Subcontract Agreement issued under a Clinical Trial Agreement

between

The Board of Supervisors of Louisiana State University and

Agricultural and Mechanical College, herein represented by

LSU Health Sciences Center – New Orleans

and

**University Medical Center Management Corporation**

**d/b/a University Medical Center New Orleans**

**PART A. General Conditions**

This Subcontract Agreement, hereafter referred to as the Agreement, entered into by The Board of Supervisors of The Louisiana State University and Agricultural and Mechanical College, herein represented by Louisiana State University Health Sciences Center – New Orleans, represented herein by its duly authorized representatives as set forth on page six below, hereafter referred to as “LSUHSC-NO”, and **University Medical Center Management Corporation dba University Medical Center New Orleans,** hereafter referred to as the “Subcontractor”, establishes policies and procedures for the participation of these institutions in the study entitled: **“INSERT FULL NAME”** (hereinafter also referred to as the “Study” or “Trial”)**,** awarded to LSUHSC-NO by **INSERT LEGAL NAME OF FUNDING AGENCY**,hereinafter referred to as “Sponsor”.

Unless otherwise changed or modified pursuant to an Exception Addendum as defined in Section F(11) hereof, the parties agree as follows:

1. The application made by LSUHSC-NO to Sponsor, and the award notice, contract, letter or other documents sent by the Sponsor to LSUHSC-NO in making the award to LSUHSC-NO that is being used to fund this Agreement (collectively referred to hereafter as the “Award”) apply to this Agreement, and are incorporated herein by reference in their entirety as if attached hereto. The terms and conditions of the Award by the Sponsor, to the extent that such terms and conditions are not inconsistent with the laws of the State of Louisiana, shall apply to this Agreement.

2. The **Period of Performance** for this Agreement shall begin **INSERT START DATE**, and shall remain in effect, unless earlier terminated in acccordance with Section D (2) of this Agreement, until the Study is completed at Subcontractor’s site and all Study documentation required to be provided under the Study is received and accepted by LSUHSC-NO.

3. The **Principal Investigator** for the Study and for this Agreement is **INSERT PI NAME** of LSUHSC-NO, who will be responsible for the overall conduct and management of the Study.

4. [Reserved]

5. **Cost:** LSUHSC-NO agrees to reimburse the Subcontractor from Study funds for actual expenditures and applicable administrative overhead in accordance with **Appendix B**, attached hereto and incorporated herein by reference.

6. **Invoices:** All invoices to be sent shall be sent to:

INSERT PROCESSOR

LSUHSC-NO Dept of Insert Department

INSERT ADDRESS

New Orleans, LA 70112

With a copy to:

LSUHSC-NO Assistant Director of Sponsored Projects

433 Bolivar Street, 6th Floor

New Orleans, LA 70112

**PART B. Scientific Conditions and Statement of Work**

The Principal Investigator will be responsible for the overall scientific conduct of the Study, and will carry out those studies to be done at Subcontractor’s facility.

Subcontractor will assist Principal Investigator in supervising the conduct of Subcontractor’s responsibilities under this Agreement and shall exert reasonable efforts to provide the work as indicated in the Study referenced in Part A of this Agreement, and as set forth in the **Statement of Work** in **Appendix A**, attached hereto and incorporated herein by reference.

**PART C. Financial Conditions**

1. Allowable Costs

a. The authorized amount will cover direct and any applicable indirect costs of the Award, as detailed in the attached budget, which becomes a part of this Agreement as **Appendix B**.

b. The allowance of direct costs will be in accordance with applicable Cost Principles of LSUHSC-NO and applicable fiscal policies and procedures of the Subcontractor, provided such policies and procedures are in compliance with LSUHSC-NO and Sponsor’s guidelines.

2. Submission of Invoices and Places of Payment

Once each month, on the fifteenth (15) day of the month, **or as mutually agreed upon by both parties as evidenced in Appendix B**, the Subcontractor shall submit to LSUHSC-NO an invoice for payment. The invoice shall show current period and cumulative expenditures, itemized by major budget category as described in Appendix B.

LSUHSC-NO shall submit to Subcontractor a remittance notice when it pays each invoice. Remittance notice shall be delivered electronically to the UMC Sponsored Projects email address ([UMC-SponsoredProjects@lcmchealth.org](mailto:UMC-SponsoredProjects@lcmchealth.org)).

**PART D. Other Administrative Conditions**

1. Liability and Indemnification

The Subcontractor shall at all times be considered to be an independent contractor and shall not hold itself out as an employee of LSUHSC-NO. **Unless otherwise provided and agreed upon in the Study**, **each party shall be solely liable for any claims, actions, demands, or damages arising out of its performance of this Agreement.**

To the extent allowable by applicable state law, LSUHSC-NO agrees to indemnify and hold harmless ("Indemnify") Subcontractor from any claim, suit of loss, other than expenses of litigation, sustained by Subcontractor, its trustees, officers, agents, contractors, representatives, sub-investigators, students and employees (collectively, "Indemnified Parties”), for any asserted injury to or death of any person, to the extent that it results from or is caused by the asserted negligence, error or willful misconduct of an LSUHSC-NO employee, officer, student, or agent.

To the extent allowable by applicable state law, Subcontractor agrees to indemnify and hold harmless ("Indemnify") LSUHSC-NO from any claim, suit of loss, other than expenses of litigation, sustained by LSUHSC-NO, its trustees, officers, agents, contractors, representatives, sub-investigators, students and employees (collectively, "Indemnified Parties”), for any asserted injury to or death of any person to the extent that it results from or is caused by the asserted negligence, error or willful misconduct of a Subcontractor’s employee, officer, or agent.

2. Termination

a. Either party shall have the right to terminate, in whole or in part, this Agreement by sending written notice of termination to the other **thirty (30) days (DEPT SOULD REVIEW CTA TO ENSURE THIS IS AMPLE TIME)** prior to the effective date of such termination.

b. It is expressly understood and agreed that in the event that the Study is terminated or the funding thereunder ceases, LSUHSC-NO may, at its option, terminate, in whole or in part, this Agreement by sending written notice of termination to the Subcontractor.

c. Upon notification that this Agreement has been terminated, whether pursuant to paragraph (a) or (b) of this Section D (2), the Subcontractor shall immediately stop all work under this Agreement on the date and to the extent specified in the notice of termination. The Subcontractor shall not place any orders or subcontracts for materials, services, or facilities, except as may be necessary for the completion of such portion of the work as is not terminated. Upon termination of this Agreement, whether pursuant to paragraph (a) or (b) of this Section D (2), LSUHSC-NO agrees to compensate the Subcontractor for all work performed prior to said termination, and not previously paid for under the provisions of Part C.

3. Changes

LSUHSC-NO may, from time to time, request changes in the scope of the services to be performed by the Subcontractor. Such changes which are mutually agreed upon between the Subcontractor and LSUHSC-NO shall be incorporated in written amendments to this Agreement.

4. Study Related Income

If Sponsor’s policy requires that LSUHSC-NO, as awardee, maintain records of the receipt and disposition of all Study-related income generated by award supported activities, then Subcontractor shall likewise maintain records of any Study‑related income generated by their participation in the award supported activity.

5. Remedies for Default

Any claim or controversy arising out of this Agreement shall be resolved by the provisions of La. R.S. 1672.2-1672.4.

6. Study Data

Personal Information Protection. Each party represents and warrants that procedures compatible with relevant personal information and data protection laws and regulations will be employed so that processing and transfer of such information and data identifiers will not be impeded.

7. Inspections and Audits

Both parties shall, to the extent not prohibited by Applicable Law: (i) inform each other as soon as practicable of any effort or request by the government, applicable regulatory authority or other persons to inspect or contact the other party with regard to the Study; (ii) provide each other with a copy of any communications sent by such persons; and (iii) provide each other the opportunity to participate in any proposed or actual responses by the other party to such communications and to make reasonable efforts to ensure that the other party may be present or represented during any such visit.

8. Duty to Update Safety Information

During and for a period of at least two (2) years after the completion of the Study, LSUHSC-NO shall promptly report to the Subcontractor’s Office of Clinical Research any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports as required by the Study protocol. In each case, the Subcontractor shall be free to communicate these findings to each Study subject and the Institutional Review Board (“IRB”).

**PART E. Special Assurances**

1. Non-Discrimination

a. Subcontractor agrees to abide by the requirements of the following as applicable: Title VI and VII of the Civil Rights Act of 1964, as amended by the Equal Opportunity Act of 1972, Federal Executive Order 11246, The Federal Rehabilitation Act of 1973, as amended, the Vietnam Era Veteran's Readjustment Assistance Act of 1974, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1972, the Fair Housing Act of 1968, as amended, and Subcontractor agrees to abide by the requirements of the Americans with Disabilities Act of 1990.

b. Subcontractor agrees not to discriminate in its employment practices, and will render services under this Agreement without regard to race, color, religion, sex, sexual orientation, national origin, veteran status, political affiliation, age and/or disabilities.

c. Any act of discrimination committed by Subcontractor, or failure to comply with these statutory obligations when applicable shall be grounds for termination of this Agreement.

**PART F. Miscellaneous**

1. This Agreement shall be construed under the laws of Louisiana. Both parties agree that this Agreement may be amended as needed to comply with state and federal regulations.

2. RIGHT TO AUDIT. The State Legislative Auditor, and/or the Office of the Governor, Division of Administration Auditors, Federal Auditors, LSUHSC-NO internal auditors or those designated by LSUHSC-NO shall have the option of auditing all accounts pertaining to this Agreement. Records will be made available at mutually agreed upon times during normal working hours for this purpose.

3. FUND USE. Subcontractor agrees not to use funds paid for services rendered under terms of this Agreement to urge any elector to vote for or against any candidate or proposition on an election ballot nor shall such funds be used to lobby for or against any proposition or matter having the effect of law being considered by the legislature or any local governing authority. This provision shall not prevent the normal dissemination of factual information relative to a proposition on any election ballot or a proposition or matter having the effect of law being considered by the legislature or any local governing authority.

4. ASSIGNMENT. Subcontractor shall not assign any interest in this Agreement and shall not transfer any interest in the same (whether by assignment or novation), without prior written consent of LSUHSC-NO and the Office of State Procurement in the Division of Administration provided, however, that claims for money due or to become due to the Subcontractor from LSUHSC-NO under this Agreement may be assigned to a bank, trust company or other financial institution without such approval. Notice of any such assignment or transfer shall be furnished promptly to both LSUHSC-NO and the Office of State Procurement in the Division of Administration.

5. PAYMENT OF TAXES. Subcontractor hereby agrees that the responsibility for payment of taxes from the funds thus received under this Agreement shall be the obligation of the Subcontractor and identified under tax identification number on file with LSUHSC-NO.

6. REBUDGETS. **Rebudgeting from one category to another may be permissible within the specific restrictions placed on the Study**. Prior approval is required, and should be submitted simultaneously to the Principal Investigator (named in Part A of this Agreement) and to the same name and address as specified in Section A (6). Subcontractor shall not exceed any category amount without first obtaining written approval to do so.

7. UNIVERSITY NOTICES. Subcontractor shall adhere to LSUHSC-NO's Code of Conduct which can be viewed at http://www.lsuhsc.edu/no/administration/ocp/conduct.aspx and the LSUHSC-NO's Deficit Reduction Act Notice which can be viewed at: http://www.lsuhsc.edu/no/administration/ocp/dranotice.aspx.

8. NOTICE. Any required notice under this Agreement shall be sent to the following:

LSUHSC-NO: AND TO:

LSUHSC-NO Contract Management Office of the Vice Chancellor for Academic Affairs

533 Bolivar Street, Room 323 433 Bolivar Street, Resource Center: B8-9

New Orleans, LA 70112 New Orleans, LA 70112

Subcontractor:

Jyotsna Fuloria, M.D., Vice President, Clinical Research

University Medical Center – New Orleans

2000 Canal St.

New Orleans, LA 70112

AND TO:

Email: UMC-SponsoredProjects@lcmchealth.org

9. ENTIRE AGREEMENT. With exception of the Award (Clinical Trial Research Agreement) for this Study signed by both parties, this Agreement supersedes all previous contracts or agreements relating to the Protocol and constitutes the entire Agreement between the parties. Neither party shall be entitled to any benefits other than those specified herein. No oral statements or written material not specifically incorporated herein shall be of any force and effect and no changes in or additions to this Agreement shall be recognized unless incorporated herein by amendment as provided herein, such amendment(s) to become effective on the date stipulated in such amendment(s). Provided however, that any other language in this Agreement to the contrary notwithstanding, if there is an Exceptions Addendum, duly executed by all required authorities of LSUHSC-NO and of the Subcontractor, appended to this Agreement, to the extent that the terms and conditions of said Exception Addendum vary from the terms or conditions of this Agreement, then the terms and/or conditions of the Exception Addendum shall prevail.

10. PUBLICITY. Neither party will use the name of the other party or any of its employees or any of its trademarks in any advertising, sales promotional material, or press release without written permission from the other party, except to the extent such disclosure is necessary for complying with Applicable Law.

11. There **IS NOT** an Exception Addendum to this Agreement, and if there is, it consists of zero (0) page(s) in length. It is understood by both parties that this Agreement may be modified or amended only by written agreements signed and duly approved by those representatives of both parties so authorized to enter into agreements, and that no amendment or modification shall take effect until so approved by all parties to the Agreement, and by the State of Louisiana Office of State Procurement, if so required by law.

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SIGNATURE PAGE(S) TO FOLLOW

IN WITNESS WHEREOF, The parties hereunder set their hands to execute this Agreement as of the date first above written.

UNIVERSITY:

***BOARD OF SUPERVISORS OF***

***LOUISIANA STATE UNIVERSITY AND***

***AGRICULTURAL AND MECHANICAL***

***COLLEGE***

***On behalf of LSU Health Sciences Center***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| By: |  | Date: |  |  |

Steve Nelson, M.D.

Interim Chancellor

LSU Health Sciences Center

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| By: |  | Date: |  |  |

Dean, LSU School of Medicine

LSU Health Sciences Center

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| By: |  | Date: |  |  |

INSERT DH NAME

Department Head

Department of INSERT

I have read this Agreement and I understand

my responsibilities pursuant to this Agreement

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| By: |  | Date: |  |  |

INSERT NAME

Principal Investigator

CONTINUATION SIGNATURE PAGE FOLLOWS

SUBCONTRACTOR:

***UNIVERSITY MEDICAL CENTER***

***MANAGEMENT CORPORATION***

***- NEW ORLEANS***

|  |  |  |  |
| --- | --- | --- | --- |
| By: |  | Date: |  |

Christine Bond

Chief Financial Officer

**APPENDIX A: STATEMENT OF WORK**

**SAMPLE ONLY! THIS NEEDS TO BE THOROUGH AND SPECIFIC TO EXACTLY WHAT UMC SHALL PROVIDE IN SERVICES**

Subcontractor hereby agrees to provide the services as agreed to in the Award as a Study Site. In accordance with the Award, terms of this Agreement and detailed budget attached hereto as Appendix B (and if applicable, Exhibit A), LSUHSC-NO will reimburse Subcontractor for the below allowable documented costs and expenses as it relates to the Study:

* Pharmacy Fees = $1,500.00
* RRC Committee = $2,000.00
* Billing Compliance set-up and execution = $2,000.00
* Budget creation and review = $1,000.00
* Subcontract creation and review = $1,000.00
* Up to **$21,664.00** per patient for the initial phase for each patient completing the Trial (up to ten patients); and
* Up to $**14,223.00** per patient for each patient completing the second phase (up to ten patients)
* For nursing time, data management, labs, pathology and dispensing: reimbursed per visit;
* For procedures as listed in the signed Award (for actual procedures performed maximum amount due per visit plus any invoiceable costs.)

SAMPLE LANGUAGE: Procedures that may be ordered by the PI and shall be reimbursed at the rates as listed below. There is no guarantee that all procedures listed below will be ordered, nor is there any guarantee of any certain quantity that may be ordered.

The Procedures listed below are common procedures and are meant to be illustrative, not all-inclusive:

* lists out procedures and their corresponding CPT codes

SEE detailed budget for a specific breakdown of allowed expenses to be reimbursed.

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**APPENDIX B: BUDGET**

For the services provided in accordance with Appendix A and upon satisfactory performance, LSUHSC-NO agrees to reimburse Subcontractor an estimated maximum total amount of up to **$INSERT TOTAL** from Award fundsin accordance with the **detailed budget attached hereto and incorporated by reference as (Exhibit A)**.

**SAMPLE**: \*\*The total amount is based on enrollment of **ten patients** and all **ten patients** who complete **both** the Initial Treatment and Second Course of Treatment.

Payments shall **only** be made for procedures ordered and performed in accordance with the Study Protocol.

Subcontractor shall submit an invoice to the department’s address as listed below which corresponds to the detailed budget. Each invoice will reference the cycle and patient’s Study ID number. Invoices should be submitted no less than quarterly. Invoices MUST include the protocol number, LSUHSC Project Number, patient name or Study ID number and shall reference the visit day.

Subcontractor must submit any final invoice within **ninety (90) days (DEPT TO ENSURE THIS IS AMPLE TIME TO MEET CTA REQUIREMENTS)** after the Site close-out visit. As the source of the funding is made by the Sponsor and strict accounting regulations apply, late invoicing may result in non-payment. Subcontractor will then have ninety (90) days after the date of the Site close-out visit to dispute any payment discrepancies or missing payments.

A copy of invoices will be sent to:

**INSERT PROCESSOR NAME**

**INSERT ADDRESS OF DEPARMENT FOR INVOICES**

New Orleans, LA 70112

\*Invoices may be sent via email to: **INSERT EMAIL ADDRESS**

**DEPT DO NOT FORGET TO ATTACH DETAILED BUDGET\GRID on NEXT PAGE;**

**REMOVE ALL HIGHLIGHTS AND TEMPLATE GUIDANCE NOTES BEFORE SUBMITTING**

**ENSURE THE SIGNED CTA, final MCA and ALL REQUIRED DOCUMENTS ARE ALSO UPLOADED BEFORE SUBMITTING**

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**Exhibit A:**

**Billing Grid – Phase 1 or DETAILED BUDGET**

**SAMPLE:**

Initial Treatment Period (SAMPLE)



Second Course Phase

