistical programmers

4.7.6 Medical Writers

4.7.7 IT support

4.7.8 Quality assurance Unit

4.7.9 The study sites selected by the CRO should comply with GLP and GCP norms.

4.7.10 Testing labs should have NABL/GLP accreditation.

## 5. Submittal of Offer.

The intending CROs shall submit their offer in two parts, the Technical Package and the Financial Bid.

### 5.1 TECHNICAL PACKAGE

5.1.1 The technical package, clearly labeled as “TECHNICAL PACKAGE”, shall consist of following information /details for eligibility criteria of bidders.

5.1.1.1 Covering letter for the Bid in Form A.

5.1.1.2 List of enclosed documents and forms.

5.1.1.3 Earnest Money Deposit in the form of a Demand Draft for Rs.10,00,000/- in a separate sealed envelope duly marked “Earnest Money Deposit”. (DD Only – in favour of ‘HLL LIFECARE LIMITED’)

5.1.1.4 The Tender Document fee of Rs.300.00 (DD Only – in favour of ‘HLL LIFECARE LIMITED’ payable at ‘THIRUVANANTHAPURAM’.

5.1.1.5 Attested Copy of Power of Attorney (in favour of the Authorised Signatory of the Bidder) to submit the Bid.

5.1.1.6 CRO should have a minimum of 3 years’ experience in the conduct of clinical trial and also have previous track record of conducting phase II & III clinical studies.

5.1.1.7 The Bidder should validate the data provided as above using suitable documentary evidence such as client certificates, audited balance sheets, annual reports etc clearly giving the reference to the evidence in front of the relevant portion.

5.1.1.8 Technical and organizational capability

5.1.1.8.1 Number of Technical staff (excluding support staff) proposed for this

project in the Form T-III

5.1.1.8.2 Academic qualification of the staff in the Form T-III

5.1.1.8.3 Experience of the proposed staff in the Form T-III

## **6. THE FINANCIAL PACKAGE**

6.1 The financial package, clearly labeled as “ FINANCIAL PACKAGE” will contain the following:

6.1.1 Form of tender (Form A).

6.1.2 Financial Bid of the Offer as per Form D.

6.2 The financial proposal should be separately completed and submitted in a separate sealed envelope in the Format prescribed in Form C. The final prices shall be entered in the form of Tender. These prices should include all costs associated with the contract.

## **7 AWARD OF CONTRACT**

### **7.1.1 AWARD CRITERIA**

7.1.2 Subject to meeting the Eligibility Criteria stipulated in clause 4 above, HLL will award, the Contract to the CRO, whose offer has been determined to be substantially responsive, complete and in accordance with the Bid documents, and whose Price has been determined to be the lowest.

7.1.3 If the financial bid of one or more parties is equal then the party having better/higher Eligibility Credentials shall be considered for award of Contract.

### **7.2 HLL'S RIGHT TO ACCEPT ANY TENDER AND TO REJECT ANY OR ALL TENDERS**

Notwithstanding Clause 5.1, HLL reserves the right to accept or reject any offer, and to annul the tender process and reject all offers, at any time prior to award of Contract without thereby incurring any liability to the affected Bidder or Bidders or any obligations to inform the affected Bidder or Bidders of the grounds for HLL's action.

### **7.3 NOTIFICATION OF AWARD**

7.3.1 Prior to the expiry of the period of offer validity prescribed by the HLL, HLL will notify the successful Bidder by Tele-fax or e-mail, to be confirmed in writing by registered post/ by courier, that his offer has been accepted. This letter (hereinafter and in the Conditions of Contract called 'the Letter of Acceptance') shall name the percentage at which HLL will pay to the CRO in consideration of the services to be provided for the works by the CRO as prescribed by the Contract (hereinafter and in the conditions of Contract called 'the Contract Price'). The Letter of Acceptance will be send to the successful bidder. No correspondence will be entertained by HLL from the unsuccessful Bidders.

7.3.2 The Letter of Acceptance shall constitute a part of the contract.

#### 7.4 **SIGNING OF AGREEMENT**

7.4.1 The successful bidder shall sign an agreement with HLL binding itself to perform study of an intra-uterine device developed by HLL as mentioned in the tender in the form that would be prescribed by HLL, within 15 days from the date of issue of the Letter of Acceptance by HLL. The advance guarantee should be submitted immediately after issue of letter of acceptance but not later than 15 days of issue of letter of acceptance. One copy of the Agreement duly signed by HLL and the CRO through their authorized signatories will be supplied by HLL to the CRO.

#### 7.5 **INTEGRITY PACT CLAUSE**

The Integrity Pact in the proforma enclosed as FORM C shall be part and parcel of this document, and has to be signed by bidder(s) at the pre-tendering stage itself, as a pre-bid obligation and should be submitted along with the financial and technical bids. All the bidders are bound to comply with the Integrity Pact Clauses. Bids submitted without signing Integrity Pact will be ab initio rejected without assigning any reason.

## **TERMS AND CONDITIONS**

### **1.0 SCOPE OF WORK:-**

#### **1.1 Preliminary stage**

The services to be provided by the CRO shall inter alia include the following:-

Clinical Research Tasks expected to be performed by the CRO/vendor

##### **1.1.1 Study Documents development**

- a) Protocol (Final & Amendment if any)
  - ✓ Protocol Review
  - ✓ Protocol Formatting
- b) Investigator Brochure
  - ✓ IB Review
  - ✓ IB Formatting
- c) Patient Informed Consent (Translated in to local languages and back translated)
  - ✓ Design
  - ✓ Review and discussion with PI
  - ✓ Review and approval
- d) Case Report Form
  - ✓ Design CRF
  - ✓ CRF review
  - ✓ Prepare CRF completion guideline
- e) Subject Assessment Diary
- f) Insurance statement (HLL/CRO/Investigator/Subject), subject insurance to be according to the current DCGI norms.
- g) Confidentiality Disclosure Agreement with Investigator
- h) Investigator Undertaking and statement

##### **1.1.2 Selection of Experienced and Qualified Investigators in contraceptives.**

##### **1.1.3 Site identification and screening**

- ✓ Site Selection visits
- ✓ Generate site selection report
- ✓ Review and approval

##### **1.1.4 Preparation of Dossier and submission to DCGI for regulatory clearance.**

- ✓ Dossier Preparation
- ✓ Submission in corporation with HLL
- ✓ Queries Raised from the regulatory agencies should be handled accordingly.

##### **1.1.5 Ethics committee submission, notification and investigators meeting**

- ✓ EC/IRB Submission

##### **1.1.6 Investigator Activities**

- ✓ Investigator meeting
- ✓ Organization and preparation
- ✓ Attendance
- ✓ Meeting minutes

**1.1.7 Study initiation**

- ✓ Preparation
- ✓ Set-up study master file
- ✓ Collect and compliance pre-study documents
- ✓ Site Initiation visits and reports
- ✓ Site Initiation meeting
- ✓ SIV report
- ✓ Review and approval

**1.1.8 Clinical Monitoring (Including Audit)**

- ✓ Routine & non-routine on site monitoring
- ✓ Source document verification
- ✓ Verify site compliance to protocol and GCP requirements
- ✓ Review of CRFs
- ✓ Review drug records
- ✓ Monitoring reports
- ✓ Review and approval

**1.1.9 Safety Recording, Reporting (to EC & HLL) and Analysis.**

**1.1.10 Data Management**

- ✓ Data Management using Oracle clinical EDC
- ✓ Data base designing
- ✓ Data management plan(DMP)/ Data Validation Plan(DVP)
- ✓ Database Validation
- ✓ CRF & Data Clarification Form (DCF)Tracking
- ✓ DCF Resolution
- ✓ Database lock

**1.1.11 Statistical Analysis [Using SAS (Latest Version)]**

- ✓ Statistical Analysis Plan (SAP)
- ✓ Programming
- ✓ Primary/Secondary End point assessment
- ✓ Safety assessment & Final Data Analysis
- ✓ Interim analysis.
- ✓ Statistical Analysis report
- ✓ Generation of tables, listings and figures

**1.1.12 Medical writing**

- ✓ Develop Clinical study report
- ✓ Review & approval
- ✓ Study report finalization

**1.1.13 Project Management**

- ✓ Set up of project management plan
- ✓ Generate study progress reports
- ✓ Develop study monitoring and report system

- ✓ Negotiate contract with investigators
- ✓ Communication with HLL (monthly conference call, emails etc.)

**1.1.14 Site Management**

- ✓ Investigators payments/grants administration
- ✓ Study file update & management
- ✓ IP shipping, accountability, archival and temperature monitoring log
- ✓ Subject Enrollment log

**1.1.15 Vendor Management ( Third Party)**

- ✓ Central Lab Identification
- ✓ Selection of LAB (Accredited lab)
- ✓ Negotiations.
- ✓ Testing laboratory should have GLP accreditation
- ✓ Data management
- ✓ Insurance

**1.1.16 Others**

- ✓ Translations
- ✓ Reporting of study progress on timely manner to HLL and sites
- ✓ Interim and Final Report preparation and submission to HLL and Investigator

1.2 It is also a term of this contract that wherever sub-contracting is involved, approval has to be taken from the HLL. In case of any dispute between the CRO and Sub-contractor, the disputed amount shall be kept in deposit by the HLL till such time the dispute is resolved as per the terms and conditions of the agreement drawn between the CRO and the Sub-contractor.

**2.0 PAYMENT SCHEDULE:-**

The fees will be paid in installments as specified below:-

Sl. No	Stages	Payment term
1	On Agreement Signing	20% of the contract amount against bank guarantee of the same amount.
2	First subject in/ recruited	20% of the contract amount
3	Submission of interim analysis	10% of the contract amount
4	100% subject recruitment	20% of the contract amount
5	Data base lock	10% of the contract amount
6	Submission of Final CSR	20% of the contract amount

**3.0 ADVANCE BANK GUARANTEE**

The successful bidder will be required to furnish Bank Guarantee from nationalized / scheduled bank by way of Advance Bank Guarantee in the prescribed proforma (Please refer FORM B), for advance payment. The Advance Bank Guarantee shall remain valid up to 30 months and the same shall be released after two months from satisfactory completion of the project.



In case the bank goes in liquidation or for any reason is unable to make payment against the said Bank Guarantee the loss caused thereby shall be borne by the CRO. The CRO forthwith, on demand from HLL, shall make good the deficit.

#### **4.0. ADDITIONS AND ALTERATIONS**

- (i) The CRO shall not make any deviations, alterations, additions, to or omissions from the work shown/described and awarded to the contractor except through and with proper approval of the HLL.

#### **5.0. TIME SCHEDULE**

- a. Regulatory submission & Identification of sites 3- 4 months from the date of award of work
- b. Recruitment period 4-5 months after approval.
- c. Study period 1 year (Including Interim data analysis on 6<sup>th</sup> month)
- d. Data analysis and final Clinical study report 2 months.

#### **6.0 EXTENSION OF TIME**

- 6.1 If the CRO requires extension of time, they shall intimate in writing to HLL within 10 days of the occurrence of such hindrance/delay.
- 6.2 The HLL after satisfying himself about the reasonableness of grounds, may grant extension of time as in his opinion be justified and communicate the same in writing. (The decision of HLL shall be final and binding). Whenever such extension of time is granted, it would be without prejudice to the rights of HLL. Any extension of time granted as stated above shall neither entitle the CRO to any claim for increase in their fees nor shall it release him from any of the obligations under the said agreement.

#### **7.0 ABANDONMENT OF WORK**

7.1 That if the CRO abandons the work for any reason whatsoever or becomes incapacitated from acting as CRO as aforesaid, the HLL shall forfeit/encash the Advance Bank Guarantee (Decision of HLL shall be final and binding). The HLL shall be at liberty to make full use of all or any of the drawings prepared by the CRO. The CRO shall also be liable to refund all the fees paid to him up to date plus such damages as may be assessed by the HLL (Decision of HLL shall be final and binding) subject to a maximum of 10% of the total fee payable to the CRO under this agreement including the recovery of liquidated damages under clause 3 hereinabove.

7.2 Provided, however, that in the event of the termination of the agreement under proper notice as provided in the clause hereinafter, the CRO shall be liable to refund any excess payment made to him over and above which is due to him in accordance with the terms of this agreement, for the services rendered by him till the date of termination of agreement.

## **8. GENERAL**

- i. The CRO shall be fully responsible for the technical soundness of the work including those of specialists engaged if any, by him and also ensure that the work is carried out generally in accordance with study specifications.
- ii. The HLL will have the work of CRO and/or his sub-CROs supervised/inspected at any time by any officer, check estimates and studies.
- iii. The appointment of HLL's own supervisory staff, if any, does not absolve the CRO of his responsibility of general supervision. The CRO shall be responsible for the completion of the clinical trial as per the protocol.

## **14. ARBITRATION**

All disputes or differences whatsoever arising between the parties out of or relating to the consultancy services, meaning and operations or effect of this contract or the breach thereof shall be settled by arbitration. Matters to be arbitrated upon shall be referred to a sole Arbitrator, to be appointed jointly by the parties HLL and the award made in pursuance thereof shall be binding on the parties. Such arbitration shall be governed by the Indian Arbitration and Conciliation Act 1996.

The jurisdiction of any disputes, suits and proceedings arising out of this tender shall be only in the courts of Thiruvananthapuram, Kerala State, India.

**In witness whereof the parties hereto have set their hands and seals the**  
\_\_\_\_\_ day of \_\_\_\_\_ **Two Thousand Fourteen**  
**above written.**

## FORM OF BID

Note : i. The Appendix forms part of the Bid

- ii. Bidders are required to fill up all the blank spaces in this form of Tender and Appendix.

**NAME OF CLINICAL TRIAL : NOVEL INTRAUTERINE DEVICE (IUD)**

To,

**HEAD (R&D)  
Corporate R&D Centre  
HLL Lifecare Ltd,  
Akkulam, Sreekariyam (P.O)  
Thiruvananthapuram-695017  
Kerala**

1. Having examined the tender document and the terms of the project attached thereto, for providing the required documents and regulatory consultancy, we the undersigned, offer to conduct the clinical trial in conformity with the terms of the service and the scope of work attached thereto.
2. We undertake, if our offer is accepted, to commence the works within one week of signing the Clinical Trial Agreement & Non-disclosure agreement to commence and to complete the whole of the Works comprised in the Contract within the Time Schedules mutually decided by M/s HLL Lifecare Ltd and us, calculated from the date of issue of the Letter of Acceptance.
3. If our Offer is accepted, we will furnish a 10% Bank Guarantee of the net amount for Performance as security for the due performance of the Contract. The amount and form of such guarantee or bond will be as in FORM B.
4. We agree to abide by this offer for a minimum period of 90 days from the last date fixed for receiving the same and it shall remain binding upon us and may be accepted at any time before the expiry of that period or any extended period mutually agreed to.
5. We declare that the submission of this offer confirms that no agent, middleman or any intermediary has been, or will be engaged to provide any services, or any other item of work related to the award and performance of this Contract. We further confirm and declare that no agency commission or any payment, which may be construed as an agency, commission has been, or will be, paid and that the tender price does not include any such amount. We acknowledge the right of HLL, if it finds to the contrary, to declare our Offer to be non-compliant and if the Contract has been awarded to declare the Contract null and void.
6. We understand that you are not bound to accept the lowest or any offer you may receive.

7. If our Offer is accepted we understand that we are to be held solely responsible for the due performance of the Contract.

DATED THIS.....DAY OF.....**2014**

SIGNATURE .....

NAME.....

DULY AUTHORIZED TO SIGN TENDERS FOR AND ON BEHALF  
OF.....

ADDRESS .....

WITNESS – SIGNATURE .....

NAME .....

ADDRESS .....

Occupation .....

FORMAT OF BANK GUARANTEE FOR ADVANCE PAYMENT

NOTE

1. This guarantee should be furnished by a Nationalised Bank/ Scheduled Bank authorised by RBI to issue a Bank Guarantee excepting Bank of Baroda. NLC reserves its rights to reject the Bank Guarantee if the same is not in the specified format.
2. This bank guarantee should be furnished on stamp paper of value not less than Rs.100.00
3. The stamp paper should have been purchased in the name of the Bank executing the Guarantee.
4. In the case of foreign bidder the B.G may be furnished by an international reputed bank acceptable to the HLL/ RBI.
5. The advance Bank Guarantee shall be valid till the completion of Study with a grace period of 3 (Three) months thereafter.
6. Any deviation in this format will not be acceptable.

-----  
ADVANCE PAYMENT GUARANTEE NO:

PLACE:

DATE:

TO

Dear Sir,

1. Pursuant to the Contract, herein after referred to as "The CONTRACT" which M/S ..... herein after referred to as the "CRO" (which expression shall, unless repugnant to the context or meaning thereof, include its successors, administrators, representatives and assignees), have concluded with M/s HLL Lifecare Limited herein after referred to as "HLL" (which expression shall unless repugnant to the context or meaning thereof, include its successors, administrators, representatives and assignees), on ..... 2014 ..... vide. Work order No: .....  
..... Dated : ..... The CRO have Undertaken to..... (scope of work) for ..... (Contract price) on FOB/ Ex-works basis.

2. According to the said Contract, the HLL, has undertaken to make an advance payment of Rs..... (Rupees ..... only) being the payment of ..... % for ..... against issuance of an advance payment guarantee by a Bank.
3. For this advance payment, We, the undersigned (Name) ..... (Address), herein after referred to as the bank, which expression shall unless repugnant to the context or meaning thereof include its successors, administrators, representatives and assignees, hereby guarantee to the effect that we irrevocably under-take to pay the HLL merely on demand without any previous notice and without any demur and without recourse to the CRO and without referring to any other source, any and all monies payable by the CRO towards the advance or part thereof paid by the HLL, but not exceeding Rs..... (Rupees ..... only) provided the HLL advice us that the CRO has failed to fulfil his contractual obligations stipulated in the said Contract. Any such demand made by HLL on the bank shall be conclusive and binding, absolute and unequivocal notwithstanding any difference between the HLL and the CRO or any dispute or disputes raised /pending before any court, Tribunal Arbitrator or any other authority.
4. This guarantee will not be discharged due to the change in the constitution of the Bank or the CRO.
5. This guarantee will become invalid three months after the completion of the .....(scope of work) by the CRO under the said Contract or as soon as this Letter Of Guarantee has been returned to us at the latest, however, on ..... unless a claim has been lodged with us under this guarantee before that date.
6. We. . . . . (Bank) further agree that if the said CRO fails to adhere to the total or individual time schedule stipulated in the said Contract and if there be delay in the . . . . . to reimburse to the HLL interest at the prevailing rate as applicable for cash/ credit facilities on the amount of advance payment made by the HLL.
7. The HLL shall have the fullest liberty without affecting in any way the liability of the bank under this guarantee from time to time to extend the time of performance by the CRO. The Bank shall not be released from its liability under these presents by any exercise of the HLL of the liberty with reference to the matter aforesaid.
8. The Bank also agrees that the HLL shall be entitled at his option to enforce this guarantee against the Bank as a Principal Debtor, in the first instance notwithstanding any other Security or Guarantee that it may have in relation to the CRO` s liabilities.
9. The Bank further agrees that the decision of the HLL as to the failure on the part of the CRO to fulfil the Contractual obligations stipulated in the said Contract and/or to the amount payable by the Bank to the HLL shall be final conclusive and binding.

10. This guarantee is revocable only with the written consent of the HLL.
11. This guarantee shall remain in force upto and including..... and shall be extended from time to time for such period as may be desired by M/S.....  
..... on whose behalf this guarantee has been given.
12. In any case, our liability under this advance payment guarantee does not exceed Rs.....( ..... ) subject however to the application of the interest clause envisaged in para-7 above which will be paid in addition on the said guarantee amount.
13. Notwithstanding anything contained herein:
  - a. Our liability under this bank guarantee shall not exceed ..... (in words)
  - b. this bank guarantee shall be valid upto .....; and
  - c. we are liable to pay the guaranteed amount or any part thereof under this bank guarantee only and only if you serve upon us a written claim or demand on or before .....

Return of this document to us by any person before the aforesaid date will, however, extinguish our liability as on the date of return.

Dated this ..... day of .....2014

FOR AND ON BEHALF OF  
THE.....BANK.  
SIGNATURE OF AUTHORIZED BANK OFFICIAL

NAME: .....

DESIGNATION: .....

STAMP/SEAL OF THE BANK: .....

SIGNED, SEALED AND DELIVERED

FOR AND ON BEHALF OF THE

BANK BY THE ABOVE

NAMED \_\_\_\_\_ IN THE PRESENCE OF:

WITNESS 1.

SIGNATURE .....

NAME .....

ADDRESS .....

WITNESS 2.

SIGNATURE .....

NAME .....

ADDRESS .....DATED



**PRE-CONTRACT INTEGRITY PACT**

THIS PRE-CONTRACT INTEGRITY PACT (HEREIN AFTER CALLED THE INTEGRITY PACT) IS MADE ON \_\_\_\_\_ DAY OF THE MONTH OF FEBRUARY 2012,

**BETWEEN**

HLL LIFE CARE LIMITED, A GOVERNMENT OF INDIA ENTERPRISE WITH REGISTERED OFFICE AT HLL BHAVAN, POOJAPPURA, THIRUVANANTHAPURAM 695 012, KERALA, INDIA. (HEREINAFTER CALLED "HLL", WHICH EXPRESSION SHALL MEAN AND INCLUDE, UNLESS THE CONTEXT OTHERWISE REQUIRES, HIS SUCCESSORS IN OFFICE AND ASSIGNS) OF THE FIRST PARTY.

**AND**

M/s \_\_\_\_\_ WITH OFFICE AT ..... REPRESENTED BY SHRI \_\_\_\_\_, (HEREINAFTER CALLED THE "BIDDER/SELLER"/CONTRACTOR WHICH EXPRESSION SHALL MEAN AND INCLUDE, UNLESS THE CONTEXT OTHERWISE REQUIRES, HIS SUCCESSORS AND PERMITTED ASSIGNS) OF THE SECOND PARTY.

**PREAMBLE**

[BOTH HLL AND BIDDER REFERRED ABOVE ARE JOINTLY REFERRED TO AS THE PARTIES]

HLL INTENDS TO AWARD, UNDER LAID DOWN ORGANIZATIONAL PROCEDURES, PURCHASE ORDERS / CONTRACT/S AGAINST TENDER /WORK ORDER /PURCHASE ORDER NO. .... HLL DESIRES FULL COMPLIANCE WITH ALL RELEVANT LAWS AND REGULATIONS, AND THE PRINCIPLES OF ECONOMIC USE OF RESOURCES, AND OF FAIRNESS AND TRANSPARENCY IN ITS RELATIONS WITH ITS BIDDER/S AND CONTRACTOR/S.

NOW, THEREFORE,

TO AVOID ALL FORMS OF CORRUPTION BY FOLLOWING A SYSTEM THAT IS FAIR, TRANSPARENT AND FREE FROM ANY INFLUENCE/PREJUDICED DEALINGS PRIOR TO, DURING AND SUBSEQUENT TO THE CURRENCY OF THE CONTRACT TO BE ENTERED INTO WITH A VIEW TO:-

1. ENABLE HLL TO OBTAIN THE DESIRED MATERIALS/ STORES/EQUIPMENT/ WORK/ PROJECT DONE AT A COMPETITIVE PRICE IN CONFORMITY WITH THE DEFINED SPECIFICATIONS BY AVOIDING THE HIGH COST AND THE DISTORTIONARY IMPACT OF CORRUPTION ON PUBLIC PROCUREMENT; AND
2. ENABLE THE BIDDER TO ABSTAIN FROM BRIBING OR INDULGING IN ANY CORRUPT PRACTICE IN ORDER TO SECURE THE CONTRACT BY PROVIDING ASSURANCE TO THEM THAT THEIR COMPETITORS WILL ALSO ABSTAIN FROM BRIBING AND OTHER CORRUPT PRACTICES AND HLL WILL COMMIT TO PREVENT CORRUPTION, IN ANY FORM, BY ITS OFFICIALS BY FOLLOWING TRANSPARENT PROCEDURES.

THE PARTIES HERETO HEREBY AGREE TO ENTER INTO THIS INTEGRITY PACT AND AGREE AS FOLLOWS:

**CLAUSE.1. COMMITMENTS OF HLL**

- 1.1 HLL UNDERTAKES THAT HLL AND/OR ITS ASSOCIATES (I.E. EMPLOYEES, AGENTS, CONSULTANTS, ADVISORS, ETC.) WILL NOT DEMAND, TAKE A PROMISE FOR OR ACCEPT, DIRECTLY OR THROUGH INTERMEDIARIES, ANY BRIBE, CONSIDERATION, GIFT, REWARD, FAVOUR OR ANY MATERIAL OR IMMATERIAL BENEFIT OR ANY OTHER ADVANTAGE FROM THE BIDDER, EITHER FOR THEMSELVES OR FOR ANY PERSON, ORGANIZATION OR THIRD PARTY RELATED TO THE CONTRACT IN EXCHANGE FOR AN ADVANTAGE IN THE BIDDING PROCESS, BID EVALUATION, CONTRACTING OR IMPLEMENTATION PROCESS RELATED TO THE CONTRACT.
- 1.2 HLL WILL, DURING THE TENDER PROCESS / PRE-CONTRACT STAGE, TREAT ALL BIDDERS WITH EQUITY AND REASON, AND WILL PROVIDE TO ALL BIDDERS THE SAME INFORMATION AND WILL NOT PROVIDE ANY SUCH INFORMATION OR ADDITIONAL INFORMATION, WHICH IS CONFIDENTIAL IN ANY MANNER, TO ANY PARTICULAR BIDDER WHICH COULD AFFORD AN ADVANTAGE TO THAT PARTICULAR BIDDER IN COMPARISON TO OTHER BIDDERS IN RELATION TO TENDERING PROCESS OR DURING THE CONTRACT EXECUTION.
- 1.3 ALL THE OFFICIALS OF HLL WILL REPORT TO CHIEF VIGILANCE OFFICER OF HLL (CVO), ANY ATTEMPTED OR COMPLETED BREACHES OF THE ABOVE COMMITMENTS AS WELL AS ANY SUBSTANTIAL SUSPICION OF SUCH A BREACH.
- 1.4 HLL WILL EXCLUDE FROM THE PROCESS ALL KNOWN PREJUDICED PERSONS AND PERSONS WHO WOULD BE KNOWN TO HAVE A CONNECTION OR NEXUS WITH THE PROSPECTIVE BIDDER.
- 1.5 IF THE BIDDER REPORTS TO HLL WITH FULL AND VERIFIABLE FACTS ANY MISCONDUCT ON THE PART OF HLL'S ASSOCIATES (I.E. EMPLOYEES, AGENTS, CONSULTANTS, ADVISORS, ETC.) AND THE SAME IS PRIMA FACIE FOUND TO BE CORRECT BY HLL, NECESSARY DISCIPLINARY PROCEEDINGS, OR ANY OTHER ACTION AS DEEMED FIT, INCLUDING CRIMINAL PROCEEDINGS MAY BE INITIATED BY HLL. FURTHER, SUCH AN ASSOCIATE MAY BE DEBARRED FROM FURTHER DEALINGS RELATED TO THE CONTRACT PROCESS. IN SUCH A CASE, WHILE AN ENQUIRY IS BEING CONDUCTED BY HLL THE PROCEEDINGS UNDER THE CONTRACT WOULD NOT BE STALLED.

**CLAUSE 2. COMMITMENTS OF BIDDERS/ CONTRACTORS**

2. THE BIDDER COMMITS ITSELF TO TAKE ALL MEASURES NECESSARY TO PREVENT CORRUPT PRACTICES, UNFAIR MEANS AND ILLEGAL ACTIVITIES DURING ANY STAGE OF ITS BID OR DURING ANY PRE-CONTRACT OR POST-CONTRACT STAGE IN ORDER TO SECURE THE CONTRACT OR IN FURTHERANCE TO SECURE IT AND IN PARTICULAR COMMIT ITSELF TO THE FOLLOWING:-
  - 2.1 THE BIDDER WILL NOT OFFER, DIRECTLY OR INDIRECTLY (I.E. EMPLOYEES, AGENTS, CONSULTANTS, ADVISORS, ETC.) ANY BRIBE, GIFT, CONSIDERATION, REWARD, FAVOUR, ANY MATERIAL OR IMMATERIAL BENEFIT OR OTHER ADVANTAGE,

COMMISSION, FEES, BROKERAGE OR INDUCEMENT TO ANY OFFICIAL OF HLL, CONNECTED DIRECTLY OR INDIRECTLY WITH THE BIDDING PROCESS, OR TO ANY PERSON, ORGANIZATION OR THIRD PARTY RELATED TO THE CONTRACT IN EXCHANGE FOR ANY ADVANTAGE IN THE BIDDING, EVALUATION, CONTRACTING AND IMPLEMENTATION OF THE CONTRACT.

- 2.2 THE BIDDER FURTHER UNDERTAKES THAT IT HAS NOT GIVEN, OFFERED OR PROMISED TO GIVE, DIRECTLY OR INDIRECTLY ANY BRIBE, GIFT, CONSIDERATION, REWARD, FAVOUR, ANY MATERIAL OR IMMATERIAL BENEFIT OR OTHER ADVANTAGE, COMMISSION, FEES, BROKERAGE OR INDUCEMENT TO ANY OFFICIAL OF HLL OR OTHERWISE IN PROCURING THE CONTRACT OR FORBEARING TO DO OR HAVING DONE ANY ACT IN RELATION TO OBTAINING OR EXECUTION OF THE CONTRACT OR ANY OTHER CONTRACT WITH THE GOVERNMENT FOR SHOWING OR FORBEARING TO SHOW FAVOUR OR DISFAVOR TO ANY PERSON IN RELATION TO THE CONTRACT OR ANY OTHER CONTRACT WITH THE GOVERNMENT.
- 2.3 THE BIDDER WILL NOT ENGAGE IN COLLUSION, PRICE FIXING, CARTELIZATION, ETC. WITH OTHER COUNTERPARTY(S).
- 2.4 THE COUNTERPARTY WILL NOT PASS TO ANY THIRD PARTY ANY CONFIDENTIAL INFORMATION ENTRUSTED TO IT, UNLESS DULY AUTHORIZED BY HLL.
- 2.5 THE COUNTERPARTY WILL PROMOTE AND OBSERVE ETHICAL PRACTICES WITHIN ITS ORGANIZATION AND ITS AFFILIATES.
- 2.6 BIDDER SHALL DISCLOSE THE NAME AND ADDRESS OF AGENTS AND REPRESENTATIVES AND INDIAN BIDDERS SHALL DISCLOSE THEIR FOREIGN PRINCIPALS OR ASSOCIATES.
- 2.7 THE COUNTERPARTY WILL NOT MAKE ANY FALSE OR MISLEADING ALLEGATIONS AGAINST HLL OR ITS ASSOCIATES.
- 2.8 BIDDERS SHALL DISCLOSE THE PAYMENTS TO BE MADE BY THEM TO AGENTS/BROKERS OR ANY OTHER INTERMEDIARY, IN CONNECTION WITH THIS BID/CONTRACT.
- 2.9 THE BIDDER FURTHER CONFIRMS AND DECLARES TO HLL THAT THE BIDDER IS THE ORIGINAL MANUFACTURE/INTEGRATOR/AUTHORIZED GOVERNMENT SPONSORED EXPORT ENTITY OF THE DEFENSE STORES AND HAS NOT ENGAGED ANY INDIVIDUAL OR FIRM OR COMPANY WHETHER INDIAN OR FOREIGN TO INTERCEDE, FACILITATE OR IN ANY WAY TO RECOMMEND TO HLL OR ANY OF ITS FUNCTIONARIES, WHETHER OFFICIALLY OR UNOFFICIALLY TO AWARD THE CONTRACT TO THE BIDDER, NOR HAS ANY AMOUNT BEEN PAID, PROMISED OR INTENDED TO BE PAID TO ANY SUCH INDIVIDUAL, FIRM OR COMPANY IN RESPECT OF ANY SUCH INTERCESSION, FACILITATION OR RECOMMENDATION.
- 2.10 THE BIDDER WHILE PRESENTING THE BID OR DURING PRE-CONTRACT NEGOTIATIONS OR BEFORE SIGNING THE CONTRACT, SHALL DISCLOSE ANY PAYMENTS HE HAS MADE, IS COMMITTED TO OR INTENDS TO MAKE TO OFFICIALS OF HLL OR THEIR FAMILY MEMBERS, AGENTS, BROKERS OR ANY OTHER INTERMEDIARIES IN

CONNECTION WITH THE CONTRACT AND THE DETAILS OF SERVICES AGREED UPON FOR SUCH PAYMENTS.

- 2.11 THE BIDDER WILL NOT ACCEPT ANY ADVANTAGE IN EXCHANGE FOR ANY CORRUPT PRACTICE, UNFAIR MEANS AND ILLEGAL ACTIVITIES.
- 2.12 THE BIDDER COMMITS TO REFRAIN FROM GIVING ANY COMPLAINT DIRECTLY OR THROUGH ANY OTHER MANNER WITHOUT SUPPORTING IT WITH FULL AND VERIFIABLE FACTS.
- 2.13 IF THE BIDDER OR ANY EMPLOYEE OF THE BIDDER OR ANY PERSON ACTING ON BEHALF OF THE BIDDER, EITHER DIRECTLY OR INDIRECTLY, IS A RELATIVE OF ANY OF THE OFFICERS OF HLL, OR ALTERNATIVELY, IF ANY RELATIVE OF AN OFFICER OF HLL HAS FINANCIAL INTEREST/STAKE IN THE BIDDER'S FIRM, THE SAME SHALL BE DISCLOSED BY THE BIDDER AT THE TIME OF FILING OF TENDER.

THE TERM 'RELATIVE' FOR THIS PURPOSE WOULD BE AS DEFINED IN SECTION 6 OF THE COMPANIES ACT 1956.

- 2.14 THE BIDDER SHALL NOT LEND TO OR BORROW ANY MONEY FROM OR ENTER INTO ANY MONETARY DEALINGS OR TRANSACTIONS, DIRECTLY OR INDIRECTLY, WITH ANY EMPLOYEE OF HLL.
- 2.15 THE BIDDER WILL NOT COLLUDE WITH OTHER PARTIES INTERESTED IN THE CONTRACT TO IMPAIR THE TRANSPARENCY, FAIRNESS AND PROGRESS OF THE BIDDING PROCESS, BID EVALUATION, CONTRACTING AND IMPLEMENTATION OF THE CONTRACT, AND WILL NOT ENTER INTO ANY UNDISCLOSED AGREEMENT OR UNDERSTANDING WITH OTHER BIDDERS, WHETHER FORMAL OR INFORMAL. THIS APPLIES IN PARTICULAR TO PRICES, SPECIFICATIONS, CERTIFICATIONS, SUBSIDIARY CONTRACTS, SUBMISSION OR NON-SUBMISSION OF BIDS OR ANY OTHER ACTIONS TO RESTRICT COMPETITIVENESS OR TO INTRODUCE CARTELIZATION IN THE BIDDING PROCESS.
- 2.16 THE BIDDER WILL NOT COMMIT ANY OFFENCE UNDER THE RELEVANT INDIAN PENAL CODE, 1860 OR PREVENTION OF CORRUPTION ACT, 1988; FURTHER THE BIDDER(S)/ CONTRACTOR(S) WILL NOT USE IMPROPERLY, FOR PURPOSES OF COMPETITION OR PERSONAL GAIN, OR PASS ON TO OTHERS, ANY INFORMATION OR DOCUMENT PROVIDED BY THE HLL AS PART OF THE BUSINESS RELATIONSHIP, REGARDING PLANS, TECHNICAL PROPOSALS AND BUSINESS DETAILS, INCLUDING INFORMATION CONTAINED OR TRANSMITTED ELECTRONICALLY. THE BIDDER ALSO UNDERTAKES TO EXERCISE DUE AND ADEQUATE CARE LEST ANY SUCH INFORMATION IS DIVULGED.
- 2.17 THE BIDDER WILL NOT INSTIGATE THIRD PERSONS TO COMMIT OFFENCES OUTLINED ABOVE OR BE AN ACCESSORY TO SUCH OFFENCES.
- 2.18 THE BIDDER(S)/CONTRACTORS(S) OF FOREIGN ORIGIN SHALL DISCLOSE THE NAME AND ADDRESS OF THE AGENTS/REPRESENTATIVES IN INDIA, IF ANY. SIMILARLY THE

BIDDER(S)/CONTRACTORS(S) OF INDIAN NATIONALITY SHALL FURNISH THE NAME AND ADDRESS OF THE FOREIGN PRINCIPAL(S), IF ANY.

**CLAUSE.3. PREVIOUS CONTRAVENTION AND DISQUALIFICATION FROM TENDER PROCESS AND EXCLUSION FROM FUTURE CONTRACTS**

**3.1** THE BIDDER DECLARES THAT NO PREVIOUS CONTRAVENTION OCCURRED IN THE LAST THREE YEARS IMMEDIATELY BEFORE SIGNING OF THIS INTEGRITY PACT, WITH ANY OTHER COMPANY IN ANY COUNTRY IN RESPECT OF ANY CORRUPT PRACTICES ENVISAGED HEREUNDER OR WITH ANY PUBLIC SECTOR ENTERPRISE IN INDIA OR ANY GOVERNMENT DEPARTMENT IN INDIA THAT COULD JUSTIFY BIDDER'S EXCLUSION FROM THE TENDER PROCESS

**3.2** THE BIDDER AGREES THAT IF IT MAKES INCORRECT STATEMENT ON THIS SUBJECT, BIDDER CAN BE DISQUALIFIED FROM THE TENDER PROCESS OR THE CONTRACT, IF ALREADY AWARDED, CAN BE TERMINATED FOR SUCH REASON.

IF BIDDER BEFORE AWARD OR DURING EXECUTION HAS COMMITTED A CONTRAVENTION THROUGH A VIOLATION OF CLAUSE 2, ABOVE OR IN ANY OTHER FORM SUCH AS TO PUT HIS RELIABILITY OR CREDIBILITY IN QUESTION, T HLL IS ENTITLED TO DISQUALIFY THE BIDDER FROM THE TENDER PROCESS.

**CLAUSE .4. EQUAL TREATMENT OF ALL BIDDERS / CONTRACTORS / SUBCONTRACTORS**

**4.1** THE BIDDER(S)/ CONTRACTOR(S) UNDERTAKE(S) TO DEMAND FROM HIS SUBCONTRACTORS A COMMITMENT IN CONFORMITY WITH THIS INTEGRITY PACT.

**4.2** HLL WILL ENTER INTO AGREEMENTS WITH IDENTICAL CONDITIONS AS THIS ONE WITH ALL BIDDERS AND CONTRACTORS.

**4.3** HLL WILL DISQUALIFY FROM THE TENDER PROCESS ALL BIDDERS WHO DO NOT SIGN THIS PACT OR VIOLATE ITS PROVISIONS.

**CLAUSE .5. CONSEQUENCES OF VIOLATION / BREACH**

**5.1** ANY BREACH OF THE AFORESAID PROVISION BY THE BIDDER OR ANY ONE EMPLOYED BY IT OR ACTING ON ITS BEHALF (WHETHER WITH OR WITHOUT THE KNOWLEDGE OF THE BIDDER) SHALL ENTITLE HLL TO TAKE ALL OR ANY ONE OF THE FOLLOWING ACTION, WHEREVER REQUIRED:-

- i. TO IMMEDIATELY CALL OFF THE PRE-CONTRACT NEGOTIATIONS WITHOUT ASSIGNING ANY REASON OR GIVING ANY COMPENSATION TO THE BIDDER. HOWEVER, THE PROCEEDINGS WITH THE OTHER BIDDER(S) WOULD CONTINUE.

- ii. IF BIDDER COMMITS VIOLATION OF INTEGRITY PACT POLICY DURING BIDDING PROCESS, HE SHALL BE LIABLE TO COMPENSATE HLL BY WAY OF LIQUIDATED DAMAGES AMOUNTING TO A SUM EQUIVALENT TO 5% TO THE VALUE OF THE OFFER OR THE AMOUNT EQUIVALENT TO EARNEST MONEY DEPOSIT/BID SECURITY, WHICHEVER IS HIGHER.
- iii. IN CASE OF VIOLATION OF THE INTEGRITY PACT AFTER AWARD OF THE CONTRACT, HLL WILL BE ENTITLED TO TERMINATE THE CONTRACT. HLL SHALL ALSO BE ENTITLED TO RECOVER FROM THE CONTRACTOR LIQUIDATED DAMAGES EQUIVALENT TO 10% OF THE CONTRACT VALUE OR THE AMOUNT EQUIVALENT TO SECURITY DEPOSIT/ PERFORMANCE GUARANTEE, WHICHEVER IS HIGHER.
- iv. TO IMMEDIATELY CANCEL THE CONTRACT, IF ALREADY SIGNED, WITHOUT GIVING ANY COMPENSATION TO THE BIDDER.
- v. TO RECOVER ALL SUMS ALREADY PAID BY HLL, AND IN CASE OF AN INDIAN BIDDER WITH INTEREST THEREON AT 2% HIGHER THAN THE PREVAILING PRIME LENDING RATE OF STATE BANK OF INDIA, WHILE IN CASE OF A BIDDER FROM A COUNTRY OTHER THAN INDIA WITH INTEREST THEREON AT 2% HIGHER THAN THE LIBOR. IF ANY OUTSTANDING PAYMENT IS DUE TO THE BIDDER FROM HLL IN CONNECTION WITH ANY OTHER CONTRACT FOR ANY OTHER STORES, SUCH OUTSTANDING PAYMENT COULD ALSO BE UTILIZED TO RECOVER THE AFORESAID AMOUNT.
- vi. TO ENCASH THE ADVANCE BANK GUARANTEE AND PERFORMANCE GUARANTEE /WARRANTY BOND, IF FURNISHED BY THE BIDDER, IN ORDER TO RECOVER THE PAYMENTS ALREADY MADE BY HLL, ALONG WITH INTEREST.
- vii. TO CANCEL ALL OR ANY OTHER CONTRACT WITH THE BIDDER. THE BIDDER SHALL BE LIABLE TO PAY COMPENSATION FOR ANY LOSS OR DAMAGE TO HLL RESULTING FROM SUCH CANCELLATION/RECESSION AND HLL SHALL BE ENTITLED TO DEDUCT THE AMOUNT SO PAYABLE FROM THE MONEY(S) DUE TO THE BIDDER.
- viii. TO DEBAR THE BIDDER FROM PARTICIPATING IN FUTURE BIDDING PROCESSES OF HLL FOR A MINIMUM PERIOD OF FIVE (5) YEARS, WHICH MAY BE FURTHER EXTENDED AT THE DISCRETION OF HLL OR UNTIL INDEPENDENT EXTERNAL MONITORS IS SATISFIED THAT THE COUNTERPARTY WILL NOT COMMIT ANY FUTURE VIOLATION.
- ix. TO RECOVER ALL SUMS PAID IN VIOLATION OF THIS PACT BY BIDDER(S) TO ANY MIDDLEMAN OR AGENT OR BROKER WITH A VIEW TO SECURING THE CONTRACT.
- x. IN CASES WHERE IRREVOCABLE LETTERS OF CREDIT HAVE BEEN RECEIVED IN RESPECT OF ANY CONTRACT SIGNED BY HLL WITH THE BIDDER, THE SAME SHALL NOT BE OPENED.

5.2 HLL WILL BE ENTITLED TO ALL OR ANY OF THE ACTIONS MENTIONED IN PARA 5.1(I) TO (X) OF THIS PACT ALSO ON THE COMMISSION BY THE BIDDER OR ANY ONE EMPLOYED BY IT OR ACTING ON ITS BEHALF (WHETHER WITH OR WITHOUT THE KNOWLEDGE OF THE BIDDER), OF AN OFFENCE AS DEFINED IN CHAPTER IX OF THE INDIAN PENAL CODE, 1860 OR PREVENTION OF CORRUPTION ACT, 1988 OR ANY OTHER STATUTE ENACTED FOR PREVENTION OF CORRUPTION.

5.3 THE DECISION OF HLL TO THE EFFECT THAT A BREACH OF THE PROVISIONS OF THIS PACT HAS BEEN COMMITTED BY THE BIDDER SHALL BE FINAL AND CONCLUSIVE ON THE BIDDER. HOWEVER, THE BIDDER CAN APPROACH THE INDEPENDENT EXTERNAL MONITOR(S) APPOINTED FOR THE PURPOSES OF THIS PACT.

**CLAUSE.6. FALL CLAUSE**

THE BIDDER UNDERTAKES THAT IT HAS NOT SUPPLIED/IS NOT SUPPLYING SIMILAR PRODUCT/SYSTEMS OR SUBSYSTEMS OR PROVIDING SIMILAR SERVICES AT A PRICE / CHARGE LOWER THAN THAT OFFERED IN THE PRESENT BID IN RESPECT OF ANY OTHER MINISTRY/DEPARTMENT OF THE GOVERNMENT OF INDIA OR PSU AND IF IT IS FOUND ANY STAGE THAT SIMILAR PRODUCT/SYSTEMS OR SUB SYSTEMS WAS SUPPLIED BY THE BIDDER TO ANY TO THE MINISTRY/DEPARTMENT OF THE GOVERNMENT OF INDIA OR A PSU AT A LOWER PRICE, THEN THAT VERY PRICE, WITH DUE ALLOWANCE FOR ELAPSED TIME WILL BE APPLICABLE TO THE PRESENT CASE AND THE DIFFERENCE IN THE COST WOULD BE REFUNDED BY THE BIDDER TO HLL, IF THE CONTRACT HAS ALREADY BEEN CONCLUDED.

**CLAUSE .7. INDEPENDENT EXTERNAL MONITOR(S)**

7.1 HLL HAS APPOINTED INDEPENDENT EXTERNAL MONITOR(S) (HEREINAFTER REFERRED TO AS MONITOR(S)) FOR THIS PACT IN CONSULTATION WITH THE CENTRAL VIGILANCE COMMISSION (NAME AND ADDRESSES OF THE MONITOR(S) TO BE GIVEN).

7.2 THE RESPONSIBILITY OF THE MONITOR(S) SHALL BE TO REVIEW INDEPENDENTLY AND OBJECTIVELY, WHETHER AND TO WHAT EXTENT THE PARTIES COMPLY WITH THE OBLIGATIONS UNDER THIS PACT.

7.3 THE MONITOR(S) SHALL NOT BE SUBJECT TO INSTRUCTIONS BY THE REPRESENTATIVES OF THE PARTIES AND PERFORM THEIR FUNCTIONS NEUTRALLY AND INDEPENDENTLY.

7.4 BOTH THE PARTIES ACCEPT THAT THE MONITOR(S) HAVE THE RIGHT TO ACCESS ALL THE DOCUMENTS RELATING TO THE PROJECT/ PROCUREMENT, INCLUDING MINUTES OF MEETINGS.

7.5 AS SOON AS THE MONITOR(S) NOTICES, OR HAS REASON TO BELIEVE, A VIOLATION OF THIS PACT, HE WILL SO INFORM THE CVO.

- 7.6 THE BIDDER(S) ACCEPTS THAT THE MONITOR(S) HAVE THE RIGHT TO ACCESS WITHOUT RESTRICTION TO ALL PROJECT DOCUMENTATION OF HLL INCLUDING THAT PROVIDED BY THE BIDDER. THE BIDDER WILL ALSO GRANT THE MONITOR(S), UPON HIS REQUEST AND DEMONSTRATION OF A VALID INTEREST, UNRESTRICTED AND UNCONDITIONAL ACCESS TO HIS PROJECT DOCUMENTATION. THE SAME IS APPLICABLE TO SUBCONTRACTORS ENGAGED BY THE BIDDER. THE MONITOR(S) SHALL BE UNDER CONTRACTUAL OBLIGATION TO TREAT THE INFORMATION AND DOCUMENTS OF THE BIDDER/ SUBCONTRACTOR(S) WITH CONFIDENTIALITY.
- 7.7 HLL WILL PROVIDE TO THE MONITOR(S) SUFFICIENT INFORMATION ABOUT ALL MEETINGS AMONG THE PARTIES RELATED TO THE PROJECT PROVIDED SUCH MEETING COULD HAVE AN IMPACT ON THE CONTRACTUAL RELATION BETWEEN THE PARTIES. THE PARTIES WILL OFFER TO THE MONITOR(S) OPTION TO PARTICIPATE IN SUCH MEETINGS.
- 7.8 THE MONITOR(S) WILL SUBMIT A WRITTEN REPORT TO THE CVO OF HLL WITHIN 8 TO 10 WEEKS FROM THE DATE OF REFERENCE OR INTIMATION TO HIM BY HLL/BIDDER AND, SHOULD CONSENT ARISE, SUBMIT PROPOSALS FOR CORRECTING PROBLEMATIC SITUATIONS.

**CLAUSE.8. CRIMINAL CHARGES AGAINST VIOLATING BIDDER(S)/  
\_\_\_\_\_ CONTRACTOR(S)/ SUBCONTRACTOR(S)**

IF HLL OBTAINS KNOWLEDGE OF CONDUCT OF A BIDDER, CONTRACTOR OR SUBCONTRACTOR, OR OF AN EMPLOYEE OR A REPRESENTATIVE OR AN ASSOCIATE OF A BIDDER, CONTRACTOR OR SUBCONTRACTOR WHICH CONSTITUTES CORRUPTION, OR IF HLL HAS SUBSTANTIVE SUSPICION IN THIS REGARD, HLL WILL INFORM THE SAME TO THE CHIEF VIGILANCE OFFICER.

**CLAUSE.9. FACILITATION OF INVESTIGATION**

IN CASE OF ANY ALLEGATION OF VIOLATION OF ANY PROVISIONS OF THIS PACT OR PAYMENT OF COMMISSION, HLL OR ITS AGENCIES SHALL BE ENTITLED TO EXAMINE ALL THE DOCUMENTS, INCLUDING THE BOOKS OF ACCOUNTS OF THE BIDDER AND THE BIDDER SHALL PROVIDE NECESSARY INFORMATION AND DOCUMENTS IN ENGLISH AND SHALL EXTEND ALL POSSIBLE HELP FOR THE PURPOSE OF SUCH EXAMINATION.

**CLAUSE.10. LAW AND PLACE OF JURISDICTION**

BOTH THE PARTIES AGREE THAT THIS PACT IS SUBJECT TO INDIAN LAW. THE PLACE OF PERFORMANCE AND HENCE THIS PACT SHALL BE SUBJECT TO THIRUVANANTHAPURAM JURISDICTION.

**CLAUSE.11. OTHER LEGAL ACTIONS**

THE ACTIONS STIPULATED IN THE INTEGRITY PACT ARE WITHOUT PREJUDICE TO ANY OTHER LEGAL ACTION THAT MAY FOLLOW IN ACCORDANCE WITH THE PROVISIONS OF THE EXTANT LAW IN FORCE RELATING TO ANY CIVIL OR CRIMINAL PROCEEDINGS.

**CLAUSE.12. VALIDITY AND DURATION OF THE AGREEMENT**

THIS PACT BEGINS WHEN BOTH PARTIES HAVE LEGALLY SIGNED IT. IT EXPIRES FOR THE CONTRACTOR/SUCCESSFUL BIDDER 12 MONTHS AFTER THE LAST PAYMENT UNDER THE



CONTRACT OR THE COMPLETE EXECUTION OF THE CONTRACT TO THE SATISFACTION OF THE BOTH HLL AND THE BIDDER /SELLER, INCLUDING WARRANTY PERIOD, WHICHEVER IS LATER, AND FOR ALL OTHER BIDDERS/UNSUCCESSFUL BIDDERS 6 MONTHS AFTER THE CONTRACT HAS BEEN AWARDED.

IF ANY CLAIM IS MADE / LODGED DURING THIS TIME, THE SAME SHALL BE BINDING AND CONTINUE TO BE VALID DESPITE THE LAPSE OF THIS PACT AS SPECIFIED ABOVE, UNLESS IT IS DISCHARGED / DETERMINED BY CHAIRMAN AND MANAGING DIRECTOR OF HLL.

**CLAUSE. 13. OTHER PROVISIONS**

- 13.1 CHANGES AND SUPPLEMENTS AS WELL AS TERMINATION NOTICES NEED TO BE MADE IN WRITING. BOTH THE PARTIES DECLARE THAT NO SIDE AGREEMENTS HAVE BEEN MADE TO THIS INTEGRITY PACT.
  
- 13.1 IF THE CONTRACTOR IS A PARTNERSHIP OR A CONSORTIUM, THIS AGREEMENT MUST BE SIGNED BY ALL PARTNERS OR CONSORTIUM MEMBERS.
  
- 13.1 SHOULD ONE OR SEVERAL PROVISIONS OF THIS AGREEMENT TURN OUT TO BE INVALID, THE REMAINDER OF THIS AGREEMENT REMAINS VALID. IN THIS CASE, THE PARTIES WILL STRIVE TO COME TO AN AGREEMENT TO THEIR ORIGINAL INTENTIONS

INWITNESS THEREOF THE PARTIES HAVE SIGNED AND EXECUTED THIS PACT AT THE PLACE AND DATE FIRST ABOVE MENTIONED IN THE PRESENTS OF FOLLOWING WITNESSES:

**HLL**

**BIDDER**

NAME: .....

NAME: .....

DESIGNATION: .....

DESIGNATION: .....

SIGNATURE: .....

SIGNATURE: .....

WITNESS

WITNESS

1.....

1.....

2.....

2.....

\* PROVISIONS OF THESE CLAUSES WOULD BE AMENDED /DELETED IN LINE WITH THE POLICY OF THE HLL IN REGARD TO INVOLVEMENT OF INDIAN AGENTS OF FOREIGN SUPPLIERS.

**GENERAL INFORMATION**

Notes:

(i) Attach an attested photocopy of Certificate of Registration.

1. Names of the firm: .....

2. Legal Status of the Firm: Individual/Association/Joint Venture/Consortium

3. Registered Address, telephone, Tele-fax.

.....  
.....  
.....

4. Contact Person, Designation and address including email id

.....  
.....  
.....  
.....

5. Number of years in Clinical Research

6. Details of registration of with DCGI.....

7. Number projects for the last three years .....

8. Names and Addresses of Associated HLLs in - Clinical trials - for last five years.

9. State the Quality System followed in the Company. Does the company have an ISO certificate or it follows an internal quality system.

**NUMBER OF CLINICAL TRIALS CONDUCTED IN THE LAST FIVE  
YEARS IN CONTRACEPTIVES FOR FEMALES**

Sl. No.	Study Title	Name and address of the Sponsor	Details of the study			Year of Completion of Study	Remarks
			Phase	Study Design	Cost		
1							
2							
3							
4							
5							

**KEY PERSONNEL DETAILS**

Sl. No.	Technical Team	Education	Designation	Total Years of Experience	Relevant Experience in years	Details in Annexure on page no.
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Note:

- 1) A summary of the qualification and work experience of each key staff, to be attached.
- 2) CVs to be submitted for all the proposed personnel in the format provided

**CVs OF KEY STAFF**

<b>Name of the Staff</b>		
<b>Designation</b>		
<b>Name of the CRO presently employed</b>		
<b>Years with the CRO</b>		
<b>Proposed position</b>		
<b>Details of task assigned</b>		
<b>Man- Months budgeted for the task assigned</b>		
<b>Key Qualifications</b>		
<b>Education</b>		
<b>Employment Record</b>		
<b>Name of the CRO</b>	<b>Position Held</b>	<b>Years of Employment</b>

**FINANCIAL DATA****Annual Turnover during the last three financial years separately:**

<b>Sl. No.</b>	<b>Description</b>	<b>FY 2010-2011 (Rs.in lakh)</b>	<b>FY 2011-2012 (Rs.in lakh)</b>	<b>FY 2012-2013 (Rs.in Lakh)</b>
(1)	(2)	(3)	(4)	(5)
1.	Annual Turnover during the last three financial years separately			

**Attach audited balance sheets in support of the data clearly marking the relevant portion. Also attach copies of Income Tax Returns filed.**

### Confidential Disclosure Agreement

This agreement (“**Agreement**”) is made and entered into this date .....of.....**2014**

by and between

**Corporate R&D Centre, HLL Lifecare Ltd.**, a company Government of India Enterprise registered under the Companies Act, 1956 and having its registered office and Corporate office at HLL Bhavan, Mahilamandiram Road, Poojappura, Thiruvananthpuram , Kerala-695012 and its Research & Development Unit at **Akkulam Sreekariyam PO**, Thiruvananthpuram,Kerala 695017 (here in after referred to as “**HLL**” which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns)

And

....., a company registered under the **Companies Act** .....and having its registered and Corporate office at .....(hereinafter referred to as.....which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns)

(HLL and .....are hereinafter individually referred to as a “**Party**” and collectively referred to as the “**Parties**”).

**Whereas** the Parties wish to discuss business opportunities in connection with **Clinical Trial Studies** (the “**Purpose**”);

**Whereas** in connection with the Purpose, each Party (the “**Discloser**”) will disclose certain commercial, scientific, technical and other type of information to other Party (the “**Recipient**”) which must remain confidential, including without limitation, any trade secrets, know-how, formulations, techniques, equipment, pre-clinical, clinical and other data, methods, results, patent, patent application, trademark, copyright or other intellectual property right, manufacturing information, technical, financial or business information, partners, and the existence, scope and activities of any research, development, manufacturing, marketing, or other projects of HLL and....., its Affiliates or business partners respectively, in whatever form and using whichever media, whether marked as confidential or not (hereinafter referred to as the “**Confidential Information**”).

“**Affiliate**” means, for the purpose of this Agreement and with respect to a Party, any entity that is a subsidiary of such Party or is directly or indirectly controlling, controlled by or under common control with such Party.

**In consideration** of these premises and in order to induce the Discloser to disclose the Confidential Information to the Recipient, the Parties hereby agree as follows:

1. The Recipient agrees to retain the Confidential Information in strict confidentiality, not to use it for any purposes other than for the Purpose and not to disclose it to others except to those of their respective authorized representatives that need to access the Confidential Information for the Purpose and only if such authorised representatives have previously undertaken to not disclose the Confidential Information to others or are bound by similar duties of confidentiality to the Recipient with respect to the Confidential Information. For the purpose of this Agreement, any disclosure of Confidential Information made by or on behalf of the Discloser, including by employees, agents or consultants of the Discloser and its Affiliates, shall be deemed a disclosure by the Discloser.
2. The Recipient acknowledges and agrees that all communications and information relating to the Purpose received from the Discloser or on its behalf prior to the date of this Agreement shall be deemed to have been received under an obligation of confidentiality from the time of receipt under the terms set out in this Agreement and forms a part of Confidential Information.
3. The obligation of confidentiality and non-use of Confidential Information shall not apply to the Confidential Information which:
  - a. was in possession of the Recipient prior to disclosure by the Discloser;
  - b. is or becomes generally available or known to the public, through no fault of or breach of its obligations hereunder by the Recipient, its Affiliates or any of its authorized representatives or consultants;
  - c. is lawfully disclosed to the Recipient by a third party not bound by non-disclosure obligations with regard to such information or to the Discloser or its Affiliates or business partners to which the Confidential Information relates;
  - d. was already known by the Recipient prior to its disclosure by or on behalf of the Discloser, otherwise than by unlawful disclosure, as evidenced by written dated records; or



- e. was independently developed by the Recipient without the benefit of the Confidential Information supplied.

The onus is on the Recipient who to prove that any of the above mentioned exceptions apply.

4. The Recipient agrees to maintain the Confidential Information as confidential taking the same caution level as it would take with its own confidential information with a similar sensitivity but in any event follow reasonable procedures to prevent unauthorised disclosure or use of the Confidential Information and to prevent it from falling into the public domain or the possession of unauthorised persons.
5. Any inventions or improvements whether patentable or unpatentable which are conceived of, discovered, or developed by the Receiver, its Affiliates or by any person claiming through them in any way derived from, related to, based on, or resulting from the use of the Confidential Information (“**Derivative IP**”) shall be promptly disclosed to the Discloser. Any Derivative IP shall be the sole property of the Discloser. The Receiver, its Affiliates and any person claiming through them shall do all acts and things as shall be necessary to vest all right, title and interest therein in the Discloser. The Receiver shall keep Derivative IP confidential in accordance with this Agreement. The Receiver therefore undertakes that it will not reverse engineer, decompile or disassemble the Confidential Information or make any variant out of the Confidential Information and strictly use or abide the terms of this Agreement.
6. The Recipient is liable for any breach of this Agreement by any of its employees, officers, directors, representatives, agents and consultants, and agrees to take any and all necessary actions (including legal proceedings), at its own cost and expense, in order to prevent and remedy to such breach.
7. The Confidential Information and any right, title and interest therein shall remain the exclusive property of the Discloser, its Affiliates or partners, as the case may be, and nothing contained in this Agreement shall be construed as creating an express or implied license to practice or use the Confidential Information for the Recipient’s or third parties’ benefit.
8. If the Recipient is required by applicable law or court order to disclose any Confidential Information, it shall first notify the Discloser in writing, sufficiently in advance so as to provide the Discloser with reasonable opportunity to seek to prevent such disclosure or to seek to obtain a protective order for such Confidential Information and shall disclose only that portion of the Confidential Information that Recipient is legally required to disclose.

9. The Recipient acknowledges and agrees that the Discloser is not making and shall not be deemed to have made any representations or warranties regarding the accuracy or completeness of the Confidential Information or any other type of information furnished in accordance with this Agreement.
10. Upon expiration or termination of this Agreement as set forth in Section 12 below or earlier upon receipt of a written request from the Discloser, the Recipient shall cease all use of the Confidential Information and promptly return to the Discloser all documents and materials of the Discloser which relate to or contain any of the Confidential Information without retaining any copy thereof. The Recipient or its Affiliates shall not use or exploit the Confidential Information retained in intangible form in the unaided memory of its directors, employees, contractors, advisors or of any person to whom such Confidential Information is shared.
11. Because the Discloser may not be adequately compensated in damages in the event of a breach of this Agreement by the Recipient, the Discloser shall be entitled, in addition to any other rights or remedies available to it (including damages), to an injunction restraining such breach or any threatened breach and to specific performance of any obligation thereof.
12. This Agreement shall become effective on the date first above written and shall remain in full effect for 5 (five) Year(s) from the date of signing or until at any earlier time, the Discloser expresses its intention to terminate this Agreement by giving written notice of termination to Recipient, whichever comes earlier, provided that such termination or expiration of this Agreement shall not affect the Recipient's obligations hereunder with respect to the Confidential Information that has been disclosed or delivered prior to termination or expiration, which shall survive as long as the Confidential Information does not fall into one of the exceptions mentioned in Section 3 above.
13. Any notice, direction or other instrument required or permitted to be given under this Agreement shall be in writing and given by delivering it by hand or sending it by registered mail with receipt requested, by recognized courier service with acknowledgement of receipt requested, by facsimile or other similar form of recorded communication addressed:

To .....at:  
HLL Lifecare Limited at:  
**Corporate R&D Centre,  
HLL Lifecare Ltd.  
Akkulam Sreekariyam PO,  
Thiruvananthapuram, Kerala  
India, 695017**

Any such communication shall be deemed to have been validly and effectively given (i) if personally delivered or sent by registered mail (with receipt requested), by internationally recognized courier service with acknowledgement of receipt requested, on the date of such delivery or receipt if such date is on a business day prior to 4:00 p.m. (local time at the place of delivery) and otherwise on the next business day, or (ii) if transmitted by facsimile or similar means of recorded communication on the business day following the date of transmission.

Any Party may change its address for service from time to time by notice given in accordance with the foregoing.

14. Neither of the Parties hereto may assign this Agreement or any of its rights and obligations hereunder.
15. No failure or delay on the part of the Discloser in exercising any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or a future exercise thereof or the exercise of any other right or remedy granted hereby or by law.
16. If any provision of this Agreement is held to be invalid or unenforceable for any reason, it shall be adjusted rather than voided, if possible, in order to achieve the intent of the Parties to the fullest extent possible. In any event, all other provisions of this Agreement shall be deemed valid and enforceable to the fullest extent possible.
17. This Agreement constitutes the entire agreement and understanding between the Parties concerning the subject matter hereof and supersedes all prior discussions, agreements and negotiations between them as to the subject matter hereof. The recitals form an integral part of the Agreement.
18. Nothing in this Agreement shall be deemed to create any obligation on the Discloser to enter into any further agreement.

19. No amendment of this Agreement shall be effective unless made in writing and signed by a duly authorized representative of each Party.

20. This Agreement shall be governed and interpreted according to the laws of Govt. of India (without reference to conflicts of laws provisions).

All disputes or differences or claims arising out of or in connection with, or under or touching this agreement shall be settled amicably between the parties through mutual negotiations and failing the same, such disputes, differences or claims, shall be settled by Arbitration. The arbitration proceedings shall be regulated and governed by Arbitration and Conciliation Act, 1996 shall be finally settled under the sole arbitrator jointly appointed by the parties. The award passed by the arbitrator shall be final and binding on the parties.

21. The place of the arbitration shall be Thiruvananthapuram, Kerala, India. The language of the arbitration proceedings shall be English.

22. The Parties may apply at all times to any competent judicial authority for interim or conservatory measures. The application of a Party to a judicial authority for such measures or the implementation of any such measures ordered by the arbitrator shall not be deemed to be an infringement or a waiver of the arbitration agreement.

**In witness whereof**, the Parties have, by duly authorized persons, executed this Agreement.

**Corporate R&D Centre,  
HLL Life care Ltd.**  
by its duly authorized representative,  
as s/he so declares

.....  
by its duly authorized representative,  
as s/he so declares

**HLL LIFECARE LIMITED**  
**(A Government of India Enterprise)**  
**CORPORATE R & D CENTRE,**  
**AKKULAM, SREEKARIYAM P.O,**  
**THIRUVANANTHAPURAM-695017**

Email: [crdc@lifecarehll.com](mailto:crdc@lifecarehll.com)

Website: [www.lifecarehll.com](http://www.lifecarehll.com)

PH: +91 471 277 4700

FAX: +91 471 277 4707

**FINANCIAL BID DOCUMENT**  
**FOR APPOINTMENT OF**  
**CLINICAL RESEARCH**  
**ORGANIZATION (CRO)**

(FOR THE STUDY OF NOVEL INTRAUTERINE DEVICE (IUD))



**MARCH 2014**

**HLL LIFECARE LIMITED**  
**Corporate R & D Centre,**  
**Akkulam, Thiruvananthapuram - 695017**

**FORMAT FOR FINANCIAL BID**  
**(ON THE LETTER HEAD OF THE COMPANY)**

DATE:

To:

**HEAD (R&D)**  
**Corporate R&D Centre**  
**HLL Lifecare Ltd,**  
**Akkulam, Sreekaryam (P.O)**  
**Thiruvananthapuram – 695017**  
**Kerala**

**SUB.:** OFFER FOR CONDUCTING CLINICAL TRIAL FOR THE STUDY OF NOVEL INTRAUTERINE DEVICE’.

DEAR SIR / MADAM:

BEING DULY AUTHORIZED TO REPRESENT AND ACT ON BEHALF OF ....., AND HAVING REVIEWED AND FULLY UNDERSTOOD ALL THE REQUIREMENTS OF BID SUBMISSION PROVIDED VIDE THE BID DOCUMENT DATED ..... PERTAINING TO THE ABOVE MENTIONED WORK, WE HEREBY PROVIDE OUR FINANCIAL PROPOSAL FOR CONDUCTING CLINICAL TRIAL FOR THE STUDY OF NOVEL INTRAUTERINE DEVICE’

**A. Part A – \_\_PROFESSIONAL COSTS**

<b>SN</b>	<b>ITEM DESCRIPTION</b>	<b>AMOUNT (RS.)</b>
I.	Total Basic Price	
III.	TAXES	
IV.	OTHERS IF ANY	
	<b>TOTAL (RS.)</b>	

**\*\* DETAILED SPLIT UP RATES SHOULD BE ATTACHED SEPARATELY**

**B. Part B – \_\_PASS-THROUGH COSTS**

<b>SN</b>	<b>ITEM DESCRIPTION</b>	<b>AMOUNT (RS.)</b>
I.	Total Basic Price	
III.	TAXES	
IV.	OTHERS IF ANY	
	<b>TOTAL (RS.)</b>	

**\*\* DETAILED SPLIT UP RATES SHOULD BE ATTACHED SEPARATELY**

VALIDITY: SIX MONTHS FROM THE DATE OF OPENING OF FINANCIAL BID

STATUTORY LEVIES IF ANY:

ANY OTHER REMARK (S):

CERTIFIED THAT THE RATE QUOTED WILL HOLD GOOD FOR SIX MONTHS DURING WHICH PERIOD NO UPWARD REVISION WILL BE ASKED FOR.

NAME OF TENDERER: \_\_\_\_\_

PLACE:

DATE:

ADDRESS AND SIGNATURE OF THE TENDERER  
(WITH OFFICE SEAL)

**(Should be given in a sealed envelope).**