**Research Core Services Agreement – Instructions:**

1. This agreement should be used to document the scope and payment terms for project-level work not already defined under an existing sub-contract that will be performed by a core facility for non-Vanderbilt academic institutions, other non-profit organizations or biotech/pharmaceutical firms.
2. The core laboratory manager and/or business manager should initiate the agreement, and attach a scope of work including pricing (Exhibit B).
3. This agreement can be approved and signed by the Office of Research, provided there are no substantial changes to the standard terms and conditions.
4. If the non-Vanderbilt organization proposes substantial changes to the standard terms and conditions, the core’s business administrator or department should submit the agreement to the Office of Contracts Management through PEER for review, negotiation and final approval. **Per the Office of Research, the terms of Section 8 “Remedies and Indemnification” are non-negotiable.**
5. If VUMC owned human clinical or research data will be shared with an external party, the agreement must be submitted to the Office of Contracts Management through PEER for review, negotiation and final approval regardless of changes to the standard terms and conditions. When submitting, use the comments field to indicate that data will be shared. OCM will facilitate and process a Data Use Agreement (DUA) in additionl to the research core services agreement.
6. The **Customer** **Institutional Official Authorized for Charges** should be obtained before submitting to the Office of Research for approval and final signature. The authorized signature section is on page 8 of the agreement.
7. The core laboratory manager and/or business administrator should keep the fully executed (i.e. signed by all parties) agreement on file.
8. The core laboratory manager and/or business administrator are responsible for following up on the agreement to complete the scope of work and collect all payments due promptly.
9. A copy of the external customer’s W9 form should be submitted to the Office of Research when the agreement is submitted for final approval.

Questions should be directed to Susan Meyn in the Office of Research.

**Agreement Review Routing:** Obtain VUMC Core Lab Manager and VUMC Core Lab Business Administrator signatures prior to submitting to external party for review and signature.

|  |  |
| --- | --- |
| **VUMC Core Lab Manager** |  |
| **VUMC Core Lab Business Administrator** |  |

**Obtain the Customer’s Institutional Official Authorized for Charges** signature in the AUTHORIZED SIGNATURES on Page 8. Then submit to Jessie Pirtle for VUMC Office of Research Reviewer review and signature. OOR will route for final executing signature.

|  |  |
| --- | --- |
| **VUMC Office of Research Reviewer**Jessie Pirtle, Assistant Director, OOR Research Finances & Systems |  |

**Research Core Services Agreement**

This laboratory services agreement (“**Agreement**”) is entered into on [month] [day], 20\_\_ (“**Effective Date**”) by and between Vanderbilt University Medical Center (“**Institution**”), by and through its [Name of one of Institution’s Research Core Laboratories or Recharge Center] (“**Core Lab**”), and [*insert legal name of customer institution]* (“**Customer**”) who is sending specimens, compounds, data, materials and/or other substances identified in Exhibit A (the “Test Materials”), to the Core Lab to conduct certain laboratory testing on Customer’s Test Materials, as specified in more detail below.

**Core Lab**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(hereinafter referred to as "Core Lab ")

AND

**Customer:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(hereinafter referred to as "Customer"):

 ***Customer Representative:***

|  |  |
| --- | --- |
| First Name: |  |
| Last Name: |  |
| Email: |  |
| Phone Number: |  |

 ***Customer Billing Information:***

|  |  |
| --- | --- |
| Company Institution Name: |  |
| Person to Receive Invoice: |  |
| Email Address: |  |
| Phone Number: |  |
| Address Line 1: |  |
| Address Line 2: |  |
| City: |  |
| State: |  |
| Zip: |  |

***Customer Accounts Payable Email Address for invoice:***

|  |
| --- |
|  |

 *Note: Invoices will be submitted by email.*

WHEREAS, as part of Institution’s research mission, the Institution operates research core laboratories and other facilities that have the scientific expertise and equipment to conduct various analytical tests on Test Materials for its research enterprise; and

WHEREAS, Customer desires the Core Lab to conduct certain analytical tests on Customer’s Test Materials; and

WHEREAS, Core Lab desires to conduct certain analytical tests on Customer’s Test Materials in accordance with the terms and conditions of this Agreement; and

WHEREAS, the research tests and services provided by Core Lab under this Agreement are of mutual interest to Institution and Customer and further the educational, scholarship and/or research objectives of Institution.

NOW, THEREFORE, Customer and Core Lab agree as follows.

 **SCOPE OF WORK**:

1. **Scope of Work**
	1. Core Lab will conduct the laboratory tests and services (“**Services**”) specified in the Scope of Work, attached hereto as Exhibit A (“Scope of Work”) and incorporated herein by reference. It is recognized and agreed that the Services conducted by Core Lab constitute research activity to explore an intellectual question or validate a scientific hypothesis of mutual academic interest and/or technologically advanced or unique product and/or procedure.
	2. Core Lab will have primary responsibility for the conduct and design of the Services. Upon request by Core Lab, Customer agrees to assist in the development of adjustments to the design or conduct of the Services to best achieve the research objectives of Customer.
	3. Any change to the Scope of Work must be approved in writing by both Parties.
2. **Performance of Services**
	1. Core Lab will coordinate the Services with a representative designated by Customer (“**Customer Representative**”) who shall be responsible for all matters related to the Services on behalf of Customer.
	2. Core Lab does not warrant that the conduct or design of the Services or the results of the Services will satisfy the regulatory requirements of any regulatory agency. More specifically, Core Lab does not warrant that the Services or Scope of Work will be conducted in compliance with the U.S. Federal Food and Drug Administration’s (“**FDA**”) Good Laboratory Practices requirements for Nonclinical Laboratory Studies (as described in Title 21, Code of Federal Regulations Part 58).
	3. Customer acknowledges and agrees that Core Lab is not and will not be certified by the Centers for Medicare and Medicaid Services or any accrediting organization under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) or any State licensure program to perform clinical laboratory testing.   Customer further agrees that the Results of any Services will be used for research purposes only and will not be used for purposes of diagnosis, treatment, or prevention of any disease or assessment of the health of human beings.
3. **Test Materials**
	1. The **Test Materials** will be provided to Core Lab by Customer for purposes of the Services as specified in the Scope of Work in Exhibit A. Customer will provide Core Lab with sufficient amounts of the Test Materials, as well as all relevant data and instructions needed to inform Core Lab of the stability of the Test Materials as well as storage and handling requirements for the safety of the Institution, the Core Lab, and its personnel.
	2. Customer will provide the Test Materials to Core Lab and shall handle all shipping and handling for Test Materials to Core Lab in a safe manner compliant with all applicable legal requirements.
	3. Customer shall provide Core Lab personnel with all necessary information about the stability of the Test Materials and all necessary requirements for the safe handling, use, storage and disposal of the Test Materials.
	4. The Test Materials are and shall remain the exclusive property of Customer. Core Lab shall use the Test Materials only for purposes of conducting the Services.
	5. Upon completion of the Services and payment of all invoices, Core Lab will return any remaining Test Materials to Customer or, upon prior written instructions from Customer, destroy any remaining Test Materials.
	6. Notwithstanding, any provision contained herein to the contrary, Institution shall not be liable to Customer for any loss of or damage to the Test Materials.
4. **Payments**
	1. Customer agrees to compensate Institution for all costs for performance of the Services, including without limitation costs of equipment use and supplies, in accordance with the quoted cost attached hereto as Exhibit B and incorporated herein by reference.
	2. Customer shall pay Institution within thirty (30) days of receipt of an invoice from Institution or be subject to late fees in the amount of 1.5% of all outstanding balances per month.

Customer shall make checks payable to Vanderbilt University Medical Center, and reference the invoice number and Core Lab and forward with a copy of the invoice to:

 Attn: Susan Meyn, Office of Research

 Vanderbilt University Medical Center

 Department of Finance

 Dept. 1236

P.O. Box 121236

Dallas, TX  75312-1236

4.3 International customers may submit pre-payments via check or wire transfer for up to 50% of the projected project cost. Note, the pre-payment proposal plan does not include any additional work that may be requested. If additional services are provided, the additional fees will be invoiced after the work has been completed.

1. **Reports of Results** Core Lab shall perform the Services and provide summary report(s) with the supporting data to Customer in accordance with the requirements specified in the Scope of Work in Exhibit A (“Results”).
2. **Confidentiality**
	1. “**Customer’s Confidential Information**” includes any information, regardless of medium, provided to Core Lab or Institution by Customer related to the Services or the Test Material that is marked as “Confidential” provided that the Results shall not be deemed as “Confidential” unless specified otherwise by Customer in the Scope of Work in Exhibit A. [List any known “Confidential Information” in Exhibit A.]
	2. “**Institution’s Confidential Information**” includes all information, regardless of medium, disclosed to Customer by Institution or Core Lab that is marked as “Confidential” provided that the Results shall not be deemed as “Confidential” unless specified otherwise by Customer in the Scope of Work in Exhibit A. [List any known “Confidential Information” in Exhibit A]
	3. “**Confidential Information**” means Customer Confidential Information and/or Institution Confidential Information; provided, however, that Confidential Information does not include information that; (i) is already known to the receiving Party, (ii) is or becomes publicly available through no fault of the receiving Party, (iii) is received from a third party which has the legal right to disclose it to the receiving Party, (iv) is developed independently by the receiving Party without access to the Confidential Information, or (v) is required to be disclosed by any applicable law or legal process. If disclosure is requested pursuant to applicable law or legal process, the receiving Party will notify, if allowed, the disclosing Party promptly of such request.
	4. Confidential Information of the disclosing Party shall be used by the receiving Party only in performance of the Services in accordance with this Agreement and shall not be disclosed to third parties without the disclosing Party’s prior written consent. This obligation of confidentiality shall survive any termination of this Agreement for a period of three (3) years.
	5. Customer acknowledges and understands that Institution is designated as a “hybrid entity” with respect to the Health Insurance Portability and Accountability Act (HIPAA) and that Core Lab is not included in any Institutional component that is a “covered entity,” as that term is defined under HIPAA. Accordingly, Customer acknowledges and agrees that Institution is not required to comply with the requirements of HIPAA. Furthermore, Customer represents and warrants that the Test Materials were not obtained by a “covered entity” as that term is defined under HIPAA and agrees that the Services are not being conducted in connection with any clinical services, but rather in furtherance of research purposes. In the event that any of the Services are to be performed for clinical purposes as part of a patient’s course of medical care instead of in furtherance of research purposes, Customer shall notify Institution promptly and shall not provide any Test Materials to Core Lab with respect to such Services until an additional agreement or business associate agreement has been signed by both Parties.
	6. Customer represents and warrants that any Test Materials comprised of human or animal materials or data were obtained by Customer and are hereby provided to Institution and Core Lab in compliance with all applicable laws, rules, and regulations pertaining to the use of human and animal materials and data for purposes of research or for any other purpose contemplated in the Services or Scope of Work. Customer represents and warrants that any and all required consents have been obtained, and any required institutional review board approvals or institutional animal care and use committee approvals have been obtained and are currently in effect and attached hereto as Exhibit C.
3. **Intellectual Property Rights**
	1. Except as expressly provided herein, any and all inventions, discoveries and improvements, patentable or otherwise, that arise exclusively as a direct result of performance by the Core Lab of the Services pursuant to and as set forth in this Agreement and that pertain to the use of the Test Materials or the Results shall be the property of Customer.
	2. Notwithstanding the foregoing in this Article on Intellectual Property Rights, all rights to any other inventions, discoveries and improvements, patentable or otherwise, conceived, made, or reduced to practice as a result of performance of the Services shall be determined in accordance with U.S. patent laws with ownership following inventorship, including without limitation, all rights to any data processes, software, technology, methodology, or know-how developed by Institution including, but not limited to, those which relate to laboratory testing or data collection or data management or that do not depend on or otherwise require the use of the Test Materials.
	3. It is recognized and understood that certain existing inventions and technologies are or may be the separate property of one party or the other, and that no existing intellectual property right of either party shall be affected by this Agreement. Nothing in this Agreement shall be construed as granting or implying any rights of either party to intellectual property of the other party that existed prior to execution of this Agreement or that were generated without use of the Test Materials.
	4. Notwithstanding the foregoing in this Article on Intellectual Property Rights, the parties acknowledge and agree that Institution is a recipient of Federal funding for research from the U.S. Government and that any intellectual property developed as a result of this Agreement might be subject to the rights and requirements of the U.S. Federal Government.
	5. The terms of this Article 7 shall survive any termination or expiration of this Agreement.
4. **Remedies and Indemnification**
	1. In the event of a material error by Core Lab in the performance of the Services which renders the Results invalid, Institution's sole obligation to Customer shall be for Core Lab, at Customer’s option and subject to availability of Test Materials, to either (a) repeat the Study at Institution's own cost, or (b) refund to Customer the contract price paid.  **IN NO EVENT WILL EITHER PARTY BE ENTITLED TO, NOR SHALL EITHER PARTY BE RESPONSIBLE FOR, ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL LOSSES OR DAMAGE ARISING IN CONNECTION WITH INSTITUTION’S DEFAULT OR BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT.**
	2. Subject to the limits or prohibitions of, and without waiving any immunities provided under applicable law, Customer shall indemnify, defend, and hold Institution and its respective trustees, officers, employees, agents, representatives, and their successors and assigns (“Indemnitees”) harmless from any and all liability, claims, damages, or loss (including reasonable attorneys fees) resulting from judgments or claims against them arising out of the activities to be carried out pursuant to this Agreement including but not limited to (i) any claim of infringement against Institution as a result of its use of the Test Materials pursuant to this Agreement, or (ii) the inherent instability or the undisclosed hazardous nature of the Test Materials, or (iii) acts or omissions of Customer, or its directors, officers, agents, representatives, or employees related to the activities to be performed pursuant to this Agreement, except to the extent that any such liability, claim, damages, or loss arises out of the negligence or willful misconduct by Core Lab, Institution, its agents or employees.
	3. This Article 8 shall survive termination of the Agreement.
5. **Term and Termination**
	1. This Agreement shall continue in force until the later of (i) completion of the Services as mutually agreed upon by the Parties, or (ii) \_\_\_\_ months from the Effective Date.
	2. Either Party may terminate this Agreement without cause by giving the other Party at least thirty (30) days advance written notice of intent to terminate. In the event that one party fails to comply with a material obligation hereunder, the other party may terminate this Agreement with fourteen (14) days advance written notice; provided that the breaching party fails to cure such breach before the expiration of the fourteen (14) day cure period.
	3. Payment for any portion of work completed and costs incurred or obligated by Core Lab at the time of termination shall be due and payable in accordance with Section 4, above, or upon expiration of this agreement.
	4. Upon termination of this Agreement and payment of all invoices, Core Lab will return all unused Test Materials to Customer in accordance with Section 3.3, above.
6. **Disclaimer of Warranties**

**NEITHER INSTITUTION NOR CORE LAB MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESSED OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDUCT OF THE SERVICES, THE RESULTS, ANY INVENTION(S) OR PRODUCTS, WHETHER TANGIBLE OR INTANGIBLE, CONCEIVED, DISCOVERED OR DEVELOPED UNDER THIS AGREEMENT; OR THE OWNERSHIP, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE SERVICES, STUDY RESULTS OR ANY INVENTION OR PRODUCT.**

1. **Miscellaneous**
	1. Independent Contractor. The relationship of the Parties established by this Agreement is that of independent contractors and nothing herein shall be construed to constitute the Parties as partners, joint venturer, co-owners or otherwise as participants in a joint or common undertaking. Neither Party shall have any authority to obligate the other in any respect nor hold itself out as having such authority.
	2. Entire Agreement. This Agreement constitutes the entire understanding and agreement among the Parties hereto with respect to the subject matter hereof and supersedes and replaces all prior agreements, both oral and written.
	3. Amendments. No modification or amendment of this Agreement shall be effective unless made in writing and signed by the authorized representatives of the Parties.
	4. Discrimination. In compliance with federal law, including the provisions of Title IX of the Education Amendments of 1972, Sections 503 and 504 of the Rehabilitation Act of 1973, the Age Discrimination in Employment Act of 1967 and 1975 and the Americans with Disabilities Act of 1990, and Title VI of the Civil Rights Act of 1964, the Parties hereto will not discriminate on the basis of race, sex, religion, color, national or ethnic origin, age, disability, or military service in its administration of its policies, programs, or activities; its admissions policies; other programs; or employment.
	5. The Parties acknowledge and agree that they are subject to United States (U.S.) laws and regulations controlling the export of goods, software and technology including technical data, laboratory prototypes and other commodities. Institution's policy is to comply with all applicable laws and regulations including the Arms Export Control Act, the International Traffic in Arms Regulations ("ITAR"), the Export Administration Regulations ("EAR") and the laws and regulations implemented by the Office of Foreign Assets Control, U.S. Department of the Treasury ("OFAC"). The transfer of certain technical data, services and commodities may require a license from the cognizant agency of the U.S. Government and/or written assurances by one of the Parties that it will not re-export or retransfer the data or commodities to certain foreign countries without prior approval of the cognizant U.S. government agency. While Institution agrees to cooperate in securing any license which the cognizant agency deems necessary in connection with this Agreement, Institution cannot guarantee that such licenses will be granted. Customer agrees to obtain permission from the U.S. government to re-transfer or re-export any goods, software and technology that requires such authorization and will not allow any U.S.-origin goods, software or technology to be used for any purposes prohibited by U.S. law, including, without limitation, support for terrorism or for the development, design, manufacture or production of nuclear, chemical or biological weapons of mass destruction. Customer also agrees to notify Institution of any technology or item that is subject to ITAR, EAR or OFAC before transporting any such items or information to Institution.
	6. Publicity. Neither Party shall, without the prior written consent of the other Party, use the other Party’s name, trademark, logo, symbol or other image in connection with any products, promotion or advertising.
	7. Force Majeure. Neither Party shall be liable to the other in damages for, nor shall this Agreement be terminable by reason of, any delay or default in such Party’s performance hereunder, if such delay or default is caused by conditions beyond such Party’s control including, but not limited to, acts of God, war, terrorism, insurrection, civil disorder, destruction of production facilities or materials by earthquake, fire, flood or storm, labor disturbances including strikes or lockouts, epidemic or failure of suppliers, public utilities or common carriers. Each Party agrees to promptly notify the other Party of any event of *force majeure* under this section and to employ all reasonable efforts toward prompt resumption of its performance hereunder when possible if such performance is delayed or interrupted by reason of such event.
	8. Assignment. This Agreement shall not be assigned in whole or in part by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.
	9. Choice of Law. This Agreement shall be governed in all respects by, and be construed in accordance with, the laws of the State of Tennessee without regard to its conflicts of laws principles. Each party hereby consents to the jurisdiction of all state and federal courts sitting in Davidson County, Tennessee and agrees that venue for any lawsuit or action with respect to this Agreement and the relationship between the parties hereunder shall lie exclusively in such courts
	10. Counterpart Signature. This Agreement may be executed in one or more counterparts (facsimile transmission or otherwise), each of which counterpart shall be deemed an original Agreement and all of which shall constitute but one Agreement.

Notices shall be addressed to the Customer representative contact & customer billing contact specified in the customer information section on the first page of this Agreement. Customers can submit notices to the Institution by email to the Core Lab or by emailing the VUMC Office of Research at VUMCcores@vumc.org.

* 1. Survival. All terms of this Agreement that are intended to survive termination or expiration in order to be effective shall survive such termination or expiration, including without limitation, terms and conditions regarding confidentiality, privacy of personal information, intellectual property rights, indemnification, disclaimer of warranty, remedies, publicity, and choice of law.
	2. National Defense Authorization Act. Customer agrees that it will not require Core Lab to use any covered telecommunications equipment or services in the performance of the Services.   As described in Section 889 of the Fiscal Year 2019 National Defense Authorization Act, this section refers to  telecommunications equipment or services produced or provided by Huawei Technologies Company, ZTE Corporation, Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities), or telecommunications or video surveillance equipment or services produced or provided by an entity that the U.S. Department of Defense reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.
	3. DOJ Rule: 28 CFR Part 202 Regarding Access to Sensitive Personal Data and Government Data. Customer hereby represents and warrants to Core Lab that it does not meet the criteria of a “Covered Person” as defined in 28 CFR Part 202 (including any amendment thereto) and does not contract with, employ, engage, or otherwise work or affiliate with any entity, organization, or individual that meets the criteria of a “Covered Person.” If Customer at any time does meet the criteria of a “Covered Person,” Customer shall promptly cease all access to, use of, and any other activities related to the data and/or biospecimens obtained from Core Lab and shall promptly notify Core Lab. Furthermore, Customer agrees that it shall not share, disclose, transfer, or otherwise permit “Access” (as defined under 28 CFR Part 202) to the data and/or biospecimens from Core Lab to or by any entity, organization, individual, or governmental representative that meets the criteria of a “Covered Person” under 28 CFR Part 202 and to comply with the requirements of 28 CFR Part 202 and any amendments thereto. If Customer at any time determines that any such “Covered Person” has obtained “Access” (as defined by 28 CFR Part 202) to such data and/or biospecimens from Core Lab, Customer shall promptly terminate such “Access” and promptly notify Core Lab.

**AUTHORIZED SIGNATURES**

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives on the day and date specified above.

|  |  |  |
| --- | --- | --- |
| **Customer** **Institutional Official Authorized for Charges** Typed Name and Title:Phone Number:Email Address: | **Signature:** | **Date:** |
| **Vanderbilt University Medical Center**Susan Meyn, Associate Vice President for Research Resources | **Signature:** | **Date:** |

**Exhibit A: SCOPE OF WORK**

|  |  |
| --- | --- |
|  **Project Timeline:** |  |
| **IRB Number:**  |  |
| **IACUC Number:** |  |
| **Confidential Information:** |  |

CORE LAB SPECIFIC RESPONSIBILITIES

1. Core Lab will provide Customer with shipping and handling instructions to ship the Test Materials to the Core Lab.
2. Core Lab will procure all equipment, materials and supplies needed to perform the Services.
3. Core Lab will provide Customer with deliverables as specified in this SOW in a format agreed on by Customer.
4. Core Lab will provide the statistical analyses as specified in this SOW.
5. Core Lab will return or destroy all remaining Test Materials if requested by Customer within thirty (30) days of completion of the Study and delivery of the Results to Customer and payment by Customer of all invoices from Core Lab.

**Exhibit B: Core Service Quote**

The following quote is provided for budgetary purposes only. All pricing is subject to change based on the cost-recovery rate in effect at the time the Services are provided. The service quote must reference name of service, unit price, and estimated units to be provided.

|  |  |
| --- | --- |
| **Total Estimated Cost:** |  |

Itemized Service Quote (insert below):

**Exhibit C**

**Attach any required institutional review board approvals or institutional animal care and use committee approvals that are currently in effect.**